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NEAR EAST UNIVERSITY

INSTITUTE OF HEALTH SCIENCES

Assessment of Knowledge, Attitude and Practice of Pharmacovigilance and Adverse Drug Reaction (ADR) Reporting among Healthcare Professionals in Central and Southern Somalia

A THESIS SUBMITTED TO THE GRADUATE INSTITUTE OF HEALTH SCIENCE

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By:

ZAINAB ALI MOHAMUD SABRIE

In Partial Fulfillment of the Requirements for the Degree of

Master of Science in Pharmacology

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APPROVAL

Thesis submitted to the Institute of Health Sciences of Near East University in partial fulfillment of the requirements for the degree of Master of Science in Pharmacology.

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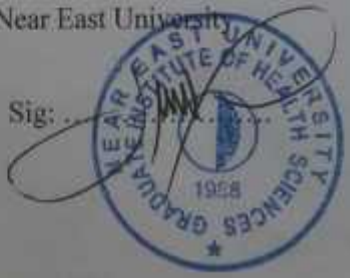

ii

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DEDICATION

To my beloved parents, brothers and sisters (Sadia, Amiin, Abdullah, Shirhan, Abdirahman, Ramla, Umhani), my best friends that i met in Jordan (Hawa, Farhia, Qamar, Shamhad, Fardowsa), my friend since junior high school (Mariam)and my dear friends (Isra, Nasteha, Ruweyda, Nashad, Naima, Asma, Sageer, Mido, Shaimaa, Aseel, Faisal, Abdirahman).

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With Love and Respect

Abstract

Adverse drug reaction (ADR) remains one of major causes of morbidity and mortality. Proper monitoring of adverse reaction is necessary. It is important for health care professionals to know how and where to report an ADR. In order to enhance the reporting rate, it is important to improve the knowledge, attitude and practices (KAP) of the health care professionals with regards to the ADR reporting and pharmacovigilance. The study was conducted at Somalia-Turkey training and research hospital, Jazera specialist hospital, Benadir hospital, Medina hospital, Alhayat Hospital, Aden Adde Hospital between June to September 2017.The study design was cross-sectional using questionnaire; The study contained all healthcare professionals (physicians, nurses, and pharmacists) in the hospitals who gave their consent. The questionnaire consisted of questions on socio-demographic characteristics of the study participants and multiple-choice questions to assess knowledge, attitudes and practices of healthcare professionals towards pharmacovigilance.

Keywords: knowledge, attitude, practice, pharmacovigilance, adverse drug reaction reporting, healthcare professionals

Page

List of tables:

1. Introduction

1.1 Overview

Pharmacovigilance is concerned with identification, evaluation, comprehending and prevention of adverse effects or any other medication related problem.

The aims of PV are to upgrade patient care and patient safety in connection to the utilization of medicines; and to help public health programmes by giving reliable, adjusted data for the effective evaluation of the risk-benefit profile of pharmaceuticals.

Pharmacovigilance importance involve: drug monitoring, pharmaceutical preparations - adverse effects, adverse drug reaction reporting, product surveillance, postmarketing, and legislation. PV adds to an idea of safety and fills in as a pointer of the standards of clinical care practiced inside a nation. Healthcare specialists are in a position to make great utilization of their patients' positive and negative encounters of treatment to contribute to therapeutic science and to an enhanced comprehension of disease and of the medicines.

In 1963, the Sixteenth World Health Assembly embraced a determination that reaffirmed the requirement for early activity concerning fast spread of data on adverse drug reactions and the reason for this was to build up a universally applicable framework to detect already obscure or ineffectively comprehended unfavorable impacts of medicines.

Globally medications are the most well-known therapeutic medical interventions, broadly utilized as a part of clinical or setting to diminish sufferings (Shalini and Mohan, 2015).

Adverse drug reaction is “any reaction to a medication which is harmful and unintended, and which happens at doses ordinarily used in man for diagnosis, prophylaxis or treatment of illness, or for the modification of physiological function”. This is against to an adverse event which is “any undesirable experience that has happened to the patient while taking a drug but may or may not be related to the drug”.

Deciding the exact number of ADRs that are experienced, however, is basically inconceivable given the challenges in evaluating causality and the low extent of ADRs that are reported. ADRs additionally fluctuate in their seriousness, by what sort of medicine they are caused and in what setting they are experienced, making recognizable proof complex. Most research which has endeavored to measure ADRs has done as such by assessing hospital patients.

Medicine and Healthcare Products Regulatory Agency (MHRA) grouped adverse drug reactions into type: A (augmented), B (bizarre), C (chronic), D (delayed) and E (end of use) reactions (MHRA, 2017). Rational drug therapy depends on the two fundamental parameters of safety and efficacy. Practically, no medication can be totally without adverse effects, yet their utilization must be related with a satisfactory risk-benefit proportion.

Keeping in mind the end goal to have the capacity to make a rational and wise choice of a therapeutic agent, it is essential for the prescriber to know about the quantum and recurrence of possible untoward risks. It isn't statistically imaginable to experience all the adverse effects of a medication in the middle of the initial three periods of clinical trials, to a great extent on the grounds that the population, in which they are assessed, is a small amount of the planned target population.

Aside from the restricted investigation population, specific enlistment of patients with coming about constrained heterogeneity and thought of few predefined adverse drug reactions (ADR's) confine the generalizability of clinical trials to clinical practice. It is possible to make a more reasonable safety profile of a medication after it has been examined for untoward unfriendly occasions in a bigger heterogeneous populace of patients over an expanded period. Building a database of knowledge relating to the unfavorable impacts of medications is the thing that structures the center rule of pharmacovigilance.

The first WHO Collaborating Centre to be established for pharmacovigilance was the Uppsala Monitoring Centre (UMC).The main role of the Uppsala Monitoring Centre is to manage the international database of ADR reports received from National Centres (WHO, 2017).

One of the significant reasons of morbidity and mortality everywhere throughout the world is adverse drug reactions (ADRs). Thus, legitimate observing of ADRs is a need (Gupta et al., 2017). ADRs are accounted for to be one of the leading reasons for death in United States of America (USA).

In other developed nations, for example, the United Kingdom (UK), France and Sweden, ADRs are the reasons for 6.5%, 3.2% and 12% hospital admissions, individually (Mjörndal et al., 2002). Then again, ADRs are underreported and undisclosed in developing nations because of absence of medicine checking and prioritization of drug safet or even absence of an ADR reporting framework (Wilson et.al, 2017).

In South India, the general frequency of the ADRs was reported to be 9.8% (Arulmani et al., 2007), while in Iran, an investigation reported that among 16.8% of patients, no less than one had an occurrence of ADRs (Gholam and Shalviri, 1999). In the Middle East district, constrained information is accessible on the frequency and pervasiveness of ADRs. However, a multicenter study in Morocco demonstrated an occurrence of ADRs of 11.5 for each 100 admissions in therapeutic and surgical units (Benkirane, 2009). It is evaluated that only 6-10% of all ADRs are reported for globally (Malaq et al., 2008).

Despite the fact that ADRs information from different nations are fundamental to embrace drug safety choices by a local administrative expert and the medication manufacturer, a few components are known to impact ADRs, for example, local population traditions, diets and complementary and alternative medicines (Alshami et al., 2014).

The knowledge, attitude, and practice (KAP) is the best tool to evaluate ADR reporting among healthcare professionals and their viewpoint towards Pharmacovigilance and patient's safety (WHO2002). In this way, in order to enhance

the reporting rate and for the fruitful running of pharmacovigilance program, it is important to enhance the knowledge, attitude and practices (KAP) of the healthcare professionals in regards ADR reporting and pharmacovigilance.

Spontaneous reporting of ADRs has played a vital part in the identification of genuine and surprising ADRs during marketing of the medication during real practice in the market. This has prompted the withdrawal of many medications in the past, for example, rofecoxib, cisapride, terfenadine, by the Kuwait Drug and Food Council (KDFC, 2016).

1.2: Pharmacovigilance Program of Somalia

A study which evaluated pharmacovigilance program in Sub-Saharan Africa with aid of US Food and Drug Administration (FDA) and the US Agency for International Development (USAID) showed that only 8 (38 percent) of 21 pharmaceutical companies in 7 countries have a unit or staff in charge for pharmacovigilance activities and 5 (24 percent) have SOP or reporting forms for pharmacovigilance. Not very many organizations (14 percent) conduct post-marketing surveillance activities.

The study distributed countries into four groups (Lazarou et al., 1998):

1. Countries with minimal or no capacity for PV (24 countries—Angola, Benin, Burkina Faso, Burundi, Cameroon, Cape Verde, Gambia, Guinea-Bissau, Liberia, Madagascar, Mauritius, Niger, Sudan, and all non-members of the WHO program except Malawi).

2. Countries with basic structures in place (15 countries— Botswana, Cote d'Ivoire, DRC, Ethiopia, Mali, Rwanda, Togo, Zambia, Zimbabwe, Kenya, Senegal, Malawi, Mozambique, Guinea, and Sierra Leone).
3. Countries with capacity to collect and evaluate safety data on the basis of legal and organizational structure (2 countries—Tanzania, Ghana)
4. Countries with performing PV systems that detect, evaluate, and prevent medicine safety issues. (4 countries—South Africa, Namibia, Nigeria, and Uganda).

An article that assessed drug safety monitoring in Somaliland recommended establishment of a center of pharmacovigilance in Somaliland and that qualified pharmacist with experience should be recruited. (Mustafa Khalid Mohamed, 2017).

Numerous adverse effects of the drug, drug interactions, interactions with food and other hazard factors like particular toxicities are known a long time after release of a prescription. Some uncommon adverse effect (1:100000) show only after the introduction of medication to a huge population (Wilson, 2017). Such uncommon adverse effects of a drug must be known through viable pharmacovigilance.

Different techniques for identifying an adverse event include spontaneous reporting, prescription event monitoring (PEM) and others. Reporting of adverse events (AEs) from physicians to adverse drug reactions (ADRs) database by utilization of these strategies can significantly affect the signal detection of surprising and uncommon ADRs. Further it can also determine the risk: benefit proportion of current medications.

About 20% patients encounter some adverse event during hospitalization and 2.37% to 4.01% admissions to clinic are caused by ADRs however it is evaluated that only 6-10% of all ADRs are reported (Lopez-Gonzale et al., 1996). Thus under reporting can defer the signal detection and have effect on public health.

Most ADRs were predictable from the known pharmacology of the medications and numerous represented known interactions and are in this way prone to be preventable. This infers that although a large number of the involved medications have demonstrated advantage, measures should be set up to diminish the weight of ADRs and along these lines additionally enhance the benefit: harm proportion of the medications.

The investigation also noticed that older drugs keep on being most common consequences of such confirmations, a finding that was consistent with different studies done earlier (Khan et al., 2013). Particular consideration therefore should be paid to the discovery and prevention of ADRs, and in a perfect world this need ought to be met through pharmacovigilance endeavors.

One of the foundations of pharmacovigilance activities is Spontaneous Reporting Systems. These include the dynamic participation of reporters in the discovery and reporting of drug blunders and ADRs. In practice, spontaneous reporting is perpetually deliberate and probably based on charitable intentions.

Spontaneous reporting is by a wide margin the best technique for creating signals on new or uncommon adverse drug reactions (ADRs). Under-reporting is a major drawback of this framework (Ganesan et al., 2016).

Originally, doctors were the main experts welcomed to report their perceptions and judgment of whether a prescription had caused a specific ADR. It was contended that tolerant ADR reports from doctors just would guarantee brilliant data and limit the revealing of random, irregular associations. Studies have appeared, in any case, that distinctive classifications of health experts will watch various types of medication related problems, and their reports contribute essentially to fruitful pharmacovigilance (Vora et al., 2012).

Just by welcoming reports from all experts associated with the care of patients will it be possible to recognize the full range of complications identified with pharmacotherapy.

Moreover, to get a delegate photo of the truth, all areas of the healthcare framework should be included, for example public and private hospitals, nursing homes, retail dispensaries, and clinics for conventional prescription. Wherever drugs are being utilized there ought to be a readiness to watch and report undesirable and restorative occasions.

Whether or not reporting by patients at last includes value is not yet certain yet there seems to be general assertion that such reports should be followed-up through the clinician. In this manner collaboration from clinicians is fundamental.

Pharmacovigilance seeks to enhance patient care and wellbeing in connection to the utilization of medications and all therapeutic and paramedical interventions, enhance public health and safety in connection to the utilization of medicines, and to add to the evaluation of advantage, harm effectiveness and danger of pharmaceuticals.

To this end, endeavors have been made to advance comprehension, instruction and clinical training in pharmacovigilance and its viable correspondence to the community. This can only be effective through coordinated effort between different associations, for example, hospitals, regulatory authorities, pharmaceutical industries, national pharmacovigilance centres, and poison control centres.

1.3: Problem Statement

Medicines resemble twofold edged swords; they can reduce infection yet in addition have capability of causing hurt regardless of how skillfully they are utilized. Other than the active ingredients, excipients, for example, coloring agents, lubricants, preservatives and so on have a potential for delivering unfriendly or undesirable impacts.

ADRs might be startling, obscure or potentially uncommon. They are in some cases life threatening, and can be significant determinants of treatment results. This along these lines requires nonstop checking of known and obscure ADRs, underlining the requirement for pharmacovigilance. Appropriate observing of ADRs requires a

powerful and productive pharmacovigilance framework to ensure the wellbeing of medications consistently.

In Somalia, in the same way as other different nations in Africa, pharmacovigilance activities are being looked with various difficulties, for example, underreporting of instances of ADRs, issues with creating and actualizing medication error reporting Systems, among others. Overlooking the significance of archiving and reporting ADRs by healthcare experts prompts repeat of preventable medication related morbidity and mortality.

1.4: Justification of the Study

Knowledge, attitude, and Practice (KAP) studies about pharmacovigilance have been done throughout the world however none has been done in Somalia. This investigation expected to evaluate subjectively, data on the knowledge, attitudes and practices of healthcare professionals on pharmacovigilance activities.

This is principally on the grounds that the achievement of pharmacovigilance activities is intensely dependent on the support of healthcare workers as they play out their day by day obligations of diagnosis, prescribing, dispensing, and administration of pharmaceutical and observing of patients.

Their feelings and practices on the boundaries they experience with the unconstrained reporting of ADRs and their recommendations to settle them are vital to pick up bits of knowledge on what should be possible to enhance the current structures and frameworks of pharmacovigilance.

1.5: Study Hypothesis

There exists an absence of knowledge, indifferent attitude and inadequate practice of pharmacovigilance among healthcare workers in central and southern Somalia.

1.6: Objectives

Main objective of this study was planned to look at the knowledge, attitudes and practices of healthcare workers on pharmacovigilance at six hospitals in central and southern regions of Somalia, and to distinguish boundaries to successful execution of pharmacovigilance.

Particular goals:

1. To decide the extension and degree of pharmacovigilance activities at the mentioned hospitals through the examination of the sources, substance and patterns of ADR reports created at the mentioned hospitals.
2. To decide the elements that impacts the practices of health care workers at the mentioned hospitals in regards to pharmacovigilance.

1.7: Significance of the Study

Information from this investigation will help with distinguishing inadequacies and refining the pharmacovigilance rehearses in the hospital with a view to completely incorporating them into the everyday activities of healthcare specialists engaged with sedate use in hospitals.

2. Background

2.1: Pharmacovigilance: History and Development

Pharmacovigilance is concerned with identification, evaluation, comprehending and prevention of adverse effects or any other medication related problem (WHO, 1972).

The first systematic international endeavors to address drug safety issues began in 1961 after the thalidomide disaster. In 1963, the Sixteenth World Health Assembly (WHA 16.36) embraced a determination that reaffirmed the requirement for early activity concerning fast spread of data on adverse drug reactions (Vvan and Egberts, 2007).

Later in 1968, A Pilot Research Project for International Drug Monitoring was made by W.H.O in order to build up a global framework for distinguishing already unknown or ineffectively comprehended adverse effects of pharmaceuticals (WHO & others. The importance of pharmacovigilance, 2002).

A WHO Technical Report took after in light of a counsel meeting held in 1971. The 1971 WHO counsel set out to advocate foundation of national communities for drug checking, to provide guidelines, and to distinguish the commitment that national centres might make to the universal framework (Beijer, 2002).

Participation of the WHO Program for International Drug Monitoring which as of now has more than 65 part nations is facilitated by the WHO Collaborating Center for International Drug Monitoring known as the Uppsala Monitoring Center (UMC).

It was noticed that information accumulation from health practitioners, systematic monitoring of populations, review of health statistics and of drug utilization data, and powerful examination of information would be essential for the targets of pharmacovigilance to be accomplished. From these developed the practice and science of pharmacovigilance.

Universal health associations and additionally part states were to add to this global pharmacovigilance activity As indicated by Article 2 of its constitution, the WHO has a reasonable command to create, set up, and advance global norms as for food, biological, pharmaceutical and similar items.

Also, the World Health Assembly made an arrangement in Article 21 of their constitution to receive directions concerning standards as for the safety, purity and strength of organic, pharmaceutical and comparative items moving in global trade (WHO, 2002).

On the other hand, member states would detail frameworks for the accumulation and assessment of individual case medication safety reports. These reports would later be gathered in a focal database which would serve the essential capacity of adding to the work of national medication administrative specialists, enhance the security profile of medicines, and help maintain a strategic distance from future debacles.

2.2: Scope and Current Practice of Pharmacovigilance

Pharmacovigilance has been tied in with recognizing new Adverse Drug Reactions (ADRs) and, if important, taking administrative activities expected to secure public

health. For instance, by changing the summary of product characteristics (SPCs) or pulling back the medication from the market.

An ADR is characterized by WHO as any poisonous, unintended, and undesired impact of medication that happens because of treatment with a medication at the typical dosages utilized as a part of man for diagnosis, prophylaxis, and treatment (WHO, 1972).

ADRs are also described as “an apparently hurtful or repulsive response because of an intervention identified with the utilization of a therapeutic item, which warrants particular treatment, or change of the dose regimen or withdrawal of the item” (Edwards and Aronson, 2000).

On the other hand, terminologies like “adverse reaction” and “adverse effect” are used in describing adverse drug reactions or side effects and are sometimes utilized interchangeably. All the more exactly, an adverse effect (AE) is seen from the perspective of the medication, while an adverse reaction is seen from the perspective of the patient.

These two terms however, (adverse effect and adverse reaction) must be recognized from “adverse event”. An adverse effect is an adverse outcome that can be attributed to some activity of a medication; an adverse event is an adverse outcome that occurs while a patient is taking a medication, yet isn’t or not really owing to it (Edwards and Aronson, 2000).

Current scope and practice since the thalidomide disaster in 1961 that offered ascend to the concept of pharmacovigilance, the field has experienced a few stages and has moved from simply distinguishing signs of medication safety to worries of illicit pharmaceuticals deal, production and offer of fake and substandard medicines and expanding use conventional medicines outside the confines of customary utilize. All these because of high rise in cross border communications, free trade, and web utilize that expansion (WHO, 2002).

Numerous different issues that are of pertinence to pharmacovigilance include: medication mistakes, lack of viability reports, use of prescriptions for signs that are not affirmed and for which there is insufficient logical premise, case reports of intense and endless harming, assessment of medication related mortality, and abuse of drugs, different pharmaceuticals, and sustenance pharmacovigilance is as yet a quickly creating field, and faces various foundational challenges.

For instance, little accentuation is as of now set on creating data that can help healthcare services proficient or a patient in the basic leadership procedure of regardless of whether to utilize a medication. Assembling and conveying of this data ought to be an essential objective of pharmacovigilance, i.e. being less centered around discovering harm and more centered around expanding learning of safety (Waller and Evans, 2003).

Pharmacovigilance strategies should likewise have the capacity to portray which patients are in danger of building up an ADR and what the course of the ADR could be i.e. pharmacogenetics and pharmacogenomics.

The WHO Program for International Drug Monitoring proposes that a fruitful reaching universal pharmacovigilance methodology needs to distinguish and actualize doable frameworks, administration, foundation, human asset, maintainable systems and advancements in pharmacovigilance.

As of late, administrative offices have been improving their frameworks request to keep pace with the improvements in pharmacovigilance, with the emphasis on being all the more professional dynamic.

Pharmacovigilance activities are crucial in anticipating pharmaceutical mistakes including educating healthcare services experts about the significance of revealing such blunders and making an awareness of patient health. Likewise, coordinated effort with administrative experts is essential in settling choices. Such joint efforts will help maintain a strategic distance from duplication of workload (Bencheikh and Benabdallah, 2009).

2.3: Importance of Pharmacovigilance

Pharmacovigilance and all medication safety issues are important for everybody whose life is touched in any capacity by therapeutic intervention (WHO, others. The importance of pharmacovigilance, 2002). During prescriptions development i.e. clinical trials, medications are entirely watched for their safety and adequacy.

The qualities of the clinical trial members don't generally entirely speak to the attributes of the population in which it will later be utilized; thus, it might be hard to extrapolate the outcomes acquired from clinical trials to the population at large (Gross et al., 2002). This is particularly valid for the elderly, for women or for individuals having a place with a minority ethnic gathering (Heiat et al., 2002).

So as to study uncommon ADRs, ADRs with a long slowness and ADRs in particular populaces, watchful checking of the medication in the post-marketing stage is fundamental. Experience has demonstrated that numerous adverse effects, interactions (i.e. with food or different pharmaceuticals) and hazard factors become known during the years after the arrival of a medicine.

The essential technique for gathering post-marketing data on the safety of medications is through Spontaneous Reporting Systems (SRS), a key segment of pharmacovigilance. The fundamental function of SRS is the early location of signs of new, uncommon and serious ADRs. Reporting of ADRs empowers doctors, pharmacists and patients to report presumed ADRs. This thusly advises partners, for example, national administrative procedures and strategy producers of the potential hazard when signs of new ADRs emerge.

Enhancing the quantity of reports and access to the information encourages an auspicious assessment of totals of ADR reports, which are regularly the primary signs of a potential issue. A notable challenge in the unconstrained describing framework is the underreporting of ADRs (Wiholm, 2000).

An investigation led by (Babigumira et al), has illustrated that PV frameworks can possibly enhance health results and to diminish healthcare services consumptions identified with tranquilize safety by recognizing and decreasing drug related issues. The investigation includes that a completely created tool to evaluate economic value could help arrangement creators and benefactors in assessing investments required to build the limit of national projects to enhance the utilization, safety, quality, cost adequacy, and reasonableness of pharmaceuticals in low and middle income countries (LMICs).

From an economical point of view, a nation's absence of a useful PV framework prompts more noteworthy expenses as far as the assets used to oversee and forestall medication related problems (MRPs), terrible health results related to morbidity and mortality and additionally lessening of prescription related quality-of life (QOL).

Looking at these effects as far as the open door cost of the assets utilized and the unfriendly safety impacts is imperative in surveying the potential benefit of beginning or reinforcing national PV activities. The expenses of overseeing distinctive medication AEs and different MRPs include: (1) cost of out-patient (OP) visits, (2) cost of hospitalization, and (3) cost of MRP-related regimen switches including new medications and counsels.

Expenses of OP visits and hospitalization for MRPs incorporate direct medicinal costs, (for example, healthcare workers time, other medications or antidotes, and laboratory tests), coordinate non-restorative costs, (for example, patient

transportation and upkeep), and roundabout costs (which incorporate the open door cost of lost profitability between MRP-related disease and healing).

The above cost minimization studies can help strategy creators and investors settle on educated choices as included patient care and pharmacovigilance activities. A system has been proposed for the evaluation of the monetary estimation of PV programs.

2.4: Impact of Pharmacovigilance

PV assumes an essential part in guaranteeing that prescribers, together with the patient, have enough data to settle on a good choice with regards to picking a medication for treatment. The safety of a medication should be taken after during its whole life cycle.

This life-cycle approach incorporates recognizing safety signals, planning concentrates to affirm them, assessing benefits and dangers, utilizing risk– advantage appraisals to coordinate investigation results and conveying key discoveries to patients and doctors (Awodele et al., 2011) and (Njogu, 2009).

This way to deal with pharmacovigilance has brought about real choices about the safety of medications, including the withdrawal of effectively affirmed drugs from the market. In June 2007 a meta-analysis was connected the utilization of rosiglitazone to an expanded danger of myocardial localized necrosis and passing from cardiovascular causes (Caldwell et al., 2006).

These outcomes, started another level headed discussion on the safety of the medication, it was later presumed that the advantages of rosiglitazone exceed its dangers inside the system of its endorsed signs (Solomon and Winkelmayer, 2007).

However, steady refreshing of item data and a kept checking of this ADR are vital. A later safety concern is the relationship amongst aprotinin and expanded mortality. In 2006, an investigation in view of observational information was distributed by Mangano et al. in which the authors scrutinized the safety of aprotinin.

On November 21, 2007, aprotinin was pulled back from the market in the European Union in light of information from the BART clinical trial demonstrating increased mortality for patients getting aprotinin.

The significance of spontaneous reporting systems can't be overemphasized in pharmacovigilance practices as a noteworthy wellhead of signal recognition. Furthermore dynamic investigation and the part of clinical trials assume an indispensable part as strategies for gathering ADR information.

Table 1: Drug Safety Concerns in Europe:

Drug	**Safety concern**	**Key proof**	**activity**
Trovofloxacin	Hepatoxicity	Spontaneous ADRs	Withdrawn
Tolcapone	Hepatoxicity	Spontaneous ADRs	Suspended
Cisapride	QT prolongation; heart arrhythmias	Spontaneous ADRs	Patient registration licences subsequently cancelled
Bupropion	Seizures, drug interaction	Spontaneous ADRs	Posology change, Warnings
Cerivastatin	Rhabdomyolysis	Spontaneous ADRs	Withdrawn
Hormone replace therapy	CVS risk; cancer long term	Epidemiological studies	Warnings and restriction of indication
SSRIs	Suicidal Behavior in children	Clinical trials	Warnings accompanied by clinical guidance
COX IIs	CVS risk	Clinical trials	Warnings and

			clinical guidance
Topical macrolides immunosuppressants	Risk of cancer	Spontaneous reports	Restriction of use, Risk management plan SSRI

A pilot venture was started by the World Alliance for Patient Safety in a joint effort with the Uppsala Monitoring Center, with the Moroccan Pharmacovigilance Center as project organizer. The point of the venture was to build up an expanded part for national activities of pharmacovigilance, to incorporate the gathering of data on the frequency of antagonistic occasions identified with pharmaceutical mistakes, to empower universal investigation of these information, and to scatter the discoveries (Bencheikh and Benabdallah, 2009).

Table 2: Examples of Mistakes by the Moroccan Pharmacovigilance Center

Product	Type of error	Details	Action
BCG vaccine	Route of administration and dose	Intramuscular instead of intradermal administration; 10 times the	Letter to physicians

		recommended dose given, because BCG vaccine contains 10 doses in one bottle	
Methylergometrine	Wrong patient	Drug prescribed for the mother but given to the neonate because of the use of one prescription sheet for the mother and the neonate	Letter from the Ministry of Health to all gynecologists and all maternity hospitals in the country
Corticosteroid	Wrong indication	Drug given for weight gain	Letter to the pharmacist
Cypro-heptadine	Wrong indication	Drug given as an appetite stimulant	Letter to the pharmacist
Dontomycin	Erroneous publicity	Described as an analgesic instead of an antibiotic	Letter to the manufacturer
Rinomycin	Lack of specific	No warning for	Modification of

	warning	people with hypertension due to phenylephrine	the SPC
Indomethacin calcium pentahydrate	Erroneous publicity	Described as a coxib instead of an NSAID	Letter to the manufacturer
Flucloxacillin Injection	Wrong dilution	Lack of information on dilution in the SPC; sterile water for injection not included in the drug package	Modification of the SPC

2.5: Barriers to Pharmacovigilance

A few investigations have distinguished reasons why it is challenging to execute pharmacovigilance. A current systematic review led by Abubakar et al, related results of various examinations that recognized holes in pharmacovigilance. They found that there was poor knowledge of ADR reporting by specialists despite the fact that some knew about pharmacovigilance.

Absence of attention to revealing methods and trouble of filling frames were additionally observed by numerous as hindrances. The investigation additionally found that specialists had little knowledge on ADR reporting activities and that numerous specialists did not know precisely what to report given that greater part of ADRS seen were notable (Abubakare et al., 2014).

Somewhere else, specialists announced that they didn't get sufficient training to report ADRs. In a study done in Nigeria, 89.6% of the physicians who reacted said they require training on ADR reporting (Awodele et al., 2011).

Greater part of specialists additionally felt announcing ADRs was an expert commitment and that mindfulness should have been raised to change the outlooks of the authors. An investigation done by Biriell and Edwards distinguished similar connection amongst them and the input of pharmacovigilance activities as methods for enhancing unconstrained reporting by hospital physicians (Vallanoet al., 2005).

Another investigation additionally revealed comparable discoveries (Herdeiro et al., 2005). Discoveries of this investigation can't be summed up to all specialists significantly on the grounds that numerous nations have not been spoken to in the survey part of health care workers.

2.6: Healthcare Professionals and Pharmacovigilance

Healthcare professionals (including doctors, dental practitioners, pharmacists and nurses)are asked for to report presumed adverse reactions saw in their practice. Of specific significance are altogether speculated responses to recently approved items,

items experiencing extra observing and suspected responses to immunizations or medications utilized as a part of pregnancy.

Healthcare professionals assume a basic part in pharmacovigilance. The constraints of clinical trials imply that when a medication is first marketed, much might be thought about its efficacy while moderately less might be thought about its safety profile. Subsequently post- marketing reconnaissance is fundamental to help identification of medication safety issues not identified during pre- marketing assessment.

Pharmacovigilance utilizes adverse reaction reporting to create speculations and flags about potential dangers of marketed drugs that require advance examination. Unconstrained announcing of suspected adverse reactions is especially helpful in distinguishing uncommon or deferred responses. It gives a framework whereby the safety of a drug can be observed for the duration of its life cycle. In this manner medicate safety appraisal ought to be viewed as a fundamental piece of regular clinical practice for healthcare professionals.

It is basic for healthcare professionals to know about the poisonous quality profile of medications, to be ever cautious for the event of surprising unfavorable responses and to report presumed unfriendly responses to the Health Products Regulatory Authority with a specific end goal to encourage opportune and exact identification and evaluation of medication safety signals.

ADR reporting is presently an acknowledged and comprehended routine in numerous nations. ADR reporting is indispensable to the healthcare professionals' obligations. Healthcare professionals are propelled by their expert soul to agree to revealing prerequisites built up by law. Causality is the likelihood that an ADR is because of a medication and alludes to singular cases and the appraisal of what a healthcare professional would call clinical probability that the ADR was because of the medication (Biron et al., 2002).

The healthcare professional might be dubious that the medication caused the ADR. Uncertainty about the causality between a suspected ADR and the medication utilized is specified by both doctors and drug specialists as a boundary to the accommodation of reports. This maybe obvious, and implies a logical state of mind that requires assurance for activity. In any case, tragically that this attitude keeps some from announcing. All things considered, pharmacovigilance concerns the social event of information on speculated ADRs.

It is the assignment of the national revealing focuses to set up the causality between detailed presumed ADRs and the medications utilized by end of however many vulnerabilities as could reasonably be expected by methods for causality appraisal and factual techniques (Meyboom, 1997).

Healthcare professional ought not to avoid distributing a first case report until the point when they have a moment or third case in their training. The Answer: "At the point when there is a doubt, report'. This wonder is an essential wellspring of deferral

in the distribution or detailing of vital signs, especially when the second case happens a year or two after the first.

A study in tertiary care hospital in Gujarat that evaluated knowledge, attitude and practices toward pharmacovigilance and adverse drug reactions in postgraduate students showed that the postgraduate resident doctors had a relatively better attitude but lack of knowledge and practices towards ADRs and pharmacovigilance. The majority of the PGs are felt ADR reporting and monitoring to be important, but only a few had ever reported an ADR. Lack of motivation and training toward ADR reporting and pharmacovigilance discourages them from reporting. The study recommended that there is need for continuous teaching and sensitization regarding pharmacovigilance and ADR reporting system for residents and improving the ongoing pharmacovigilance activities in the hospital (Vora et al., 2017).

Another study in a teaching hospital in South India evaluated the knowledge, attitude, and the practice of pharmacovigilance among the healthcare professionals demonstrated that knowledge and attitude towards pharmacovigilance may be bit by bit enhancing among healthcare professionals, but unfortunately the actual practice of ADR reporting is still inadequate among them (Vora et al., 2017).

Another study in secondary and tertiary governmental hospitals in Kuwait was evaluated the knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists and participants in the study stated that the main reason for declining to participate was lack of time. Results from this study

show that the majority of pharmacists had good knowledge regarding the concept of PV and ADRs in terms of their definitions and purposes.

Pharmacists in the study had very positive attitudes toward ADR reporting; nearly all of them thought it was necessary to report ADRs and that reporting them would have a positive impact on the healthcare system. Most of them also believed that it was a formal professional obligation to report ADRs. This observation is supported by similar studies with pharmacists from other countries, who concurred that reporting ADRs is a professional obligation.

Data from this study showed that the majority of pharmacists (88.6%) are willing to implement ADR reporting in their practice and almost half of them (49.5%) would prefer using an email or a web-based reporting system. About two thirds of pharmacists included in this study reported having identified ADRs during the course of their practice.

The study aimed to explore the perceived barriers that exist in Kuwait to have a national reporting center. Some of these barriers included lack of cooperation and communication between HCP and patients, lack of professionalism (careless pharmacists) and lack of motivation for pharmacists, such as lack of financial incentives. Participants in the study also reported that pharmacists and physicians are the most qualified individuals to undertake the role of ADR reporting, which is in line with results from other studies.

Another study in Rajkot city evaluated knowledge, attitude, and the practice of pharmacovigilance among private healthcare professionals found that there was a great need to create awareness among the private doctors to improve the reporting of ADRs (Gupta et al., 2017).

Another study in a South Indian teaching hospital assessed knowledge, attitude, and the practice of pharmacovigilance among medical students and found that participants have good knowledge about pharmacovigilance but there is lack in attitude and practice towards reporting ADR (Alsaleh et al., 2017).

Another study in a tertiary care hospital in South India which evaluated knowledge, attitude, and the practice of pharmacovigilance among doctors and nurses found that around 70% of the participants were mindful of the location of ADR monitoring center in the Institute, purpose of monitoring ADR and a form used to notifying ADR. More than 80% participants were aware regarding who can report ADR and more than 90% were aware of what type of ADRs reported.

29% of nurses were better mindful of the local number to report ADR while 36% of doctors were more mindful of the drugs withdrawn due to ADRs. Regarding attitude among healthcare professionals towards ADRs reporting showed that more than two-third of doctors and nurses felt that reporting of ADR is necessary (89% and 94%) and is a professional obligation (70% and 67%).

However, 67% of the doctors and 52% nurses believed that ADR can cause significant illness or death to the patient. Concerning the practice of

pharmacovigilance 93% of doctors and 77% of nurses have seen patients experiencing ADRs but at the same time, only 52% of physician and 25% of nurses reported ADRs to AMC in the Institute.

There was no significant difference in knowledge and attitude scores towards reporting of ADRs between doctors and nurses. The median (IQR) practice score was significantly higher in doctors than nurses. The median total score was also significantly greater in doctors than nurses. Similarly, while comparing the knowledge, attitude and practice between senior and junior level doctors, senior level doctors had a significantly higher score in knowledge, practice and overall score. Similarly, senior level nurses had a significantly higher score in attitude and overall score, while there is no significant difference in knowledge and practice (Dhananjay and Himasri, 2017).

Another study in Abbottabad in Pakistan which assessed knowledge, attitude, and the practice of pharmacovigilance among medical and pharmacy students towards pharmacovigilance and adverse drug reactions showed that medical and pharmacy students demonstrated low knowledge, attitude and practice scores which show that there is a need for standard education and training of the students in regards to pharmacovigilance and ADR management (Adithan, 2017).

Another study in a tertiary care hospital in Andhra Pradesh evaluated knowledge, attitude, and the practice of pharmacovigilance among healthcare professionals revealed that a larger part of the health-care experts had knowledge and attitude about pharmacovigilance but they lack in practice. Hence in order to improve

practice of pharmacovigilance we would like to recommend the consideration of the following steps for effective implementation of pharmacovigilance: regular training programmes on pharmacovigilance, mandatory provision of ADR reporting forms in every inherent clinical departments by the institutions, regular electronic communication updates on the safety of drugs to all health care professionals, timely financial funding for such programmes in institutions, promotion of patient self-reporting, filling the communication gaps regarding pharmacovigilance among healthcare professionals (Komaram and Dhar, 2016).

Another study in northern Indian tertiary care teaching hospital assessed knowledge, attitude, and the practice of pharmacovigilance among the undergraduate medical students towards pharmacovigilance showed that students have a good attitude but have an inadequate knowledge and poor practice towards pharmacovigilance. For this, pharmacovigilance related activities need to be incorporated in the undergraduate academic curriculum (Komaram and Dhar, 2016).

Another study in a tertiary care teaching hospital of South India hospital assessed knowledge, attitude, and the practice of pharmacovigilance among the undergraduate medical students towards pharmacovigilance showed that Students lack adequate knowledge and skill of reporting ADR, but they have a positive attitude toward pharmacovigilance program (Dhananjay and Himasri, 2017).

Another study in a teaching hospital in Northern India evaluated knowledge, attitude, and the practice of pharmacovigilance among health care professionals, 77% subjects

responded right regarding the definition of pharmacovigilance. Therefore, it appears to be essential to hold mindfulness programmes to improve the ADR reporting.

Most of the doctors (71 %) felt that the ADR reporting should be compulsory, To improve the spontaneity in the reporting rates, the doctors recommended the organization of training programmes and an uncomplicated reporting system with a quick feedback regarding their specific reports. our study strongly suggested that there was a great need to create awareness among the doctors to improve the reporting of ADRs. The training sessions must clarify the roles of the various healthcare professionals in pharmacovigilance. There should be closer relationship between the doctors and the pharmacovigilance centres.

Another study in a Nepalese hospital assessed knowledge, attitude, and the practice of adverse drug reactions and pharmacovigilance among healthcare professionals identified the KAP scores to be low and recommended educational and managerial intervention. It is expected that though these programs the KAP and awareness among the healthcare professionals will improve (Subish et al., 2017).

Another study in Mumbai assessed knowledge, attitude, and the practice of adverse drug reactions and pharmacovigilance among medical professionals showed that there is lack of sufficient knowledge towards pharmacovigilance and attitudes and practice of ADR reporting is poor(Katekhaye et al., 2017).

A study in Kenyatta hospital evaluated knowledge, attitude, and the practice of adverse drug reactions and pharmacovigilance among medical professionals showed

some of the interviewed healthcare workers believed only new and severe ADRS should be recorded, while very few of them felt only ADRs that one is certain about should be recorded. However, the majority of those interviewed felt that all ADRs should be reported.

A study in Saudi Arabia evaluated knowledge, attitude, and the practice of adverse drug reactions and pharmacovigilance among healthcare professionals showed that there was a limited knowledge towards pharmacovigilance, Educational intervention and a practical training program need to be applied by the drug regulatory body as well as health authorities to enhance the pharmacovigilance and drug safety culture in Saudi Arabia.

A study in Delhi evaluated knowledge, attitude, and the practice of adverse drug reactions and pharmacovigilance among community pharmacists showed that community pharmacists had positive attitude towards ADRs reporting but their knowledge and practice regarding pharmacovigilance need to be improved. There is a need of regular training to increase their role in pharmacovigilance.

A study at King Khalid university hospital in Saudi Arabia evaluated knowledge, attitude, and the practice of adverse drug reactions and pharmacovigilance among physicians showed that there is a need for more teaching and training guide for physicians regarding the pharmacovigilance system and ADRs reporting. More research is needed to study the knowledge and attitudes of other healthcare professionals and in various settings.

A study in a tertiary centre in Northern Nigeria evaluated knowledge, attitude, and the practice of pharmacovigilance and adverse drug reaction reporting among healthcare workers showed that adverse drug reaction reporting is low among health care workers (doctors, nurses and pharmacists) in Kano, Nigeria. There is a need for general training and re-enforcement of guidelines for ADR reporting among health care staff.

An investigation in a teaching hospital in Nigeria assessed knowledge, attitude, and the practice of pharmacovigilance and adverse drug reaction reporting among healthcare experts indicated that the healthcare professionals have a restricted mindfulness about pharmacovigilance. The findings highlight the need for educational and managerial interventions to improve monitoring and reporting of adverse drug reactions within an all-inclusive pharmacovigilance system in this country.

Another study in a primary healthcare center in Malaysia evaluated knowledge, attitude, and the practice of pharmacovigilance and adverse drug reaction reporting among doctors and pharmacists indicated that respondents reflected inadequate knowledge on ADR reporting (MM and BC, 2017).

Another study in a Klang Valley in Malaysia evaluated knowledge, attitude, and the practice of pharmacovigilance and adverse drug reaction reporting among private practitioners indicated unsatisfactory level of knowledge, practices, and attitudes towards ADR reporting among high proportion of private practitioners in Klang valley, Malaysia (Agarwal et al., 2013).

A study that evaluated knowledge and perceptions of pharmacy students about adverse drug reactions reporting and pharmacovigilance showed that the pharmacy students had sufficient knowledge and there are significant differences in perception among the students on adverse drug reaction reporting (Rajiah et al., 2017).

A study in China that evaluated knowledge and perceptions of pharmacy professionals about adverse drug reactions reporting and pharmacovigilance suggested that most pharmacy professionals in China had a positive attitude but lack of knowledge and practices towards pharmacovigilance.

A study in a tertiary care teaching hospital of Sekkim that evaluated knowledge, attitude, an practice of healthcare professionals about adverse drug reactions reporting and pharmacovigilance indicated that the respondents have a norm knowledge and positive attitude toward ADR reporting and pharmacovigilance. There is however a lack of awareness and poor ADR reporting practices.

Another study evaluated knowledge and opinion of hospital pharmacists regarding adverse drug reaction reporting in Northern China showed that hospital pharmacists had a reasonable knowledge of and positive attitudes towards pharmacovigilance. The majority of pharmacists had never reported an ADR in their career. Pharmacists' ADR education and increasing involvement in patient care would be important in improving ADR reporting in hospitals.

3. Materials and Methods

3.1: Materials

Questionnaires

SPSS V20.0 Software

3.2: Study Setting

The investigation was done in 6 tertiary clinics which are Somalia-Turkey training and research hospital, Jazera specialist hospital, Benadir hospital, Medina hospital, Alhayat Hospital, Aden Adde Hospital between June to September 2017. This study was qualitative which involved answering questionnaires from nurses, doctors and pharmacists to assess their knowledge, attitude and practice.

3.3: Type of Study

The study design was cross-sectional, KAP questionnaire study.

3.4: Sample Size

Convenient sampling method was utilized as a part of all health care professionals who are working in above hospitals were enrolled in the study. Before the study, The KAP questionnaires toward pharmacovigilance and ADRs were developed and peer viewed of all questions by expert members of our institutions. Preliminary fieldwork showed that there are a total of 950 healthcare professionals working in central and

southern region hospitals; only healthcare professionals who work on the above hospitals on daily basis are included in this study (n=400).

3.5: Process

All investigation members were reached straightforwardly in their individual office, clarified the reason for the examination and circulated the polls, given 30 min to fill them and hand it back. Any illumination required in understanding the polls and extra time to filled shape was given. Information accumulation occurred during four months (June to September 2017).

A portion of the healthcare professionals finished the questionnaire on the same day, while others were occupied and their filled surveys were gathered on an alternate day. And the study incorporated all health care professionals (physicians, nurses, and pharmacists) in the hospitals who gave their consent and who were working at those hospitals during the time frame.

Pharmacists with minimal dispensing activities, for example, those working in therapeutic stores or associated with the administration of total parenteral nutrition was excluded from the study, and all healthcare workers who did not consent to be interviewed were excluded.

The self-administered, pretested and structured questionnaire was designed to consist of twenty-nine (29) close ended questions divided into three (4) sections, as follows:

Section One- Demographics

It included 5 items that covered participants' gender, age, professional status, marital status and nationality.

Section Two- Awareness

Included 11 items with two (2) Likert scale-type response options- (Agree, Disagree), to test knowledge of pharmacovigilance and adverse drug reaction reporting among healthcare professionals.

Section Three- Attitude

The attitude section included eleven (6) items with two (2) Liker scale-type options- (Agree, Disagree) examined their attitude towards pharmacovigilance and adverse drug reaction reporting among healthcare professionals.

Section Four-Practice

The practice section included seven (4) items with two (2) Likert scale-type options- (Agree, Disagree) examined their practice towards pharmacovigilance and adverse drug reaction reporting among healthcare professionals.Pretesting of questionnaire was done on 5 randomly selected health professionals of the institute. The survey was disseminated in English. The questionnaire consisted of questions that were pre-

tested for reliability in past studies (Palaian, et al.,2011), (Isfahani, 2013), (Khan, 2013), (Santosh et al;2013), (Khan et al., 2015).

3.6: Data Management and Quality Assurance:

All information from the top to bottom meetings was interpreted into MS Word (2010) documents. Information was entered and cross checked by the investigator to ensure accuracy and completeness. Backing up of files to compact discs and flash sticks was done regularly to avoid loss. Privacy of the information was guaranteed by putting away all information in password controlled records and catalogs, which were just open to the primary examiner.

3.7: Ethical Approval

The study protocol was approved by the institutional review boards of the above institutions. There were no immediate advantages to the members. In any case, the discoveries will be conveyed to the healthcare workers and data will aid foundation and improvement of pharmacovigilance activities in the hospitals. The names of the respondents were covered and privacy of data maintained.

The independent variables included in the data analysis were age, sex, marital status, and professional status and nationality. There were three main outcome variables, namely, knowledge of healthcare workers towards Pharmacovigilance, attitude of the healthcare workers towards Pharmacovigilance, and practice of the healthcare workers towards pharmacovigilance.380 out 400 distributed questionnaires were finished with a response rate of (95%).

3.8: Statistical Analysis

Data from the returned pretested survey was coded and gone into Statistical Package for Social Sciences (SPSS) version 20 software. Descriptive statistics were used to analyze the data [frequency and percentages; mean ± standard deviation (SD)]. The comparison of knowledge, attitude and practice (KAP) between doctors and nurses and pharmacists for each question was analyzed used Chi-square test. The p value was set at <0.05 with a confidence interval of 95%.

4. RESULTS

4.1: Response Rate

Four hundred questionnaires were conveyed among the healthcare professionals and 380 responded (response rate 95%). There was a poor knowledge of pharmacovigilance among healthcare professionals, only 54% defined pharmacovigilance accurately and only 8.1% knew about the correct international center of pharmacovigilance, 57.6 % said there is no center of pharmacovigilance in Somalia, attitude of healthcare professionals was moderate.

Just 27% effectively responded about that pharmacovigilance reporting is voluntary,79.6% concurred with setting up pharmacovigilance monitoring center in their institution, and 82.9% agreed with teaching pharmacovigilance in detail to health care practitioners, the practice of healthcare practitioners towards pharmacovigilance was moderate, 65.7% ever reported an adverse drug reaction, and 70.2% experienced an adverse drug reaction during clinical practices,41.6 % agreed that managing patient is more important than reporting and adverse drug reaction while 25% did not know where and how to report an unfavorable medication response.

4.2: Knowledge of Healthcare Professionals towards Pharmacovigilance

In the questionnaire, eleven items were designed to evaluate the pharmacist's knowledge of PV, ADRs and their reporting (table 8). When asked about the

definition of PV, 54% of pharmacists chose the announcement, which best characterized PV as indicated by the WHO definition. Members were then asked about their knowledge regarding the purpose of PV and 40.4% provided the correct answer. Of note, 18% reported not knowing the definition or purpose of PV, respectively.

A similar answer profile was observed when participants were asked about the definition of ADRs where 46% provided the right answer. Several items in the survey were intended to evaluate the knowledge and awareness of the participants about ADR reporting; 32.6% of respondents chose the right answer when asked which ADRs should be reported. However, 57.6 % were aware of the non-existence of an ADR reporting framework in Somalia. Pharmacists had significantly better knowledge of ADRs than physicians (mean±SD, 6.7059±2.86559 vs. 6.4848±2.29453; $P<0.001$).

The attitudes of Pharmacists regarding their capability to handle and report ADRs were significantly more positive than those of physicians (mean±SD, 4.9412±0.95159 vs. 4.5±0.98058; $P<0.05$). Physicians practices towards pharmacovigilance were significantly more positive than those of Pharmacists (mean±SD, 6.1970±1.34987vs 5.5882±1.23381; $P<0.05$).

4.3: Attitudes about ADRs and their Reporting

82.9% were agreed that pharmacovigilance ought to be educated in detail to health care practitioners, only 27 % were willing to report adverse drug reaction voluntarily,

Most of subjects (79.6%) agreed with establishment of pharmacovigilance monitoring centre in their working institutions.

4.4: Practices and Barriers about ADRs and their Reporting

When evaluating the actual practice of the study participants in regards to ADR reporting, 65.7% affirms having reported ADRs for their patients throughout their practice (Table 10). Pharmacists were asked how many ADRs they recall having revealed 32% reported less than 5 ADRs and 48% reported 5-10 ADRs and 20% reported more than 10 ADRs. Components negatively affecting ADR reporting were researched and the most vital obstruction upsetting announcing is that health care professionals believe that managing patient is more important than reporting adverse drug reaction (41.6%).

This is followed, although to a significant lesser extent, by pharmacist (25%) that they don’t know how and where to report. With this respect, recommendations were made by study participants to expand mindfulness among HCPs and patients about ADRs, their reporting and PV by providing targeted continuing professional development training. It was also recommended to set up an ADR reporting center as soon as possible in every hospital with a well-defined official policy and reporting process from the MOH.

Table 3: Gender distribution of health care professionals

Gender	Number of healthcare professionals	Percentage (%)
Female	163	42.89%
Male	217	57.10%
Total	380	100%

Age distribution of health care professionals

Table (2) showed the age distribution of health care professionals that participated in this study. The results showed that most of the participants were between ages of 24 and 30 years (54.73%) and only (5.52%) of the respondents were elder than 40 years.

Table 4: Age distribution of health care professionals

Age	Number of healthcare professionals	Percentage (%)
19-24	88	23.15%
24-30	208	54.73%
30-40	63	16.57%
>40	21	5.52%
Total	380	100%

Professional Status

Table (3) showed the Professional Status of health care professionals that participated in this study.

The results showed that only nineteen (19) participants were pharmacists while most of the participants were nurses (177).

Table 5: Professional Status

Professional Status	Number of healthcare professionals	Percentage (%)
Pharmacist	19	5%
Nurse	177	46.57%
Resident	105	27.63%
Physician	79	20.78%
Total	380	100%

Marital Status

Table (4) showed the Marital Status of the health care professionals who participated in this study. The results showed that most of the participants were single (47.89%).

Table 6: Marital Status

Marital Status	Number of healthcare professionals	Percentage (%)
Single	182	47.89%
Divorced	32	8.421%
Widowed	31	8.157%
Married	135	35.52%
Total	380	100%

Nationality

Table (5) showed the nationality of the health care professionals who participated in this study. The results showed that most of the participants were Somalis (84.47%).

Table 7: Nationality

Nationality	Number of healthcare professionals	Percentage (%)
Somali	321	84.47%
Turkish	59	15.53%
Total	380	100%

Table 8: knowledge of healthcare professionals towards pharmacovigilance

Knowledge related questions	Correct response (%)	Incorrect response (%)
Define pharmacovigilance	54%	46%
Define adverse drug reaction	46%	54%
Do you know about pharmacovigilance	Yes No	82% 18%
Where the international center for adverse drug reaction monitoring is located?	Sweden America Canada	8.1% 71.4% 18.36%
Is the any center of ADR reporting system in Somalia?	Yes No	38.4% 57.6%

Which adverse drug reactions should be reported?	All serious adverse drug reactions Adverse drug reactions to herbal and non-allopathic drugs Adverse drug reactions to new drugs Adverse drug reactions to vaccines Unknown Adverse drug reactions to old drugs All of the above	40.8% 4% 12% 6% 4% 32.6%
Pharmacovigilance includes	Drug related problem Medical devices and vaccines Herbal products All of the above	35% 9.8% 9.8% 45%
The purpose of pharmacovigilance	To enhance patient safety in relation to use of drugs To identify predisposing factors to adverse drug reactions To identify unrecognized adverse drug reactions To calculate incidence of adverse drug reactions	40.4% 31.9% 14.8% 12.7%

Do you know differences between the terms AE and ADR	Yes No	57% 43%
Naranjo's scale is used for causality assessment of an AE	True False	46% 54%
All serious ADRs of the drug are not well documented before marketing	True False	53% 47%

Table 9: Attitude of healthcare practitioners towards pharmacovigilance

Pharmacovigilance reporting should be	Voluntary Compulsory	27% 72.9%
Do you agree with establishing pharmacovigilance monitoring center in your institution?	Yes No	79.6% 28.6%
Should pharmacovigilance be taught in detail to health care practitioners?	Yes No	82.9% 17.1%
ADR should be reported even if causality is not established	True False	62% 38%
Even a single reported ADR can contribute to medical knowledge	True False	57% 43%
ADR case reports should be published in popular medical journals	True False	68% 32%

Table 10: Practice of healthcare practitioners towards pharmacovigilance

Questions	Options	Percentage
Have you ever reported an adverse drug reaction?	Yes No	65.7% 34.3%
Have you ever experienced an adverse drug reaction during clinical practices?	Yes No	70.2% 29.7%
Number of identified adverse drug reaction in patients	<5 5-10 >10	32% 48% 20%
What are the factors discourage you from taking part in pharmacovigilance programs?	Don't know how and where to report Managing patient is more important Lack of time to report Other (please specify)	25% 41.6% 22% 11.11%

Table 11: Groups' relationship with total awareness and total attitude and total practice scores

	Total Awareness			Total Attitude			Total Practice		
	Mean	SD	p-value	Mean	SD	p-value	Mean	SD	p-value
Gender									
Female	6.91	3.12	0.201	4.81	0.97	0.286	6.29	1.37	0.322
Male	6.82	2.91		4.78	0.96		5.98	1.25	
Age									
19-24	5.98	2.73		4.78	0.92		6.07	1.41	
24-30	6.94*	3.17	0.04	4.91	0.84	0.045	6.13	0.98	0.039
30-40	6.90	3.11		4.73	0.73		5.73	1.36	
>40	5.92	2.52		4.70	0.95		5.55	1.28	
Professional Status									
Pharmacist	6.70*	2.86	0.038	4.94*	0.95	0.04	5.58	1.23	
Nurse	5.58	2.11		3.95	0.43		4.87	0.77	
Resident	6.12	2.32		4.25	0.65		5.34	0.97	
Physician	6.48	2.49		4.50	0.98		6.19*	1.34	0.032
Nationality									
Somali	6.97	2.95	0.071	4.96	0.67	0.039	6.14	1.45	
Turkish	6.78	3.14		4.4	0.63		6.25	0.98	0.067

Table 12: Correlation between total awareness, total attitude and total practice scores

	Total awareness		Total attitude		Total practice	
	r	p- value	R	p- value	r	p- value
Awareness	-	-	0.314	0.028	0.235	0.017
Attitude	0.314	0.028	-	-	0.283	0.012
practice	0.235	0.017	0.283	0.012	-	-

5. Discussion

The present investigation is a questionnaire-based survey led to evaluate the knowledge, attitude and practice with regards to pharmacovigilance and ADR reporting among health care professionals working in above six tertiary care teaching hospitals. Around the world, underreporting of ADR is a well-recognized problem associated with spontaneous ADR reporting system. Amongst various elements knowledge, attitude and practice of healthcare professionals assume a critical part in spontaneous reporting of ADRs.

Hence, the present study was undertaken to evaluate the knowledge, attitude and practice of healthcare professionals on ADR reporting. An aggregate of 380 health care professionals had participated in the survey. To the best of our knowledge, this is the first study in Somalia that assessed knowledge of healthcare professionals towards pharmacovigilance. The knowledge level about pharmacovigilance thought to be poor in this study. A study led in a teaching hospital in south India demonstrated that knowledge score was higher than this study.

Another investigation directed in a tertiary care hospital in Gujarat demonstrated that KAP of postgraduate students towards pharmacovigilance was poor (Vora, Nagar, Patel, and Upadhyaya, 2017). Another investigation in Kuwait demonstrated that KAP of pharmacists working in secondary and tertiary hospitals towards pharmacovigilance was good (Alsaleh et al., 2017).

Another study conducted at Mysore (Gupta and Udupa, 2011) and Muzzafarnagar (Ghosh et al., 2010) has indicated high knowledge but poor practice for ADR reporting. The study conducted by (Chatterjee et al., 2006) which expressed that clinical negligibility or underreporting of ADRs from clinicians due to lack of time and no or little knowledge about types of reaction. A survey among medical residents in France (Graille et al.,1994) demonstrated that the majority of them had a lower knowledge with respect to pharmacovigilance.

An investigation from Italy (Cosentino et al., 1997) revealed that physicians had little information concerning ADRs and ADR reporting frameworks. A study from India (Bharathan and Raju, 2006) also identified that the mindfulness about pharmacovigilance program and the knowledge of ADR reporting were very low among the doctors to be reported among prescribers. The fact that dominant part of respondent's concurred pharmacovigilance ought to be instructed in detail to healthcare professionals is a major finding from our study. In this study there was no hole between the ADR experienced (70.2%) and ADR reported (65.7%) by healthcare professionals. Another study conducted by Hardeep et al reported that 59% of study participants had such knowledge (Hardeep et al., 2013). The components in charge of underreporting were also determined in this study.

Pharmacovigilance programs have assumed a noteworthy part in discovery of ADRs and restricting of a few medications from the market after endorsement included benoxaprofen, cerivastatin, cisapride, Domperidone (injectable), valdecoxib, and sibutramine. Therefore, Pharmacovigilance is one of the imperative post-marketing

tools in ensuring the safety of pharmaceutical, herbals and related health products (Ninan et al., 2012; Williams, 2018).

The spontaneous reporting system is the productive cautioning arrangement of adverse drug reactions (ADRs); however, under-reporting of ADRs is one of the real issues related with pharmacovigilance programs (Berrotaran et al., 2007). The major purposes behind underreporting in this study incorporate: don't know how and where to repot (25%), managing patient is more essential (41.6%),lack of time to report (22%). While the knowledge and attitudes of health care professionals appear to be strongly related with reporting (Habila Jamal, 2018).

Along these lines, one of the better approaches to enhance the revealing and to conquer underreporting is to expand the KAP of the healthcare professional concerning ADR monitoring and pharmacovigilance programs. As the study plainly shows the lower knowledge towards pharmacovigilance among healthcare professionals, so it is recommended to conduct educational intervention to improve knowledge of HCP's, as well as pharmacovigilance should be included in the educational programs.

As just little proportion of healthcare professionals have ever been trained on reporting ADR's, so instructional courses ought to be made piece of the professional studies. No center linked to pharmacovigilance exists, so a pharmacovigilance center should be established at national level which should be linked to International monitoring center. It is additionally prescribed that further examinations ought to be

directed which assess the KAP of healthcare professionals, both before and after educational intervention.

As to practice of healthcare practitioners towards pharmacovigilance was moderate, 65.7% ever reported an adverse drug reaction and 70.2% experienced an adverse drug reaction during clinical practices. Essentially, any pharmaceuticals, new and old, must be checked for ADRs for the span of its life cycle.

This objective can be proficient by a fiery Pharmacovigilance system. Be that as it may, there is basic nonattendance of care about PV among health care professionals (Patel et al., 2007; Gupta et al., 2015).

Executing PV in their preparation by the masters can contribute large to the security of meds. While differentiating knowledge, attitude and practice with regards to reporting ADR between doctors and nurses the level of knowledge and attitude were equal. However, doctors had a better score in respects than practice. This may be an aftereffect of the conviction that reporting ADRs is fundamentally the commitment of the treating physicians and diverse components, for instance, anxiety as for the results, vulnerability about the ADRs, trouble in causality appraisal and the extra weight of printed material.

The total scores in like manner on a very basic level higher in specialists in relation with nurses. Basically, when looking at in view of the level of experience the senior level specialists and nurses had a significantly higher score than their juniors. This

may be a result of better care and understanding of the nearby pharmacovigilance system that is in nearness all through the past five years.

This shows the hugeness of guiding general pharmacovigilance getting ready framework to ensure that the more present and junior assets are readied periodically (Khan, et al., 2013; Rishi et al., 2012; Kira et al., 2014).

The examination in like manner underlines in transit those particular variables, for instance, finding out about the ADR structures and its simple entry, past introduction to preparing programs on pharmacovigilance commitment of ADR reporting. The essential concentration of the pharmacovigilance is to propel the safe and the rational use of medications.

It has expected an essential part in distinguishing proof of ADRs yet past examinations suggest that under-reporting of ADRs is one of the main problems related with pharmacovigilance program (Fadare et al., 2011).

Major clarification behind under revealing is absence of learning and ability about pharmacovigilance program, which was reflected in our examination, and is solid with the revelations of other studies (Torwane et al., 2015; Upadhyaya et al., 2015).

This was demonstrating that procedure refinement is required with respect to ADR uncovering and pharmacovigilance. It should be possible by instructive intercessions like fuse of pharmacovigilance related activities in the undergraduate practical, continuous medical education (CME), and workshop on pharmacovigilance (Datta and Sengupta, 2015).

Strengths and Limitations of the Study:

To our knowledge there is no investigation in Somalia that evaluated the KAP of pharmacovigilance among healthcare professionals. And our study incorporated in addition to physicians, pharmacists and nurses because among healthcare providers, nurses and pharmacist are in a novel position to report and monitor adverse drug reaction. However this study may not be generalized to all parts of Somalia considering the relative small sample size. So, we suggest that similar studies carried out in other parts of the country.

6. Conclusion

All in all, this investigation demonstrated that the healthcare professionals had a generally better state of mind and practice however constrained information towards pharmacovigilance. The discoveries of the investigation recommend that there is requirement for ceaseless training with respect to pharmacovigilance and ADR revealing framework among health-care givers. In this manner these endeavors may create increment in mindfulness towards pharmacovigilance among healthcare professionals at last may convert into increment in the adverse drug reaction (ADR) reporting.

Results from this study propose that healthcare professionals working in hospitals in Somalia will report ADRs if there is an appropriate support system in place. It distinguished the variables discouraging ADR reporting and underlined on spontaneous ADR reporting. The under-reporting issues can be adjusted by directing occasional educational interventional programs and sensitizing programs for the health care professionals working in a tertiary care hospital.

ADR reporting can be additionally expanded by enhancing access to ADR reporting forms, utilizing easy to understand techniques, for example, electronic reporting and by educational interventions targeting especially the junior healthcare professionals.

The health care professionals practice towards ADR reporting demonstrated positive pattern towards enhancing ADR revealing and protecting the safety of the patients. In order to better understand the PV progress, we should periodically evaluate the KAP of health professionals PV activities in Somalia. This study was proposed to give an outline of the degree of revealing and ADR drifts in order to build up the level of training in these clinics.

Recommendations: this study recommends that pharmacovigilance centers ought to be set up in the above hospitals to serve as a central place for all pharmacovigilance activities inside the clinics and to send a pharmacist to each and every ward in the hospital to reinforce pharmacovigilance and pharmaceutical practices and that the PV centre should make PV activity forums regular for disseminating updates and new discoveries to make a culture of reporting and to get the healthcare workers constantly updated on PV events. We also recommend that further studies should be conducted to build up the pharmacovigilance practices carried out after implementation of the above recommendations.

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