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"Detection of Adverse Events in Obstetrics Inpatients in Public Hospitals: A Study Using the Global Trigger Tool"

Majd Hifzi Jaber

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"Detection of Adverse Events in Obstetrics Inpatients in Public Hospitals: A Study Using the Global Trigger Tool"

Prepared by: Majd Hifzi Jaber

B.Sc.: Midwifery Science, Ibn Sina College for Health Sciences

Supervisor: Dr. Motasem Hamdan, Ph.D.

School of Public Health

Jerusalem-Palestine

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Thesis Approval

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Prepared by: **Majd Hifzi Jaber**

Registration No: **21010619**

Supervisor: **Dr. Motasem Hamdan**

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The names and signatures of the examining committee members are as follows:

1. Head of Committee: Dr. **Motasem Hamdan, Ph.D** Signature:
2. Internal Examiner: Dr. **Asma Imam**, **Ph.D** Signature:
3. External Examiner: Dr. **Shahenaz Najjar, Ph.D** Signature:

Jerusalem-Palestine

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Dedication

I dedicate this dissertation to my beloved parents; Nadira and Hifzi; May GOD let them rest in mercy and peace.

To my well-regarded sisters and brothers, and

To those who treasure Palestine as a home land.

Majd Hifzi Jaber

Declaration

I certify that this thesis submitted for the degree of Master is the result of my own research, except where otherwise acknowledged and that this thesis (or any part of the same) has not been submitted for a higher degree to any other university or institution.

Singed:

Majd Hifzi Jaber

Date: 24th December, 2014

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Abstract

Background: World Health Organization estimates that tens of millions of patients globally undergo disabling injuries or death annually attributable to unsafe medical practices and care. Adverse events (AEs) are unintended injuries or complications unexpected to occur from an attentive medical practitioner found in mid of health workers in the same circumstances resulting in death, disability or prolonged hospital stay that arise from health care management. Recent claims that adverse events in hospitals increase rather than decrease. Adverse events have not been subjected to detailed study to identify their characteristics. This information could be invaluable, however, for guiding research efforts aimed at reducing the occurrence of undesired adverse events in obstetric departments. Thus, maternal harm and morbidity have prompted us to conduct a retrospective chart review of obstetric medical records. The aim of this study was to assess the incidence and characteristics of adverse events (nature/type and outcomes) among inpatients admitted to three public hospitals obstetric departments in the West Bank during the year 2012.

Methodology: A cross-sectional design was used. A retrospective chart review process was modeled with a random discharged sample of seven hundred and ninety two (n=792) obstetric medical records using the Institute of Healthcare Improvement Global Trigger Tool (IHI) (GTT). The study was conducted between January 2013 and December 2013 for the former year 2012.

Results: Of all the 792 files reviewed, 258 (32.6%) cases experienced a substantial rate of adverse events. The study results indicated that the vast majority of admitted women (75.9%) ranged between 20-35 years old, (33.5%) were in their prime gravida, and (53.7%) had a mean of 1.66. length of stay for one day. Whereas (2.7%) had to be instrumented with vacuum delivery, (41.7%) had C-section mode of delivery. The results also showed that 270 (34.1%) of the records that have triggers have adverse events. Most of these adverse events 126 (48.8%) led to E level harm for events that resulted in temporary harm that required intervention. A further 108 (41.9%) cases were categorized with F level harm (temporary harm which required prolonged hospitalization), and the remaining 24 (9.3%) cases were distributed among G, H and I levels of harm (events that result in permanent harm, require intervention to sustain life and result in death, respectively) that led to slight or short lived disabilities. We identified a solitary death incidence case. The results showed that A'alia hospital patients significantly have an adjusted odds ratio 3.6 times (CI 2.3%-5.5%) more risk of exposure to adverse events than the PMC Ramallah patients, and Jenin hospital patients have very small higher risk of exposure than PMC Ramallah patients ($P<0.001$). Those stayed 3 or more days at hospital have an adjusted odds ratio 9.3 times (CI 5.1%-16.9%) more risk of exposure to adverse events than those stayed for one day, and those stayed for 2 days have about 1.8 risk of exposure to adverse events ($P<0.001$). Caesarian delivery significantly increased the risk of exposure to adverse events about 2.9 times than the normal delivery (CI 1.94%-4.26%) ($P<0.001$). As for the parity, those having the first delivery (prime gravida) have about 2.5 times more

risk of adverse events than those have more than para three, and the increase in the parity significantly decreased the risk of adverse events (CI 1.547%-3.813%) (P<0.001).

Conclusion: The incidence and severity of AEs in studied public hospitals obstetrics departments is considerable. The study results suggest that adverse events are a serious source of harm to patients and a large drain on healthcare resources. Some are major events; others are frequent or minor events that go unnoticed in routine clinical care but together have massive economic and medical consequences. Hospital managements should implement interventions that will minimize AEs such as improving medical records and event reporting, and hospital managements need to focus on system failures rather than the errors of individuals to yield better health results. Also, future research should be conducted by studying the contributing factors for those AEs and using an observational study as well. MoH should create a "Palestinian Health Care Inspectorate" so that health care professionals in Palestine have to have a statutory duty to report ‘critical incidents’.

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"تحديد الأحداث السلبية الضارة بالمرضى المنومين في أقسام الولادة التابعة لثلاث مستشفيات حكومية في الضفة الغربية، فلسطين : دراسة باستخدام أداة الرصد العالمية"

الخلفية: تشير إحصائيات منظمة الصحة العالمية إلى أنه على الصعيد العالمي هناك عشرات الملايين من المرضى يتعرضون للأذى أو يقضون نحبهم كل عام جراء الممارسات الطبية الخاطئة في الرعاية الصحية. تعرَّف "الأخطاء الطبية" بأنها "أخطاء في الممارسة المهنية لا يُتوقع حدوثها من ممارس طبي يقظ من أواسط الممارسين الطبيين وجد في نفس الظروف"، وهي تعد ضمن الإطار العام للأحداث السلبية. يمكن الاستدلال من الأحداث أن الأخطاء الطبية في المستشفيات في ازدياد مستمر، ولهذا فقد قمنا بهذه الدراسة الفريدة من نوعها في بلادنا والتي قد تثرينا بمعلومات قيمة في عمل الأبحاث والدراسات المهمة والتي تسترعى انتباه راسمي السياسات إلى حجم مشكلة الأحداث السلبية غير المأمونة، كما أنها تلقي الضوء على المجالات الرئيسية التي ينبغي الانتباه إليها للتخفيف من حجم هذه الأحداث السلبية غير المرغوب فيها وخصوصا في أقسام الولادة.

منهجية البحث: تهدف هذه الدراسة إلى قياس مدى حدوث وتأثير الأحداث الضارة للتخفيف من الأخطاء و التقليل من معدل الوفيات في أقسام الولادة في ثلاث مستشفيات حكومية في الضفة الغربية، فلسطين على امتداد الفترة لعام (2012). تم أخذ عينة عشوائية مكونة من (792) ملفا تمت مراجعتها من الأرشيف لأقسام الولادة في هذه المستشفيات في دراسة استرجاعية باستخدام أداة الرصد العالمية (GTT).

النتائج: أظهرت نتائج هذه الدراسة أن معدل الأحداث الضارة بلغ (32.6%) من بين إدخالات المرضى لأقسام الولادة في المستشفيات في الفترة المذكورة. وقد كشفت الدراسة أن الغالبية العظمى (75.9%) تتراوح أعمارهن ما بين 35-20 عاما، وأن (33.5%) في حملهن الأول. فترة الإقامة في المستشفى بلغت (53.7%) ليوم واحد والمعدل لذلك هو (1.66)، وبينما (2.7%) تم توليدهن بواسطة "الشفط"، فإن (41.7%) اضطررن للخضوع للعمليات القيصرية الجراحية. أشارت النتائج أيضا أن (34.1%) من الملفات التي تحتوي على أداة الرصد (GTT) ترتبط بالأحداث السلبية الضارة. معظم الأحداث الضارة (48.8%) التي تصيب المرضى خلال تلقيهم الرعاية الطبية في المستشفيات يعانون إصابات أو أحداثا ضارة نتجت عن ضرر مؤقت صاحبه تدخل وإجراء طبي، كما أن (41.9%) من الحالات المسجلة تطلب علاجهم إقامة طويلة في المستشفى مما يستنزف جزءا من الموارد البشرية. تصاحب نحو (0.4%) من الحالات أحداث ضارة وخيمة لدرجة قد تقضي إلى الوفاة أو العجز الدائم. يعتقد أن مستشفى "عالية" في "الخليل" يشكل خطرا في الأحداث العكسية على المريضات أكثر بثلاث مرات ونصف منها في مجمع فلسطين الطبي في رام الله (فترة الثقة 5.5%-2.3%) في حين أن النساء اللواتي مكثن في المستشفى لثلاثة أيام فأكثر كانت نسبة تعرضهن للأحداث الضارة أكثر بتسع مرات من اللواتي بقين ليوم واحد (فترة الثقة 16.9%-5.1%). كان هناك دلالة مهمة (P<0.001) من حيث العمليات القيصرية، فقد ارتفعت نسبة الأحداث الضارة عند النساء اللواتي أجرين عمليات قيصرية بحوالي ثلاث مرات منها عند اللواتي لم يقمن بإجراء أي عملية قيصرية (فترة الثقة 4.26%-1.94%). وأما النساء التي أنجبن للمرة الأولى، فقد ارتفعت نسبة الأحداث الضارة عندهن بمرتين ونصف عنها من تلك اللواتي أنجبن أكثر من مرة (فترة الثقة 1.547%- 3.813%).

الإستنتاجات والتوصيات: خلصت هذه الدراسة إلى أن الأحداث الضارة المعاكسة هي مصدر تهديد جدي لسلامة وصحة المريض، بعض هذه الأفعال الضارة دائمة وأخرى ثانوية والتي لا يتم الانتباه إليها في الرعاية اليومية إلا أنها تستنزف موارد طبية واقتصادية كبيرة. أظهرت الدراسة أيضا أن الأداة المستخدمة ناجعة في قياس الضرر الحاصل. توصي هذه الدراسة راسمي السياسات باتخاذ إجراءات للتخفيف من الأحداث المعاكسة وذلك بتحسين كتابة التقارير والتبليغ عن الأحداث الضارة، كما أن إدارة المستشفى يجب عليها التركيز على أخطاء وإخفاق النظام أكثر من التركيز على أخطاء الأفراد الشخصية للحصول على أفضل نتائج ممكنة. كما توصي الدراسة أيضا بالقيام بدراسة "مراقبة" لإلقاء الضوء على المجالات الرئيسية التي ينبغي الانتباه إليها بصورة دقيقة. ومن ضمن توصيات هذه الدراسة كذلك إنشاء ما يسمى "هيئة مراقبة الرعاية الصحية الفلسطينية" وذلك من أجل إلزام ممارسي ومقدمي الرعاية الصحية بالتبليغ عن أية أخطاء قد تحدث معهم أثناء تقديم الخدمة .

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List of Acronyms and Abbreviations:

Abbreviation	Abbreviation Expansion
AEs	Adverse Events
AHRQ	Agency for Healthcare Research and Quality
CBC	Complete Blood Count
CI	Confidence Interval
GTT	Global Trigger Tool
IHI	Institute of Healthcare Improvement
IOM	Institute of Medicine
MoH	Ministry of Health
NPSA	National Patient Safety Agency
PG	Prime Gravida
PMC	Palestine Medical Compound
RNs	Registered Nurses
RR	Risk Ratio
SPSS	Statistical Package for Social Sciences
UK	United Kingdom
USA	United States of America
WB	West Bank
WHO	World Health Organization

Chapter One: Introduction

1.1 Introduction

Patients count on the verity that people and organizations that exist to help them will not injure them. "First do no harm" is not just a slogan in health care; it is an essential goal. Each healthcare system has an obligation to society to ensure that all people in their time of need are supported, cared for and healed to the extent of possible. From that viewpoint, patient safety can be viewed both as a public health issue and as a patient‘s right (Davis, 2004).

Patient safety is an open apprehension that has obtained considerable awareness, particularly since the discharge of two reports from the U.S. Institute of Medicine. The first report; “To Err Is Human,” re-examined the text on adverse events, or injuries resulting from medical care (The Institute of Medicine, 2000). Base on the data from two large population-based chart review studies, the data estimated that adverse events occur in 2.9% (Thomas et al., 2000) to 3.7% (Leape et al., 1991) of hospitalizations. The first of these studies (Thomas et al., 2000) initiated that even if the majority of injuries are insignificant, about 1 in 10 results in death. The researchers concluded that roughly 50% of the adverse events were caused by errors (The Institute of Medicine, 2000; Leape et al., 1991 and Brennan et al., 1991). The second report; “Crossing the Quality Chasm,” which offers policies for developing the health system, affirmed patient safety a basic constituent of care quality (The Institute of Medicine, 2001). Nevertheless, the projected incidence of adverse events extracted in “To Err Is Human” possibly will underrate the general safety difficulty, since injuries taking place following discharge were not included in the estimation. Patients may be especially susceptible to injuries throughout this period because they may still have practical mutilations and because discontinuity may occur at the border of acute care (Cook et al., 2000). These discontinuities may be exacerbated by the present health care environment, where patients are departuring the hospital “quicker and sicker” (Kosecoff et al., 1990) and may get care from hospitalists rather than their primary care physicians (Kelley, 1999).

The high-status Institute of Medicine (IOM) defines quality of healthcare as: *"the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge"* (Kohn et al., 2000). The same Institute of Medicine captures in its report "Crossing the Quality Chasm‘ the most important aspects for quality improvement by providing six specific aims/dimensions of quality. These aims are built around the core need for health care to be: safe, effective, patient-centered, timely, efficient and equitable. Achieving optimal outcomes on each of these six areas would result in meeting patient needs. Clinicians and other health workers would benefit through their increased satisfaction from doing a good job through improving health and personal productivity, and minimizing pain and suffering.

Patient safety is a global public health topic and a core principle of patient care. Health care has been considered a high-risk activity due to the likelihood of harm to patients as a result of care (Aranaz-Andre's et al., 2009). Preventable harm to patients resulting from their healthcare is unacceptable at any time (Wilson et al., 2012). Achieving safe patient care has become an increasing focus for obstetric community (Grobman, 2012).

Vincent (2006), defined patient safety as: *"the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare*". The definition characteristics of patient safety imply that safety does not exist in a device, person or department, however, it emerges from the healthcare system interactions. Therefore, improving patient safety depends on understanding these interactions.

The Agency for Health Care Research and Quality (AHRQ) defines patient safety as *"the absence of the potential for, or the occurrence of, health care associated injury to patients created by avoiding medical errors as well as taking action to prevent errors from causing injury"*. Most incidents occurring in health care are not detected because they are not reported. Breakdown to report not only provides inaccurate data about numbers of incidents occurring, but reduces attention to contributing factors to incidents as well (Waters et al., 2012).

The Institute of Healthcare Improvement (IHI) defines an adverse event as *"an unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death"* (Institute for Healthcare Improvement, 2009). The number of medical interventions in perinatal care has also increased steadily over time, raising many questions about the benefits, safety and risks for healthy childbearing women (Hodnett et al., 2010). Understanding about types of adverse events and underlying causes can improve organizational management and safety of health care systems (Waters et al., 2012).

Adverse events are a major source of morbidity and mortality. There is a growing body of evidence that adverse events (AEs) result in lost productivity, prolonged hospital stays, disability, or even death; they are costly for society (Kohn et al., 2000).

In recent years, much attention has been paid to patient safety in health care and to the registration and examination of safety incidents, particularly in hospitals. There is a paucity of data on patient safety in primary health-care settings (Tsang et al., 2010).

1.2 Problem statement

Unsafe care could represent a major source of morbidity and mortality throughout the world. The WHO approximates that tens of millions of patients universally undergo disabling harms or even death every year because of hazardous medical practices and care. Virtually, one in ten patients is harmed while receiving health care in a hospital (WHO, 2008).

In our region, Wilson and colleagues (2012) evaluated AEs' rate among patients admitted to hospitals in Egypt, Jordan, Kenya, Morocco, South Africa, Sudan, Tunisia, and Yemen. The population sample was medical, surgical, pediatric, and obstetric inpatients in acute care public or private hospitals. Of the 15,548 records reviewed, 8.2% showed at least one adverse event, with a range of 2.5% to 18.4% per country. Of these events, 83% were judged to be preventable, while about 30% were

associated with death of the patient. About 34% adverse events were from therapeutic errors in relatively non-complex clinical situations (Wilson et al., 2012).

In Palestine, a retrospective review of patient medical records conducted in nongovernmental Palestinian hospitals showed that 14.2% of records reviewed had an adverse event (Najjar et al., 2013). Almost 60% of these events were judged to be preventable, about 70.1% were associated with temporary harm and required prolonged hospitalization. Moreover, 22% of these adverse events were prenatal adverse events (Najjar et al., 2013). However, no data are available about the magnitude of the problem in public hospitals.

1.3 Justification and significance of the study

The MoH is the main provider of health care in Palestine including obstetrics services. Until recently, obstetric care is a neglected area of research in Palestine. No researches had been conducted to detect adverse events in obstetrics departments in Palestinian governmental hospitals. Adequate evidence about the rate of adverse events in public hospitals sector in general and obstetrics in particular is still missing.

Although international literature reveals that assessment of patient safety and adverse events rate in obstetric departments has been in use for decades, there has been hardly studies –and none in the MoH sector- assessing obstetric and gynecological adverse events (Najjar et al., 2013). This assessment could help organizations in underlying ‘‘root causes’’ for adverse events and for generating improvement initiatives for managers and staff involve in patient care.

Palestine, as a developing country, has started to deliberate lately on moving toward providing quality services in hospitals. Since 2011, access to quality health services has been on the strategic plan of the Palestinian Ministry of Health (MoH)(MoH Health Strategy, 2010). To meet this goal, MoH has extended their partnership with East Jerusalem hospitals on quality improvement efforts and accreditation. Despite

these enterprises, hospitals and health policymakers in Palestine still need the evidence and baseline patient safety data that are essential for creating views and plans on improving patient safety and maintaining positive interventions after implementation.

This study is the first systematic analysis of adverse events in obstetrics departments in the MoH hospitals. The results of this study will be useful to improve patient safety in these hospitals and the MoH obstetric departments. Findings of our study can form the baseline for future plans to improve safety of care in obstetrics departments.

1.4 Aim of the study

The aim of this study is to assess the incidence and characteristics of adverse events (nature/type and outcomes) among inpatients admitted to the obstetrics departments of three MoH hospitals in the West Bank in 2012.

1.5 Specific objectives of the study

1. To assess the incidence of adverse events occurred among patients admitted to the obstetrics departments of the MoH hospitals.
2. To identify the nature and type of adverse events that occurred in obstetrics patients admitted to the MoH hospitals.
3. To identify the outcome of adverse events (injury caused harm, prolonged hospitalization, additional treatment or death) that occurred in obstetrics patients admitted to the MoH hospitals.
4. To assess the associations between the incidence of adverse events and the characteristics of patients and hospitals.

1.6 Summary

This introductory chapter provided a synopsis about the importance of AEs. This chapter encompassed the definition of AE and how much damage is being resulted. Also, this chapter included background information about the significance and justification of the study. The overall aim, specific objectives were also stated.

Chapter Two: Literature Review

2.1 Introduction

This chapter reviews national and international studies conducted in the area of assessment of adverse events in obstetric admitted women. A comprehensive search was employed to uncover theoretical and research work related to the study concepts. Medical databases search, previous master thesis, books and journals were reviewed in regard to pregnant women adverse events.

2.2 Literature review

Patient safety is a global issue, affecting countries at all levels of development. Although estimates size of the problem is scarce particularly in developing and transitional countries, it is likely that millions of patients worldwide suffer disabling injuries or death every year due to unsafe medical care (WHO, 2008). One important indicator of patient safety is the rate of AEs among hospital patients (Baker et al., 2004). Labor and delivery units account for most claims involving patient injury and death (Waters et al., 2012). However, several previous nationwide studies have demonstrated that adverse events occur frequently in hospitals; there is little evidence about obstetric adverse events, but, none of these studies below provided data specific to obstetrics department, but the number of adverse events is clearly worrying (Soop et al., 2009).

2.2.1 International studies:

Brennan and colleagues (1991) carried out a retrospective study to estimate the incidence of adverse events and negligence in hospitalized patients. They reviewed 30,121 randomly selected records from 51 randomly selected acute cares, non-psychiatric hospitals in New York State in 1984. They found that adverse events occurred in 3.7% of the hospitalizations, and 27.6% of the adverse events were due to

negligence. Although 70.5% of the adverse events gave rise to disability lasting less than 6 months, 2.6% caused permanently disabling injuries and 13.6% led to death. Adverse events rate in obstetric department was 1.5%, and negligence rate was 38.3% (Brennan et al., 1991).

Vincent and colleagues (2001) examined the feasibility of detecting adverse events through retrospective record review in British hospitals. They conducted preliminary estimates of the incidence and cost of adverse events in two acute hospitals in Greater London area. They reviewed 273 records from general medicine, 290 records from general surgery, 277 records from orthopedic surgery, and 174 records from obstetrics. The study stated that (10.8%) of 1014 patients experienced an adverse event. And the overall number of events was (11.7%). (34%) patients developed an injury or complication, (19%) patients that resulted in moderate impairment, (6%) patients had permanent impairment, (8%) patients contributed to death. Overall, (48%) adverse events were judged preventable. (4%) patients in obstetrics department had adverse events, (71%) of adverse events judged preventable (Vincent et al., 2001).

Balas et al. (2004) conducted a prospective study with the aim to describe the nature and prevalence of errors and near errors reported by 393 full-time hospital staff nurses in Pennsylvania hospital during 2004 in America. Participants worked in all hospital units. Spiral-bound logbooks were used to collect information for the primary study. (30%) reported making at least one medical error and (33%) of nurses reported at least one near error, for a total of 199 errors and 213 near errors in the 28 day data collection period (Balas et al., 2004).

In Thailand, Asavaroengchai and colleagues (2009) conducted a cross-sectional medical record review to identify adverse events in hospitalized patients at King Chulalongkorn Memorial Hospital during 2008, using the Global Trigger Tool (GTT) by Institute for Healthcare Improvement. The aim was to evaluate the effectiveness of the trigger tool on identifying adverse events in Thai hospitalized patients, and to

classify the events by the patient safety goals at Thailand. Adverse events, severity rating, and preventability were determined by reviewer teams. Types of adverse events were described according to the Patient Safety Goals of Thailand. Five hundred seventy six medical records were reviewed. The total patient-days were 4,460 days. Two hundred thirty six adverse events were detected with a mean rate of 41.0 events per 100 patients or 50.4 events per 1,000 patient-days. (53%) were temporary harm, while (51.7%) were preventable. Regarding the category of adverse event, (31.8%) were related to patient care process, (20.3%) were in safe surgery and (17.8%) were in medication and blood safety. Asavaroengchai et al. (2009) concluded that AEs using the GTT detected more events than previous reports. Most events had low severity and were preventable. Moreover, most of them were related to prevention of complications, safe surgery and medication safety, and recommended that assessment of validity is needed before using GTT in medical service (Asavaroengchai et al., 2009).

Classen and colleagues (2011) evaluated the incidence of adverse events for inpatients at three hospitals, using numerous methods for measuring adverse events. They carried out a retrospective record review using the Global Trigger Tool; voluntary reporting system and patient safety indicators from the Agency for Healthcare Research and Quality. They selected three large US tertiary care centers that had well-established operational patient safety programs. They randomly selected inpatients files from all adult (age on admission greater than eighteen years) (length of stay more than twenty four hours) admitted during 2004. Along with the 795 patient records reviewed, 393 adverse events were detected by the three methods. The Global Trigger Tool methodology detected 354 adverse events (90.1% of the total), the voluntary reporting systems detected 4 adverse events (1.0%), and the Patient Safety Indicators detected 35 adverse events (8.99%). In general, adverse events occurred in 33.2% of hospital admissions (range: 29–36%) or 91 events per 1,000 patient days (range: 89–106). Medications, surgery, procedures, and nosocomial (hospital-associated) infections were most common, and the most severe events were related to surgery (Classen et al., 2011).

Martijn et al. (2011) conducted a multi-method study; prospective incident reporting study by 20 midwives during 2 weeks, a questionnaire on safety culture and retrospective content analysis of randomly selected 1,000 patient records in 2009. The study was done for low risk pregnant women. The main objective was to describe the incidence and characteristics of patient safety incidents in midwifery-led care for low-risk pregnant women in Netherlands. There were 14,888 recorded contacts, from which, 86 safety incidents were referred to. A pregnant woman in primary midwifery care has a 8.6% probability to experience a safety incident (95% CI=4.8–14.4). Only 25 of the 86 safety incidents had a noticeable effect on the patient, which meant a 2.5% probability of experiencing a safety incident with a noticeable effect. This percentage includes both incidents with and without noticeable effects for the woman and her child. Results pointed out that a low prevalence of patient safety incidents was found in midwifery care for low-risk pregnant women (2.5% probability per patient of a safety incident). This is a relatively small percentage of safety incidents. Enhancement of patient safety should address the better devotion to practice guidelines for patient risk assessment, better achievement of interventions for known lifestyle risk factors and better availability of midwives during birthing care (Martijn et al., 2011) .

Aranaz-Andre´s and colleagues (2009) determined the impact and preventability of adverse events (AEs) at health care in Spanish hospitals. The study was retrospective cohort study in twenty-four Spanish hospitals. Participants were patients from all ages. They stayed more than 24 hours in one of the selected hospitals and they had been discharged between the 4th and the 10th of June 2005. They identified 525 patients suffering AE associated directly with medical care. 43% of these AEs were considered preventable. Overall, 45% were considered minor AEs, 39% moderate and 16% severe. There were no significant differences in AEs severity by hospital size. However, AEs associated with surgical services were more likely to be severe than those associated with medical services. 31.4% of AEs resulted in a longer stay and 23.4% led to hospital admission. AEs associated with medical care caused 6.1 additional days per patient. Of the patients, 66.3% required additional procedures and 69.9% required additional treatments. Incidence of death patients with AEs was 4.4%

(CI95%:2.8–6.5). Age over 65 years was associated with a higher incidence of preventable AEs. The highest percentages of preventable AEs were related to miss-diagnosis (84.2%), nosocomial infections (56.6%) and to care (56%) (Aranaz-Andre's et al., 2009).

Paradis and colleagues (2008) conducted their study at three urban, community hospitals in Portland, Oregon USA, to quantify excess costs and length of stay associated with voluntary reported patient safety event. Hospital stays with adverse event were 22% longer than those without events. Medication and treatment errors were the most expensive and most common unplanned events, representing 77% of all unplanned event types and 77% of added costs. There was no significant difference in additional cost or length of stay by the outcome designated on the report. They concluded that though rarely utilized to measure patient safety related costs, the events captured by voluntary reports add significantly to the cost and duration of hospital care (Paradis et al., 2008).

In a study to estimate the incidence, nature and consequences of adverse events and preventable adverse events in Swedish hospitals by Soop and colleagues (2009), structured retrospective medical record review was done based on the use of 18 screening criteria in twenty-eight Swedish hospitals. Sample was 1967 hospital admission between 2003 and 2004.12.3% of the 1967 admissions had adverse events, of which 70% were preventable. 55% of the preventable events led to impairment or disability, 9% of the preventable events led to permanent disability and 3% of the adverse events contributed to patient death. Preventable adverse events led to a mean increased length of stay of 6 days (Soop et al., 2009).

Mendes and colleagues (2009) evaluated the incidence of adverse events. A retrospective cohort study was done based on patient record review in three teaching hospitals in the State of Rio de Janeiro, Brazil. The random sample of the study was (1103) of 27350 adult patients admitted in 2003. Patients under 18 years old, psychiatric patients and patients whose length of stay was less than 24 hours were

excluded, while obstetric cases were included. The incidence of patients with adverse events was 7.6%. The overall proportion of preventable adverse events was 66.7%. The patient's ward was the most frequent location of adverse events (48.5%). In regard to classification, surgical adverse events were the most frequent ones (35.2%). They concluded that the incidence of patients with adverse events at the three hospitals was similar to that in international studies. Nevertheless, the proportion of preventable adverse events was much higher in the Brazilian hospitals (Mendes et al., 2009).

In Canada, Baker and colleagues (2004) estimated the incidence of AEs among patients in Canadian acute care hospitals. They randomly selected 1 teaching, 1 large community and 2 small community hospitals in each of 5 provinces (British Columbia, Alberta, Ontario, Quebec and Nova Scotia). A review was done on a random sample of charts for nonpsychiatric, nonobstetric adult patients in each hospital for the fiscal year 2000. At least, 1 screening criterion was identified in 1527 (40.8%) of 3745 charts. The physician reviewers identified AEs in 255 of the charts. AE's rate was 7.5 per 100 hospital admissions (95% CI, 5.7– 9.3). Among the patients with AEs, 36.9% at the events judged to be preventable (95% CI 32.0%–41.8%) and death as 20.8% (95% CI, 7.8%–33.8%). Physician reviewers estimated that 1521 additional hospital days were associated with AEs. Although men and women experienced equal rates of AEs, patients who had AEs were significantly older than those who did not (mean age [and standard deviation] 64.9 [16.7] v. 62.0 [18.4] years; $p = 0.016$). The study concluded that the overall incidence rate of AEs was 7.5%. That suggests from the 2.5 million annual hospital admissions in Canada similar to the type of the study, about 185,000 are associated with an AE and close to 70,000 of these are potentially preventable (Baker et al., 2004).

Gawande et al. (1999) conducted a retrospective chart review of 15,000 nonpsychiatric discharges. The admissions were selected randomly from Colorado and Utah hospitals/USA during 1992 to identify and analyze surgical adverse events. With use of a 2-stage record review process modeled on previous adverse event studies, they estimated the incidence, morbidity, and preventability of surgical adverse events that caused death, disability at the time of discharge, or prolonged

hospital stay. Moreover, they characterized the distribution by type of injury and by physician specialty and determined incidence rates by procedure. Results showed that 66% of all adverse events were surgical, the annual incidence among hospitalized patients who underwent an operation was 3.0% (CI 2.7% to 3.4%). Among surgical adverse events 54% (CI 48.9% to 58.9%) were preventable. They identified 12 common operations with significantly elevated adverse event incidence rates that ranged from 4.4% for hysterectomy (CI 2.9% to 6.8%) to 18.9% for abdominal aortic aneurysm repair (CI 8.3% to 37.5%). Operation carried a significantly higher risk of a preventable adverse event was hysterectomy (2.8%). Among all surgical adverse events, 5.6% (CI 3.7% to 8.3%) resulted in death, accounting for 12.2% (CI 6.9% to 21.4%) of all hospital deaths in Utah and Colorado. Technique-related complications, wound infections, and postoperative bleeding produced nearly half of all surgical adverse events. These findings provide direction for research to identify the causes of surgical adverse events and for targeted quality improvement efforts (Gawande et al., 1999).

In The Netherland, Martijn and colleagues (2013) carried out a case-by-case analysis, using a previously validated instrument which covered five broad domains: healthcare organization, communication between healthcare providers, patient risk factors, clinical management, and clinical outcomes. The study aimed to perform a structural analysis of determinants of critical risk incidents in care for women with a low risk profile at the start of pregnancy. The study included 71 critical incidents in primary midwifery care and subsequent hospital care in case of referral after 36 weeks of pregnancy that were related to substandard care and for that reason were reported to the Health Care Inspectorate in The Netherlands in 36 months (n=357). Results showed determinants that were associated with risk concerned healthcare organization (n=20 incidents), communication about treatment procedures (n=39), referral processes (n=19), risk assessment by telephone triage (n=10), and clinical management in an out of hours setting (n=19). The 71 critical incidents included three cases of maternal death, eight cases of severe maternal morbidity, 42 perinatal deaths and 12 critical incidents with severe morbidity for the child. Suboptimal prenatal risk assessment, a delay in availability of health care providers in urgent situations,

miscommunication about treatment between care providers, and miscommunication with patients in situations with a language barrier was associated with safety risks. Study concluded that systematic analysis of critical incidents improves insight in determinants of safety risk. The wide variety of determinants of risk of critical incidents implies that there is no single intervention to improve patient safety in the care for pregnant women with initially a low risk profile (Martijn et al., 2013).

2.2.2 Regional studies:

Wilson and colleagues (2012) reviewed medical records retrospectively of hospital admissions during 2005 in Ministries of Health of eight countries; Egypt, Jordan, Kenya, Morocco, South Africa, Sudan, Tunisia, Yemen, WHO Eastern Mediterranean and African Regions (EMRO and AFRO) and WHO Patient Safety. They assessed the frequency and nature of adverse events rate in these selected hospitals at developing or transitional economies. The population consisted of 26 convenience hospital samples from which 15,548 patient records that were randomly selected and was categorized to medical, surgical, pediatric and obstetric inpatients in acute care public or private hospitals. Of the 15,548 records reviewed, 8.2% showed at least one adverse event, with a range of 2.5% to 18.4% per country. Of these events, 83% were judged to be preventable, while about 30% were associated with death of the patient. About 34% adverse events were from therapeutic errors in relatively non-complex clinical situations. Wilson and colleagues (2012) concluded that unsafe patient care signifies a serious and considerable danger to patients in the hospitals that were studied, therefore should be a high priority public health dilemma (Wilson et al., 2012).

Almerie et al (2010) conducted a retrospective facility-based review of cases of near-miss and maternal mortality that took place in the years 2006-2007 at Damascus Maternity University Hospital, Syria. This study aimed to document the frequency and nature of maternal near-miss at hospital level in Damascus, and to evaluate the level of care at maternal life-saving emergency services by comparatively analysing near-misses and maternal mortalities. Main outcomes included maternal mortality

ratio (MMR), maternal near miss ratio (MNMR), mortality indices and proportion of near-miss cases and mortality cases to hospital admissions. There were 28,025 deliveries, 15 maternal deaths and 901 near-miss cases. The study showed a MNMR of 32.9/1000 live births, a MMR of 54.8/100,000 live births and a relatively low mortality index of 1.7%. Late pregnancy haemorrhage was the leading cause of maternal mortality (60%) while sepsis had the highest mortality index (7.4%). Twenty six percent (26%) of near-miss cases were admitted to Intensive Care Unit (ICU). Near-miss analyses provide valuable information on obstetric care. The study highlighted the need to improve antenatal care which would help early identification of high risk pregnancies. It also emphasised the importance of both: developing protocols to prevent/manage post-partum haemorrhage and training health care professionals to manage infrequent but fatal conditions like sepsis. An urgent review of the referral system and the emergency obstetric care in Syria is highly recommended.

2.2.3 Local studies:

Najjar and colleagues (2013) reviewed retrospectively a sample of 640 random records of discharged patients from internal medicine, surgical, orthopedic, and obstetric departments using the Global Trigger Tool in two large non-governmental Palestinian hospitals with the aim to evaluate patient safety levels and to provide guidance for policymakers involved in safety improvement efforts. The study showed that one out of seven patients (14.2%) suffered harm, (59.3%) of these events were judged to be preventable; about (70.4%) were associated with temporary harm and required prolonged hospitalization, (13.8%) of the women admitted to the obstetric department experienced adverse event; (68.2%) of these events judged to be preventable (Najjar et al., 2013). The Global Trigger Tool showed that adverse events in Palestinian hospitals likely takes place at a rate of 20 times higher than previously measured. Although reviewers reported that detecting adverse events was feasible, Najjar and colleagues (2013) identified conditions suggesting that the tool may be challenging to be used in daily practice (Najjar et al., 2013).

Imam and Najjab (2012) conducted a retrospective, descriptive, facility based survey study in four governmental hospitals in the West Bank, Palestine. The study was carried out according to the Maternal Near-Miss (MNM) identification: surveillance of registers (log books) to identify maternal complications and identify potential near miss cases (total of 18,849 cases were admitted to maternity departments in the four hospitals during the year 2010); a review of patient files: random stratified sample of potential cases selected (198 records out of 403 suspected cases) and assessed for case management; an in-depth interview with selected cases; a Knowledge, Attitudes, and Practices (KAP) survey was completed by health care professionals working in the maternity wards at the four target hospitals. The percentage of near miss was 2.13%. Complications: Suspected MNM cases in this study include 41.9% pre-clampsia 30.2% APH, 18.4% PPH; ICU Admission: Out of 179 women included in this study, 37 (20.6%) were admitted to ICU; Case Management of PPH: In 39 postpartum hemorrhage cases, 84.6% of the women received Oxytocin and/or Methergine and 69.2% received Cytotec. KAP Study: 71% of health staff who responded in the KAP survey correctly answered questions related to post-partum hemorrhage case management; 26% correctly answered questions related to the management of PET; approximately 42% of health staff respondents were able to define near-miss classification. Health system level improvements recommended for continuous education system based on a thorough training needs assessment and clear training plan on the NEMCP, with rigorous follow up, surveillance system to identify maternal near miss cases and auditing mechanism to review case management, also better and more systematic documentation of individual case files; and improve the archiving and filing systems in the hospitals as relates to the maternity files (Imam and Najjab, 2012).

Several literature that exist on adverse events and preventable AEs focused on medication, patient safety, culture, disclosure, litigation, cost and types of adverse events (therapeutic error, diagnostic, operative, obstetric, neonatal, non-surgical procedure, drug related, fracture, falls and anaesthesia). They were described utilizing multimethods, and were conducted in governmental and nongovernmental hospitals and facilities. This current study, unlike other studies, is being carried out in governmental hospital settings and focusing on obstetric admitted patients merely,

with respect to (nature/type and outcomes) of AEs and using GTT like multiple similar studies.

2.3 Summary

This chapter has reviewed the historical literatures available about AEs mainly in obstetric departments. Besides, some studies about the adverse events; locally, regionally and globally were presented.

Chapter Three: Conceptual Framework

3.1 Introduction

This chapter entails the conceptual framework of the study, which guided the research process.

3.2 Conceptual framework

The research framework was developed by the researcher and used to detect AEs' incidence, nature/type and outcome of these events which is shown in Figure 3.1. Assessment of the incidence and characteristics of adverse events is used to develop strategies to support long-term compliance with patient safety practice in obstetrics departments.

The research process set the following framework as described by IHI-GTT:

- Firstly, randomly selected patient medical records were reviewed for the triggers.
- Secondly, once a positive trigger is found, only review the relevant fraction of the record. A positive trigger designates only the presence of a trigger, not essentially an adverse event.
- Thirdly, once AE is present on admission to the hospital, it should be included, if it provided evidence that it meets the definition of being harm related to medical care. All such adverse events are counted because it measure what the patient experienced, not what happened within the hospital. The focused review will determine whether an adverse event has occurred. If adverse event is not found, review will be finished, or the reviewer should then move on and look for other triggers.

  Reviewers will find many positive triggers, but will identify many fewer adverse events. Infrequently, reviewers will find adverse events with no precursor trigger. When a reviewer discovers a positive trigger, the reviewer

should make sure other pertinent portions of the record such as progress notes and orders that were familiar in close nearness to the occurrence of the trigger. Documentation that the patient experienced harm from medical care should be present for an adverse event. In shaping whether an adverse event has occurred, consider that an adverse event is defined as "unintended harm to a patient".

- Fourthly, once reviewers have firmed that an adverse event has occurred, allocate category of harm as follows (Based on National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorizing Errors):
  - Category **E**: Temporary harm to the patient and required intervention.
  - Category **F**: Temporary harm to the patient and required initial or prolonged hospitalization.
  - Category **G**: Permanent patient harm.
  - Category **H**: Intervention required sustaining life.
  - Category **I**: Patient death.

These categories are not progressive (i.e., an event does not have to first meet the definition of E and F before it can be categorized as G). For category E, some intervention is required. As an example from category F is a patient, who has had surgery and after having been discharged returns back to the hospital with a postoperative wound infection. The criteria for category G would be filled if during an elective operation patient suffers from permanent nerve damage due to a laceration.

- Fifthly, and the final stage, is to analyze and calculate the incidence (rate) of the adverse event using descriptive statistics and frequency.

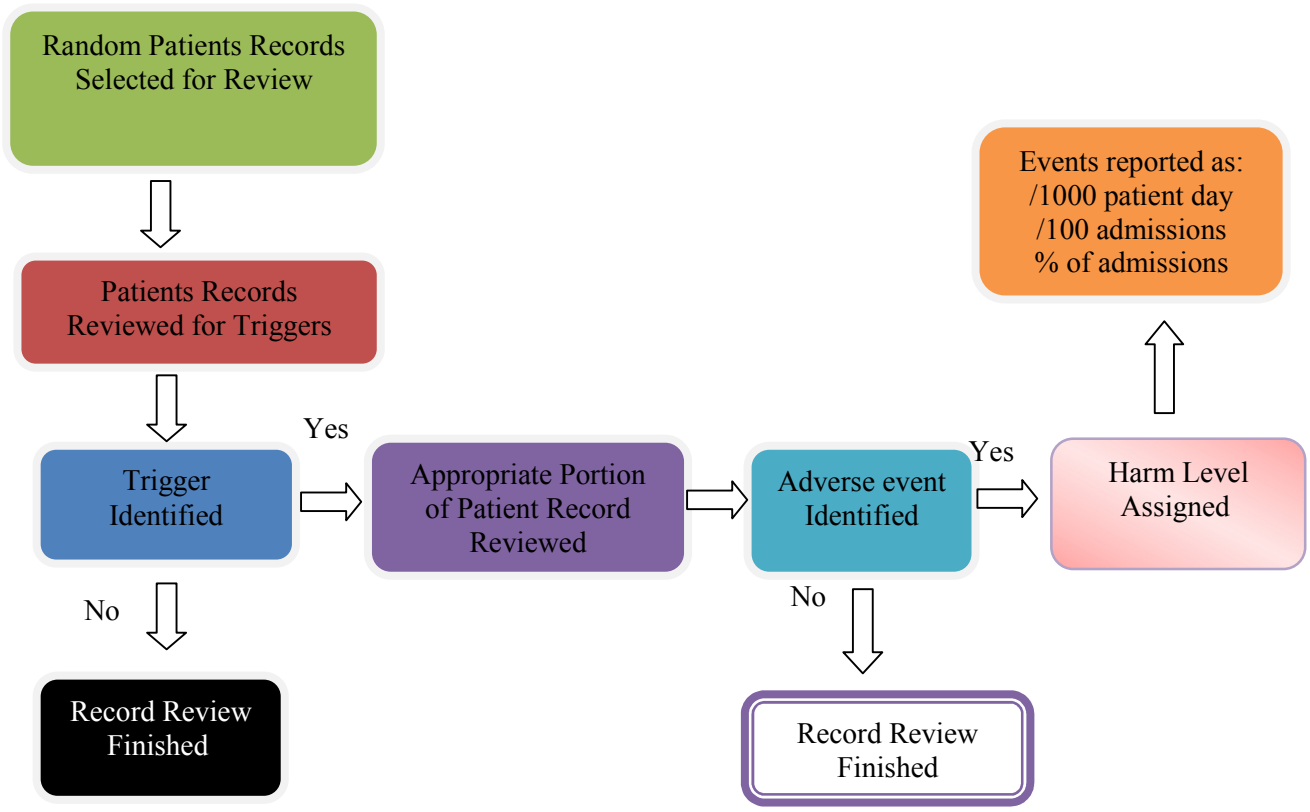

Figure 3.1 Conceptual framework of the study.
Source: (IHI Global Trigger Tool for measuring adverse events, Griffin et al., 2009.)

3.3 Reviewing process

In identifying the adverse events using the GTT, 792 medical records were sampled, 1310 positive triggers were identified in 754 medical records. Figure 3.2 shows the algorithm and number of result of each process of review. We noted that 270 (34.1%) medical records with triggers have AEs, and 258 AEs were found while the rate of AEs was 32.6%. In the AEs' severity, 126 (48.8%) have caused temporary harm and required intervention, 108 (41.9%) caused temporary harm and require prolonged hospitalization, and 12 (4.6%) caused permanent harm, 11 (4.3%) caused harm required intervention to sustain life and in one case (0.4%) the patient harm caused death (See Figure 3.2).

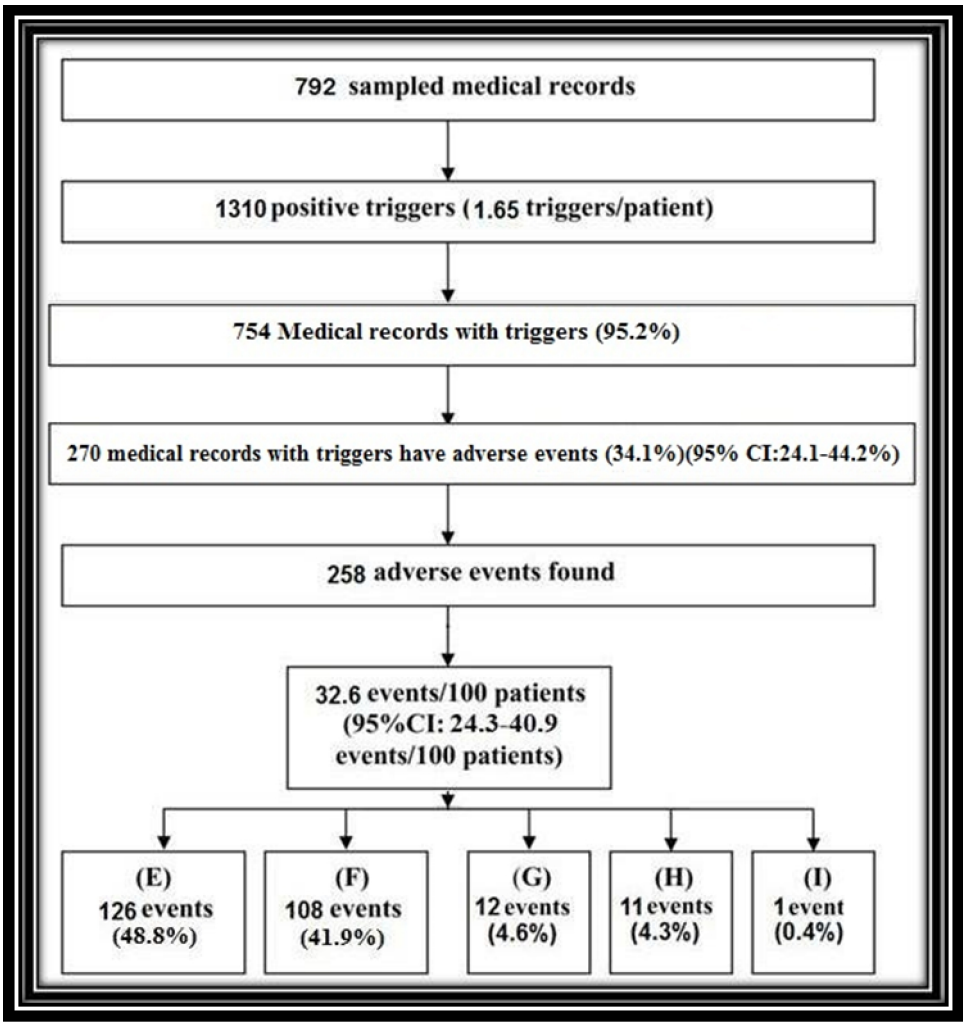

Figure 3.2: Number of result in each process of review. E, F, G, H, and I indicate severity-rating.

3.4 Operational definitions

This section provides the main concepts that were used in our study and their operational definition.

- Patient safety: according to the AHRQ patient safety is ‘‘the absence of the potential for, or the occurrence of, health care associated injury to patients created by avoiding medical errors as well as taking action to prevent errors from causing injury’’ (Pronovost et al., 2005).

- Adverse events: unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death (Institute for Healthcare Improvement, 2009; Griffin and Resar, 2009). For the purpose of this study, it was measured by GTT-IHI.

- Near-misses: unplanned events caused by error that do not result in patient injury but have the potential to do so (Griffin and Resar, 2009). WHO defines a maternal near-miss as "a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy." Near-miss is considered an adverse event that leads to a serious morbidity in the mother after delivery but which she survives (WHO, 2009). To identify the cases of near misses: it is those women who present potentially fatal complications during pregnancy, delivery or during postpartum period, those who survive merely a high possibility of death (Pattinson and Hall, 2003).

- Trigger: a clue that helps a health care organization identify adverse events and assess the overall harm that occurs from medical care within that organization. Trigger tool methodology is based on identifying and addressing errors that are highly associated with negative outcomes (Suzanne et al., 2005).

- The GTT-IHI detects adverse events defined as harm to the patient as a result of medical diagnosis or therapeutics, irrespective of error or preventability. Adverse outcomes caused solely by underlying disease or by the intended consequences of treatment were not considered as adverse events. Each adverse event was categorized for harm to the patient according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) categories (Hartwig et al., 1991). The NCC MERP categories range from 'A' (near miss, no event) to 'I' (adverse event directly contributed to death). For the purposes of this study, we were concerned only with events categorized as 'E' or higher. (Annex E) for definitions of each level of harm).

- Commission versus Omission: The IHI Global Trigger Tool focuses on and includes only those adverse events related to the active delivery of care (commission) and excludes, as much as possible, issues related to substandard care (omission). While adverse events due to omission of evidence-based treatments commonly occur and should be a focus in quality improvement efforts, they are not the focus of measurement with the IHI-GTT (Griffin and Resar, 2009).
- Preventable event: an event that could have been avoided by any action or inaction on the part of the health care provider (William et al., 2012).

3.5 Summary

This chapter illustrated the conceptual framework of our research study as well as the operational definitions of the variables.

Chapter Four: Methodology

4.1 Introduction

This chapter describes the several methodologies used to assess the incidence of adverse events. It displays the study settings, study design, sample frame, sampling method, selection criteria, study tool, review methodology, testing reliability and validity, data analysis and ethical considerations.

4.2 Study design

The study employs a "retrospective" design using IHI-GTT for measuring AEs. The GTT methodology is a retrospective review of a random sample of inpatient hospital records using triggers (or clues) to identify possible adverse events. The review team consists of two primary reviewers and a physician at each hospital. Records were selected from obstetric departments in three selected hospitals in WB.

Many studies were conducted in various countries using various methods to detect the rate of adverse events. Detection of patient harm and adverse events can be done by using voluntary reporting, hospital incidence reporting, structured retrospective chart review and other methods. Hospital incidence reporting system has limitation on sensitivity and underreport in detecting the adverse events (Asavaroengchai et al., 2009). In our study, we used the GTT for identifying adverse events. Trigger tool may provide a more simplified review process for detecting adverse events in a developing country setting (Asavaroengchai et al., 2009). The GTT method has specific methodology to detect patient harm based on a retrospective examination of medical record by trained reviewers. Researchers have compared the value of trigger tools with other methods for identifying adverse events. Generally trigger tools have been found to compare well to other approaches, to be relatively sensitive and to identify significantly more adverse events compared to self-report or other chart audit approaches (Griffin et al., 2009). However, public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients (Griffin et al., 2009). The IHI-GTT for measuring AEs provides an easy-to-use method for accurately identifying adverse events (harm) and

measuring the rate of AEs over time. Tracking AEs over time is a useful way to tell if changes being made are improving the safety of the care processes. And GTT is the only method that is applicable for prenatal and pediatric departments (Griffin et al., 2009).

Classen and colleagues (2012) found that using GTT identified at least 10 times more serious adverse events than voluntary safety reports or the Agency for Healthcare Research and Quality's Patient Safety Indicators methods. The GTT had a higher sensitivity to detect patients with at least one AE (94.9%) and a higher specificity (100%) to detect patients with no AEs. Several studies have evaluated the GTT's utility in the adult inpatient population; Najjar et al (2013) test the utility of GTT method for detecting incidence of adverse events in Palestinian hospitals including obstetrics department. Trigger tools offer an approach to standardizing error identification that may provide more consistent and accurate information than traditional error reporting systems, such as incident reports, traditional chart audits, or voluntary reporting.

If more than one adverse event was identified within the index admission, only the most serious one was described and counted. Consequently, the entire number of admissions coupled with an adverse event is being estimated. A key admission is associated with an adverse event, despite of whether it occurred before and contributing to or during the index admission (Brennan, 1991).

4.3 Study setting

The setting of our study is three Palestinian MoH hospitals. These hospitals were A'alia hospital in the south, PMC Ramallah hospital in the middle, and Jenin[1] hospital in the north of WB. These three hospitals are the largest providers of obstetrical services in the WB major three governmental hospitals in that area, and they have the largest number of obstetric admissions comparing to other MoH hospitals. The total number of deliveries in these hospitals was 8158, 3730, and 4801 respectively in 2012. Hospital bed size ranged from 250 to 300 beds in 2012.

[1] *Jenin Hospital is no longer the name, the current one is the Martyr Dr. Khalil Suleiman Hospital, but here it is used because of the shortness of the name not for any other purpose, with respect.*

Budget limitations dictated that we limited our selection of hospitals. We selected three large governmental hospitals. Yet, we present information on their main characteristics; the three hospitals are: (1) extensively known for their concern about and efforts on quality improvement, (2) enthusiastic and willing to improve patient safety, (3) accessible and serve large communities (4) and are comparable in size and type of obstetric departments.

4.4 Study population and sample

The study population consisted of all patients admitted to obstetrics departments in the studied three hospitals in 2012. The MoH health report 2013 showed that the total number of deliveries were 19,734 (Jenin 6,638, Alia 7,173 and PMC Ramallah 5,932) (MoH report 2013).

A random sample of 792 of medical patient records selected from records of patients admitted to obstetric departments in these hospitals. A total of 22 records per month were randomly selected from each hospital. Patient files were selected based on random probability sampling. In this way, every element of the population being sampled had an equal probability of being selected. This made up of a total of 792 records (264 medical records from each hospital) reviewed from the three hospitals (22 medical records X 12 month X 3 hospitals =792).
This shows that the study sample formed about 4% of the total cases admitted to the obstetrics department in 2012.

4.5 Sampling method and selection guidelines

Medical records were selected randomly. The list of all discharged patients was printed out and the 10^{th} record was selected for review. We followed the recommendation of the IHI-GTT tool to sample 11 patient records from the entire population of discharged adult patients (with some exclusions noted below). Records were selected every two weeks (for example, patients discharged between the 1st and 15^{th} of the month for the first two week sample and between the 16^{th} and end of the

month for the second two week sample), for a total of 22 records per month. If a record did not meet these criteria, it was not used; instead, one of the "extras" should be chosen. The team reviewed only 11 records, so the extra records were not used unless this occurred.

The (IHI) guidelines used by selecting medical record criteria (Griffin et al., 2009):

• Closed and completed medical record (discharge summary and all coding is complete).

• Length of stay at least 24 hours and formally admitted to the hospital; this was to avoid outpatient cases.

• Patient age 18 years or older.

4.6 Medical records review methodology and guidelines

4.6.1 Review team:

The review team consisted of six reviewers and three physicians:

- Two-primary record reviewers (experienced midwives) at each hospital were set up. Panel members (midwives and physicians) have clinical experimental backgrounds and knowledge about the contents and layout of the hospitals' records, and record screening, interest, availability to participate, adequate knowledge of English (medical records language) and fluency in the local language (Arabic). They also know about how care is generally provided in the hospitals, and have individually and independently reviewed the clinical case records and identified adverse and favorable events as well as errors or omissions in the provision of care. Both of them used the IHI-GTT for measuring adverse events worksheet (Annex A), and meet after completing their separate reviews to compare adverse events findings and came to consensus; which they record on a review summary sheet (Annex B). In addition, the team was trained on a pretest of 20 unrelated medical records. This method insured a common data collection method between the two reviewers.

- A physician in each hospital did not review the records, but authenticated the consensus of the two primary record reviewers. The physician authenticated the findings of the adverse events and the rating of severity, and provided answers to questions the record reviewers had about findings in a specific record.

4.6.2 Identifying triggers:

Reviewers reviewed the following sections of the selected medical record looking for triggers:

- Discharge codes, particularly infections, complications, or certain diagnoses.
- Discharge summary (look for the specifics of assessment and treatment during the hospital stay).
- Medications administration record.
- Laboratory results.
- Prescriber orders.
- Operative record (operative report and anesthesia record, if applicable).
- Nursing notes.
- Physician progress notes.

• If time permits, any other areas of the record (such as history, physical, consultation notes or emergency department notes).

Reviewers set a 20-minute limit for review of each patient record. The "20-minute rule" applied to all records regardless of size. once this is reached stop and move on to the next set of records.

The study first and foremost involved 3 consultant physicians and 6 experienced midwife reviewers at all hospitals. A consultant physician acted as lead medical assessor, working for a minimum of 10 year obstetric colleagues. Each reviewer screened sets of notes under supervision of the consultant physicians until they were judged to be entirely acquainted with the review process. Records were reviewed once only. A review of the medical records of the sampled patients (792), lasting no more than 20 minutes each, was conducted independently by each of two trained midwives and a physician at each hospital, for the presence of any of (1,310) triggers using the

GTT-IHI. The GTT-IHI review form is attached as Annex (B). For the purposes of this study, triggers were defined as sentinel settings assumed to be associated with the occurrence of an adverse event. The identification of a trigger by each of the nurse reviewers led to a further, more comprehensive review of the care delivery. The level of harm to the patient was assessed in cases where an adverse event was identified. A physician reconciled the independently recorded triggers and adverse events by each nurse, after assessing the presence of the identified triggers and the level of harm.
The reviews began in January 2013 and ended in December 2013 for the former year from January 2012 to December 2012. Two (2) hour training session for the reviews was set to establish a working process for ongoing reviews.

By identifying a "positive trigger", the reviewer checked other relevant portions of the record, such as progress notes and orders that were documented in close proximity to the occurrence of the trigger. That helps to identify whether that patient experienced harm during the process of medical care.

4.6.3 Prenatal module triggers:

This is the list of all prenatal triggers contained in IHI global trigger tool; with description of each trigger and what the reviewer should look for to determine the presence of adverse event (Griffin et al., 2009):

1. Terbutaline use: Use of Terbutaline could result in an unnecessary intervention of a cesarean section that is created by the administration of a medication. Look for complicating factors. Use of Terbutaline in pre-term labor is not a positive trigger.
2. 3rd- or 4th-Degree Lacerations: By definition a 3rd- or 4th-degree laceration is an adverse event. Also look for additional events to the mother or child associated with the laceration as part of a cascade so appropriate severity can be assessed.
3. Platelet Count: Less than 50,000 in CBC look for adverse events related to bleeding such as strokes, hematomas, and hemorrhage requiring blood transfusions. Look for information about why the platelet count decreased to

see if it was as a result of a medication. Usually, a platelet transfusion is an indication that the patient has a low platelet count. Events related to transfusions or bleeding may indicate that an adverse event might have occurred.

4. Estimated Blood Loss: Greater than 500 ml for Vaginal Delivery, or greater than 1,000 ml for Cesarean Delivery; the accepted limit for "normal" blood loss after vaginal delivery is 500 ml, and a blood loss of 1,000 ml is considered within normal limits after Cesarean birth.
5. Specialty Consult: May be an indicator of injury or other harm.

4.7 Statistical analysis

The patients' hospitalizations were analyzed in this study by the researcher herself. A summary of each case was constructed from the original case records and panel assessment forms by the researcher. A review of all the individual and panel maternal harm assessment forms was then undertaken. In line with the aim of our research objectives, we used descriptive statistics, such as frequencies and percentages for continuous numeric variables, to summarize the patient sample characteristics, AEs rate, and AEs type and harm categories. Confidence interval (CI), *P*-value and odds ratio and adjusted odds ratio were also used in this statistical analysis. Cohen's kappa statistics test was used to examine inter-rater reliability. Data entry, cleaning and analysis were done using IBM SPSS version 20.0 (IBM SPSS Inc., Chicago, IL, USA).

A multi-variate regression analysis model was set up to examine the association between availability of adverse event and significant independent variables.

The general premise used in the analysis was that nursing or midwifery staff would enter their notes in designated sections of the case records (nursing notes, monitoring charts for vital signs) and doctors (and medical assistants) would enter information in the medical notes.

4.8 Testing reliability and validity

The validity and reliability of GTT has been approved in several international studies (Classen et al., 2011). The tool tested before in Palestine by Najjar and colleagues (2013). They used the same method in testing adverse events in surgical, orthopedics, pediatrics, as well as in obstetrics and gynecology department within two non-governmental Palestinian hospitals.

An inter-rater reliability analysis using the Cohen‘s kappa statistics test was performed to determine consistency between the two primary record reviewers and between the primary reviewers. Agreement between reviewers was defined when the reviewers identified the presence of AEs during their independent review of the patient‘s chart. The following criteria were used to interpret the Kappa statistic: poor (<0.00), slight (0.00–0.20), fair (0.21–0.40), moderate (0.41–0.60), substantial (0.61–0.80) and almost perfect (0.81–1.00) (Landis and Koch, 1977).

To ensure reliability in our study, internal consistency (inter-rater reliability) among reviewers was assessed. The inter-rater reliability between the two primary reviewers was substantial (κ statistic 0.706, 95% CI). The reliability between the two midwives and the physician, was (κ statistic 0.617; 95% CI).

The level of agreement between nurses on the presence of any trigger and the agreement between all reviewers on the presence of an adverse event, both overall and by site were calculated. The agreement between nurses was substantial on both triggers and adverse events. A good agreement seems to take place among triggers that are consistently recorded in chosen portions of the medical record. Individual triggers also varied on their yield to detect adverse events.

4.9 Ethical consideration

The study proposal was approved by the research review committee of Al-Quds University, the School of Public Health as well as permission to conduct the study in

the hospitals' obstetric departments was obtained from the Palestinian Ministry of Health (MoH) (Annex C).

4.10 Summary

This chapter covered the study design, study tool, sampling methodology, validity and reliability of the study tool, data collection, data analysis besides to ethical consideration and statistical analyses used in this study.

Chapter Five: Results

5.1 Introduction

This chapter introduces the results including the characteristics of the participants as well as the average, percentages and frequencies for each of the screening's items.

5.2 Characteristics of the participants

Table 5.1 shows the characteristics of the patients' charts reviewed. A total of 792 inpatients medical records were reviewed from obstetric departments in 3 geographically disperse location hospitals. Of the total, (75.8%) of women aged between (>20-35) years (mean age 28.13 years, SD±6.34), (33.5%) were Prime Gravida (PG), and (53.7%) stayed in hospital for one day (mean length of stay 1.66 days, SD±1.25). Those who had cesarean section (CS) were (41.7%).

Table 5.1: Participants' characteristics.

No:	Participant characteristic	Frequency	(%)®
1	**Mode of delivery**		
	Normal delivery	462	(58.3)
	Cesarean section	330	(41.7)
2	**Length of stay**		
	One day	425	(53.7)
	Two days	286	(36.1)
	Three days or more	81	(10.2)
3	**Number of previous deliveries**		
	P.G.	265	(33.5)
	P1	115	(14.5)
	P2-P3	197	(24.9)
	>P3	189	(23.9)
4	**Women age**		
	18- 20 yrs	72	(9.2)
	>20-35 yrs	601	(75.8)
	>35 yrs	119	(15)

®*Data are expressed as number (percent)*.

5.3 Triggers used in the study

Table 5.2 shows the frequency of triggers identified. A total of 1,310 triggers were identified in the reviewed charts during the year 2012. It was noted that Terbutaline

was not triggered at all since it was not used in governmental hospitals. The use of Oxytocic agent has the highest percentage among the triggers (56.5%) followed by general anesthesia (22.6%).

Table 5.2: Types and numbers of triggers identified in the chart reviewed during year 2012.

No:	Trigger	Frequency (Total n=1310)	(%)®
	Terbutaline use		
1	Yes	0	(0.0)
	Oxytocic agents		
2	Yes	740	(56.5)
	General anesthesia		
3	Yes	297	(22.6)
	Estimated blood loss >500 ml (vaginal) >1000 ml (C-section)		
4	Yes	195	(14.9)
	Instrumented delivery (vacuum)		
5	Yes	37	(3.0)
	Specialty consult		
6	Yes	33	(2.5)
	Platelet count less than 50,000		
7	Yes	5	(0.3)
	3-rd or 4-th degree laceration		
8	Yes	3	(0.2)
Total		**Total Yes = 1310 Triggers**	100 %

®*Data are expressed as numbers (percent) of triggers.*

5.4 Incidence of AEs

The retrospective review of medical records (Table 5.3) shows that the incidence of adverse events in the three studied hospitals was as follow: a total of 258 AEs were identified; the highest was in A'alia hospital in Hebron 109 (42.2%) and significantly higher than that in the other hospitals at ($p<0.05$), followed by Jenin hospital 83 (32.2%), and 66 (25.6%) in the PMC Ramallah hospital.

Table 5.3: Frequency and percentage of adverse event by hospital during year 2012.

No:	Hospital	Adverse event Frequency (%)®	DF	Chi-Square
1	A'alia-Hebron	109 (42.2)	2	0.001*
2	Jenin	83 (32.2)		
3	PMC Ramallah	66 (25.6)		

®*Data are expressed as number (percent) of adverse events detected. *Statistically significant (p ≤0.05*).

5.5 Triggers associated with adverse events

The results of Table 5.4 show that 270 (34.1%) of the records that have triggers have adverse events, while it was found that availability of trigger was significantly more likely than patients whose admissions were not experiencing an event ($p<0.05$).

Table 5.4: Adverse event by availability of any trigger during year 2012.

No:	Availability of any trigger	Adverse event		DF	Chi-Square
		Yes (%)	No (%)®		
1	Yes	270 (34.1)	522 (65.9)	1	0.001*
2	No	21 (2.6)	771 (97.4)		

*®Data are expressed as number (percent) of adverse events detected. *Statistically significant (p ≤0.05*).

5.6 Availability of adverse events by the mode of delivery

Table 5.5 shows the availability of adverse events by the mode of delivery. There was found 110 (42.6%) AEs in those who had normal delivery, while 148 (57.4%) AEs were detected in those who had C-Section.

Results of this table also indicate that cesarean section was significantly more likely than patients whose admissions with normal delivery to experience multiple preventable events ($p<0.05$).

Table 5.5: Adverse event by mode of delivery.

No:	Mode of delivery	Adverse event	DF	Chi-Square
		Yes (%)	1	0.001*
1	Normal delivery	110 (42.6)		
2	C-section	148 (57.4)		

*®Data are expressed as number (percent) of adverse events detected. *Statistically significant (p ≤0.05*).

5.7 Assessment of severity

For the assessment of AEs' severity (Table 5.6), 126 (48.8%) of AEs have caused temporary harm and required intervention, 108 (41.9%) caused temporary harm and require prolonged hospitalization, and 12 (4.6%) caused permanent harm, 11 (4.3%) caused harm required intervention to sustain life and in one case (0.4%) a noticeable effect on the patient harm caused death.

Table 5.6: Frequency and percentage of harm category.

No:	Harm category	AEs per harm category (frequency)	(%)
1	**E**: Temporary harm to the patient and required intervention	126	(48.8)
2	**F**: Temporary harm to the patient & required initial or prolonged hospitalization	108	(41.9)
3	**G**: Permanent patient harm	12	(4.6)
4	**H**: Intervention required sustaining life	11	(4.3)
5	**I**: Patient death	1	(0.40)
6	**Total**	**258**	**(100.0)**

Griffin et al., 2009, Detection of adverse events in obstetric patients using the Trigger Tool approach.

5.8 Factors associated with exposure to adverse events

A multi-variate regression analysis model was used to examine the association between availability of adverse event and independent variables (Hospital, age, LOS, mode of delivery and parity). As seen in Table 5.7, adjusted ORs show that A'alia hospital patients significantly have 3.6 times more risk of exposure to adverse events than the PMC patients, and Jenin hospital patients who have very small higher risk of exposure than PMC patients (OR 3.564, CI 95% 2.310-5.499, P<0.001). Regarding those who stayed 3 days or more at hospitals, they have 9.3 times more risk of exposure to adverse events than those who stayed for one day, and those stayed for 2 days have about 1.8 risk of exposure to adverse events (OR 9.319, CI 95% 5.126-16.943, P<0.001). Furthermore, caesarian delivery significantly increased the risk of exposure to adverse events about triple times than the normal delivery (OR 2.857, CI

95% 1.94-4.26, P<0.001). Moreover, as for the parity, those having the first delivery (prime gravida) have about 2.5 times more risk of adverse events than those have more than para three, and the increase in the parity significantly decreased the risk of adverse events (OR 2.429, CI 95% 1.547-3.813, P<0.001).

Table 5.7: Regression analysis of characteristics of participants by adverse events.

Variable	**Unadjusted**		***P*-value**	**Adjusted***		***P*-value**
Hospital	**OR**	**95% CI**		**OR**	**95% CI**	
A'alia-Hebron	2.31	1.600 - 3.352	0.001	3.564	2.310-5.499	P<0.001
Jenin	1.38	0.940 - 2.014		1.064	0.693-1.635	
PMC Ramallah	1.0	Reference		1.0	Reference	
Length of Stay (LOS)						
One day	1.0	Reference		1.0	Reference	P<0.001
Two days	2.29	1.643 - 3.189	0.001	1.791	1.219-2.632	
Three days or more	10.31	5.961 - 17.835		9.319	5.126-16.943	
Mode of delivery						
Normal delivery	1.0	Reference	0.001	1.0	Reference	P<0.001
C-section	2.54	1.879 - 3.443		2.875	1.94-4.26	
Parity						
P.G	1.56	1.056 - 2.316	0.026	2.429	1.547-3.813	P<0.001
P1	0.96	0.583 - 1.593		1.324	0.758-2.312	
P2-P3	0.85	0.551 - 1.322		0.925	0.570-1.502	
>P3	1.0	Reference		1.0	Reference	
Age						
18-20 years	1.0	Reference	0.796	NA	NA	
>20-35 years	1.13	0.668 - 1.925				
>35 years	1.24	0.662 - 2.320				

** Adjusted for hospital, LOS, mode of delivery, and parity (P<0.05). CI confidence interval 95%, OR: Odds ratio. R^2 =0.252*

The main findings in this chapter showed that the independent variables that affected the adverse events of the inpatients were summarized mostly in the suggested model using the multi-variate regression analysis, as shown in Table 5.6:

1. Age of the patients was not significantly associated with adverse events when adjusted for the other variables.

2. The incidence of adverse events in this study was 32,6%. This might be due to different lengths of stays as one of the reasons.

3. Those who have long stays in hospitals are more prone to risk of adverse events than those who stay for fewer days.
4. Moreover, we found that women experiencing C-section are more flat to increase the adverse events than those experiencing normal delivery.

5. Furthermore, those having the first delivery (prime gravida) have more risk of adverse events rather than those have more than one delivery, and the increase in the parity significantly decreased the risk of adverse events.

Chapter Six: Discussion

6.1 Introduction

This study provides basic understanding of the adverse events (nature/type and outcomes) among inpatients admitted to three obstetric departments in governmental hospitals in three regions in the West Bank. It also describes and tracks events surrounding adverse events using a standardized adapted version assessment form to learn lessons for the improvement of clinical practice to decrease morbidity and mortality among these inpatients.

The study findings are discussed in relation to other literature and previous studies. Afterwards, we address the possible strengths and theoretical contributions of this dissertation. Next, we assessed limitations of the study designs. After that, we discuss the overall conclusion. Finally, we end this chapter by describing the importance and implications for practice and health policy and formulate recommendations for practice and future research.

A total of 792 files were reviewed in the three studied MoH hospital. During the process of reviewing the patient records, the researcher frequently noticed incompleteness and under-reporting of medical records. This can be mostly attributed to the reluctance of medical staff to document adverse events due to fear of legal liability, in addition to other possible reasons such as the lack of time due to work pressure and in some cases negligence of staff to document these events.

The present study showed that adverse events identified by GTT attained up to 32.6% events per 100 patients. This indicates that 34.1% patients have at least one adverse event. One of the reasons might be due to different lengths of stays. Compared with other studies, the present level of adverse events is higher than that of other studies. Paradis and colleagues (2008) carried out a study in Portland, Oregon, USA; they found that hospital stays with adverse event were 22% longer than those without events. Vincent et al. (2001) in two acute hospitals in Greater London area estimated that around 5% of the 8.5 million patients admitted to hospitals in England and Wales each year experience preventable adverse events, leading to an additional three

million bed days. Moreover, Aranaz-Andre's et al. (2009) in a study to determine the impact and preventability of adverse events (AEs) associated with health care in Spanish hospitals denoted that 31.4% of AEs resulted in a longer stay and 23.4% led to hospital admission. AEs associated with medical care caused 6.1 additional days per patient. Also, Soop et al. (2009) in Swedish hospitals estimated that preventable adverse events led to a mean increased length of stay of 6 days. Furthermore, Wilson and colleagues (2012) in their study in eight developing countries reported that the adverse event rate increased with length of hospital stay, starting at 4% increasing to 25% for stays of 30 days.

It is concluded that those who have long stays in hospitals are more prone to risk of adverse events than those who stay for fewer days, and different lengths of stays might be one of the reasons that would raise AEs.

In identifying the adverse events using the GTT, our findings show that the rate of adverse events is much higher than that of other countries. For example, Wilson et al. (2012) conducted a study across eight developing countries, they reported that the rate of AEs was 8.2%, there is at least one adverse event with a range of 2.5% to 18.4% per country. Other studies by Wilson and colleagues (1995) in 28 hospitals in New South Wales and South Australia revealed that 16.6% of these admissions were associated with an adverse event, Gawande et al. (1991) reported 3% AEs in Colorado and Utah, Neale and colleagues (2001) reported 10.8% of patients admitted to two large hospitals in Greater London experienced one or more adverse events, 7.5% in Canada by Baker and colleagues (2004), British hospitals (11.7%) by Vincent et al. (2001). Adverse events rate in obstetric department was 1.5% as Brennan and colleagues (1991) reported in their study in New York State hospitals, also Vincent et al. (2001) in their study in United States and Australia found that (4%) patients in obstetrics department had adverse events.

High rate of AEs in this study also may be attributed to lower quality care, while that in other countries, especially in developed ones, is mostly attributed to better quality care.

In this study, the vast majority (75.9%) of the admitted women was categorized in the age group of 20-35 years with a mean age 28.13 years, and that was not significant

when adjusting independent variables reflecting that the adverse event rate did not increase with patients' age. This is inconsistent with the study conducted by Wilson and colleagues (2012), which showed that the rate of adverse events increases with age, and also with the study conducted by Vincent and colleagues (2001) who found that patients with adverse events were older than those who did not experience an adverse event. Also, Brennan and colleagues (1991) reported that rates of adverse events increased strongly with increasing age, persons 65 or older had more than double the risk of persons 16 to 44 years of age; this was contradictory to our study results.

While 57.4% of admitted women who had Caesarian section delivery mode had a higher risk of exposure to AEs than those who were not prone to vacuum, WHO (2010) reported whether medically necessary or not, all Caesarians "put women at increased risk of adverse events, including death". Caesarian delivery significantly increased the risk of exposure to adverse events about 2.9 times than the normal delivery ($P<0.001$), and this is consistent with the study done by Turpentine and Ramirez (1999) who concluded that intrapartum complications such as persistent neonatal brachial plexus injury or fetal death increased the cesarean delivery rate of the obstetrician experiencing these adverse events. Also, reliable with the study curried out by WHO (2010), which concluded that delivery by Caesarian section carries an increased risk of short-term adverse outcomes for the mother. Admitted women need to be educated on seeing the benefits of obtaining vaginal delivery compared to C-section delivery.

Yet, another risk factor is the location where care is provided such as the location of the hospital.

The results also showed that A'alia's hospital patients significantly have 3.6 times more risk of exposure to adverse events than the PMC's Ramallah patients, and Jenin's hospital patients have very small higher risk of exposure than PMC's Ramallah patients ($P<0.001$). Those who stayed 3 days or more at hospitals have 9.3 times more risk of exposure to adverse events than those stayed for one day, and those stayed for 2 days have about 1.8 risk of exposure to adverse events ($P<0.001$). This is consistent

with the study carried out by Wilson and colleagues (2012) who found that the adverse event rate increased with length of hospital stay, starting at 4% increasing to 25% for stays of 30 days, and consistent with the study conducted by Najjar and colleagues (2013) who found that the proportion of harm category increased with length of stay.

The use of Oxytocic agent has a highest percentage among the triggers by 56.5% in identifying the adverse events using GTT. Postpartum haemorrhage (PPH) or extreme bleeding at or after childbirth is likely to be life-threatening impediment and could be one of the foremost sources to maternal mortality and morbidity universally. Primary PPH, characterized as bleeding from the genital region of about 500 ml or more in the first 24 hours post delivery, takes place in 5% to 15% of all deliveries. The most recurrent reason for PPH is uterine atony (>50%) (Prendiville et al., 1988). Oxytocic agents administered prophylactically throughout the third stage of labour have been shown to lessen the risk of PPH by about 40%. It has a short half-life around 3–5 minutes. The study results are consistent with the results of the study conducted by Hassan and Wick (2007) in an observational study in one of the largest referral governmental hospitals located in the center of the West Bank who categorized the childbirth care provided as suboptimal and argued that the routine use of Oxytocin to speed up labor is one of the reasons cited. These study results are also consistent with that of Prendiville and colleagues (1988) who argued that prophylactic Oxytocin showed a lower incidence of post-partum blood loss >500mL (RR 0.50, 95% CI 0.43-0.59). It is recommended that intravenous Oxytocin 3-5 units (with the option of repeated doses) are the first-line drug treatment for PPH. Also, in line with the study conducted by Abu-Omar (2008) who found that Oxytocin is as effective in the prevention of postpartum hemorrhage, but associated with significantly fewer maternal side effects. Oxytocics administered after the 2nd stage of labor compared with after the 3rd stage of labor (placental expulsion) are associated with a significantly fewer rate of postpartum bleeding (Odds ratio 0.59, 95% confidence interval 0.39-0.88).

The trigger of general anesthesia counted (22.6%) in the file records of the three hospitals. In A'alia hospital in Hebron and Jenin hospital, it was noted that general

anesthesia had been used foremost and regularly, while spinal anesthesia had been carried out infrequently. But, contrary to this, in PMC Ramallah hospital, general anesthesia is being used uncommonly, while spinal anesthesia is being handled in large quantities.

The findings showed a low reporting for 3rd and 4th degree laceration among patients in the studied hospitals. This is ascribed either to the staff who really do not appreciate what these lacerations properly represent and this elevates awareness for careful monitoring of surgical procedures or prenatal procedures and the use of best medical care practices, or the fear of legal liability where a monthly report is being issued to the MoH.

Of all the 792 files reviewed, 258 cases with adverse events; most of these adverse events 126 (48.8%) were categorized with E level harm according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) categories Index for Categorizing Medical Errors. E level harm is classified for events that result in temporary harm that require intervention. A further 108 (41.9%) cases were categorized with F level harm (temporary harm which required prolonged hospitalization) and the remaining 24 (9.3%) cases were distributed among G, H and I levels of harm (events that resulted in permanent harm, required intervention to sustain life and resulted in death, respectively).

Our findings confirm the observations of others (McDonald, 1976) - that errors in medical practice are common.

In highly technical, complicated systems, even minor errors may have disastrous consequences. Medicine is no exception; errors in the performance of highly technical procedures can also have catastrophic results. Standards of practice must always include an acceptance of some degree of error. Our physician-reviewers identified temporary harm to the patient and required intervention in about half the adverse events we studied. The high number of adverse events in our study may also be related in part to the mode of delivery and parity of hospitalized patients.

Even if the adverse events are excluded for E category of severity-rating, our rate of adverse events (32.6%) is inconsistent with previous reports using trigger tool studies. For comparison, findings of harm category are twofold approximately higher than a previous study conducted in Palestine by Najjar and colleagues (2013) in two referral teaching and nonprofit hospital, and non-governmental hospitals, where one out of every seven patients (14.2%) suffered harm. Of the AEs by Najjar et al. (2013), (70.4%) caused temporary harm, requiring prolonged hospitalization, and (4.4%) required interventions to sustain life. This might be due to the greater capability of the GTT to identify adverse events. But, Brennan and colleagues (1991) argued that although (70.5%) of the adverse events gave rise to disability lasting less than 6 months, (2.6%) caused permanently disabling injuries and (13.6%) led to death while these results were more than four-folded than these study results. However, Wilson et al. (2012), advocated that the deaths of between 0.5% and 2% of patients in hospitals are associated with an adverse event, which was often, but not always, preventable, while Vincent and colleagues (2001) also denoted (34%) patients developed an injury or complication, (19%) patients that resulted in moderate impairment, (6%) patients had permanent impairment, (8%) patients contributed to death. Overall, (48%) adverse events were judged preventable. (4%) patients in obstetrics department had adverse events, (71%) of adverse events judged preventable.

With regard to the preventability of AEs, our study results were similar to those reported by Soop and colleagues (2009) who conducted a study in twenty-eight Swedish hospitals and indicated that (70%) of AEs were preventable. Fifty-five (55%) of the preventable events led to impairment or disability, (9%) of the preventable events led to permanent disability and (3%) of the adverse events contributed to patient death. Baines et al. (2013) argued that (37.5%) were found to be preventable, (4.8%) led to permanent disability and (8.6%) steered to death.

Despite the lack of a clear explanation, our results do indicate that there is an apparent room for improvement in the obstetric ward. Further results of this study show that admitted patients in obstetric departments had a high risk of experiencing AEs; receiving unplanned treatment, inadequate training or supervision of clinical staff were the largest categories apparently directed to a higher risk of substandard care.

Despite a perceived high risk of harm in these hospitals, a continuous awareness of a possible presentation of high risk complications especially during pregnancy, should be part of daily practice.

We identified 258 adverse events whose severity could have been decreased. We believe that those adverse events are relevant to safety in general but, especially in the hospitalization period because they highlight the difficulties in providing care during hospitalization. While patients are in hospitals, their condition and therapy are assessed infrequently. All of the adverse events in our study were associated with one or more deficiencies. This finding is consistent with other studies of hospital adverse events conducted by Brennan et al. (1991) and Leape et al. (1995). Added to the mentioned earlier problems, apparently, contributed to many of the preventable adverse events, ineffective communication. On the basis of our findings, this communication should also contain specific information about what the follow-up general practitioner need to do. In addition, more effort must be made to effectively communicate this information to the patient.

We relied exclusively on data from hospital records. Although we have shown that adverse events can be identified accurately from information in hospital records, but, such records may not provide evidence or insight into the specific causes of an adverse event, and also relied on implicit, not explicit review. Because we did not study the entire range of medical services, it was not possible to set up explicit criteria for each type of adverse event. Thus, many factors may increase the risk that a patient will have an adverse event during hospitalization.

It is believed that these findings indicate that there are certain risk factors, many definable, contribute for the occurrence of adverse events. The incidence of adverse events is attributed in part due to the shortage of medical staff, work load in these governmental hospitals and limited resources. Inadequate training or supervision of clinical staff, absence of or the failure to implement a relevant protocol or policy, the absence of essential resources, inadequate communication or reporting, delay in providing service or inadequate staffing.

We need improved clinical processes and supervision to be effective in efforts at patient safety. Given that the medical record is the source, it is not surprising that factors focus on individual rather than system failures. This does not take away from what is presented but should drive the need for further study of the context and systems in which the care is being provided.

6.3 Strengths of the study

This was the first study that assesses the rate of adverse events in governmental hospitals in Palestine using the GTT tool, which makes it the baseline to any future studies.

Another strength of the study reviewed medical files that were selected randomly. Moreover, the medical records review process was done by two independent reviewers at each hospital and the results about the AEs and harm category were re-checked and validated by a medical specialist, gynecologist.

6.4 Limitations of the study

Our observations and conclusions must be interpreted within the limitations of a retrospective review of records. Few features of the study could have biased the results. We relied on the judgments of physicians and midwifes in the file records and this may also have contributed to biases. Also, for a study of this scope and magnitude, it would have been difficult to do otherwise, since the researcher was inquired to identify adverse events in the obstetric departments of the Palestinian governmental hospitals counted 3 out of 13 hospitals in the West Bank. Thus, it would have been less likely to generalize study recommendations.

6.5 Conclusions

With this first study in Palestinian governmental hospitals on adverse events, we demonstrate that the level of adverse events is comparable with international data, mostly from Western countries. We contribute to the growing body of evidence that indeed, controlling adverse events at hospital departments is essential to prevent and

reduce adverse events. This is also true in developing countries such as Palestine. The use of well established instruments to assess adverse events is very well possible also in this context, after minor cultural adaptations. Introducing these methods contributes to the awareness of the importance of reducing adverse events among hospital staff, managements and policy makers.

The research findings demonstrate an unstructured approach to reduce adverse events in Palestine. It is the intention of the researcher, to disseminate this thesis to the relevant stakeholders in healthcare.

The researcher anticipates that the data and the international evidence base documented throughout this thesis will afford practical assistance towards the development and ultimate implementation of a national standard on reducing AEs in Palestine. The introduction of a national policy, in conjunction with training can have a positive impact on all parties involved. In establishing a structured and open approach to communicating effectively with patients trust can slowly be rebuilt, at a time when there are two recognised victims, the patient who suffered harm and the healthcare professional(s) involved.

The results suggest that AEs are a serious source of harm to patients admitted to obstetric department in public hospitals. The GTT provides a standardized measure of incidence and harm of AEs that happen in hospitals and can be used to determine trends and the impact of patient safety improvement programs. Our study also shows that retrospective review of records can be used in other health services to gain important information on occurrence of adverse events.

Additional affirmative studies are required. Constructive efforts to identify the principal causes and to find solutions to patient harm. These efforts could be practicable and competent to be put into action in highly resource controlled health systems.

6.6 Recommendations

This study has implications for policy-makers (Ministry of Health), hospitals' managements, and health practitioners and future research. Based on the findings of this study, the following recommendations are suggested:

Recommendations for policy-makers and hospital managements

- Our study reveals that AEs monitoring using GTT is feasible in Palestine. Efforts should be done by hospital managements to encourage continuous monitoring of AEs. The efficiency of monitoring is larger than the simple use of the traditional reporting approach.
- If the risk of AEs is to be minimized in the future, particularly among pregnant women groups, the causes of AEs need to be addressed, focus should be given to prevention strategies.

- The Ministry of Health should disclose statistics on medical errors in its facilities, identify the causes and sources of these errors, and to develop the necessary measures to address them to ensure they do not recur again.

- A high percentage of AEs required prolonged hospitalization. This should motivate hospital managements to implement interventions that minimize AEs, thereby diminishing undesirable costs of services associated with AEs.

- Medical records and event reporting must be improved, and hospital management needs to focus on system failures rather than the errors of individuals. In some cases, documentation in patient files was insufficient to clearly and accurately identify AEs cases occurring in the maternity units or operation rooms at the time of or abruptly post delivery. Documentation underperformances displayed by poor physicians, and midwives included unclear handwriting, and incomplete information about case management. Consequently, training and awareness of personnel on documentation and moral and authorized responsibilities pertaining to accurate documentation and case management are of major significance.

- A significant approach for supervision is the evaluation of critical incidents in hospitals and particularly in obstetric departments. Health care professionals in

Palestine have to have a statutory duty to report ‘critical incidents’ to a recommended what will be so-called "Palestinian Health Care Inspectorate". This system will conduct periodically a review of the magnitude of AEs and maternal deaths and the health service events adjoining these impediments in an endeavor to define and monitor the standard of obstetric care.

Recommendations for future research:

- It is recommended that further research is directed towards high-risk groups about AEs focusing on narratives and intervention, and towards research in hospitals and primary health care.
- Future research could extent this exploratory study by studying the contributing factors for those AEs, also by using an observational study.
- There is also a need for interventional studies to search whether organizational factors may decrease the hazard of AEs' errors and their cost.

6.7 Summary

This chapter presented the discussion and implications of the major findings related to this study with the comparison to the results of other studies conducted in the related fields, and to the related conceptual models. Consistency and inconsistency of the findings are also compared to other studies related to this field.

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Annex A: (IHI Global Trigger Tool for Measuring Adverse) Events Worksheet.

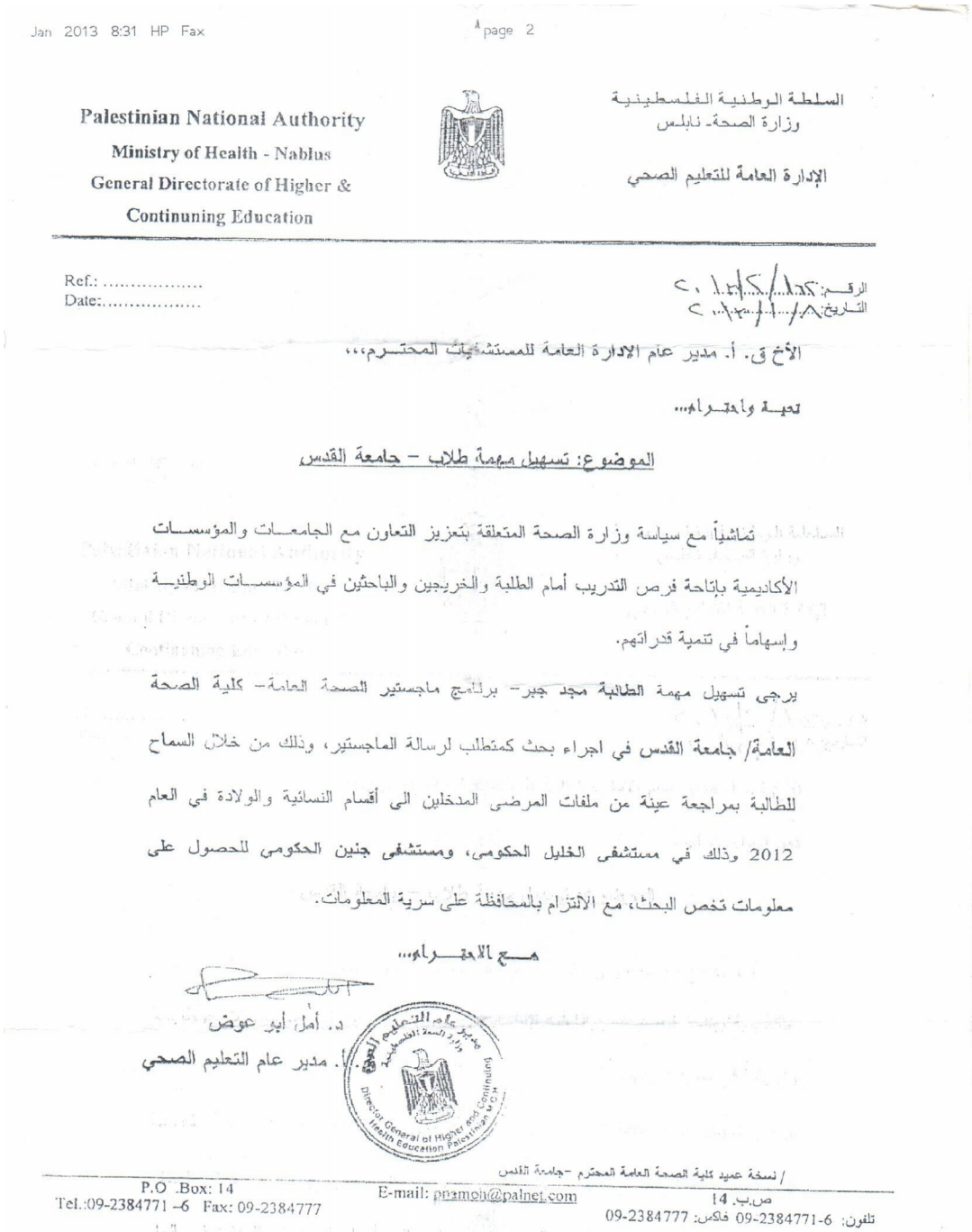
	Cares Module Triggers	+	Event Description and Harm Category (E-I)
C1	Transfusion or use of blood products		
C2	Code/arrest/rapid response team		
C3	Acute dialysis		
C4	Positive blood culture		
C5	X-ray or Doppler studies for emboli or DVT		
C6	Decrease of greater than 25% in hemoglobin or hematocrit		
C7	Patient fall		
C8	Pressure ulcers		
C9	Readmission within 30 days		
C10	Restraint use		
C11	Healthcare-associated infection		
C12	In-hospital stroke		
C13	Transfer to higher level of care		
C14	Any procedure complication		
C15	Other		
	Surgical Module Triggers		
S1	Return to surgery		
S2	Change in procedure		
S3	Admission to intensive care post-op		
S4	Intubation/reintubation/BiPap in Post Anesthesia Care Unit (PACU)		
S5	X-ray intra-op or in PACU		
S6	Intra-op or post-op death		
S7	Mechanical ventilation greater than 24 hours post-op		
S8	Intra-op epinephrine, norepinephrine, naloxone, or romazicon		
S9	Post-op troponin level greater than 1.5 ng/ml		
S10	Injury, repair, or removal of organ		
S11	Any operative complication		

	Medication Module Triggers	+	Event Description and Harm Category (E-I)
M1	Clostridium difficile positive stool		
M2	Partial thromboplastin time greater than 100 seconds		
M3	International Normalized Ratio (INR) greater than 6		
M4	Glucose less than 50 mg/dl		
M5	Rising BUN or serum creatinine greater than 2 times baseline		
M6	Vitamin K administration		
M7	Benadryl (Diphenhydramine) use		
M8	Romazicon (Flumazenil) use		
M9	Naloxone (Narcan) use		
M10	Anti-emetic use		
M11	Over-sedation/hypotension		
M12	Abrupt medication stop		
M13	Other		
	Intensive Care Module Triggers		
I1	Pneumonia onset		
I2	Readmission to intensive care		
I3	In-unit procedure		
I4	Intubation/reintubation		
	Perinatal Module Triggers		
P1	Terbutaline use		
P2	3rd- or 4th-degree lacerations		
P3	Platelet count less than 50,000		
P4	Estimated blood loss > 500 ml (vaginal) or > 1,000 ml (C-section)		
P5	Specialty consult		
P6	Oxytocic agents		
P7	Instrumented delivery		
P8	General anesthesia		
	Emergency Department Module Triggers		
E1	Readmission to ED within 48 hours		
E2	Time in ED greater than 6 hours		

Annex B: (IHI Global Trigger Tool for Measuring Adverse Review Summary Sheet).

Record #	LOS	Triggers	Events (Note trigger identifying event)	Event present on admission?
Totals				

Annex C: The College letters to the Palestinian MoH to facilitate the student's mission.



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Palestinian National Authority
Ministry of Health - Nablus
General Directorate of Higher & Continuning Education

السلطة الوطنية الفلسطينية
وزارة الصحة- نابلس
الإدارة العامة للتعليم الصحي

Ref.: .....
Date:.....

الرقم: ٢٠١٢/٤٨٤
التاريخ: ٢٠١٢/١١/٢٨

الأخ ق. أ. مدير عام الادارة العامة للمستشفيات المحترم،،،

تحية واحترام،،

الموضوع: تسهيل مهمة طلاب – جامعة القدس

تماشياً مع سياسة وزارة الصحة المتعلقة بتعزيز التعاون مع الجامعات والمؤسسات الأكاديمية بإتاحة فرص التدريب أمام الطلبة والخريجين والباحثين في المؤسسات الوطنية وإسهاماً في تنمية قدراتهم.

يرجى تسهيل مهمة الطالبة مجد جبر- برنامج ماجستير الصحة العامة- كلية الصحة العامة/ جامعة القدس في اجراء بحث كمتطلب لرسالة الماجستير، وذلك من خلال السماح للطالبة بمراجعة عينة من ملفات المرضى المدخلين الى أقسام النسائية والولادة في العام 2012 وذلك في مستشفى الخليل الحكومي، ومستشفى جنين الحكومي للحصول على معلومات تخص البحث، مع الالتزام بالمحافظة على سرية المعلومات.

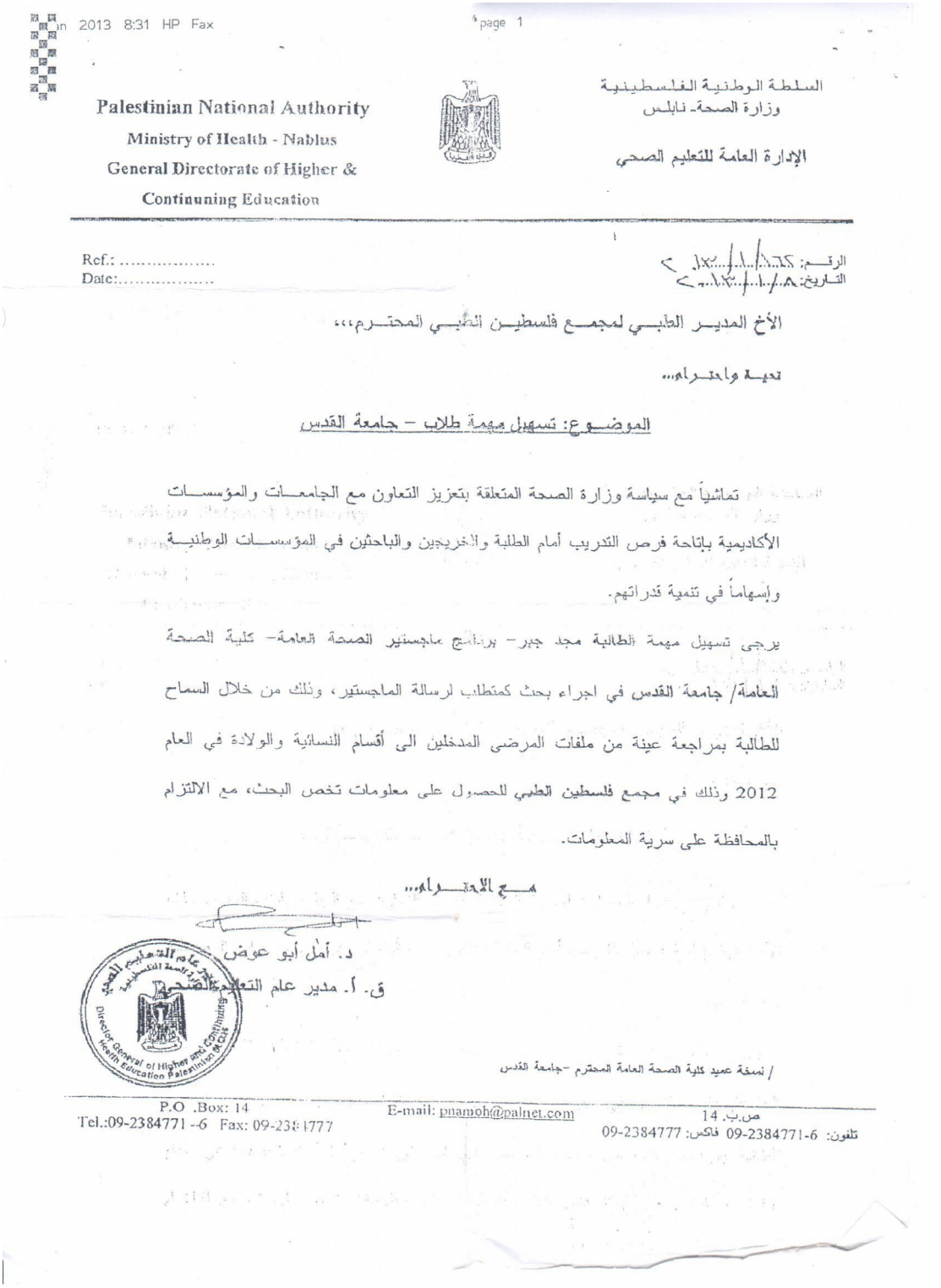
مع الاحترام،،

د. أمل أبو عوض
مدير عام التعليم الصحي

/ نسخة عميد كلية الصحة العامة المحترم -جامعة القدس

P.O .Box: 14
Tel.:09-2384771 -6 Fax: 09-2384777
E-mail: pgamoh@palnet.com
ص.ب. 14
تلفون: 09-2384771-6 فاكس: 09-2384777

Annex D: The College letters to the Palestinian MoH to facilitate the student's mission.



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Palestinian National Authority
Ministry of Health - Nablus
General Directorate of Higher & Continuning Education

السلطة الوطنية الفلسطينية
وزارة الصحة- نابلس
الإدارة العامة للتعليم الصحي

Ref.: .....
Date:.....

الرقم: ٢٠١٢/١٠٥٤
التاريخ: ٢٠١٢/١٠/٨

الأخ المدير الطبي لمجمع فلسطين الطبي المحترم،،،

تحية واحترام،،

الموضوع: تسهيل مهمة طلاب – جامعة القدس

تماشياً مع سياسة وزارة الصحة المتعلقة بتعزيز التعاون مع الجامعات والمؤسسات الأكاديمية بإتاحة فرص التدريب أمام الطلبة والخريجين والباحثين في المؤسسات الوطنية وإسهاماً في تنمية قدراتهم.

يرجى تسهيل مهمة الطالبة مجد جبر- برنامج ماجستير الصحة العامة- كلية الصحة العامة/ جامعة القدس في اجراء بحث كمتطلب لرسالة الماجستير، وذلك من خلال السماح للطالبة بمراجعة عينة من ملفات المرضى المدخلين الى أقسام النسائية والولادة في العام 2012 وذلك في مجمع فلسطين الطبي للحصول على معلومات تخص البحث، مع الالتزام بالمحافظة على سرية المعلومات.

مع الاحترام،،

د. أمل أبو عوض
ق. أ. مدير عام التعليم الصحي

/ نسخة عميد كلية الصحة العامة المحترم -جامعة القدس

P.O .Box: 14
Tel.:09-2384771 -6 Fax: 09-2381777
E-mail: pnamoh@palnet.com
ص.ب. 14
تلفون: 09-2384771-6 فاكس: 09-2384777

Annex E: Categories of harm severity based on the NCC MERP* Index

Category E: Temporary harm to patient that required intervention
Category F: Temporary harm to patient that required prolonged hospitalization
Category G: Permanent harm to patient
Category H: Harm to patient required intervention to sustain life
Category I: Harm to patient resulted in patient death

* National Coordinating Council for Medication Error Reporting and Prevention.