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Trends in Medical Malpractice in the Private Health Sector in Jeddah, Saudi Arabia

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**Trends in Medical Malpractice in the Private Health Sector in Jeddah,
Saudi Arabia**

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Thesis Committee Chair: Ghada N. Farhat, PhD, MPH

A thesis submitted to the Faculty of
the Rollins School of Public Health
of Emory University in partial fulfillment
of the requirement for the degree of
Master of Public Health
Global Health
2017

ABSTRACT

PURPOSE: About 10% of patients around the world are affected by medical malpractice. Understanding the causes of medical malpractice and its distribution over different medical specialties in Saudi Arabia's private health sector is important for policy makers to institute control measures as the country undergoes privatization of its health sector. Therefore, we assessed the trend in medical malpractice in the private health sector in Jeddah, Saudi Arabia during a five-year period from 2011 to 2015 and its distribution by medical specialties and health professional-related characteristics.

METHODS: We performed a descriptive secondary data analysis on medical practice cases reported by the Medical Jurisprudence Committee(MJC)in Jeddah, Saudi Arabia, in the private health sector during 2011-2015.

RESULTS: There were 368 medical malpractice cases reported to the MJC during 2011-2015. The trend of medical errors was fluctuating with the lowest number reported in 2012 (53 cases, 14.4%) and the highest in 2014 (99 cases, 26.9%). The mean number of litigations was 73.6 cases annually. 24.5 % of the total litigations resulted in severe outcomes; 10.9 % of those outcomes were disabilities and 13.6 % were deaths. Hospitals accounted for most of the cases (77.7 % of the cases) and clinics accounted for the rest (22.3%). Obstetrics and gynecology contributed the highest number of cases (17.9%) followed by general surgery (12.8%), while ophthalmology and urology contributed the lowest percentages, 2.9% and 2.7%, respectively. More male defendants (70%) were involved than females (30%), and more non-Saudis than Saudis, based on their larger representation in the private health sector workforce. But when occurrence rates were estimated, taking in account the workforce size within gender and nationality groups, men and women were found to contribute equally to medical errors, whereas the contribution of Saudis was 2-fold higher than non-Saudis. The average duration of the lawsuit in the MJC from receipt till the issuance of the final verdict was 15.2 months.

CONCLUSION: This study described the pattern of malpractice cases by medical specialty, health facility and health professional-related characteristics, and the duration of medical litigation. This data is useful for policy makers to institute appropriate control measures.

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Tables of contents

CHAPTER 1: INTRODUCTION.....	1
CHAPTER 2: LITRATURE REVIEW.....	5
Epidemiology of Medical Errors.....	5
Consequences of Medical Malpractice.....	7
Global Medical Malpractice System.....	8
Medical Malpractice in the Middle East.....	8
Epidemiology of Medical Malpractice in Saudi Arabia.....	9
Medical Litigation in Saudi Arabia	11
Types of Medical Liability in Saudi Arabia.....	13
CHAPTER 3: MANUSCRIPT.....	15
Abstract	15
Introduction.....	16
Methods.....	19
Results.....	21
Discussion.....	24
CHAPTER 4: CONCLUSION AND RECOMMENDATIONS.....	33
REFERENCES.....	35

List of Tables

Table	Page
1. Distribution of medical malpractice cases in the private health sector in Jeddah, Saudi Arabia, 2011-2015.....	30
2. Distribution of medical malpractice cases by medical specialty in the private health sector in Jeddah, Saudi Arabia,2011-2015.....	31
3. Characteristics of involved health professionals in the private health sector in Jeddah, Saudi Arabia, 2011-2015.....	31
4. Occurrence rate of medical malpractice by gender and nationality of health professionals in Jeddah, Saudi Arabia, 2011-2015.....	32
5.The average duration of medical lawsuit once received by the Medical Jurisprudence Committee in Jeddah, Saudi Arabia, 2011-2015.....	33

CHAPTER 1: INTRODUCTION

Medical malpractice is an act or omission by a health professional that digresses from standard norms and practices in the medical field, resulting in patient injury. In other words, malpractice occurs when health practitioners engage in negligence by falling short of standards (1). Adverse effects that stem from malpractice include unintended injuries or complications that result in death, disability or elongated hospital stay (2).

The foremost principle in treating patients and delivery of health care is to avoid causing harm and injury. While physicians and other health professionals uphold this principle, errors can happen unintentionally resulting inpatient harm (3&4). Although many medical errors occur without reporting, many of them can be avoided and prevented (5). Research indicates that up to half of the adverse effects can be potentially prevented because they result from avoidable errors. However, some adverse effects cannot be avoided, like the adverse effects due to the allergic reaction to some antibiotics and other medications (2).

About 10% of the patients around the world are affected by medical malpractice based on World Health Organization (WHO) information (6). The incidence of medical errors varies widely from one country to another. In the United States, it was estimated to be about 3% of hospitalized patients, whereas in Australia it was about 16.5 %. In general, countries tend to underreport medical errors (7).

Most medical errors occur when the physicians are not experienced or when a new procedure or technique is introduced (8). Medical errors also may result from other different causes including lack of attention and care, insufficient or lack of knowledge, slips, negligence, absence and poor attendance of the health professionals (9). Poor communication or

attentiveness among the medical team may also result in the occurrence of medical errors and adverse events (5).

Up to 60% of medical malpractice cases result from surgical errors. These can occur as a result of lack of surgical experience, lack of competence and skills, high workload, fatigue, and lack of the proper technology (10,11&12). Another common source of medical errors is medication errors, which may occur as a result of mistakes during ordering, administration, transcription or distribution of medications (13). Organizational factors contributing to medical errors include inappropriate work policy and procedures, lack of continuous training and education of health professionals, lack of organizational management, low quality of equipment and lack of their availability, and shortage in skill level and number of health professionals (14 &9).

Patient-related factors can also increase the risk of medical errors. These factors include old patient age and conditions requiring acute interventions or intensive care to save patients' lives. Invasive procedures that carry a high risk of adverse events include neurosurgery, cardiothoracic surgery and vascular surgery (8). Potential results of harmful health care practices are lifelong injury, increased duration of hospital admission, increased hospital costs, or death (15&8).

Every country around the world has its own medical malpractice system. The United States, for example, adopts a "tortliability system" where the patient is compensated only when the injury is proven to be a result of medical malpractice. Many Organization for Economic Cooperation and Development (OECD) countries adopt a "no-fault system" where the patient is compensated whether or not the injury is proven to be a result of medical malpractice (16).

Saudi Arabia has shown remarkable progress over the last 20 years regarding the delivery of health services in both the public and private sectors, which has been attributed to the well-trained health professionals and the introduction of new medical equipment in health facilities. In parallel to this progress, the annual trend of medical practice lawsuits in Saudi Arabia has been increasing as a result of the increase in population size and the increase in patient's awareness about their rights (17). The total number of claims in 1999 was 440, whereas in 2008, the number of claims increased to a total of 1,356 representing all health care providers in Saudi Arabia(8). Most medical errors in Saudi Arabia are reported to occur in obstetrics and general surgery (17&18).

The medical litigation process in Saudi Arabia starts when a patient or his/her agent legal guardian makes a complaint of medical malpractice to the Directorate of Health Affairs (DHA) in their city/region. The DHA then refers the complaint to the regional medico-legal committee for investigation by interviewing the plaintiff first and then interviewing the defendant by the primary investigation committee. If the primary investigation committee decides that there is a medical error, the investigators write their report to the medical jurisprudence committee(18). The medical jurisprudence committee issues the final verdict by a majority vote system. The verdict can be appealed within 60 days of issuance (9).

Medical practice law in Saudi Arabia is based and governed by Islamic law. There are three types of professional liability which include civil, disciplinary and punitive liability (17). One of the criticisms against medical litigations in Saudi Arabia is the long duration of the process from the initiation of the lawsuit until the issuance of the final verdict (5).

Medical errors tend to be under-reported in many countries, including Saudi Arabia (8). As such, the exact prevalence of medical errors is difficult to estimate (8). Although a few studies have been published about medical errors and adverse events in Saudi Arabia, the epidemiological information about these errors are deficient and it is difficult to compare among these studies due to the lack of consistent definitions and standards for measuring medical errors. A comprehensive descriptive analysis of medical errors in private health sector by the place of occurrence (health facility type), medical specialty, and health professional-related characteristics such as gender and nationality is lacking in Saudi Arabia.

Therefore, this study was conducted to examine the total number and the trend of medical malpractice cases in the private health sector in Jeddah, Saudi Arabia during a five-year period from 2011-2015. Specifically, this study 1) estimated the distribution of medical malpractice cases by health facility type (hospital versus clinic) and over the different medical specialties, 2) analyzed the distribution by health professional-related characteristics including profession, gender, and nationality, 3) assessed the proportion of cases resulting in severe patient outcomes (death and disability), and 4) estimated the duration of medical litigation from its initiation to the issuance of the final verdict.

CHAPTER 2:LITRATURE REVEIW

Epidemiology of Medical Errors

Medical errors may result from surgical procedure errors, therapeutic mishaps, cognitive mistakes like incorrect diagnoses or prescribing the wrong treatment, and complications due to drug treatment (8).

According to World Health Organization (WHO), about 10% of the patients around the world are affected by medical malpractice (6). Only very few studies were conducted to determine the rate of medical malpractice among hospitalized patients. In the United States, the adverse effect rate was about 3.7% of hospitalized patients based on a study conducted in 1984 among hospitalized patients. In 1995, a study conducted in Australia showed that adverse effects occurred in about 16.5% of the hospitalized patients (8). In the UK, a study conducted in 1999-2000 showed that adverse effects were estimated to occur about 11.7% in the hospitalized patients; in Denmark it was estimated to be 9% (19). A study conducted in Canada in 2000 showed that the incidence rate of adverse effects among hospitalized patients was 7.5%, resulting in death in 21% of the cases. The study estimated that about 37% of adverse effects were preventable (2). In contrast, data about medical malpractice in clinics is scarce, and it was found to be about 8-9% in both the Australian and the US studies (8).

Medical errors may result from surgical procedures, therapeutic mishaps, cognitive mistakes like incorrect diagnoses or prescribing the wrong treatment, and complications due to drug treatment (8). It can also result from lack of attention and lack of care, insufficient or lack of knowledge, slips, negligence, absence and attendance failure of the health professionals (9). Poor communication or attentiveness among the medical team may also result in occurrence of the

medical errors and adverse events (5). Other factors can lead to the occurrence of medical errors including overload and the high turnover of the patients and the absence of close observation of high risk patients (5). Most medical errors can occur when the physicians are not experienced or when a new procedure or technique is introduced. Other factors that may result in medical errors include reading radiographs or pathological specimens incorrectly, as well as laboratory errors, resulting in incorrect diagnoses (8). Laboratory errors can occur at the pre-analytic, analytic or post analytic stage; most occur at the pre-analytic stage, such as mislabeling and wrong data entry (20).

Surgical errors are the most common type of medical errors, constituting up to 60% of medical malpractice cases (10). It can occur as a result of lack of surgical experience, lack of competence and skills, high workload, fatigue, lack of the proper technology, low hospital admission for some surgical operations and weak hospital systems in addition to improper communication among medical staff and also lack of communication with the patients (10,11&12).

Medication errors are another common source of medical errors. They may occur at the level of ordering, administration, transcription or distribution of medications (13). A study conducted in two hospitals in Boston found that 6.5% of patients experienced confirmed adverse events while another 5.5% experienced potential adverse events related to drugs. About 40% of adverse drug events were due to errors in drug administration (8). Another study showed that adverse drug reaction resulted in the admission of more than 20% of seniors to the hospitals in Ontario (21). The incidence of adverse drug reaction varied widely from about 1.5% up to 35% in hospitalized patients (13).

It is also important to note that patient-related factors such as old age increase the likelihood of medical errors due to patient frailty and co morbid diseases. Certain invasive procedures carry a high risk of adverse events like neurosurgery, cardiothoracic surgery and vascular surgery. Patients with complicated cases and patients requiring acute interventions or intensive care to save their lives are at a greater risk to suffer from adverse events (8).

Medical errors are not only a result of provider-related or patient-related factors, but can also be attributed to organizational factors like inappropriate work policy and procedures, lack of continuous training and education of health professionals, lack of organizational management, lack of equipment or their low quality, shortage in quantity and quality of health professionals (14 &9). Overall, any deficiencies associated with the delivery of health services introduce a risk of medical errors and adverse events (22).

Consequences of Medical Malpractice

Lifelong injury, increased duration of hospital admission, increased hospital costs, or death, are potential results of harmful health care practices. These negative outcomes are not necessarily due to intentionally harmful practices, but rather due to the complicated healthcare system nowadays (15&8).

The most serious consequence of medical malpractice is death. In Canada for example, adverse effects due to medical malpractice results in about 9,000 - 24,000 patients dying each year from medical errors that could have otherwise been avoided (2). Medical errors in the United States may results in up to 98,000 unnecessary deaths annually and about one million injuries. In Australia, adverse effects result in about 13.7% permanent disabilities and about 5%

deaths. A study conducted in Utah found that adverse drug events cost about \$2,250 for every patient and prolonged duration of hospital stay by about 2 days (8).

Global Medical Malpractice System

Every country around the world has its own medical malpractice system. For example, the United States adopts a "tort liability system", whereas many OECD countries like Australia, Canada (Quebec), Sweden and many others adopt a "no-fault system". In a tort liability system, if the cause of the injury is proven to be a result of medical malpractice then the patient will be compensated, and if not proven, then the patient will not be compensated. In a no-fault system, the injured patient is compensated whether the cause was confirmed to be due to medical malpractice or not. Such a system encourages physicians to report and detect the causes of the medical errors rather than deterring them from providing suboptimal care. The criticism against the tort litigation system is that it does not compensate the victims sufficiently, as well as the long duration and the high cost of litigation, making patient access to courts difficult. On the other side, despite the fact that the no-fault system is efficient in providing compensation for the injured patients, the right of the patients to appeal is limited (16).

Medical Malpractice in the Middle East

No comprehensive data on medical errors exist in Middle Eastern countries. Medication errors in Middle Eastern countries varied widely, with 7% to 90% of errors resulting from prescription and 9% to 80% resulting from administration errors. Most of the prescription errors occurred as a result of the wrong dosage or the wrong frequency. Lack of medication knowledge by the physicians who prescribe the medications and by the nurses who administer them was a contributing factor to medication errors (23). While no formal research studies on the topic exist,

a 2014 newspaper report about medical errors in the United Arab Emirates indicated that there were more than 500 lawsuits filed against physicians in 2013 (24).

Medical malpractice in Saudi Arabia

Epidemiology of Medical Malpractice in Saudi Arabia

Health services in Saudi Arabia have shown remarkable progress over the last 20 years in both the public and private sectors. Such improvement has been a result of well-trained health professionals and introduction of new medical equipment in health facilities (17). There are many health care providers in Saudi Arabia, including the Ministry of Health (MoH) (governmental services provided to the public), the private health sector, military medical services, university medical services and others (17).

Despite improvement in the delivery of health services, the increase in population size in parallel with an increase in population awareness have resulted in a higher number of medical practice lawsuits in Saudi Arabia, with an annual trend that has been increasing over the last 20 years (17). Only few studies have been conducted about medical malpractice in Saudi Arabia .

Al-Saeed conducted a study in 2010 about medical liability litigation in Saudi Arabia and found that in 1999, the total number of claims was 440, whereas in 2008, the number of claims increased to a total of 1,356 (representing all health care providers in Saudi Arabia). Al-Saeed's (2010) study also found that the mean of the final verdicts of accusation relative to the total claims is about 50% for the different medical specialties. Additionally, the mean number of final verdicts in the public health sector in Saudi Arabia was about 217 cases, whereas the private health sector had 197 cases 1999-2008. About 90% of the medical errors in Saudi Arabia

occurred in MoH hospitals (48%) and in the private health sector (44%), whereas, 5.5% occurred in military hospitals and 1.2% in university hospitals (3).

According to Samarkandi (2006), about 26% of medical errors in Saudi Arabia occurred in the obstetrics specialty, followed by general surgery and other related surgical subspecialties, which accounted for about 17% of medical malpractice errors. Medical specialty for adults and pediatrics represented 13% and 10% of medical errors respectively. Dentistry was at the bottom of the list, with 2.5% of medical errors (17). The study argued that most medical errors occurred in MoH hospitals because they cover most of the small cities with non-sufficient and under-trained health care professionals and underequipped health facilities. Private health facilities on the other hand, although well equipped and with sufficient staff, may not provide thorough healthcare (e.g. laboratory investigation, radiology, etc.) at the patient's discretion (so as to reduce costs), thereby potentially resulting in medical malpractice (17).

In 2013, Aljarallah and Alrowaiss conducted a study about medical errors and litigation in Saudi Arabia for two years in 2007-2008, including all health care providers and found that there 642 cases (275 cases in 2007 and 367 in 2008) had occurred. Most of the errors resulted from surgery, which accounted for about 25%, followed by obstetrics and gynecology (22%), internal medicine (12%), pediatrics (8%), dentistry (6%), otorhinolaryngology (3%), and ophthalmology (2%) (18).

Henry et al. conducted a study about medical errors in Al-Qassim region, Saudi Arabia from 1992 till 2009. He found that during this period there were 293 cases of medical errors. Most errors occurred in obstetrics and gynecology (28%), followed by internal medicine (14%),

pediatrics (12%), general surgery (9%), anesthesia (7.5%), orthopedics (5%), emergency (4.5%), neurosurgery (2%), otorhinolaryngology (1.6%), ophthalmology (1.2%) (16).

Al-Saleem and Al-Surimi conducted a study in 2016 about the laboratory errors in Riyadh region, Saudi Arabia and found that there were 2.3 errors for every 1,000 laboratory samples, all of which were found occur during the pre-analytic stage (20).

Medical Litigation in Saudi Arabia

In 2006, Saudi Arabia adopted a new regulation for medical practice entitled "executive forms and procedures". The main items of this act are: 1) every health professional should have a valid practicing license from the Saudi Commission for Health Specialties, 2) in order to renew the license, the practitioner should attend a minimum required number of continuing medical education hours on an annual basis, 3) the health professional should compensate the patient if he/she harmed or injured that patient, and 4) a health professional practicing without a license would be subject to imprisonment or financial penalty (25). Since 2009, all health professionals were obligated to have medical liability insurance (26).

Despite the fact that filing a medical lawsuit is easy in Saudi Arabia, the issuance of the final verdicts may take from several months to several years, particularly when there is monetary compensation involved. According to Aljarallah and Alrowaiss's (2013) study about medical errors and litigation in Saudi Arabia, the process of investigation takes many steps to reach the final verdict (18). Firstly, the medical litigation process starts when a patient or his/her agent legitimate makes a complaint of medical malpractice to the Directorate of Health Affairs (DHA) in their city/region (17). The DHA then refers the complaint to the regional medico-legal

committee. There are eight medico-legal committees in KSA, with one committee for each administrative region, according to a study conducted by Henary et al. in 2012(5).

At this point, the plaintiff is interviewed by the medico-legal investigators, after which the defendants (medical professionals who are responsible or who were present during the medical malpractice incident) are interviewed. The medical file of the patient is reviewed carefully in the primary investigation committee, which usually includes three investigation members: two physicians (one of them from the same medical specialty in which the error occurred) and one legal expert to find out if there was an error or not (18). If the primary investigation committee decides that there is no error, the case does not go to the medical jurisprudence committee and instead, the case is discussed directly with the plaintiff to inform him/her that there is no medical error (18).

If the primary investigation committee decides that there is a medical error, the investigators write their report to the medical jurisprudence committee. The medical jurisprudence committee is headed by a judge with three physicians (two of them from the MoH and one is a teaching staff from medical school) and one legal expert, and in cases where the litigation was against a pharmacist, the committee will also include two pharmacist members (18). The medical jurisprudence committee issues the final verdict. The decision of the committee is made by majority of votes and it can be appealed within 60 days of the verdict issuance (18). Non-Saudi defendants are banned from travelling outside Saudi Arabia until the final verdict is issued (5).

Types of Medical Liability in Saudi Arabia

Medical practice law in Saudi Arabia is based and governed by Islamic law. There are three types of professional liability which include civil, disciplinary and punitive liability. Civil liability is the right of the patient injured or harmed by a responsible medical professional and it may range from indemnity due to loss of an organ to indemnity due to death (17&18). Punitive liability can be applied to health professionals who violate the regulations of medical practice, even if no harm occurs to the patient (17). Disciplinary liability applies to situations when health professionals have failed to meet the standards and ethics of their profession (17).

In the case of medical litigation, a committee may impose a warning, ban medical practice, require the withdrawal of the medical license, or even imprison those health professionals found guilty of medical malpractice(17). However, although such options of punishment exist, one of the criticisms against medical litigation in Saudi Arabia is the bureaucracy that interferes with the timeliness of the process, as the progression from the beginning of lawsuit until the issuance of the final verdict is too slow and takes a long time, thereby potentially delaying justice (5).

Problem Statement

Medical errors tend to be under-reported in many countries, including Saudi Arabia (8). As such, the exact prevalence of medical errors is difficult to estimate (8). Although a few studies have been published about medical errors and adverse events in Saudi Arabia, the epidemiological information about these errors are deficient and it is difficult to compare among these studies because there are no common set of standards for the research methods, which leads to great variation in the estimation of the rate of errors from one study to another.

Researchers must use consistent definitions and standards for measuring medical errors. A comprehensive descriptive analysis of medical errors in private health sector by the place of occurrence (health facility type), medical specialty, and health professional-related characteristics such as gender and nationality is lacking in Saudi Arabia.

Purpose Statement and Research Questions

The purpose of this study was to examine the total number and the trend of medical malpractice cases in the private health sector in Jeddah, Saudi Arabia during a five-year period from 2011—2015. Specifically, this study 1) estimated the distribution of medical malpractice cases by health facility type (hospital versus clinic) and over the different medical specialties, 2) analyzed the distribution by health professional-related characteristics including profession, gender, and nationality, 3) assessed the proportion of cases resulting in severe patient outcomes (death and disability), and 4) estimated the duration of medical litigation from its initiation to the issuance of the final verdict.

Research Significance

Saudi Arabia is undergoing privatization of the health sector. This evaluative study of medical malpractice in the private health sector can help policy makers in the healthcare system improve the delivery of health services by minimizing medical errors and the duration of medical litigation in order to make the right decisions towards improving the health care in Saudi Arabia.

CHAPTER 3: MANUSCRIPT

Abstract

PURPOSE: About 10% of patients around the world are affected by medical malpractice. Understanding the causes of medical malpractice and its distribution over different medical specialties in Saudi Arabia's private health sector is important for policy makers to institute control measures as the country undergoes privatization of its health sector. Therefore, we assessed the trend in medical malpractice in the private health sector in Jeddah, Saudi Arabia during a five-year period from 2011 to 2015 and its distribution by medical specialties and health professional-related characteristics.

METHODS: We performed a descriptive secondary data analysis on medical practice cases reported by the Medical Jurisprudence Committee (MJC) in Jeddah, Saudi Arabia, in the private health sector during 2011-2015.

RESULTS: There were 368 medical malpractice cases reported to the MJC during 2011-2015. The trend of medical errors was fluctuating with the lowest number reported in 2012 (53 cases, 14.4%) and the highest in 2014 (99 cases, 26.9%). The mean number of litigations was 73.6 cases annually. 24.5 % of the total litigations resulted in severe outcomes; 10.9 % of those outcomes were disabilities and 13.6 % were deaths. Hospitals accounted for most of the cases (77.7 % of the cases) and clinics accounted for the rest (22.3%). Obstetrics and gynecology contributed the highest number of cases (17.9%) followed by general surgery (12.8%), while ophthalmology and urology contributed the lowest percentages, 2.9% and 2.7%, respectively. More male defendants (70%) were involved than females (30%), and more non-Saudis than Saudis, based on their larger representation in the private health sector workforce. But when occurrence rates were estimated, taking in account the workforce size within gender and nationality groups, men and women were found to contribute equally to medical errors, whereas the contribution of Saudis was 2-fold higher than non-Saudis. The average duration of the lawsuit in the MJC from receipt till the issuance of the final verdict was 15.2 months.

CONCLUSION: This study described the pattern of malpractice cases by medical specialty, health facility and health professional-related characteristics, and the duration of medical litigation. This data is useful for policy makers to institute appropriate control measures.

3.1 Introduction

Medical malpractice is an act or omission by a health professional that digresses from standard norms and practices in the medical field, resulting in patient injury (1). According to World Health Organization (WHO), about 10% of the patients around the world are affected by medical malpractice (6). Incidence of medical errors varied widely from one country to another and most countries tend to under report medical malpractice (8).

Only very few studies were conducted about medical malpractice that use the rate of injuries of hospitalized patients. In the United States, the adverse effect rate was about 3.7% based on a study conducted in New York in 1984 among hospitalized patients. In 1995, a study conducted in Australia showed that adverse effects occurred in about 16.5 % of hospitalized patients (8). In the UK, a study conducted in 1999-2000, showed that adverse effects were estimated to occur in about 11.7% in the hospitalized patients; in Denmark it was estimated to be 9% (19). A study conducted in Canada in 2000 showed that the incidence rate of adverse effects among hospitalized patients was 7.5 %, where death occurred in about 21% of the cases and about 37% of these adverse effects were thought to be preventable (2). In contrast, data about the medical errors in the doctor's office is scarce, and was found to be about 8-9 % in both the Australian and Harvard studies (8).

Most medical errors occur when the physicians are not experienced or when a new procedure or technique is introduced (8). Other causes of medical errors include lack of attention and care, insufficient or lack of knowledge, slips, negligence, absence and attendance failure of the health professionals (9). Poor communication or attentiveness among the medical team may

result in occurrence of the medical errors and adverse events (5). Surgical errors may occur as a result of lack of surgical experience, lack of competence and skills, high workload, fatigue, lack of the proper technology (10,11&12). Errors during ordering, administration, transcription or distribution of medications may result in adverse drug events (13).

Organizational factors including inappropriate work policy and procedures, lack of continuous training and education of health professionals, lack of organizational management, low quality of equipments and lack of their availability, low quality and number of health professionals can also lead to the medical malpractice (14 &9).

Certain factors can lead to an increased risk of medical errors. Such factors include old age patients, patients requiring acute interventions or intensive care to save their lives. Use of invasive procedures that carry a high risk of adverse events like neurosurgery, cardiothoracic surgery and vascular surgery can also increase the risk of medical errors (8).

Surgical errors are the most common type of medical errors, constituting up to 60% of medical malpractice cases (10). Some adverse effects cannot be avoided like the adverse effects due to allergic reactions to some antibiotics and other medications but research indicates that up to half of adverse effects can be potentially prevented (2). The potential results of harmful health care practices are lifelong injury, increased duration of hospital admission, increased hospital costs, or death (15&8).

Health services in Saudi Arabia have shown remarkable progress over the last 20 years in both the public and private sectors. Such improvement has been a result of well trained health professionals and introduction of new medical equipment in health facilities (17). There are many health care providers in Saudi Arabia, including the Ministry of Health (MoH)

(governmental services provided to the public), the private health sector, military medical services, university medical services and others (17).

Despite improvement in the delivery of health services, the increase in population size in parallel with an increase in population awareness have resulted in a higher number of medical practice lawsuits in Saudi Arabia, with an annual trend that has been increasing over the last 20 years (17). The total number of claims in 1999 was 440, whereas in 2008, the number of claims increased to a total of 1,356 representing all the health care providers in Saudi Arabia(3). Most medical errors in Saudi Arabia occurred in the obstetrics specialty and general surgery (17&18).

About 90% of the medical errors in Saudi Arabia occurred in MoH hospitals and the private health sector combined (48 % in MoH and 44 % in private health sector), 5.5% in the military hospitals and 1.2% in the university hospitals. Most medical errors occurred in MoH hospitals because they cover most of the small cities with non-sufficient and under-trained health care professionals and underequipped health facilities. Private health facilities on the other hand, although well equipped and with sufficient staff, may not provide thorough healthcare (e.g. laboratory investigation, radiology, etc.) at the patient's discretion (so as to reduce costs), thereby potentially resulting in medical malpractice (17).

Medical practice law in Saudi Arabia is based and governed by Islamic law(17). The medical litigation process in Saudi Arabia starts when a patient or his/her agent legitimately makes a complaint of medical malpractice to the Directorate of Health Affairs (DHA) in their city/region. The DHA then refers the complaint to the regional medico-legal committee for investigation by interviewing the plaintiff first and then interviewing the defendant by the Primary Investigation Committee. If the Primary Investigation Committee decides that there is a

medical error, the investigators write their report to the Medical Jurisprudence Committee (18). The Medical Jurisprudence Committee issues the final verdict by majority of votes and it can be appealed within 60 days of the verdict issuance (18).

Medical errors tend to be under-reported in many countries, including Saudi Arabia (8). Although a few studies have been published about medical errors and adverse events in Saudi Arabia, a comprehensive descriptive analysis of medical errors in private health sector is lacking. The purpose of this study was to examine the total number and the trend of medical malpractice cases in the private health sector in Jeddah, Saudi Arabia during a five-year period from 2011-2015, to estimate the distribution of medical malpractice cases by health facility type (hospital versus clinic) and over the different medical specialties, to analyze the distribution by health professional-related characteristics including profession, gender, and nationality, to assess the proportion of cases resulting in severe patient outcomes (death and disability), and to estimate the duration of medical litigation from its initiation to the issuance of the final verdict.

3.2 Methods

Study Design

This study performed a descriptive secondary data analysis on medical practice cases reported in Jeddah, Saudi Arabia, in the private sector during the period of 2011-2015; 368 cases were reported during this period.

Data Sources

The medical malpractice data was obtained from the Ministry of Health's medico-legal department, Directorate of Health Affairs in the city of Jeddah, Saudi Arabia .The data received comprised of aggregate figures of the final verdicts issued for medical malpractice cases reported in the private health sector in Jeddah during 2011-2015.The data included a breakdown of the verdicts by medical specialty and characteristics of the health care professional including profession, gender and nationality. Data on the health workforce in the private health sector in Jeddah were retrieved from the 2011 Statistical Yearbook of Ministry of Health, Saudi Arabia (27). This data source was used to obtain denominator data to estimate the occurrence of medical errors by gender and nationality of the health care professional.

Study Variables

The study variables included the year and health facility (hospital/ clinic) in which the medical error occurred, medical specialty (obstetrics and gynecology, general surgery, orthopedics, neurosurgery, urology, otorhinolaryngology, ophthalmology, other surgical specialties, internal medicine, pediatrics, dentistry, other specialties), and characteristics of the defendant including profession (physician, pharmacist, nurse or technician), gender (male/ female), and nationality (Saudi/ non-Saudi).Other variables included severity of outcome (defined as death or disability versus not) and verdict issuance (yes/ no).

Statistical Analysis

A descriptive analysis of the medical malpractice cases during 2011-2015 was conducted. The distribution (N, %) of cases was examined by year of occurrence, place of occurrence, medical specialty, and characteristics of the health care professional (profession, gender and nationality). The proportion of cases resulting in severe outcomes was estimated. Verdict issuance was also examined. Because this study was able to obtain denominator data about the number of physicians in Jeddah by gender and nationality (but not other variables), the rates of occurrence of medical errors by gender and nationality subgroups for each health profession category were calculated. The gender- and nationality-specific occurrence rates were calculated by dividing the number of cases within a specific gender and nationality category by the total number of health professionals within that same category. Occurrence rate ratios, confidence interval and p-values were obtained for comparison. SAS version 9.4 (SAS Institute, Cary, NC) was used for statistical analyses.

Ethics

The analysis involved a secondary data analysis on a de-identified aggregate dataset that did not include personal identifiers. Thus, it did not meet the definition of human subject research and was classified as exempt from review by the Emory University Institutional Review Board.

Results

Description of medical malpractice cases

The review of medico-legal records showed that the total number of litigations between 2011 and 2015 was 368 cases, with the lowest number reported in 2012 (53 cases, 14.4%) and

the highest number reported in 2014 (99 cases, 26.9 %). The mean of the litigations number was 73.6 cases annually. The Medical Jurisprudence Committee issued 282 verdicts with penalties against healthcare professionals, representing 76.6 % of the lawsuits filed, and in 86 lawsuits (23.4 %) the defendant was not found guilty.

Medical errors in the private health sector in Jeddah during this period resulted in severe outcomes in 90 cases (24.5 %). Disabilities were reported in 40 cases (10.9% of the total) and death occurred in 50 cases (13.6%). Hospitals were responsible for the larger share of medical malpractices (77.7%), whereas clinics accounted for 22.3% of the cases [Table 1].

Distribution of medical malpractice cases by medical specialties

The distribution of litigations over different medical specialties varied, with the highest claims reported against obstetrics and gynecology practitioners (17.9% of the total litigations, N= 66), followed by general surgery (12.8%, N= 47), orthopedic (11.4 %, N= 42), pediatrics (10.1 %, N=37 cases) and dentistry practitioners (9.5 %, N=35). Fewer claims were reported against ophthalmologists (2.9%, N=11) and urologists (2.7%, N=10) [Table 2].

Distribution of medical malpractice cases by characteristics of the healthcare professional

Analysis of the distribution of medical malpractice cases by characteristics of healthcare professionals revealed that physicians were responsible for most of the medical errors that occurred (92.8%), followed by nurses (5.6%) and technicians (1.6%). There were no claims reported against pharmacists.

Seventy percent (N= 263) of accused health care professionals were male and 30% (N= 113) were female. Saudi health care professionals represented 12% (N= 45) and non-Saudis represented 88% (N=331) [Table3].

Based on Saudi MoH statistics for 2011 (1431 Hijri), there were 2,508 physicians in the private health sector in Jeddah (1,752 males and 756 females; 159 Saudi and 2,349 non-Saudi), 1,853 nurses (103 males and 1,750 females; 57 Saudi and 1,796 non-Saudi), and 820 allied health personals (342 males and 478 females; 78 Saudi and 742 non-Saudi) (27). obtained the gender- and nationality-stratified rate of occurrence of medical errors for each health profession. Occurrence rate ratios were calculated for gender as male to female and for nationality as Saudi to Non-Saudi. Occurrence rate ratios showed that male and female physicians were equally responsible for medical errors (Rate Ratio= 1.00;95% CI 0.81-1.24; p-value =0.98). Also, we found that the occurrence rate of medical errors in Saudi physicians compared to non-Saudi physicians was 2 times higher (Rate Ratio= 2.02;95% CI 1.53-2.67; p-value <0.001,). Among nurses, males were found to have a 4-fold higher rate of occurrence of medical errors than females (Rate Ratio= 4.3; 95% CI 1.5-12.5 ; p-value= 0.04), but nationality differences were not statistically significant (Rate Ratio= 1.66; 95% CI= 0.23-12.2; p-value= 0.59). Occurrence rate ratio among technicians either by nationality (Rate Ratio=1.59 ;95% CI= 0.19-13; p-value= 0.64) or gender (Rate Ratio= 3.49; 95% CI= 0.68-17.9 ; p-value= 0.14) were not statistically significant [Table 4].

Duration and process of lawsuits

The average duration of the first court session of the medical lawsuit after its transfer from the Primary Investigation Committee to the Medical Jurisprudence Committee was 5.3

months, and the average duration till the issuance of the verdict was 15.2 months (Table 5). The mean number of court sessions was 3.8 for each case.

Discussion

This study aimed to examine the trend of medical malpractice and its distribution over the different medical specialties and by characteristics of the health professionals involved in the private health sector in Jeddah, Saudi Arabia during 2011-2015.

The results of the study showed that over a 5-year period, there were 368 medical lawsuits filed against private health sector professionals in Jeddah city. The trend of these litigations was fluctuating with the lowest number reported in 2012 (53 cases, 14.4%) and the highest number reported in 2014 (99 cases, 26.9 %). Our study showed the practice of obstetrics and gynecology was the leader in terms of its contribution to medical errors. This study observed that 70% of medical errors were contributed by males and 30% by females, and about 88% were reported against non-Saudis and 12% against Saudis. When occurrence rates were estimated, taking in account the workforce size within gender and nationality groups, men and women physicians were found to contribute equally to medical errors, whereas the contribution of Saudi physicians was 2-fold higher than non-Saudis; and among nurses, males were found to have a 4-fold higher rate of occurrence of medical errors than females, but nationality differences were not statistically significant.

The foremost principle in treating patients and delivery of healthcare is to avoid doing harm and injury. The health care facilities and professionals often do their best to provide the safest healthcare to the patients. No physician or other health professional wants to make a

mistake or harm patients. However, mistakes may happen and injury can take place and unintentionally, the patient can be hurt as a result of medical care (3 &4).

Discussing medical errors in Saudi Arabia is a very sensitive issue for both the healthcare professionals and the healthcare stakeholders and it is difficult to access the records of medical errors. There is a lack of transparency and disclosure among health professionals in reporting the medical errors unless the error resulted in severe injury to the patient. A few studies were conducted about medical errors in Saudi Arabia and all of them reported the number and percentage of medical errors for each specialty and none of the previous studies estimated the rate of hospitalized or followed-up patients (18,5&28). Globally, very few studies were conducted about medical errors, all in hospitalized patients. In the United States, the medical malpractice rate was about 3.7% based on a study conducted by Harvard University in 1984 among hospitalized patients. In 1995, a study conducted in Australia showed that adverse effects occurred in about 16.5% of hospitalized patients (8). In the UK, a study conducted in 1999-2000, showed that adverse effects were estimated to occur about 11.7% of hospitalized patients; in Denmark it was estimated to be 9% (19). A study conducted in Canada in 2000 showed that the incidence rate of adverse effect among the hospitalized patients was 7.5% (2). In contrast, data about the medical errors in the clinic is scarce, and it was found to be about 89% in both the Australian and Harvard studies (18).

Saudi Arabia is currently adopting a new strategy called "Vision 2030 " in order to diversify the country's resources and not merely depend on the oil for its economy, and one of these diversifications is the privatization of many sectors, including the health sector (29). This is the first study to be conducted on medical errors, specifically in the private health sector, in order

to help policy makers in the healthcare system make the right decisions toward improving the health care in Saudi Arabia in line with the achievement of "Vision 2030".

Jeddah city is located on the Red Sea coast in the western region of Saudi Arabia. About 4.3 million people live in Jeddah based on the last census (30). The city has 33 private hospitals with 3,109 beds and 398 polyclinics based on the latest statistics in 2016 (1436 Hijri) (31). The results of the study showed that there were 368 medical lawsuits filed against private health sector professionals in Jeddah and received by the Medical Jurisprudence Committee during 2011-2015. The trend of these litigations fluctuated with the lowest number reported in 2012 (53 cases, 14.4%) and the highest number reported in 2014 (99 cases, 26.9%). The mean of the litigations number was 73.6 cases annually, which was different from three studies conducted previously that showed increasing trends of the medical errors in Saudi Arabia (17,3&18). It is important to note that not all the medical litigations reached the Medical Jurisprudence Committee as many of the plaintiffs reconciled with the defendants when they are compensated by money and some waived off the lawsuit as they believed the health event was due to destiny, especially in the case of death litigations; this is one of the limitations of this study. Also another important limitation is that we could not calculate the incidence rate of medical errors due to the lack of denominator data (number of hospitalized or followed-up patients); this was also observed in all of the previous studies in Saudi Arabia.

In our study, medical malpractice was found to result in severe outcomes in 24.5% of the total litigations; 10.9 % of those outcomes were disabilities and 13.6 % were deaths. These estimates are considerably lower than those reported in a study conducted in 2007-2008, where medical errors reported in both the public and private sectors resulted in death in 28% of the cases and in disabilities in another 30% (18). However, this study did not have data about the

medical specialties that are responsible for the cases of disabilities and deaths, which is another limitation of this study.

Our results indicated that most of the medical errors occurred in the hospitals (77.7 % of the cases) compared to only 22.3 % that occurred in the clinics. This finding is reasonable because invasive procedures that pose a higher risk for medical errors, like surgical operations and emergency interventions, take place in hospitals rather than clinics.

Similar to reports from three previous studies about medical errors in Saudi Arabia, the practice of obstetrics and gynecology was leading in terms of its contribution to medical errors (17.9% of cases) (17,10&5). The occurrence of medical errors in obstetrics can be attributed to the overload and the high turnover of patients in this specialty, absence of close observation of high risk patients, improper communication and lack of teamwork among the health care professionals and also lack of communication between the physicians and the patients (5).

Consistent with results of earlier studies (17,10&5), general surgery came second after obstetrics and gynecology, contributing to 12.8 % of the cases. Because surgery involves invasive procedures, many factors contribute to the occurrence of medical errors like inexperience of surgeons, lack of competence and skills, high workload, fatigue, lack of the proper technology, low hospital admission for some surgical operations and weak hospital systems in addition to improper communication among medical staff and also a lack of communication with the patients (10,11&12). The fewest medical malpractices occurred in neurosurgery, otorhinolaryngology, internal medicine, ophthalmology, urology and other specialties. This could be explained either by the low volume of patients treated in a specialty like neurosurgery or the very limited use of invasive procedures in a specialty like internal medicine, as opposed to the high volume specialties, the use of invasive procedure, or both in

specialties like obstetrics and general surgery. This may give a misleading picture when there is an interest in identifying high-risk specialties for medical errors. This study's data did not allow an adjustment for patient volume across the specialties, a factor that should be taken in account in comparison to the occurrence of medical errors across specialties.

In this study, there was discrepancy between the number of medical litigations (N= 368) and the number of accused health professionals (N= 376), indicating that a medical error can be done by more than one health professional and also one health professional can be involved in more than one medical error. Our finding that physicians were responsible for most of the medical errors is plausible as physicians are responsible for diagnosing and treating the patients and also they lead patient management and give directions to the other medical staff like nurses and technicians.

This study showed no gender difference in the occurrence of medical errors among physicians, although there was a difference by nationality, with Saudi physicians having a 2-fold higher occurrence of medical errors than non-Saudis.

Despite the Primary Investigation Committee transferring the lawsuit to the Medical Jurisprudence Committee after deciding that there was a medical error, this study observed that only 76.6% of defendants were found to be guilty. This plays a role in delaying justice and the issuance of the final verdict.

A study was done in Al-Qassim region of Saudi Arabia about the average duration of the medical litigation from the initiation of the lawsuit until it is received by the Medical Jurisprudence Committee. This duration averaged 5.1 months. On the other hand, the average duration of the lawsuit from the time it is received by the Medical Jurisprudence Committee till the issuance of the final verdict was 9.1 months, amounting to an average total duration from

initiation of lawsuit till the issuance of the final verdict of 13.9 months (5). In this study, we found the average duration of the lawsuit in the Medical Jurisprudence Committee once received till the issuance of the final verdict was 15.2 months, which was longer by six months. This could be explained by the few cases of medical litigations in Al-Qassim region (average medical litigation number = 17.2 cases annually) compared to Jeddah city (average medical litigation number for only private health sector = 73.6 cases annually). This study did not have data about the duration of the lawsuit from its initiation till reaching the Medical Jurisprudence Committee and this is one of this study's limitations; however, if the same time duration in the previous study from the initiation of the lawsuit until it reached the Medical Jurisprudence Committee is assumed, the total average duration will be 20.3 months, which is too extensive of a duration. The length of time could be attributed to many factors including that members of Medical Jurisprudence Committee are working part time only, and also the increased awareness among patients of their rights resulting in increased medical litigations in Saudi Arabia.

The main strengths of the current study is that it was the first study conducted about medical malpractice in the private health sector in Saudi Arabia. Moreover, this study was able to estimate the occurrence rate and ratio of cases by gender and nationality of health professionals. However, this study has some limitations. First, not all the medical litigations reached the Medical Jurisprudence Committee as many of the plaintiffs reconcile with the defendants when they are compensated by money and some waive off the lawsuit as they believe it was a destiny especially the death litigations, resulting in underestimation of the number of cases. Second, the data contains only aggregate figures of the number of cases by a limited number of characteristics, which restricted our ability to evaluate other important factors. Third, this study could not calculate the incidence rate of medical errors by patient volume due to the

lack of denominator data. Fourth, this study did not have data about the duration of the lawsuit from its initiation till reaching the Medical Jurisprudence Committee to estimate the exact total duration of the litigation from its initiation till the issuance of the final verdict. Fifth, this study did not have data about the medical specialties that are responsible for the cases of disabilities and deaths. Sixth, the number of Saudi physicians was very low (6.3%) compared to non-Saudis, which may not reflect the exact proportion ratio of medical errors based on nationality.

In conclusion, this study described the pattern of malpractice cases by medical specialty, health facility and health professional-related characteristics, and the duration of medical litigation. This data is useful for policy makers to institute appropriate control measures.

Table 1. Distribution of medical malpractice cases in the private health sector in Jeddah, Saudi Arabia, 2011-2015

Variables	Medical Malpractice Cases (N= 368) N (%)
Year	
2011	61 (16.6)
2012	53 (14.4)
2013	79 (21.5)
2014	99 (26.9)
2015	76 (20.7)
Patient Outcome	
Death	50 (13.6)
Disability	40 (10.9)
Health Facility	
Hospital	286 (77.7)
Clinic	82 (22.3)
Verdict of accusation	
Yes	282 (76.6)
No	86 (23.4)

Table 2. Distribution of medical malpractice cases by medical specialty in the private health sector in Jeddah, Saudi Arabia,20112015

Medical Specialty	Total number of medical malpractices (N= 368) N (%)
Obstetrics & Gynecology	66(17.9)
General Surgery	47 (12.8)
Orthopedics	42(11.4)
Neurosurgery	20 (5.4)
Urology	10 (2.7)
Otorhinolaryngology	17 (4.6)
Ophthalmology	11 (2.9)
Other Surgical Specialties	30 (8.2)
Internal Medicine	17 (4.6)
Pediatrics	37 (10.1)
Dentistry	35 (9.5)
Other Specialties	36 (9.8)

Table 3. Characteristics of involved health professionals in the private health sector in Jeddah, Saudi Arabia, 20112015

Characteristics	No. of Involved Health Professionals (N =376) N (%)
Occupations	
Physicians	349 (92.8)
Pharmacists	0 (0)
Nurses	21(5.6)
Technicians	6 (1.6)
Gender	

Male	263 (69.9)
Female	113 (30.1)
Nationality	
Saudi	45 (12)
Non-Saudi	33 (88)

Table 4. Occurrence rate of medical malpractice by gender and nationality of health professionals in Jeddah, Saudi Arabia, 2011-2015

Health Professionals	Occurrence Rate (%)	Occurrence Ratio	95% Confidence Interval	P-value
<u>I. Physicians</u>				
Gender		1.00	(0.8 , 1.2)	0.99
Male	13.9		(12.4 , 15.6)	
Female	13.9		(11.6 , 16.5)	
Nationality		2.02	(1.53 , 2.7)	< 0.001
Saudi	26.4		(20.2 , 33.8)	
Non-Saudi	13.1		(11.8 , 14.5)	
<u>II. Nurses</u>				
Gender		4.25	(1.5 , 12.5)	0.04
Male	3.9		(1.2 , 9.9)	
Female	0.9		(0.55 , 1.5)	
Nationality		1.66	(0.23 , 12.2)	0.59
Saudi	1.8		(0.0 , 10.3)	
Non-Saudi	1.1		(0.67 , 1.5)	
<u>III. Technicians</u>				
Gender		3.49	(0.68 , 17.9)	0.14
Male	1.5		(0.53 , 3.5)	
Female	0.4		(0.01 , 1.6)	
Nationality		1.59	(0.19 , 13)	0.64
Saudi	1.3		(0.0 , 7.6)	
Non-Saudi	0.8		(0.33 , 1.8)	

Table 5. The average duration of medical lawsuit once received by the Medical Jurisprudence Committee in Jeddah, Saudi Arabia, 2011-2015

Medical lawsuit process	Average number of months
First court session	5.3
Issuance of verdict	15.2

Chapter 4: Conclusion and Recommendations

In this study, the trend of medical malpractice and its distribution over the different medical specialties and by characteristics of the health professional involved in the private health sector in Jeddah, Saudi Arabia during 2011-2015 was examined. The time trend of medical errors in the private health sector in Jeddah, Saudi Arabia over a five-year period (2011-2015) fluctuated, and the highest number of cases was reported in obstetrics and gynecology followed by general surgery, whereas the lowest was reported in ophthalmology and urology. Most of the cases were contributed by physicians, males, and non-Saudis, which could be explained by their larger constitution in the workforce. In fact, when the workforce size within gender and nationality groups was taken in account, men and women physicians were found to have equal occurrence rates of medical errors, whereas Saudi physicians had a 2-fold higher rate than non-Saudis. Among nurses, males were found to have a 4-fold higher rate of occurrence of medical errors than females, but nationality differences were not statistically significant. The average

time duration of litigations in the Medical Jurisprudence Committee was too long, which results in a delay of providing justice and taking necessary corrective action to prevent additional errors.

Based on this study's findings, a set of recommendations to policy makers in the Saudi MoH is proposed. First, data quality and access should be improved to enable a more accurate enumeration of the magnitude of medical practice. For example, the total number of patients followed-up by each health facility should be accessible in order to estimate the rate of occurrence within individual facilities. Also the number of patients followed-up by each specialty should be accessible to estimate the rate of medical errors for each specialty and to compare it among different specialties. Because there are high-volume and low-volume specialties, comparing counts exclusively may not identify the high-risk specialties for malpractice. Second, high-risk specialties, once identified, should be targeted with policies and interventions to reduce medical errors and their consequences. Because high-volume specialties risk shortages in manpower, a coherent workforce development plan should be developed and implemented by the Ministry to ensure an adequate supply of skilled health care professionals in these specialties. This plan would include a training needs assessment and incentivization for medical students and professionals-in-training to pursue these specialties. Third, continuous on-the-job training for health professionals in preventing and managing medical errors should be implemented in all specialties and health facilities, specifically for those who showed a high occurrence rate of medical errors like Saudi physicians and male nurses. Fourth, in order to expedite the process of medical litigations, members of the Medical Jurisprudence Committee should be full time employees who can devote their full attention to reviewing incoming cases.

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