SCHOOL OF PUBLIC HEALTH. COLLEGE OF HEALTH SCIENCES, UNIVERSITY OF GHANA

ADVERSE EVENTS IN HOSPITALIZED OBSTETRIC CLIENTS AT THE GREATER ACCRA (RIDGE) REGIONAL HOSPITAL

BY

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DECLARATION

I, Otchi Elom Hillary, declare that, except for other people's investigations which have been duly acknowledged, this work is the result of my own original research, and that this thesis, either in whole or in part has not been presented elsewhere for another degree.

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LIST OF ABBREVIATIONS

ACOG	American College of Obstetrician Gynaecologists
AEs	Adverse Events
ANC	Antenatal Care
AVE	Average Variance Extraction
BP	Blood Pressure
C/S, CS	Caesarean Section
CDC	Centres for Disease Control and Prevention
CFA	Confirmatory Factor Analysis
CR	Composite Reliability
EFA	Exploratory Factor Analysis
FH	Foetal Heart
GEE	Generalized Estimation Equation
GHS	Ghana Health Service
HSBB	Health Systems Building Block(s)
HAIs	Healthcare Associated Infections
IOM	Institute of Medicine
IQR	Interquartile Range
IRR	Interrater Reliability
KBTH	Korle Bu Teaching Hospital
KMO	Kaiser-Meyer-Olkin
LMIC	Lower Middle-Income Country
MDC	Medical and Dental Council

MO	Medical Officer
MPH	Master of Public Health
MSV	Maximum Shared Variance
NCC MERP	National Coordinating Council for Medication Error Prevention
N&MC	Nurses and Midwifery Council
OBGYN	Obstetrics and Gynaecology
PCA	Principal Component Analysis
PHU	Public Health Unit
PI	Principal Investigator
SD	Standard Deviation
RMSEA	Root Mean Square Error of Approximation
WHO	World Health Organization

DEFINITION OF TERMS

1. Adverse Event (AE):	Unintended injury that results in temporary or permanent disability, prolonged hospital stay, and life sustaining intervention, or death and that is caused by healthcare management rather than by the patient's underlying disease process.
2. Error:	Failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.
3. Adverse Drug Reactions/Adverse Drug Event:	A response to a drug that is noxious, unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease
4. Unintended Injury	Any disadvantage to the patient that leads to prolonged or strengthened treatment, temporary or permanent (physical or mental) impairment or death
5. Healthcare Management:	The actions of individual hospital staff as well as the broader systems and care processes
6. Preventable Adverse Events	An adverse event resulting from an error in management due to failure to follow accepted practice at an individual or system level.
7. Hospitalization	Any hospital stay greater than 24 hours of the date of admission

DEDICATION

I dedicate this work to my parents who are now with the Lord - **Ellison Gordon OTCHI and Dora Yawa Asare-OTCHI**. They have been very instrumental in ensuring that I am where I am today.

ABSTRACT

Introduction

All over the world, obstetric clients are harmed and even die because of unsafe care. The risk of an obstetric client being hurt or dying when receiving care in hospitals because of an adverse event is greater than the risk of dying in aviation or motor vehicle accidents or by breast cancer. Adverse Events (AEs) in obstetrics unlike in medicine and surgery has not been extensively explored. Similarly, there is still little understanding of the types, factors associated with AEs, frequency of occurrence and the degree of preventability of adverse events at the hospital, even in the advent of clinical audits. The objective of this study was to assess adverse events among hospitalized obstetric clients at the Greater Accra Regional Hospital.

Method

The medical records/folders of obstetric clients who were on admission from January, 1 to December 31, 2015 at the Greater Accra Regional Hospital were reviewed retrospectively. A total of 1402 folders satisfied the inclusion criteria to determine the proportion of adverse events. A case control study of cases (350) and controls (350) were also selected in the determination of the factors associated with AEs and the degree of preventability. Descriptive and inferential statistics were performed. Models were evaluated for goodness-of-fit measures. The reliability and validity of the scale was also tested using Cronbach's alpha coefficient.

Results

The mean gestational age of the clients was 37.4 weeks±4.9 weeks. The major types of AEs were related to surgery while the least type of AEs was related to patient care. The proportion of adverse events was 12.0% in the entire sample of 1402 and more than half (93, 55.4%) of these occurred in the

labor & delivery ward. AEs increased with increasing age but was not statistically significant *(p=0.879)*. There was about three-fold (OR=3.35; 95% CI=1.21-9.57) increase in odds of developing adverse events among Antenatal Clinic (ANC) non-attendants and this difference was statistically significant (p=0.044). Similarly, the odds of developing adverse events among obstetric clients who had had a previous surgery and post-term were also high and statistically significant (p<0.05). More than half (208, 64.1%) of the AEs that occurred were preventable. Leadership & governance *(inadequate use of protocol and adherence)* related factors accounted for more than half (149, 53.2%) of the manner in which AEs among obstetric clients could have been prevented.

Conclusion

The proportion of adverse events among obstetric clients was high. Patient characteristics such as age, surgical history, number of ANC attendance and gestational age are the main factors associated with adverse events among obstetric clients. The degree of preventability of adverse events was also high due to inadequate intrapartum monitoring and lack of adherence to protocols/guidelines.

Key Words

Obstetric clients, adverse events, patient safety, quality, health systems building blocks, healthcare, confirmatory factor analysis

CHAPTER ONE

INTRODUCTION

1.1 Background

The healthcare system is expected to cure disease and alleviate pain but causes sufferings and harm among obstetric clients that are preventable. It is a right of patients, including obstetric client to be protected by healthcare providers. However, there continues to be overwhelming evidence about the significant number of obstetric clients who are harmed in the process of seeking healthcare, which sometimes results in permanent or temporary injury, disability, and prolonged length of stay in the hospital or sometimes even in death **(Landrigan, Parry, Bones 2010).** Obstetric clients are frequently harmed, traumatized, often suffer needless pain, disability or die in the process of seeking healthcare (Vincent, 2013).

The delivery of appropriate care in today's world is dependent on the safe, efficient and effective functioning of multiple systems and other specialized services. Studies in the US and Australia, have shown that care that is received by the hospital-going population falls below the recommended standards (Brennan et al., 1991; Thomas et al., 2000; Thomas, Studdert, Newhouse, et al., 1999). For instance, many patients in the US received unnecessary investigations and treatments. Medicare for instance, had the payment to about 721 hospitals cut *(from the October 1 fiscal year to September, 2015)* because of 'high rates of infections and other patient injuries' including infections from bed sores, catheters, blood clots and other complications that are deemed preventable (Rau, 2014, 2017). Elsewhere in Australia, adult patients were estimated to have

received a little more than half (i.e. 57%) of the care that is recommended. The compliance to the standard of care also varied from alcohol dependence (13%) to coronary artery disease (90%) (Vincent, 2013; Walton, Harrison, Kelly, Smith-Mary, Manias, Jorm and Ledema, 2016; Wilson, Runciman, Gibberd, Harrison, Newby, Hamilton, 1995).

The possibility or risk of patients being hurt or dying when receiving care in hospitals because of an adverse event is greater than the risk of dying in aviation or motor vehicle accidents or from breast cancer. It is estimated that, there is a one in eight million likelihood of death per a domestic jet flight than 1 in 10 in healthcare (Bones, Hackbarth, Phil, Goldmann, & Sharek, 2010; Ennen & Satin, 2016; Kohn, Corrigan, Donaldson, 2000; Szekendi, Sullivan, Bobb, Feinglass, Rooney, Noskin, 2006; Zegers, Bruijne, Wagner, Groenewegen, Waaijman, van der Wal, 2007).

Preventable AEs are a leading cause of morbidity and mortality globally (Adhikari, 2016; Jha, Prasopa-Plaizier, Larizgoitia, & Bates, 2010) but an under-recognized category contributing substantially to the global burden of disability and premature mortality. It is estimated that, 43million AEs occur each year around the world, causing 23 million Disability Adjusted Life Years (DALYs). More than two-thirds of these AEs occur in developing countries, including Ghana (Adhikari, 2016). AEs are thus very common and brings complexity into healthcare quality, safety as well as epidemiological problems.

Modern healthcare continues to harm the lives and well-being of patients despite the efforts of the many well-intentioned and dedicated professionals at the frontline. The rates of avoidable medical

harm among hospitalized patients remain very high, irrespective of the enormous attention and efforts paid to patient safety since 1999 *(over the last 19years)* after '*To Err is Human'* was published. Despite the numerous global initiatives aimed at drawing the attention of various stakeholders to the AE epidemic, harm rates remain very common with very little evidence of improvement in healthcare quality and safety across health systems globally, especially in Africa, but also in Ghana (Brennan, Leape, Laird, Hebert, Localio, Lawthers, Newhouse et al., 1991; Vincent, 2013; Jha, Prasopa-Plaizier, Bates, 2010; Landrigan, Parry, Bones, Hackbarth, Goldmann, Sharek, 2010; Stockwell, Bisarya, Classen, & Kirkendall, 2015).

Many countries, such as Ireland, US, Britain, Australia, Canada and New Zealand have since the publication of the Harvard Study in the New England Journal in 1991 published their results on AEs. Most Lower Middle-Income Countries (LMIC) such as Ghana are however yet to follow their example in making published country data about AEs available (Kohn et al., 2000; Pittet & Donaldson, 2006; WHO World Alliance for Patient Safety, 2005).

Healthcare is a very complex and complicated socio-technical system where things usually happen or change quickly. **The complexity of large healthcare systems such as the Greater Accra (Ridge) Regional Hospital is epitomized by the varied perspectives of the number of actors, ambiguities, conflicting goals, distributed decision-making processes, frequent interruptions, time pressures, rapid changes, the potential for catastrophic failures; and the multiple connections among the subsystems and forms of process automation (WHO, 2009).** It is a very daunting task to organize this complexity into care processes. The role that leadership at every level of an organization plays in patient safety, and by extension averting adverse events cannot

be overemphasized. It is an environment where people ought to be mindful and remain sensitive to the possibility of failure, especially in instances where demands and resources are often unpredictable. In some settings such as in low-income countries, including Ghana, the resources are even unavailable. Healthcare is error prone largely because of its complexity and technological sophistication resulting in adverse events (AEs) for patients (Hollnagel, 2012; West, 2000b).

Prospects for obstetric clients and their babies all over the world continue to improve and this is evidenced in the nearly 50% global decline in maternal deaths worldwide from 1990 to 2010 (http://www.who.int/mediacentre/factsheets/fs348/en/). This has been possible as a result of some effective interventions which have all proven effective in reducing maternal mortality. Some of these interventions include preventing excessive bleeding through the increasing use of uterotonics and the treatment of severe eclampsia and preeclampsia with the use of magnesium sulphate, the use of long-lasting insecticide treated bed nets (LLINs) and intermittent preventive treatment (IPT) in pregnancy, political and financial commitments, and technological advancements. In spite of these, more than 287,000 women *(with about 1 in every two minutes)* continue to die annually from pregnancy and childbirth related complications. Most of these women live in developing and poor countries, including Ghana. The majority of these deaths are preventable (Morgan et al., 2013).

Institutional maternal deaths and adverse events remain very challenging in Ghana. The Greater Accra (Ridge) Regional Hospital, for instance in 2015, recorded an institutional maternal mortality of 490/100,000 (Ridge Regional Hospital Annual Report, 2015) which was slightly higher than the national figure of 350/100,000 (Greater Accra (Ridge) Regional Hospital, 2016) in 2015.

Similarly, Ghana's institutional maternal mortality rate has remained stagnant since 2012 (152/100,000) to 2016 (151.1/100,000) (Ghana Health Service (GHS), 2017a). The complex process of obstetric care is most often accompanied by unexpected risks of adverse events. For instance, the inherent risk of a patient who is seriously ill *(e.g. disease, pathophysiologic imbalance, etc.)* adds to an extraneous risk that is created by the process of care itself.

Obstetrics related adverse events is an emerging and important area because of the interest of providers and other stakeholders to improve care outcomes. The **Greater Accra Regional Hospital** is ranked as the largest within the GHS and the third largest in Ghana that provides obstetric services. It sees increased volume, also of tertiary and high-risk obstetric cases. The case mix seen at the Hospital is similar to that of the Teaching Hospitals in Ghana.

1.1.2 Quality & Patient Safety

Quality healthcare is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (Institute of Medicine (IOM), 2001; World Health Organization (WHO), 2018b). Patient safety is one of the six dimensions *(illustrated in Box 1)* and a key component of healthcare quality (Elmontsri, Almashrafi, Banarsee, & Majeed, 2017; Francis, 2011; Institute of Medicine (IOM), 2001, 2006). It is the freedom from injuries that are produced accidentally (DeLisa, 2004) as a result of medical care, whereas harm is considered when any structure or function of the body is impaired and/or any inimical effect arises as a result of disease, injury, suffering, disability or death, and is usually physical (Gandhi, Berwick, & Shojanla, 2016; Grol, Wensing, Eccles, 2005).

Patient safety is also defined by WHO and IOM cited In Elmontsri et al. (2017) as the 'reduction of risk of needless harm [adverse events] associated with healthcare to an acceptable minimum' and 'the freedom from accidental injury'. It is about avoiding, preventing and ameliorating harm or adverse events to patients during the process of their seeking medical care. Nurses, according to a study by Lynden cited in Karimi et al. (2016) defined patient safety as the protection of emotional, psychological and physical wellbeing of the patient and his/her family (Elmontsri et al., 2017; Karimi et al., 2016; Vincent, 2011). In as much as there appear to be variations in the respective definitions, one theme that seems so common in all of these is the fact that patient safety aims at reducing the rate of preventable harm *(i.e. adverse events)* to patients during their process of seeking healthcare. In healthcare, patients suffer preventable harm because they *(i.e. patients)* do not get the beneficial health services, they are made to undergo procedures and treatments that will not be beneficial to them, and when the appropriate services received by patients are provided badly (Cantiello, Kitsantas, Moncada, & Abdul, 2016).

Leaders globally and in Africa have demonstrated some levels of commitment towards improvement in patient safety and healthcare quality. A resolution on patient safety was agreed by Member States of the WHO at the World Health Assembly (WHA55.18) in 2002. Concern was raised about the challenge increasing adverse events prevalence was posing to the quality and safety of healthcare, causing preventable human suffering, and the high toll it is exacting with respect to loss of finance and opportunity cost to the health system. In September 2008, one of the agenda items adopted by African Leaders during its Fifty-Eighth Session (Part III) Regional

Committee meeting was 'Patient Safety in African Health Systems: Issues & Solutions'. The WHO facilitated a hospital-to-hospital partnership program with fourteen (14) hospitals from seventeen (17) different countries *(including Ghana)* from the AFRO Region and twelve (12) hospitals from three (3) countries in Europe from 2009-2014. Patient safety, according to the leaders, seeks to ensure that the provision of healthcare is safe for patients and staff alike (Jee-In & Hyeoun-Ae, 2017; WHO Regional Office for Africa, 2008). This was one of the major global and continental efforts at improving patient safety and reducing the burden of preventable AEs in Africa.

Patient safety is seen as the assurance that the provision of medical care will proceed correctly and provide the best possible chance to achieve the desired outcomes. The basic approach to patient safety hinges on the classical medical principle of *'first do no harm'* which ensures the balance of risks and benefits (Donaldson & Fletcher, 2006; Pittet & Donaldson, 2006; Valentine, 2016).

Box 1: Dimensions of Healthcare Quality

Effectiveness: providing care that is based on the evidence and scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding overuse, underuse)
Safety: avoiding injury to people from the care that is provided with the intention of helping them
Patient centeredness: providing care that is responsive and respectful to individual patient preferences, needs and values and ensuring that patient values guide all clinical decisions.
Timeliness: reducing or avoiding needless delays in the provision of care
Equity: providing care that does not discriminate on the basis of gender, race, geographic location, and socioeconomic status
Efficiency: avoiding waste during the provision of care, including waste of supplies, equipment, ideas, and energy. It is also about ensuring that the benefits of the available resources are maximized
***Integrated:** providing care that is coordinated across the various levels and providers and makes available the full range of health services throughout the life course

Source: *Institute of Medicine: Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, D.C.: National Academy Press, 2001; ***WHO Handbook for National Quality Policy and Strategy: A practical approach for developing policy and strategy to improve quality of care, 2018*

1.1.3 Burden of Adverse Events

Adverse Events (AEs) are unintended injuries or complications that are caused by healthcare management other than by the underlying medical condition or disease process of the patient leading to disability at the time of discharge, prolonged hospitalization or death. AEs are unintended and noxious events that occur in association with medical care (Brennan, 1991; Mahan, Holdsworth, Welch, Borego, & Spyropoulos, 2017; Thomas, Studdert, Newhouse, et al., 1999).

They are the poorer outcomes that occur as a result of medical management other than the patients' own underlying medical conditions. Medical management comprises of all aspects of care, including diagnosis; treatment; failure to diagnose or treat; and the systems and equipment that are used to deliver care. An adverse event is any physical injury to the patient. It is either an act of omission or commission other than the patient's own underlying medical condition (Brennan et al., 1991; Rafter, Hickey, Conroy, Condell, Connor, et al., 2016; Thomas et al., 2000).

Adverse events include events that are caused by errors some of which are harmless, others cause injury, and yet some others are 'near misses' i.e. - they do not cause injury to the patient, either by chance or because they are intercepted, e.g. due to the medication that is administered. The latter is a major and an ongoing challenge in healthcare. A substantial number of patients, including obstetric clients still die due to the care that they receive from hospitals (Baker, Norton, Flintoft, Blais, Brown, Cox, Etchells, et al., 2004; Brennan, 1991; Hoogervorst-Schilp, 2015; Rafter, Hickey, Conroy, Condell, O'Connor, et al., 2016).

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) has developed five categories used extensively to assess the severity of AEs (Deilkås et al., 2017). Details are presented in Box 2. In this study, the adverse events identified were not staged according to their severity as suggested by the NCC MERP categories.

Box 2: Categories used to assess the severity of AEs

1. Category E: Contributed to or resulted in temporary harm to the patient and required intervention
2. Category F: Contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
3. Category G: Contributed to or resulted in permanent patient harm
4. Category H: Required intervention required to sustain life
5. Category I: Contributed to the patient's death

Source: Deilkås et al., 2017

Major medical record reviews have revealed very high levels of harm to patients in many countries with minimal to modest evidence of improvement in safety. These improvements are mostly evidenced more in the developed countries than in the developing. Sylvia Burwell, the Secretary of the US Health and Human Services have stated, for instance, that there was, a 17% decline in the frequency of mistakes in the US between 2010 and 2013 (Rau, 2014). The continuous vulnerability of patients, including obstetric clients in many healthcare systems across various parts of the world has also been highlighted (Leveson, Samost, Dekker, Finkelstein, & Raman, 2016; Smits, Zegers, Groenewegen, Timmermans, Zwaan, Wal, et al., 2010; Thomas et al., 1999; Thomas, Studdert, & Runciman, 1999).

It is estimated that, in the US alone, 44,000 to 98,000 persons die annually in hospitals during the process of seeking healthcare (Kohn, Corrigan, & Donaldson, 2000). This estimate goes as high as 400,000 according to some studies (by other authors) (James, 2017). It is further estimated that more than half a million people die annually from hospital-associated harms in the United States. Specifically, the adjusted estimates of Healthcare Associated Infections (HAIs) in the US were 1.7

million (Klevens et al., 2007; Kochanek, Murphy, Xu, & Tejada-Vera, 2016; Stockwell et al., 2015). The nature, scale and gravity of the adverse events vary between low-, middle-, and high-income countries. For instance, estimates for low-income countries such as Ghana with respect to medication-related AEs experience twice as much Disability Adjusted Life Years (DALYs) unlike in high-income countries (Kohn et al., 2000; WHO Global Patient Safety Challenge, 2017). Similarly, 500,000 people are said to be harmed by unsafe care, according to a study in 26 hospitals across the African and Eastern Mediterranean Regions of the WHO with more than 10,000 deaths annually. If this estimate is extrapolated to include all the health facilities in Africa, the numbers will be in the millions. There is also a disproportionate burden of AEs in Africa (World Health Organization, 2014).

It is estimated that, mortalities due to preventable AEs exceed motor vehicle accidents, breast cancer or HIV/AIDS and is the third leading cause of death in the US (Mendes, Pavao, Martins, & Travassos, 2018) and the 14th globally (World Health Organization (WHO), 2018a).

Healthcare related harm and adverse events are very numerous and either leads to death, disability or prolonged hospitalization affecting one's quality of life and life expectancy (Brennan, 1991; Magdelijns, Stassen, Stehouwer, & Pijpers, 2010). It is not surprising that, more than half a million women die annually from complications related to pregnancy globally and 3100 of these women are from Ghana (Raven, Hofman, Adegoke, & van den Broek, 2011; World Health Organization (WHO), 2011). More than half of these deaths are suggested to be preventable (WHO, 2011, 2014).

1.1.3 Cost of adverse events

Adverse Events (AEs) are a huge financial burden to the healthcare system (Galadani, 2013) aside the considerable harm it does to patients (Vries, 2008). It is suggested that, obstetric AE is associated with an excess mortality of 15 deaths per 10,000 and excess cost of $3,000/case. A notable number of obstetric clients do experience an AE that often compromises their ability to receive quality and safe care (Grohman, 2012). The impact of obstetric adverse event is important because in this context, two patients are often injured i.e. the mother and the baby.

Medication-related AEs are estimated to cost billions of dollars to healthcare systems globally and are said to contribute to more than 140,000 deaths in the US alone (Jha et al., 2010). There are associated direct and indirect costs borne by patients or victims and society as a whole as a result of AEs in addition to the catastrophic health consequences that is suffered. The direct costs often refer to the higher healthcare expenditures while the indirect costs refer to the loss of productivity, disability costs and the personal costs of care. The estimated total costs of AEs *(including lost income, lost household production, disability and healthcare costs)* based on the analysis of 459 AEs identified by reviewing medical records of 14,732 randomly selected discharges from 28 hospitals in Utah and Colorado was nearly $662 million dollars of which healthcare costs alone totaled $348 million. The national cost of AEs in the US is estimated to be $37.6 billion of which $17.6 billion are attributable to preventable AEs (Jha et al., 2016; Kohn et al., 2000; Thomas et al., 1999).

1.1.4 Distribution of Adverse Events Among Obstetric Clients

There are approximately 139 million births occurring globally every year. Obstetric clients continue to receive quality and safe care from skilled Frontline healthcare workers in spite of the complexity of their conditions. However, an unacceptably high number of patients, including obstetric clients continue to be harmed due to actions of omission or commission by these Frontline healthcare workers, or as a consequence of their hospital stay. Approximately 600,000 women die globally annually due to pregnancy and childbirth with more than 99% of these occurring in developing countries like Ghana. Specifically, 2800 pregnant women lost their lives in Ghana during pregnancy and childbirth/delivery in 2015 *(giving an estimated MMR of 315/100,000 live births)*. It is extrapolated that, 289,000 women will die during pregnancy, childbirth, or soon after birth (Ghana Health Service (GHS), 2016) and about a quarter of these deaths are due to haemorrhage (Jha, Prasopa-Plaizier, Larizgoitia, & Bates, 2016; Knight et al., 2009). It is further estimated that, in 2015, about 10.7 million women died from maternal causes worldwide (Briozzo, Gómez, León, Tomasso, & Faúndes, 2016) and 830 women also died everyday worldwide as a result of pregnancy-related causes (Alkema et al., 2015) and more than two-thirds (i.e. 86%) of these were from Sub-Saharan Africa [including Ghana] and southern Asia. Sub-Saharan African countries [including Ghana] continue to bear a significant burden of maternal mortality despite the global decline of 45% (i.e. 385 deaths per 100,00 live births according to data from 171 countries) between 1990 and 2013. Again in 2015, 66% of global maternal deaths occurred in Sub-Saharan Africa (Alkema et al., 2015).

The effects of the AEs on obstetric clients are even more dire, especially because two people are involved *(i.e. the expectant mother and the baby)* (Ansong-Tornui, Armar-Klemesu, & Hussein, 2007). In acute care hospitals in the US, it is estimated that, 2.5% to 17% of patients suffered one or more adverse events and in 5% to 13% *(of these cases)*, the patients die (Zegers et al., 2007). Approximately 50% of the AEs are preventable. Some studies suggest that, 58% of all adverse events are surgical related [including obstetrics]. AEs that would not have happened if the appropriate ordinary standard of care is provided **to** the patient when needed is classified as a preventable AE. AEs in healthcare, thus constitutes a serious problem with very debilitating consequences for the entire health system (Gagnier, Morgenstern, & Kellam, 2016; Michel, Quenon, de Sarasqueta, & Scemama, 2004; Vincent & Taylor-Adams, 1998; Zegers et al., 2007).

Adverse events are a very grave public health concern that cause needless harm and cost lives to unimaginable number (Gandhi et al., 2016) of the hospital-going population annually in every kind of healthcare setting. The occurrence of any adverse event in healthcare is not necessarily the result of Frontline healthcare professional making a mistake, but that conditions in the system often enable them to occur. It is often suggested that, most AEs are caused by good people working in dysfunctional systems. The systems approach is seen as the best approach in investigating the nature and prevalence of AEs in order to identify the apparent causes and underlying factors when errors occur. The basic assumption underlying the systems' view is that humans are liable to err and errors are inevitable (Reason, 1995, 2000). It is therefore imperative now than ever before to interrogate the systems within which healthcare professionals work. AEs are suggested to be due to a variety of system features such as leadership/governance, human resource, service delivery, medical technology, health finance and health information interacting and operating at different levels. There have been instances where obstetric clients have suffered a delay in the provision of

care because of their inability to purchase the needed medication, equipment malfunction or absence of senior leadership to facilitate decision-making (Gawande, Zinner, & Studdert, 2003). There is therefore the need to avert the inevitable lapses of the human beings by strengthening the health system in our quest to make healthcare safer (Rafter et al., 2015; Reason, 2000; Reason, 1990; Vincent & Taylor-Adams, 1998). Avedis Donabedian also proposed the structure-process-outcome triad as an alternative perspective to the evaluation of the quality and safety of healthcare. Structure consists of the qualifications of the healthcare providers, settings and the administrative systems through which care is provided while 'process' entails the components of care delivered. Outcomes include recovery, restoration of function and survival. He added that, the process of care ensures the application of 'good' medical care to attain the desired outcomes (Ayanian, Markel, & Ph, 2016; Donabedian et al., 1966).

Things are easier to go wrong in **healthcare**, largely because patients are attended to by many providers in varied and different settings, with none of them having a complete and detailed information about the patient. In healthcare, there is no single provider that has a complete and holistic picture of the patient's medical condition. An obstetric client with sickle-cell disease *(genotype SS)* is, for instance, attended to by the obstetrician, haematologists, physician and other specialists in 'silos' (Kohn et al., 2000; Wachter, 2012). An interdisciplinary effort and the forging of an entirely new relationship will be required among Frontline **healthcare** workers in order to keep patients' safe. There will be the need to dissolve territories, turfs and the silo mentality in order to advance the cause of healthcare quality and patient safety. AEs are occurrences that diminishes the quality of care and are inconsistent with the goals of healthcare organizations to *'first do no harm'* to patients (West, 2000b).

This study sought to explore issues related to AEs among hospitalized obstetric clients other than complications in pregnancy. It is not interested in complications in pregnancy *(which is defined here as any difficulty or abnormality that arises during the process of labour or delivery).* The medical definition of complication, according to the Merriam-Webster dictionary, is: 'a secondary disease or condition that develops in the course of a primary disease or condition and arises either as a result of it or from independent causes.'

1.2 Problem Statement

It is estimated that, 1 in 10 patients are injured while receiving healthcare and even in developed countries, adverse events and preventable harm among hospitalized patients is between 2.5% to 16.6% (Brennan et al., 1991; Vincent, Neale, & Woloshynowych, 2001; Wilson et al., 1995). Also, it is estimated that, 1.5% of hospitalized obstetric clients experience adverse events and 38% of these are due to negligent care by healthcare workers (Benn et al., 2009; Brennan, 1991; Vincent & Amalberti, 2016). Furthermore, it has been noted globally that, the number of deaths associated with avoidable injury to patients is 400,000 in hospitals annually. More than half of these incidents occur in surgical care and are preventable (James, 2017). Wide variations however exist in reported prevalence of adverse events in developing countries [such as Ghana] and the developed countries (Jha et al., 2012). Most studies on the subject also exclude hospitalizations due to obstetric conditions mostly as a result of little information and data availability among this population (Mann et al., 2006). Adverse events have been recorded in maternal care globally [including Ghana] where many avoidable female deaths occurred even when basic equipment and personnel for emergency obstetric care were available (Ansong-Tornui et al., 2007).

There have been instances where obstetric clients have suffered prolonged hospitalization, temporal or permanent harm, or fitted as a result of eclampsia; or even death as a result of lack of protocol adherence, prolonged waiting; failure to act on lab results; inadequate theatre space, ventilators and oxygen; and absence of emergency medications such as labetalol and hydralazine in the obstetrics emergency, labour wards and the pharmacy. There are also medication errors such as from excessive $MgSO_4$ resulting in a reaction. There still remains increased risk of poor obstetric outcomes for patients despite the numerous efforts and measures put in place (Gawande et al., 2003; Ghana Health Service (GHS), 2017b).

Finally, obstetric outcomes attributable to adverse events are unknown and need to be studied. This study therefore seeks to assess the phenomenon of adverse events among obstetric clients hospitalized at the obstetrics unit of the Greater Accra (Ridge) Regional Hospital to inform policy decision on the appropriate systems and strategies to address them.

1.3 General Objective

The general objective of this study was to assess adverse events among obstetric clients who were hospitalized at the obstetrics unit of the Greater Accra (Ridge) Regional Hospital in Accra, Ghana.

1.4 Specific Objectives

The specific objectives of the study were to:

1. Determine the prevalence of any adverse events among obstetric clients hospitalized in Greater Accra (Ridge) Regional Hospital.

a. Determine the types of adverse events among obstetric clients hospitalized in the Greater Accra (Ridge) Regional Hospital.

2. Identify the factors associated with adverse events among obstetric clients hospitalized in the Greater Accra (Ridge) Regional Hospital.
3. Assess the degree of preventability of adverse events among obstetric clients in the Greater Accra (Ridge) Regional Hospital.

1.5 Research Questions

1. What is the prevalence of any adverse events among obstetric clients hospitalized in the Greater Accra (Ridge) Regional Hospital?
    a. What are the types of adverse events that occur among obstetric clients hospitalized in the Greater Accra (Ridge) Regional Hospital?
2. What are the factors that are associated with the occurrence of adverse events among obstetric clients hospitalized in the Greater Accra (Ridge) Regional Hospital?
3. To what extent can these adverse events among obstetric clients hospitalized in the Greater Accra (Ridge) Regional Hospital be prevented?

1.6 Conceptual Framework

The conceptual model for this study is illustrated in Figure 1. The direction of causation of adverse events is from left to right. The six (6) health systems building blocks developed by the WHO is used as the main themes for the determination of the factors associated with adverse events (on the left) among obstetric clients who were hospitalized at the obstetric department of the Greater Accra (Ridge) Regional Hospital. The framework describes a complex relationship that exists between

the respective Health Systems Building Block (HSBB) and its effect on the outcome of preventable adverse events among obstetric clients. It is guided by the thinking that; the occurrence of a preventable adverse event is dependent on the level of interrelationship between the health systems building blocks. Systems are made up of multiple interdependent components of people, equipment, processes, outputs/outcomes. Each component may directly or indirectly affect the function or output/outcome of the system as a whole and/or the other components.

They *(i.e. the health systems building blocks)* have been identified as the independent variables and the factors that influence the practice of healthcare *(by the frontline healthcare workers)*. The conceptual framework is guided by the fact that, before any single adverse event occur in a hospital environment, it would have been caused by a multiplicity of health system factors *(in this instance any or a combination of the health system building blocks)* other than the frontline health worker. These variables *(i.e. the health systems building blocks)* are expected to relate harmoniously with one another. The variables are interdependent and interrelated. A preventable adverse event will occur when any of the six (6) health systems building blocks is not in synch with the others, is absent or inadequate. An absence of or inadequate leadership/governance in any healthcare institution such as absence of supervision and seeking help, availability and adherence to protocols/guidelines and decision-making aids will result in preventable adverse events to the obstetric client. Similarly, a preventable adverse event could also occur when the frontline healthcare workers *(i.e. human resource)* do not also have adequate knowledge/skills, appropriate attitude/motivation or when they encounter very difficult tasks/procedures in the process of providing care. It was reported in the news in Ghana that a healthcare worker slapped an obstetric client for making noise during delivery. The report suggests that, this client was in severe pain and also bleeding profusely necessitating her wailing (Tawiah, 2018). There was a similar incident in

Sweden were a nurse is also reported to have slapped a pregnant woman who was on admission and was being treated for sepsis (Low, 2017). There have been instances where patients have developed pressure ulcers, injection abscess or even fallen off their beds on the floor because the beds had no restrains during their hospitalization. The healthcare workers in whose care sick patients have been entrusted have ended up inflicting all sorts of pain and harm on them in blatant defiance of the basic ethos of the provision of healthcare i.e. *'first do no harm'.*

Again, the inability of patients *(including obstetric clients)* to pay for the cost of services can also result in a preventable adverse event. Even when clients had valid National Health Insurance Service (NHIS) Cards, in most instances these cards have not been helpful because they are often required to do out of pocket payments to access service. There have been instances where there was delayed administration of medication to an obstetric client because the relative of the patient did not have money immediately to purchase it (Yates, Brookes, & Whitaker, 2017). Furthermore, obstetric clients have suffered preventable adverse event as a result of inadequate theater space, absence of emergency medications such as labetalol and hydralazine. There have also been instances of medication errors *(especially overdose or drug-drug interactions)* such as magnesium sulphate ($MgSO_4$) resulting in a reaction or even death (Idama & Lindow, 1998). A Consultant obstetrician gynecologist in one of the biggest hospitals in Ghana narrated how he sometimes have to play 'God' and decide who survives and who does not because of inadequate theatre space (Pers Communication, 2016). This is a hospital that does an average of twelve (12) caesarean sections in a day and has only one functional theatre for obstetric cases *(both emergency and routine)*. All these medical technology related issues have the potential to result in a preventable adverse event

if left unattended to. The accurate judgement of the presence of or otherwise of an adverse event is dependent on the accuracy and completeness of the documentation in the medical records.

Incomplete documentation or defective notes also has the potential to result in a preventable adverse event. This has an effect on the continuity of care that ought to be provided at any particular point in time. There have been instances where AEs have either been underreported or not disclosed by frontline healthcare workers for varied reasons including blame, shame and ostracization by their colleagues and this has in many instances contributed to the absence of reliable information on the patient. Also, the poor handwriting of some members of the healthcare team could also result in a preventable adverse event. For instance, a Fasting Blood Sugar result of 1.5mmol/dl instead of 9.5mmol/dl could result in a different management approach *(such as infusion of dextrose which could worsen the glycemic status of the patient)*. The situation could sometimes be more precarious in instances where adverse events reporting is voluntary other than mandatory. In that instance, there is no compulsory to report when things go wrong.

Finally, the organization of service delivery could also result in a preventable adverse event among obstetric clients. Some of the elements of the service delivery issues considered in this study include delay or incorrect timing of surgery, inadequate management, delay in receiving treatment, inadequate intrapartum monitoring, failure of an investigation to be arranged (Neale, Woloshynowych, & Vincent, 2001), sub-optimal care and attention to the patient, test results not reviewed or reported, and complexity or seriousness of the condition of the patient. This conceptual framework suggests that, a delay or an incorrect timing of surgery has the potential of leading to preventable adverse events among obstetric clients. For instance, when an obstetric client starts

bleeding in 'small' drops and the midwife/doctor fails to attend to her urgently, hemorrhage or an adverse event related to bleeding could occur. The obstetric client has the potential to bleed to death if those 'small' drops of blood are not arrested immediately. Similarly, whenever there is a delay in the treatment of an obstetric client, inadequate use of antenatal services or when their test results are not properly reviewed or reported, something untoward could happen. An obstetric client whose labs *(such as sugar in the urine)* and increasing blood pressure is overlooked during the ANC period is likely to develop one adverse event or the other *(such as Eclampsia or Preeclampsia or both)* during the period of the pregnancy or delivery or after delivery. This could have been avoided had there been appropriate system defenses or barriers to avert it.

The conceptual framework emphasizes the point that, there is the need to be more holistic in our approach at reducing the burden and prevalence of adverse events *(i.e. making healthcare safe)* for obstetric clients. In the event of a preventable adverse event, it is needful for the investigators to identify what went wrong with respect to the interrelationships between the six (6) health systems building block other than immediately blaming the frontline healthcare worker. For instance, when a third-degree perineal tear occurs, let us look at all the leadership/governance, human resource, health finance, medical technology, health information and the organization of service delivery related issues. This adverse event might have happened because of the absence of protocol, inadequate equipment to assess the fetus, inadequate ANC service, and the healthcare providers failure to provide episiotomy on time. The cause of one AE is as a result of a multiplicity of factors other than the frontline healthcare worker alone. The structure *(i.e. leadership/governance, health finance, medical technology, health workforce and health information)* and process *(i.e. organization of service delivery)* issues are equally as important as the outcomes of care

(Donabedian et al., 1966). Humans are fallible and errors are inevitable (Reason, 1990; Wangler, 2011), there is therefore the need to design health systems to account for all the weaknesses of man. This conceptual framework seeks to suggest that, the health system could be designed to make it difficult if not impossible for a preventable adverse event to occur.

A preventable adverse event should be related to diagnosis, patient care, treatment, surgery, medication and/or infection.

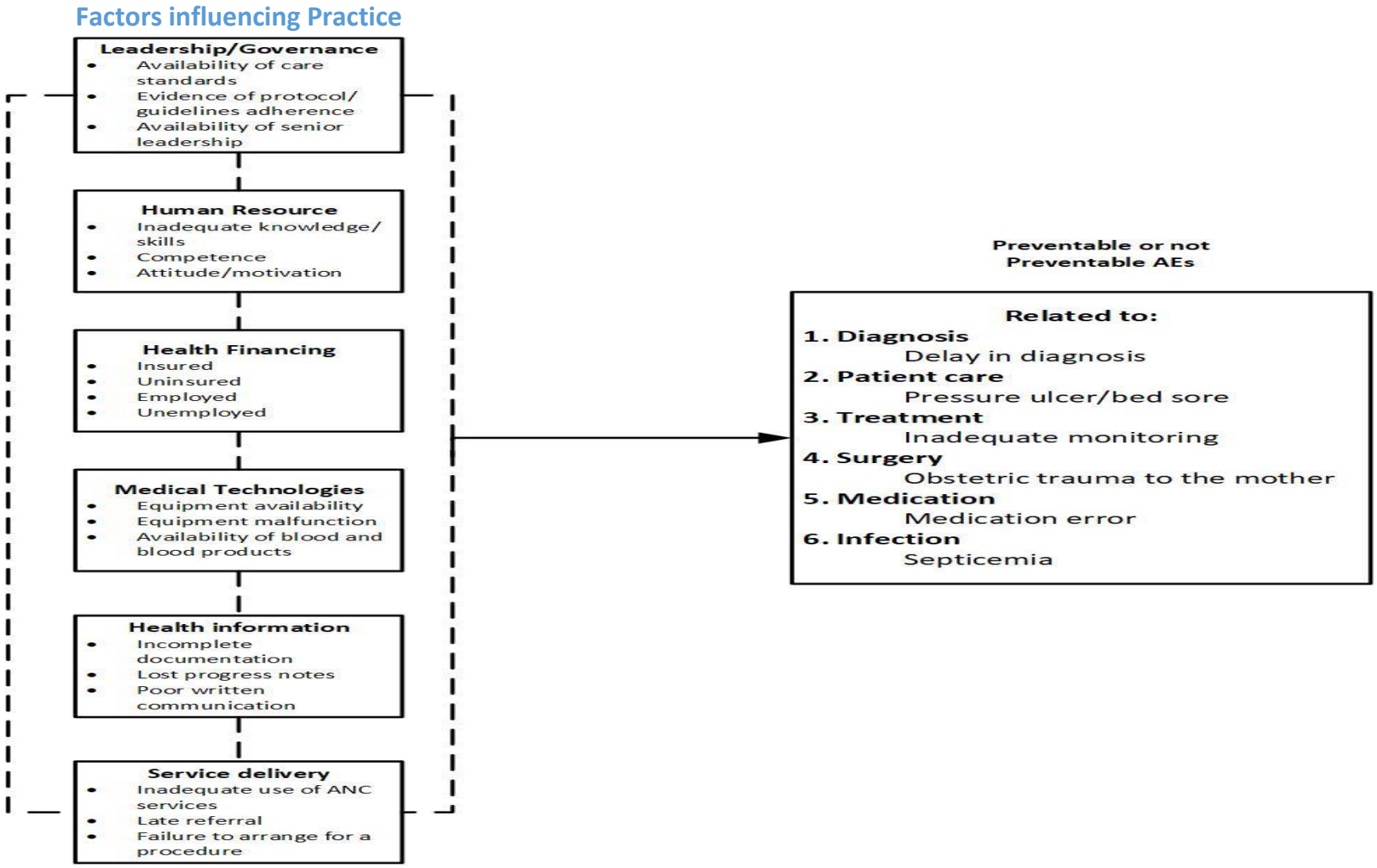

Figure 1: ***Conceptual framework illustrating the health systems factors associated with preventable adverse events***

1.7 Justification

In healthcare, people may commit errors and these errors cause accidents that may result in morbidity or adverse events including mortality. There continues to be a growing appreciation that a number of obstetric clients experience one form of adverse events or the other from healthcare providers in their quest to seek care. Adverse events in obstetrics and healthcare could be expensive and disastrous to the obstetric client and then the baby. Studies in this area, particularly in developing countries are still formative and continue to evolve, making it very appropriate to undertake this research. The reduction in adverse events and the need to collect data that can be studied and acted upon is an important mark of improvement in healthcare outcomes (Holden, Quin, & Holden, 2004). Healthcare thus continues to record alarming increases of AEs with serious impact on patients, caregivers and the entire health system. The organizational approach to adverse event prevention has largely been to seek out the culprits for blame and punishment. What is often forgotten or ignored is that, most often when an individual is at fault, then the whole system is also at fault. Therefore, punishing individuals without changing the system only perpetuates the system other than addressing the underlying cause (Boysen, 2013).

Very little is known about the critical system factors *(such as leadership/governance, human resource, health information, medical technology, service delivery and health finance)* underlying the cause of these AEs.

Adverse events are a part of the larger concept of quality and safety in healthcare and are very important to healthcare largely because of their impact on the patient and their ability to provide an insight into the quality of healthcare. Adverse events could also help in identifying and exploring the variability in the performance of quality and safety of healthcare. Their

prevalence in healthcare is seen as a very important indicator as well as a measure of quality and safety of healthcare among hospitalized patients (Baker et al., 2004). They also help in exploring important performance variations, mostly as a result of the direct relationship between adverse events, patients' healthcare experience and the process of care itself.

This study, sought to identify the weaknesses in the process of care that predispose to adverse events and thus help to better understand the type, incidence, causative factors and the degree of the preventability of AEs. The epidemiologic data from this study will also seek to bring to the fore the need for a comprehensive patient safety policy that will seek to make healthcare safer for obstetric clients and other members of the population who patronize our health facilities. It is necessary to study the type, incidence, degree of preventability, and the factors associated with AEs to determine where quality and patient safety initiatives need to be modified or refocused to be relevant to obstetric care in Ghana.

1.8 Thesis Organization & Structure

There are five (5) main chapters contained in this thesis. The first chapter is Chapter 1 and it contains a description of the background of the study. This chapter also contains the problem statement, the objectives, the justification and the conceptual framework of the study. Chapter 2 contains the literature review, which includes an introduction to the study of adverse events and adverse events among obstetric clients. The literature is reviewed in this chapter guided by the specific objectives of the study. The theoretical model is also discussed in this chapter. In the Chapter 3 of this study, the methodology that was employed to arrive at the results is presented.

Chapters 4 and 5 contain the analysis of the data and the discussion of the results/findings. The discussion of this work was situated within the context of the current literature and theoretical framework. Conclusions are made from the aggregated results and this, together with the recommendations is presented in Chapter 6. The study findings have implications for policy, quality, patient safety and future research.

1.9 Chapter Summary

This chapter provided an introduction to the study. The problem statement of this study was provided. The study objectives, the research questions were all identified and the justification for the study was also explained. The operational definitions of the relevant terms used in the study were provided. The conceptual framework for this study has also been provided and explained.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

All over the world, the hospital going population continues to be meted out with unsafe and substandard care. The hospital environment and medical wards remain harmful in spite of the intense efforts on healthcare quality and safety since '*To err is human'* (Barnes et al., 2006; Brennan, 1991; Vincent, 2013) was published. A substantial number of patients, including obstetric clients continue to die while seeking care in hospitals. The vulnerability of patients [including obstetric clients] continues to be evident. The overall quality of healthcare in some settings appears to be improving; however, it appears to be unsafe simultaneously (Barnes et al., 2006; Brennan, 1991; Vincent, 2013).

It is estimated, for instance, **that, 60% of the failings on the wards reach the patients and 10% of these causes physical injury**. In Australia, it is suggested that only about 57% of adult patients receives the recommended care while in the USA, about 50% of patients are said to have received investigations and treatment that were unnecessary. A study by Jonge et al. (2013) in the Netherlands also revealed that, a planned home birth was safer than that of a hospital birth. For instance, out of a total of 288 (2.0 per 1000) adverse events identified, 141 (1.5 per 1000) were found among women who delivered at home while 147 (2.7 per 1000) were found in women who delivered at the hospital. Adverse events were less among women who delivered at home than those who delivered at the hospital giving credence to how unsafe healthcare is. The authors further suggested that, delivering at the hospital was associated with risks and that even among low risk women, the rate of medical interventions was higher (Jonge,

Jeanette, Zwart, Dillen, & Roosmalen, 2013; McGlynn et al., 2003; Vincent, 2011, 2013). Janssen et al. (2009) also found that obstetric clients who delivered in the hospitals were more likely to have a severe *(i.e. third- or fourth degree)* perineal tear, postpartum haemorrhage, pyrexia, wound infections and other adverse events than among home births. They added that, it was also more likely to deliver a newborn with trauma at the hospital than at home (Janssen et al., 2009). It is also suggested that most of the errors that results in preventable injuries are generated from the wards in the hospital (Pannick et al., 2015). People are dying not from heart attacks and bacterial infections, but largely as 'a result of system-wide failings and poorly coordinated care' according to Dr. Martin Makary, a professor of surgery and health policy at Johns Hopkins University School of Medicine. He described medical care as 'awry' (Sterberg, 2016). Every patient has a right to have safe care and be protected from, the potential harm that may be associated with the healthcare system. Healthcare professionals and institutions are therefore obliged to provide a high standard of safe and quality care at all times. The emphasis on patient safety is on the system of health delivery that prevents errors, learns from the errors that do occur, and built on a safety culture that involves healthcare professionals, organizations and patients.

2.2 Theoretical Framework: Accident Causation Theory

Theoretical and conceptual models have been developed by psychologists and researchers to help understand and analyze accident causation. An accident has been broadly defined by various authors (Merriam Webster, 2016; Vernon, 1919) However, there are some characteristics of what an accident is and these include:

- An accident is an event that is unintentional, abnormal and undesired, and happens unexpectedly.

- An accident is an event that involves the interaction between varied conditions and elements such as humans and non-humans.
- An accident involves the breakdown of the necessary defenses or controls in a system within which the event (i.e. accident) occurred.
- It is an event that is unplanned and uncontrolled that has the potential of leading to an injury to the person or property.
- It is an event that results in a hurt or injury through the transfer of energy.

The causes of accidents have been explained by different authors through the use of models. There have also been many studies that have been conducted especially in industry to identify and understand the causes of accidents. For instance, studies by Vernon (1919) identified fatigue, carelessness and inattention, unsuitable temperature and defective artificial illumination (or lights). Greenwood (1919) however have suggested contrary to Vernon (1919) that accidents happen by chance, or because people are prone to cause accidents or that when one suffers an accident it increases his/her chances of suffering subsequent accidents *(if the conditions were reproduced)*. Both authors however agree that, industrial accidents are usually a function of fatigue. They added that the faster one works the greater the number of accidents, and the wearier one is when working at the same rate the greater the risk of misadventure (Greenwood & Woods, 1919; Vernon, 1919). Authors like Harvey (1984) and Ysbrand (2007) join Greenwood (1919) in the belief that, there are individuals who are really accident prone. The authors make a direct relationship between individuals/personality and the cause of an accident (Harvey, 1984; Ysbrand et al., 2007).

Other models that focused on human, product, task or environmental factors have also been proposed by Heinrich (1939), Gordon (1949), Surry (1963) and Haddon (1973). Heinrich

(1939) like Greenwood (1919) also blamed the cause of accidents on the 'mistakes of people'. He espoused this very eloquently in his Domino theory where he described the sequence of accidents as a series of five (5) factors presented in Box 3 *(below)*.

Box 3: A description of the sequence of an accident by Heinrich (1939)

1. Social environment and inherited behaviour, such as smoking or alcoholism
2. Fault of a person such as recklessness or carelessness
3. Unsafe act or condition such as performing a task without wearing or using the appropriate personal protective equipment (PPE)
4. Accident
5. Injury is the outcome of some accidents

According to this author *(i.e. Heinrich, 1939)*, an injury can occur as a result of an accident only when an unsafe act or conditions by either reckless or careless persons or poorly designed and maintained equipment. He further described how the environment in which an individual is raised and educated makes him prone to cause accidents.

Heinrich's (1939) model is however criticized by authors such as Iskrant (1962) and the Cleveland State University (2015) as being too simplistic because the causes of accidents that he identified are arranged in absolute sense other than by chance or probabilistic. The critics developed the epidemiological model where the causes of accidents are dependent on the successful interactions between host *(the individual who suffers the accident)*-agent *(deliverer or an object that caused the injury directly)*-environment *(the accident setting which is physical, biological or socioeconomic)* similar to earlier proposition that accidents are caused by *'multiple factors'*. This *(i.e. epidemiological model)* identifies predisposing characteristics

(such as conditions that may make an individual vulnerable to an accident) and situational characteristics *(such as risk-taking behaviour and poor attitude)* necessary for an accident to occur (Cleveland State University, 2015; Iskrant, 1962).

The systems model with its emphasis on effective feedback and interrelationship was also proposed. The proponents suggest for instance that, systems that utilizes high quality and timely feedback are less susceptible to accidents and vice versa. An interrelationship also needs to exist between the individual, the equipment and environment. The focus of accident causation with this model is the interaction the individual and the demands that is placed on him/her by the tasks of his/her work. This therefore implies that, if you want to prevent an accident from occurring, all you have to do is to remove the individual who is accident prone environment *(similar to arguments made by Greenwood, 1919).*

James Reason had by the end of the 1980s introduced the multiple-cause of accidents where he suggested that accidents are caused when latent and active failures interact. He *(in 2000)* suggested that, within complex systems such as health facilities, there are various barriers or multiple layers such as hospital policies, clinical guidelines or protocols that is put in place to prevent accidents or adverse events from occurring. He added further that, there are random weaknesses or holes *(labeled as latent conditions)* in these defenses or barriers such that when they align, the AE producing agent is able to *"pass straight through"* to cause an accident or an adverse event *(labeled as active failures).* Two ways are suggested as to how these failings occur. One is that, the actions do not go on as intended even though the plan is adequate *(labeled as an error)* while the other is that, though the original plan was flawed, the actions still proceed as intended (Reason, 1990). Reason illustrates how a combination of these active and latent

failures are able to cause accidents or adverse events using the analogy of what has become popularly known as the "Swiss cheese model" illustrated in Figure 2.

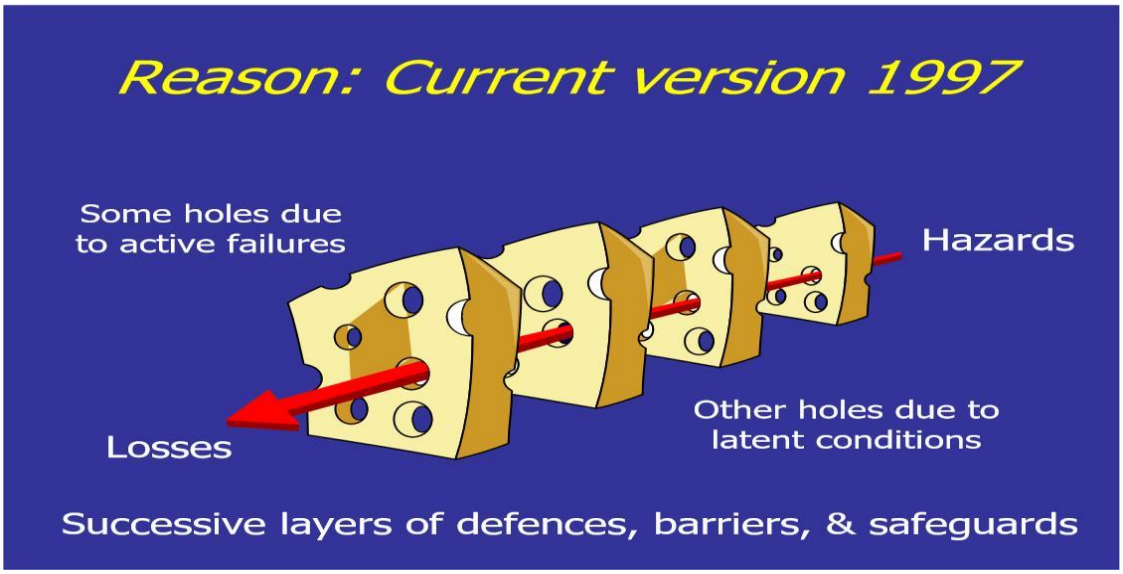

Figure 2: Diagram of a Swiss Cheese Model

Diagram Adopted from (Reason, Hollnagel, & Paries, 2006)

He classified accident causing factors into organizational shortcomings or systems *(such as the levels of staffing, time of patient discharge or bed shortages)* environment or workplace and unsafe acts. He is one of the few authors who moved away from 'blaming' human error for the cause of accidents to focusing attention on the environment in which work is performed. He focuses on the conditions or situations *(which might be fertile to produce an error or incident)* in which the person is trying to perform other than the person or individual (Elliott, Page, & Worrall-Carter, 2012; Reason, 1990). These conditions were labeled by Reason as vulnerable system syndromes – a cluster of organizational pathologies that renders some systems more liable to adverse events such as blaming front line individuals for adverse events, such as the clinicians or nurses at the bedside involved in the event. The strength of Reason's (2000) model

is its focus on the system or the environment in which the event occurred, rather than on the individual involved, as the cause of the event, and to randomness rather than deliberate action, in medical errors (Perneger, 2005). This is because when an accident occurs, it is usually due to a specific trigger such as human resource related *(e.g. staff workloads or staffing levels)*, which has influenced the long-term failures in the design of the system (Elliott et al., 2012). This position is however contrary to all the earlier proponents notably Greenwood (1919), Harvey (1984) and Ysbrand (2007) all of who had bought into the *'accident proneness'* theory. Furthermore, analyzing the two positions only seem to suggest a perpetual shift of the 'blame' of accident from the individual to the environment and/or vice versa. This is similar to the view of Dekker (2011) who has also argued that the search for organizational deficiencies or latent factors only relocates the blame for AEs to senior managers, policy makers and regulators. He advocates that safety should rather be viewed as an emergent property of complex systems such as healthcare in which there is a trade-off between safety and other goals (Dekker & Pruchnicki, 2013).

The organizational or situational contexts in which an AE occurred is described as latent failures because these are conditions which are present in a complex system but may not be obvious and thus, they easily contribute to an adverse event or patient harm. They are often as result of the decisions made by top-level management, policy makers, designers or builders. Some of these include poor design, inadequate supervision, manufacturing defects or maintenance failures, unworkable procedures, clumsy automation, shortfalls in training and less than adequate tools and equipment (Reason, 1997; Perin, 2005 cited in (Elliott et al., 2012). Latent failures may be present in the system for many years before they are revealed by active failures. They are sometimes referred to as *'accidents waiting to happen'.* They are most often hidden in the organization and are very difficult to detect *(e.g. lack of training, poor design,*

gaps in supervision). It involves failures of organization or design *(e.g. systems and processes)* that allow active failures to cause AEs. Latent failures lead to weaknesses in the defenses of the organization, thus increasing the likelihood that, when active failures occur, they will combine with existing preconditions, breach the defenses of the system and result in an adverse event. It is loosely equivalent to causal or contributing factors of adverse events. For instance, two medications with similar names but differing actions being contained in ampoules of similar shape, size and color. The clinical nurse at the bedside is neither responsible for labeling nor packaging the design of these drugs. Nonetheless, the bedside nurse is the one who can easily confuse these drugs and become a victim of poor design during the administration of the medications to the patient (Carthey, 2013; Elliott, Page, & Worrall-Carter, 2012; Perneger, 2005; Thompson & Avillion, 2017). Active failures are easily identifiable and are the immediate observable causes of an accident. They are committed by people at the service delivery end or by frontline staff *(i.e. doctors, pharmacist, the ward nurse, the biomedical scientist, the operating room team etc)* of the healthcare system. They occur at the point of contact between a human being and some part of the larger system. The occurrence of AEs is preceded, sometimes by long periods of gradually increasing, but unrecognized risks referred to as 'incubation periods. Whenever an AE occurs, it means there has been a gap in its detection. It means that somebody somewhere did not anticipate what and how things could go wrong. It means that something was not caught as soon as it should.

There is always the possibility of adverse events occurring in healthcare as a result of the human factor which is influenced, often by factors that are external to the frontline healthcare worker. There is therefore the need to move away from the simplistic conceptions of human error, fault and blame. This is so because, adverse events are not deliberately caused by human beings, whether they are novices or experts. The immediate past Head of the Obstetrics & Gynaecology

Department of the Korle Bu Teaching Hospital in a personal communication remarked that, *'young man, no doctor dresses to the hospital to come and kill women' (Pers Comm., 2014)*. The decisions of these clinicians are often guided by the available information to them at the crucial time and the work environment within which they perform their tasks/duties. System and human factors are estimated to account for 70-80% of all accidents according to Runciman, Webb, Lee, & Holland, 1993 cited in (Elliott et al., 2012), which is the reason why AEs are deemed preventable (Dean, Schachter, Vincent, & Barber, 2002).

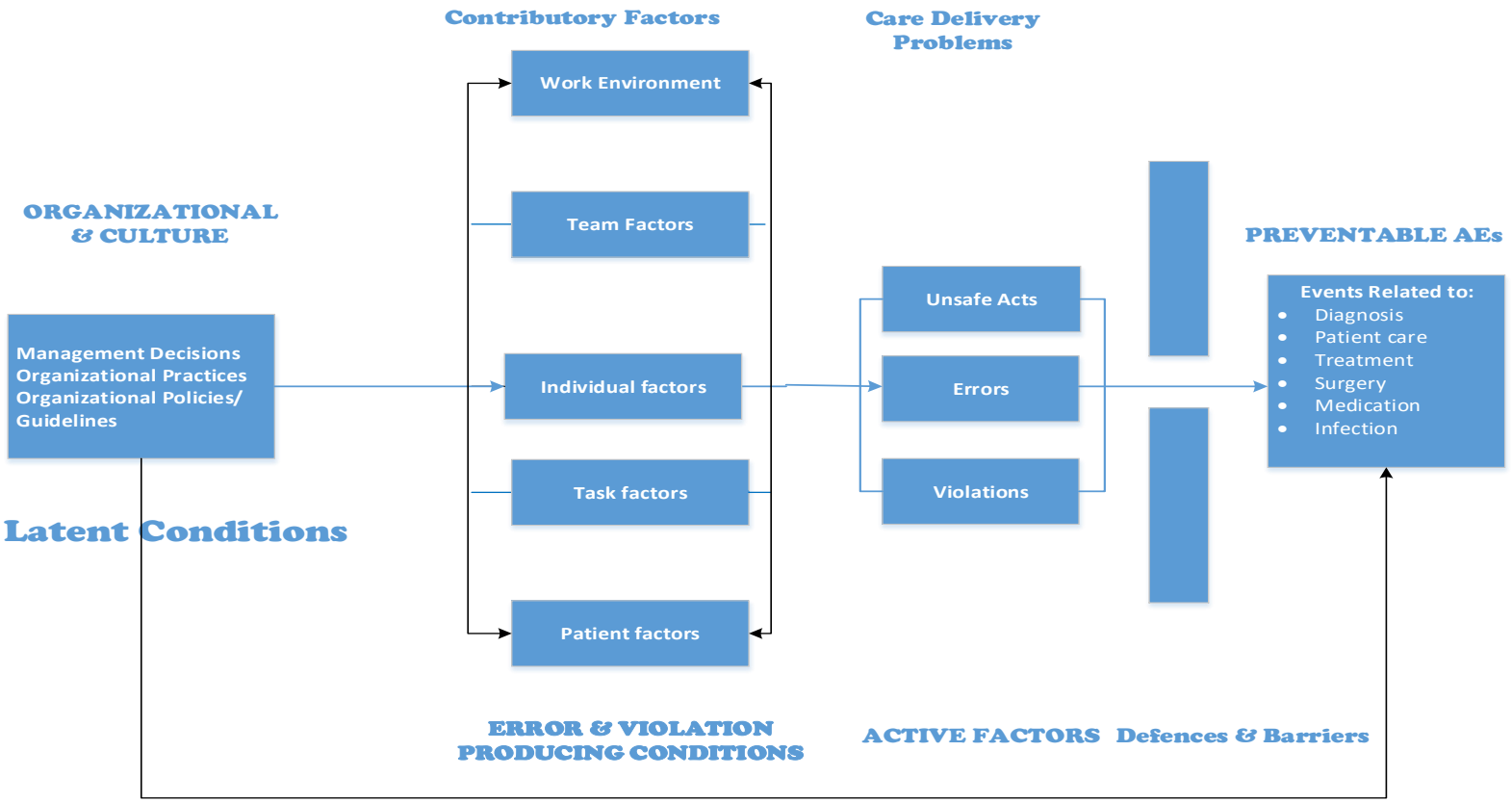

Figure 3: Theoretical Framework

Adapted from Reason, 1997 (cited in Essentials of Patient Safety, (Vincent, 2011)*)*

The theoretical framework illustrates the direction of causation of an adverse event from left to right. It is a summary of why adverse events occur in healthcare. The author uses the analogy of a 'Swiss cheese' to illustrate the inherent weaknesses *(unintended)* of the *[healthcare]* system. The adverse event sequence begins as latent failures in the organizational processes such as management decisions *(e.g. Concerning planning, scheduling, policy making, regulating, communicating, etc.)*. They arise as a result of decisions that are taken at the highest echelons or levels of an organization such as the Board or Management. It is often a result of flawed or fallible decisions made by people who are very distant or 'far away' from the frontline or sometimes not even involved in the workplace. Latent failures *'lie in wait'* very deep within the organization and provide the conditions in which adverse events occur and include: *incomplete use of mandatory checklist; machine and process design flaws; a stressful environment; inadequate supervision; manufacturing defects; inadequate equipment maintenance and defects; maintenance failure, underlying disease, inadequate knowledge or experience; fatigue, insufficient communication and environmental factors, etc* (Vincent & Taylor-Adams, 1998).

The effects of latent failures may take a long time to become evident. When they *(latent failures)* combine with local triggering factors, the defenses of the system are breached. The latent failures created are transmitted along the organizational pathway where they create local conditions, fertile for the commission of errors, violations and unsafe acts. Many of these unsafe acts will be committed but very few of them may result in an adverse event (Boysen, 2013; Leveson et al., 2016; Perneger, 2005; Reason, 1990, 2000).

Active failures are committed by those whose actions or inactions can result in an immediate adverse consequence, such as pilots, air traffic controllers or in [healthcare] by people who are

directly in contact with the patient *(nurses, doctors, anaesthetists, biomedical scientists, pharmacists, etc.)* i.e. the human beings at the frontline. These are the people who interface the human-system whose actions or inactions do sometimes have immediate adverse events (Vincent & Taylor-Adams, 1998). Human beings, lacking unlimited concentration, focus and memory, will always be prone to operational errors. The term active failures include: action slips or failures such as picking up the wrong sample bottle, memory failures such as lapses and mistakes in memory through ignorance or misreading a situation, and 'violations' such as deviations from safe operating procedure, practices and/or standards. Violations are often the result of poor examples from senior colleagues and low morale to just follow the laid down rules and procedures (Vincent & Taylor-Adams, 1998).

Attention of the theoretical framework is focused more on the healthcare system *(i.e. leadership/governance, human resource, medical technology, health finance, service delivery, and health information)* than on the individual provider *(i.e. nurse, physician, biomedical scientist, pharmacist, etc)*. It is also focused on how random an adverse event can easily occur other than being caused deliberately (Perneger, 2005).

Two main schools of thought are often seen as the panacea to making healthcare safe and which have to be discouraged. The perfection school of thought which believes that errors and adverse event will not occur if people 'try hard enough'. This thinking is based on the assumption that 'error-free performance can be attained, and frontline healthcare providers such as nurses, doctors etc can achieve this if they are more vigilant. The punishment school of thought believes that, if healthcare workers who make mistakes are punished, fewer errors will occur in the future because they will be more careful. These assertions have been proven to be

unrealistic with evidence from human factors research and cognitive psychology. These authors assert that human performance is influenced by the context within which it occurs and that, factors such as design of tasks & processes, culture, teamwork and environmental conditions have a part to play (Carthey, 2013; Reason, Carthey, & de Leval, 2001) and this have been aptly evidenced in the accident causation model and the theoretical framework of this study.

2.3.0 Patient Safety

'There is no quality without safety, and no safety without quality. Safety is at a virgin state in most of Africa [including Ghana] and it is difficult to prioritize patient safety action unless it is explained in terms of how it contributes to systems strengthening' *Dr. Jean Bosco Ndihokubwayo – Patient Safety Regional Focal Point, WHO African Regional Office (AFRO).* Patient safety has become an essential concern globally since the IOM report *'To Err is Human'* was published *(in 1999)* some nineteen (19) years ago. It is a global issue affecting all health facilities, whether private, government or quasi-government, and has become one of the important lenses through which a functioning health system is determined. Patients are harmed or injured by the very healthcare system that is designed to help them (Institute of Medicine (IOM), 2001)!

Studies in patient safety is frequently based on a broad definition of errors or adverse events as occurrences that harm or could have harmed a patient. An error *(i.e. 'medical error is the failure of a planned action to be completed as intended-error of execution or the use of a wrong plan to achieve an aim-error of planning')* per se does not necessarily lead to patient harm but it often highlights weak and unsafe steps in the process of care. There is therefore a seed in every error to identify and gain insight into any unsafe practices or into the defensive barriers that

has prevented the actual harm (Agency for Healthcare Research and Quality (AHRQ), 2006; Leveson et al., 2016; Valentine, 2016).

Healthcare systems globally and especially of most countries on this continent *(i.e. Africa)* including Ghana are bedeviled with a number of patient safety issues and challenges such as lack of systems of critical support including protocols *(availability and adherence)*, guidelines and tools, inadequate data on patient safety issues, sub-optimal infrastructure, high rates of infection from blood-borne pathogens, unsafe surgical care, poor healthcare waste management, unsafe medications, among others. In instances where protocols and guidelines exist, there are issues with adherence. The prevalence rate for healthcare associated infections from some countries in Africa is estimated at 18.9% (Boysen, 2013; Leveson et al., 2016; Perneger, 2005; Reason, 1990, 2000). The most severely affected population among this prevalence rate are surgical patients [including obstetrics] *(58th Session of the WHO Regional Committee for Africa Final Report, 2008).* The health systems in the West, or developed countries, are equally not spared. As recent as 2009, the Mid Staffordshire inquiry made some startling revelations about some patient safety issues in the Mid Staffordshire NHS Foundation Trust in the UK. It was revealed, for instance that, patients soiled their bed linens and were left for lengthy periods without assisting them in their toileting, in spite of the persistent requests for help, they *(i.e. patients)* and their relations were treated with what was described as callous indifference by staffs. Wards and toilet facilities were left in filthy conditions, and triaging in accident and emergency was undertaken by untrained staff. The fact is, no health system in the world is spared with respect to quality and patient safety challenges in quality healthcare (Francis, 2013).

Patient safety is a proactive *(intentional, deliberate and scientific)* process of evaluating, ameliorating and learning from harm to improve safety [and patient experience] in the wider

healthcare context and systems. It involves managing risks over a period of time to ensure that the appropriate benefits are maximized and the harm to patients in the healthcare system are minimized. It involves the application of the requisite processes and/or structure which has the potential of reducing the probability of an AE from occurring due to contact with the healthcare system (Vincent & Amalberti, 2015, 2016). It is a fully inclusive process involving patients, relatives, healthcare providers, managers, and all the relevant stakeholders. The process of patient safety cuts across all of the healthcare systems. Twelve action areas *(illustrated in Box 4)* further define patient safety. Safety does not just happen; it has to be created by ensuring the continuous deployment of the right consequences and resources.

Box 4: WHO Patient Safety Action Areas

1. Develop and implement national policy for patient safety
2. Improve knowledge and learning in patient safety
3. Raise awareness
4. Address the context in which health services and systems developed
5. Minimize healthcare associated infection.
6. Protect healthcare workers
7. Ensure healthcare waste management
8. Ensure safe surgical care
9. Ensure appropriate use, quality and safety of medicines
10. Promote partnerships
11. Provide adequate funding.
12. Strengthen surveillance and capacity for research.

Source: WHO-AFRO (World Health Organization, 2014)

2.3.1 What is an Adverse Event?

AEs are common in clinical practice and healthcare, affecting up to a third of hospitalized patients. They demonstrate a flaw in healthcare quality and safety, and carry a huge cost to the patient, staff and organization. There have been numerous definitions of adverse events, as there have been publications on the subject of patient safety, over the years. There is yet to be a universal agreement on what an adverse event really is. However, there seems to be a gradual convergence and agreement in most definitions that an adverse event is an *'unintended injury that results in temporary or permanent disability, prolonged hospital stay, and life sustaining intervention, or death and that is caused by healthcare management rather than by the patient's underlying disease process'.* AEs normally imply patient harm such as medical or iatrogenic injury and is an indication of a bad healthcare outcome. It is an injury that is not due to the patients' underlying disease or condition from the medical management of intervention (Brennan, 1991; Lessing et al., 2010; Olsen et al., 2007; Walshe, 2000; Zegers et al., 2007). There are one of four outcomes generally found in most of the definitions of adverse events and these are *temporary or permanent disability, prolonged hospitalization, life threatening intervention and/or death,* except in the studies by Vincent et al. (2000). Studies by some authors such as Deilkas et al. (2017) that did a retrospective study of 23 hospitals in Norway and 63 hospitals in Sweden; Harkanen et al. (2014) whose study was in an 800 bed University hospital in Finland; and Mayor et al. (2017) whose study was among 11 hospitals in Welsh NHS did not provide any definitions in their work. Probably, the challenge we have in addressing the issues of adverse event is also due to nomenclature and the urgent need for all the players in the field of patient safety to ensure some level of harmony in what adverse event really is.

Kieran Walshe, a senior research fellow at the University of Birmingham, seems to have some solutions to the varied definitions of AEs and suggests some unique characteristics of AEs to include **negativity** *(i.e. in this he seems to suggest that AEs are detrimental, injurious, undesirable or unfavourable to the patient and the process of healthcare)*; patient(s) have some negative or potential impact; and an indication that the event is as a result of some aspect of the healthcare process *(either through omission or commission)* other than outside the healthcare process such as actions of the patient or the natural progression of the disease (Walshe, 2000) similar to the views of others such as Brennan (1991), Zegers (2007), Deilkas (2017) among others. The NHS in England however, uses the concept of *'untoward incident'* with the following characteristics: *'a serious event in which a patient or patients were harmed or could have been harmed, that was unexpected, and would be likely to give rise to serious public concern or criticism of the service involved'* with the first guidance issued in 1955 (Department of Health London, 2000).

The newspapers in Ghana get inundated with varied adverse event related stories. A young woman is reported to have suffered serious complications including bareness after surgical towel *(i.e. gossypiboma, textiloma, gauzoma or muslinoma is the retention of gauze material in the body inadvertently)* was left in her abdomen for more than a year after a caesarean section in one of the government hospitals in the Brong Ahafo Region in Ghana. Incidentally, the woman also lost her baby during the process. Even though the hospital is reported to have accepted the incidence on their part, the young lady was never compensated after futile court proceedings for the harm that was inflicted on her (Boateng, 2016). The true incidence of gossypiboma in Ghana and other parts of the continent is unknown because it is often under-reported in health facilities, largely as a result of medicolegal and purported embarrassment to the surgeons. It **was** suggested by Dakubo & Naaeder (2013) for instance that twelve (12) cases

of gossypiboma were reported in the Korle Bu Teaching Hospital's general surgery unit from 2003 to 2012. More than half (58%, 7) of the index surgeries were done in the KBTH. It **was** estimated by the authors that 27,839 surgeries were done during the period with 1554 deaths (i.e. mortality rate of 5.6%) occurring giving a gossypiboma rate of 2.5 per 10,000 major general surgery operations. The longest duration of gossypiboma among the cases was 4 years (Dakubo & Naaeder, 2013).

In another related story in a health facility in Greater Accra, 'a sickle-shaped metallic foreign body which could best be described as a surgical needle' was revealed by a scan in the abdomen of a pregnant woman who was delivered via a caesarean section. This woman is reported to have come to the facility to deliver. She is reported to have suffered severe complications and pains in her lower abdomen, and loss of business after 10 months of her discharge from the facility. She has sued the hospital for GH¢500,000 in damages and blamed the doctor for 'reckless disregard for his professional obligation' (Boadu, 2014). Mortality rates of gossypiboma is estimated to be between 15% to 22% (Dakubo & Naaeder, 2013).

Similarly, a 42-year-old woman was also reported to have died in one of the large hospitals in Greater Accra shortly after delivering her baby boy. This was as a result of neglect during the labour period. The husband threatened to sue the health facility in question (Fuseini, 2014). One of the health experts in Ghana, Dr. Bentil, is reported to have said that people are dying in the hospitals not because of their sickness but rather as a result of a doctor or a health worker not attending to them on time. According to him, this may occur as a result of delay, inefficiency or failure of the medical professional to make a definitive diagnosis. This trend, according to him, is very prevalent in most countries *(including Ghana)* on the continent. He

added that it is unacceptable for women to be dying [through child birth] as a result of someone's incompetence or laziness (The Ghanaian Journal, 2009).

It is estimated that 4% of patients are harmed when receiving healthcare in hospitals in New York and this amounts to 98,600 injuries per annum. This figure translates into 1.3million injuries annually in the US when extrapolated to the entire population (IOM), 1999; Brennan et al., 1991; Reason, 1995; Vincent, 2003). In the US alone, obstetrics related adverse events constitute about 8% of malpractice claims according to a 5-year (2005-2009) retrospective cross-sectional study. Other types of adverse events such as diagnostic, surgery, and treatment/medication were very high with figures between 20% to 32% respectively over the same period. A third of the outcomes resulted in deaths. Ironically, the number of paid claims decreased over the same period (i.e. 2005-2009). Obstetrics is a very high-risk specialty. It is the medical specialty that is also mostly litigation prone largely as a result of the potential injuries to both the prospective mother and the foetus (Habib, 2010; Rubin & Bishop, 2013).

Very often, obstetric patients or pregnant women are healthy adults with high expectations of good pregnancy outcomes. One study excluded obstetrics cases because, according to the authors, *'few AEs were identified and were particularly interested in examining problems of care arising from specialties in which the course of a hospital admission is much less structured than it is in the management of childbirth' (Neale et al., 2001).* The authors ended up using cases from general medicine, general surgery and orthopaedics. Most authors, such as Zegers et al. (2008), have excluded the obstetric specialty in most AE studies over the period (Neale et al., 2001; November, Chie, & Weingart, 2008).

2.3.2 Measurement & Reporting of Adverse Events

Measurement of AEs remains a challenge nineteen (19) years on after the publication of 'to err is human'. Until recently, adverse event reporting has been haphazard and fraught with marked variation in the operational definition, standardization, coverage, measurement and the complexity with the systems of reporting. For instance, among the NHS Trusts in England, a fifth of them did not have reporting systems covering their entire organization, while the rates of reporting also varied widely. It remains very important to advancing the course of quality and safety in healthcare and also forms the basis for eliciting accountability from frontline healthcare workers and for brainstorming to arrive at the appropriate solutions for safer care (Department of Health London, 2000; Mayor, Baines, Vincent, Lankshear, Edwards, Aylward, Hogan, Harper, Davies, Mamtora, Brockbank, 2017).

Various data sources have been used as the basis for the detection or measurement of adverse events in hospitals and some of these include reporting systems *(i.e. mandatory vs voluntary)*, medical records review, active or automated surveillance of the treatment data of patients, and progress monitoring of patients to anticipate conditions that could lead to adverse events (Aspden, Corrigan, Wolcott, & Erickson, 2004). Each of these available methods have its own identified strengths and weaknesses, hence the need to use them complimentarily to derive the desired maximum benefits, especially with respect to data quality. The reporting *(i.e. voluntary and mandatory)* and the medical review approaches only identify AEs that have already occurred, while the active surveillance *(also referred to as the concurrent or prospective)* approach is able to identify critical paths in the care process at which failures are likely to occur. In the active surveillance or concurrent and prospective approach, adverse events could be averted because a clinician can quickly be contacted to intervene unlike in the reporting

systems. For all of these measurement or detection methods, voluntary reporting is the least effective in identifying AEs, while active surveillance or a concurrent and prospective approach is said to be the most effective (Aspden et al., 2004). Studies have shown that only 10% to 20% of AEs are ever reported, and of these, 90% to 95% do not cause any harm to the patients. In effect, most of the serious AEs are rarely reported voluntarily by frontline healthcare workers and the less important AEs are even neglected. An Iranian study, for instance, showed that only a little over a quarter (28%) of nurses reported medication-related AEs (Karimi et al., 2016).

The US uses a mandatory adverse event reporting system with about 98% of all institutions sending reports or the adverse events list developed by the Agency for Healthcare Research and Quality (AHRQ) and the National Quality Foundation (NQF). No consensus still exists on the 'right' tool for adverse event surveillance or its data collection (Aranaz-Andrés et al., 2011; Brennan, 1991; Care, Shojania, Health, Centre, & Shojania, 2016; Levinson, 2010; Mayor, Baines, Vincent, Lankshear, Edwards, Aylward, Hogan, Harper, Davies, Mamtora, Brockbank, 2017). Ghana, for instance, has a voluntary reporting system for food and drugs, and blood transfusion developed by its Food & Drugs Authority (FDA) and the National Blood Service (NBS) respectively. The FDA, for instance, has an electronic system that receives reports from across the country including the general public and healthcare workers. The rate of reporting, however, according to the FDA *'still falls short of the recommended reporting rate of 200-230 reports per year per 1 million inhabitants' (DrugLens Issue 5, June 2017).* Other authors such as Mayor et al (2017) have attempted to address the challenge with adverse event measurement and reporting by using the Harm2 tool which they describe as *'a hybrid one-stage tool involving a combination of the GTT and the two-stage review process'.* This tool, according to the authors, has proved superior by identifying AEs in 11.3% of episodes of care compared to the GTT which produced a 9.0% and the two-stage review which produced a 10.3% respectively.

Even with this, the authors concluded by saying that, *'the Harm2 tool performed with moderate reliability in the determination of AEs'.* Other approaches such as the retrospective, prospective and cross-sectional methods have also been compared by various authors who concluded that, 'retrospective methods of data collection by review of medical records is as effective as the prospective method *(i.e. data gathered during hospital stay)* for estimating AEs ((Classen et al., 2011; Michel et al., 2004). This method is often referred to as the gold standard to AE estimation and was first used by Brennan 1991 in the Harvard Medical Practice Review.

Retrospective medical records review approaches to adverse event measurement are, however, described, as very difficult and convoluted. This method requires adequate documentation and profound knowledge in the clinical area on the part of the reviewers. There is also some element of subjectivity on the part of the reviewer. This is a very laborious, labour intensive and painstaking process which relies on nurses and/or physicians reviewing the medical records or folders of the patients, and also requires that, the medical records/folders should be made available by the hospital staff. Inspite of all the challenges, it is seen by some authors as one that provides the best characterization of the overall rate of harm at a given time, unlike other methods *(such as cross-sectional studies)* (Gandhi et al., 2016; Levinson, 2010; Shojania, Duncan, Mcdonald, & Wachter, 2001; Thomas et al., 2000; Thomas et al., 1999).

Most studies do a two-stage review involving nurses who do an initial screening and review and then physicians or medical officer reviewers who do the second stage of review to determine the presence of AEs, especially in trigger positive folders. There are, however, diverse approaches to the two-stage review process of measuring adverse events. In the New

Zealand AE study, nurses did the initial screening of the medical records after which trained physician reviewers were guided with seven evaluation questions at arriving at a judgement using a 6-point Likert scale. However, in this study, the medical records saw a single physician or medical officer review after the initial nurses' review and referred all discrepant judgement *(i.e. among the nurse and physician/medical officer reviewers)* to expert reviewer. In this study again, only a tenth of the medical records were sub-sampled for the discrepancy judgement (Davis, Lay-Yee, Briant, Ali, & Scott, 2002). Most of the studies outside Ghana and Africa have involved more than one hospital and have aimed at determining national prevalence of AEs (Levinson, 2010; Natasha Rafter, Hickey, Conroy, Condell, O'Connor, et al., 2016; Thomas et al., 2000). In one study that assessed the feasibility of detecting adverse events in a British hospital through medical records review, clinicians reviewed the records only once after an initial review and flagging by nurses (Vincent, Neale, & Woloshynowych, 2001).

Olsen et al., (2007) have also used incident reporting, proactive surveillance of pharmacists and local real-time medical record and folder review at the time of discharge to detect and report AEs. They collected AE data prospectively from adults who have been discharged from surgical and medical units in one of the district general hospital of the NHS and found that twenty-six (26) adverse events and forty (40) potential AEs were detected by medical record review while the other methods such as incident reporting *(detecting no AEs and 11 PAEs)* and proactive pharmacist surveillance *(which detected 30 medication errors all of which were PAEs)*. The authors concluded that, when clinicians undertake a structured medical record/folder review *(i.e. retrospective medical records review)*, it provides an important risk identification process to develop a contextual quality improvement and patient safety programme'. They suggested that, enough assessment of clinical AEs could not be gotten from incident reporting alone. Therefore, other data collection methods that are systematic need to

be used to augment incident reporting methods (Olsen et al., 2007). Prevalence surveys are also said to lack in efficiency and scalability. They are also said to have variations in inter-observer rates with respect to the reported AEs, while discharge diagnostic codes also have low sensitivity and positive predictive value (PPV) for detecting AEs according to Rochefort et. al., 2016 cited in (Brennan et al., 1991).

2.4.0 Prevalence of any Adverse Events among Obstetric Clients

Many hospitalized patients continue to suffer varied degrees of adverse events or death as result of the care they receive from the hospital (i.e. 10% of hospitalized patients) (Brennan et al., 1991; Ennen & Satin, 2016; Vincent et al., 2001; Zegers et al., 2009). The true estimate of prevalence of preventable adverse events is yet to be determined even though there have been numerous studies with varied prevalence (or incidence) rates across the world.

AEs have been identified in 2.5% and 16.6% of hospital admissions in studies by the Harvard Medical Practice (HMPS), The Quality in Australian Healthcare Study, Irish, Canadian and others. This translates into 121 AEs for every 1,000 discharges (10% of hospital patients). It is estimated that, 70% of the AEs identified in the HMPS led to slight or short-lived disability. Permanent disability was identified in 7% of the cases while 14% resulted in death (Baker et al., 2004; Brennan, 1991; Ennen & Satin, 2016; Lessing et al., 2010; Neale et al., 2001; Rafter et al., 2016; Vincent et al., 2001; Zegers et al., 2009). The Iberoamerican study has also identified a prevalence of 10.5% in 58 hospitals across 5 countries in Latin America (Aranaz-Andrés et al., 2011).

Also, preventable AEs in hospitals annually, excluding obstetrics, is estimated to be 3,023,000 (Jha et al., 2009). Again, out of the estimated 35 million hospitalizations annually in the US, the mortality that is attributed to preventable adverse events is 400,201 (Lipshutz, Caldwell, Robinowitz, & Gropper, 2015; Sterberg, 2016; White, Pichert, Bledsoe, Irwin, & Entman, 2005). Estimates from developing countries are said to be higher, though there is paucity of data in this regard (Bones et al., 2010; Pittet & Donaldson, 2006). AEs which results in injury to patients is estimated to be in excess of 850,000 annually or 10% of admissions among the NHS hospitals (Department of Health London, 2000). The authors of the global burden of unsafe medical care: analytic modelling of observational studies, suggests for instance that, 'using a conservative approach, we estimated that there are at least 43 million injuries each year due to medical care [out of the estimated 421 million hospitalizations globally], and that nearly 23 million DALYs are lost as a consequence'. The authors further suggested that, 'more than two-thirds of all the adverse events and the DALYs lost to them occurred in low-income and middle-income countries [including Ghana]'. This estimate excludes hospitalizations due to childbirth (Jha et al., 2012). The incidence of AEs globally is highest in LMICs such as Ghana, than in HICs. Studies by Jha and his colleagues showed, for instance, that whereas HICs had an estimated 16.8million injuries due to AEs among hospitalized patients, the rate in LMIC was 50% more. About 81% and 79% of adverse events in HICs and LMICs respectively resulted in premature deaths (Jha et al., 2012). It is estimated for instance that deaths attributable to adverse events affects more than 10,000 people in only twenty-six (26) health facilities in the Eastern Mediterranean and African regions. This estimate will be running into millions of avoidable deaths if we multiply *(the affected people i.e. 10,000)* by the approximately 60,000 health facilities situated in Sub-Sahara Africa. Similarly, more than 50% of patients admitted for surgery will develop a HAI (World Health Organization (WHO), 2015).

There has been a lack of convergence about the true prevalence of AEs following the report of the IOM *'To Err is Human'* some 17years ago. This has been as a result of either differences in the methodologies of the studies or is a true difference in patient safety of the different healthcare settings. Several studies estimate the prevalence of AEs and preventable adverse events from 0.1% to 65.4% and 0.1% to 33.9% respectively (Lessing et al., 2010). A systematic review of scholarly reports of AEs among hospitalized patients involving 74,000 patient records showed an overall incidence of 9% with 40% being preventable. Seven percent (7%) of such events were fatal. Surgery and medication related adverse events were 40% and 15% respectively (Stevens, 2015). Two studies in the US that are worth mentioning, i.e. the HMPS that reviewed in excess of 30,000 randomly selected medical records of discharges identified AEs in 3.7% of hospitalizations, while a Colorado & Utah study *(which used half the total number of folders than the former)* identified AEs in 2.9% of all hospitalization (Kohn et al., 2000). These inconsistencies and variation in prevalence of AEs may be explained by the different healthcare systems and/or methodological differences in the studies.

Studies in the US using more restrictive definitions estimate that 3% to 4% of patients who are hospitalized bear a serious AE, whereas those in other developed countries estimate between 8% to 16% with a substantial proportion i.e. 30% to 50% being preventable (Jha et al., 2016; Vries et al., 2008). The Irish AE study after the sample frame was weighted for estimated a 12.2% (95% CI 9.5-15.5) prevalence. The incidence was 10.3 AEs for each 100 admissions (95% CI: 7.5-13.1). Among public hospitals in Ireland in 2009, this translated into 41,000 AEs out of about 340,000 admissions (Rafter, Hickey, Conroy, Condell, O'Connor, et al., 2016).

A fivefold difference has been shown in the frequency of AEs by other studies (Rafter, Hickey, Conroy, Condell, O'Connor, et al., 2016). Some authors such as Lessing et al. (2010) have

identified the effect of sample size in the estimation of the prevalence of AEs among hospitalized patients. The authors suggest, for instance, that the prevalence of AEs decreases with an increasing sample size. According to them, the prevalence falls below 10% and 1% when the number of respondents is approximately 2,000 and 20,000 respectively (Madigan, 2007 Cited In Lessing et al., 2010).

A cross-sectional Canadian study that assessed the association between inpatient hospital experiences with patient safety indicators [i.e. adverse events inclusive] identified a total of 1085 (4.3%) of patients with at least one documented patient safety indicator (i.e. AE) in their patient record. Obstetric related events were the second most prevalent (n=373; 1.5%) adverse events related to haemorrhage (n=502; 2.0%). Surgical-related events and infections accounted for 1.0% (n=248) and 0.8% (n=211) respectively (Kemp, Santana, Southern, McCormarck, & Quan, 2016). Obstetrics AEs remain one of the top 10 in US hospitals accounting for 2.6 per 1000 hospital discharges and 1.8% of the total AEs (http://www.ahrq.gov/research/findings/nhqrdr/nhqr13/chap4.html, accessed on 02/12/2015 @ 07:49GMT). One hundred (100) AEs specific to pregnant women were identified from 240 identified AEs in a systematic review of AEs during pregnancy and the newborn period (Hughes, 2008). Florea et al. (2010) also identified 578 AEs from 6752 deliveries in a 12month study. This was equivalent to 1 AE in every 11.7 deliveries. The authors added that, 13.4% (67) showed minor harm to the mother, baby or both while 7.4% (37) showed major harm (Florea et al., 2010).

Twijnstra, Zeeman, & Jansen, (2010) observed a total of 10,470 medical records at the obstetrics and gynaecology departments of six hospitals. They identified 960 (14.5%) obstetrical and 351 (9.1%) gynaecological-related complications. According to the authors, the

difference that was found between general hospitals and university hospitals with respect to the percentage of complications and AEs was not statistically significant.

The nature and frequency of adverse events have also been studied in some selected countries in Africa and the Middle East (namely Kenya, Egypt, Morocco, Tunisia, South Africa, Jordan, Yemen, and Sudan). A total of 15,548 medical records were reviewed. The prevalence of adverse events was estimated to be 8.2% (the range was between 2.5% and 18.4%). Studies in hospitals in Palestinian have also found that, 14% (i.e. one of every seven patients) hospitalized in that country suffer one form of adverse event or another (Elmontsri et al., 2017).

Rutberg et al. (2016) have also showed an incidence of 15% out of 4994 admissions in Swedish hospitals. Postpartum or obstetric-related AEs were 2% (90) while 34% (31) were judged to be preventable. The specialty and procedures utilized within different specialties have an effect on the nature and incidence of AEs. Surgical disciplines, including obstetrics is suggested to often have a higher incidence of AEs than non-surgical ones. Some reasons such as the treatment complexity and invasiveness of care compared with other disciplines have been suggested as the probable cause of the high incidence.

In a comparative study to determine the effectiveness of various methods of measuring adverse events in 37 wards in seven (7) hospitals among a total of 778 patients across 3 various disciplines i.e. medicine *(n=278)*, surgical *(n=263)* and obstetric *(n=237)* in France, 241 AEs were identified in 174 patients. The prevalence rate of adverse events among obstetric patients

was 8.7% (21) and 4.1% (10) from all the methods were judged to be preventable (Michel et al., 2004).

Data on adverse events among obstetric cases are generally rare, unlike in other fields such as medicine and surgery (Michel et al., 2004). Most studies tend to exclude admissions with diagnosis related to obstetrics, mostly because the methods and instruments are considered inappropriate for those medical specialties (Baker et al., 2004; Rafter, Hickey, Conroy, Condell, Connor, et al., 2016; Smits, Zegers, Groenewegen, Timmermans, Zwaan, Wal, et al., 2010; Zegers et al., 2007). However, it is suggested by various authors that the incidence of AEs among surgical cases/departments [including obstetrics] is higher than AEs among nonsurgical cases/departments (Aranaz-Andrés et al., 2011; Zegers et al., 2009). Table 1 presents further evidence of the prevalence of adverse events together with details from selected authors.

Table 1: Summary of selected AE studies in the literature

No	Study	Study setting (Year)	Inclusion of high-risk patients	Definition of AE	Method of review	Perspective of the Reviewer	Causation	% of patients with ≥1AE	% of AEs that were preventable
1	Thomas et al (n=14700)	28 hospitals in Utah & Colorado (1992)	Yes	'injury caused by medical management rather than by the disease process and resulted in prolonged length of stay or disability at discharge'	Retrospective review of medical records	Medicolegal	≥ 4	2.9 (3.2)	NR
2	Wilson et al. (n=14179)	28 hospitals in New South Wales & South Australia (1992)	Partial (did not include obstetrics patients)	'unintended injury or complication that resulted in disability, death or prolonged hospital stay and was caused by healthcare management rather than by the underlying disease process'	Retrospective review of medical records	QI	≥ 2	16.6 (10.6)	51
3	Brennan et al; Leape et al (n=30,195)	51 hospitals in New York (1984)	Yes	'unintended injury that was caused by medical management and that resulted in measurable disability'	Retrospective review of medical records	Medicolegal	≥ 4	3.7	NR
4	Vincent et al (n=1014)	2 hospitals in England (1999-2000)	Yes	'unintended injury caused by medical management rather than by disease process'	Retrospective review of medical records	QI	≥ 4	10.8	48

No	Study	Study setting (Year)	Inclusion of high-risk patients	Definition of AE	Method of review	Perspective of the Reviewer	Causation	% of patients with ≥1AE	% of AEs that were preventable
5	Davis et al (n=6579)	13 hospitals in New Zealand (1998)	Partial (did not include obstetrics patients)	'unintended injury or complication that resulted in disability, death or prolonged hospital stay and was caused by healthcare management rather than by the underlying disease process'	Retrospective review of medical records	QI	≥ 2	12.9	37
6	Baker et al (n=3745) ***	20 Canadian hospitals (2000)	Yes	'unintended injury or complication that resulted in disability, death or prolonged hospital stay and was caused by healthcare management rather than by the underlying disease process'	Retrospective review of medical records	QI	≥ 4	7.5	36.9
7	Zegers et al. (n=7926)	21 Dutch hospitals (2008)	No (included obstetrics and children <1 year)	'an unintended injury that results in temporary or permanent disability, death or prolonged hospital stay, and is caused by healthcare management rather than the patients underlying disease process'	Retrospective review of medical records	QI	≥ 4	5.7	39.6

No	Study	Study setting (Year)	Inclusion of high-risk patients	Definition of AE	Method of review	Perspective of the Reviewer	Causation	% of patients with ≥1AE	% of AEs that were preventable
8	Michel et al. (n=778)	37 wards in 7 hospitals in France (2004)	Yes	'an unintended injury caused by medical management rather than by a disease process and which resulted in death, life threatening illness, disability at time of dis-charge, admission to hospital, or prolongation of hospital stay'	comparative method of cross sectional, retrospectiv e and prospective methods	QI	Not indicated	14.5% (retrospective); 15.4% (prospective); 9.8% (cross sectional)	4.0% (retrospectiv e); 6.4% (prospective); 3.5% (cross sectional)
9	Aranaz-Andres et al. (n=11,379)	5 Latin American Countries involving 58 secondary & tertiary hospitals (2011)	Yes	'any event causing harm to the patient that was perceived to be more related to the healthcare management rather than to the patient's underlying condition'	Cross sectional	QI	Not indicated	10.46	59
11	Mayor, et al. (n=4536)	11 hospitals in Welsh NHS hospitals	Yes		Retrospecti ve	QI	Not indicated	11.3	59.6

No	Study	Study setting (Year)	Inclusion of high-risk patients	Definition of AE	Method of review	Perspective of the Reviewer	Causation	% of patients with ≥1AE	% of AEs that were preventable
10	Deilkas et al. (n=10986 from Norway; n=19141 from Sweden)	23 hospitals in Norway & 63 hospitals in Sweden (2017)	No (psychiatric patients)		Retrospective	QI	Not indicated	15.2% (Norway); 16.8% (Sweden)	
12	Hwang, et al (n=630)	A tertiary teaching hospital in Korea with 910 bed capacity (2011)	No (psychiatric patients)	'an event that resulted in unintended harm to the patient, which occurred because of medical care or services rather than as a cause of underlying diseases or medical conditions'	Retrospective medical records review	QI	>=4	45 (7%)	61
13	Harkanen, et al (n=463)	University hospital in Finland with 800 bed capacity (2014)	No (study done only to investigate adverse drug reactions)		Retrospective	QI	Not indicated	125 (25%)	72.5

No	Study	Study setting (Year)	Inclusion of high-risk patients	Definition of AE	Method of review	Perspective of the Reviewer	Causation	% of patients with ≥1AE	% of AEs that were preventable
14	Rafter, et al. (n=1574)	30 acute care hospitals across the republic of Ireland	No (paediatrics, maternity & orthopaedics)	'an unintended injury or complication resulting in disability at the time of discharge, prolonged hospital stay or death and that was caused by healthcare management rather than by the underlying disease process'.	Retrospective	QI	Not indicated	12.2	70
15	Nilsson, et al. (n=64,917) over a 3-year period (2013-2016)	59-63 hospitals in Sweden during the period	Paediatric s & psychiatry were excluded. Obstetrics and gynaecology were included. Age groups ≥18 years used. All somatic acute care units included	'an unintended physical injury resulting from or contributed to by medical care that required additional monitoring, treatment or hospitalization or that resulted in death'	Retrospective	QI	Not indicated	11.8	61.4

No	Study	Study setting (Year)	Inclusion of high-risk patients	Definition of AE	Method of review	Perspective of the Reviewer	Causation	% of patients with ≥1AE	% of AEs that were preventable
16	Mendes et al. (n=695)	4 general hospitals involved in Brazil	Yes	'an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge or both'	Retrospective	QI		12.8	42.7

2.4.1 Types of Adverse Events among Obstetric Clients

Adverse events vary by the type of specialty in the hospital (Rafter, Hickey, Conroy, Condell, O'Connor, et al., 2016; Vincent et al., 2001). However, various types of adverse events have been identified by various authors, countries and healthcare organizations globally. In the US for instance, in 2001, 27 adverse events were identified and labeled by the National Quality Forum (NQF) as a *"never events"* i.e. "should never occur" in healthcare. The event list was increased to 29 as recent as 2011 and were categorized into seven (7) namely: *"surgery, product or device, patient protection, care management, environmental, radiologic and criminal"* respectively. Some of the most commonly adverse events types reported to the Joint Commission in September, 2009 were wrong-site surgery (867, 13.5%), suicide (770, 12.0%), operative/post-operative complication (710, 11.0%), delay in treatment (536, 8.3%), medication error (526, 8.2%), and patient fall (406, 6.3%). This was out of a total of 6428 reports received by 30th September, 2009 *(PS Primer, 2017; https://psnet.ahrq.gov/primers/primer/3/never-events accessed on 14/04/2018 @ 14:00GMT)*. Similarly, the state of Minnesota also identified pressure ulcers (120), falls (82), wrong site surgery (36), retained objects (27), biological specimen (26) wrong procedure (19) and medication errors (11) as some of its major events in it 2017 annual report published in February, 2018. AEs are also categorized according to the NCC MERP guidelines developed and used for assessing the severity of AEs *(presented in Box 1)*. The authors of the Irish study classified adverse events in the surgical and medical specialties as operation related, therapeutic event, medication, diagnostic, other event not covered elsewhere, non-surgical procedure, fracture, anaesthetic, fluid and pregnancy related respectively. The adverse event with the highest frequency was operation related (Rafter et al., 2016).

Studies by Jha et al (2012) to determine the burden of unsafe medical care globally identified seven adverse events for their analysis namely: adverse drug events, catheter-related urinary tract infections, catheter-related blood stream infections, nosocomial pneumonia, venous thromboembolisms, falls, and decubitus/pressure ulcers (Jha et al., 2012). In this study, the authors found that, adverse drug events or adverse events related to medication had a decreased incidence in LMICs (2.9%) than in HICs (5.0%) and fewer AEs related to nosocomial pneumonia in LMICs (0.4%) than in HICs (0.8%). The rates of falls and catheter-related urinary tract infections were however increased and thus higher in LMICs than in HICs. Adverse events included transfusion errors and medication-related AEs *(i.e. adverse drug events)*, surgical injuries and wrong-site surgery, hospital-acquired or other treatment-related infections, preventable suicides, restraint-related injuries or death, falls, burns, pressure ulcers and mistaken identity. AEs are categorized as diagnostic, treatment related, preventive and others (Hughes & Leape, 2013; Kohn et al., 2000a; Levinson, 2010). However, in a systematic review of 12 articles, that involved the medical records/folders of 74,485 patients by Vries et al. (2008), adverse events were classified as operation, drug, diagnostic, therapeutic, procedural, fall/fracture, postpartum/obstetric, anaesthesia, neonatal and system-related respectively. Rubin et al. (2003) have also classified adverse events under five broad themes: prescriptions, communications, appointments, equipment and clinical errors of which prescription related events accounted for the highest frequency (397, 42.2%) of the total events (940) (Rubin, George, Chinn, & Richardson, 2003). Other classification is with respect to management, diagnostic and medication (Jha et al., 2016).

Healthcare Associated Infections (HAIs) are other adverse event types affecting healthcare organizations. It is estimated that, 'millions' of people acquire one form of infection or the other while receiving care, treatment and services in healthcare organizations across the world

(JCI, 2014). HAIs, surgical complications and medication-related adverse events are considered the most frequent AEs. It is estimated by the US Centers for Disease Control and Prevention (CDC) that there are 1.7million HAIs and 99,000 deaths occurring annually in hospitals in the US *(https://www.cdc.gov/washigton/-cdcatwork/pdf/infections.pdf accessed on 12/04/2018 @ 11:48am)*. Of these, surgical wound infections accounted for 22%, Urinary Tract Infections (UTIs) accounted for 32% while other infections of the blood, lungs and body parts accounted for the remaining 46% (Thompson & Avillion, 2017). A study by Rutberg et al (2016) in Sweden hospitals also identified HAIs accounting for about a third (36%) of the total AEs. The authors noted that postoperative wound infections and urinary tract infections were the most common among the HAIs (Rutberg, Borgstedt-Risberg, Gustafson, & Unbeck, 2016). One of the most frequently occurring incidents that impair patient safety in obstetrics is postpartum fall. It is of little wonder that the Joint Commission on Accreditation of Healthcare Organization identified 'reducing the risk of patient falls' as one of its annual goals on patient safety (Chen, Chen, & Su, 2010).

A retrospective study conducted in ten (10) selected health facilities in Ghana including two teaching hospitals revealed that, hospital acquired infections were estimated to be 10%. The prevalence ranged from a least of 3.5% to a highest of 14.4%. Surgical site infections had the highest prevalence (32.6%, CI: 26.2-39.7) among the total HAIs identified and among the total surveyed patients (2.8%, CI: 2.2-3.7). The common type of AEs identified in this country study were respiratory tract infections, urinary tract infections, surgical site infections and blood stream infections. The surgical specialty recorded the highest prevalence rate of 11.2% while obstetrics recorded 7.1% (GHS Unpublished, 2017). The rate of complications for some of the major operations among patients undergoing general surgical procedures in the UK is estimated to be 20-25%, and 30-50% of these are thought to be avoidable. Wrong site, wrong procedure,

wrong patient surgeries occur in about 1 in 112,000 surgical procedures in operating rooms (Thompson & Avillion, 2017; Vincent, 2011).

AEs among obstetric clients include judgement lapses that lead to wrong procedure and wrong or delayed operations. It is estimated for instance that 54% of the AEs in patients undergoing operation is preventable. Obstetric outcomes are often primarily attributed to the technical skills of the obstetrician. The competence of the obstetrician is heavily questioned when an obstetric AE occurs (Fann, Moffatt-Bruce, DiMaio, & Sanchez, 2016).

AEs that occur in patients undergoing surgery, including those that are obstetrics and gynaecology-related, are estimated to account for 48% of all AEs and more than half (i.e. 54% to 74%) are preventable. Vries et al. (2008) for instance stated that, of all the adverse events that occur, more than half (i.e. 58%; IQR 54.5-70.9) is accounted for by the surgical professions, obstetrics and gynaecology, and in anaesthesiology. This is consistent with studies by Vincent et al (2001) in British hospitals, Rafter et al. (2006) among Irish hospitals, Zegers et al (2008) among Dutch hospitals and Thomas et al (2000) among US hospitals. Surgical outcomes are said to be heavily dependent upon the technical skills of the surgeon (Fann et al., 2016; Vries et al., 2008). Similarly, studies by Aranaz-Andres et al. (2011) have identified how much more prevalent AEs are in surgical departments than in medical specialties. Some of the types of AEs identified by the authors included HAIs (37.1%), surgical procedures (28.5%), medication (8.2%) and diagnosis (6.1%). This was a cross-sectional study involving fifty-eight (58) hospitals *(that were providing secondary and tertiary acute care)* across five (5) Latin American Countries (i.e. Argentina, Mexico, Columbia, Costa Rica, and Peru). The data were purposively collected. In a voluntary online survey that used a mixed methods approach (qualitative and quantitative) and relied on voluntary patient reporting across all the States in the USA, except North Dakota, adverse events related to surgery [including obstetrics] were

the second highest prevalent (24.5%) after failure in diagnosis and treatment (30%). The total sample size involved in this study was 681. Adverse events related to infections (i.e. hospital acquired infections) and medications accounted for the third and fourth highest respectively. This study aimed at capturing the perspectives of patients and patient families experiencing AEs and their impact (Southwick, Cranley, & Hallisy, 2015).

In LMICs like Ghana, surgical-related AEs are estimated to be about 5 to 10 folds higher. Undergoing a surgical procedure carries a greater risk of an AE than other medical interventions. Again, 5% to 10% and 25% to 40% of hospitalized patients in both developed and LMICs are reported to develop surgical infections, catheter-related infections and nosocomial pneumonia infections. Unsafe blood and blood products are another potential source of infection-related AEs and among obstetric clients, this is a major concern because one of the leading causes of mortality is severe haemorrhage (Atul, 2009; Jha et al., 2016).

Some studies among women in the Netherlands who opted for 'planned delivery' versus 'planned hospital birth' have showed considerable increases in the 'postpartum hemmorhage rates', and 'the removal of the placenta manually' (Jonge et al., 2013). Hypertensive disorders are estimated to be one of the leading causes of mortality among women who are in the last few months of their pregnancy in South Africa, and two-thirds of these deaths are preventable (World Health Organization (WHO), 2016). In a study to estimate the excess length of stay, and deaths due to adverse events during hospitalizations, the least type of adverse event identified was transfusion reaction *(with a rate of 0.004 per 1000 discharges)* while obstetric trauma in vaginal delivery with instrumentation accounted for the majority of AEs detected with a rate of 224.21 per 1000 discharges. Obstetric trauma *(vaginal birth without*

instrumentation) was further identified by the authors as the second highest adverse with a rate of 86.61 per 1000 discharges at risk. Some of the most serious adverse events were postoperative sepsis and postoperative wound dehiscence with 9.42 extra days and 9.63% attributable to mortality. HAIs also accounted for 9.58 extra days and 4.31% attributable mortality. This study relied on a 7.4 million Nationwide Inpatient Sample (NIS) of a primary data source that the AHRQ developed. The authors used 20 AHRQ patient safety indicators (PSIs) or adverse events for the data extraction (Zhan & Miller, 2003).

It is estimated that more than 50% of all maternal deaths occurs within 24hours of delivery, mostly as a result of excessive bleeding. There have been increasing trends seen in PPH in some developed countries such as Canada, USA and the New South Wales between 1991 and 2006 (American College of Obstetricians and Gynecologists, 2006; Charbit et al., 2007; Evensen, Anderson, & Fontaine, 2017; Moldenhauer, 2016).

Obstetric clients are at greater risk of maternal morbidity and mortality due to the adverse events of anaemia. There are some estimates that show an association between a higher risk of maternal mortality and anaemia. Some authors also believe that the relationship between anaemia and maternal mortality reflects the late arrival at admission and the extent of hemorrhage other than prenatal anaemic condition effect. Anaemia is very prevalent among obstetric clients, both in developed and developing countries. It is estimated for instance that, 18% and an average of 56% of obstetric clients are anaemic in developed and developing countries respectively. Other studies have demonstrated the relationship between maternal anaemia and birth weight, preterm birth, foetal death, spontaneous abortions among others, with obstetric clients in developing countries being more at risk than those in developed

countries. Perinatal mortality was found in one study to triple when maternal Hb levels fall below 8g/dl in comparison with Hb levels above 11g/dl (Allen, 2000; Sifakis & Pharmakides, 2000).

Perineal tears are one of the commonest types of adverse events among obstetric clients, especially during their period of delivery. Varied degrees of perineal morbidity are prevalent among postnatal women. It is estimated, for instance, that up to about 90% of women experience a first degree *(perineal)* tear *(small, skin-deep tears which heal naturally)* or second degree *(deeper tears affecting the muscles of the perineum which require suturing)* during the process of childbirth. The estimate in nulliparous women is suggested to be 73% (Groutz, Hasson, Wengier, & Gold, 2011; Hirayama et al., 2012). Some obstetricians *(in Ghana)* suggest that first and second-degree perineal tears should not be considered as an adverse event because of their high incidence and how common they are in obstetric practice *(Pers Comm, Obstetrician Reviewers, 2017).* They are of the view that a tear *(first and second-degree)* will be experienced by at least 7 out of every 10 nulliparous women during the process of delivery. The incidence of third degree *(a partial or complete disruption or injury to the perineum involving the anal sphincter muscles, which may involve either or both the external (EAS) and internal anal sphincter (IAS) muscles)* and fourth degree *(a disruption of the anal sphincter muscles with a breach of the rectal mucosa)* perineal tears is estimated at 0.6%-9.0% of all vaginal births where a mediolateral episiotomy is done. These are described as serious adverse outcomes of vaginal delivery which may lead to sexual and urinary problems, fecal incontinence and perineal pain if left untreated. The prevalence of third and fourth perineal tears are generally low. Other studies suggest estimates as low as 0.1% in Israel to a as high as 7.3% in Pennsylvania from 1990 to 1991 among 258,507 vaginal births. The overall risk of obstetric anal sphincter is estimated at 1% in all vaginal deliveries. Higher incidences have,

however, been recorded in Denmark, Norway and Sweden in the last 30years, unlike Finland that has recorded lower rates over the same period. The incidence in Japan is estimated to be 1.7% among 7946 singleton vaginal deliveries from 1997 to 2005. In another multicounty level study that involved twenty-four (24) countries from Africa, Asia and Latin America, a prevalence of as low as 0.1% was recorded in China, Cambodia and India, while the highest prevalence of 15% was recorded in the Philippines. Some of the suggested risk factors for third- and fourth-degree tears included high birth weight (i.e. more than 4kg), persistent occipital posterior position, nulliparity, induction of labour, epidural analgesia, second stage longer than 1 hour, midline episiotomy, and forceps delivery (Groutz et al., 2011; Hirayama et al., 2012; National Institute for Health and Clinical Excellence (NICE), 2006; NHS Litigation Authority, 2012; Royal College of Obstetricians and Gynaecologists (RCOG), 2003; Walsh, Mooney, Upton, & Motson, 1996). These risk factors notwithstanding, the incidence of perineal trauma could be reduced to the barest minimum by ensuring a perineal massage antenatally or applying warm packs during the second stage of labor (East et al., 2012).

In a related study, 87% of postnatal mothers reported some degree of at least one index morbidity within 12 months after birth. It was noteworthy in this study that the morbidity of obstetric clients who had a tear and those who had episiotomy did not show any significant difference (Williams, Dip, Midwife, Researcher, & Herron-marx, 2007). ‘There is [absolutely] no consensus with respect to the preventive measures and clinical management of severe perineal tears’ (Groutz et al., 2011).

There is marked variation in adverse event categorization and types in the literature. Various authors have come up with varied perspectives on AE categorization irrespective of the specialty. Most of the adverse event types are also universal and cut across specialty and disciplines as was presented. There is a need for a convergence and harmonization to ensure comparison of the types of AEs among hospitalized patients globally including obstetric clients and devise appropriate measures to mitigate their occurrence.

2.6 Factors Associated with Adverse Events among Obstetric Clients

Causative factors to AEs are defined as any of the reported conditions which resulted in an AE that could have been avoided or prevented. Teamwork, interruptions, communication, distractions and failure in other processes of care have been identified as some of the multiple variabilities in systems of surgical care including obstetrics. It is often the result of a complex interaction and interplay between a different set of systems, that include the behaviour of human beings, performance and interdependency, technology, socio-cultural, a gamut of weaknesses that are either procedural or organizational (Hernan et al., 2015; Vincent, 2013; Zeeman, 2006). Identifying the causative factors of AEs is a very important first-step towards improving women's health, reducing the incidence of AEs and by extension improving the quality and safety of healthcare. Compared to some 19 years ago and since *To Err is Human' was published*, the causes of poor and sub-optimal quality and safety in healthcare is now considerably understood. During the process of healthcare provision, AEs occur. The cause of an AE is not due to a single provider or cause but rather a chain or series of events (Hernan et al., 2015; Vincent, 2013; Zeeman, 2006).

A study by Jha et al. (2016) used the Donabedian triad of 'structure, process and outcome' to classify adverse events. The authors identified some of the structural related factors as stress, fatigue of the providers, knowledge related issues such as its deficiency, and non-availability, lack of knowledge transfer, lack of devices, procedures with no human factors engineering, and lack of structural accountability. Some of the process-related issues included errors that occur during the care delivery process through misdiagnosis, poor follow-up of tests, unsafe injection processes and poor patient safety measures, while outcome-related issues included AEs due to medications, HAIs, surgical errors, unsafe blood products and falls among obstetric clients. Donabedian (1966) was of the conviction that, it was not enough to assess or evaluate the quality and safety of healthcare just by the outcomes rather than other equally important aspects such as the structure and the process especially when some of these outcomes are often difficult to measure such as social restoration and physical disability of the patient. Hence his *(i.e. Donabedian)* suggestion to also be mindful of the structure *(healthcare professionals, their competencies and knowledge, etc)* and the process of care *(i.e. how care is actually delivered)*. This model is similar and consistent with the six (6) WHO Health Systems Building Blocks *(leadership/governance, service delivery, health work force, health information, medical technology and health finance)* model used to measure and assess a functioning health system (WHO, 2010). All the building blocks with the exception of service delivery could be classified as structure *(or input)*-related as proposed by the Donabedian triad. A study by Flotta, Rizza, Bianco, Pileggi, & Pavia (2012) on 'patient safety and medical errors: knowledge, attitudes and behaviours among Italian hospital physicians' discovered that what caused AEs among physicians were systems structure/process (68.8%); and human (19.1%). The other (11.9%) causes arose when providers became negligent, reckless, and/or intentionally violate rules. Some additions are made to the Jha et al (2016) list of the systems' structure/process related causes which included- overwork, poor communication; poor design of teamwork within the

workplace, equipment maintenance is either inadequate or unavailable, disagreement among healthcare providers on goals and inexperienced health professionals who are poorly supervised. When an AE occurs, one of the most common initial and default reactions is to find, name, blame and shame somebody. There are however multiple causative factors such as faulty systems and processes responsible for the occurrence of adverse events, hence a systems approach is required to prevent and modify the conditions that contributes to their occurrence. Gawande et al. (2001) identified 86% of adverse events reported by surgeons in three (3) teaching hospitals (i.e. Massachusetts' teaching hospitals) were due to system factors, while the remaining were due to cognitive factors such as error in judgement, failure in memory and failure of vigilance. They further found that, system factors even contributed to a subset of the cognitive factors because the errors in judgement were 'strongly associated with reports of inadequate supervision' (Gawande et al., 2003).

Authors like Reason (2000) are of the view that the causes of adverse events could be viewed mainly from two perspectives. He identified these as the system and person approaches. According to him, the person approach is specialized in blaming, naming and shaming individuals *(i.e. frontline healthcare workers)* for inattention, forgetfulness, or moral weakness. The systems approach is interested in finding answers to the question, 'under what conditions do people work?' They (i.e. the systems approach) are interested in this so they try to build barriers and structures around people to prevent the causation of any errors or mitigate their effect, should they occur. Proponents of the person approach hold individuals liable when adverse events occur because they believe they (i.e. individuals) were generally reckless, careless and deviants with respect to their choices, hence they have to be severely dealt with consistent with the accident proneness theorists. Adverse events are treated more as a moral

issue because the proponents assume that, 'bad things happen to bad people'. This school of thought is at variance with the systems approach that believes that, 'human beings are fallible and errors are [inevitable] even in the best of organizations. For these proponents, adverse events are more as a result of the trappings in the workplace and organizational processes (i.e. latent factors) other than caused by the individuals. They assert further that it is the conditions under which individuals work that can be changed and not the individuals' conditions. They therefore believe that building very robust system defenses, such as ensuring the use of protocols and checklists, could go a long way in averting the occurrence of adverse events (Reason, 2000).

Other possible factors associated with AEs include shortage of staff, physical space limitations with respect to the work environment, devices/equipment failures, critically ill or labile patient, hierarchical structures in the healthcare organization where a junior ranked nurse may feel intimidated or uncomfortable asking questions or seeking clarity on an issue. Short-term memory and fatigue on the part of healthcare providers have also been identified as other causes (Hughes, 2008).

There have been instances in many countries where frontline healthcare providers were found to have deliberately killed their patients exposing the possibility of obvious criminals in the health delivery system (Marks & Richmond, 2008; Mohammed, Cheng, Rouse, & Marshall, 2001; Smith, 2008). However, there could also be a complicated function of varied factors such as situational factors, characteristics of the individual, duration of practice and sometimes random chance which could all be accumulated by the frontline healthcare provider. AEs are also the result of the characteristics of the individual obstetrical care providers combined with

the dynamics imposed by the existing work structures. The non-technical skills of all the care team members involved in the care of patients such as leadership and communication, and breakdowns in these lead to disruptions and AEs (Fann et al., 2016).

Some further reasons that have been ascribed for the factors associated with AEs and invariably contributing to the complexity in healthcare is the process of care *(service delivery)* which include variable processes and absence of standardized procedures, inefficiencies and complexities in the process of care, equipment interfaces that are confusing, neglect of management as well as the responsibility that comes with diffusion. The factors that are associated with these AEs are either avoidable *(such as a nurse administering the wrong medication because of a short concentration span)* or unavoidable *(such as developing a rare allergic reaction from a medication that was properly prescribed and administered)*. There is therefore growing evidence of the causal relationship between human resource issues such as role of knowledge, task issues such as level of skill and technology, the environment in which organizations operate, organizational structures such as complexity, centralization, bureaucracy, and processes such as power, learning, informal organization (Hughes, 2008; West, 2000b).

It is suggested that many of the AEs that occur in hospitals are rooted in the organization of healthcare itself. A lack of coordinated care or failure in teamwork and a communication breakdown have all resulted in unfavorable outcomes for the patient (Elmontsri et al., 2017; West, 2000b). Adverse events include wrong or delayed operations and judgement lapses that sometimes lead to incorrect procedures (Fann et al., 2016). West (2000) describes the sociological factors as 'intrinsic characteristics' that facilitate the causation of AEs and are relevant to the level of risk and danger in the settings of healthcare. These, according to her,

include the division of labour and the complexity of healthcare organizations with respect to their structural secrecy; the principle of homophily and socio-structural communication barriers; spread of responsibility and the issue of several hands; and other pressures or environmental issues that leads to the displacement of goals when the eyes of organizations are taken off the ball (West, 2000a).

Any in-depth analysis uncovers human *(health work force)* and system factors as the main components that are often present when an error turns into an actual adverse event. Human factors *(health work force)* play a major role in the cause of adverse events and are implicated in approximately 70% of all medical errors (Valentine, 2016). The contribution of human errors to accidents is estimated to be a maximum 90% in hazardous technologies and 82% of preventable incidents in anaesthesia with the remainder being equipment related. It is even suggested that, even when equipment fail, it is exacerbated by human error (Reason, 1995; WHO World Alliance for Patient Safety, 2005). This estimate is described as less surprising considering the fact that, humans are responsible for designing, building, operating, maintaining, organizing and managing these systems. The technologies of humans are said to be very dominant as far as the risks to modern medical technologies are concerned.

Human error is often blamed for accidents and bad outcomes in complex surgery and in healthcare in general. The doctor or nurse who administered a bad injection is immediately singled out and blamed, obviously because they are thought of as being associated with the disaster. A more detailed analysis of any adverse event usually shows a sequence of occurrences and deviations from safe practices influenced by the wider context of the organization and the environment where work is performed (Leveson et al., 2016).

Reason (1995) defines an error as the 'failure of a planned action to be completed as intended *(e.g. error of execution)* or the use of a wrong plan to achieve an aim' *(e.g. error of planning)* (WHO AE Reporting Guidelines, 2005). Several efforts have been made to investigate the factors that affect the reliability and safety of the provision of healthcare.

Humans rather than technical failures have been identified as the significant threat to hazardous and complex systems, such as healthcare (Reason, 1995). Human errors are classified either as a consequence or their presumed cause. Consequential classification of errors is when the error is described in terms of the proximal actions that contributed to the mishap (such as wrong site surgery, administration of wrong drug).

Authors such as Vincent and Amalberti (2016a) identified seven levels of safety organized under seven themes to include: patient, individual, staff, team, working conditions, organizational and the wider institutional context factors are described as the causative factors and influences on adverse events. In a study by Williams et al. (2015), the most common contributory factors identified in their study 'Harms from discharge to primary care' included staff factors *(not following protocols)* and organizational factors *(lack of clear guidelines or ineffective processes)*. Multiple failings in patient care other than any single failure, are responsible for many serious adverse events. Individual failures sometimes combine when a frontline health worker, such as a junior doctor or nurse works with inadequate experience, unfamiliar equipment, poor supervision, deficiencies in teamwork and a very sick patient. Most often, there is a progressive degradation in the care of a patient due to a combination of error and system vulnerabilities (Vincent & Amalberti, 2016b). *Hernan, Giles, Fuller, Johnson, Walker and Dunbar (2015)* summarizes these as latent or blunt end factors which are identified notably as management systems, organizational structure, workplace culture, policies and

procedures that affect how care is delivered. He further identifies active or sharp end factors that directly relate to the work environment and human performance closer to the AE such as team (e.g. supervision, leadership, interpersonal communication), task (e.g. use of protocols and guidelines) and individual factors (e.g. knowledge, skill, experience and attitude), and patient characteristics (e.g. complexity of health conditions, personality and communication ability) (Hernan et al., 2015).

Karimi et al. (2016) also suggest that most medication related AEs by nurses is due to their working conditions. The authors explored how medication related AEs could easily be caused by inadequate human resource at the front-end, overtime or consecutive shifts by frontline healthcare workers. The possibility of an AE occurring increases when frontline healthcare workers undertake unpredictable activities such as night and long shifts which reduce their capacity and physical function. It is estimated that more than half (approximately 60%) of all maternal mortality between 1995 and 2005 was due to medical, midwifery and nursing errors. Improving the conditions at work involve improvements to design interfaces, physical environment, the decrease in distraction or ergonomics of equipment and interruptions which influence the tendency to Adverse Events. This was a systematic review that included 18 studies from Arab countries (Elmontsri et al., 2017). These are similar to Steelman et al's (2016) work of a retrospective study of reported cases in the University Health System Consortium Safety Intelligence Patient Safety Organization database in Chicago. The authors identified failures in communication including handoffs, staff inattention, knowledge deficit and environmental issues (such as interruptions, distractions, emergency and lightening) as major contributory factors to surgical specimen events. Communication failures alone accounted for more than half (n=172; 52%) of the surgical specimen events reported while the

human resource related issues such as staff inattention; and knowledge, training and experience altogether accounted for more than two-thirds (n=288; 87%). The authors added that, some of the events involved more than one causative factor (Steelman et al., 2016).

Thompson and Avillion (2017) also identified communication, planning and knowledge, and systemic or institutional failures as the major contributory factors to AEs. In addition, absence of or inappropriate policies and procedures and failures in the following areas: monitor care, recognize errors when they occur or are about to occur and correct them, to procure and maintain equipment, to recruit and retain staff, maintain appropriate staff levels, and poor planning and execution.

Three aspects of responses are analysed in the analysis of failure and these include: What happened *(the outcome and chronology, where in the required stage the failure occurred)*. How did it happen *(the problems associated with the delivery of care and the nature of the faults)*? and Why did it happen *(the causative factors)*? Classifications of failures are placed into skill-rule-knowledge based perspectives. It is suggested that it is necessary to find out **what** *(i.e. getting detailed insights into the deeper causes)* went wrong other than **why** *(i.e. deriving superficial causes)* (Rasmussen, 1983).

The following sub-sections discusses the factors associated with AEs guided by the six (6) Health Systems Building Blocks of the World Health Organization (WHO).

2.7.1 Health work force

This refers to all clinical staff such as nurses, pharmacists, physicians, biomedical scientists, dentists etc. as well as management and support staff engaged in activities with the main intention of enhancing health. Obstetricians and obstetrical care providers are highly skilled, trained and competent persons who work with complex systems in very unpredictable environments. Much of the delivery of healthcare depends on humans i.e. doctors, nurses, pharmacists and other frontline healthcare workers providing care. Inadequate numbers of skilled and competent healthcare workers have been suggested to be one of the key issues that affects the provision of safe care. Lack of competence and incomplete or inaccurate reporting of results to the pregnant woman are blamed as the cause of unnecessary harm or adverse event to obstetric clients (Habib, 2010).

It is estimated that there is a global deficit in 57 countries of 2.4million nurses, midwives and doctors. Out of the estimated total of 59.2 million global health workforce only 3% are found in Africa dealing with a quarter (25%) of the burden of disease globally. Again, the estimated health work force density for every 1000 population in Africa is 2.3 compared to 24.8 in the Americas (Alhassan et al., 2013; Jha et al., 2016). Inadequate numbers of staff are said to result in limited attention to each patient at the point of admission. It has been shown by some authors that higher incidence of AEs and poor outcomes of patients is associated with inadequate number of nursing staff. This oftentimes leads to increased workload where the optimum patient care of the individual frontline healthcare worker is exceeded. Furthermore, effective communication is hindered among staff and there is also an increased reliance on memory whenever vital tasks are to be performed. Communication *(when information between staffs, and between staffs and patients is exchanged effectively)* alone has been identified as the

singular cause of almost 70% of all the sentinel events in the US (Flotta et al., 2012; Hernan et al., 2015).

Healthcare professionals who belong to the surgical disciplines: obstetricians and gynaecologists, and anaesthesiologists have been identified as the category of frontline healthcare workers associated with more than half (i.e. 58.4%) of the total causes of adverse events in healthcare. Obstetricians and gynaecologists are the third ranked frontline healthcare providers to cause AEs after general and orthopaedic surgeons respectively. The medical discipline, including internal medicine, cardiology, paediatrics, gastroenterology, and medical oncology follow the surgical disciplines closely (Vries et al., 2008). Adverse events in healthcare occur largely because todays' healthcare system has become so complicated that for a treatment and an outcome to become successful for each patient, a range of factors are depended upon other than the competence of just the individual healthcare worker or because bad people in the healthcare deliberately want to hurt patients.

In healthcare, people make errors and these errors cause accidents that result in morbidity and adverse events including mortality. Though work could be undertaken to moderate and limit the risks of human fallibility, it cannot be eliminated. It is very utopian to think of an error-free healthcare delivery. What we can set out to attain is an error-tolerant system *(i.e. a healthcare system that is designed to have the capability of averting or reducing the risk of translating errors to harm patients).* In attaining this *(i.e. Error-tolerant healthcare)* however, there is the need for individual practitioners, processes and systems to be up to scratch. It is noteworthy, however, that the failings of individuals are absolutely preventable. The tendency for errors is so inherent to the activities and behaviours of humans that it is best to consider it as intrinsically

biologic, because it is the same mental process that produces the flawless performance and error (Cuschieri, 2006). About a third of AEs have been found by Scott (2009) to involve errors of execution *(slips, lapses or oversight in appropriately performing the management of patients who have been correctly diagnosed)* while close to half were errors of reasoning or quality of decisions *(failure in eliciting, synthesizing, deciding or acting on a clinical information that leads to the death of about a quarter of patients)*. Mistakes and errors of all kinds are inevitable and part of the normal part of work especially in complex settings like healthcare (Scott, 2009; West, 2000a). Human errors could be blamed for the cause of adverse events in some instances. When there is a focus on healthcare workers and their interaction with the environment, mistakes and errors could be reduced considerably. The organizational approach to adverse event prevention has largely been to seek out the culprits for blame and punishment. The attitude to adverse events in healthcare delivery system needs to change from defending 'name, blame and shame' to openness and transparency. This becomes counterproductive to AE reporting. What is often forgotten or ignored is that the whole system is at fault when an individual is at fault. Therefore, the flawed system is only perpetuated when an individual is punished without addressing the underlying cause *(of the flaw or fault)*. The IOM, for instance, adds that, AEs are more as a result of poor systems than of negligent practitioners (Boysen, 2013; Thompson & Avillion, 2017). Often times, while a particular action or inaction may result in the immediate cause of an adverse event, a close and detailed analysis often reveals a sequence of deviation from practices that are safe and influenced by environmental and larger organizational factors (Neale et al., 2001; NHS Litigation Authority, 2012).

The understanding of accident causation with respect to lessons learnt from industries such as aviation, popularly labeled as 'highly reliable organizations', have stressed the need to reduce the emphasis on the person or group of persons who may have caused the events and aim at the pre-existing organizational and management factors. Reason (1990), for instance, suggested that incidents often precede some sought of 'unsafe act' where one makes an error or a mistake. In order to understand how this error happened, it is necessary to look further back to the 'error-producing conditions' resulted in the unsafe act and to the 'latent failures', or the management decisions that were made and others likely to have an effect on the outcome (Leveson et al., 2016; Reason, 1990; Vincent & Amalberti, 2016b).

Prolonged working hours and excessive workload, fatigue and shortness of sleep have been found to reduce the performance of frontline healthcare workers by various authors. It has been shown for instance that, increased risk of medication related AEs and HAIs are associated with inappropriately high workload among nurses (Valentine, 2016). AEs can also happen sometimes because, subordinates or personnel whose status and ranking are lower find it difficult to challenge or question the decisions of persons of higher status or rankings. A systematic review by Lee and Scott (2016), for instance, identified that nurses with higher degrees had fewer adverse events such as pressure ulcers and prolonged length of stays. What most healthcare professionals lose sight of is that decision-making is a key skill. It is suggested that decision errors can occur in all types of patient care environments.

Adverse events in surgery and obstetric are largely as a result of the characteristics of the individual surgeon coupled with the dynamics imposed by the existing work system. The nontechnical skills of all members involved in the care of patients, such as leadership and

communication, are critical components of teamwork, and any breakdown in these becomes a recipe for disruption and an adverse event (Fann et al., 2016).

Collegiality or a working relationship between nurses and physicians, or the lack of this, is one of the important markers of AEs in healthcare settings. West (2000), has suggested the possible implications that social dynamics could have on obstetric and medical adverse events. For instance, a midwife who is experienced may feel reluctant to call a senior doctor, especially when the junior doctor is seen as the one who refuses to respond appropriately to calls. Status distinctions are therefore believed to be the cause of increased incidences of AEs where they are marked and vice versa. Lee and Scott (2016) in a systematic review of AEs also identified that inappropriate collegial relationships result in increased hospitalizations, higher mortality rate, increased medical errors and fewer patient falls (Lee & Scott, 2016; West, 2000a). The complexity of the function of length of time in practice, characteristics of the individual, situational factors, physical environment, teamwork, random chance or the organization of healthcare. The need to go beyond the individual healthcare provider and recognize the importance of the organizational context and the wider process of care is often very key (Hernan et al., 2015; Walshe, 2000).

AEs have occurred during the preparation or administration process of medication. Some of the reasons ascribed to some of this occurrence include interruptions, poor staffing and lack of attention. The authors add that medication related AEs occur when frontline healthcare workers do not have proper knowledge, do not follow the rules or use bad rules, forgetfulness of an important information or in the performance of a task or commit a mistake in the administration of medication (Thompson & Avillion, 2017).

The rate of AEs has been associated with the attitude of health workers towards safety in some studies. Leadership is also very significant in the cause of adverse event as it recognizes it as a system-related problem (Elmontsri et al., 2017).

There is the need to understand the limitations of humans and design the workplace and equipment such that they allow for variability in humans and their performance. Some of the key elements necessary to build a safer care environment for vulnerable clients have been identified to include the design of the system factors, structure and the process of care. Systems other than individuals have been identified as being responsible for safe healthcare outcomes (Valentine, 2016). The underlying contributing factors to errors, standard care and poor-quality services need to be understood, monitored and set targets for improvement as part of efforts to prevent AEs. Similarly, five (5) interventions are identified as strategies to improve care in the wards and prevent AEs from occurring and these are: improve the levels of staff and the composition of the team, standardize the process of care, improve collaboration and communication, improve the climate of patient safety, and recognize and treat patients who are deteriorating very early. Of these strategic interventions, three (3) are health workforce related (Pannick et al., June, 2015).

In a study on gossypiboma, the authors identified a lack of instrument count as a major cause in all the 12 cases (2003 to 2012). Other factors that were identified included performing an operation when the entire staff complement is not available (7), when one operates in deep fields (7 cases), when the surgery is extensive (7cases), when the bleeding is excessive (6 cases), when emergency procedures are performed at night (4 cases), changing part of the

surgical team without proper handing over (2 cases), and changing the surgical procedure unexpectedly (1 case) (Dakubo & Naaeder, 2013).

Studies in a primary care setting by Gehring et al (2012) that used a defined patient safety incidents list have shown that about 30% and 16% of physicians and nurses respectively have reported at least one patient safety incident occurring either daily or weekly (Gehring et al., 2012). Studies suggest that fatigued doctors are likely to make as much as five times more diagnostic errors that leads to patients' deaths than their non-fatigued colleague (Jha et al., 2016).

2.7.2 Health Technology & Essential Medicines

The use of medicines and medical technology have also been found to be one of the problems associated with the cause of adverse events and source of harm to patients (American College of Obstetrician Gynaecologists (ACOG), 2009; O'Connor, Ritchie, Drouin, & Covell, 2012). Medication related AEs are the most common type of AE among all the others. It frequently occurs in hospitals and in a study in the US, is estimated to account for 20% of all incidents. It accounts for one (1) in every 131 deaths among outpatients and one (1) in every 854 deaths among inpatient with an estimated incidence of between 4.8% to 5.3% in the US. It is also suggested that medication-related AEs are responsible for 7.5% to 10.4% of all hospitalizations in developed nations (Kohn et al., 2000; Wittich, Burkle, & Lanier, 2014). Various rates have been estimated in countries such as the UK (12% among patients who are in primary care), 42% in Sweden and 58% in Mexico. All these estimates are with respect to only the prescription stage of the medication process. Rates during the dispensing stage of the medication process have also been estimated in a systematic review to account for 3%.

Medication-related AEs could account for 6% to 7% of the total admissions to the hospital in some countries and about two-thirds are preventable (Sheikh et al., 2016).

Drug-related AEs in hospitals in the US was further estimated to be between 380,000 to 530,000 annually in 2006 occur. It is further estimated that, 800,000 drug-related AEs occur in long term care annually and are preventable while 530,000 occur among outpatient settings and are also preventable in the US (Anderson, McGuinness, & Bourne, 2010). Yet another study estimates that averagely a patient suffers at least one AE related to medication each day, and more than 1.5million drug-related AEs occur in the US alone annually (Burke, 2007; Institute of Medicine (IOM), 2006). In another study in an urban hospital of a tertiary status, 73 AEs were identified from a total of 2967 patient who were admitted to various units such as obstetrics, medicine, surgery and coronary ICU for 37-days. Twenty-seven (27) incidents were judged ADEs, and 34 were judged to be preventable while 12 were 'problem orders' (Bates, 2013). As the mean number of drug increases, the potential for ADEs also increases. There is the potential for AEs related to medication to increase and become one of the major contributors to avoidable morbidity and mortality in the wake of the introduction of new medicines for a wider range of indications (American College of Obstetrician Gynaecologists (ACOG), 2009; Jha et al., 2016; Karimi et al., 2016; Kohn et al., 2000a). Medication-related AEs can result in client dissatisfaction with the health system, prolonged hospitalization, increased treatment costs and maternal mortality. Among obstetric clients, AEs have been identified to be associated with augmentation of labour with oxytocin and surgical delivery such as with vacuum, forceps or caesarean section (Jonge et al., 2013; Karimi et al., 2016).

Ghana has had its own share of medication-related AEs and other health technology related AEs in its health system. It has been reported that a doctor allegedly cut the supply of oxygen from a nine-week old baby boy because his parents were unable to pay the cost of medical expenses of GHS533 in the facility. Similarly, a post market surveillance on the quality of some maternal healthcare related products notably Ergometrine and Oxytocin failed the respective laboratory quality tests which led to women bleeding profusely to death. The authors assayed 169 samples of Ergometrine out of which 55.6% failed while 97.5% of 40 Oxytocin samples also failed the Assay and Sterility test respectively. The verdict of the authors was that, 'an extremely high percentage of Oxytocin and Ergometrine available on the Ghanaian market do not meet the required standards of quality' (Sabutey, 2018).

Again, an account is given of how a young chartered accountant died in one of the hospitals in Ghana after three shots of oxytocin at different intervals failed to arrest her bleeding after birth. An audit of the AE revealed that, 'the substance that was served as oxytocin was just water'. There have been instances where the FDA in Ghana have had to cause the arrest of companies for the supply of fake, contaminated and substandard medicines such as Ergometrine and Oxytocin injections and Quinin from the Ghanaian markets. These pose serious threats to the patient safety and public health and invariably hamper the efforts of reducing the high maternal mortality in Ghana. There is a related incident where a Physician Assistant have been arrested in some part of Ghana for allegedly causing the deaths of three patients after they were given an injection of Benzathine Penicillin in one of the healthcare facilities. Some initial investigations *(by the FDA, Ghana)* have revealed that the solution (i.e. 0.9% Normal Saline) that was used to reconstitute the Benzathine Penicillin Powder might have been contaminated.

There was a case report by Veisi, Salimi, Mohseni, Golfam and Kolaei (2010) where there was an accidental intrathecal injection of tranexamic acid instead of a 1.5% bupivacaine in the Kermanshah University of Medical Sciences. The authors report that, the patient, a 21-year old with twin gestation died an hour after futile efforts of CPR. The cause of this AE was linked to the fact that the ampoules of tranexamic acid and bupivacaine were in a 'look-alike ampoule'. A similar incident is reported to have happened in the Greater Accra Regional Hospital where the woman also died (Pers. Communication, 2017). Some suggested solutions to averting future incidents were proposed by the authors as: standardizing arrangements for drugs in the operating room, ensuring that drugs labels are read prior to drawing them up, drug companies were entreated to create different sizes of drug labels and vials, and finally ensuring a continuous review of medication errors in hospitals to identify associated causative factors and develop systematic interventions for prevention.

The measurement of drug-related AEs is fraught with many inaccuracies and inconsistencies just as with adverse events in general. Many medication-related AEs go unreported and undocumented. For instance, only 92 out of 731 ADEs among 648 patients were reported by frontline healthcare workers notably nurses, doctors and pharmacists. Similarly, 28% of midwives in Iran do not report ADEs (Karimi et al. 2016). This makes current estimates of medication-related AEs low. Detection of ADEs could be very daunting when there are no computerized systems available for surveillance (Kohn et al., 2000; Landrigan et al., 2010). In Ghana, the Food and Drugs Authority (FDA) and the National Blood Service (NBS) both collect voluntary reports on adverse events related to medication and transfusion respectively. The FDA, through its pharmacovigilance centre received its highest number of voluntary/spontaneous reports of 1600 in the year 2016. However, this figure is well below the

expected 5400 reports per year from a country with a population of about 27million, like Ghana (FDA, 2017).

Kohn et al. (2000) identified an association between ADEs and allergic history of the patient to the same class of medicine, incorrect name of the drug, dosage or abbreviation, consideration of frequency of dosage that is critical and unusual or atypical, and wrong calculation of the dosage. Similarly, there could be an effect on practices such as prescription, transcription, dispensing, administration and monitoring when the systems of medication are weak and there are also challenges with human factors such as shortage of staff, tiredness and poor conditions of the working environment. Medication related AEs can occur during any of the medication use processes such as prescribing, dispensing and administering. One of the most important factors responsible for medication-related AEs is inappropriate prescription. Among 15 admissions with ADEs, prescription errors accounted for five (5) while inappropriate measures in prescribing by physicians also accounted for five (5) which were preventable. This was the results of a study among 366 patients on admission in a cardiology department. Even when information on medication history is readily available potential drug interactions are not routinely screened for by physicians. Studies have also shown that ordering and administration are also very common factors associated with medication-related AEs. For instance, an analysis of more than 4,000 admissions found that, 28% of 247 ADEs were mostly as a result of errors that happened during the ordering and administration stages of drugs (Karimi et al., 2016; Kohn et al., 2000).

Making the accurate diagnosis is one of the first steps to optimal healthcare. However, in about 5% to 14% of the instances, this is missed among hospitalized patients including obstetric

clients. One of the leading factors associated with AEs is diagnostic-related AEs. It is estimated for instance that, 94,000 to 142,000 patients died from adverse events related to diagnostic errors globally between 1990 and 2013. Diagnostic errors are the instances where there is failure on the part of the physicians to promptly and in an actionable manner arrive at a diagnosis that is correct leading to a delayed diagnosis *(the necessary information needed to make a decision was not available when it was needed)*, misdiagnosis (incorrect diagnosis), or a missed diagnosis (no diagnosis) (Ra, Sultana, Sheikh, & Mn, 2016). Misdiagnosis is estimated to account for 10% to 15% in developed countries with the most sophisticated medical technology while diagnostic errors also accounts for 10% to 20% of all clinical outcomes. Khullar et al. (2016) for instance, add that this leads to the death of about 160,000 patients annually in the US. Timely and inadequate follow-up of important tests results have also been said to account for life threatening conditions, needless deaths and other AEs. The rates of test follow-ups in developing countries is described as 'suboptimal'. It is also suggested that up to 45% of hospitalized patients do not also receive the recommended evidence-based care (Jha et al., 2016; Khullar & Jena, 2016; Scott, 2009).

A study by Steelman et al. (2016) reported in the University Health System Consortium Safety Intelligence Patient Safety Organization database showed that specimen labelling (49%, 319), specimen transporting/storage (38%, 247) and specimen collecting (24%, 156) were the major categories of surgical specimen events in a descriptive study involving 648 AEs and near misses of surgical specimen management. The authors added that, before any serious harm happened to the patient, most of the surgical specimen errors were discovered. Most of these events were either near misses or no harm happened to the patients even though the event reached them or there was only an inconvenience or an emotional distress. Southwick et al.

(2015) also identified failure in diagnosis and treatment as the leading category of error (30%, 541) with the subcategory of delay in diagnosis and treatment being the highest in a mixed methods study that sought to capture the perspective of patients and their families experiencing adverse events. Mahumud et al. (2016), however, identify cognitive errors related to faulty data gathering and information processing, system factors associated with availability and functioning of medical equipment and the relationship between the varied professionals in the healthcare system, as some of the contributory factors of diagnostic errors in healthcare.

The use of medical devices has been identified as a major source of AEs and the cause of substantial harms in healthcare. It is estimated, for instance, that over a million-medical device related AEs are occurring yearly at a rate of 6.3 events for every 1000 patient days globally. Another study estimates the rate of infection that is medical device related to be 34.2 per 1000 patient days **(Jha et al., 2016).** The Medical Devices Agency in the UK received a total of 6610 reports of adverse events related to medical devices. Of this, 37% were due to manufacturing problems (i.e. design, quality control, packaging, etc); 27% were as a result of device faults which occurred during their use; 12% was due to user error, while 24% had no links to the device failure according to a publication by the Department of Health (2000) titled, *'An Organization with a Memory'.*

The WHO estimated in 2000 that, up to 40% of the 16 billion injections that were administered were given with syringes and needles that were reused without sterilization. The number of deaths attributable to unsafe injections is estimated to be about 500,000 and this accounts for 0.7% to 1.5% of all the global disease burdens (AI & AN, 2016; Kermode, 2004; WHO World Alliance for Patient Safety, 2005; World Health Organization (WHO) 2002, 2002). It is even

estimated that, this could be as high as 70% in some countries. All of these contribute to high rates of hospital acquired infections (Jha et al., 2016). Defective equipment can also contribute to the cause of adverse events. A systematic review ascribed 8% of adverse events to equipment issues (White, Pichert, Bledsoe, Irwin, & Entman, 2005).

The work environment can be seen as the organizational characteristics of a work setting that facilitates or constrains professional practice. It can be a fertile ground for the occurrence of AEs. It is suggested by the IOM, for instance, that a poor system and design of work set the frontline healthcare provider up for automatic failure. A systematic review by Lee and Scott (2016) identified, for instance, that a favorable work environment is related to lower mortality rates, less patient falls, less hypotensive events, fewer occurrences of CLABSI and fewer complaints from patients/relatives. The physical work environment and processes both affect the provision of safe, efficient and effective care. Especially frontline healthcare providers are encouraged to engage in 'inter-professional collaborative teamwork and be provided with the technological and information infrastructure needed' (O'Connor et al., 2012).

2.7.3 Leadership & Governance

Leadership and governance ensure frameworks for strategic policy combines with oversight effectiveness, building coalition, accountability, regulations, inducements and attentiveness to the design of the system (WHO, 2009). In this study, leadership and governance include availability of senior leadership, availability of protocols/guidelines, decision-making aids, adherence to/follow available protocol/guidelines, regulations, supervision and seeking help. One of the most important components of any patient safety programme is a leadership with the recognition that safe care is a problem that is related to the system and ensures that

investments are made in the development of robust systems that guarantees that patients are safe from harms (Clarke, 2007). It is suggested that, in hospitals and hospital units where safety is a high managerial priority, it is characterized by fewer adverse event rates, lower rates of patients' complaints and better clinical governance ratings (World Health Organization (WHO), 2009). Similarly, effective leadership have also been identified to impact positively on health outcomes such as mortality, length of stay, patient satisfaction and high organizational culture (Sfantou et al., 2017).

Lack of leadership and management support in clinical units has been strongly correlated with adverse patient outcomes. In an adverse event study in London, UK, 46 adverse events were recorded during an operation on an invasive procedure with 10 of them described as preventable. The main contributory factors according to the authors were *'poor technique and poor monitoring of unsupervised junior staff'*, a failure of leadership (Neale et al., 2001). In the same study, lack of adherence to protocols/guidelines during a preoperative assessment and care also led the patients to developing deep vein thrombosis and infections. A similar study amongst nurses found that increased manager support was related to fewer complaints from patients/families, lower healthcare associated infections and medication errors (Lee & Scott, 2016).

Wide variation with the range of compliance to the relevant standards of patient care between 18% and 47% have been identified in a systematic literature review study that sought to improve patient safety by ensuring the development of standards that are harmonized, ensure adherence of hospitals and encourage collaboration from hospital managers, physicians and patients (Siddiqi et al., 2012). It was further found that in most of the participating hospitals,

there were an absence of clear protocols to guide action, substandard infrastructure and physical standards that ensured the safety of patients, and more importantly, the leadership and management commitment was found to be 'wanting'.

Among the obstetric care team, there is the need to encourage the provision of safe and quality care. Communication and collaborating effectively among team members will also go a long way in guaranteeing the safety of patients. A strong leadership is needed to ensure that this is done. Similarly, the culture of safety could be seriously undermined when there are no known structures or procedures for resolving behaviours that are disruptive and scornful (Gandhi et al., 2016). This can create a burnout that can go a long way to undermine the culture of safety and cause an increase in the prevalence of adverse event (American College of Obstetrician Gynaecologists (ACOG), 2009).

Leadership is expected to create and sustain a safety culture where members of staff are encouraged to be honest and continuously learn, and there is a balance of accountability between individuals and organizations (Neale et al., 2001; Gandhi et al., 2016).

2.7.4 Health Service Delivery

Health service delivery is about effective, safe, quality personal and non-personal health interventions that are provided to those who are in need, when and where needed *(including infrastructure)* with a minimal waste of resources (WHO, 2009).

Inadequate monitoring and treatment of both early and late complications of pregnancy and communication have been identified as one of the factors of obstetric adverse events. It is estimated that, 1.5% of obstetrics patients who are hospitalized experience an AE and negligent care accounts for 38% of these outcomes. Patient behaviour characteristics such as non-adherence and substance abuse have also been identified as contributors to the cause of AEs among pregnant women in hospitals (White et al., 2005).

Adverse events are also caused by surgical errors which involves the performance of an incorrect operation or procedure on either the wrong site or on the wrong patient. The use of the surgical safety checklist, *'a 19-item safe surgery checklist that includes a sign-in procedure before induction of anaesthesia, a time-out procedure before skin incision and a sign-out procedure before patient leaves the operating room'* has been shown elsewhere to reduce the incidence of AEs significantly and has received endorsement from the International Federation of Gynaecology and Obstetrics (FIGO) (American College of Obstetrician Gynaecologists (ACOG), 2009; World Health Organization (WHO), 2009).

Increased recognition of the value of unambiguous and succinct communication between all members of the healthcare team, including patients, has proven to immensely increase the safety of the care delivered by obstetricians. Handing over of patients (i.e. handoffs) which occurs for nurses and other frontline healthcare workers when they are changing shifts have been identified as one of the great potentials for miscommunication. Obstetricians are expected to deal honestly with their patients and to ensure that their communication is complete, concise, clear and timely. Open communication and transparency in healthcare increases trust, improves

patient satisfaction and decrease the incidence of AEs (American College of Obstetrician Gynaecologists (ACOG), 2009).

2.7.5 Health Information Systems

Poor or inadequate documentation *(such as data that is missing, not recorded or given as a verbal orders)* have been identified as one of several instances that contribute directly to adverse events in obstetric care. A study by White et al. has attributed 8 cases (9%) to documentation alone (White et al., 2005).

Poor documentation has been identified as one of the factors associated with preventable AEs in obstetric care. These include incomplete documentation and in other instances the documents may be lost. There have been instances where healthcare personnel have failed to document the important patient information necessary for appropriate management by other members of the care team (White et al., 2005b). Accurate and consistent reporting of adverse events remain a challenge in healthcare largely because voluntary reporting, which is the main reporting system only captures between 2% and 8% of AEs. It is further suggested that only 10% to 20% of errors are ever reported, and the percentage that does not cause harm to the patient is estimated at between 90% to 95% (Stockwell et al., 2015).

The quality of care could be affected by failures in communication or information flow between care providers. More than 70% of adverse events in obstetric care is caused by communication and teamwork alone. Obstetricians also sometimes commit errors in judgement or communication whenever they have had to collaborate among themselves or with other

departments either as recipients and/or providers of other services (Lyndon, Zlatnik, & Wachter, 2012; Shannon, 2011).

2.7.6 Health Financing

Ghana, like many other African countries such as Mali, Senegal, Rwanda, Uganda and Burundi have all implemented and continue to implement free delivery services combined with community-based health insurance schemes which exempt them from payments at the point of service (Wekasah et al., 2016).

Studies in Kenya, Mali, Nigeria and Ghana have demonstrated an increase in facility-based delivery; increased caesarean section birth rates and this has reduced the risk of maternal deaths from obstructed labour; has increased utilization of maternal health services, including ANC and hospital deliveries, from (26.7% to 85.6%) (Wekasah et al., 2016).

Financial incentives have been showed to have the potential to increase access to and utilization of maternal health services, especially among the poor and thereby increasing maternal health outcomes. The Government of Ghana (GoG) introduced the free maternal healthcare policy in 2008 to facilitate access *(especially financial)* to maternal health services in the country. This was also one of the measures that were aimed at improving maternal health outcomes such as skilled delivery, ANC attendance, and maternal mortality among others. Though the country has witnessed some modest improvement in some of these stated indicators, institutional maternal mortality remains high **(358/100,000 live births).**

2.8 Degree of Preventability of Adverse Events among Obstetric Clients

Adverse events among obstetric clients are often preventable (Sonesh, 2015). However, its judgement and the degree of preventability are often difficult. The degree of preventability of AEs is estimated by various to be as low 4% *(among 37 wards in 7 hospitals)* in France and as high as 72.5% *(in an 800-bed university hospital)* in Finland. Authors are unanimous on the preventability of AEs but the degree of preventability remains contentious and vary from one author to another (Aranaz-Andrés et al., 2011; Brennan, 1991; Michel et al., 2004; Rafter et al., 2016; Thomas, Studdert, & Runciman, 1999; Vincent et al., 2001; Wilson et al., 1995; Zegers et al., 2009). The Irish study identified 287 AEs out of which 72.5% (179) were judged to be preventable (Rafter et al., 2016) while the study involving 58 hospitals in five (5) Latin America countries also detected a 59% degree of preventability according to the judgement of the reviewers. The authors *(in this Latin-American study)* found the highest prevalence of preventability among obstetrics and medical specialties (Aranaz-Andrés et al., 2011). Similarly, a study by Szekendi et al. (2006) found one (1) AE in every 243 medical records/folders reviewed. The study period was three (3) months and the total folders reviewed was 327. They also noted that 163 of the AEs were preventable *(i.e. AEs that resulted in a harm to the patient)* and 138 did not result in any harm to the patient (Szekendi et al., 2006).

The degree of preventability is often influenced by the perspective i.e. quality improvement or medicolegal, of the authors of the studies. A lower cut-off point of ≥ 2 *(using a Likert-scale of 1-6)* is used when quality improvement perspective is the focus while a higher cut-off point of ≥ 4 is used when the perspective is medicolegal. The medicolegal cut-off is often stricter and higher than the quality improvement obviously because of the implications (Brennan, 1991; Davis et al., 2002; Thomas, Studdert, Newhouse, et al., 1999; Thomas, Studdert, & Runciman, 1999; Zegers et al., 2009). Preventing AEs is often targeted at the physical environment of the

operating room, teamwork, tools and technology, tasks and workload, electronic medical records, and organizational processes (Fann et al., 2016) however, a total systems safety has been identified as one of the desired approaches to reduce adverse events. It involves a consideration of redesigning the systems; the inevitability of some human failures and some human factors contriving to mitigate these failures; a culture of safety and a reporting and analysis system for errors that is robust. There is also the need to embrace safety as a core value (Gandhi et al., 2016). Programmes aimed at reducing and preventing AEs should be targeted at potential failure points within the system, such as those relating to the physical environment of the operating room, teamwork, tools and technology, tasks and workload, electronic medical records, and organizational processes (Fann et al., 2016).

2.9 Chapter Summary

This chapter reviewed some of the available literature on the subject of adverse events and more specifically with respect to obstetric clients who have had an episode of hospitalization. The theoretical and empirical literature is explored. Specifically, literature on the prevalence, types, factors associated with AEs and degree of preventability of adverse events was reviewed. The literature review on the factors (causes) associated with adverse events was guided by the six (6) health systems' building blocks developed by the WHO. The literature on patient safety is very heavy in other disciplines such as medicine and surgery other than obstetrics care. There is enough evidence on the types, nature, prevalence and degree of preventability of adverse events in the developed countries. Most of these countries have estimated their national prevalence of AEs. African countries came close to this between 2009 to 2014 when the WHO-AFRO Region supported a hospital-to-hospital partnership between 14 hospitals in 17 African countries including Ghana and 12 hospitals in Europe making it possible for participating hospitals to undertake patient safety situational analysis of their respective hospitals. The

program and other studies showed that, there was a marked and an unequal burden of adverse events specifically healthcare associated infections in Africa compared to Europe. These findings are however generalized and not specific to any discipline or specialty such as obstetric. It was also discovered in this chapter that, there is no unanimity among authors about the types of AEs. Various authors have come up with what they deem fit and necessary in the space of the patient safety discussion. There is however some form of gravitation towards the 27 serious reportable AE types in healthcare developed by the AHRQ (Kizer & Stegun, 2000). However, these AE types are generic and sometimes are less or even not applicable to other specialties such as obstetrics.

Again, there is a lack of convergence on the role of human beings in the cause of an adverse event. Some authors such as Greenwood (1919) and Heinrich (1939) are unwavering about the fact that, adverse events are caused by human beings. Their view is buttressed by the *'accident proneness' and the 'domino theory'* schools of thought where both authors minces no words in the role human beings play in accident *(adverse event)* causation. Greenwood (1919) even asserts further that, some human beings are more prone to accidents than others and that, the likelihood of one being involved in a subsequent accident increases after an initial one. Reason (1999, 2000) however disagreed and introduced the systems perspective to accident causation while Donabedian (1966) also introduced his triad to evaluation of health services/system. He *(i.e. James Reason)* introduced the 'Swiss Cheese' model to buttress his argument and asserted that, the causes of accidents would have to be seen as either 'latent' or 'active' failings of the system other than the human being. He argues further that, for an adverse event to have happened at the front end i.e. active failure, it would have been caused by a *'resident pathogen'* or latent failings *(such as failings at the management levels etc)* that might have been ignored. Critics of the Swiss Cheese Model (SCM) argue that, the SCM is seen as a linear causal model

and that it can neither explain nor provide a precise understanding of why highly automated systems fail while others also argue that, the model is archaic and obsolete. Another critique is that, the SCM only seem to relocate blame with respect to the cause of accidents (or adverse events) in organizations (Larouzée & Guarnieri, 2015; Leveson, 2009; Leveson et al., 2016). Again, even though various efforts have been made by different authors to explore the effect of the system components on adverse events in healthcare, the health systems building blocks of the WHO is yet to be explored.

CHAPTER THREE

METHODS

3.1 Introduction

This section presents the research design and method used in addressing the objectives outlined in the study. It includes sampling, data collection, the study population and site, ethical consideration and analysis of the data. The variables used in the study are also presented and explained in this chapter. This study focused on adverse events among obstetric clients hospitalized at the Greater Accra (Ridge) Regional Hospital and are presented as follows.

3.2 Study Design

There are various indirect sources of information on adverse events which include administrative records, medical records/folders of patients, confidential inquiries, incident reporting, complaints and claims data at public health facilities. Incident reporting is mostly voluntary at these facilities and denominator information is unavailable to enable one determine the rate of any type of adverse events. In view of this, multiple study designs and approaches were used to help attain the stated objectives and to provide answers to the research questions of this study. These **were**: retrospective review of medical records and case-control study designs.

3.2.1 Retrospective Medical Records Review

The study was a retrospective review of medical records of obstetric clients on admission at the Obstetrics Unit of the Greater Accra (Ridge) Regional Hospital. Records of obstetric clients

who were admitted from 01/01/2015 to 31/12/2015 were reviewed in a **four-stage** process by obstetrician gynaecologists, and midwives. The entire data set (i.e. medical records) that was available for the study was 2881.

Epidemiological studies of AEs mostly employ retrospective non-randomized sampling of hospital record review (Olsen et al., 2007). Retrospective records reviews have revealed substantial rates of AEs in hospital practice in the US, Australia, Canada, the UK and Ireland, and are useful when large sample sizes are involved. This approach to adverse event investigation has been used extensively (Vries et al., 2008). Prospective study approaches have, however, been employed where smaller sample sizes are involved, as a result of the need to monitor the progression of patients (Settervall, Domingues, de Sousa, & Nogueira, 2012).

Retrospective records review depends largely on the completeness, accuracy and legibility of patient records. It can also be time consuming, and adverse events themselves may not explicitly be stated nor recognized most of the time until the patient is either readmitted or dead. It is also a painstaking process that relies on nurses and/or physicians reviewing the medical records/folders of the patients. The knowledge of the reviewers and their clinical acumen also play a major role (Rafter et al., 2016). This method has however yielded huge epidemiological data that have had effects on governmental policies and on actions taken by healthcare providers. It is also believed to provide very rich clinical details and is as effective as prospective method of data collection (Brennan, 1991; Davis et al., 2002; Neale et al., 2001; Vincent et al., 2001). It is also seen as one that provides the best characterization of the overall rate of adverse events at a given time unlike other methods such as cross-sectional and prospective studies (Gandhi et al., 2016; Levinson, 2010; Shojania et al., 2001; Thomas et al.,

2000; Thomas, Studdert, & Runciman, 1999). Retrospective methods are however impractical for the routine detection and hospital-wide adverse event monitoring. Potential adverse events can only be detected through a medical records/folder review based on the information it contains (Rochefort et al., 2016).

3.2.2 Case Control Study Design

A case control study design was used to assess the factors that are associated with adverse events among obstetric clients in the study facility. There was equal numbers of cases and controls and they were unmatched. Matching is the process of deliberately selecting cases that are of similar characteristics *(such as age, gender, education etc)* with the control group. The merits in matching is more with respect to efficiency other than introducing confounders *(as is often held by some authors)* because true confounders will only occur if the confounder is associated with both the exposure and the disease. There is however the tendency to over-match and thereby obscure the actual relationship of the exposure to the disease and likely leading to biased estimates. Again, matching also has the tendency of creating a sample of controls that are not representative of the exposure in the population and this can result in an instance where the control sample will be shifted towards the cases and invariably losing the effect of the matching because it can no longer be studied (Carlson & Morrison, 2009; Marsh, Hutton, & Binks, 2002; Pearce, 2016; Rose & Laan, 2009). Case control study designs have been suggested as the most suitable designs for investigating rare occurrences or outcomes *(such as adverse events)* (Carlson & Morrison, 2009; Mann, 2003; Rose & Laan, 2009).

3.3.0 Study Location/Area

The Ridge Regional Hospital was designated as the Greater Accra Regional Hospital *(Figure 4)* in 1997 and functions as a secondary level referral hospital. It has a total bed capacity of 200 *(until the construction of the newly built edifice in 2017)* of which 44% (87) are in the obstetrics and gynaecology department. It is currently ranked as the third largest health facility in the country that provides maternity services and is the largest maternity facility within the Ghana Health Service (GHS). It receives tertiary and high-risk obstetric cases that have been 'referred' from the Korle Bu Teaching Hospital (KBTH). The institutional maternal mortality (i.e. 490/100,000) is slightly higher than the national average of **358/100,000 (MoH, 2015).**

Figure 4: Picture of the Greater Accra (Ridge) Regional Hospital

A total of 11,406 pregnant women visited the antenatal clinic in 2015, representing a 46% increase on the previous year (2014). Total deliveries in 2015 were 8566. Forty-seven percent

(47.7%, 4,090) of the total deliveries was by caesarean section and approximately 40.5% (3468) of all its ANC cases in 2015 were referrals from other facilities. A total of 102 (1.2%) post-delivery infections including post-CS surgical site infections, puerperal sepsis/endometritis, abdominal abscess, and secondary PPH due to infections was recorded out of the total number of deliveries (8566). The major avoidable factors to the contribution to maternal deaths were health personnel; logistics and facility; and patient characteristics related. The major cause of maternal mortality was obstetric haemorrhage (47.6%). Again, obstetric haemorrhage and hypertensive disorders alone contributed more than half (66.6%) of the total maternal mortality in the hospital (Greater Accra (Ridge) Regional Hospital, 2016).

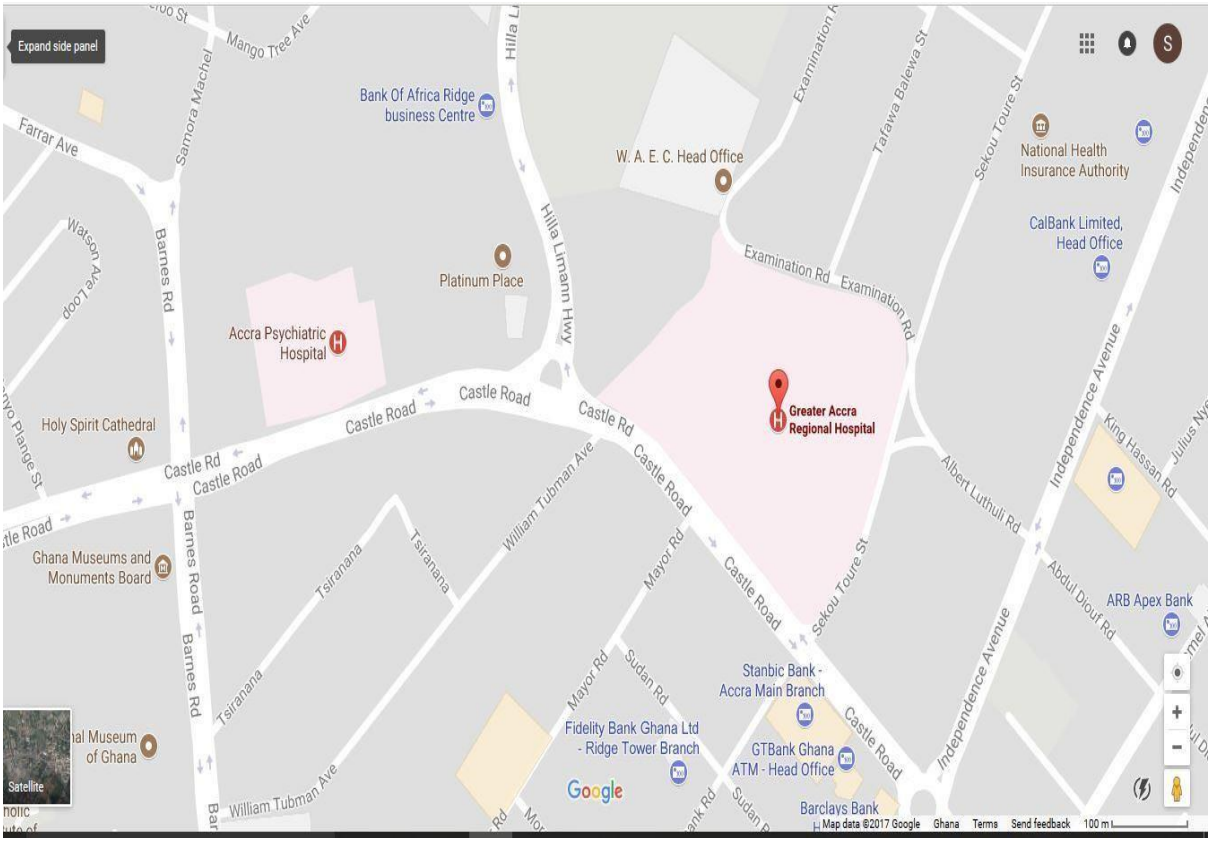

Figure 5: Spatial Location of Greater Accra (Ridge) Regional Hospital

3.4.0 Study Population

The study population was all obstetric clients who were hospitalized from **1st January to 31st December, 2015** and were at various stages of gestation at the Obstetric Unit of the Greater

Accra (Ridge) Regional Hospital. Obstetric clients are pregnant women, women in labour or women who have delivered.

3.4.0 Inclusion and Exclusion Criteria

A pregnant woman who is at any stage of gestation and on admission for more than twenty-four (24) hours was included. The study also included women in labor or have delivered within five (5) days. Adverse Events that are experienced by obstetric clients during hospital stay or during prior outpatient visits were included. Adverse Events that occurred when patients were transferred directly from outpatient care to inpatient care within the same facility were included. Adverse Events also included the whole period of hospitalization of the patient, if she had been treated in different departments during the period of her hospital stay. Medical records that had complete documentation with respect to certain important social, demographic and obstetric variables necessary to make relevant and appropriate judgement of the types, factors associated with adverse events and degree of preventability of AEs were also included. However, adverse events that occurred prior to the arrival of a patient on the hospital premises were excluded. Obstetric clients who stayed in the hospital for less than 24 hours were excluded.

3.4.1 Sampling technique & Sample Size *(for Retrospective Medical Records Review)*

This was a retrospective medical records review (i.e. patients' folders) of obstetric folders from 1st January, 2015 to 31st December, 2015.

The total sample size for the study was calculated using the formula:

Equation 1:

$$N = \frac{p\,(1-p)\,Z^2}{ME^2}$$

Where:

P = an estimated prevalence of 15% (Deilkås et al, 2017)

ME = a margin of error of 2.5% (i.e. 0.025)

Z = a Z-score of 1.96 for 95% confidence interval and substituting them into the equation

therefore, the estimated sample size was = 784. Using a design effect of 1.5, the estimated sample size worked out to: 784*1.5= 1176. A 10% non-response rate was calculated, and this took the total estimated sample size to 1141.

This was used to estimate the prevalence of adverse events among obstetric clients hospitalized at the study site.

3.4.2 Sampling technique & Sample Size *(for Case Control Study)*

A case-control study design was used to determine the factors that are associated with adverse events among obstetric clients in the study facility. This study design is appropriate in determining the manner of causation in rare diseases/events and also useful in understanding new diseases/conditions. The case-control was unmatched. The cases were derived from the cross-sectional study.

This was calculated using the formula:

$$N = \frac{2\bar{P}(1-P)(Z_{\alpha/2}+Z_{\beta})^2}{\Delta}$$

P_1 = prevalence in group 1 (15%)

P_2 = proportion of disease in group 2 (8%)

$\bar{P} = \frac{\bar{P}_1 - \bar{P}_2}{2}$ (Average) = 15% (Deilkas et al., 2017)

Δ = 7% (expected difference between nulliparous and multiparous)

$Z_{\alpha/2}$ = surface level set at 5%

Z_{β} = power set at 0.8 or 80%

N = number per group

Total sample size estimated were **325 cases and 325 controls**.

A total of **325 cases and 325 controls** were thus selected from the overall study population of 2843. Complete data sets were used for the analysis in both the cases and the controls. The controls were randomly selected from the trigger negative medical records (i.e. 2456 folders) using MS Excel 2010. **Every control was assigned a number and randomly selected the numbers-sampling without replacement**. The cases were obstetric clients *(i.e. pregnant women, women in labor and/or delivered)* and should have been on admission for not less than 24 hours. The cases should also have at least one adverse event (e.g. burst abdomen, surgical site infection, etc) present during the period of hospital stay. The cases were the medical records/folders with positive triggers for AEs. A trigger could be described as the harm itself or provide a hint that suggests that harm has occurred (e.g. perineal tear). The controls did not have any adverse event present during the hospital stay.

3.6.0 Data Collection Techniques/Methods and Tools

3.6.1 Retrospective Medical Records Review

The data collection method was based on the adaptation of the instrument used by the Department of Health & Human Services (HHS) Office of Inspector General (Levinson, 2010) involving a **four-stage** review of patient folders. The adaptation of the study instrument was done by the Principal Investigator (PI). Administrative data and medical records of patients were reviewed to identify AEs.

There was a four (4)-stage review of medical records/folders of obstetric clients. The first (1st) stage of the review involved a screening method to identify folders/medical records that had a length of stay of more than 24 hours and adequate documentation. These folders were included. The second (2nd) stage of the review process involved the identification of folders that were likely to include an adverse event. This was done to reduce the number of cases that required the third (3rd) stage obstetrician gynaecologist review. Nurse/midwife reviewers did a full review of all the medical records during the first and second-stages to identify evidence of potential adverse events or triggers *(e.g. surgical site infection, perineal tear, fall, error in diagnosis etc)* that may identify adverse events *(illustrated in Figure 6)*. About 11% (313) of both the triggers of positive and negative folders were randomly selected and reviewed again by the team of nurses/midwives as part of the accuracy and consistency checks of the data collection process. For all the triggers identified in the positive folders by the nurses/midwives, they determined the extent to which the events were preventable, their impact on the patient, and whether or not the event was due to the healthcare management process. The judgement of the degree of preventability was done guided by an algorithm developed by Levinson et al. (2010) illustrated in Figure 7.

Obstetrician reviewers later did a full review and an independent assessment of approximately 50% (191 out of 387) of all the trigger positive medical records and also determined the extent to which the events were preventable, their impact on the patient, whether the event was due to medical management or the disease process and identified opportunities for improvement after the initial data collection by the nurses. All the mortality folders were not reviewed by the obstetrician/physician reviewers because they could not be found after the initial review by the nurses/midwives. These *(i.e. mortality folders)* were therefore not included in the analysis.

Every folder was reviewed twice independently by two (2) different obstetricians after the initial review by the nurses/midwives. The second independent review constituted the fourth (4^{th}) stage of the review process. Folders that had conflicting judgments in the review process were referred to an independent reviewer *(i.e. a third obstetrician reviewer whose grade was not lower than a Senior Specialist)*. There was a total of 30 of such discrepant folders that were re-reviewed by the independent reviewer. This was done to ensure consistency and accuracy between reviewers as part of the data collection process. There were **eight (8) obstetrician gynaecologists** who did the review from 10^{th} March to 29^{th} September, 2017. Ten percent (10%) of all the trigger-negative medical records/folders were randomly selected and reviewed by all ***(i.e. eight (8))* obstetrician reviewers** for adverse events as part of a sensitivity analysis of the trigger methodology in stage one (1). For each event, obstetricians classified its type, associated (i.e. causative) factors and the degree of preventability. Assessment of the degree of preventability was guided by the algorithm developed by Levinson (2010) as illustrated in Figure 7. The sampling and data collection process was equally concerned about the actual care that was provided, the specific categories of the providers of care, the actual care that was received by the specified group of people (i.e. obstetric clients) and the capacity of the providers to also **provide the care**.

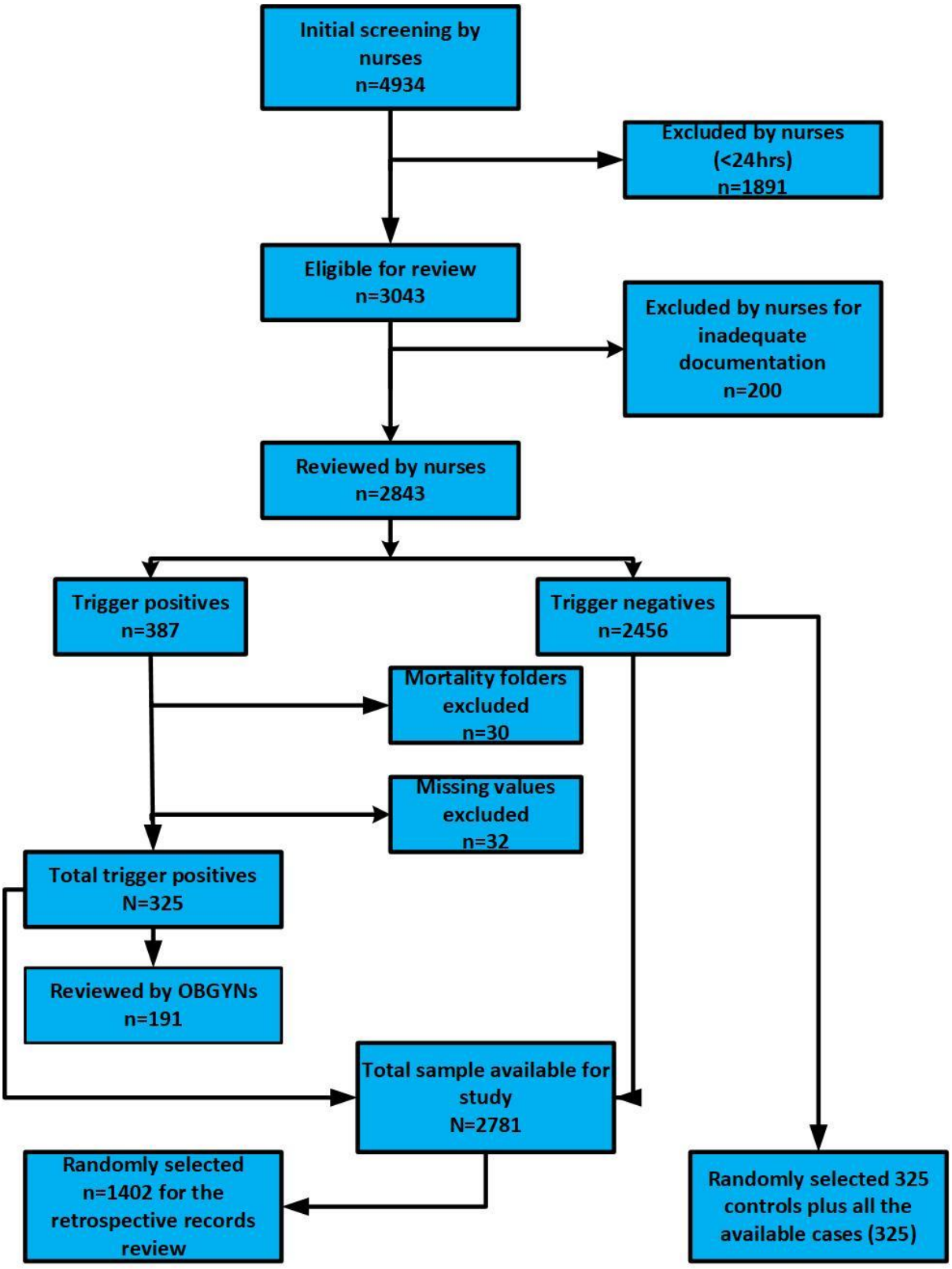

Figure 6: The Data Collection Process

Suggested responses of judgement on preventability was also guided by Figure 7 *(adopted from Levinson, 2010)*. The judgement of an adverse event was also guided by the confirmation of the clinical diagnosis, justification of treatment provided (including surgery) and the completeness of any surgical procedure.

The data collection instrument had some open-ended questions which allowed the reviewers to identify at least three (3) factors that are associated with the cause of the adverse event, describe the manner in which the AE could have been averted and the reasons for the failure to prevent any adverse event that occurred. Responses to these questions were provided by the reviewers based on their clinical judgement and experience during the review process. These responses were provided for every folder that recorded the presence of an adverse event or had a positive trigger.

The documents that were reviewed *(together with the medical records/folders)* as part of the process *(whenever available)* included:

1. Fluid intake-output chart
2. Post-delivery observation form
3. 4-hour chart
4. Nurses' treatment sheet
5. Nurses' notes
6. Nursing record
7. Form of consent for operative treatment
8. **Pre-operative checklist**
9. Anesthetic record

10. Post-operative records
11. ANC record book
12. Patient folder
13. Partograph
14. MgSO4 Protocol chart
15. In-patient treatment costing sheet
16. Ridge Maternity vital signs/observation chart

The first phase of the data collection process was from 28th November, 2016 to 26th January, 2017, while the second phase of reviews by the obstetrician gynaecologists was from 10th March, 2017 to 29th September, 2017. The nurse/midwife reviewers converged daily *(except on Sundays)* at the medical records department of the Greater Accra (Ridge) Regional Hospital throughout the period of the review. Obstetrician reviewers, however, did the reviews at their own pace and convenience in their respective locations. Folders were delivered to them *(i.e. obstetrician gynaecologist reviewers)* by the Principal Investigator (PI) **whenever it was requested for.**

Adverse events that could have been averted by ensuring improved assessments or alternative actions were called 'preventable adverse event' while those that could not have been averted either as a result of the complexity of the condition of the patient or the care required (Levinson, 2010) were called 'non-preventable adverse event'.

In Figure 7, the algorithm that was used to guide the judgement of preventability of an adverse event among obstetric clients is shown. A determination of preventability is made by a reviewer when he/she determines that the harm could have been averted had the care team at the time

used alternative actions or improved assessments. A preventable AE could be a medical error (such as administering the wrong dose of magnesium sulphate to a patient), substandard treatment (such as failure to regularly turn a pressure ulcer patient), inadequate monitoring among others. The classification of the preventability of AEs was done by individual experts who worked separately or independently unlike in other studies (Brennan, 1991) that had a panel of experts who shared the same space and worked together.

In this study, the WhatsApp platform was created to facilitate discussions among the reviewers. There was also the obstetrics protocol *(of the Greater Accra (Accra) Regional Hospital)* that was a useful reference to the reviewers in the process of the review.

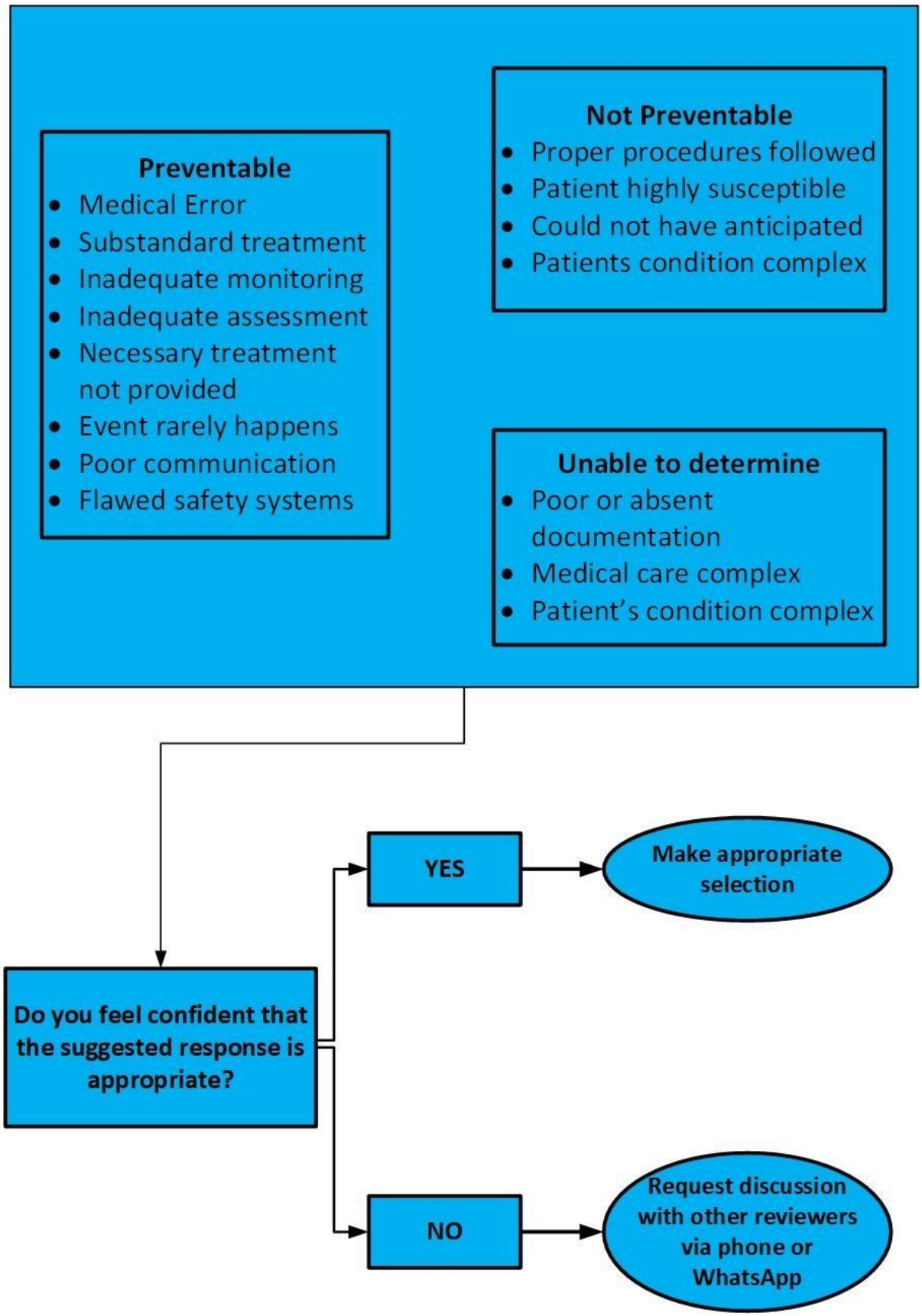

Figure 7: Algorithm used by the Reviewers to Evaluate the Preventability of Adverse Events among Obstetric Clients in the Study Site (Adapted from Levinson, 2010)

A 6-point *(even numbered)* Likert-scale for assessing the preventability of the adverse events was used to classify the occurrence. Adverse events that occurred during the study period *(i.e. 2015)* were recorded by the reviewers. Obstetricians were also allowed to use their clinical experience and judgment to determine the degree of preventability. Discrepancies in any two (2) obstetrician reviewers were noted by the PI and were settled by a third (3^{rd}) independent reviewer. Reviewers were also asked to assess the level of preventability of adverse events on a six (6) point Likert scale i.e. from 1 *(virtually no evidence of preventability)* to 6 *(virtually certain evidence of preventability)*. For instance, if a reviewer identifies an AE such as excessive bleeding, (s)he will determine the degree of preventability and select appropriately guided by the 6-point Likert scale e.g. slight to modest evidence of preventability (2) to virtually certain evidence of preventability (6). When the reviewer thinks that the AE is not preventable, he will just go to the preventability scale and select 1 (virtually no evidence of preventability).

3.6.2 Case Control Study

There was a selection of **650 cases and controls** to help estimate the factors that are likely to cause adverse events among obstetric clients in the study site. **Equal numbers of cases *(i.e. 325)* and controls *(i.e. 325)*** were estimated and used for this study. The sample selection *(of cases and controls)* relied on medical records that had complete documentation and met the inclusion criteria. The total number of cases that was used comprised of all the trigger positives identified during the retrospective review process. The controls were randomly selected from the total trigger negative data set using MS Excel. **The controls were assigned numbers and these numbers were selected non-randomly without replacement—sampling without replacement.** The controls also comprised all the trigger negative medical records identified

during the retrospective medical records review. There was unmatching of the cases and controls. Various authors believe that using multiple approaches to data collection can provide useful diagnostic information relating to the variables being studied (Collier & Elman, 2008; Rice & Holloway, 2014).

3.7.0 Quality Control/Assurance

This section describes the quality control/assurance systems that were instituted as part of measures to guide a successful conduct of the study.

3.7.1 Reviewer Recruitment and Training

The team of reviewers included fourteen (14) nurses/midwives with two (2) to seven (7) years working experience. There were **eight (8) obstetrician reviewers** who were made up of three (3) Consultants, three (3) Senior Specialists and two (2) Residents. Three (3) of the reviewers *(two obstetricians and 1 midwife)* were internal *(i.e. worked as members of staff of the facility where the study was conducted)*. The other reviewers were drawn from the Korle Bu Teaching Hospital (KBTH), Maamobi General Hospital all in the Greater Accra Region, and from the University of Cape Coast Teaching Hospital in the Central Region of Ghana. This **was** unlike a study in Sweden by Deilkås, et al., (2017) who used only internal members of staff as the medical reviewers using the Global Trigger Tool (GTT). The recruitment criteria for the obstetrician gynaecologists included the following:

1. Practicing in the specialty for not less than 5 years
2. At a minimum, be in Senior Residency training program
3. Available and willing to do the review on probono basis
4. Should be in good standing with Medical & Dental Council (MDC)

5. Interested in patient safety and quality of care among obstetric clients

Two (2) of the reviewers dropped *(out of the initial total of 10 obstetrician gynaecologists)* because of their unavailability to review their assigned folders. Their folders were reassigned to the other reviewers.

The recruitment criteria of the nurse/midwife reviewers included the following:

1. Should be in good standing with the Nurses & Midwifery Council (N&MC)
2. Practicing nursing/midwifery for not less than 2 years
3. Available and committed to do the review
4. Interested in quality and patient safety among obstetrics clients

The recruitment of the reviewers was through the personal contact of the Principal Investigator (PI) and the Clinical Supervisor *(who is a Consultant Obstetrician Gynaecologist)*. A two (2) day face-to-face training was organized for the nurse reviewers *(or data collection team)*. During the training, the study protocol, institutional obstetric protocol, definitions and the review forms were explained. Some examples of AEs were also discussed.

There was a three (3) hour face-to-face training for the obstetrician reviewers. Prior to the training, the project protocol was shared via mail for their study and perusal. The team was taken through the various algorithms and the data collection instrument developed by the PI. A WhatsApp platform was created for the nurse/midwife and obstetrician reviewers to facilitate discussions, share information, seek and provide clarity on issues, among others. Each of the reviewers were given five (5) initial folders for practice by the PI after the training session. All the reviewers were trained by the PI. The Clinical Supervisor was however called upon to provide clarity on specific obstetric related issues whenever necessary. The review

process for all the reviewers was structured to assess the factors associated with AEs and preventability. Reviewers were guided through a series of questions before any final judgement was made. Appropriate feedback was provided to each reviewer. Inter-rater reliability was estimated by calculating the K-statistic for both nurses and obstetricians.

3.7.2 Data Processing/Data entry

Data were checked for completeness and correctness and was double-entered into data sheets on a daily basis. Data cleaning and verification were done regularly to identify answers that were out-of-range, missing data and responses that were inconsistent. Data entry was done using Excel V for Windows 10.

3.7.3 Reliability and Validity Testing

As part of measures to ensure the reliability and minimize variation of the review process between reviewer, some of the medical records/folders *(11% of all the medical records)* were randomly selected and reviewed again by two nurses in the first stage. In the third (3^{rd}) stage, all the positive-trigger folders *(identified by the nurse/midwives)* were reviewed by obstetrician gynaecologists. Every folder was reviewed independently by two obstetricians during the third (3^{rd})-stage review. For instance, folder 0001 was reviewed by reviewer AA and BB. Discrepancies in the identification of adverse events between any two obstetrician gynaecologist reviewers were resolved by a third reviewer. The issue of reliability was further addressed by multiple training sessions for each category of staff *(by the Principal Investigator and the Clinical Supervisor)*. A reliability test was also performed among the reviewers.

3.8.0 Study Variables

Demographic variables included age at hospital admission, marital status and occupation. Clinical variables were number of ANC attendance, date and time of referral, date and time of admission, date and time of discharge, time of diagnosis, time treatment started, date and time of AE, location in the hospital where AE occurred, gestational age, FH status, parity, gravidity, referral institution, referral diagnosis, definitive/working diagnosis, systolic and diastolic BP, mode of delivery, outcome of delivery, condition (normal/complication) and medical/surgical history. Other clinical study variables are presented in Table 2.

Table 2: The various outcome measures of the study

Determining the presence of an adverse event was based on:	
1	An unintended (physical/mental) injury which:
	Results in: • temporary or permanent disability • death or • prolonged hospitalization *(any hospital stay greater than 5 days after delivery)*
	Caused by: healthcare management rather than the patient's underlying medical condition or disease
Factors likely to cause an adverse event were also based on a 4-point Likert scale of	
1	Unlikely to be relevant
2	Possibly relevant
3	Somewhat important
4	Very important
Types of AEs	
1	Adverse events related to medication
2	Adverse events related to patient care
3	Adverse events related to surgery
4	Adverse events related to infection
5	Adverse events related to diagnosis

Table 3: The various outcome measures of the study

Degree of preventability of the adverse events was based on a 6-point Likert scale of	
1	**No preventability** a. (virtually) no evidence for preventability
2	**Low preventability** b. Slight to modest evidence of preventability (i.e. management causation) c. Preventability not quite likely (50/50, but close to call)
3	**High preventability** d. Preventability more likely than not (more than 50/50, but close to call) e. Strong evidence of preventability f. (Virtually) certain evidence of preventability

3.8.1.0 Data Analysis

3.8.2.0 Outcome Measures

In Table 2, a summary of the measures is presented. The determination of adverse events was based on four (4) criteria as illustrated in table 2. Degree of preventability and causative factors was measured on a six (6) and four (4) point Likert scales respectively as illustrated in Table 2. Also, patient's demographic characteristics such as age, marital status, number of ANC visits; and admission characteristics, such as length of stay at the hospital, admissions status (elective, C/S, referral), and admission and discharge diagnosis were also measured.

3.8.2.1 Statistical analysis

Qualitative data **(i.e. responses from the open-ended questions from the questionnaire)** were analysed based on the three stages of analysis by Miles and Huberman (1994) which involved data reduction and display stage where scripts were independently read and re-read by identifying key codes and categories which were placed in context charts. Secondly, conclusions were drawn by identifying category clusters and by noting relationships within the data which lead to the development of themes and sub-themes. Finally, the results were confirmed by weighting the evidence and making contrasts and comparisons. Triangulation with other findings was made to ensure that there was agreement. Inter-rater reliability (IRR) of adverse events measures were performed by arranging for multiple reviews of the folders by the different reviewers. The results of the screening were later compared. IRR is a measure of whether if the same test is applied to the same respondent or subject by the same rater *(or reviewer)* on two different occasions, the same results will be produced (Walshe, 2000). Cronbach's alpha[1] was also obtained for all possible combinations of items. The following rule of thumb applies in dealing with Cronbach's alpha: "> .9- Excellent, > .8- Good, >.7- Acceptable, >.6- Questionable, > .5- Poor and <.5- Unacceptable[2]". AMOS V. 25.0 was used to perform the Confirmatory Factor Analysis (CFA).

The prevalence of any adverse events was defined as all adverse events that are found by the review of the study as a proportion of *(sampled 2015)* admissions, while the incidence rate was also defined as all the adverse events recorded by frontline healthcare providers during the 2015

[1] Cronbach's alpha is a test reliability technique that requires only a single test administration to provide a unique estimate of the reliability of a given test. It is the average value of the reliability coefficients one would obtain for all possible combinations of items when split into two half-tests (Gliem & Gliem, 2003)

[2] George, D. & Mallery, P. (2003). SPSS for Windows step by step: A simple guide and reference. 11.0 update (4th ed.). Boston: Allyn & Bacon.

sampled admission *(and later assessed to be an adverse event by a study reviewer)* (Davis et al., 2002).

3.8.2.2 Demographic characteristics

Patient characteristics were described with means as well as medians with interquartile ranges (IQRs). The positive predictive values were also reported. All prevalence rates were calculated at 95% Confidence level. Average length of stay, classification of the respective BPs; frequencies, percentages; and cross tabulations were also performed.

3.8.2.3 Types of adverse event

Frequencies, percentages, means, standard deviations (SD), median, inter quartile range (IQR), tables and charts illustrating the types of adverse events among obstetric clients were done. Chi-square tests & p-value to determine whether the most commonly reported factors have any significant interrelationships were also explored. Pearson's Correlation *(if normally distributed)* between the variables of the nature of AEs was also done. Pairwise comparisons to determine which of the variables contribute highest to the nature of adverse events among obstetric clients were undertaken.

3.8.2.4 Factors Associated with AEs

A 62-item questionnaire to identify various factors associated with AEs was developed guided by the literature. Data that were collected from about 325 positively triggered clients was used to verify the dimensionality of the factors associated with AEs and to assess the validity and reliability of the instrument. Exploratory Factor Analyses (EFA) were performed for the Likert Scale items and four (4) components were extracted. The Principal Component Analysis (PCA) was the extraction method used. It *(i.e. Principal Component Analyses (PCA))* was performed to reduce the components to fit a regression model. The factor scores were used in a multiple regression analysis against other variables.

The Confirmatory Factor Analysis (CFA) was used to test the hypothesis of the model of the EFA after fitting the four (4) extracted components *(i.e. 1, 2,3 and 4)*. Factor loadings were determined for each item in a factor. Factor loadings of +/-0.60 indicated significance at the α <0.05 level. Items with factor loadings +/-0.60 or greater were retained in the factor *(unlike >0.4, as used in other studies by other authors such as Berghaus et al., (2005); Sower et al., (2001)*; and these contributed significantly to the overall variations observed in the factor (Berghaus, Lombard, Gardner, & Farver, 2005; Sower, Duffy, Kilbourne, Kohers, & Jones, 2001). Other considerations that were made in deciding which factors to retain was the use of the scree plot, where the factors were graphed against their respective eigenvalues and keeping only those that occur before the drop in the eigenvalues starts to level-off. Factors were also rotated to ensure a simplification of their structures and to also enhance interpretability.

A reduced subset of the original questions was later selected based on the factor model. One original variable was selected to represent each factor. The variables were also selected based

on a consideration of their representation of the general themes of the factor, the relative strength of their factor loadings *(i.e. >0.60)* and their relevance to adverse event causation. After the selection of a final model, standardized factor scores were calculated on the variables. These scores were later assessed as causative factors in a model-based logistic regression analysis to determine whether they were associated with the observation of the presence of an adverse event or not.

The various extracted components were validated by estimating the construct and divergent validity. Frequencies, percentages, means, standard deviations (SD), median and inter quartile range (IQR) were also validated, and a multiple logistic regression analysis was performed. Tables illustrating the factors associated with adverse events among obstetric clients were presented. The factors were also analysed thematically. SPSS Amos V. 25.0 was used to perform the Confirmatory Factor Analysis (CFA).

Reliability testing was performed using the Cronbach alpha *(which has been established as the approach to evaluating the reliability of an instrument that avoids the weaknesses inherent in the test-retest and split half approaches.* Cronbach alphas equal to or greater than 0.700 indicated good internal consistency reliability (Sower et al., 2001). Kappa statistic was also computed to test the inter-rater reliability between the reviewers i.e. between doctors; between nurses/midwives; and between doctor & nurses/midwives.

3.8.2.5 Degree of Preventability

The prevalence and preventability of events among obstetric clients were analysed in categories of preventability. An algorithm was adopted (Figure 8) and used as a guide by the

reviewers in their judgement. This was done to ensure consistency among the reviewers. There was also a list of associated (i.e. causative) factors that was pulled from the literature that also guided the reviewers. All adverse events were also summarized with frequencies and percentages; means, standard deviations (SD), median, inter quartile range (IQR), tables & charts. PCA was performed to reduce the components to fit a regression model. For all the analysis, p-values ≤ 0.05 was considered statistically significant. The variables were reduced to binary data. The factor score was saved into one component using a score system. Multilevel linear regression analysis was performed to investigate the association between patient characteristics and AEs (i.e. types, associated (i.e. causative) factors and the degree of preventability). Stata software, version 13.0 (STATA Corp., College Station, TX) was used for all the statistical calculations.

Confounders that may be associated with adverse event were also identified. Parity was coded as nulliparous or parous. Gestational age was categorized into preterm *(less than 37 to 37+6weeks)*, term *(38 to 40+6weeks)* and post-term *(41+0 to 41+6weeks)* (American College of Obstetrician Gynecologists (ACOG), 2013; Engle, 2016). Maternal age was also coded as: <35years and >35years respectively.

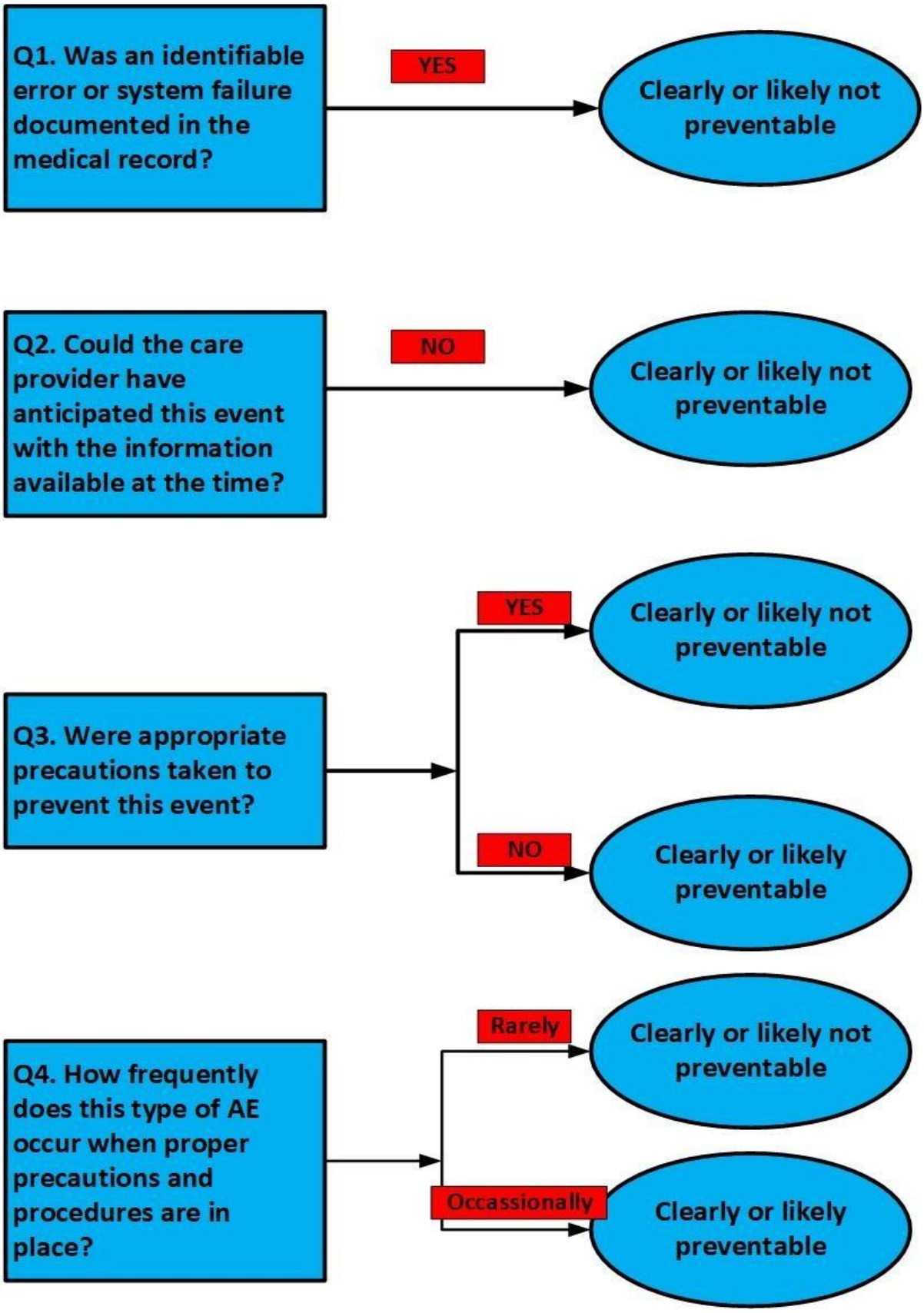

Figure 8: Algorithm to determine the degree of preventability of AE among obstetric clients at the study site (Adopted from Levinson, 2010)

3.9.0 Ethical Approval

Approval for the study was sought from the Ethics Review Committee (ERC) of the Ghana Health Service (GHS). Since this study was a retrospective folder review *(i.e. secondary data)*, informed consent from patients was not necessary. The study posed minimal direct risks to patients since this was a retrospective records review. The data collection process did not collect any information on patient names other than the folder numbers and other variables indicated in the data collection instrument *(shown Appendix 1)*. Permission was sought by the PI and was subsequently granted by the facility manager *(find evidence of this in Appendix 6)*. The team members at the Records Department only experienced minimal distraction in their daily activities by way of retrieving the medical records/folders for the data collection team. An arrangement was however made with the Head of the Medical Records Department to ensure that the medical records were retrieved outside their normal working hours to avert the distractions.

The nurse reviewers were compensated for their time. They were also provided with snack and lunch during the process of reviewing. The obstetrician gynaecologist reviewers were not given any monetary compensation. However, they were informed that they would be duly acknowledged in all publications and reports of the study. They were also informed of being co-authors in any publication and write-up, provided they contributed to the manuscript development. There was no other compensation or financial incentives paid to the obstetrician gynaecologist reviewers. There was also minimal distraction to the obstetrician gynaecologist because the reviews were done at their convenience. Permission was, however, sought and was granted from the study location, i.e. the Greater Accra (Ridge) Regional Hospital, before accessing any of the medical records. The reviewers had their capacity built in adverse event

investigation. The capacity of the obstetric unit and the quality assurance (QA) outfit was developed to enable them investigate and undertake adverse event investigation and reporting. The study instrument was also made available to the obstetric unit in undertaking adverse event investigation.

3.9.1 Confidentiality

In this study, efforts were made to ensure the confidentiality and/or anonymity of the patients and the healthcare providers. All the members of the data collection team were made to sign a confidentiality undertaking that deterred them from making any public disclosures of their findings. The Head of the Medical Records Department of the Ridge Regional Hospital, and other members of the data collection team, were made to sign an informed consent form/reviewer. They were also provided with details of the study process, its benefits/risks to the institution and their role in the entire study.

The anonymity of patients and healthcare providers were of utmost importance in this study. The records of the data collected each day were stored in a locked locker with only the principal investigator having access and was also never left unattended. The data collected were password protected. Each patient record was given a unique identity and these patient identifiers were also kept separately from the primary database. The medical records/folders were kept out of the medical records department as a result of this study for about six (6) months. The identities of patients and/or physicians were not revealed in any research report or publication. The names of patients were not included in the database. After the collection and analysis of the data, all the identifiers of the medical records were destroyed. All institutional identifiers were removed in the event that any sensitive data were published. All

the ethical principles of beneficence, non-maleficence and respect were strictly adhered to. There was no conflict of interest situation in this and none arose during the study period. Data were used strictly for the purpose of the PhD program.

CHAPTER 4

RESULTS

4.1 Introduction

The findings of the study are presented in this chapter. These findings are based on data extracted from medical records/folders and in line with the objectives of the study. They are presented as follows:

4.2.1 Socio-Demographic Characteristics

As illustrated in Table 4, more than two-thirds of the obstetric clients were married (1164, 83.0%), resided in Greater Accra (1249, 89.1%), and were referred from a government facility (1097, 78.2%). About two-thirds (1075, 76.8%) of the total clients were aged between 20-34 years. Obstetric clients who were less than 20 years (11, 16.7%) were more likely to develop adverse events than the other age groups. Again, adverse events were high among obstetric clients referred from government facilities (141, 12.9%) than from private facilities (27, 8.9%); singles (30, 12.6%) than in the married (138, 11.9%); and among Christians (137, 11.6%) than Muslims (31, 14.2%). These differences were however not statistically significant *(p-value >0.005)*. The mean maternal age of the clients was 30.0years ± 5.8years. The minimum maternal age was 14 years, while the highest maternal age was 48years. None of the mean differences in these variables was statistically significant. The maternal age was coded as: <20years, 20-34 years and >=35 years respectively.

Table 4: Socio-demographic characteristics of the obstetric clients (from the retrospective records review) in the Greater Accra Regional Hospital

Variables	Negative n (%)	Positive n (%)	*P-value*	Total
Age group				
<20years	55 (83.3)	11 (16.7)	0.197	
20-34years	955 (88.8)	120 (11.2)		
>=35years	224 (85.8)	37 (14.2)		1402
Mean Maternal Age	**30.0 years ± 5.8 years**			
Location of residence				
Greater Accra	1104 (88.4)	145 (11.6)	0.218	
Outside Accra	130 (85.0)	23 (15.0)		1402
Marital status				
Single	208 (87.4)	30 (12.6)	0.746	
Married	1026 (88.1)	138 (11.9)		1402
Religion				
Christian	1047 (88.4)	137 (11.6)	0.268	
Muslim	187 (85.9)	31 (14.2)		1402
Referral institution				
Government	956 (87.2)	141 (12.9)	0.057	
Private	278 (91.2)	27 (8.9)		1402

Source: Field data, 2016

Key
Negative: No adverse event present
Positive: Adverse event was present

4.2.2 Maternal Characteristics

As shown in Table 5, the mean gestational age of the clients was 37.4 weeks±4.9weeks. The gestational age was statistically significant *(p-value <0.013)* and the risk of developing an AE increased with increasing maternal age. ANC non-attendants also had a higher risk of

developing an AE (7, 28.0%) than the attendants (161, 11.7%) and this difference was statistically significant *(p-value 0.013)*. A third (436, 31.0%) of the women were nulliparous while more than half (749, 54.4%) had gravidity >=3. Neither parity nor gravidity had any significant difference on the outcome *(i.e. adverse events)*. However, AEs decreases with increasing parity and gravidity.

Table 5: Maternal characteristics of obstetrics clients in the Greater Accra Regional Hospital, Accra

Variables	Negative n (%)	Positive n (%)	*P-value*	Total
ANC attendance				
Attendant	1216 (88.3)	161 (11.7)	0.013***	
Non-attendant	18 (72.0)	7 (28.0)		1402
Condition				
Normal	228 (87.7)	32 (12.3)	0.858	
Complication	1006 (88.1)	136 (11.9)		1402
FH Status				
Absent	20 (87.0)	3 (13.0)	0.875	
Present	1214 (88.0)	165 (12.0)		1402
Gravidity				
1 or 2	571 (87.4)	82 (12.6)	0.536	
>=3	663 (88.5)	86 (11.5)		1402
Parity				
0	387 (88.8)	49 (11.2)		
1 or 2	575 (86.6)	89 (13.4)	0.259	
>=3	272 (90.1)	30 (9.9)		1402
Gestational age				
Preterm	456 (91.4)	43 (8.6)		
Term	765 (86.3)	122 (13.8)	0.013***	
Post-term	13 (81.3)	3 (18.8)		1402
Mean Gestational Age	**37.4 weeks ± 4.9weeks**			
BP				
Normal BP	328 (86.5)	51 (13.5)		
Pre-Hypertension	559 (87.2)	82 (12.8)	0.131	
Hypertension stage I&II	347 (90.8)	35 (9.2)		1402

Source: Field data, 2016 *** *Statistically significant*

Key

Negative: No adverse event present **Positive:** Adverse event was present

The AE positivity decreased with increasing blood pressure among the patients with adverse event. This meant that, clients who had normal blood pressures had higher AE positivity than those who were hypertensive. There was however no statistical significance *(p = 0.131)* as shown in Table 5. Foetal heart (FH) was present in about 98.4% (1379) of the folders reviewed. Adverse events were present in 165 (12.0%) of the cases with positive foetal heart but FH was not statistically significant *(p = 0.875)*.

As shown in Table 6, the International Classification of Diseases (ICD) Code 10 was used to classify the medical conditions and diseases that the women suffered. More than a third of them were diagnosed with having maternal care related to foetus and amniotic cavity and possible delivery problems (858, 61.2%). About a third of the women (385, 28.5%) who had their diagnosis stated had more than one (1) clinical diagnosis. Adverse events were highest among obstetric clients who were diagnosed with complications of labour and delivery (14, 16.1%) and least among women who were diagnosed with "oedema, proteinuria and hypertensive disorders in pregnancy, childbirth and puerperium" (32, 9.5%). The diagnosis of the clients was not statistically significant *(p = 0.179)*. Similarly, adverse events rates were highest among obstetric clients who were jaundiced (5, 55%); diabetic (1, 33%); tuberculosis (1, 50%); and proteinuria (2, 20%) and vice versa. None of the mean differences of these conditions were statistically significant except those with jaundice *(p < 0.001)*. More than half (909) of the clients delivered via CS, however, obstetric clients who delivered vaginally (61, 12.4%) suffered more AEs than those who delivered via CS (107, 11.8%). This difference was however not statistically significant *(p = 0.740)*.

Table 6: Maternal characteristics of obstetric clients in the Greater Accra Regional Hospital, Accra, Ghana

Variables	Negative n (%)	Positive n (%)	*P-value*	Total
Diagnosis				
Oedema, proteinuria and hypertensive disorders in pregnancy, childbirth and puerperium	304 (90.5)	32 (9.5)		
Maternal care related to foetus and amniotic cavity and possible delivery problems	755 (88.0)	103 (12.0)	0.179	
Complications of labour and delivery	73 (83.9)	14 (16.1)		
Others	102 (84.3)	19 (15.7)		1402
No of diagnosis per client				
1	890 (87.5)	127 (12.5)		
2	313 (89.9)	35 (10.1)	0.350	
3	31 (83.8)	6 (16.2)		1402
Mode of delivery				
CS	802 (88.2)	107 (11.8)	0.740	
Vaginal delivery	432 (87.6)	61 (12.4)		1402
Medical Conditions				
Hypertension				
Negative	1206 (88.0)	164 (12.0)	0.927	
Positive	28 (87.5)	4 (12.5)		1402
Sickle cell disease				
Negative	1228 (88.0)	167 (12.0)	0.851	
Positive	6 (85.7)	1 (14.3)		1402

Source: ***Field data, 2016***

Key
Negative: No adverse event present
Positive: Adverse event was present

As shown in Table 7, obstetric clients who were jaundiced (5, 55.6%), diabetic (1, 33.3%), had proteins in their urine (proteinuria) (2, 20.0%) or tuberculosis (1, 50.0%) had a high AE positivity than clients without any of these conditions. The mean difference among jaundiced clients was statistically significant *($p < 0.001$)* while the other disease conditions was not. Again, AE positivity increased among clients with no previous surgery (150, 12.6%) than among those with a previous surgery (18, 8.7%).

Table 7: Maternal characteristics of obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra, Ghana (ctd)

Variables	Negative n (%)	Positive n (%)	*P-value*	Total
Jaundice				
NAD	1230 (88.3)	163 (11.7)	< 0.001***	
Positive	4 (44.4)	5 (55.6)		1402
Diabetes				
NAD	1232 (88.1)	167 (11.9)	0.254	
Positive	2 (66.7)	1 (33.3)		1402
TB				
NAD	1233 (88.1)	167 (11.9)	0.098	
Positive	1 (50.0)	1 (50.0)		1402
Proteinuria				
NAD	1226 (88.1)	166 (11.9)	0.433	
Positive	8 (80.0)	2 (20.0)		1402
Surgical history No previous surgery	1044 (87.4)	150 (12.6)	0.109	
Previous surgery	190 (91.4)	18 (8.7)		1402

Source: Field data, 2016 **** Statistically significant*

Key
Negative: No adverse event present
Positive: Adverse event was present

4.3.0 Prevalence of any Adverse Events among Obstetric Clients

The prevalence rate of Adverse Events (AEs) among obstetric clients in the study site was 12.0% (95% CI: 10.4% to 13.8%). This translates into 12 adverse events per 100 admissions. This simply implies that, for every 100 obstetric clients that are admitted in any of the units of the obstetrics department, 12 of them will suffer an adverse event during her hospital stay. Further still, approximately one (1) in ten (10) of every obstetric client admitted to any of the wards in the obstetric department will develop an adverse event during her hospital stay. Some obstetric clients experienced more than one AE which was preventable.

The prevalence of an adverse event was defined as all adverse events that were found by the review of the study as a proportion of the *(sampled 2015)* admissions associated with one or more AEs while the incidence rate was also defined as all the adverse events that were recorded by frontline healthcare providers during the sampled admission *(and later assessed to be an adverse event by a study reviewer)* (Davis et al., 2002).

4.3.1 Types of Adverse Events among Obstetric Clients

The findings on the types of adverse events among obstetric clients are presented in Table 8. More than half *(193, 66.3%)* of the total adverse events were surgical related. Some of these adverse events included obstetric trauma to the mother *(i.e. perineal, vaginal, and clitoral tears)*, trauma to the baby, excessive bleeding, etc. The perineal tears include first and second degree; and third- and fourth-degree tears. The least type of adverse event recorded was *'adverse events related to patient care' (2, 0.7%).*

The findings as presented in Table 9 shows that 168 (12.0%) obstetric clients experienced an adverse event out of the total medical records/folders screened (i.e. 1402). Some of the patients (16, 9.5%) experienced more than one adverse event out of the total adverse events recorded (168, 100%). The majority (93, 55.4%) of the adverse events occurred in the labour ward *(as illustrated in Table 10).*

Table 8: Types of adverse events among obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra

Nature/Types of AEs	n	%
Events Related to Surgery	**193**	**66.3**
Obstetric trauma to the mother (i.e. perineal tear, vaginal tear, clitoris tear)	142	48.8
Excessive Bleeding	26	8.9
Trauma to baby	11	3.8
Postpartum haemorrhage	11	3.8
Acute Respiratory Failure	1	0.3
Equipment Malfunction	1	0.3
DVT with or without Pulmonary Embolism	1	0.3
Burst Abdomen	0	0.0
Bladder or Ureteric Damage	0	0.0
Hypovolaemic Shock	0	0.0
Events Related to Treatment	**69**	**23.7**
Avoidable Delay in Treatment	47	16.2
Eclampsia (institutional)	16	5.5
Inadequate Monitoring Follow-Up of Treatments	5	1.7
Failure to Provide Prophylactic Treatment	1	0.3
Blood transfusion reaction	0	0.0
Avoidable Delay in Responding to An Abnormal Test	0	0.0
Errors in the Performance of an Operation, Procedure or Test	0	0.0
Errors in Administering Treatment	0	0.0
Events Related to Diagnosis	**15**	**5.2**
Delay in Diagnosis	8	2.7
Failure to act on results (i.e. lab) of monitoring or testing	4	1.4
Error in Diagnosis	3	1.0
Events related to medication	**8**	**2.7**
Severe Hypotension	3	1.0
Drug Reaction	2	0.7
Drug (inappropriate)	2	0.7
Delirium	1	0.3
Medication Error	0	0.0
Events Related to Infection	**4**	**1.4**
Respiratory Infection (Pneumonia)	2	0.7
Surgical or Procedural Site Infection	1	0.3
Septicaemia	1	0.3
Hepatitis B	0	0.0
Acute Hepatic Encephalopathy	0	0.0
Events Related to Patient Care	**2**	**0.7**
Left Ventricular or Congestive Cardiac Failure	2	0.7
Pressure ulcer/bed sore	0	0.0
Foetal Distress	0	0.0
Patient Fall with Injury	0	0.0

Source: ***Field data, 2016***

Table 9: Frequency of Adverse Events among obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra

Adverse Event	Frequency (n)	Percent (%)
Negative	1234	88.0
Positive	168	12.0
Total	**1402**	**100**

Table 10: Number & Location of Adverse Events among obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra

Number of AEs per client	Freq (%)
1	152 (90.5%)
≥2	16 (9.5%)
Total	168 (100%)
Location of AEs	
Labour & delivery ward *(ER, ICU, theatre)*	93 (55.4%)
Ward	75 (44.6%)
Total	**168 (100%)**

Source: Field data, 2016

Box 5: Examples of Adverse Events among obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra

Example 1: An Adverse Event

A 35-year-old gravida 2 para 1 was referred from *GHAH (located in the Greater Accra Region)* on 29th April, 2015 on account of big abdomen. She was 40 weeks pregnant and spent 6 days on admission. The client is married, a Christian and an antenatal clinic attendant. She sustained two (2) adverse events during the period of her admission:

1. Rupture of the urethra
2. Perineal tear

Example 2: An Adverse Event

A 19-year old student, married and resident in Greater Accra. She is a Christian and a regular ANC attendant from a government hospital. She is gravida 1 para 0, gestational age of 28 weeks and had a positive foetal heart. The diagnosis was severe pre-eclampsia + twin gestation and had a length of stay of 14 days. This client sustained three (3) adverse events during the period of her admission:

1. Medication error
2. Inadequate monitoring
3. Failure to act on lab >12hours

Example 3: An Adverse Event

A 29-year old resident of Madina, single, a Christian and a non-antenatal clinic attendant. She was referred from GHEH *(located in the Greater Accra Region)* on account of oligohydramnios. The foetal heart was present. She was gravida 1 para 1 and the gestational age was 33 weeks old. The adverse event the client suffered was **delay in treatment.**

This was as a result of lack of theatre space. An emergency CS (9:05PM) was done seven (7) hours after diagnosis (4:00AM).

4.4.0 Factors Associated with Adverse Events among Obstetric Clients

The factors associated with adverse events among obstetric clients hospitalized at the study site *(i.e. Greater Accra (Ridge) Regional Hospital)* was deduced using a case-control study after the estimation of the prevalence with a cross-sectional study. A total of 650 cases and controls were analysed. There was equal number of cases and controls which were unmatched.

As shown in table 11, more than two thirds (495, 76.2%) of both the cases and controls were between the ages *(maternal)* of 20-34years. The mean *(maternal)* age of the respondents was 28.9 years ± 5.8 years. Adverse events among the cases increased with increasing maternal age though not statistically significant *(p-value 0.827)*. The rate of developing adverse events also increased among the cases whose place of residence was outside Accra (40, 61.5%), married (270, 50.3%) and were Christians (271, 50.4%) referred from a government facility (250, 50.3%) than the controls. The average length of stay (ALOS) of the clients was 4.2days ± 5.7 days.

Table 11: Demographic Characteristics of the obstetric clients with respect to cases and controls in the Greater Accra Regional Hospital, Accra

Variables	Controls (0) n (%)	Cases (1) n (%)	*P-value*	Total
Age group				
<20years	18 (51.4)	17 (48.6)		
20-34years	250 (50.5)	245 (49.5)	*0.827*	
>=35years	57 (50.0)	63 (52.5)		650
Mean Maternal Age (SD)	**28.9 years ± 5.8 years**			
Average Length of Stay (SD)	**4.2days ± 5.7 days**			
Location of residence				
Greater Accra	300 (51.3)	285 (48.7)	*0.050*	
Outside Accra	25 (38.5)	40 (61.5)		650
Marital Status				
Single	58 (51.3)	55 (48.67)	*0.756*	
Married	267 (49.7)	270 (50.3)		650
Religion				
Christian	267 (49.6)	271 (50.4)	*0.678*	
Muslim	58 (51.8)	54 (48.2)		650
Referral institution				
Government	247 (49.7)	250 (50.3)	*0.781*	
Private	78 (51.0)	75 (49.0)		650

Source: Field data, 2016

The findings in table 12 show that, approximately equal percentage of both cases (49.0%) and controls (51.0%) were regular ANC attendants and had their FH present. ANC non-attendants had a higher percentage positivity of adverse events (17, 77.3%) among the cases than among the attendants (308, 49.0%). This percentage positivity was also highest among the cases (17, 77.3%) who were non-attendants than the control group (5, 22.7%). Adverse events among

obstetric clients increased with increasing gestational age among the cases. This trend was however opposite among the control group of the same variable *(i.e. gestational age)*. A client who is diagnosed of having *"complications of labor and delivery"* had a lower AE positivity while those diagnosed with the condition of *"maternal care related to foetus and amniotic cavity and possible delivery problems"* also had the least AE percentage positivity (46.3%) among the cases. The mean differences of ANC attendance, number of AEs per client, BP and diagnosis were statistically significant *(p-value <0.005)*. The parity of more than half (449, 69.1%) of both the cases and controls were 1 or 2. Clients who were nulliparous (101, 50.3%) had a higher percentage positivity than those who were parous (224, 49.9%). Parity however did not have any statistical significance *(p-value 0.932)*.

Table 12: Maternal demographic characteristics of obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra (among cases and control)

Variable	Controls (0) n (%)	Cases (1) n (%)	*P-value*	Total
No of AEs per client 0	325 (100.0)	0 (0.0)		
1	0 (0.0)	283 (100.0)	*0.000****	
2	0 (0.0)	7 (100.0)		650
ANC attendance attendant	320 (51.0)	308 (49.0)		
non-attendant	5 (22.7)	17 (77.3)	*0.009****	650
Condition Normal	58 (44.6)	72 (55.4)		
Complication	267 (51.4)	253 (48.7)	*0.170*	650
FH Status Absent	7 (33.3)	14 (66.7)		
Present	318 (50.6)	311 (49.4)	*0.120*	650
Gravidity				
1 or 2	147 (48.7)	156 (51.3)		
>=3	178 (51.2)	170 (48.9)	*0.529*	650
Parity				
0	100 (49.8)	101 (50.3)		
1 or 2	225 (50.1)	224 (49.9)	*0.932*	650
Gestational age Preterm	124 (54.2)	105 (45.9)		
Term	198 (48.7)	209 (51.4)	*0.040****	
Post-term	3 (21.4)	11 (78.6)		650
BP				
Normal BP	77 (45.6)	92 (54.4)		
Pre-Hypertension	145 (50.9)	140 (49.1)	*0.381*	
Hypertension stage I	103 (52.5)	93 (47.5)		650
Diagnosis				
Oedema, proteinuria and hypertensive disorders in pregnancy, childbirth & puerperium	92 (53.5)	80 (46.5)		
Maternal care related to foetus and amniotic cavity and possible delivery problems	190 (53.7)	164 (46.3)	*0.001****	
Complications of labour and delivery	18 (40.9)	26 (59.1)		
Others	25 (31.3)	55 (68.8)		650
Number of diagnosis per client				
1	239 (50.3)	236 (49.7)		
≥2	86 (49.1)	89 (50.9)	*0.791*	650

Source: Field data, 2016 **** Statistically Significant*

In the Univariate analysis in Table 13, number of ANC attendance was statistically significant (p-value <0.005). For instance, there was a three (fold) increase in odds of developing AE among ANC non-attendants than among ANC attendants. Even though gestational age was not statistically significant *(in the univariate analysis) (p> 0.05)*, the odds {1.29 (0.941.79)} of developing an AE among post-terms was higher than among those with term pregnancy. Again, clients with multiple diagnosis had higher odds of developing AEs than those with single diagnosis {1.04 (0.74-1.48)} though this was not statistically significant.

Table 13: Univariate Analysis of Predictors Associated with Adverse Events (AEs) among obstetric clients hospitalized at the Greater Accra Regional Hospital

Predictors	OR (95% CL)	*P-value*
Age	1.00(0.98 - 1.03)	*0.796*
Regions		
Outside Accra vs. Greater Accra	1.68 (0.98 - .84)	*0.052*
Marital status		
Married Vs.Single	1.07 (0.71 - 1.60)	*0.756*
Religion1		
MuslimVs. Christian	0.92 (0.61 - 1.38)	*0.678*
ANC Attendance		
Non-Attendant Vs Attendant	3.53 (0.29 - 9.69)	*0.014****
Referral Institution		
PrivateVs. Government	0.95 (0.66 -1.37)	*0.782*
Condition1		
Complication VsNormal	0.76 (0.52 - 1.12)	*0.170*
FH Status		
Present vs. Absent	0.49 (0.19 - 1.23)	*0.128*
Gravidity		
>=3 vs. 1 or 2	0.91 (0.67 - 1.23)	*0.529*
Parity		
Multiparous vs.Nulliparous	0.99 (0.71 - 1.37)	*0.932*
Gestational age		
Postterm vs. Term	1.29 (0.94 - 1.79)	*0.119*
BP		*0.381*
Pre-Hypertension vs. Normal	0.81 (0.55 - 1.18)	
Hypertension vs. Normal	0.76 (0.50 - 1.14)	
Length of Stay (LOS)	1.01 (0.98 - 1.04)	*0.371*
No ofdiagnosis		
2 vs. 1	1.04 (0.74 - 1.48)	*0.791*
Postpartum		
Complication vs Normal	0.53 (0.39 - 0.72)	*0.000****
Outcomeof baby		
Still vs. Live	2.27 (1.09- 4.73)	*0.027****

Source: Field data, 2016 **** Statistically Significant*

In the Multivariate Logistic regression presented in table 14, surgical history, gestational age and number of ANC attendance were statistically significant *(p≤0.05)*. The odds of developing AE among ANC non-attendants, post-term pregnancy and previous surgery were very high. The odds of developing an AE among the prehypertensive *(0.80 (0.54-1.20))* and the hypertensive *(0.82 (0.53-1.26))* were higher than those with normal BP, though not statistically significant.

Table 14: Multivariate Logistic Regression of Predictors of Adverse Event (AE) among obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra

Predictors	**OR (95%CL)**	***P-value***
Surgical history		
Previous surgery Vs. No Previous Surgery	0.51 (0.32 - 0.79)	0.003***
Gestational age		
Post -term Vs Term	1.43 (1.01 - 2.04)	0.044 ***
ANC attendance		
Non -Attendant Vs. Attendant	3.35 (1.21 - 9.57)	0.02 0***
Length of stay	1.01 (0.98 - 1.05)	0.442
BP		
Pre-hypertension vs. Normal	0.80 (0.54 - 1.20)	0.283
Hypertension vs. Normal	0.82 (0.53 - 1.26)	0.379
age		
>=35 vs. < 35	1.18 (0.74 - 1.88)	0.484

Source: Field data, 2016 *** *Statistically significant*

This table (Table 15) seeks to account for the correlation between the reviewers. It tries to control for the reviewer effect because of the correlation between them *(i.e. reviewers)*, especially when some of the doctors reviewed more than one (1) folder. Gestational age

was a 43% higher increase in odds among clients with post-term pregnancy than those with term pregnancy. There is a 44% decrease in odds of suffering from an AE in those with no previous CS than in those without a previous CS. There is also an increasing trend in blood pressure related adverse events among the respondents.

Table 15: Multivariate Logistic Regression using Generalized Estimation Equation (GEE) to Determine Adverse Events among Hospitalized Obstetric Clients at the Greater Accra Regional Hospital, Accra

Predictors	OR (95CL)	P -value
Surgical history		
Previous surgery Vs. No Previous Surgery	0.56 (0.38 - 0.83)	0.004***
Gestational Age		
Post-term Vs Term	1.43 (1.03 - 2.00)	0.032
ANC attendance		
Non-Attendant Vs Attendant	1.01 (0.98 - 1.04)	0.230
Length of Stay	1.01 (0.98 - 1.05)	0.430
Blood Pressure (BP)		
Pre-hypertension vs. Normal	0.75 (0.51 - 1.11)	0.147
Hypertension vs. Normal	0.66 (0.44 - .98)	0.048***
Age		0.879
>=35 vs. < 35	1.03 (0.66 - 1.61)	

Source: Field data, 2016 *Statistical significance****

As shown in Figure 9, adverse events (AEs) among obstetric clients in the study site increases with increasing age. This implies that, the older an obstetric client is, the more likely it is for her to develop an adverse event.

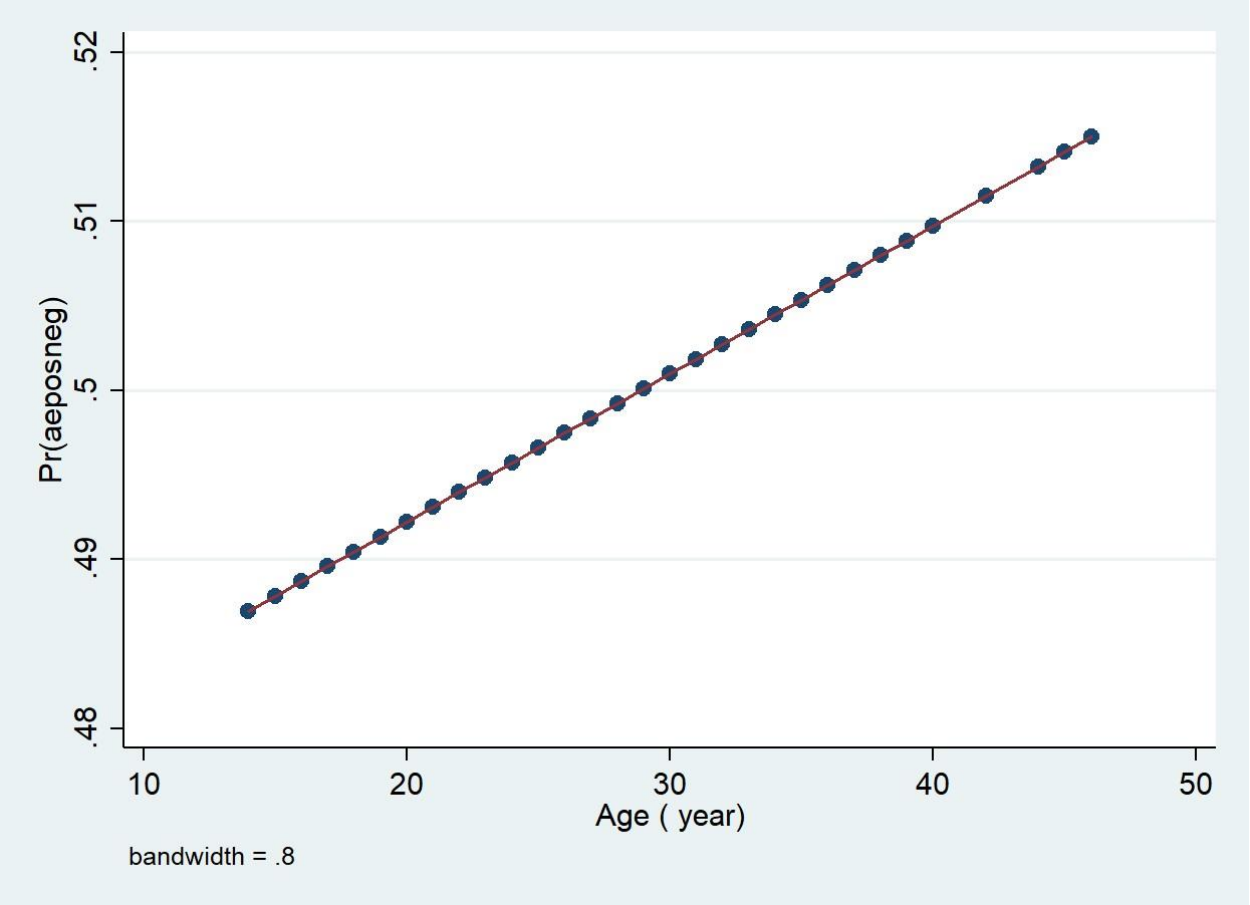

Figure 9: Distribution of age versus the probability of developing an AE among obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra

The scree plot (Figure 10) of the estimated factors associated with AEs is presented. A Principal Components Analysis (PCA) was performed to extract a fixed number of factors *(i.e. 4 components and 24-items from a 63-item questionnaire)*. The 64-items were organized thematically around the six (6) health systems building block. The four (4) extracted factors accounted for 52% of the total variance explained. The extracted factors were interpretable. Based on the assumption that, the components were related or correlated, the Promax Rotation Method was used. This assumption was consistent with the theory of interrelatedness between the components.

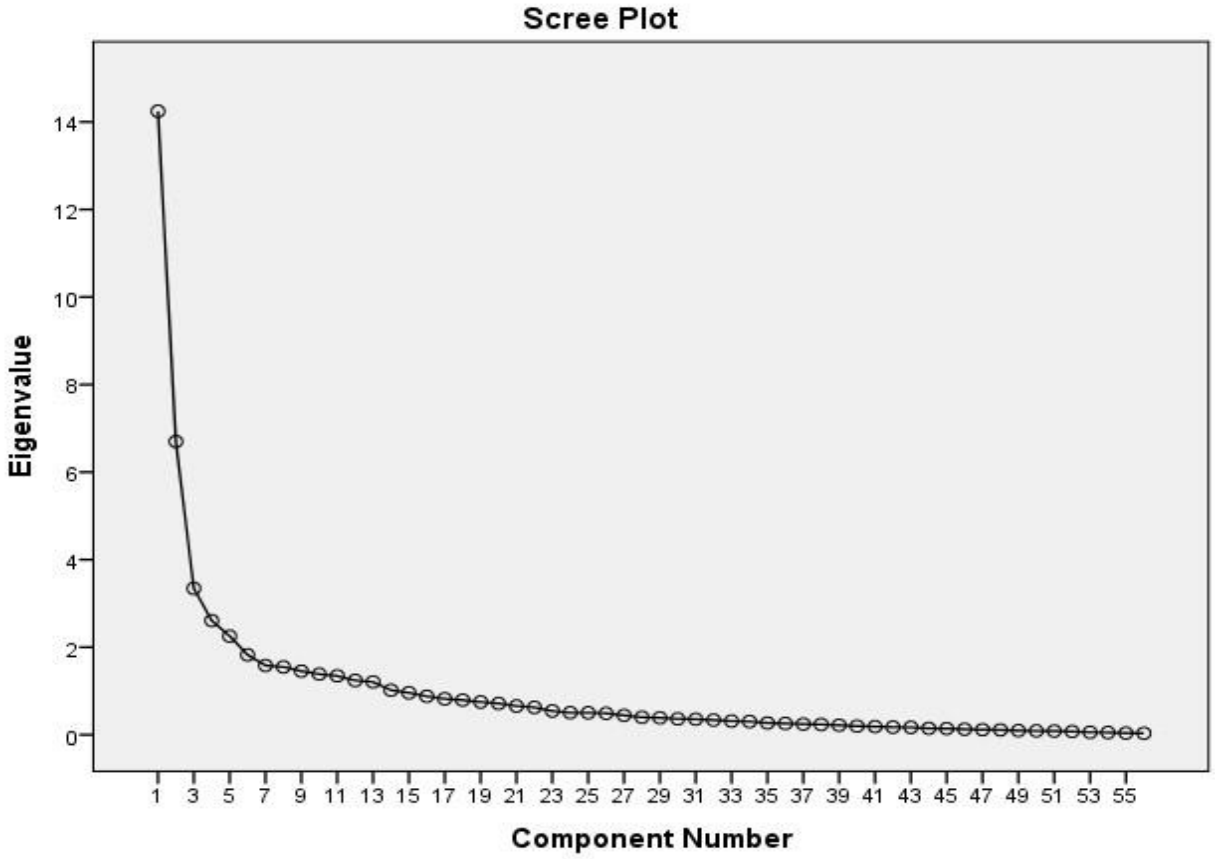

Figure 10: Scree Plot illustrating the cut-off of the various components of the Exploratory Factor Analysis

4.4.1 Description of the Factor Loadings

There were four (4) factors *(i.e. leadership/governance, health information, medical technology and service delivery)* extracted, as are presented in Table 16. Factor loadings (correlations) >0.60 obtained for the final model are also presented. The extracted factors were inconsistent with the factors on the original modified instrument. The six (6) health systems building blocks *(i.e. leadership/governance, human resource, health finance, medical technology, health information and service delivery)* and sixty-four (64)-items of the original instrument were reduced to four (4) health systems building blocks *(which did not include health finance and human resource)* and twenty-four (24)-items. There were

more items *(i.e. 9 items)* loaded on factor 1 than any of the other three (3) factors as illustrated in Table 16. About a third of the items *(i.e. 24)* were strongly correlated *(>0.6)*. The number of independent constructs that was measured by the instruments also seemed smaller. It is possible to reduce the length of the instrument without any substantial loss of information by either combining or removing questions that are strongly correlated.

There was an amalgamation of some items in the human resource *(such as attitude/motivation, competence, and teamwork)* and leadership/governance *(such as availability of protocols/guidelines, availability of decision-making aids, and evidence of protocol/guideline adherence)* building blocks which produced nine (9) items in Component 1 *(which was later named as leadership/governance)*. Another item which originally belonged to the 'service delivery' building block was part of this component. This Component was renamed ***'leadership/governance'.*** The Cronbach alpha score for this component was 0.924 *(> 0.700)*.

The second component was relabeled, ***'health information'*** and contained six (6) items, including all the items in this component in the original instrument. Two (2) more items i.e. *failure to arrange for a procedure* and *inadequate use of ANC services* were also part of this new component. These items originally belonged to the service delivery building block in the original instrument. The Cronbach alpha score for this component was 0.855 *(>0.700).*

There were five (5) items that were loaded on the third (3) component. This component was relabeled ***'medical technology'***. The items in this component were reduced from fourteen (14) on the original instrument. The items in this component were mainly about

equipment availability and malfunction, lights out, late referral and test results difficult to interpret. The Cronbach alpha score for this component was 0.799 *(>0.700).*

The fourth and final component was relabeled as ***service delivery*** and it had four (4) items that were loaded. These items included *delay (>12hours) in diagnosis, availability of blood and blood products, availability of test results,* and *problems with provision or rescheduling of services.* There were originally 19 items on the service delivery building block of the original instrument. The Cronbach alpha score for this final component (i.e. service delivery) was 0.788 *(> 0.700).*

In Table 16, the Cronbach alpha for each scale is shown. The reliability as measured by the Cronbach's alpha for all the four (4) components was extremely good *(i.e. >0.700),* indicating a very good internal consistency reliability for each of the four (4)-multi-item scale.

The establishment of the validity and the reliability of the instrument was very critical especially as there is no known scale that have been used in our setting or context *(i.e. Ghana)* with respect to the items and themes under study. The instrument proved valid and reliable after it was subjected to various rigorous validity *(i.e. content and construct)* and reliability testing.

Table 16: The outputs of the Confirmatory Factor Analysis (CFA)

S/N of Items	Description of Items	Component Loadings			
		1	*2*	*3*	*4*
LG1.1	availability of decision-making aids	.851			
LG1.4	availability of guidelines/protocols	.846			
LG1.3	availability of care standards	.824			
LG1.2	evidence of protocol/guidelines adherence	.810			
HR2.3	team work	.754			
HR3.5	competence	.752			
HR3.1	attitude/motivation	.714			
HR2.2	inadequate knowledge n skills	.677			
SD6.6	inadequate intrapartum monitoring	.619			
HI5.3	poor written communication		.851		
HI5.1	incomplete documentation		.846		
HI5.2	lost progress notes		.824		
HI5.4	inadequate handover		.810		
SD6.9	failure to arrange for a procedure		.754		
SD7.3	inadequate use of ANC services		.752		
MT4.5	equipment availability			.671	
MT4.6	equipment malfunction			.632	
SD7.8	late referral			.629	
MT4.8	test results difficult to interpret			.608	
MT5.2	lights out			.606	
MT4.2	delay >12 hours in diagnosis				.719
MT4.1	availability of blood n blood products				.666
MT5	availability of test results				.623
SD7.4	problems of provision or scheduling of services				.613
	Cronbach's Alpha	***0.924***	***0.855***	***0.799***	***0.788***

Source: Field data, 2016

The overall Cronbach alpha[3] score for the Likert scale items was 0.995.

[3] Cronbach alpha is a measure of the internal consistency of a test scale i.e. how closely related a set of items are as a group. It is considered to be a measure of scale reliability. It describes the extent to which all the items in a test measure the same concept or construct. The acceptable alpha score is from 0.70 to 0.95 (Tavakol, M. (2011). Making sense of Cronbach's alpha. *International journal of Medical Education; 2:53-55, DOI: 10.5116/ijme.4dfb.8dfd; ISSN:2042-6372; accessed at:* https://www.ijme.net>cronbachs-alpha *at 5:31am*

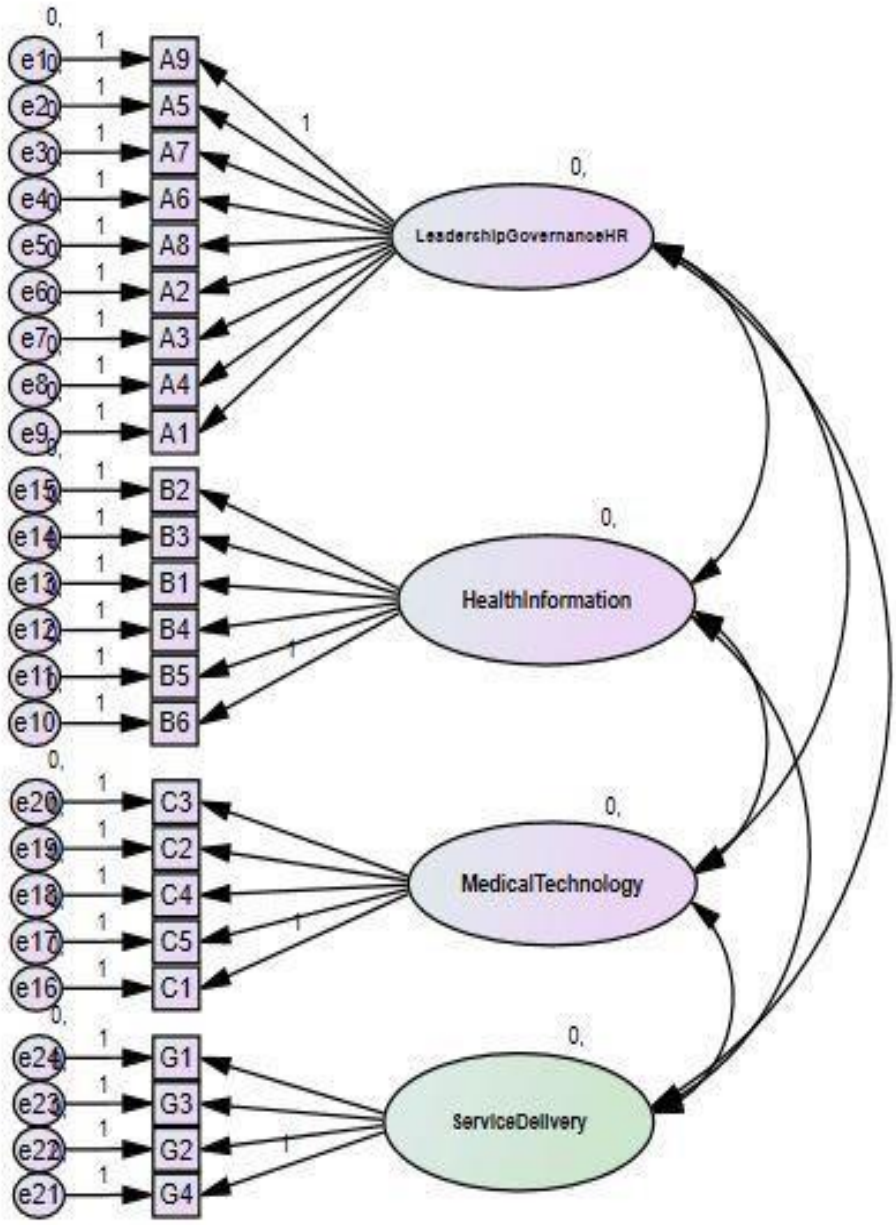

Figure 11: The outputs of the Exploratory Factor Analysis (EFA). Standardized parameter estimates for the factor structure of the causative factors of adverse events. The squares indicate 23-items on the causative factors, the oval represents the latent factors.

Table 17: Covariances of the Variables for the Exploratory Factor Analysis (CFA)

Variable 1	Variable 2	Estimate	SE	Correlation
Health Information	Governance & HR	0.07	0.03	0.17
Medical Technology	Governance & HR	0.10	0.03	0.23
Service Delivery	Governance & HR	0.15	0.04	0.29
Medical Technology	Health Information	0.23	0.03	0.54
Service Delivery	Medical Technology	0.29	0.04	0.56
Service Delivery	Health Information	0.28	0.04	0.56

Source: Field data, 2016

4.4.2 Confirmatory Factor Analysis (CFA)

A Confirmatory Factor Analysis (CFA) was performed to test the model for the Exploratory Factor Analysis (EFA). Validity intends to measure and yield scores that reflects the true variables that are being measured. It is how sound the interpretation of scores are from a test. A construct is a construction that is aims at organizing and making sense out of our environment. It is either a theoretical or conceptual construction *(http://dspace.nwu.ac.za/bitstream/handle/10394/12269/Vosloo_JJ_Chapter_5.pdf?sequence=6)*. Kaiser's Measure of sample Adequacy (MSA) was estimated for each confirmatory factor to determine whether factor analysis was appropriate. This test provides an indication of the intercorrelations among the variables. An estimate of 0.5 indicates the appropriateness of the data for factor analysis. The overall MSA score was 0.865 indicating that the data was appropriate for the analysis. This was done as part of the validation process of the instrument.

Model fit tests were done to determine which of the components to select *(i.e. whether to select 1,2,3 or 4) (as illustrated in Table 16)*. Different models of the CFA were fitted.

Four (4) components *(1,2,3,4)* with multiple correlation were the best fit model among all the others. It has a marginal fit in all the indices as presented in the table. The Chi-square was significant implying the model was a poor fit *(null hypothesis if the model fits).*

An RMSEA was done to select the best model. This study examined the indicator variables that made the name of the instrument. The instrument was developed to assess causative factors of adverse events among obstetric clients at the Greater Accra (Ridge) Regional Hospital. The hypothesized model from the Exploratory Factor Analysis (EFA) was assessed by AMOS version 25 Maximum Likelihood Factor Analysis. The model was evaluated by the following fit measures:

i. The chi-square
ii. The Comparative Fit Index (CFI)
iii. The Root Mean Square Error of Approximation (RMSEA)
iv. RMR

The result of the overall model *(illustrated in Table 18)* indicates a good fit between the proposed model and the observed data. The chi-square was statistically significant, indicating lack of fit. Although the absolute fit measure of the CFI indicates a good fit (0.975), the RMSEA indicates a marginal fit with 0.067. Both the CFI and the NFI indicated an excellent fit with both being greater than the recommended values of 0.95.

CFI > 0.95 (implies a good fit for the data)

RMSEA < 0.05 (good fit for the data)

AIC (wants the lowest AIC implies a good fit for the data compared to the other models)

RMR (<0.05 implies a good fit for the data)

Table 18: Root Mean Square Error of Approximation (RMSEA) Confidence Interval (CI)

Components	Chi square	CFI	RMSEA	LOW	HI	AIC	RMR	
C4	1472.97	0.78	0.12	0.113	0.13	1628.97	0.77	
C3	1783.89	0.72	0.13	0.126	0.14	1881.89	0.119	
C3	1767.67	0.73	0.13	0.125	0.14	1865.67	0.120	
C3	1709.58	0.74	0.13	0.123	0.13	1807.58	0.115	
C2	2013.25	0.68	0.14	0.135	0.15	2109.25	0.124	Uncorrelated
C4	1700.91	0.74	0.13	0.122	0.13	1844.91	0.177	Uncorrelated
C4	1499.95	0.78	0.12	0.114	0.13	1649.95	0.110	2,3,4 Correlated
C4	1472.97	0.78	0.12	0.113	0.13	1628.97	0.077	1,2,3,4 Correlated

Source: Field data, 2016

Table 19: Construct Validity and Reliability for Confirmatory Factor analysis (CFA) of the Causative Factors of Adverse Events among Obstetric Clients at the Greater Accra Regional Hospital, Accra

Variables	**CR**	**AVE**	**MSV**	**Max R(H)**	**L**	**HI**	**MT**	**SD**
Leadership (L)	0.957	0.714	0.108	0.977	**0.845**			
Health Information (HI)	0.910	0.632	0.487	0.982	0.173	**0.795**		
Medical Technology (MT)	0.852	0.536	0.500	0.984	0.287	0.698	**0.732**	
Service Delivery (SD)	0.802	0.505	0.500	0.985	0.328	0.647	0.707	**0.710**

Source: Field data, 2016

Discriminant validity based on the square root AVE being greater than any inter-factor correlation. Convergence validity with AVE > 0.50. Reliability with CR > 0.7. The KMO was 0.87

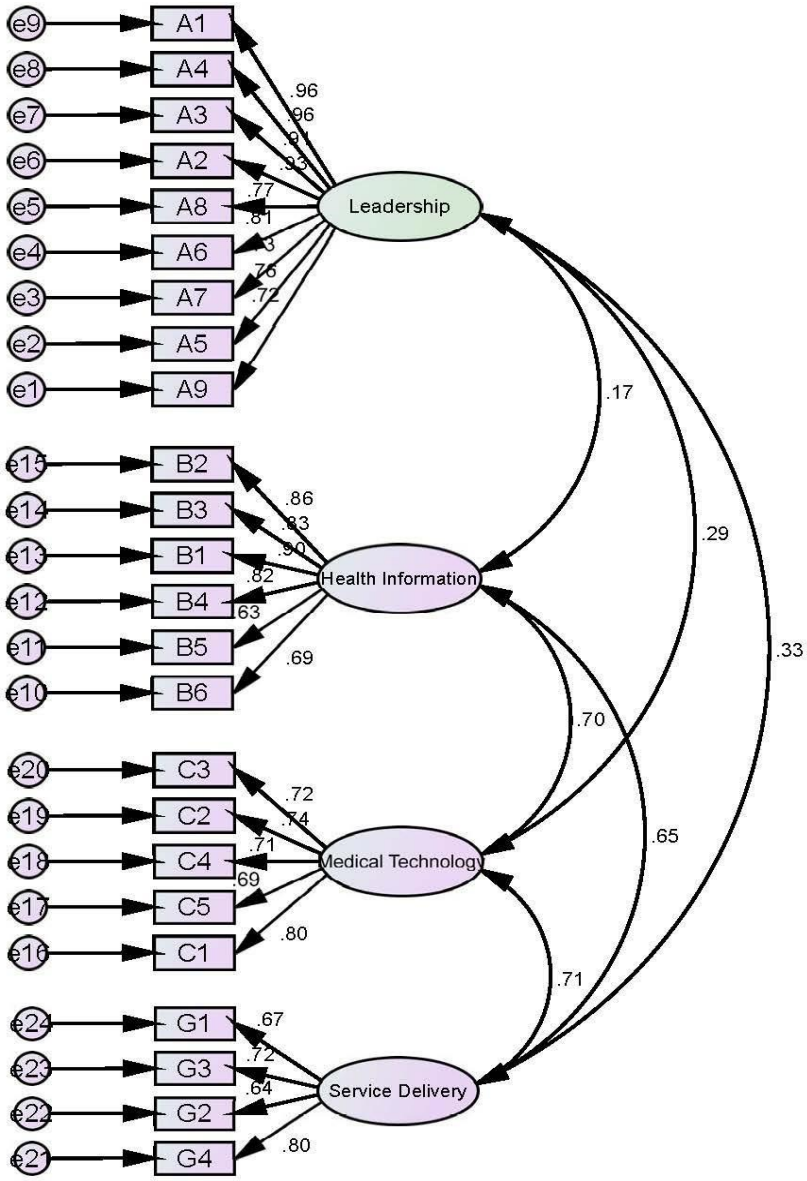

Figure 12: Standardized parameter estimates for the factor structure of the causative factors of adverse events. The rectangles indicate 23-items on the causative factors, the oval represents the latent factors. Confirmatory Factor Analysis (CFA), Root Mean Square

4.3.2 Logistic Regression

Logit $(\pi)\ \beta_0 + \beta_1 Factor_1 + \beta_2 Factor_2 + \beta_3 Factor_3 + \beta_4 Factor_4$

Where π = Preventability = $\begin{cases} 1 = Yes \\ 0 = No \end{cases}$

βi = Coefficient for the four factors extracted = $(\beta_o, \beta_1, \beta_2, \beta_3, \beta_4)$

Table 20: Logistic Regression

Factors	βi	S.E.	Wald	df	Sig.	e^{β}	95% CI for	
							Lower	Upper
Service Delivery	-0.43	0.24	3.37	1	0.067	0.649	0.409	1.03
Medical Technology	-0.16	0.37	0.19	1	0.664	0.853	0.416	1.748
Health Information	-0.99	0.44	5.05	1	0.025	0.369	0.155	0.88
Leadership & Governance	0.71	0.26	7.26	1	0.007	2.028	1.213	3.391
Constant	1.53	0.25	38.64	1	0	4.604		

Source: Field data, 2016

Factor scores and a reduced subset of the original variables selected, based on the factor model, were evaluated as predictors *(i.e. causative factors)* of adverse events among hospitalized obstetric clients. The factor scores were used as the independent variables to predict the preventability of AEs.

The odds of having AEs increase by 200% per unit increase in leadership & governance. There is a decrease in odds among all the other components *(i.e. service delivery, medical technology, health information)*. For instance, a unit increase in the score of medical

technology reduces the odds of preventability of AEs by 15%. Similarly, a unit increase in the score of service delivery reduces the odds of preventability of AEs by 36%.

Though leadership & governance has high scores in OR (2.028) it does not necessarily lead to the preventability of AEs because of its very little relationship with the other components *(building blocks i.e. service delivery, health information & medical technology)*. From the model in the CFA (Figure 12), there is a greater correlation between all the building blocks except with leadership & governance which has very weak correlation with the others *(i.e. building blocks)*.

Box 6: Causative factors of adverse events among the study site in the study population

Example 1: Causative factor

A high-risk case which was not seen by the appropriate specialist at ANC. The antenatal risk factors were also not identified by the attending staff.

This AE could have been averted by ensuring frequent antenatal visits by the client and frequent antenatal screening using ultrasound.

This is a 23-year-old gravida 2 para 0. The gestational age was 40. She is a Christian, married and an ANC attendant. The AE in this case was a perineal tear

Example 2: Causative factor

Failure of the patient to comply with the advice of securing blood by getting the relatives to
donate.

This AE could have been averted by ensuring adequate voluntary blood donation, adequate persuasive counselling of client during the antenatal period to ensure that relatives donate on her behalf.

This is a 35-year-old trader, gravida 4 para 3, 41 weeks gestation and a regular ANC attendant. The AE in this case was delay in treatment & perineal tear.

The factors associated with AEs are further categorized using the Donabedian triad in figure 13.

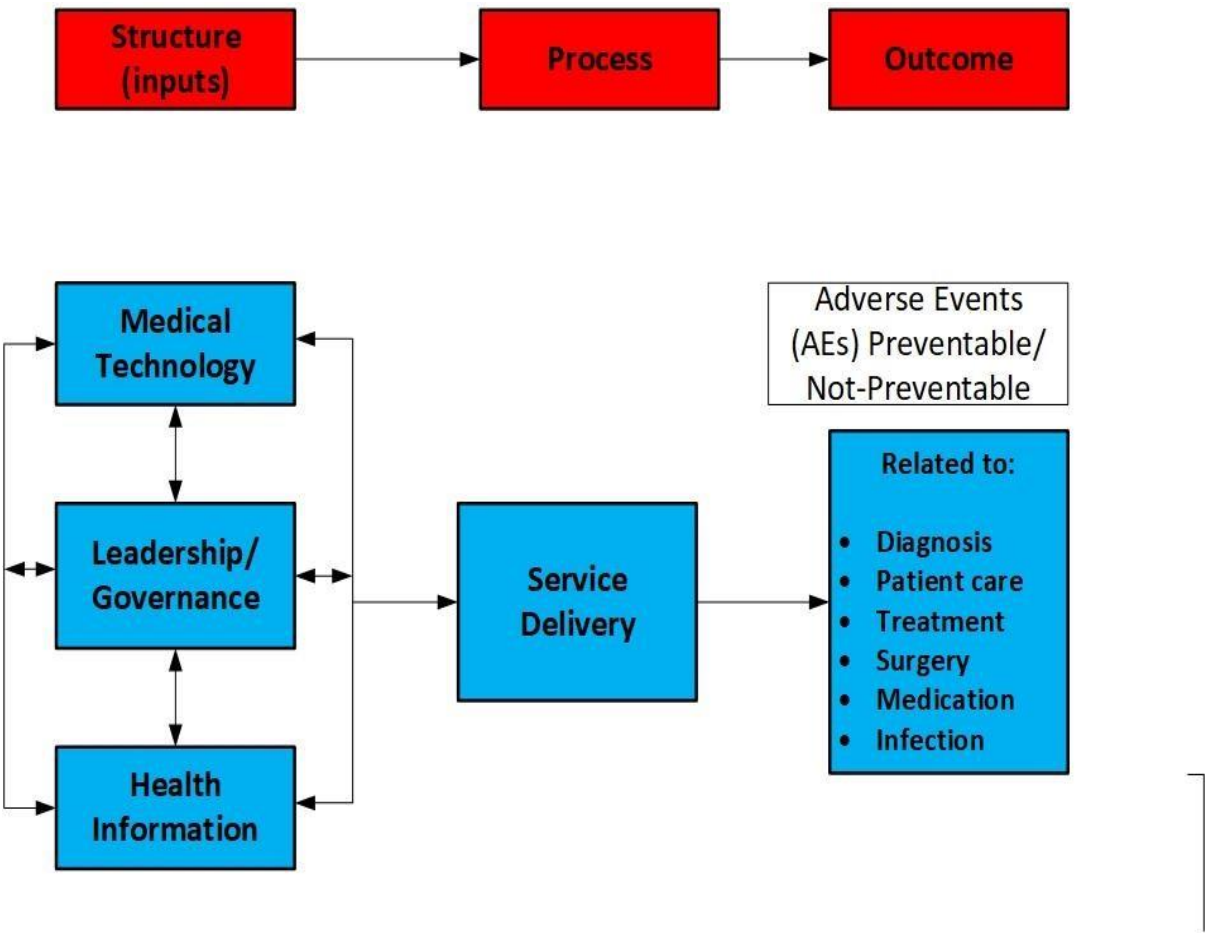

Figure 13: The factors associated with adverse events among obstetric clients using the WHO Health Systems Building Blocks and the Donabedian Triad

4.5.0 Degree of Preventability of Adverse Events (AEs) among Obstetric Clients

Of the total adverse events that occurred among the study participants (i.e. *obstetric clients*), over two-thirds (285, 87.7%) of them were preventable (Table 21). There was a strong evidence of preventability among more than a third (134, 41.3%) of the total adverse events that occurred among the study participants. There was no evidence of preventability among 12.3% (40) of the total adverse events that occurred among the study participants in the study sites.

Some of the reasons why some of the AEs were judged not preventable include:

Case 35004: 'comorbidity of Hepatitis B and Retroviral Infection (RVI) contributed to the death of the patient'

Case 75042: 'comorbidity was an important factor: severe preeclampsia and CPD led to the IUFD [intra uterine foetal death] since FHR was regularly monitored as ordered. All measures were put in place but the adverse event occurred'

Case 33058: 'complexity of the condition (PPH) may also be a factor since 1st degree PPH has various causes which may or may not be known or even suspected by the staff'

Case 17862: 'systematic gestational DM. Client's health history and lifestyle may have exposed her to the diabetes'

Case 15682: 'difficult/fast procedure. The procedure was difficult to undertake especially when the IV line was not properly fixed due to tissue infiltration'

Table 21: Evidence that Adverse Event (AE) was preventable among obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra

Preventability of Adverse Events	**Frequency (n)**	**Percent (%)**
Yes	285	87.7%
No	40	12.3%
Total	325	100.0

Source: Field data, 2016

Table 22: Strength of Evidence for preventability of adverse events among obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra

Strength of Evidence for Preventability	Frequency (%)
(Virtually) No evidence for preventability	40 (12.3%)
Slight to modest evidence for preventability (i.e. management causation)	36 (11.0%)
Preventability not quite likely; < 50-50 but close call	41 (12.6%)
Preventability more likely than not; more than 50-50 but close to call	48 (14.8%)
Strong evidence for preventability	134 (41.3%)
(Virtually) Certain evidence for preventability	26 (8.0%)
Total	**325 (100)**

Source: Field data, 2016

4.5.1 Description of the manner in which AEs could have been prevented

This section was analysed guided by the four (4) components/health systems building block *(i.e. leadership/governance; service delivery; health information and medical technology)* that was extracted from the EFA and then the CFA.

As shown in figure 14, Leadership/Governance related issues alone contributed more than half (i.e. 149, 53.2%) of the total number of the manner in which the adverse events which occurred among hospitalized obstetric clients could have been prevented while service delivery related issues contributed a third (94, 33.6%). The least manner in which AEs which occurred could have been prevented was health information related (16, 5.7%).

The manner in which the AEs could have been prevented with respect to the various health systems building blocks is described in the following statements:

Case 4750: 'close monitoring of the client and early or immediate intervention of the medical doctor could have helped. Early interventions to hasten the delivery could have also prevented the prolonged labour (leadership).'

Case 674: 'early initiation of [blood] transfusion plus early administration of tranexamic acid (at least at the ER before transfer to the theatre'. 'This client, for instance, suffered a greater than 20hours delay in blood transfusion upon her admission (leadership)'.

Case 1223: 'proper and focused antenatal care to [identify] clients who are at risk of any complications for further management. There should also be frequent investigations (i.e. scans, lab) to know the progress of the pregnancy (health information).'

Case 2179: 'blood should be reserved at all times to use in cases of post-partum haemorrhage (PPH). Every effort should be made to secure blood for women with haemorrhage (service delivery).'

Case 2369: 'by making sure that the scan machine works at all times, or an alternative should be provided (service delivery).'

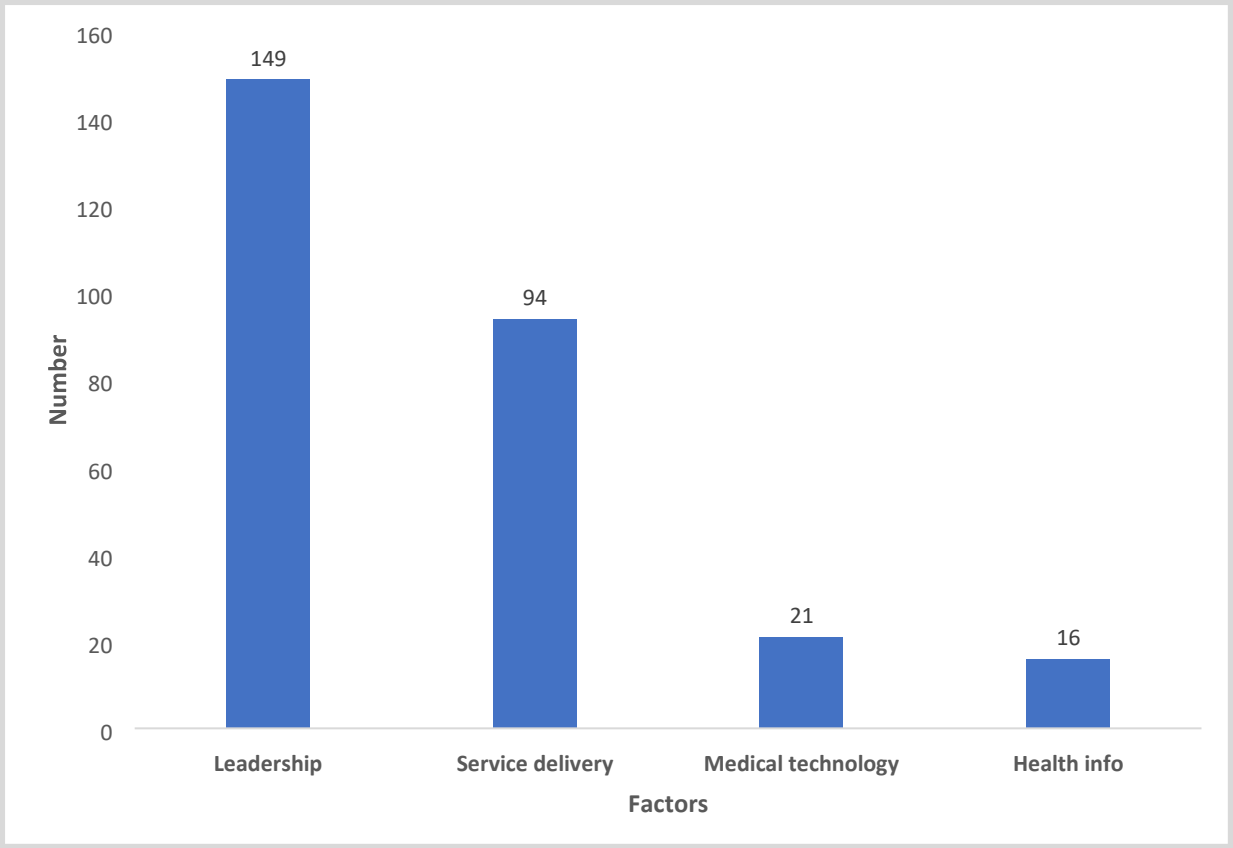

Figure 144: The manner in which adverse events among obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra could have been avoided

4.5.2 Reasons for the failure to prevent the AE?

The reasons for the failure to prevent the adverse events (AEs) among the obstetric clients were analysed guided by the health systems building blocks i.e. leadership/governance; service delivery; medical technology and health information.

As shown in figure 15, reasons that are leadership/governance related accounted for a little more than a third (65, 44.5%) of the total reasons while health information related reasons accounted for the least (17, 11.6%).

Some of the reasons for the failure to prevent the adverse events as suggested by the reviewers include the following:

Case 674: 'emergency drugs such as tranexamic acid and blood were not available when they were needed (medical technology).'

Case 1021: 'lack of care and attention; inadequate intrapartum management'

Case 1614: 'delay in providing timely episiotomy; inadequate intrapartum monitoring; poor communication of progress of labour to client.'

Case 2174: 'late delivery of blood. Failure of the condom tamponade to arrest the bleeding (service delivery & leadership/governance).'

Case 4830: 'arrangements were not made to perform episiotomy'

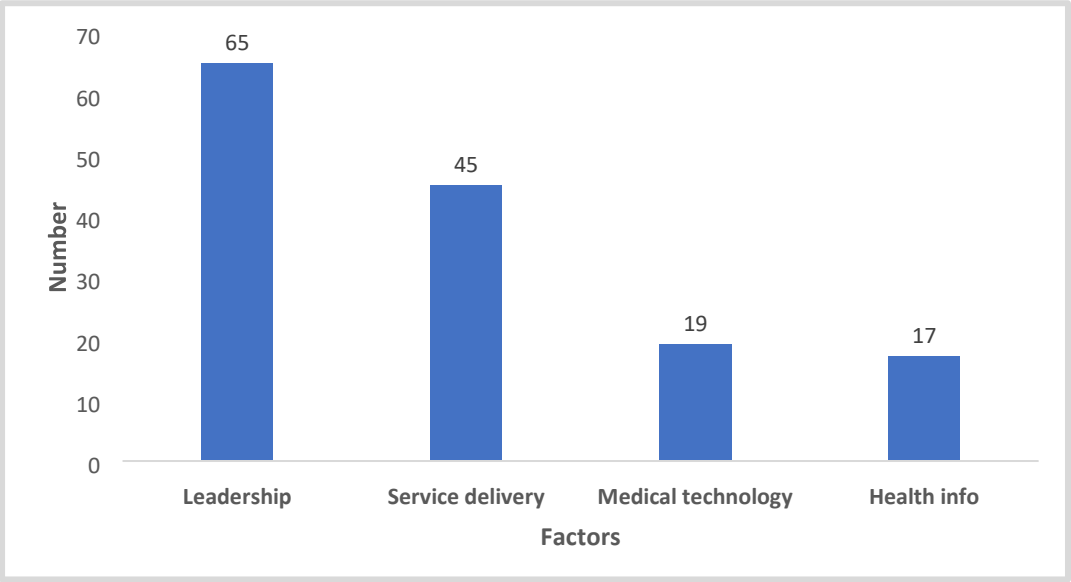

Figure 15: Reasons provided for failing to prevent the adverse events among obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra

4.6.0 Data Quality Issues Identified by the Reviewers During the Review Process

Case 11368: *Documentation was generally poor. History was not taken on admission; partograph was ordered late and not filled. No indication was stated for induction of labour. Time of admission and discharge was not stated. There was no discharge summary and incomplete nursing notes.*

Case 21551: *Inconsistencies in the documentation of laboratory reports. Incomplete documentation. Partograph was not used and there was also no documentation of postpartum care and the fate of the patient*

Case 74450: *There was no documented pelvic assessment though previous CS was on account of prolonged labour. There was also no documentation of inter-pregnancy interval*

Case 19005: *Incomplete and inconsistent documentation. Protocols were not followed. Fate of the patient not known (i.e. not documented).*

Case 25213: *No clearly documented discharge*

4.7.0 Agreement Between Reviewers

As shown in table 23, the agreement of the presence of an adverse event was 74.6% *(kappa =0.50)* among the doctors, and that among the doctors & nurses/midwife reviewers was 70.6% but with a lower kappa statistic *(0.33)*.

Table 23: Agreement between the reviewers in judging the preventability of adverse events among obstetric clients hospitalized at the Greater Accra Regional Hospital, Accra

% Agreement	Expected Agreement	Kappa	Std. Error	Z	Prob >Z
* Doctors Doctors 74.60%	49.43%	0.4978	0.0869	5.73	0.0000
* Doctors Nurses 70.63%	56.42%	0.3261	0.0866	3.77	0.0001

CHAPTER 5

DISCUSSIONS

5.1 Introduction

As part of a comprehensive assessment of adverse events, this study estimated any prevalence, types, causative factors, and the degree of preventability of AEs among obstetric clients hospitalized in the obstetric department of the Greater Accra (Ridge) Regional Hospital in 2015. It provides the starting point towards understanding the epidemiology of adverse events among obstetric clients who have been hospitalized. The results of this work should be understood and interpreted in the context of healthcare quality and patient safety.

5.2.0 Prevalence of any AEs among Obstetric Clients

One of the objectives of this study was to determine the prevalence of adverse events among obstetric clients hospitalized at the Greater Accra (Ridge) Regional Hospital. The findings of the study showed that, among obstetric clients who had any episode of hospitalization at the obstetric department of the Greater Accra (Ridge) Regional Hospital, the prevalence of adverse events was 12.0% (95% CI: 10.4% to 13.8%). This translates into twelve (12) adverse events per 100 admissions or 120 adverse events per 1000 admissions among the study participants *(i.e. obstetric clients)*. This estimate, however, included classifying primary and secondary degree perineal tears as adverse events. The overall prevalence of adverse events among hospitalized obstetric clients was, however, reduced to a 6.3% when primary and secondary degree perineal tears were excluded. This finding *(of AE prevalence)* excludes the mortality cases *(i.e. the medical records/folders)*.

However, had the mortality cases been included in this study, the prevalence might have been higher than what has been estimated. The finding from this study is higher than that estimated by other authors Brennan et al (1991), Zegers et al. (2008), Thomas et al. (2000), etc.

For instance, Brennan et al., (1991) estimated a prevalence of 1.5%±0.2% among obstetrics cases and 3.7% (95% CI: 3.2-4.2) among their entire sample estimate of 30,121 records of hospitalized patients from a population of 2,671,863 non-psychiatric patients discharged from non-federal acute care hospitals in New York in 1984. Studies by Zegers et al. (2008) to determine the incidence, type, nature, preventability and impact of AEs among hospitalized patients and potentially preventable deaths in Dutch hospitals showed a 4.7% incidence among obstetric patients. They found an overall incidence of 5.7% of all admissions. They used a total sample size of 7926 *(about half i.e. 3943 of which were deceased)* from twenty-one (21) randomly selected hospitals of various categories *(university (4), tertiary teaching (6) and general (11) hospitals)* across the Netherlands. Again, studies in two (2) states in the US *(i.e. Utah and Colorado)* also had a much lower AE rate of 3.7% and 2.9% (Thomas et al., 2000) respectively than this study.

However, similar results are found in studies among thirteen (13) hospitals in New Zealand that recorded a prevalence rate of 12.9% (Davis et. al., 2002); Australia recording 10.6% (Thomas, Studdert, Runciman et.al, 2000); while a UK study involving two teaching hospitals also had rates of 10.8% and 10.9% respectively by Vincent et al., 2001. The obstetric related AEs were 4% of all the medical records reviewed (1014) in the study by Vincent et. al., (2001) among the two teaching hospitals in his study population in the UK. The Irish study also recorded a prevalence of 12.2% among 1574 patients across eight (8)

hospitals in Ireland (Rafter, Hickey, Conroy, Condell, Connor, et al., 2016). Again, a prevalence of 10.5% was also found in 58 countries in Latin America by Aranaz-Andres et al (2011). Similarly, studies in Swedish hospitals by Rutberg et al., (2016) have also yielded a prevalence of 15% out of 4994 admissions. The authors found for instance that, 2% (90) of the AEs were postpartum or obstetric related and 34% (31) were judged to be preventable. A study by Mendes et. al (2018) among four hospitals in Brazil also yielded a 12.8% prevalence rate similar to this and other studies. Even though the authors indicated that they included patients from all the respective specialties, there was no evidence in the write-up with respect to obstetric conditions or cases. For instance, the WHO also estimates that, the chance of being harmed by healthcare globally is 1 in 300 unlike 1 in 1,000,000 in aviation (World Health Organization (WHO), 2018a).

The Canadian AE study which reviewed about 1500 inpatient hospital admissions from four (4) hospitals across 5 provinces in Canada estimated an AE prevalence of 7.5%. This estimate, however, excluded obstetrics and other specialty such as paediatrics, psychiatric or rehabilitative cases. The Canadian study was done in the year 2000. The authors of the New Zealand study estimated an incidence of 6.6% AEs among pregnancy/childbirth and a total incidence of 11.3% (Davis et. al., 2002). The authors reviewed a total of 6579 medical records from a random sample of 13 public hospitals in New Zealand.

Studies by Elmontsri et al (2017) in some lower-middle-income countries such as Kenya, Egypt, Tunisia, Morocco, South Africa, Sudan and Palestinian hospitals have yielded adverse event prevalence estimates between 8.2% and 14% respectively.

The finding from this current study *(of a 12.2% prevalence of AEs among obstetric clients)* is similar to a nationwide study across ten (10) healthcare facilities in Ghana which estimated a hospital acquired infection (HAI) prevalence rate of between 3.5% to 14.4% among the general patient population in the study facilities. The authors also identified a prevalence of between 3.5% *(for surgical site infections)* to a least of 1.8% *(for urinary tract infections)* among obstetric clients. These two studies do not however support the popularly held view by Jha et al (2012) and other authors that AE rates in LMICs is 50% more higher than their High-Income Countries (HICs) counterpart. Ghana may have to be excluded from these kinds of generalizations and extrapolation.

Various reasons could have accounted for the differences in the prevalence estimates among the various studies. One of the differences could be on the types of adverse events. For instance, none of these studies *(particularly for Brennan et al. (1991), Zegers et al. (2008), and Thomas et al. (1992))* mentioned perineal tear as a type of AE that was identified during their study period. In most of the studies, the reviewers are given a list of "triggers" to guide the screening process (Rafter et al., 2016).

Again, the studies with lower prevalence rates compared with this study are often guided by a medicolegal other than a quality improvement perspective. This differences in perspectives greatly influences the outcome of the study findings. For instance, studies that had a quality improvement perspective such as Wilson et al. (1992), Vincent et al. (2000), Davies et al. (1998), Baker et al. (2000), Aranaz-Andreas et al. (2011), Deilkas et al. (2017) and Harkanen et al. (2014) all had estimated prevalence rates from as low as 5.7% to a high of 25% similar to this study findings of 12.0%.

Also, some authors believe that, the sample size has a great influence on the estimated prevalence rates of adverse events. It is suggested for instance by Lessing et al. (2010) that the prevalence of AEs decreases with increasing sample size. The authors indicated that, the prevalence of AEs could be as low as 1% or even below 10% when the sample size is either 20,000 or 2,000 respectively. The sample size for this study *(i.e. 1402)* was slightly lower than 2000 which is likely to have affected the estimate of this study. This position may not be true in all instances. For instance, studies by Davis et al. (1998) and Harkanen et al. (2014) had estimated sample sizes of 6579 and 463 respectively had estimated prevalence of 12.9% and 25%.

The review methodology does not also seem to have much effect on the prevalence rates. Even though this study used a **four-stage** review process other than the two-stage or three-stage process that is usually used, the findings were mostly comparable. The main influencer of adverse event prevalence rate is more of the perspective (i.e. medicolegal or quality improvement) other than all the other concerns of types, methodology and sample size.

The present study could compare with any study internationally because the definition of an adverse event *(i.e. "an unintended injury that results in temporary or permanent disability, death or prolonged hospital stay, and is caused by healthcare management rather than the patients underlying disease process")* was consistent with what have been used by various authors (Brennan, 1991; Smits, Zegers, Groenewegen, Timmermans, Zwaan, van der Wal, et al., 2010) in the field. The prevalence of any of the adverse events identified is however likely to have been underestimated mostly because of the quality of documentation with respect to availability, adequacy and completeness of the medical

records. This is however a common challenge to all retrospective studies. Inspite of this challenge, substantial amounts of AEs and rich clinical details have been revealed by retrospective reviews (Davis et al., 2002; Neale et al., 2001; Thomas et al., 2000; Vries et al., 2008; Zegers et al., 2009). However, the comparison of the rate of prevalence will have to be done cautiously, especially when most studies such as Brennan et al., 1984, Vincent et al. (2000), Wilson et al. (1992), and Baker et al. (2000) exclude specialties like obstetrics, paediatrics, mental health, and orthopaedics among others.

5.2.1 Types of Adverse Events among Obstetric Clients

The types of adverse events among hospitalised obstetric clients at the Greater Accra (Ridge) Regional Hospital are determined in this study. The types of adverse events considered in this study is broader than those described in other studies. In any study, the types of adverse events is often as a result of the nomenclature used in its classification. For instance, various quality and safety organizations such as the NQF, Medicare, AHRQ and others have a list of *'Serious Reportable Events'.* Over the years, varied standards have been used by policy makers, researchers and health facilities in the classification of an AE. This makes it possible for varied results to be obtained depending on the lists of AEs that are used for the identification and classification. In this study, the adverse events types were classified into six (6) major categories/themes namely: events related to surgery, treatment, diagnosis, medication, infection and patient care respectively. The surgical-related adverse events accounted for most of the adverse events that happened during the study period. Some of the surgical related adverse events include: obstetric trauma to the baby; obstetric trauma *(i.e. perineal tears),* excessive bleeding and postpartum haemorrhage. Primary and secondary degree perineal tears were very common among

obstetric clients at the study site, and consistent with other studies (Groutz et al., 2011; Lede, Belizfin, & Carroli, 2000; Walsh et al., 1996).

Some authors (East et al., 2012; Groutz et al., 2011; Walsh et al., 1996) have suggested that primary and secondary degree tears are very common with a prevalence of between 73% to 90% unlike third- and fourth-degree tears with a prevalence up to 10.2% among obstetric clients reported in studies in developing countries such as the Philippines. Third- and fourth-degree tears are less common and more serious (Hirayama et al., 2012). The obstetrician gynaecologists *(who did the review)* were similarly of the view that, first and second-degree perineal tears were so common in practice that they should not be considered as adverse events. They were again of the view that, in as much as first and second-degree tears could be averted by episiotomy, they did not think it was necessary to inflict harm. Again, they were of the view that not all the tears could be anticipated (Personal Communication, 2017). Third- and fourth-degree tears can, however, not be prevented by episiotomy. However, the routine use of episiotomy has been suggested to produce very few to insignificant benefits clinically to the patient other than increasing the medical costs and inflicting more maternal discomfort. The routine use of episiotomy, as suggested, should be abandoned (Lede et al., 2000). Some of the risk factors for perineal tears have been identified to include parity, higher birth weight, forceps delivery. BMI and maternal age had no associated risks (Enyindah, Fiebai, Anya, & Okpani, 2007; Groutz et al., 2011; Hirayama et al., 2012; Walsh et al., 1996). In as much as there is no agreement on the preventive measures and on clinical management of perineal tears, active manual support of the perineum is said to go a long way to reduce the incidence of tears, as evidenced in other countries such as Finland. It is further suggested that, other measures such as early identification of patients at risk, better prenatal care that allows the detection

of heavy babies through scans, changes in daily obstetric practice, avoidance of midline episiotomy, selective use of mediolateral episiotomy and the avoidance of forceps delivery (Groutz et al., 2011) could go a long way to reduce the prevalence of perineal tears among obstetric clients. If we apply the Kieran Walshe (2000) characteristics of an AE, that '*AEs are detrimental, injurious, undesirable or untoward to the patient and the process of healthcare; patients have some negative or potential impact; and an indication that the event is as a result of some aspect of the healthcare process either through omission or commission other than the healthcare process such as actions of the patient or the natural progression of the disease',* then even a primary or secondary degree perineal tear qualifies to be an adverse event just as a third and fourth degree perineal tear. This subject will be an interesting area that will require further exploration by future investigators.

The classification used in this study was similar to that used in the estimate of the national incidence of adverse events among Medicare beneficiaries in the US in 2008 (Levinson, 2010). In that study, AEs related to surgery or other procedures accounted for the third highest, while events related to medication was the highest. The other two categories used in the study were AEs related to patient care and infections. Unfortunately, the authors in that study did not indicate whether obstetric clients were included or excluded except to use the phrase, 'Medicare Beneficiaries'. Nonetheless, there were some similarities in the specific AE types with respect to each of the categories such as 'excessive bleeding' as a surgical-related AE, 'surgical or procedural site infection' as an infection-related AE, among others. No pressure ulcers were identified in this study, mostly because of the relatively short length of stay (mean=4.2days±5.7days) of the obstetric clients in the facility.

AEs are higher in the surgical disciplines of neurosurgery, cardiac thoracic surgery, vascular procedures and [obstetrics] (Brennan, 1991). This is similar to what Vries et al. (2008) also found that, more than half (41.0 IQR 39.5 to 45.8) of the AEs that occur in hospitals (80.8 IQR 75.6 to 83.2) occur in the operation room followed by the patient's room/ward (24.5 IQR 21.6 to 26.5), labour and delivery room (3.7 IQR 2.8 to 6.5), emergency room (3.0 IQR 2.9 to 3.0) and intensive care units (3.1 IQR 2.7 to 3.5) respectively. These findings are similar and consistent with this study that found that more than half of the adverse events were surgical related and found in the labour and delivery wards, and the lying-in wards of the study area.

5.4 Factors Associated with Adverse Events among Obstetric Clients

This study provides an overview of the causative factors of adverse events among obstetric clients hospitalized at the Greater Accra (Ridge) Regional Hospital. Identifying the causative factors to AEs is an important first step towards their prevention and a very important goal in quality improvement and patient safety. This is one of the few if not only study that uses the health systems' building block model to determine the factors associated with adverse events among obstetric clients on admission. Other models have been used by different authors to assess or judge causality such as Smits et al.'s (2008) model of *'Human, Patient, Organizational, Technical',* as was used in the Dutch study. The Donabedian model of structure, process and outcomes was also used by Jha et al. (2016) while Rasmussen Cited in Caravon (2011) also used the Skill-Rule-Knowledge based framework in his assessment or determination of causality of adverse events. Another model that was used by Valentine (2016) had the causative factors classified either as human or systems while Vincent & Amelberti (2016a) organized their causative factors

under seven (7) broad headings namely patient, individual, staff, team, working conditions, organizational factors and wider institutional context. There is yet another popular model which have been used by some authors notably Reason (1995). This model organizes the possible active factors that are likely to cause an adverse event. These include team *(e.g. supervision, leadership, interpersonal communication),* task *(e.g. use of protocols and guidelines)* and individual factors *(e.g. knowledge, skill, experience and attitude)*, and patient characteristics *(e.g. complexity of health conditions, personality and communication ability).* This model has some similarities *(especially with respect to the items that are organized around the themes)* with the health systems building block model that was used by this study.

In this study, the causative factors of adverse events among obstetric clients that were detected by the reviewers were mostly related to leadership/governance, service delivery, medical technology and health information issues. For example, availability of protocols and guidelines, and evidence of adherence to protocol and guideline were some of the leadership/governance related issues that was identified. Smits et al. (2010), for instance, also identified inadequate or unavailable protocol, lack of task coordination within the healthcare team, inability of an individual to apply his/her knowledge to a novel situation as some of the factors associated with adverse events in healthcare organizations. This finding *(by Smits et al., 2010)* is similar to the findings from this study. Medical technology related adverse events were also replete in this study. There were instances of equipment malfunction or availability, unavailability of test results that facilitated the cause of preventable AEs among the study participants. This was similar to the work by Thompson and Avillion (2017). Defective equipment can also contribute to the cause of adverse

events. A systematic review ascribed 8% of adverse events to equipment related-issues (White et al., 2005b) similar to study.

There were instances in this study like others where the unavailability of emergency drugs such as tranexamic acid and blood had contributed to adverse events among the obstetric clients. This is consistent with studies by Kohn et al. (2000) who delved deeper into the common causes of medication related errors in healthcare. The use of computerized drug order entry systems is believed to be one of the technological approaches that has the potential to reduce medication-related AEs. The need to involve pharmacists during the review of drug orders thereby drastically reducing the potential of medication-related harms have also been stressed (Kohn et al., 2000; Gandhi et al., 2016).

Human resource related issues such as competence, attitude/motivation, inadequate knowledge and skills, inaccurate or incomplete reporting of results to the obstetric client, and team work were all implicated as factors associated with preventable adverse events in this study. This implied that, preventable adverse events will occur when our healthcare workers are less competent, when they have the wrong attitude/motivation, and when they do not have adequate knowledge and skills to deliver on their tasks/duties. This finding was also consistent with others such as Karimi et al. (2016), Williams et al. (2015), Reason (1995), Valentine (2016) and Fann et al. (2016) all of who identify the role of human resource in one way or the other as a contributory factor to preventable adverse event. In anaesthesia, human resource has been identified to account for up to 82% of preventable adverse events. In this study, the human resource related issues were organized around leadership/governance block of the health systems building block. Incidentally, the leadership/governance block accounted for most of the preventable adverse events identified in this study. Facility managers and policy makers will therefore have to work

to ensure that, only healthcare workers with the right attitude/motivation, knowledge, skills and competence are recruited to provide service. The recruitment process will have to be as stringent as possible ensuring that these are part of the minimum criteria. There is also the urgent need to redesign our training curriculum to ensure that the products fit the stated criteria. This is imperative if we want to avert the occurrence of preventable adverse events to our obstetric clients in the country. Inadequate numbers of human resource have been identified in some studies (Dakubo & Naaeder, 2013; Karimi et al., 2016) as a major cause of preventable adverse events. There is the need to understand the limitations of humans and design the workplace and equipment such that they allow for variability in humans and their performance. Some of the key elements necessary to build a safer care environment for vulnerable clients have been identified to include the design of the system factors, structure and the process of care.

Unfortunately, this study could not explore the effect of human resource numbers on the cause of preventable adverse event. This could be an interesting area of future research which could buttress the current evidence produced by this study to enable policy makers have a complete picture of the issues and design an appropriate intervention to improve outcomes.

It was noteworthy that the factors associated with adverse events with respect to the health systems building blocks were interrelated. Also, none of the identified factors are capable of individually preventing an adverse event from occurring unless they are coordinated more synergistically. This is consistent with the fact that, the health systems' building blocks (HSBB) ability to ensure the realization of the desired outcomes of healthcare are

mostly dependent on the level of synergy and interrelationship between the various components *(of the HSBB).*

Protocol availability or non-availability and its adherence or non-adherence have been identified by different authors *(including Guerra-Garcia et al., 2017; Vincent & Amelberti, 2016; Valentine, 2016; Smits et al., 2010, Gawande et al., 2003)* as one of the main factors associated with preventable adverse events in healthcare especially among the surgical disciplines including obstetrics. The findings of this and other studies lend some credence to this. Studies for instance by Smits et al. (2010) found *'human factors'*, mostly knowledge and rule-based, such as wrong reasoning by the healthcare worker and/or not checking to see whether all the necessary instruments were present before the beginning of a procedure, as the cause of more than half of the total adverse events that happened during the study period. In the same study, organizational factors, particularly inadequate or unavailable protocols, were found to be the cause of most preventable adverse events that occurred in the hospitals (Smits, Zegers, Groenewegen, Timmermans, Zwaan, van der Wal, et al., 2010). There was a similar study in Spain where the authors identified about 71% of the contributory factors to the AEs to be related to professional factors *(including training, conduct, communication, stress and others)*. About 24% of the other contributory factors were related to 'organizational factors' and were caused by the absence of or deficiencies in work protocols (Guerra-Garcia et al., 2017). There have been various instances in Ghana and elsewhere where foreign bodies/materials have been left in the internal organs of patients just because surgeons failed to use or adhere to the basic protocol of their practice *(i.e. the use of the surgical safety checklist during a surgical procedure)*. In some instances, obstetric clients have been incapacitated (Boadu, 2014; Boateng, 2016; Dakubo & Naaeder, 2013; Takyi-Boadu, 2016). The failure to adhere to

the necessary protocols is very grave and have had very dire consequences, also in other industries such as aviation. The use of a surgical safety checklist and other protocols have been found to significantly improve outcomes in healthcare in a number of settings (Haynes et al., 2009; Kent, Stephens, & Posner, 2017; World Health Organization (WHO), 2009). In this study, it was found that the study site used consent form and the surgical verification checklist in about 99% of all their surgical cases. This was very worthy of note. The surgical verification checklist *(a copy of which is attached in the appendix)* was the version of the surgical safety checklist *(though significantly dissimilar)* used by the study site.

In this study, adverse events among obstetric clients were mostly caused by surgical history, gestational age, postpartum period, antenatal attendance and blood pressure. Obstetric clients with these characteristics were more at risk of developing an adverse event than those without.

This study found that clients with increasing maternal age were also more at risk of developing an adverse event than younger people were. This is consistent with several other studies (Du et al., 2010; Kenny et al., 2013; Malaysiana, Maternal, & Kehamilan, 2016) that showed how older obstetric clients had increased risk of developing adverse events when hospitalized than younger ones. The authors of the paper, 'Incidence of adverse events & negligence in hospitalized patients: Results of the Harvard Medical Practice Study 1' by Brennan et al. (1991) also found that elderly people were at higher risk of developing a preventable adverse event than younger people were. Similarly, Zeger et al. (2009) and Baker et al. (2004) found similar results among the Dutch and Canadian population respectively. The clinical complexity of the care of women with advanced

maternal age could be one of the reasons for the increasing AEs among such a population (Zegers et al., 2009). It seems safer to deliver at a younger maternal age than being older because of the risk of developing an adverse event. Studies in other specialties other than obstetrics have also showed how adverse events is prevalent among patients with increasing age (Natasha Rafter, Hickey, Conroy, Condell, Connor, et al., 2016).

The finding of this study is also consistent with others in Ghana and elsewhere (Alderliesten, Vrijkotte, & Wal, 2007; Boateng & Arthur, 2014; Raatikainen, Heiskanen, & Heinonen, 2007; Say & Raine, 2007) that women who are regular ANC attendants *(with a minimum of 4 visits during the gestation period for uncomplicated pregnancies)* are less at risk of developing a preventable adverse event *(or outcomes)* than ANC non-attendants. Adequate ANC have been identified as an effective means of identifying and mitigating the risk factors of pregnancy and improving outcomes. This makes it very imperative for frontline healthcare workers responsible for the care of obstetric clients to make ANC more beneficial to the attendees and also see it as an important opportunity to improve pregnancy outcomes. This finding also implies that, clients who have not had the necessary ANC attendance ought to be treated with the utmost care since they are most susceptible to developing a preventable adverse event. There is the urgent need to continue to design our health systems to encourage obstetric clients to attend ANC especially when the percentage ANC attendance in the 2017 Ghana Maternal Health Survey (GMHS) of 98% did not see any significant increase in that of 2007 (i.e. 96%). Maybe the time is just up for us to review the quality of service that is provided these obstetric clients during their antenatal period. Regular ANC attendance is protective of preventable adverse event and every effort must be put in place to encourage it.

Again, though variables such as diagnosis and hypertension of the obstetric clients was not statistically significant, clients with multiple diagnosis and increasing blood pressure were more likely to develop a preventable adverse event than those with a single diagnosis and decreasing blood pressure. This makes it imperative for frontline healthcare workers to be very vigilant and careful in the management of obstetric clients with such characteristics if the prevalence of preventable adverse events have to be reduced. Providers will have to increase surveillance and counselling in their management of obstetric clients. This finding is also consistent with a systematic review involving 55 eligible studies by Bramham, Parnell, Nelson Piercy, Seed, Poston & Chappell (2014). It is very imperative for frontline healthcare workers to handle these categories of clients with maximum caution as part of efforts to reduce the occurrence of a preventable adverse event.

Delay in diagnosis was one of the contributory factors of preventable AEs among the study participants. This has been identified as one of the leading categories of adverse events generally (Southwick, 2015). This had festered because of the sup-optimal test follow-up culture in the study site. This attitude is similar to countries in developing countries (Khullar & Jena, 2016). This was one of the medical technology items *(of the health systems building block).*

The default and easier approach of blaming somebody does not change the causative factors likely to contribute to the occurrence of the harm. One of the first steps in delivering safe healthcare should include the identification and studying of the factors associated with preventable AEs and their patterns of occurrence within the health delivery system. There is the need for the adoption and development of the necessary safety practices that ensures that failures that can result in AEs are reduced to the barest minimum. Recognition of the

responsibility of all the providers of healthcare to comply with the established safety practices is necessary; and to avoid behaviours that would be characterized as *'at-risk behaviour'* or *'reckless behaviour'*. At-risk behaviour is the type of rule bending that tends to naturally occur over time in systems where the rate of adverse events is very low, while reckless behaviour is the type of behaviour that clearly puts patients at significant risk of harm and shows a conscious disregard of unreasonable risk. Instances of adverse events or failure to follow safety protocols ought to be investigated fairly and openly. The general principle when dealing with these situations is summarized as *'console the human error; coach the at-risk behaviour; and punish the reckless behaviour'* (American College of Obstetrician Gynaecologists (ACOG), 2009). It is desirable to catch errors in advance even though recognizing them after they happened is often the norm and it is equally important to make improvements. Harm can certainly befall any patient in any system.

The underlying contributing factors to adverse events, standard care and poor-quality services need to be understood, monitored and set targets for improvement as part of efforts to prevent AEs. Some five (5) interventions are identified as strategies to improve care in the wards and prevent AEs from occurring and these are: improve the levels of staff and the composition of the team, standardize the process of care, improve collaboration and communication, improve the climate of patient safety, and recognize and treat patients who are deteriorating very early. Of these strategic interventions, three (3) are leadership/governance (including health workforce) related (Pannick et al., June, 2015).

This study is consistent with the fact that, though human beings (i.e. leadership/governance) accounted for most of the occurrence of preventable adverse

events among obstetric clients, there is often a departure from safe practices which was often influenced by the organizational context and the working environment.

5.5 Degree of Preventability of Adverse Events among Obstetric Clients

In this study, designed to determine the degree of preventability of adverse events among obstetric clients, it was observed that most of the AEs that occurred were preventable. Assessing the degree of preventability of AEs helps to provide valuable insights that helps to understand the causative factors of AEs and these could be used to develop solutions that can help avert future occurrences and make the provision of care safe. This study found that more than two-thirds of the AEs that occurred among obstetric clients could have been prevented had the appropriate processes of care been followed and strictly adhered to. The results obtained for this study are higher than others found in prior studies that assessed preventability of adverse events in other disciplines in healthcare such as medicine, surgery and in rare instances *(such as in this study)* obstetrics (Baker et al., 2004; Brennan et al., 1991; Brenner et al., 2014; Classen et al., 2011; Thomas, Studdert, Newhouse, et al., 1999; Vries et al., 2008; Zegers et al., 2009). Various reasons could be ascribed to this. The first is the perspective with which the review of these AEs was done. The perspective for this study was quality improvement other than medicolegal, hence a preventability cut-off point >=2 was used like in other similar studies conducted in 28 hospitals in Australia (Wilson et al., 1995) and 13 hospitals in New Zealand (Davis et al., 2002). Other notable studies such as by Brennan et al. (1999) and Thomas et al. (1992) had done similar retrospective medical records review from a purely medicolegal perspective in hospitals in the New York, Utah and Colorado where they set their preventability cut-off point at >=4. In this study, however, even if the preventability cut-off point is increased from >=2 to

>=4, the level of preventability still remains high (i.e. 55.5%). The preventability cut-off and the perspective notwithstanding, the findings are similar to that by Aranaz-Andreas et al. (2011), Hwang et al. (2011), Rafter et al. (2016), Harkanen et al. (2014) and Elmontsri et al. (2017) all of who identified a preventability rate between 59.0% to 83.0%.

The other reason could be the status or type of the study site as a referral facility, both for Greater Accra and the rest of the country. It was noteworthy that patients are 'referred' even from the Korle Bu and Komfo Anokye Teaching Hospitals in Accra and Kumasi. Patients are also referred from other parts of the country (10.9%) other than Greater Accra. It has been suggested elsewhere that there is increased incidence of AEs in teaching/referral hospitals than in other types of hospitals. In the US, for instance, the federal government in 2017 slashed payments to about 751 hospitals, 115 (15.3%) of them were academic *(tertiary)* medical centres that treat sicker patients, and recorded the highest percentage of adverse events such as infections, bed sores and other mishaps (Rau, 2017; Zegers et al., 2009). In a Spanish study done in some primary healthcare facility, the authors estimated a degree of preventability of 96.4% among the study participants (Guerra-Garcia et al., 2017). A study among thirteen (13) hospitals across the British NHS involving about 4536 inpatient episodes identified 10.3% (95% CI 9.4% to 11.2%) of AEs, of which about half (51.5%) was preventable (Mayor, Baines, Vincent, Lankshear, Edwards, Aylward, Hogan, Harper, Davies, Mamtora, Brockbank, 2017).

The settings *(i.e. developed and developing countries)* where the various studies were conducted could also be an important reason for the high levels of preventability of the AEs. This study was conducted in a developing country *(i.e. Ghana)*, where the health system is still evolving, unlike in other settings like the New York, Utah, Colorado, UK,

Australia, and Netherlands where similar studies have been conducted. The quality and sophistication of the healthcare system in these countries is visibly higher compared to what we have in Ghana and at the Greater Accra (Ridge) Regional Hospital. Even though there were similar factors associated with the preventability of AEs across the healthcare system, irrespective of setting and geography, they were very marked in this study site. In this study, for instance, a preventable AE occurred because of the unavailability of blood for transfusion, there was a lack of an emergency medicine, such as tranexamic acid, in the hospital when it was needed most. The findings of this study further affirm the long-held views that, preventable AEs are higher in developing than in developed countries. For instance, Elmontsri et al. (2017) found an 83% degree of preventability among seven (7) developing countries namely Egypt, Kenya, Morocco, Sudan, South Africa, Tunisia, Jordan and Yemen similar to this study.

This study is one of the few, if not the first and only, to use the health systems' building block model to determine the degree of preventability of adverse events among obstetric clients. The study found that leadership/governance was one of the highest contributory factors to the occurrence of AEs among hospitalized obstetric clients. Leadership is seen as a very important element in patient safety generally and the prevention of AEs specifically (Elmontsri et al., 2017). Even though the leadership/governance factor contributed most to the factors associated with preventable AEs, the study further showed that neither leadership/governance alone nor any of the Health Systems Building Blocks i.e. service delivery, medical technology and health information could independently avert the occurrence of preventable AEs, unless there were adequate synergy and coordination between all of them. The variables are all correlated with one another and there is therefore the need for an efficient operating mechanism that is dependent on the collaboration of all

the components/subparts to avert preventable AEs. This is consistent with the view suggested by Elmontsri et al. (2017) that a lack of coordinated care has the potential of resulting in unfavourable outcomes for the patient.

The availability of protocols/guidelines, evidence of protocol/guidelines adherence, availability of decision-making aids, teamwork, and inadequate knowledge/skills were some of the leadership/governance related issues that caused or contributed to the AEs. This is also consistent with other studies (Gawande et al., 2003; Haynes et al., 2009; World Health Organization (WHO), 2009). For instance, in a systematic literature review by Elmontsri et al. (2017), the authors state in part that *'the use of aids would benefit making informed decisions and creating a culture of safety through complying with rules and procedures*. Unfortunately, there is still very little standardization in healthcare [also in Ghana and other developing countries] unlike in other industries, such as in aviation. And unfortunately, we in healthcare are still yet to take any lessons' (Vincent, 2011). There is so much variation across the continuum of care in the study site and even in the same department/unit/ward. This was evidenced and marked in the protocol non-adherence by the providers as evidenced in this study. There is an urgent need to simplify, standardize and improve the process of care. The reliance on humans will have to be reduced if we would want to prevent AEs. Smits et al. (2016), for instance, found that 94% of AEs could have been prevented but resulted in permanent disability, were caused by humans.

Various other notable models, such as the 'Human, Patient, Organizational, & Technical', were used in the Dutch hospitals study by Smits et al. (2008). The high preventability rate observed in this study were mostly due to leadership/governance and service delivery flaws in the study area. In most instances case management protocols/guidelines were not

available. In instances where they were available, they were not adhered to by the care providers. Other reasons for the high preventability of the AEs include: inadequate intrapartum monitoring of the clients, late initiation of blood transfusion, unavailability and late administration of prescribed emergency drugs such as tranexamic acid, equipment *(e.g. scan machine)* malfunction, inadequate theatre space; failure to perform timely episiotomy, and the inability of personnel to detect risks of complications for further management during the antenatal period of the obstetric client. All these could also be categorized as 'structure (or input)' variables according to the Donabedian triad (Donabedian et al., 1966) *(as shown in Figure 13).*

This study makes the statement that, preventable adverse events could greatly be reduced to the barest minimum if the structure/input variables particularly leadership/governance, health information and medical technology and service organization (the process of care) are available in the appropriate quantities and mix, and synergistically working together. The presence of anyone of them will not be a panacea to an error free healthcare system!

5.6 Agreement Between Reviewers with Respect to the Judgement of Preventability of Adverse Events among Obstetric Clients

Improving the reliability of adverse event determination to include the estimation of inter-rater reliability issues has proven very daunting. Very few studies compute their IRR (Baker et al., 2004; Brennan, 1991; Rafter et al., 2016; Zegers et al., 2007). The kappa statistic from this study *(as presented in Table 17)* was of moderate strength between the obstetrician reviewers (0.4978) and low between the nurse/midwife reviewers (0.3261). This was mostly due to the frequent disagreement about the classification of primary and

secondary degree perineal tears as an adverse event. This reliability test involved numerous sets of obstetrician and midwife/nurse reviewers and hence the extent of variation. This finding was however similar, and in some instances better, than that found in other studies. For instance, the Canadian study by Baker et al. (2004) recorded a kappa of 0.47 for the measurement of agreement between their physician reviewers. Brennan et al. (1991) also recorded a kappa statistic of 0.61 among their physician reviewers about the presence of an adverse event. Authors of the Dutch study (Zegers et al., 2009) also recorded a K-statistic between two-pairs of doctors that they described as *'not better than that in other studies'*. Again, authors of the New Zealand study also recorded a kappa of 0.47 which they described as *'moderate strength'* as the measure of agreement between their Medical Officer (MO) reviewers and their expert reviewer in the determination of their adverse events (Davis et al., 2002). Authors in the Utah & Colorado study also had a 79% percent agreement and a K-statistic of 0.4 (Thomas et al., 2000). However other notable studies particularly the Swedish study that assessed the incidence of AEs from 2013-2016 in Sweden did not do any assessment of inter-rater reliability or Kappa statistic. No reasons were however given by the authors (Nilsson et al., 2018). Consistency between reviewers is a major challenge for all folder/medical record reviews. There is therefore the need to ensure the standardization of reviewer training and computerize adverse event data entry as one of the ways of increasing inter-rater reliability.

It is well known that retrospective record review studies to identify AEs and their degree of preventability often record moderate kappa statistic values ranging from 0.2 to 0.6 (Brennan et al., 1991; Davis et al., 2002; Thomas et al., 2000; Wilson et al., 1995; Zegers et al., 2009). This Kappa statistic of this study findings is similar to all of such studies.

5.7 Strengths and Limitations of this Study

The study sample is drawn from all eligible medical records in the obstetrics department of the Greater Accra (Ridge) Regional hospital in 2015. To the best of my knowledge, this study is the first largest explorative study in any single hospital in Ghana to determine the AE rates, causative factors, types, and the degree of preventability. The large sample size from a single institution which made it possible to assess various causative factors could not have been achieved with a small sample size. Both the IRR and Kappa statistics were computed. It is also one of the few studies that employed a **four-stage** review process, unlike others that employ the two-stage review process. The **four-stage** review process was very robust. There was however, the unlikelihood of identifying all the adverse events within the study sample. This was so because the documentation in some of the medical records was incomplete. There was also a challenge in reviewing all the positively flagged folders because they could not be found during the retrieval process. The storage of medical records in the study site was a major challenge. Folders that were found during the search were however re-reviewed by the experts. The methodology for identifying adverse events relied solely on data from medical records, therefore, only events that were documented in the records was included. As a result, there were instances where available records in the patient's folders were insufficient for AE determination. Insufficient records were, however, excluded from the study. Again, medical records that were not accessible were also excluded from the study. Judgements regarding the factors associated with AEs were sometimes difficult and inaccurate but the multi-stage review process addressed this. Finally, the analysis is limited to a single secondary level referral health facility in Ghana. Any generalizations will have to be done cautiously. Much work needs to be done to

standardize medical practice, documentation of medical records and procedures for adverse event reporting.

Also, the two different study designs *(i.e. cross-sectional and case control)* ensured some methodological robustness of the study. The study designs made it possible to estimate both the prevalence and to identify the factors likely to cause AEs making it possible to attain the objectives of this study.

The results of this study provide the need for public awareness of the patient safety situation in the Greater Accra Regional (Ridge) Hospital and the need to take urgent steps to improve the situation to prevent harm to obstetric clients.

Again, the instrument used in this study has addressed a critical call, especially in Ghana and the continent, **for instruments which tested** validity and reliability to measure adverse events among hospitalized obstetric clients in such settings, to improve the provision of quality and safe healthcare. This is invariably a very important tool for future empirical studies that focusses specifically on adverse events among obstetric clients.

CHAPTER 6
CONCLUSIONS AND RECOMMENDATIONS

6.1 Introduction

This chapter presents the conclusions of the study in relation to the specific objectives of the research. It also **offer** recommendations that could improve the health outcomes, and the quality and safety of obstetric clients at the Greater Accra (Ridge) Regional Hospital and they are presented as follows:

6.2 Conclusions

6.2.1 Prevalence of AEs Among Obstetric Clients

The prevalence of adverse events among obstetric clients hospitalized at the Greater Accra (Ridge) Regional Hospital **was** high accounting for 12% *(including first- and second-degree perineal tears)* and 6% *(excluding first- and second-degree perineal tears)* of all admissions to the Greater Accra (Ridge) Regional Hospital.

6.2.2 Types of Adverse Events among Obstetric Clients

The specific types of adverse events among obstetric clients **were** surgical related, such as: excessive bleeding, perineal tears, trauma to the baby and postpartum haemorrhage; and treatment related such as avoidable delay in treatment, eclampsia (institutional) and inadequate monitoring.

Efforts at improving surgery and treatment to obstetric clients will go a long way to improve the quality and safety of healthcare given to them *(i.e. obstetric clients).*

6.2.3 Factors Associated with Adverse Events among Obstetric Clients

Patient characteristics, such as age, surgical history, number of ANC attendances and gestational age, are the main factors associated with preventable adverse events among obstetric clients hospitalized at the Greater Accra (Ridge) Regional Hospital. These characteristics are key to identify patients who are at risk for specific adverse events by obstetrician gynaecologists.

Adverse events among obstetric clients increases with increasing maternal age. As the age of the obstetric client increases, the likelihood of her developing an adverse event while on hospitalization also increases.

It has been noted that, some of the factors associated with preventable adverse events are unavailability of protocols/guidelines, inadequate adherence to the available protocol/guidelines and inadequate intrapartum monitoring. Others are inadequate knowledge/skills of the healthcare provider, unavailability of blood & blood products, and delay (>=12hours) in diagnosis. The rest are inadequate use of ANC services, equipment availability and malfunction.

6.2.4 Degree of Preventability of Adverse Events among Obstetric Clients

The degree of preventability of AEs among obstetric clients hospitalized in the Greater Accra (Ridge) Regional Hospital is marked, substantial and high.

Secondly, a large number of adverse events can be prevented by addressing leadership/governance issues such as ensuring the availability and use of protocols/guidelines, availability of decision-making aids, ensuring adherence to the protocols/guidelines, improving intrapartum monitoring, improving knowledge/skills of frontline healthcare providers and teamwork.

Finally, AEs among obstetric clients could be prevented once there is an efficient and effective coordination and correlation between all the components of the health systems' building blocks. No single component of the health system's building block can prevent an adverse event from occurring on its own *(i.e. without the other sub-parts)*. A preventable AE can occur whenever the relationship between leadership/governance and all the other sub-components of the HSBBs is weak or non-existent. Leadership is required to ensure that all the health systems building blocks are working together synergistically and this will go a long way to make patient care safer in our hospitals and healthcare facilities.

6.3.0 Recommendations

6.3.1 Prevalence of any AEs Among Obstetric Clients

The following recommendations are expected to be carried out by the study site in the

Short-term:

1. Institute measures **(such as developing an AE reporting guideline and develop template for AE reporting)** to ensure mandatory reporting and strong monitoring of adverse events.

2. The SBAR *(which is the acronym for Situation, Background, Assessment and Recommendation)* should be introduced as a more structured method of communication among members of staff.

6.3.2 Types of Adverse Events among Obstetric Clients

The following recommendations are expected to be undertaken in the short to medium term by the study site:

1. Improve the capacity of frontline health workers to detect, report, prevent and learn from adverse events and service failures.

2. Improve upon the data quality issues in the obstetrics department, especially in the area of documentation of case notes, by both the clinicians and the nurses

6.3.3 Factors Associated with Adverse Events among Obstetric Clients

It is acknowledged that the factors associated with preventable adverse events are very deep-seated and pervasive and cannot be attributed to an individual frontline healthcare worker, there is the need to direct interventions and strategies aimed at preventing their occurrences to the individuals as well as the organizational systems. This can be done by institutionalizing clinical governance systems with the following proposed arrangements:

Short-term

i. A coherent quality improvement and patient safety programme

ii. Protocols/guidelines should be made available for all the care processes and their use will also have to be enforced at all times.

Medium term

iii. Succinct and clear arrangements for accountability and reporting of adverse events with ultimate responsibility at the institutional level for arrangements in assuring and improving quality and safety.

iv. Risk management processes that will include measures to detect and deal with professional performance that is inappropriate.

Long term

v. Ensure the creation of patient safety culture across the hospital. The patient safety culture being proposed include:

   a. Learning culture

   b. Reporting culture

   c. Just culture

6.3.4 Degree of Preventability of Adverse Events among Obstetric Clients

Short term

1. Frontline healthcare workers will have to be made aware (through in-service training programs) of when and how to access a more senior opinion and seek guidance in the management of cases. In most instances where AEs occurred, the management of the cases were done by junior staff. The assistance and presence of experienced and senior staff in the management of difficult cases would go a long way to avert the occurrence of preventable harm to obstetric clients.

Medium term

2. Ensure a safe and dependable health service by developing robust systems of clinical governance and accountability at all levels of the health system.

6.4.0 Recommendation for Policy Makers (e.g. Ministry of Health, GHS)

The following are some recommendations made to the Ministry of Health (MOH) and other stakeholders in the policy making process as part of the general policies and guidelines to improve quality and patient safety among obstetric clients specifically and the larger patient population in Ghana.

Medium term

1. Develop and ensure the implementation of a national set of minimum standards in healthcare.
2. Develop a national system for the reporting and explicit guidelines for the data collection and integration from all health facilities across the country.
3. Facilitate the development of a standard definition of adverse events in Ghana, describe a minimum adverse event dataset, and ensure a standardized approach for the collection and integration of AE data.

Long term

4. Develop and ensure the implementation of a national policy on patient safety.
5. Support the conduct of a national study to determine the national 'true' prevalence/incidence of adverse events

6.5.0 Recommendation for Future Research

The following recommendations are made for future researchers to explore as we continue to make knowledge in the study area abundant for improvement in the quality and safety of the healthcare system in the country:

a. Explore the impact of adverse events on the healthcare provider

b. Explore the cost implications of adverse events on the healthcare system

c. Explore the effects of the latent factors on outcomes

d. Explore the importance of primary and secondary degree perineal tears as an adverse event among obstetric clients.

e. Explore the various levels and types of leaders and determine their effect on the occurrence of preventable adverse events

f. Explore the impact of adverse events on maternal mortality

6.6.0 Contribution to Knowledge

The following contribution to existing knowledge in the subject of adverse events among hospitalized obstetric clients is made:

1. The relationship between leadership/governance and the other Health Systems' Building Blocks in preventing AEs has been established. This study has showed the integral role leadership/governance plays in averting the occurrence of preventable adverse events in healthcare.

2. A model that explores the relationship between leadership, health information, medical technology and service delivery has been developed.

3. The estimation of the prevalence rate of adverse events among obstetric clients has been established.

4. The use of social media platform i.e. WhatsApp, to facilitate communication and discussions among reviewers has also been established.

5. Developed and validated an adverse event reporting template for adverse event reporting of obstetric clients in Ghana.

6.7.0 Lessons Learnt

A number of lessons have been learnt from this study which can guide future researchers to be more effective and efficient in the conduct of research in such an area. Some of these lessons are:

1. When time of the study is of great essence, it will be more appropriate to use panel discussion of the reviewers to determine the adverse events, their associated factors and degree of preventability other than facilitating the process through WhatsApp and allowing them to do it independently. The study has showed that, though the WhatsApp process is equally effective and efficient as the panel discussion, the process could be very slow.

2. Data quality issues are a big deal. More than half of the data that was originally collected could not be used because of inconsistency in the facility data collection. Future researchers should be sure that data are available and consistent on the variables they want to study. In this study, it was realized that, important variables such as education status of

the pregnant woman, date and time of diagnosis; date and time of admission; and date and time of the occurrence of the adverse event among others were not routinely and consistently collected. This made it impossible to analyze these very important variables which could have significantly enriched the study findings.

3. Extensive reading on your topic and subject area is a critical success factor. The candidate must demonstrate knowledge on the subject area at every encounter else he/she risks being told what must be done.

4. Relationship with every member in the research process and the humility of the researcher to accept divergent and sometimes opposing views is a great success factor. People went out of their way to do things for me largely on the basis of these. I often wonder how I could get all those quality of obstetrician gynecologists to review folders for me without paying a penny to any of them. How I could get the support and interest of the Medical Director of the Greater Accra Regional Hospital and for him to even agree to be a Clinical Supervisor of the work. How I could get the support of the then Greater Accra Regional Director of Health Services *(i.e. Dr. Linda Van Otoo)* to support the process in getting me an obstetrician gynecologist in the Greater Accra Region to support the process.

5. Another important success factor and lesson learnt for me is the commitment and interest of the Supervisors. You can be very intelligent and everything but without the commitment, interest and direction of your Supervisors, you will be heading nowhere. Even though the PhD is owned and driven by the student, the role of the supervisor cannot be overemphasized.

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APPENDICES

Appendix 1: Data Collection Instrument

PART A: Demographic Characteristics Date: …… Code: …….

No	Variable	Response
1	Folder ID	
2	Age	
3	Location of residence	
4	Education	
5	Occupation	
6	Marital Status	
7	Religion	
8	No. of ANC attendance	
9	Referral institution	
10	Date of referral **(DD/MM/YYYY)**	
11	Time of referral **(MM/HH)**	
1	Referral diagnosis	
14	Condition (Normal/Complication)	
15	FH status (Present/ Absent)	
16	Gravidity	
17	Parity	
18	Gestational age **(WEEKS)**	
19	Date of Admission	
20	Time of admission **(MM/HH)**	
21	Systolic BP **(MMHG)**	
22	Diastolic BP **(MMHG)**	
23	Diagnosis	
24	Time of diagnosis	
25	Time treatment started	
26	Adverse event	
27	Location in the Hospital where AE occurred	ER, OR, Ward, ICU, Labor & Delivery room, Procedure room, diagnostics (lab, radiology etc), others
28	Date of adverse event **(DD/MM/YYYY)**	
29	Time of event **(MM/HH)**	
30	Time of intervention **(MM/HH)**	
31	Date of Death/Discharge **(DD/MM/YYYY)**	
32	Time of death/discharge **(MM/HH)**	
33	Post mortem	
35	Remark	
36	Amount (GHS) paid after discharge (without an AE)	

No	Variable	Response
37	Amount (GHS) paid after discharge (with an AE)	
	Medical & Surgical History	
38	Hypertension	
39	Heart Disease	
40	Sickle Cell disease	
41	Jaundice	
42	Diabetes	
43	Respiratory disease	
44	Epilepsy	
45	Mental illness	
46	HIV	
47	Proteinuria	
48	G6PD	
49	Surgical Prev. C/S Myomectomy others	
50	Post-Partum period	
51	Outcome (Live/Still)	
	***For all surgeries:**	
52	Surgery start time	
53	Surgery finish time	
54	Type of anesthetic technique	
55	Use of the surgical safety checklist	
56	Administration of surgical prophylaxis	
57	Use of Consent form	

PART B: Nature of Adverse Events

No	Variables	Tick (√)
1	Acute Kidney Injury	
2	Acute respiratory failure	
3	Bladder or Ureteric damage	
4	Blood transfusion reaction	
5	Burst Abdomen	
6	Delirium or Change in Mental Status	
7	Delay in diagnosis	
8	Delay in treatment	
9	Drug reaction (appropriate drug)	
10	Drug (inappropriate dose/treatment)	
11	Drug interaction	
12	DVT with or without Pulmonary Embolism	
13	Eclampsia (institutional)	
14	Equipment malfunction	
15	Error in diagnosis	
16	Excessive bleeding (>500mls) for SVD and >1000mls for CS	
17	Failure to act on lab results >12hours	
18	Failure to provide prophylactic treatment	
19	Fall	
20	Hypoglycemic event (FBS <3.6mmol/l)	
21	Inadequate monitoring or follow up of treatment	
22	Left Ventricular or Congestive Cardiac Failure	
23	Lights out	
24	Obstetric damage to the mother e.g. perineal tear (*please indicate severity*), ruptured uterus or cervical laceration	
25	Major trauma to baby e.g. fracture of the clavicle or long bone	
26	Medication error with significant reaction e.g. excessive $MgSO_4$ resulting in a reaction	
27	Pneumonia	
28	Postpartum Hemorrhage >1L	

No	Variables	Tick (√)
29	Pressure ulcer/bed sore	
30	Septicemia	
31	Severe Hypotension (BP Systolic <80)	
32	Surgical Site Infection (SSI)	
33	Others	

PART C: Causative/Contributory Factors

The occurrence of an adverse event, and the actions or omissions of those involved, may be influenced by many contributory factors. Many of these could only be assessed satisfactorily by interviewing the staff involved in the care of the patient please indicate, where possible, likely causative factors. Mark unlikely factors with U possible factors with 1, 2 or 3.

Please rate **each** of the following factors according to its importance, as you see it, in the occurrence of this particular adverse event.

Unlikely to be relevant Possibly relevant Somewhat important Very important
U 1 2 3

1.0	**Leadership & Governance**	**U**	**1**	**2**	**3**
1.1	Availability of decision-making aids				
1.2	Evidence of protocol/guidelines adherence				
1.3	Availability of care standards				
1.4	Availability of guidelines/protocols				
1.5	Regulations				
1.6	Availability of senior leadership				
1.7	Supervision & seeking help				
2.0	**Human Resource**				
2.1	High workload				
2.2	Inadequate knowledge and skills of individuals				
2.3	Competence				
2.4	Staff status & rank				
2.5	Staff availability				
2.6	Long shift/ work hours				
2.7	Clarity in work roles				
2.8	Psychological precursors (inattention, forgetting, distraction pre-occupation, fatigue & stress) ,				
2.9	Inadequate number				
3.0	Skill mix of staff				
3.1	Attitude/motivation				
3.2	Difficult task or procedure				
3.3	Design & clarity of task				
3.4	Communication				
3.5	Team work				

3.0	**Health Financing**				
3.1	Insured				
3.2	Uninsured				
3.3	Employed				
3.4	Unemployed				
4.0	**Medical technologies**	**U**	**1**	**2**	**3**
4.1	Availability of blood and blood products				
4.2	Delay (>12 hours of request) in receiving diagnostic test (specify) results				
4.3	Delay (>12 hours of patient arrival) in diagnosis				
4.4	Medicines Availability				
4.5	Equipment availability				
4.6	Equipment malfunction				
4.7	Theatre space				
4.8	Test results difficult to interpret				
4.9	Failure to arrange for an investigation				
5.0	Availability of test results				
5.1	Failure in technical performance				
5.2	Lights out				
5.3	Work flow				
5.4	Equipment design				
5.0	**Health information**				
5.1	Incomplete documentation				
5.2	Lost progress notes or reports				
5.3	Poor written communication (e.g. defects or missing case notes)				
5.4	Inadequate handover				
6.0	**Service delivery**				
6.1	Medication error				
6.2	Transfusion error				
6.3	Delay in receiving treatment				
6.4	Insufficient care follow-up				
6.5	Inadequate management				
6.6	Inadequate intrapartum monitoring and prolonged labor				
6.7	Delay or incorrect timing of surgery				
6.8	Misdiagnosis				
6.9	Failure to arrange for a procedure or an investigation or a consultation				
7.0	Lack of care and attention to the patient				
7.1	Test results not reviewed				

7.2	Test results not reported				
7.3	Inadequate use of ANC services				
7.4	Problems with provision or scheduling of services (e.g. theatre list, lab tests, x-rays)				
7.5	Complexity and seriousness of the condition				
7.6	Poor coordination of overall service				
7.7	Delay in diagnosis				
7.8	Late referral				
7.9	Was co-morbidity an important contributory factor?				

PART D: Contributory Factors

D: Give details on the 3 MOST IMPORTANT contributory factors to this AE

1_____

_____

_____

_____

2_____

_____

_____

_____

3_____

_____

_____

_____

PART E: Preventability of Adverse Events

E: ASSESS THE PREVENTABILITY OF THE ADVERSE EVENT	Yes	No
In your judgment, is there some evidence that the AE was preventable? Rate on a 6-point scale the strength of evidence for preventability		
1 (Virtually) no evidence for preventability		
2 Slight to modest evidence for preventability (i.e. management causation)		
3 Preventability not quite likely; less than 50 -50 but close call		
4 Preventability more likely than not; more than 50-50 but close to call		
5 Strong evidence for preventability		
6 (Virtually) certain evidence for preventability		
If you ticked 2-6, please answer the following questions: Describe briefly the manner in which the AE could have been prevented_____ _____ _____ _____ Can you identify any reason(s) for the failure to prevent this AE? _____ _____ _____ _____ _		

Appendix 2: Validated Data Collection Instrument (of causative factors)

PART C: Causative/Contributory Factors

The occurrence of an adverse event, and the actions or omissions of those involved, may be influenced by many contributory factors. Many of these could only be assessed satisfactorily by interviewing the staff involved in the care of the patient please indicate, where possible, likely causative factors. Mark unlikely factors with U possible factors with 1, 2 or 3.

Please rate **each** of the following factors according to its importance, as you see it, in the occurrence of this particular adverse event.

Unlikely to be relevant U **Possibly relevant 1** **Somewhat important 2** **Very important 3**

1.0	**Leadership & Governance**	**U**	**1**	**2**	**3**
1.1	Availability of decision-making aids				
1.2	Evidence of protocol/guidelines adherence				
1.3	Availability of care standards				
1.4	Availability of guidelines/protocols				
1.5	Inadequate knowledge and skills of individuals				
1.6	Competence				
1.7	Attitude/motivation				
1.8	Team work				
1.9	Inadequate intrapartum monitoring				
2.0	**Medical technologies**	**U**	**1**	**2**	**3**
2.1	Equipment availability				
2.2	Equipment malfunction				
2.3	Late referral				
2.4	Test results difficult to interpret				
2.5	Lights out				
3.0	**Health information**				
3.1	Incomplete documentation				
3.2	Lost progress notes or reports				
3.3	Poor written communication (e.g. defects or missing case notes)				
3.4	Inadequate handover				
3.5	Failure to arrange for a procedure				
3.6	Inadequate use of ANC services				
4.0	**Service delivery**				
4.1	Availability of blood and blood products 6				
4.2	Delay (>12 hours of patient arrival) in diagnosis 5				
4.3	Availability of test results 7				
4.4	Problems of provision or scheduling of services				

Appendix 3: Glossary of Terms

Antepartum Haemorrhage: Any bleeding per vagina at gestational age of 28 weeks or more.

Caesarean Section: Delivery of a baby through an abdominal incision rather than through the vagina

Delirium: Mental disturbance characterized by confusion, disordered speech, and hallucinations

Diagnosis: This is the process of determining the disease or condition that one is suffering from by seeing his/her signs and symptoms.

Eclampsia: Is the occurrence of new-onset, generalized, tonic-clonic seizures or coma in a woman with preeclampsia

Gestation: This is the carrying of an embryo or foetus inside a female viviparous animal. Gestational age in human obstetrics refers to the foetal age plus two (2) weeks

Gravida: The number of times the woman has been pregnant, regardless of whether these pregnancies were carried to term or not

Hypoglycaemia: Condition of abnormally low blood sugar (glucose) level i.e. <3.4 mmol/l

Infection: The invasion and multiplication of microorganisms such as bacteria, viruses and parasites that are not normally present within the body.

Medication: The use of legal drugs to treat or cure an illness or injury

Not preventable AE: AE could not have been avoided given the complexity of the patient's condition or the care required

Parity: The number of times the woman has delivered after the age of viability. It includes the births after 24 weeks or those having weight of 500 grams.

Patient care: The process that involves collecting information from and about the patient, assessing this information, planning a treatment based on the evidence, implementing that plan and then following up with what happened by monitoring and evaluating the response of the patient to treatment (Yorke, 2016).

Postpartum Haemorrhage: This is a loss of more than 500 mls of blood following vaginal delivery, or 1000 mls of blood following caesarean section

Pre-eclampsia: This is when the pregnant woman develops high blood pressure (i.e. 140/90 mmHg) and protein in the urine after the 20th week of pregnancy.

Preventable AE: AE could have been avoided through improved assessment or alternative actions

Sepsis: A systemic response to a serious, usually localized infection of bacterial origin, such as systemic inflammatory response syndrome

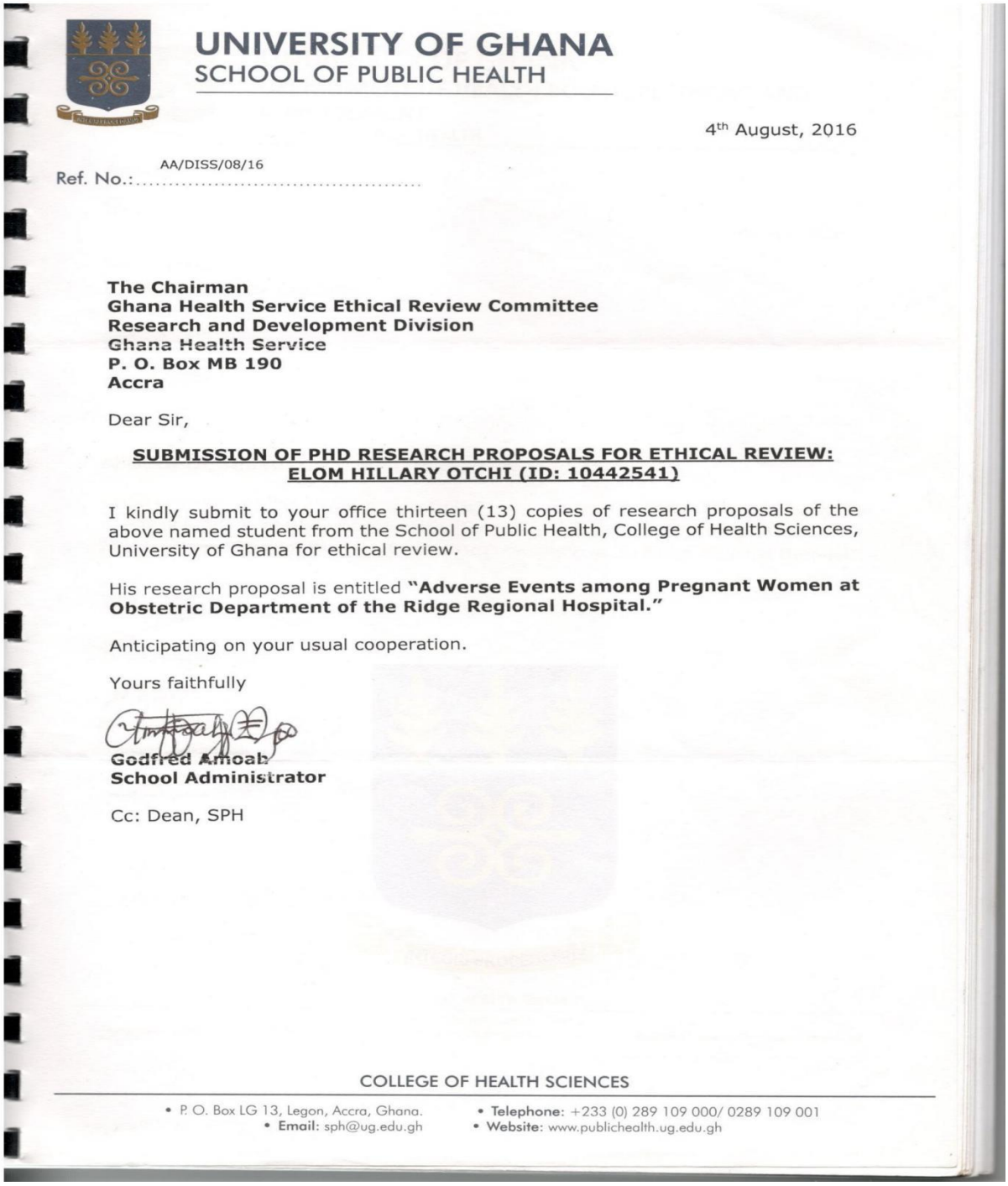
Surgery: it is the branch of medicine that employs operations in the treatment of disease or injury. This involves cutting, abrading, suturing or otherwise physically changing body tissues and organs (www.medicinenet.com).
Treatment: This is defined as the medical care that is given to a patient for an illness or injury, he/she is suffering from. It is provided to relieve one of an illness or injury.

Unable to determine: Reviewers (i.e. obstetrician gynaecologists) were unable to determine the preventability because of incomplete documentation or complexity of the case.

Urinary Tract Infection (UTI): Infection of the tract through which urine passes and can include the kidney, ureters, bladder, and/or urethra.

Sources: Sehrish Khan, Syed Mohammed Baqir (nd). Basic Terminologies of obstetrics (available at: https://www.slideshare.net/ZeeshanKhan97/common-terminologies-ofobstetrics)

Appendix 4: Introductory Letter from SPH



UNIVERSITY OF GHANA
SCHOOL OF PUBLIC HEALTH

4th August, 2016

Ref. No.: AA/DISS/08/16

The Chairman
Ghana Health Service Ethical Review Committee
Research and Development Division
Ghana Health Service
P. O. Box MB 190
Accra

Dear Sir,

SUBMISSION OF PHD RESEARCH PROPOSALS FOR ETHICAL REVIEW: ELOM HILLARY OTCHI (ID: 10442541)

I kindly submit to your office thirteen (13) copies of research proposals of the above named student from the School of Public Health, College of Health Sciences, University of Ghana for ethical review.

His research proposal is entitled **"Adverse Events among Pregnant Women at Obstetric Department of the Ridge Regional Hospital."**

Anticipating on your usual cooperation.

Yours faithfully

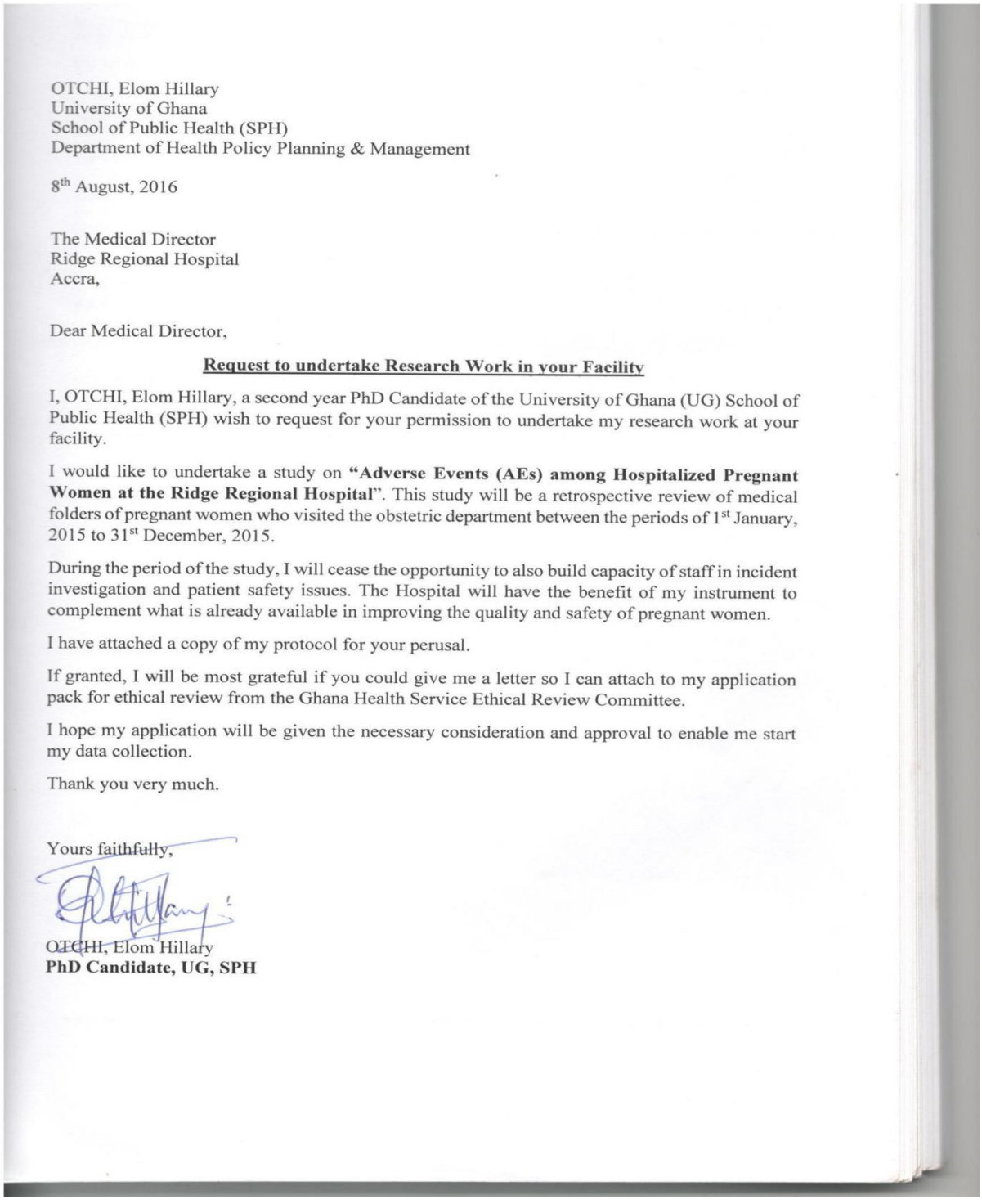
Godfred Amoah
School Administrator

Cc: Dean, SPH

COLLEGE OF HEALTH SCIENCES

• P. O. Box LG 13, Legon, Accra, Ghana. • **Telephone:** +233 (0) 289 109 000/ 0289 109 001
• **Email:** sph@ug.edu.gh • **Website:** www.publichealth.ug.edu.gh

Appendix 5: Request to undertake research work in Ridge Regional Hospital



OTCHI, Elom Hillary
University of Ghana
School of Public Health (SPH)
Department of Health Policy Planning & Management

8th August, 2016

The Medical Director
Ridge Regional Hospital
Accra,

Dear Medical Director,

Request to undertake Research Work in your Facility

I, OTCHI, Elom Hillary, a second year PhD Candidate of the University of Ghana (UG) School of Public Health (SPH) wish to request for your permission to undertake my research work at your facility.

I would like to undertake a study on **"Adverse Events (AEs) among Hospitalized Pregnant Women at the Ridge Regional Hospital"**. This study will be a retrospective review of medical folders of pregnant women who visited the obstetric department between the periods of 1st January, 2015 to 31st December, 2015.

During the period of the study, I will cease the opportunity to also build capacity of staff in incident investigation and patient safety issues. The Hospital will have the benefit of my instrument to complement what is already available in improving the quality and safety of pregnant women.

I have attached a copy of my protocol for your perusal.

If granted, I will be most grateful if you could give me a letter so I can attach to my application pack for ethical review from the Ghana Health Service Ethical Review Committee.

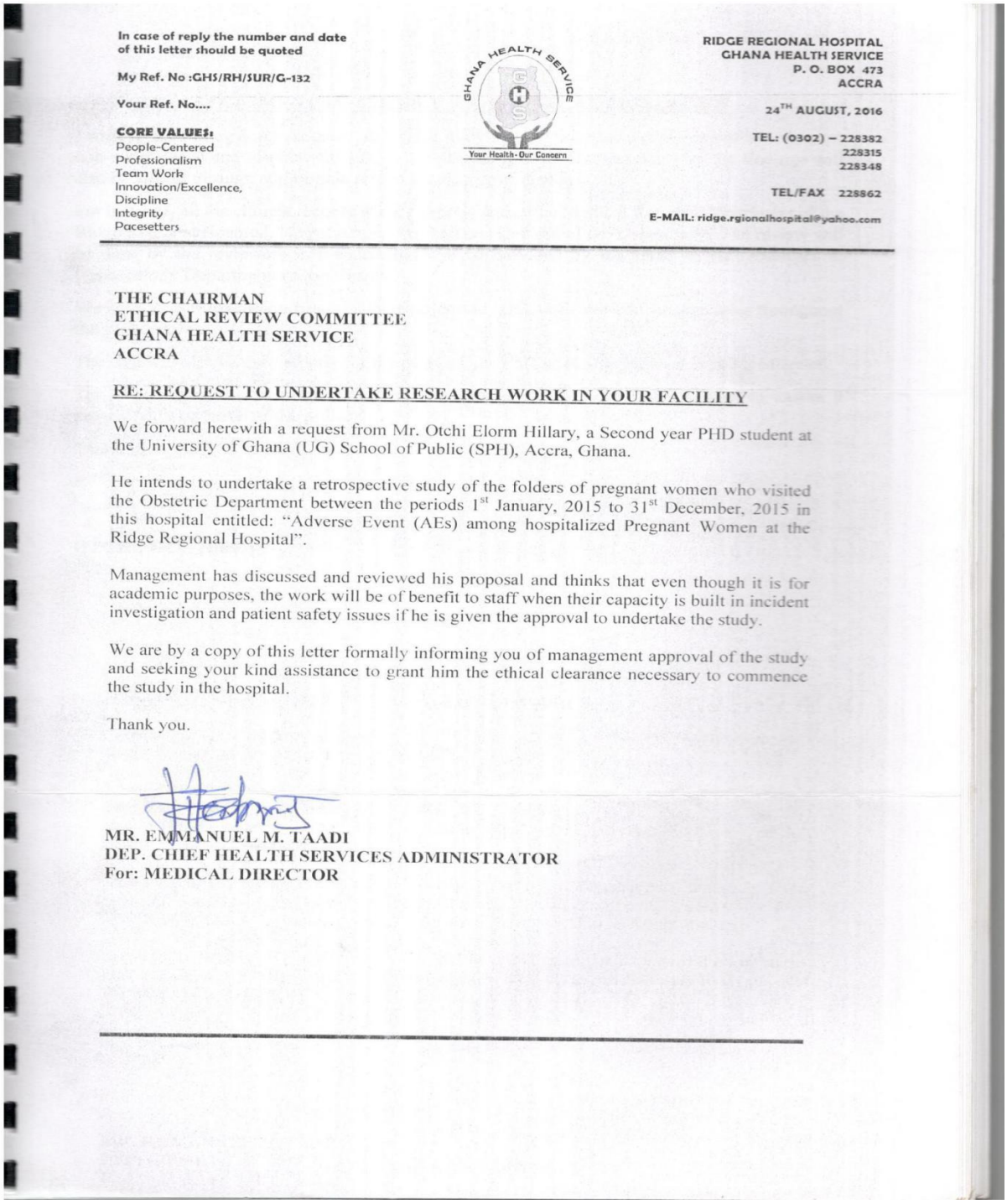
I hope my application will be given the necessary consideration and approval to enable me start my data collection.

Thank you very much.

Yours faithfully,

OTCHI, Elom Hillary
PhD Candidate, UG, SPH

Appendix 6: Greater Accra (Ridge) Hospital Institutional Approval



In case of reply the number and date of this letter should be quoted

My Ref. No :GHS/RH/SUR/G-132

Your Ref. No....

CORE VALUES:
People-Centered
Professionalism
Team Work
Innovation/Excellence,
Discipline
Integrity
Pacesetters

GHANA HEALTH SERVICE
Your Health - Our Concern

RIDGE REGIONAL HOSPITAL
GHANA HEALTH SERVICE
P. O. BOX 473
ACCRA

24TH AUGUST, 2016

TEL: (0302) – 228382
228315
228348

TEL/FAX 228862

E-MAIL: ridge.rgionalhospital@yahoo.com

THE CHAIRMAN
ETHICAL REVIEW COMMITTEE
GHANA HEALTH SERVICE
ACCRA

RE: REQUEST TO UNDERTAKE RESEARCH WORK IN YOUR FACILITY

We forward herewith a request from Mr. Otchi Elorm Hillary, a Second year PHD student at the University of Ghana (UG) School of Public (SPH), Accra, Ghana.

He intends to undertake a retrospective study of the folders of pregnant women who visited the Obstetric Department between the periods 1st January, 2015 to 31st December, 2015 in this hospital entitled: "Adverse Event (AEs) among hospitalized Pregnant Women at the Ridge Regional Hospital".

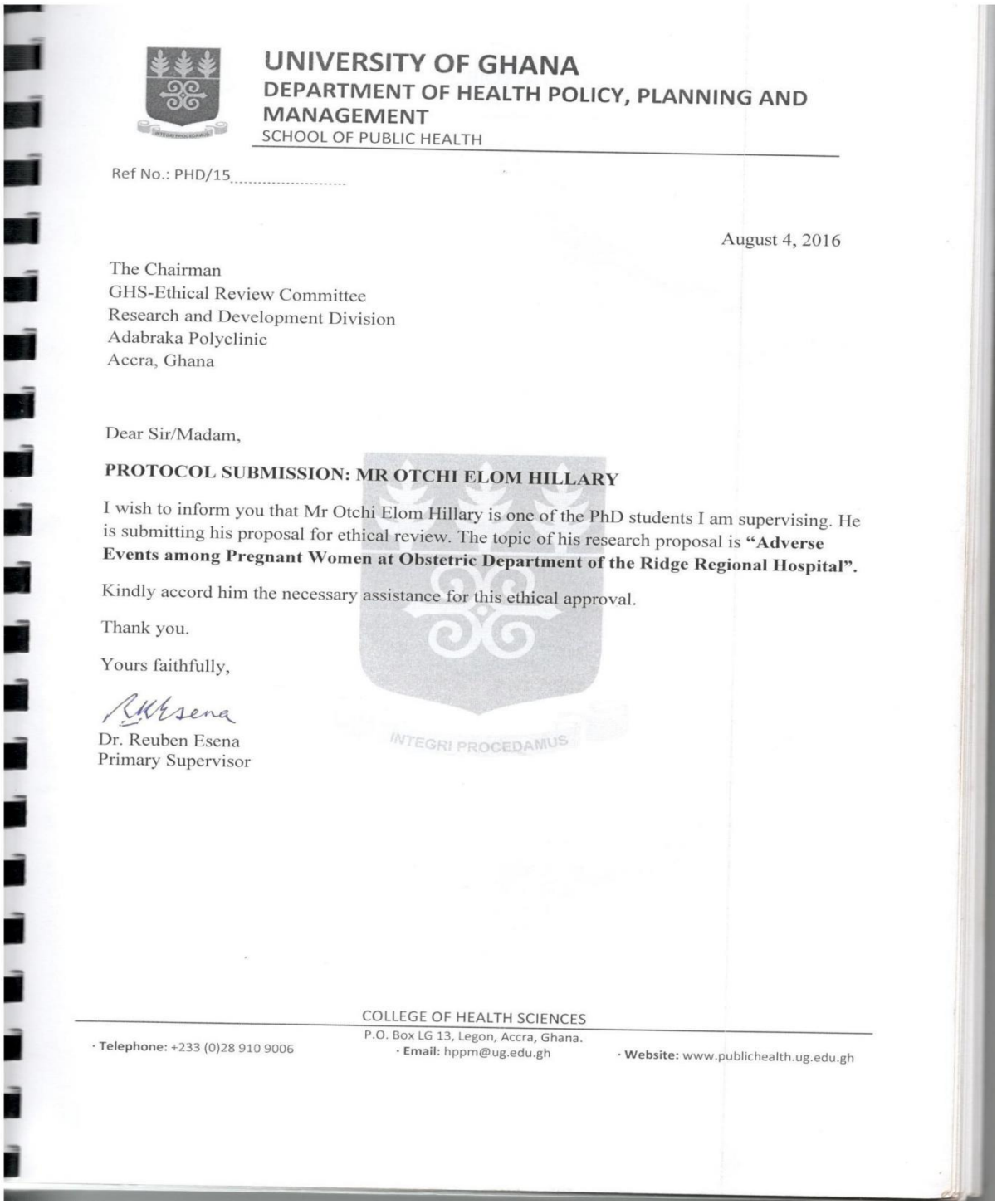
Management has discussed and reviewed his proposal and thinks that even though it is for academic purposes, the work will be of benefit to staff when their capacity is built in incident investigation and patient safety issues if he is given the approval to undertake the study.

We are by a copy of this letter formally informing you of management approval of the study and seeking your kind assistance to grant him the ethical clearance necessary to commence the study in the hospital.

Thank you.

MR. EMMANUEL M. TAADI
DEP. CHIEF HEALTH SERVICES ADMINISTRATOR
For: MEDICAL DIRECTOR

Appendix *7: Protocol Submission Letter to GHS-ERC from Primary Supervisor*



UNIVERSITY OF GHANA
DEPARTMENT OF HEALTH POLICY, PLANNING AND MANAGEMENT
SCHOOL OF PUBLIC HEALTH

Ref No.: PHD/15.....

August 4, 2016

The Chairman
GHS-Ethical Review Committee
Research and Development Division
Adabraka Polyclinic
Accra, Ghana

Dear Sir/Madam,

PROTOCOL SUBMISSION: MR OTCHI ELOM HILLARY

I wish to inform you that Mr Otchi Elom Hillary is one of the PhD students I am supervising. He is submitting his proposal for ethical review. The topic of his research proposal is **"Adverse Events among Pregnant Women at Obstetric Department of the Ridge Regional Hospital".**

Kindly accord him the necessary assistance for this ethical approval.

Thank you.

Yours faithfully,

Dr. Reuben Esena
Primary Supervisor

INTEGRI PROCEDAMUS

COLLEGE OF HEALTH SCIENCES
P.O. Box LG 13, Legon, Accra, Ghana.
· Telephone: +233 (0)28 910 9006 · Email: hppm@ug.edu.gh · Website: www.publichealth.ug.edu.gh

Appendix *8: Protocol Submission Letter to GHS-ERC from Primary Supervisor*

In case of a reply, the number and t he date of this letter should be quoted

My Ref. No: **GHS/RH/AMI/G-32**

Your Ref. No.

GHANA HEALTH SERVICE
Your Health - Our Concern

RIDGE REGIONAL HOSPITAL
GHANA HEALTH SERVICE
P. O. BOX 473
ACCRA-GHANA

Tel: (0302)228382
228315
228348

22ND SEPTEMBER, 2016

THE CHAIR
GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE
ACCRA, GHANA

Dear Chair,

Protocol Submission: OTCHI, Elom Hillary

I write to inform you that, OTCHI, Elom Hillary is one of the PhD Candidates of the University of Ghana (UG) School of Public Health (SPH) I am supervising.

He is undertaking his study on **"Adverse Events (AEs) among Hospitalized Pregnant Women at the Ridge Regional Hospital"**. This study will be a retrospective review of medical folders of pregnant women who visited the obstetric department between the period of 1st January, 2015 to 31st December, 2015.

He is submitting his protocol for ethical review and I hope he is accorded the necessary assistance. I will play my part as a Supervisor to guide and provide the necessary supervision in ensuring a successful completion of the work.

Thank you.

Yours faithfully,

Dr. Emmanuel Srofenyoh
Consultant Obstetrician Gynaecologist

Appendix 9: GHS-ERC Ethical Approval Letter

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.

My Ref. GHS/RDD/ERC/Admin/App/16/180
Your Ref. No.

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Tel: +233-302-681109
Fax + 233-302-685424
Email: ghserc@gmail.com

Elorm Hillary Otchi
University of Ghana
School of Public Health
Department of Health Policy Planning
Legon

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	**GHS-ERC 08/09/2016**
Project Title	"Adverse Events among Pregnant women Hospitalized at the Obstetric Department of Ridge Regional Hospital"
Approval Date	26th October, 2016
Expiry Date	25th October, 2017
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report **after completion** of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED.....
DR. CYNTHIA BANNERMAN
(GHS-ERC CHAIRPERSON)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra

Appendix *10: Participant's Information Sheet*

Title: Adverse Events among Obstetric Clients Hospitalized at the Obstetrics Department of the Greater Accra (Ridge) Regional Hospital

Principal Investigator: OTCHI, Elom Hillary **Introduction**

AEs are poor patient outcomes that arise as a result of healthcare and are a huge financial burden to the healthcare system aside the considerable harm that it does to patients. In as much as the healthcare system is expected to cure disease and alleviate pain, it also causes preventable harms and suffering. This study seeks to investigate adverse events among pregnant women who are hospitalized at the obstetric department of the Ridge Regional Hospital.

I am conducting this study as a PhD Candidate of the School of Public Health of the University of Ghana.

Your participation in this study is voluntary and refusal to participate (or discontinue participation) will involve no penalty or loss of any benefits to which you are otherwise entitled to. Kindly read the consent before deciding whether or not to be part of the study.

Description of Procedure

You are being invited to participate because you will be requested to assist in making the folders and medical records of all the pregnant women who were hospitalized between 01/01/2015 to 31/12/2015 in the obstetric department available to the data collection team.

Duration of the Study

The study spans from December, 2016 to March, 2017.

Risks and Benefit

There is no risk in participating in this survey. There will only be minimal distraction with your daily activities during the process of fetching the medical records for the data collection team. An arrangement will however be made to ensure that, the medical records are fetched outside your normal working hours to avert any distractions. There is no direct benefit. However, information obtained will be useful in providing some recommendations to improve upon the institutional maternal health outcomes.

Participant Rights Your participation in the study is voluntary and you may choose to withdraw at any stage of the process.

Confidentiality This study is purely for academic purposes. Information provided will be used strictly for that purpose. The data collected will also be password protected and each patient record will also be given unique identifiers and kept from the primary database. All medical record identifiers will be destroyed. All institutional identifiers will be removed in the event that any sensitive data will have to be published.

Conflict of Interest: There is no conflict of interest in this study. The data is largely for the purpose of my PhD degree. The institution will be duly informed should there be the need to use the data for any other purpose.

Informed Consent Form

The informed consent has been read to me and I understand all the conditions of this project. I have had the opportunity to ask questions about it and any question I have asked have been answered to my satisfaction. I consent voluntarily to participate as a subject in this study and understand that, I have the right to withdraw from the study at any time without in any way affecting my further medical care.

Name of participant…….

Signature/thumbprint……

Date …….……..…..

Researcher's signature……. Date……

Contacts for additional information:

If you have any further questions regarding clarification or you require more information about the study, you can contact:

1. **OTCHI, Elom Hillary** (Principal Investigator) on: 0244 768 976
2. **Dr. Reuben K. Esena** (Primary Supervisor) on: 0244 577 664
3. **Hannah Frimpong** (Administrator, Ghana Health Service Ethics Review Committee) on: 0507 041 223

Appendix 11: Poster Presentation at the Institute of Healthcare Improvement (IHI) African Forum in Durban, South Africa

ADVERSE EVENTS AMONG PREGNANT WOMEN HOSPITALIZED IN A SECONDARY HEALTHCARE FACILITY IN GHANA

[1]Otchi, EH; [2]Esena, RK; [3]Srofenyoh, [4]EK; Ameh, EO; [5]Ken-Amoah, S [6]Asah-Opoku, K; [7]Beyuo, T; [8]Oduro, F; [9]Agbenor, E

[1]University of Ghana, School of Public Health & AfIHQSA; [2]University of Ghana, School of Public Health [3,4]Ghana Health Service [6]University of Ghana School of Medicine & Dentistry; [7,8]Dept. of Obst & Gynae-KBTH; University of Cape Coast, School of Medical Sciences

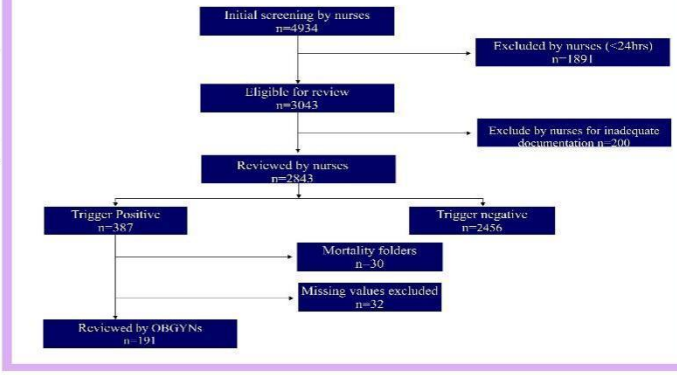
Presented at Institute of Healthcare Improvement (IHI) Africa Forum, Durban South Africa, 19th to 21st February, 2017

INTRODUCTION

Healthcare quality and patient safety efforts seem to have failed to gain the necessary traction in an era of immense efforts to reform the health system by ensuring safe and high-quality care. The study sought to determine the types of AEs among pregnant women hospitalized in a secondary healthcare facility in Ghana.

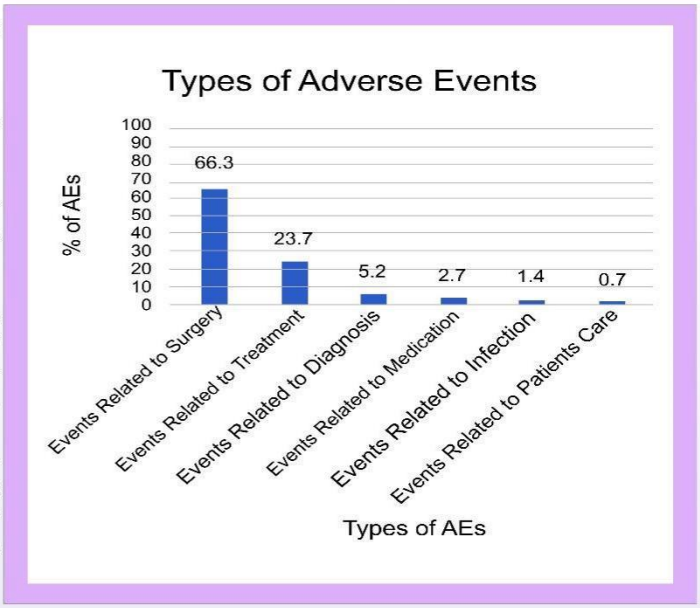
METHODS

Study Design: Exploratory study design. Medical records of pregnant women on admission at the Obstetrics Unit of a secondary healthcare facility in Ghana were reviewed retrospectively from 01/01/2015 to 31/12/2015.



RESULTS

The overall incidence of adverse events among hospitalized pregnant women was estimated to be 12.0% (95% CI: 10.4% to 13.8%). The incidence excluding primary and secondary degree perineal tears was 6.3% (95% CI: 4.1% to 7.6%). Some patients (16, 9.5%) experienced more than one AE out of the total number of AEs recorded. The major adverse event type was surgery (e.g. obstetric trauma to the mother and excessive bleeding). About two-thirds (285, 87.7%) of the AEs that occurred were judged to be preventable.



CONCLUSION

Adverse events among pregnant women was high. The majority of the adverse events were surgical related while the least were events related to patient care, and are preventable.

Appendix 12: Consultants/Specialists & Residents Reviewers

1. Dr. Emmanuel K. Srofenyoh - Consultant, Obstetrician & Gynecologist, Greater Accra Regional Hospital, Accra.
2. Dr. Sebastian Ken-Amoah - Consultant, Obstetrician & Gynecologist, Cape Coast Teaching Hospital, Cape Coast.
3. Dr. Evans Agbenor - Consultant, Obstetrician & Gynecologist, Cape Coast Teaching Hospital, Cape Coast.
4. Dr. Emmanuel Ameh - Senior Specialist, Obstetrician & Gynecologist, Maamobi Government Hospital, Accra.
5. Dr. Ansah-Opoku - Senior Specialist, Obstetrician & Gynecologist, Korle Bu Teaching Hospital, Accra.
6. Dr. Titus Beyuo - Senior Specialist, Obstetrician & Gynecologist, Korle Bu Teaching Hospital, Accra.
7. Dr. Frederick Oduro - Resident, Obstetrician & Gynecologist, Korle Bu Teaching Hospital, Accra.
8. Dr. Fareeda Adusei Wilson - Resident, Obstetrician & Gynecologist, Greater Accra Regional Hospital, Accra.
9. Dr. Ekow Adom Mensah - Resident, Family Physician, Korle Bu Teaching Hospital.

Appendix 13: Reviewer Confidentiality Form

Title: Adverse Events among Obstetric Clients Hospitalized at the Obstetrics Department of the Greater Accra (Ridge) Regional Hospital

Principal Investigator: OTCHI, Elom Hillary **Introduction**

AEs are poor patient outcomes that arise as a result of healthcare and are a huge financial burden to the healthcare system aside the considerable harm that it does to patients. In as much as the healthcare system is expected to cure disease and alleviate pain, it also causes preventable harms and suffering. This study seeks to investigate adverse events among obstetric clients who are hospitalized at the obstetric department of the Ridge Regional Hospital.

I am conducting this study as a PhD Candidate of the School of Public Health of the University of Ghana.

Your participation in this study is voluntary and refusal to participate (or discontinue participation) will involve no penalty or loss of any benefits to which you are otherwise entitled to.

Kindly read and sign the confidentiality statement before deciding whether or not to be part of the study.

I, ……, agree to keep whatever information I am privileged to know by way of my involvement in this study confidential. The outcomes of the reviews shall not be disclosed to any other person or group of persons who are not part of the study reviewers.

Signature: ……..

Date: ……..