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Epidemiology of Hajj Pilgrimage Mortality: Analysis for Potential Intervention

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Epidemiology of Hajj Pilgrimage Mortality: Analysis for Potential Intervention

A dissertation submitted in partial satisfaction of the

requirements for the degree Doctor of Public Health

by

Mahmoud Abdalgader M Gaddoury

2019

ABSTRACT OF THE DISSERTATION

Epidemiology of Mortality of the Hajj Pilgrimage: Analysis for Potential Intervention

by

Mahmoud Abdalgader M Gaddoury

Doctor of Public Health

University of California, Los Angeles, 2019

Professor Haroutune K. Armenian, Chair

Background

The Hajj is the annual mass gathering of Muslims that occurs in Makkah, Saudi Arabia. The Saudi Vision 2030 predicts the attendance of 30 million pilgrims each year by 2030. Cost-effective healthcare services during the Hajj are important to manage this increase in the number of pilgrims. Communicable diseases have always been a concern during the Hajj. However, little is known about the impact of the preexisting chronic diseases on morbidity and mortality during the Hajj. Furthermore, the quality of services provided by Hajj hospitals warrants further study.

Objectives

A relatively large number of pilgrims admitted to Hajj hospitals die during their stay. This dissertation aims to describe patterns of inpatient, all-cause mortality during the Hajj and the relationship between mortality and preexisting chronic diseases as well as the services provided in Hajj hospitals.

Study Design and Population

The population included pilgrims who were admitted to Hajj hospitals in Makkah and sacred sites during five Hajj seasons between 2012 and 2017, excluding 2015. A retrospective, matched, case-control study design was utilized with a ratio of deaths to surviving controls of 1:2, resulting in 2,237 cases of mortality being matched to 4,474 control cases based on age and gender using a one-stage sampling approach. The data was extracted from hospital admissions offices and medical records.

Methods

Preexisting chronic diseases included diabetes mellitus, hypertension, and cardiovascular diseases. Medical services provided by Hajj hospitals included intensive care unit (ICU) admission, intubation, radiology imaging (MRI and CT scan), endoscopy, and blood transfusion. Covariates included individual-level variables (age, gender, nationality, length of stay, mode of admission, discharge diagnosis, and Hajj status) as well as hospital-level variables (hospital location, hospital of discharge, bed-to-doctor ratio, and bed-to-nurse ratio). Hierarchical, logistic regression models were used to examine the medical services. The effect measure modification of the copresence of more than one chronic disease was also examined. For every independent variable that was evaluated, the prevalence, crude and adjusted odds ratios (AORs), and corresponding 95% confidence intervals (CIs), were calculated.

Results

The rate of inpatient all-cause mortality was higher in Makkah hospitals compared to sacred site hospitals. Also, inpatient, all-cause mortality was significantly associated with diabetes (AOR: 1.44, 95% CI: 1.27-1.63), hypertension (AOR: 1.34, 95% CI: 1.17-1.53), and cardiovascular diseases (AOR: 1.32, 95% CI: 1.14-1.53). Moreover, effect measure modification was present in the association between diabetes and cardiovascular diseases and the association between hypertension and cardiovascular diseases, but not the association between diabetes and hypertension. Finally, patients who were admitted to the ICU or who received radiology imaging, endoscopy, or blood transfusion were more likely to die during their hospital stay compared to those patients not receiving those services (ICU AOR: 8.00, 95% CI: 7.8-8.2; radiology AOR: 1.60, 95% CI: 0.98-2.60; endoscopy AOR: 1.99, 95% CI: 1.37-2.88; blood transfusion AOR: 4.00, 95% CI: 2.59-6.24). However, the mortality rate was lower in intubated patients compared to nonintubated patients (AOR: 0.54, 95% CI: 0.35-0.82).

Conclusion

The current focus on public health issues during the Hajj should be equally distributed between communicable and noncommunicable diseases. Although advanced services are provided by Hajj hospitals, interventions to address the increased risks, including mortality, faced by pilgrims with preexisting, chronic diseases should be further investigated and considered.

This dissertation of Mahmoud Abdalgader M Gaddoury is approved.

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2019

DEDICATION

To my mom, and dad who taught me the meaning of life

To my wife Rasha, my kids Leen, Aleen, Abdulgader, and Malak who I wouldn't make it without their encouragement and support

Table of Contents

List of Figures

List of Tables

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Research Interests

- Healthcare services Epidemiology
- Mass gathering Medicine
- Disaster Epidemiology
- Quality Evaluation and Improvement

1 Background: The Public Health Problem

1.1 Mass Gatherings

There currently exists no agreed-upon definition of a mass gathering. Many authors use the criteria of a minimum of 1,000 persons at a defined location for a defined period of time (Yezli & Alotaibi, 2016). However, most published literature considers gatherings of more than 25,000 participants as a mass gathering (Locoh-Donou et al., 2013). World Health Organization [WHO] (2008) definition incorporates public health impact by defining mass gatherings as events attended by a sufficient number of individuals to potentially strain the public health resources of the community, city, or nation hosting the event. This broader definition of a mass gathering may be useful for two reasons. First, it recognizes that planning and delivery of health services during mass gatherings is complicated by the context and situation in which the care will be provided. Second, this definition includes "nontraditional" mass gatherings as well as traditional, large, public events.

Mass gatherings can be categorized as either spontaneous or planned, and either recurrent or sporadic (WHO, 2015a; Chang et al., 2010). Spontaneous mass gatherings are more difficult to plan for and include such events as the funerals of religious and political figures (Arbon, Bridgewater, & Smith, 2001; Chang et al., 2010). Because planned mass gatherings tend to be more organized, they are easier to prepare for. These events are typically sports-related, social, cultural, religious, or political in nature (Arbon, Bridgewater, & Smith, 2001).

Kumbh Mela, a huge Hindu pilgrimage held at various locations along the Ganges River in India, is considered to be the largest religious gathering on earth (Verma, Verma, & Khurana, 2018). Purification rites involve bathing in the Ganges River, which could pose a risk for transmitting contagious diseases. The typical Kumbh Mela is celebrated every three years, often attracting thousands of non-Hindu enthusiasts. However, Maha Kumbh Mela is held only once every 144 years (Memish, Stephens, Steffen, & Ahmed, 2012). In the summer of 2016, the holy city of Ujjain was greatly stressed by an influx of an estimated 60 to 70 million people over the one-month festival.

Weddings, funerals, and sports events can be attended by millions of people. Table 1.1 lists the largest peaceful mass gatherings in recent history. Although the medical care needed at these events is typically only of minor severity, an effective emergency medical system must always be ready to respond, assess, and treat any life-threatening conditions that may arise.

Several key features of mass gatherings have been discussed in the literature as well-recognized, essential influences on the demand for healthcare during such events (Milsten, Maguire, Bissell, & Seaman, 2002). These key characteristics include: (1) the weather (temperature and humidity), (2) the duration of the event, (3) whether the event is predominantly outdoors or indoors, (4) whether the crowd is predominantly seated or mobile within the venue, (5) if the event is bounded (fenced or contained) or unbounded, (6) the type of event, (7) the mood of the crowd, (8) the availability of alcohol and drugs, (9) the crowd density, (10) the geography of the venue (terrain or locale), and (11) the average age of the crowd. While this is not an exhaustive or complete list of the characteristics of mass gatherings that may influence public health needs, an improved understanding of these variables could improve event planning (Milsten et al., 2002).

1.2 Mass Gathering Medicine

"Mass Gathering Medicine can be defined as an area of medicine that deals with health aspects during mass gatherings, including the health effects and risks related to mass gatherings and strategies for effective health services delivery during these events" (Yezli & Alotaibi, 2016). Over recent decades, a great deal of literature has been published addressing the issue of medical care at mass gatherings (Arbon, 2007; Milsten et al., 2002; De Lorenzo, 1997). However, a new medical discipline, mass gathering medicine, was formalized and established in 2010 when The Global Forum on Mass Gathering Medicine was held in Jeddah, Saudi Arabia with the support of the Saudi Ministry of Health (MOH) and *The Lancet Infectious Diseases* (Al Rabeeah et al., 2012), thus forming an integrated scientific discipline of multiple specialties to manage the complex public health issues surrounding mass gatherings. This discipline was formally introduced at the World Health Assembly of Ministers of Health in Geneva in May 2014 (Yezli & Alotaibi, 2016).

This newly recognized discipline may be better described as mass gathering “health,” rather than “medicine,” since more than what is encompassed by the traditional concept of medicine is necessary to ensure the wellbeing of individuals at mass gatherings (McConnell, 2012). This discipline addresses the diverse health risks associated with mass gatherings. In addition to the obvious risk of infectious disease transmission, other environmental factors can impact health, such as injuries; extreme heat or cold; the ingestion of drugs, alcohol, or contaminated foods; or deliberate acts intended to cause harm (WHO, 2015a). Furthermore, existing, noncommunicable diseases can also pose risks to attendees.

1.3 Performing the Hajj

The Hajj is a pilgrimage of Muslims to Makkah and the sacred sites in Saudi Arabia. It occurs annually and attracts more than two and a half million people from all over the globe. It is considered one of the five pillars of Islam, and all adult Muslims are required to perform it at least once in their lives if they are physically and financially able. Pilgrims dress modestly and simply, proclaiming the equality and humility of all believers before God, regardless of worldly differences in race, nationality, class, age, gender, or culture (Esposito, 2003).

The Hajj takes place from the 8th to the 13th day of Dhul-Hijja, the 12th month of the Muslim Calendar. Pilgrims start arriving in Makkah around the middle of the preceding month and stay until the end of Dhul-Hijja (approximately 45 days). The Hajj follows the Hijri calendar, causing the date to move forward by 10 to 11 days each year. According to the Hijri calendar, months begin when the new moon is first visible. Because the lunar year is 10.87 days shorter than the solar year, it cycles completely through the seasons over 33.6 years, with the season of the Hajj varying with this same periodicity. This yearly variation in seasons creates serious health risks (Memish, Stephens, Steffen & Ahmed, 2012). For example, in the hot season, air cooling systems are required in all buildings to avoid heatstroke. On the other hand, more elderly pilgrims are expected to attend the Hajj in colder seasons, requiring appropriate health services.

In addition to the Holy Mosque (Al-Haram) in Makkah, there are two further areas essential to performing the Hajj: the Mawaqit[1] and the sacred sites (Al-Masha'er Al-Moqadasah; Figure 1.1). As a center of pilgrimage, the Ka'aba[2] had a sanctuary around it that was a safe area for pilgrims and other visitors to Makkah that is known as Al-Haram, meaning protected, forbidden, and revered (Angawi, 1988). From the time of the Prophet, the boundaries of Al-Haram have been formally delineated and typically run through the peaks of the hills or bottoms

[1] Miqat (singular) refers to the boundary where it becomes necessary for pilgrims to adorn the Ihram garments and it is impermissible to pass except in the state of Ihram.
[2] Ka'aba A Muslim shrine in Mecca toward which the faithful turn to pray.

of the valleys in roughly an oblong shape 25 miles from East to West and 15.5 miles from North to South (Angawi, 1988).

In addition to the Holy Mosque, the metropolitan area of Makkah encompasses sacred sites to the southeast, where the preponderance of the Hajj rituals are carried out. Al-Masha'ir Al-Muqadasah is comprised of three distinct regions: Arafat, 12.4 miles from the Holy Mosque; Muzdaliah, 8 miles from the Holy Mosque; and Mina, 3.7 miles from the Holy Mosque. These constitute the main venues of the Hajj and are connected by roadways and tunnels (Angawi, 1988).

Arafat is the location where the grand assembly of Muslims takes place. It covers 5.3 square miles; of which, 1.7 square miles are mountainous with limited development. The remainder is flat land that is easier to occupy (Ministry of Communication, 1979). Muzdalifah encompasses 3.7 square miles, slightly more than half the area of Arafat (Ministry of Municipal and Rural Affairs, 1985). Much has been done to flatten the mountainous areas that occupy 1.1 square miles of Muzdalifah.

The principal rites of the Hajj are Ihram, Tawaf, Sa`i, Woqooff, Nafrah, Rajm, and Eid al-Adha (Figure 1.2). Ihram is a ritual cleansing, consecration, and declaration of intent to perform the Hajj. Pilgrims don the special Ihram garb of white terrycloth representing the equality of all believers before God, regardless of race, gender, age, or social standing. Men wear a covering each for their upper and lower bodies, and women wear white robes but need not cover their faces.

Pilgrims, ideally, relocate to Mina on the 8th day of Dhul-Hijja in order to leave for Arafat after sunrise on the 9th day. The day itself is called the Day of Arafat (Yawom A'rafah).

This is the largest gathering of Muslims from all corners of the world. The pilgrim devotes the day to Woqoof - being and staying in Arafat. Woqoof is the most crucial pillar of the Hajj with any pilgrim missing Woqoof being considered as having missed the Hajj (Al Shafi'I, 1980). Pilgrims leave for Muzdalifah, 4.3 miles from Arafat, only after sunset, where pebbles are gathered and pilgrims spend the night. However, women, children, and the weak are permitted to leave for Mina after midnight. On the 10th day of Dhul-Hijja, pilgrims return to Mina, where they visit Jamarat Al-Aqaba. This is the shrine marking the place at which the Prophet Abraham stoned Satan when he tried to persuade Abraham not to execute a command of Allah. Pelting is one of four other injunctions to be observed on that day. The remaining three are to sacrifice Al-Haddey (an animal), to shave or shorten the hair, and to perform Tawaf Al-Ifada[3].

On the 11th, 12th, and 13th days of Dhul-Hijja, having finished Tawaf and Sa'i[4] at the Holy Mosque in Makkah, pilgrims return to Mina where they spend the following three days. There they pelt the three Jamarat[5] (the small, medium, and large [Aqaba]) with stones. Women, children, the weak, and those involved in services rendered to pilgrims can deputize other people to do this task. The time of pelting starts from the afternoon and extends until the following morning, with spending the entire night there being one of the conditions of Hajj that should be adhered to. However, if that proves too difficult, then one should strive to spend at least half of the night (Ibn Quadama, 1979).

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[3] Tawaf Al-Ifada is to go around the Kaaba (the most sacred site in Islam) seven times in a counterclockwise direction.

[4] Sa'i is to walk seven rounds of a defined route between the Safa and Marwa hills. It serves to commemorate Hagar's (wife of Prophet Abraham) search for water for her son and God's mercy in answering her prayers.

[5] The Jamarat are three stone pillars which are pelted as a compulsory ritual. They represent the three locations where Abraham pelted Satan with stones when he tried to dissuade him from sacrificing his son Ismail.

The Hajj can be terminated early, and pilgrims may leave after pelting the Jamarat on the 12th day if they so desire. Those who remain pelt the Jamarat on the 13th day and then leave for Makkah where they can stay as long as they wish. Most pilgrims visit the city of Al-Madinah Al-Munawarah after performing the Hajj. The visit to Al-Madinah Al-Munawarah is not a prerequisite of the Hajj. However, pilgrims take advantage of being in Saudi Arabia to visit the Prophet Muhammad's Mosque in Al-Madinah Al-Munawarah. Those who choose not to visit Al-Madinah Al-Munawarah may return home after completing Tawaf Al-Wada'a – the farewell Tawaf.

1.4 Public Health Challenges during the Hajj

The public health challenges posed by mass gatherings have the potential to impact both the host country and the countries to which the gatherers return. Because local health systems must operate at maximum capacity for the duration of the mass gathering, their systems can become strained (WHO, 2008, 2015a). As a result, multiple disciplines, agencies, and ministries must cooperate to mitigate the risks posed by mass gatherings. However, international events involving different languages and cultures complicate risk communication (Yezli & Alotaibi, 2016). In addition to these concerns, a significant number of casualties could result from the introduction of infectious or noninfectious public health threats, the impacts of which could spread to populations outside the event. Deliberate actions, such as terrorist activities, create further risks to mass gatherings (WHO, 2015a).

Over the years, the Hajj has been a significant public health challenge that requires dedicated attention from several government and nongovernment sectors in Saudi Arabia. The Saudi MOH and the Ministry of Al-Hajj are jointly responsible for providing healthcare services during the Hajj. The MOH has a fundamental mission during the Hajj season of providing the best healthcare for pilgrims through continuous expansion of health facilities, employing qualified health personnel, avoiding bottlenecks at health facilities, and setting “Emergency or Disaster Plans” in coordination with other relevant organizations (Saudi Ministry of Health [MOH], 2012). An additional objective is protecting Saudi residents from potential public health risks, such as communicable diseases.

Pilgrims coming to the Hajj face serious communicable and noncommunicable threats. Increases in globalization, affluence, and the affordability of air travel are leading to greater numbers of pilgrims attending the Hajj each year, compounding the risks to Saudi residents, visiting pilgrims, and the individuals that they come into contact with after the Hajj. Transmission of infections remains a common occurrence particularly attributed to the attendance of pilgrims from low-income countries with inadequate medical systems, crowded accommodations, poor hygiene, extreme heat, inadequate pre-Hajj vaccination, and poor food preparation and storage. These factors contribute to the spread of infectious diseases, such as respiratory/airborne diseases, meningitis, food- and water-borne diseases, and blood-borne diseases (Shujaa & Alhamid, 2015).

Several studies have attributed the majority of hospital admissions at the Hajj to infectious respiratory diseases (Ahmed, Arabi & Memish, 2006; Al Ghamdi, Akbar, Qari, Fathaldin, & Al-Rashed, 2003; El-Sheikh, El-Assouli, Mohammed & Albar, 1998; Gautret et al., 2009; Gautret, Soula, Delmont, Parola & Brouqui, 2009; Wilder-Smith, Earnest, Ravindran & Paton, 2003; Wilder-Smith, Foo, Earnest & Paton, 2005). Acute respiratory tract infections are prevalent during the Hajj – particularly when the pilgrimage falls in the winter season – due to the close contact among pilgrims, dense air pollution, shared sleeping accommodations (primarily tents), and the increasing percentage of elderly pilgrims (El-Sheikh, El-Assouli, Mohammed & Albar, 1998).

In a study of 64 patients with community-acquired pneumonia admitted to two large hospitals during the 1994 Hajj pilgrimage, a microbiological diagnosis could be established in 46 cases (72%). The most common causative pathogen was Mycobacterium tuberculosis (TB, 20%), followed by Gram-negative bacilli (18.8%; Alzeer et al., 1998). In Saudi cities hosting pilgrims, the prevalence of drug-resistant tuberculosis and the annual risk of infection were three times higher than the national average (Al Kassimi et al., 1993; Khan et al., 2001). Although, the exact risk of TB transmission among pilgrims is difficult to quantify, a study of 357 Singaporean pilgrims found increased immune reactivity to TB in 10% of study participants after attending the Hajj (Wilder-Smith, Foo, Earnest & Paton, 2005). This exposure was likely due to the prevalence of pilgrims from developing countries where tuberculosis is endemic.

The emergence of several new coronaviruses (CoVs) and influenza viruses, such as influenza A H1N1, severe acute respiratory syndrome-CoV, and Middle East Respiratory Syndrome-CoV, pose new public health risks for the Hajj. Fortunately, no significant outbreaks have occurred at the Hajj according to a study of French pilgrims attending the Hajj in 2012 (Gautret et al., 2013). Furthermore, a 2009 study did not detect influenza A H1N1 in the 559 tested pilgrims (Kandeel et al., 2011). In another study, fewer than 100 cases of influenza A H1N1 were reported during the Hajj at the peak of the pandemic (Ziyaeyan et al., 2009).

Gastroenteritis outbreaks due to food poisoning are common occurrences at all religious mass gatherings, including the Hajj. Salmonella, Staphylococcus aureus, Bacillus cereus, and Clostridium perfringens are the most common causative agents at such events (Al Joudi, 2007; Al Mazrou, 2004). During the 2002 Hajj, gastrointestinal illnesses were the third-leading cause of hospital admission (Rashid et al., 2008). Fortunately, these admissions have low morbidity and mortality (Meysamie, Ardakani, Razavi, & Doroodi, 2006). Despite the frequency with which diarrhea causes hospital admissions during the Hajj, few reports have examined its incidence or cause (Al Ghamdi et al., 2003; Al-Tawfiq & Memish, 2012; Madani et al., 2006).

Another public health risk at the Hajj is transmission of blood-borne diseases. By the end of Hajj activities, approximately 90% of male pilgrims have their scalps closely shaved, risking nicks and abrasions (Rafiq, Rashid, Haworth, & Booy, 2009). Two separate studies found that roughly 60% of pilgrims incurred scalp cuts (Al Rabeah et al., 1998; Harunor & Shuja, 2006). Repeated use of unsterile razors could potentially transmit blood-borne diseases, such as Hepatitis B, Hepatitis C, and HIV. However, no reports of blood-borne disease outbreaks during the Hajj have been published.

To minimize health risks to pilgrims and prevent importation of communicable diseases into Saudi Arabia, the Ministry of Health issues updated annual health regulations (Al Ghamdi & Kabbash, 2011; Al-Tawfiq & Memish, 2012; Memish & Al Rabeeah, 2012). Specific health requirements must be met for pilgrims to obtain an entry visa for the Hajj, including vaccinations against yellow fever, meningitis, and polio. All travelers arriving from countries in Africa, South America, and Central America must present a valid vaccination certificate for yellow fever at the border. Individuals without such a certificate will be offered the vaccine and then observed for ten days. All vehicles including aircraft and ships arriving from countries with prevalent yellow fever must have certification that WHO-recommended treatment has been done to eradicate all insect vectors of disease (Memish et al., 2014).

Moreover, all pilgrims younger than 15 years who travel from countries where polio remains prevalent must be vaccinated (Al Ghamdi & Kabbash, 2011; Memish & Al Rabeeah, 2012). To further prevent polio transmission, a single dose of the polio vaccine is administered to pilgrims arriving in Saudi Arabia from countries where polio has been reported, with approximately 327,834 pilgrims vaccinated at the port of entry in 2017 (Table 1.2; Saudi General Authority for Statistics [GAS], 2017). People at increased risk of severe influenza are advised to receive the influenza vaccine, i.e., pregnant women, children under the age of five, elderly individuals, immunosuppressed individuals (such as those with HIV/AIDS), and individuals with asthma or chronic heart or lung diseases. In addition, vaccination is recommended for all pilgrims from within Saudi Arabia, especially those with the risk factors described above, and all Saudi health-care workers in Makkah and Medina (Saudi MOH, 2017b).

Many reports discuss noncommunicable diseases, such as stampede or crush injuries, fires, heat exhaustion, heatstroke, severe acute cardiovascular events secondary to heat, intense emotional stress, dehydration, and terrorist attacks (Fatani et al., 2002; Fatani, Al Afif, & Hussain, 2000; Gatrad & Sheikh, 2001; Rafiq et al., 2009). Despite the peaceful nature of the Hajj and the enormous efforts undertaken by its organizing bodies, many pilgrims performing the Hajj have died over the past 40 years. The majority of these incidents resulted from stampedes, demonstrations, and fires. Terrorist incidents have also plagued this peaceful gathering. In 1989, a bomb exploded near Makkah's Holy Mosque killed one person ("A history of Hajj tragedies," 2006).

Human stampedes are one of the most feared and fatal incidents that can occur during any mass gathering, claiming hundreds of lives each year (Helbing, Johansson, & Al-Abideen, 2007). The majority of stampedes at the Hajj have taken place on the Mina Bridge. The Saudi government has taken efforts to avoid such tragedies, including replacing the Mina Bridge with a much larger bridge designed for better crowd management (Figure 1.3). Because a catastrophic stampede could easily be triggered by crowd panic due to a fire, fireproof awnings were installed in all tents in Mina. Furthermore, strict regulations are in place to prevent fires. For example, pilgrims are not permitted to erect tents or cook food at Mina (Ahmed et al., 2006; Khan, & Noji, 2016; Memish et al., 2012). Although the measures in place greatly reduce the risk, large-scale disasters due to stampede or fire still have the potential to cause significant loss of life, as indicated by the stampede and fire events at the Hajj summarized in Table 1.3.

1.5 The Donabedian Model

In his paper *Evaluating the Quality of Medical Care* (1966), Avedis Donabedian stated that, "Many advantages are gained by using outcomes as the criterion of quality in medical care. However, several considerations limit the use of outcomes as measures of the quality of care". Moreover, in his book *An Introduction to Quality Assurance in Health Care* (2002), he discussed what the quality-assessment literature calls case-mix standardization, which is a fundamental concept in epidemiology.

To measure quality more accurately, he presented what is now known as "the Donabedian structure, process, and outcome model." In this model, Donabedian suggested that instead of using only outcome indicators to measure the quality of healthcare services, one can use more comprehensive approaches that cover different aspects of a healthcare system. Although he found it problematic to define quality, Donabedian defined quality assurance as all actions taken to establish, protect, promote, and improve the quality of healthcare (Donabedian, 2002). He argued that the criteria of quality are nothing more than value judgments that are applied to several aspects, properties, ingredients, or dimensions of a process called medical care.

The Institute of Medicine (IOM) described broader quality issues and defined six aims that care should fulfill. According to the IOM, care should be safe, effective, patient-centered, timely, efficient, and equitable to be considered of high-quality (Corrigan, 2005). These aims are similar to what Donabedian called quality attributes that can be taken singly or in a variety of combinations to define and measure quality (Donabedian, 2002). The choice of which of these elements, as well as their relative prioritization, should be guided by the context in which quality of care is being assessed (Donabedian, 2002).

1.5.1 Definition of structure, process, and outcome

Donabedian's definition of quality of care consists of relationships between a triad of structure, process, and outcome (SPO). He postulated that the relationships between SPO constructs such that good structures should promote proper processes and proper processes should, in turn, promote good outcomes (a unidirectional pathway). The SPO framework, often represented by a chain of three boxes containing SPO constructs connected by arrows (Donabedian, 2002), can be used to draw inferences about the quality of healthcare (Donabedian, 1988).

Structure is defined as the way a healthcare system is set up. It includes material resources (such as facilities and equipment), human resources (such as the number, variety, and qualification of professional and support personnel), and organizational characteristics (such as the presence of teaching and research functions, the organization of medical and nursing staff, and methods of paying for care).

Process is defined as the activities usually carried out by professional personnel but also includes contributions to care performed by other individuals, particularly patients and their families.

Outcome is defined as the impacts of healthcare on individuals and populations, which can be either desirable or undesirable. This can, further, include the cost of services as a component of outcome. Donabedian distinguished between two types of outcomes. The first are technical outcomes, which are the objective results and can include measures of morbidity and mortality. The second types of outcomes are interpersonal outcomes. These are subjective measures of outcomes and include patients' satisfaction with care and how they perceive the care to have impacted their quality of life (Donabeidan, 2002).

Donabedian A, Wheeler JR, Wvszewianski L. Quality, cost, and health: an integrative model. Med Care. 1982 Oct:20(10):975-92.

1.6 Conceptual Model

To assess the quality of healthcare services provided during the Hajj, Donabedian's "structure-process-outcome" framework was used. His three-part approach makes quality assessment possible by assuming that structures influence processes and that processes alter outcomes. Structures include the relevant aspects of the organization and patients. The actual provision of care represents the process, and health measures serve as the outcomes. This model enables the conceptualization of components that influence quality of care. As such, it has been widely used by policymakers and researchers. Therefore, Donabedian's model has been chosen for this study.

To develop the model, I propose that impediments posed by structure or organization (i.e., patient and hospital characteristics) may compromise processes (such as patient diagnosis and therapy administered). These structural/organizational and process/performance weaknesses may ultimately lead to poor outcomes (i.e., all-cause mortality; Figure 1.4). The implied relationships between the three variables usually remains linear. The model states that when the health status of pilgrims is poor (structure), the time of hospitalization will be longer and the procedures provided will be more complicated (process), and the mortality will be greater (outcome).

1.7 Focus of the Dissertation

Saudi Arabia, through the 2030 Vision and the 2020 National Transformation Program, outlined an agenda for more balanced growth and socioeconomic development. An economic and service pillar, health will play a significant role in implementing the 2030 Vision. As Saudi Arabia expects the number of pilgrims and visitors to increase to an average of 30 million by 2030 (Saudi Vision 2030, 2017), the healthcare sector will need to increase its capacity and provide more efficient and high-quality services. Just as medicine has increasingly moved towards evidence-based medicine in which clinical choices are informed by research, healthcare design is frequently guided by rigorous research linking hospitals' physical environments to healthcare outcomes. As such, it is moving towards evidence-based design (Hamilton, 2003). This study will help authorities achieve more efficient resource allocation and adjustment in upcoming Hajj seasons.

The overall objective of this dissertation is to comprehensively examine the current patterns of mortality during the Hajj and to examine the burdens imposed by this population inflow to assess how this annual event can affect the quality of services provided in the hospitals at Makkah and sacred sites. To do so, information from the MOH hospitals in Makkah and sacred sites for five Hajj seasons was utilized. After a detailed description of the Hajj population from a health perspective (Chapter 2), which covers the first specific aim, two separate studies that address the second and third specific aims will be presented (Chapters 3 and 4). The specific aims of the study are:

Specific Aim 1: To describe the patterns of mortality during hospitalization in Makkah and sacred site hospitals according to patient demographics, clinical characteristics, hospitalization episode, hospital characteristics, and meteorological and environmental variables.

Specific Aim 2: To estimate the total effect of patient preexisting chronic diseases on all-cause mortality occurring during hospitalization in Makkah and sacred sites hospitals during the Hajj, while considering the Effect Measure Modification (EMM) of patients having multiple preexisting chronic diseases.

Specific Aim 3: To estimate the total effect of exposure to selected inpatient diagnostic and therapeutic procedures on all-cause mortality occurring during hospitalization in Makkah and sacred sites hospitals during the Hajj.

Understanding the current patterns and associations of Hajj population characteristics as well as the medical services provided to pilgrims during the Hajj season can greatly assist in evaluating the quality of services provided in Makkah and sacred site hospitals. This is important for directing resource distribution policies and mortality prevention. Sharing this information with the public health community at both national and regional levels may also encourage other mass gathering organizers to share their best practices and inform regional policymakers of the best methods for establishing and sustaining a framework for mass-gathering medical services.

Table 1.1
Largest peaceful mass gathering (Source: Wikipedia)

	Type of event	Location	Year	Attendees (Millions)
World Expo	Fair	Shanghai, China	2010	73
Kumbh Mela	Religious	Allahabad, India	2007	60–70
Kumbh Mela	Religious	Haridwar, India	2010	50
Hindu temple pilgrimage	Religious	Sabarimala, Kerala, India	Annual	5–50
Arba'een, Imam Hussein's shrine	Religious	Karbala, Iraq	Annual	9–60
Funeral of C N Annadurai	Political	Tamil Nadu, India	1969	15
Funeral of Ayatollah Khomeini	Political and religious	Tehran, Iran	1989	6–12
Feast of the Black Nazarene	Religious	Manila, Philippines	2011 Annual	8
25th anniversary of El Shaddai	Religious	Manila, Philippines	2003	7
World Youth Day and Pope's visit	Religious	Manila, Philippines	1995	5
Welcome to Ayatollah Khomeini	Political and religious	Tehran, Iran	1979	5
Funeral of Gamel Abdel Nasser	Political	Cairo, Egypt	1970	5
Removal of President Hosni Mubarak	Political	Cairo, Egypt	2011	5
Funeral of Abdel Halim Hafez	Cultural	Cairo, Egypt	1977	4
Funeral of Umm Kulthum	Cultural	Cairo, Egypt	1975	4
Funeral of Pope John Paul II	Religious	Rome, Italy	2005	2–4
Antiwar rally (invasion of Iraq)	Political	Rome, Italy	2003	3
Celebration of Red Sox victory	Sports	Boston, MA, USA	2004	3
Defense of workers' rights	Political	Rome, Italy	2002	2–3
Hajj	Religious	Makkah, Saudi Arabia	Annual	2–3
Closing mass, World Youth Day	Religious	Rome, Italy	2000	2·7
Beatification of Pope John Paul II	Religious	Krakow, Poland	2002	2·5
Gay Pride parade	Political	Sao Paolo, Brazil	2006	2·5
Stanley Cup parade	Sports	Philadelphia, PA, USA	1974	2
Republic protests	Political	Izmir, Turkey	2007	2
Champion Fédération Internationale de Football Association World Cup	Sports	Madrid, Spain	2010	2
Attukai Temple (women)	Religious	Trivandrum, Kerala, India	2007	2
Bicentennial of May Revolution	Cultural	Buenos Aires, Argentina	2010	2

Table 1.2
Preventive activities at the port of entry by year and type of vaccination during the Hajj 2012 – 2017. (Saudi MOH)

Year	Poliomyelitis* vaccine	Prophylactic vaccine	Total
2012	516,495	427,942	944,437
2013	430,490	286,548	717,038
2014	361,482	331,028	692,510
2015	324,989	282,967	607,956
2016	333,990	294,662	628,652
2017	327,834	297,354	625,188

*Given to children and pilgrims coming from endemic areas.

Table 1.3
Catastrophic events at the Hajj (1975 – 2015). Adapted from “Health response to Hajj mass gathering from emergency perspective, narrative review” by A. Shujaa & S. Alhamid, 2015, *Turkish journal of emergency medicine*, 15(4), 172-176. Adapted with modification.

Type of incident	**Time of incident**	**Death**	**Injured**
An exploding gas cylinder caused a fire in a tent colony.	December 1975	200 pilgrims	
A stampede inside a pedestrian tunnel. (Al-Ma'aisim tunnel)	July 2, 1990	1,426 pilgrims	
A stampede at the stoning of the Devil ritual.	May 23, 1994	270 pilgrims	
A tent fire in MINA.	April 15, 1997	343 pilgrims	1500 pilgrims
A stampede at Jamarat Bridge.	April 9, 1998	118 pilgrims	180 pilgrims
A stampede at the stoning of the Devil ritual.	March 5, 2001	35 pilgrims	
A stampede at the stoning of the Devil ritual.	February 11, 2003	14 pilgrims	
A stampede at the stoning of the Devil ritual.	February 1, 2004	251 pilgrims	244 pilgrims
A stampede at Jamarat Bridge.	January 12, 2006	346 pilgrims	289 pilgrims
A crane collapsed in Makkah. (Holy Mosque)	September 11, 2015	111 pilgrims	394 pilgrims
A stampede in Mina	September 24, 2015	2,070 pilgrims	

Figure 1.1: Map of Makkah, and sacred sites. (www.hajjsolutions.com)

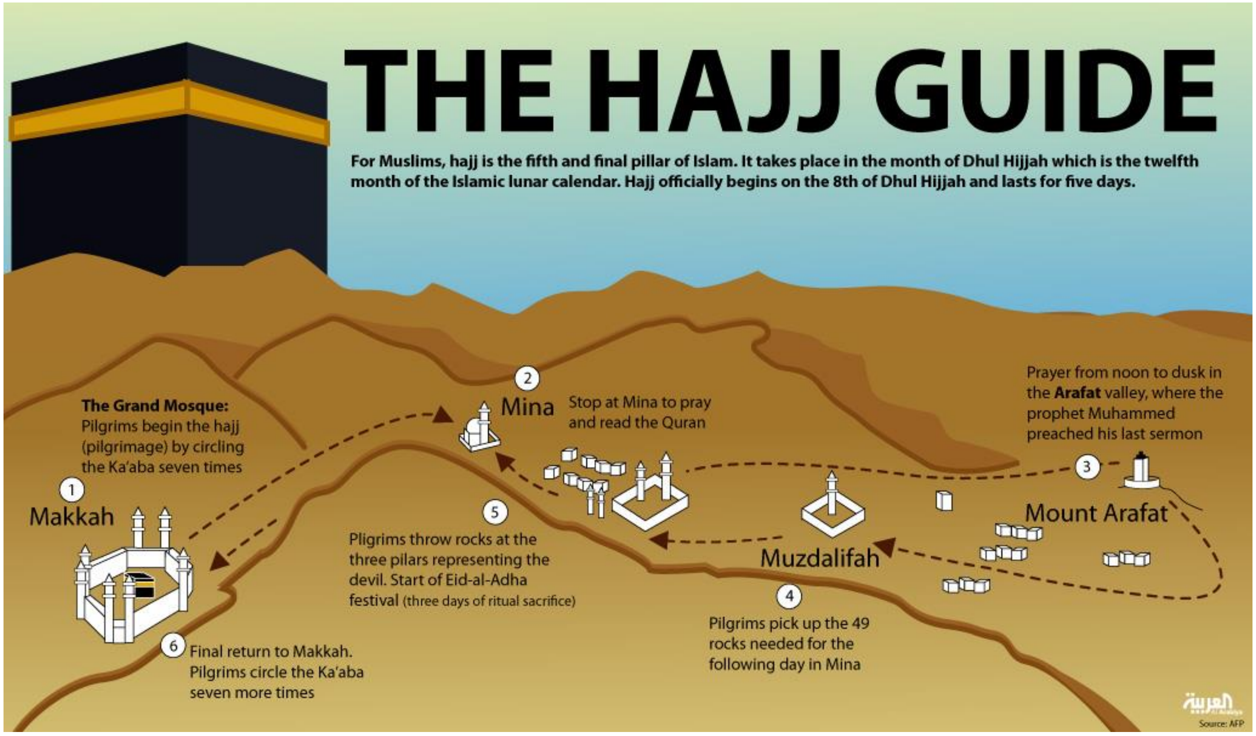


Figure 1.2 The stages of Hajj. (Infographic designed by Farwa Rizwan / Al Arabiya News)

Figure 1.3: The Jamarat "Stoning Rituals" (Courtesy to Saudi Press Agency [SPA]): till 2006, the Jamaraat as in the right top picture, which got demolished after a stampede and a huge project built as shown in the left top and the lower pictures. Adapted from "Hajj stampede disaster, 2015: Reflections from the frontlines" by A. A. Khan & E.K. Noji, 2016, *American journal of disaster medicine, 11(1)*, pp. 59-68.

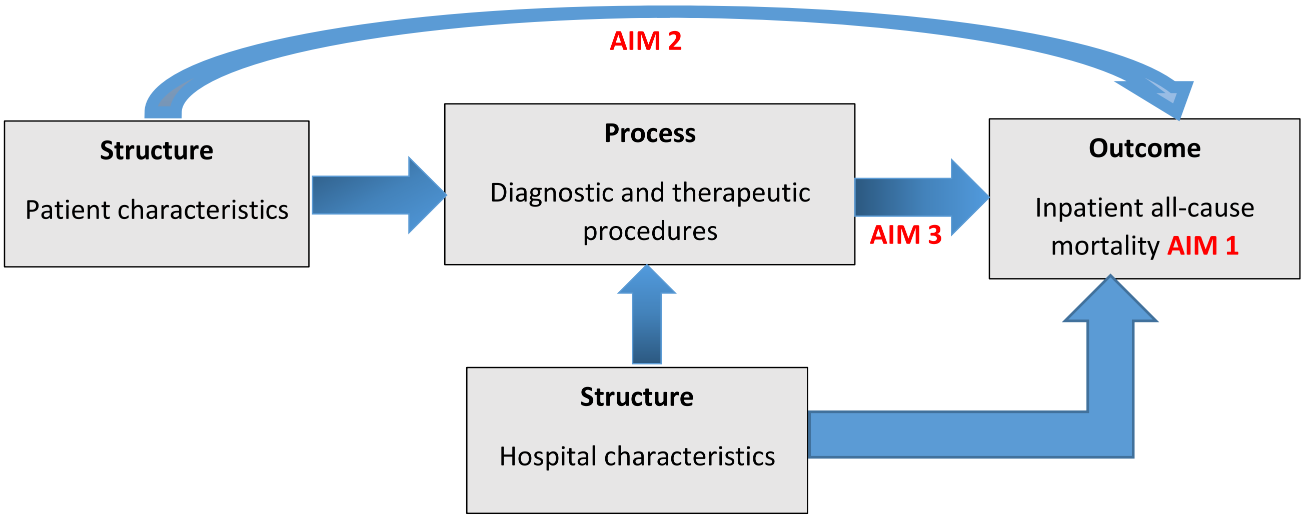


Figure 1.4: Dissertation conceptual framework.

2 Spectrum of Mortality Data of Hajj Hospitals

2.1 Introduction

The Hajj is the largest annual religious or ritual mass gathering. The number of pilgrims coming to the Hajj has increased from about 60,000 in 1920 to more than 3 millions in 2012 with 1,752,932 of them from outside Saudi Arabia (Memish et al., 2014; GAS, 2012). Due to the continued expansion work of the Holy Mosque in Makkah, the Saudi Government reduced the number of issued entry permits to pilgrims for Hajj seasons (Saudi MOH, 2017a; Appendix A, Table A1). Thus, between 2012 and 2017, 1,479,307 international pilgrims, on average, visited Saudi Arabia through its 16 ports of entry for the Hajj (Saudi MOH, 2017a; Appendix A, Table A2). Among pilgrims who came to the Hajj in the period between 2012 and 2017, males outnumbered females for both domestic and international pilgrims (domestic: 58% versus 42%; international: 55% versus 45%; Saudi MOH, 2017a; Appendix A, Tables A3 & A4).

Between Hajj seasons 2012 and 2017, the total number of visits to emergency rooms, outpatient clinics, and primary healthcare centers was 2,640,781 (197 per 1,000 pilgrims). Primary healthcare centers received the highest rates (average rate: 142 per 1,000 pilgrims) compared to outpatient clinics and emergency departments. Sacred site facilities received a greater number of primary healthcare center and outpatient clinic visits compared to those of Makkah, with the number of visits to emergency departments varying from year to year (Saudi MOH, 2017a; Appendix A, Table A5).

The Saudi MOH provides free universal healthcare services to all pilgrims during their stay in Saudi Arabia, the length of which varies from 5 to 45 days. During the Hajj, more than 25,000 healthcare professionals supplement existing staff of the healthcare facilities impacted by the Hajj (Appendix A, Table A6). Furthermore, the MOH establishes a command and control center; oversees surveillance, communication, and infection control systems; and issues health-education programs in multiple languages. Moreover, laboratory and epidemiological investigations are conducted in coordination with the WHO and Center for Disease Control (Khan & Noji, 2016).

MOH hospitals have approximately 3,000 beds in the city of Makkah and 3,000 beds in nearby cities. Also, additional beds are available to serve the pilgrims in other, specialized MOH hospitals (e.g., pediatric and obstetric hospitals), governmental non-MOH hospitals (military and university hospitals), and private hospitals (Khan & Noji, 2016; Appendix A, Table A7). In addition, around 150 temporary primary healthcare centers operate nearby during the Hajj season (Khan & Noji, 2016; Memish et al., 2012; Saudi MOH, 2017; Appendix A, Table A8).

Weather and other environmental conditions, including warm and cold temperatures, can contribute to a large variety of illnesses (Abdelmoety et al., 2018; Agar, Pickard, & Bhangu, 2009; Allen et al., 2006; Baird et al., 2010; Centers for Disease Control and Prevention, 1996; Ghaznawi & Ibrahim, 1987; Khogali, 1983; Schulte & Meade, 1993; Wetterhall, Coulombier, Herndon, Zaza, & Cantwell, 1998). Seasonal variation in mortality and disease is a well-known phenomenon. Numerous studies have found a seasonal variation in incidence for a multitude of causes of death, such as cardio-respiratory and infectious diseases (Altizer et al., 2006; Burkart et al., 2011; Feinstein, 2002; Rau, 2006; Villa, Guiscafré, Martinez, Munoz, & Gutierrez, 1999; Xuan, Egondi, Ngoan, Toan, & Huong, 2014). Nevertheless, the number of studies focusing on seasonal variation in diseases in developing countries is limited, especially for Middle Eastern countries (Armenian et al., 1988; Douglas, Rawles, Al Sayer, & Allan, 1991).

During the summer season, high temperatures are associated with heat illness, which can be minor (e.g., heat cramps, edema, prickly heat, and syncope) or very serious (e.g., heat exhaustion and heat-stroke; Abdelmoety et al., 2018; Saudi MOH, 2016a). Many factors play a role in heat illness outcomes, including old age, chronic diseases, overcrowding, physical exertion, lack of acclimatization, and dehydration (Green et al., 2001; Zeng et al., 2012). Without proper treatment, patients can suffer from organ failure, convulsions, coma, and increased intracranial pressure (Atha, 2013; Epstein & Roberts, 2011). Not surprisingly, a strong correlation exists between high temperatures or humidity and the use of medical care at mass gatherings, including the Hajj (Abdelmoety et al., 2018; Baird et al., 2010; Ghaznawi & Ibrahim, 1987; Khogali, 1983). As the Hajj follows the Hijri calendar, the season in which it takes place varies from year to year. To date, few studies have investigated the relationship between temperature and mortality for the Hajj, and those that do exist have focused on heat rather than the impacts of Hajj seasonal variation (Abdelmoety et al., 2018; Khogali, 1983)

This study describes the patterns of inpatient all-cause mortality occurring at Makkah and sacred sites hospitals during the Hajj season based on patient demographics, clinical characteristics (including age; gender; nationality; resident status; mode of admission; preexisting chronic diseases); diagnostic and therapeutic procedures provided during hospitalization; and hospitalization episode characteristics (hospitalization length of stay [LOS], discharge date, discharge time, and principal discharge diagnosis). Also, it examines the patterns of inpatient all-cause mortality occurring in Makkah and sacred sites hospitals during the Hajj based on hospital characteristics, such as hospital location, hospital medical staffing, and the weather conditions at the time of admission. It finishes by discussing the Islamic view of death and its impact on mortality during the Hajj.

2.2 Methods

2.2.1 Study design and population

A cross-sectional study design was utilized to describe the patterns of inpatient all-cause mortality during Hajj hospitalization. The study population consisted of all patients discharged from hospitals serving the Hajj in Makkah and sacred sites between 15th of Dhul-Qa'dah and 30th of Dhul-Hijja during five Hajj seasons (2012, 2013, 2014, 2016, and 2017).

The 2015 Hajj was excluded because two major events occurred that year that significantly increased the number of deaths. First, a thunderstorm at the beginning of the Hajj season caused a large crane to fall in the Holy Mosque in Makkah, which was used for huge expansion of the Holy Mosque halted during Hajj season, causing the death of 111 and injury of 238 pilgrimages (Khan, & Noji, 2016). Second, a stampede in Mina caused more than 2,000 deaths among pilgrims (Gambrell, 2015; Kasolowsky, 2016). Mortality caused by such major accidents is beyond the scope of this study and would add more deaths than what would typically occur.

The study inclusion criteria were to (a) be a pilgrim of (b) any age, (c) any nationality, and (d) any gender; (e) have been admitted to one of the twelve Hajj hospitals in Makkah and sacred sites for at least for 12 hours; and (f) died during hospitalization. Exclusion criteria were (a) not a pilgrim, (b) having no medical records, and (c) death occurring outside of the hospital.

During the 45-day span of the Hajj season over the five, studied years, 47,211 patients were discharged from the hospitals serving the Hajj. Of these, 10,507 patients were not pilgrims and 1,743 died outside the hospital, leaving 34,160 patients eligible for the study. The number of patients discharged varied from year to year with the highest number discharged in 2012 (8,213) and the lowest in 2013 (5,649; Appendix A, Table A9).

2.2.2 Data collection

The data collection process took place between August 4, 2017 and September 25, 2017 and included two stages. First, site visits to each hospital were conducted to collect administrative data from the admission offices, ensure the ability to access patient medical files, and prepare a location for file review. Four hospitals in Makkah and eight hospitals in sacred sites were included in the study (Appendix B, Table B1).

Sacred sites hospitals were located in Arafat and Mina and are temporary healthcare facilities that provide essential medical services to pilgrims only during the Hajj season. They are fully operational with specialized staff and state-of-the-art equipment. Staff temporarily relocate to these facilities from all over the country and return to their primary locations after the Hajj. The Saudi MOH approved access to the administrative data, and the Ethical Committee at King Fahad Medical City in Riyadh, Saudi Arabia approved the study.

Second, medical students were recruited and trained to review the patient medical records for inpatient all-cause mortality cases and selected control subjects[6]. The field team consisted of 12 medical students who reported directly to the principal investigator. Field training took place in Makkah in August 2017. This included training in human research ethics and medical records review. Moreover, the codebook, definitions, and identification of each variable were explained. A data collection form was created in Microsoft Excel and explained to the students. Also, the study inclusion and exclusion criteria were described, and questions regarding the entire process were answered. A pilot study was conducted at the end of the training period to test clarity and feasibility. All students showed proper conduct. Records used in the pilot study were not included in the final study.

[6] The selection of control subjects will be explained in Chapter 3.

For each hospital, selected medical files were extracted for review by medical records department employees and the trained students. Students were paired into six teams to review the medical records and insert the data into the Microsoft Excel spreadsheet (Appendix B, Figures B2, B3, and B4). Each team consisted of file reviewer and data entry personnel. Patient medical records contained information on preexisting chronic diseases (i.e., diabetes mellitus, hypertension, and history of cardiovascular diseases). Keywords indicating the presence of the preexisting chronic diseases were searched for in the selected patient medical records. In addition, to obtain information about preexisting chronic diseases status, the medical records were reviewed for "key clinical findings" that can indicate the diagnostic and therapeutic procedures provided during the hospitalization period. Intubation, advanced radiology imaging, endoscopy, and blood transfusion were reported as present (yes) if explicitly recorded in doctors' order sheets; intensive care unit (ICU) forms; daily nurses' notes; or if an order request form, endoscopy findings report, or a radiology report were included in the patient's medical records.

2.2.3 Variables

Mortality data obtained from the admissions office and medical records were used to quantify the case characteristics. In addition to the variables obtained in the data collection stage, dummy variables were created. Information regarding inpatient all-cause mortality was obtained from the administrative dataset. Inpatient all-cause mortality was defined as death that occurred during hospitalization. The discharge status variable has three categories: died, improved, or transferred. For the current study, only dead patients were included.

Several *demographic characteristics* are included in the dataset. Gender was coded into two categories (male or female). Age was a continuous variable measured in years. It included cases from 1 through 98 years old. Based on the sample age distribution and given that the majority of the Hajj mortality was in older-aged individuals, age was categorized into six groups (41 years or younger, 41-50 years, 51-60 years, 61-70 years, 71-80 years, and 81 years or older). Classification of the age variable in this manner provided and preserved as much of the originally collected information as possible while minimizing the impact of errors in age reporting.

The dataset represented a diverse population with patients of different nationalities. Given that pilgrims coming from the same region have common traits, nationality was divided into five regions by geographic location (Arab, African, Asian, European, and North American). Asian countries were further subdivided into four regions (central, east, south, and southeast) bringing the number of regions into seven. (Appendix B, Table B5) Arab countries were defined as countries where Arabic is the official language.

Patient type contained three categories: Saudi citizen, a resident of Saudi Arabia, and pilgrims coming from outside Saudi Arabia. Because only a few patients were Saudi citizens or residents, the variable was dichotomized into domestic patients versus international patients. Domestic patients were identified as Saudi citizens or non-citizens who reside in Saudi Arabia, while international patients were those who were visiting Saudi Arabia to perform the Hajj.

Hospitalization episode characteristics include information regarding admission and discharge (date, time, and location of admission and discharge), mode of admission, and length of stay. Although the Hajj, itself, is only a 10-day event, people usually arrive earlier and remain afterward. The 45-day study period was divided into three phases. The event period was the time around which the Hajj rituals are carried out by pilgrims, between the 7th and 16th days of Dhul-Hijjah. It is the period when seasonal hospitals at sacred sites are open. The pre-event and post-event periods are those before and after the rituals of the Hajj, respectively. Based on the date of discharge, pre-event was the period from day 1 to day 21, event was between days 22 and 30, while post-event was between days 31 and 45.

Time of admission was used to classify the cases as occurring in the daytime or nighttime and then linked to the heat index at the time of the death. Daytime cases were defined as inpatient deaths occurring between 8 a.m. and 8 p.m. Nighttime cases were defined as inpatient deaths occurring between 8 p.m. and 8 a.m. Due to the close distance and the similarity in time of operation between Mina and Arafat hospitals, hospitals located in Mina and Arafat were grouped and referred to as sacred sites hospitals. As mentioned before, all of the hospitals situated in Mina and Arafat are seasonal hospitals that operate only during the Hajj season.

Mode of admission has three categories (emergency admission, elective admission through outpatient clinics, or transferred from another hospital). Because of the limited number of the patients who were admitted through departments other than the emergency department, mode of admission was dichotomized into admission through the emergency department and admission through other departments. Admission through other departments refers to patients who were admitted through outpatient clinics or transferred from another hospital. Hospital length of stay was measured in days. For all cases, hospitalization length of stay was calculated by subtracting the date of admission to the hospital from the date of mortality, counting the date of admission as zero.

Preexisting chronic diseases and *diagnostic and therapeutic procedures* were binary (yes or no) variables. Eight variables were used to capture information regarding preexisting chronic diseases, diagnostic and therapeutic procedures. The three preexisting chronic diseases included in this study were: diabetes mellitus, hypertension, and history of cardiovascular diseases. Healthcare services provided during hospitalization included ICU admission, intubation, endoscopy, blood transfusion, and advanced radiology imaging. Cerebrovascular diseases were included in cardiovascular diseases as both typically share common etiology. Advanced radiology imaging referred to patients who underwent a Computed Tomography (CT) scan or Magnetic Resonance Imaging (MRI).

Discharge principal diagnosis was established using the primary cause registered on the medical records using the International Classification of Diseases, Tenth Revision (ICD-10). Discharge diagnosis was classified into 14 categories: infectious and parasitic diseases (codes starting with A or B); diseases of the circulatory system (codes starting with I); diseases of the respiratory system (codes starting with J); diseases of the digestive system (codes starting with K); diseases of the nervous system (codes starting with G); diseases of the blood, blood-forming organs, or immune system (codes starting with D50 through D89); malignant or in-situ neoplasms (codes starting with C or D00 through D09); endocrine, nutritional, or metabolic disease (codes starting with E); pregnancy, childbirth, puerperium, or certain conditions originating during the perinatal period (codes starting with O or P); diseases of the genitourinary system (codes starting with N); injury, poisoning, or certain other consequences of external causes (codes starting with S or T); diseases of the musculoskeletal system or connective tissue (codes starting with M); mental or behavioral disorders (codes starting with F); and symptoms, signs, or abnormal clinical or laboratory findings not classified elsewhere (codes starting with R; Agency for Healthcare Research and Quality [AHRQ], 2012). These categories were selected based on the Clinical Classification Software (CCS) for ICD-10 created by the AHRQ (2012), which provides a way to classify diagnoses into a limited number of categories. CCS aggregates individual ICD-10 codes into broad diagnosis groups to facilitate statistical analysis of mortality data.

In addition to the administrative dataset, hospital characteristic indicators (including the number of physicians, nurses, and beds) were continuous variables and were extracted from the Services Availability and Readiness Assessment (SARA) dataset. The Global Center for Mass Gathering Medicine, a collaboration between the WHO and the Saudi MOH, has established a project to assess the availability and readiness of healthcare services during the Hajj through the SARA project (Textbox 1).

Textbox 1. SARA project.

SARA "is a health facility assessment tool designed to evaluate and monitor the availability and readiness of the healthcare sector and to generate evidence to support the planning and managing of a healthcare system" (WHO, 2017). SARA is designed as a systematic survey to produce a set of indicators of service availability and readiness. The survey objective is to generate reliable information about service delivery (such as the availability of crucial human and infrastructure resources); the availability of necessary equipment, basic amenities, essential medicines, and diagnostic capacities; and the readiness of health facilities to provide basic healthcare interventions (WHO, 2017). SARA has three main focus areas, with the first being the physical delivery of services, which is based on the health infrastructure, core health personnel, aspects of service utilization, and the total capacity of hospitals to provide general health services. The second area is the ability of a health facility to offer a specific service. The third area is the capacity to provide that service as measured by criteria including trained staff, guidelines, equipment, diagnostic capability, medicines, and commodities.

The bed-to-nurse ratio and *bed-to-doctor ratio* were calculated by dividing the total number of beds by the total number of nurses and doctors, respectively, working in each Hajj hospital during each season. Meaning, for each hospital, five different staffing grades were assigned with smaller ratios indicating better staffing. The bed-to-nurse ratios and bed-to-doctor ratios were then categorized into three staffing grades (Grades 1-3). The reason for using staffing grades instead of the actual ratios was to determine what staffing levels are adequate and safe, not just whether there is a relationship between staffing and outcomes, in order to be more consistent with the primary concern of clinicians and policymakers (Clarke and Donaldson, 2008). Categorizing the staffing grades was based on the distribution of the data. Grade 1 for nurse staffing (the best) was defined as a bed-to-nurse ratio less than 3, grade 2 was a ratio between 3 and 5, and grade 3 (the worst) was a ratio of 5 or greater. For doctors, grade 1 (the best) was defined a bed-to-doctor ratio less than 2, grade 2 was a ratio between 2 and 3, and grade 3 (the worst) was a ratio of 3 or greater (Appendix B, Table B6).

Seasonal variation in inpatient all-cause mortality from year to year was illustrated using meteorological variables about Makkah weather. A simplified, visual heat index (NOAA's National Weather Service [NWS] Heat Index [HI]) was used to account for seasonal climatic variation between the Hajj seasons. Meteorological variables about Makkah weather was extracted from the internet (Timeanddate, 2018). For each case, air temperature (in Celsius), and relative humidity (in percentage) were collected to calculate the HI at the time of the admission. The NWS HI was developed through a multiple regression analysis of Steadman's equations, as a way of using only two conventional independent variables – ambient temperature and relative humidity to measure actual heat. Solar radiation, windiness, clothing resistance, and human physiology and workload are implicitly assumed in the NWS index (Rothfusz, 1990). Even though this index was designed for outdoor working conditions; in practice, it is used for both indoor and outdoor work environments (Coco et al., 2016; MSU, 1999). Therefore, the NWS HI was used in this study.

The HI readily presents a table of approximate thermal comfort for temperatures 27 °C or higher and a relative humidity of 40% or higher. The HI was categorized into four groups. Group 1 included HIs equivalent to 32.7 °C or less. Group 2 included HIs between 32.7 and 39.4 °C. Group 3 included HIs between 39.4 and 46.1 °C. Group 4 included HIs greater than 46.1 °C. These categories were based on the grading criteria of the Occupational Safety and Health Administration guidelines for outdoor work (2006; Opitz-Stapleton et al., 2016). Corresponding health impacts for different HI values are included in Appendix B, Figure B7.

2.2.4 Data analysis

First, descriptive analysis was performed to describe inpatient all-cause mortality based on demographics, inpatient hospital stays, hospital characteristics, and HI. Frequencies and percentages were calculated if the variable was categorical, and the mean and standard error were calculated if the variable was continuous. Among the demographic characteristics, age was both a continuous and categorical variable. Nationality was described in term of regions and distinct countries. Inpatient hospital stays, hospital characteristics, and HI were categorical variables, except for length of stay, which was continuous. In addition, frequencies and percentages of preexisting chronic diseases were calculated and stratified by age group. Also, inpatient medical procedures were described by event phases.

Second, yearly, total all-cause mortality rates among pilgrims were estimated and stratified by death location. The total all-cause mortality rate was defined as the number of pilgrims who died inside or outside the hospital divided by the total number of pilgrims that attended the Hajj. Subsequently, yearly, inpatient all-cause mortality rates among total hospitalized pilgrims were quantified and stratified by death location. The inpatient all-cause mortality rate was defined as the number of inpatients who died in the hospital divided by the total number of hospitalizations during the Hajj period. Tables and graphical representations were used to summarize central tendency, spread, and frequencies of all relevant variables. All analyses were performed in SAS 9.4 (Statistical Analysis Systems, Inc, Cary, NC).

2.3 Results

Among those who were discharged from the included hospitals, 2,237 patients died during their hospitalization. During the 2012 Hajj, there were 1,315 deaths in Makkah and sacred sites hospitals, and in 2017 there were 657 deaths. In 2012 and 2017, 40.0% and 68.8% of these deaths occurred in hospitals, respectively. The total all-cause mortality rates varied over the years with the highest rate occurring in 2012 (42 per 100,000 pilgrims) and the lowest in 2017 (28 per 100,000 pilgrims; Table 2.1).

Throughout the five seasons included in the study, 34,160 pilgrims were hospitalized in Makkah and sacred sites hospitals (30 per 10,000 pilgrims). During the same period, the inpatient all-cause mortality rate was 65 per 1,000 hospitalized pilgrims. The rate fluctuated from year to year with the highest in 2013 and 2016 (69 per 1,000 hospitalized pilgrims) and the lowest in 2014 (60 per 1,000 hospitalized pilgrims; Table 2.2).

The demographic characteristics of patients are shown in Table 2.3. The majority of the cases were in Makkah (72.3%). Among those who died in Makkah, 1,008 (62.3%) were males, while 390 (63.0%) of those who died in sacred sites hospitals were males. One thousand two hundred thirty-one of the patients who died in Makkah (55%) and 504 of those who died in sacred sites hospitals (81.4%) were aged between 60 and 80 years old (Table 2.3).

The study population was comprised of 89 different nationalities, with 1,947 (87.1%) international pilgrims and only 290 (12.9%) domestic pilgrims. Seventy-five percent of the cases were from only 11 nationalities. Indonesian pilgrims constituted 21.8% of the total deaths (Table 2.3). Three geographic regions represented 83.3% of the pilgrims. Six hundred fifty-six (29.3%) patients were from Southeast Asia, 646 patients (28.9%) were from South Asia, 569 patients (25.4%) were from Arabic countries.

A total of 1,367 (84.5%) patients were admitted to Makkah hospitals through the emergency department, with the remaining 251 patients (15.5%) admitted through other departments (Table 2.5). Five hundred sixty-five patients (91.3%) were admitted to sacred sites hospitals through the emergency department, while only 54 patients (8.7%) were admitted through the other departments.

Figure 2.1 shows the distribution of the inpatient all-cause mortality by the length of hospital stay. The mean total hospital stay length was 5 days (standard error [SE] = 0.13). When stratified by hospital location, the mean length of stay was 6.3 days in Makkah (SE = 0.17) and 1.2 days (SE = 0.07) in sacred sites hospitals. Moreover, the maximum length of stay was 45 days for Makkah hospitals and 7 days for sacred sites hospitals (Figure 2.2A & B). The proportion of deaths during the pre-event, event, and post-event phases were: 22.3% (498), 45.1% (1,010), and 32.6% (729), respectively (Table 2.6).

Table 2.7 shows the discharge diagnoses of hospitalized patients. Cardiovascular diseases were the most common cause of death and accounted for 31.0% of inpatient all-cause mortality (693 patients). Pulmonary diseases were the second-leading cause of death and accounted for 18.3% of inpatient all-cause mortality (410 patients) followed by Infectious diseases accounted for 12.3% of deaths (276 patients). Injury and external causes, tumors, and diseases of blood origin were more frequently reported in Makkah hospitals compared with sacred sites hospitals (Table 2.7).

A total of 1,242 patients (55.5%) had at least one of the preexisting chronic diseases listed in Table 2.8. One-third of the inpatient all-cause mortality cases presented with diabetes mellitus (710 patients), one-quarter with hypertension (554 patients), and one-fifth with cardiovascular diseases (441 patients). Of the 2,237 cases of inpatient deaths, 922 required admission to the ICU (41.2%), and 310 patients required tracheal intubation (13.9%). One hundred forty patients received endoscopy procedures (6.3%), 388 patients underwent advanced diagnostic imaging (17.3%; CT or MRI), and 100 patients required a blood transfusion (4.5%). Most of the advanced medical procedures included in the study took place in Makkah hospitals during the time of the event (ICU admission [79.3%], tracheal intubation [68.4%], endoscopy [88.6%], advanced radiology imaging [74.5%], and blood transfusion [82.0%]; Tables 2.9 and 2.10).

Table 2.11 presents the distribution of inpatient all-cause mortality by hospital staffing grades. Fifty percent of bed-to-doctor ratios were grade 1, with only 7 of the hospitals (11.7%) being grade 3. One thousand ninety-one of the deaths (48.8%) occurred in hospitals classified as grade 1, while only 363 (16.3%) occurred in hospitals classified as grade 3. Seventeen bed-to-nurse ratios were grade 3 (28.3%), where 987 of the deaths occurred (44.1%). Doctor staffing grade had a more skewed distribution than that of nurse staffing. For instance, there was no hospital classified as nurse staffing grade 1 and doctor staffing grade 3 or vice versa. Furthermore, the majority of hospitals had grade 1 ratios for both (33.3%; Appendix B, Table B6).

During the study period, the HI varied between 25 ºC and 64.1 ºC. Seven hundred fifty-five of the deaths (33.8%) occurred during the highest HI level (>46.1 ºC), followed by deaths occurred at the lowest HI level (<32.7 ºC). Four hundred sixty-three (20.7%), and 378 (16.9%) occurred during the second and third HI levels, respectively. (Figure 2.3)

2.4 Discussion

The Hajj creates a unique medical situation, as a massive number of Muslims from around the globe come to perform it. The existing public health risks to pilgrims can be exacerbated by preexisting medical conditions, advanced age, hot and humid weather, overcrowding, inadequate food intake, and strenuous physical activity while performing Hajj rituals. This study estimated the inpatient mortality rate before describing the inpatient all-cause mortality in Makkah and sacred sites hospitals with respect to demographics, hospital stay episode, hospital characteristics, and weather conditions.

2.4.1 Comparing the study results to published literature

The total mortality rate in the current study was 30 per 10,000 pilgrims. This number is consistent with prior mortality rate estimates for pilgrims from previous seasons (Meysamie et al., 2006; Pane et al., 2013). The inpatient all-cause mortality rate was 65 per 1,000 discharged patients. This number was close to the inpatient mortality rate estimated by other papers (Khan et al., 2006; Madani et al., 2006). In the current study, less than 1.0% of the total number of pilgrims were hospitalized during their stay in Makkah and sacred sites. This is inconsistent with two prospective studies conducted with 105,713 Iranian pilgrims in 2004 and 2005, where 1.3% of individuals were hospitalized, and 545 French pilgrims in 2007, where 3% of individuals were hospitalized (Gautret et al., 2009; Meysamie et al.,2006). However, these reports were limited to a specific nationality, limited number of cases, singular hospital, and shorter duration.

During the study period, the number of pilgrims hospitalized in Makkah hospitals was more than twice the number of pilgrims who were hospitalized in sacred sites hospitals, 23,391 (68.5%) versus 10,769 (31.5%). Also, a higher inpatient all-cause mortality rate was reported by Makkah hospitals (69 per 1,000-hospitalized pilgrims) compared to sacred sites hospitals (57 per 1,000-hospitalized pilgrims). This discrepancy could be explained by the fact that Makkah hospitals are permanent hospitals that operate for the 45-day period included in the study while hospitals at sacred site are seasonal hospitals that only operate for approximately ten days. Also, pilgrims spend the majority of their 45-day period in Makkah and are at the sacred sites during the actual ritual where many of them experience more intense physical activity that can affect their health.

In this study, the majority of inpatient all-cause mortality patients were over 50 years of age (85.1%), with nearly one-third of patients older than 70 years (28.5%). A notably greater proportion of men died during hospitalization compared to women. As already observed in numerous surveys, the population of patients who died was characterized by advanced age and a preponderance of males (Khan et al., 2006; Madani et al., 2006; Mandourah, Ocheltree, Al Radi, & Fowler, 2012; Pane et al., 2013). Many pilgrims are only financially capable of performing Hajj at an older age after decades of saving money for that purpose. The likelihood of death is understandably high in such elderly pilgrims. According to geographical distribution, most cases of mortality occurred in Indonesians, followed by Indians, Pakistanis, Egyptians, and Bengalis. These results were similar to the figures from other studies (Baksh et al., 2015; Ibrahim, 2008; Khan et al., 2006; Madani et al., 2006). The reason for similar percentages could be that the number of pilgrims coming from these countries represent a significant proportion of the pilgrims. Comparatively, they relatively attended more healthcare facilities compared with other country's pilgrims.

Admissions through the emergency department accounted for 86.4% of the patients in this study, with approximately half of the patients dying in the hospital within 48 hours of admission (49.2%). The maximum length of stay was only 7 days for sacred sites hospitals and 45 days for Makkah hospitals. Patients who still required medical care when sacred sites hospitals cease operation were transferred to one of Makkah hospitals. This difference in length of stay could be due to the disparity in operation time between Makkah and sacred sites hospitals. Another explanation could be the nature of Hajj hospitals in which the goals of hospitalization are to stabilize patients such that they can be discharged quickly to be able to complete the Hajj rituals and free hospital beds to accommodate the large influx of patients requiring hospitalization during the Hajj period. However, as this study only included inpatient all-cause mortality cases, it cannot be extrapolated to patients who were alive at discharged.

Cardiovascular diseases were the most common cause of death, followed by pulmonary disease. In a study comparing documented and verbal autopsy of the cause of death among Indonesian pilgrims, cardiovascular diseases were the leading cause of Indonesian pilgrim mortality in 2008 by both methods (Pane et al., 2013). In the same study, one-third of Indonesian pilgrim mortality was attributed to respiratory diseases. This number is larger than the number reported in the current study. Respiratory, infectious disease, including pneumonia and tuberculosis, is a life-threatening illness to the elderly, especially those with comorbidities, such as diabetes or hypertension (Mandourah, Ocheltree, Al Radi, & Fowler, 2012). Two studies have shown that pneumonia is the primary cause of critical illness during the Hajj and that etiologies include Streptococcus pneumoniae and Gram-negative bacilli (Mandourah et al., 2012; Shafi, Booy, Haworth, Rashid, & Memish, 2008). Infectious diseases pose a huge burden to the Hajj healthcare system and are a threat to healthcare professionals and public-health security (Al Ghamdi & Kabbash, 2011; Alzahrani et al., 2012; Shirah, Zafar, Alferaidi, & Sabir, 2017; Shujaa, & Alhamid, 2015). The risk of severe illness and mortality during the Hajj may increase due to the physical stress. Also, the risk of disease transmission may increase due to the intense crowding during the pilgrimage.

Although many reports estimate infectious diseases to be the leading cause of outpatient and emergency room visits, they contribute fewer cases of mortality compared to cardiovascular and pulmonary diseases, as shown by the current study and previous studies (Madani et al., 2006; Meysamie et al., 2006; Shakir, Gazzaz, Dhaffar, & Shahbaz, 2006). The prevalence of preexisting chronic diseases in this study was 31.6% for diabetes, 24.8% for hypertension, and 19.7% for cardiovascular diseases, with the majority of cases reported in those of advanced age. These numbers are higher than the prevalence of preexisting chronic diseases estimated in previous studies (Arabi, & Alhamid, 2006; Madani et al., 2006; Pane et al., 2013). This difference can be explained by the fact that previous studies included patients discharged alive while the current study included only inpatient mortality cases who might be sicker, have a higher hospital-admission rate, or an increased risk of death.

All the medical services included in the study were higher during the event period compared to the pre- and post-event periods. No previous study estimated ICU admissions or medical services among inpatient mortality cases. However, Mandourah et al. (2012) estimated the short-term (3-week) mortality rate to be 16.2% and the intubation rate to be 69.1% among all critically ill patients during the 2009 and 2010 Hajj.

Nurse staffing showed a relationship with inpatient all-cause mortality with lower staffing associated with increased mortality. A similar trend was found by a previous study in South Korea, although it was conducted in a different setting (Cho, & Yun, 2009). Contrary to expectations, doctor staffing showed notably different patterns as inpatient all-cause mortality was higher in hospitals with better staffing. One explanation could be that the data about doctor staffing was aggregated at the hospital level, and, thus, the averaged staffing grades used in this study would not be equivalent to the real staffing of the units where the included patients were cared for. Another explanation is the lack of controls for hospital characteristics, which would also lead to selection and referral bias, as hospitals with better staffing could receive more complicated cases. However, a recent study examining mortality among Indonesian pilgrims over eight seasons found increased mortality in the year when there was a medical staff reduction (Pane et al., 2019).

In the current study 1,133 of the cases (50%) occurred on hot weather days (>40 ºC), in keeping with previous reports. A review of the effect of warm weather showed a strong association between high temperatures or humidity and the use of medical care during mass gatherings (Baird et al., 2010). Also, a similar relationship between health outcomes and warm temperatures was previously noted during the Hajj (Abdelmoety et al., 2018; Ghaznawi & Ibrahim, 1987; Khogali, 1983). Findings from studies in Makkah showed that extreme temperatures led to a major disaster with more than 1,000 deaths from heatstroke in a few days and more than 18,000 people requiring emergency department treatment for heat exhaustion (Ghaznawi & Ibrahim, 1987; Khogali, 1983). In a recent study of 267 patients during the 2016 Hajj, 80 (29%) were diagnosed with heatstroke, leading to a 6.3% mortality rate, and 187

(67.75%) were diagnosed heat exhaustion, leading to a 0.01% mortality rate (Abdelmoety et al., 2018).

2.4.2 Potential biases, confounding assessment, and strengths

Several sources of bias may complicate this analysis. Misclassification is one threat that might affect the study. Nondifferential, independent misclassification could be introduced to the study during data insertion by the healthcare providers or during data extraction by the field data collectors. However, bias introduced by independent, nondifferential misclassification of a binary variable is predictable in direction, namely, toward the null value (Rothman et al., 2008).

Although there are advantages to using administrative data, limitations and challenges exist concerning the quality of the collected data. Because administrative data is already being collected, it is relatively inexpensive to use. Medical records are the only available source of routine data linking clinical information with administrative data. Good record-keeping is essential to the quality and continuity of healthcare, and it is reasonable to expect that clinical information should be available in the patient records. Nonetheless, it is possible that some diagnoses or information were missed. These factors could have limited the precision of the study estimates. Finally, the data only reflects inpatient mortality, which may affect the generalizability of the findings. However, the increased coverage in term of number of Hajj seasons and number of hospitals, and large sample size improves the precision and generalizability of the estimates.

The study has several strengths. To best of my knowledge, no previous study has described inpatient all-cause mortality during the Hajj in relation to multiple factors (including patient and hospital characteristics, the diagnostic and therapeutic procedures provided during the pilgrims' hospitalization, and weather conditions). Also, the study used all cases of death that occurred in the main hospitals serving the Hajj over five seasons.

2.4.3 Weather-related mortality during the Hajj

Higher mortality rates have been reported during winter in western countries, China, and some Middle Eastern countries (Armenian et al., 1988; Davie, Baker, Hales, & Carlin, 2007; Keatinge, 2002; Pan, Li, & Tsai, 1995). Cardiovascular diseases, respiratory diseases, and old age are more associated with mortality during extreme weather (Braga, Zanobetti, & Schwartz, 2002; Carder et al., 2005; Conlon, Rajkovich, White-Newsome, Larsen, & O'Neill, 2011; Leung, Yip, & Yeung, 2008). Hajj mortality has always been associated with hot weather, as the region experiences high temperatures most of the year (Abdelmoety et al., 2018; Ghaznawi & Ibrahim, 1987; Khogali, 1983). However, a study that extracted data from years when the Hajj fell during the winter season with less extreme temperatures found that the mortality rate among Indonesian pilgrims was moderately lower than that reported in the current study (Pane et al, 2019).

The Hajj seasons included in the current study were during summertime. Although HI varied, inpatient all-cause mortality cases on the colder and warmer days were relatively consistent. Heat illness during the Hajj in summer is inevitable, especially in high-risk pilgrims performing the activities of Hajj under a maximum temperature between 45ºC and 55ºC, with high humidity, during times of physical exertion, sun exposure, and crowded areas. Many factors can explain the effect of HI on mortality patterns. The Hajj population is a unique population that has several factors that could increase the effects of heat stress, including age and preexisting chronic diseases. Also, the possibility of that poor thermoregulation in the elderly and those with underlying diseases may explain the association between mortality rates and high temperatures (Bull, 1980). Hence, hot weather can only explain a limited number of cases. However, the current study tends to describe rather than establish an association as the latter would need to adjust for many variables to reach a valid estimate.

2.4.4 Impact of religious belief on mortality during the Hajj

Islamic rules state that the Hajj should not cause severe difficulties for Muslims, exempting those who would incur harmful physical or financial consequences in the course of completing this pilgrimage. Even though this would exempt individuals with underlying medical issues, such as those examined in this study, few forgo participation, thus risking medical complications and challenging their healthcare providers. One such challenge includes patients with diabetes. Many believe that their disease management will be unaffected by the pilgrimage. Unfortunately, this causes few to seek medical advice in advance to mitigate the challenges that arise during the Hajj. For example, the completion of the Hajj rituals may lead to less-diligent blood glucose monitoring. Furthermore, some patients turn to alternative medicines in lieu of their prescribed medications in a misguided effort to control their blood glucose during the Hajj.

Patient needs may be better addressed with an understanding of the religious beliefs underpinning the Hajj. The Islamic religion considers life as sacred and a trust from God (Allah), prohibiting the intentional taking of a life. However, Muslims view death as a transition from one state of existence to the next, with life on earth as an examination and death as an eternity in which one will receive the rewards or punishment appropriate for one's endeavors on earth. Therefore, death is accepted to be part of a divine plan (Neuberger, 2004). As such, dying while performing the Hajj rituals could be perceived by some to be an opportunity for forgiveness, which raises the possibility of some Muslims seeking to die at a sacred site. In one study, terminally ill individuals reported provided priority to have Hajj opportunity compared to healthy individual and women between the ages of 35 and 60 years were diagnosed with a terminal illness during their stay in Hajj which indicate that they were secured Hajj permission regardless their health status (Pane et al.,2019). The authors relate this trend to a cultural-religious belief that results in young, terminally ill women coming to the Hajj prior to their death. However, changing entry regulations for the Hajj may decrease this trend if terminally ill patients no longer receive entry priority (Pane et al., 2019). The survey of Muslim patients and healthcare providers conducted by Tayeb et al. (2010) sheds light onto the Muslim perspective of an ideal death, which contrasts that of Western society. Although Muslims believe that foreknowledge of ones death is impossible, preference for one's place of death would be a holy place, should one have such a choice.

2.4.5 Future work and policy implications

This present study is a preliminary study linking mortality to patient, hospital, and weather characteristics. Further investigations are needed to assess the relationship between the season in which the Hajj takes place (summer or winter) and health outcomes, particularly mortality. For this proposed study, a retrospective design would be appropriate comparing health and mortality patterns in at least two seasons separated by ten years. A better understanding of how climate affects mortality and susceptible populations is crucial not only to public health agencies, but also to policymakers and Hajj leaders who develop intervention strategies for extreme temperatures. For instance, the Saudi MOH developed a national Hajj extreme heat action plan to manage the effects of high heat and reduce the significant healthcare expenditures that can result from heat-related illnesses (Saudi MOH, 2016b). However, no study has yet assessed the impact of this plan.

The relationship between weather and mortality taking into account regional and population variations is likely to be of growing importance as ongoing climate change alters temperature patterns, possibly increasing the frequency and magnitude of extreme heat events. The participants of the Hajj will also be affected by this, and Hajj authorities will need to identify factors that can prevent undue mortality.

The association between levels of nurse and physician staffing in hospitals and patient mortality has been established in many settings (Aiken, Clarke, Sloane, Sochalski, & Silber, 2002; Costa, Wallace, & Kahn, 2015; Needleman, Buerhaus, Mattke, Stewart, & Zelevinsky, 2002; Pronovost et al., 2002; Sales et al., 2004; Wallace, Angus, Barnato, Kramer, & Kahn, 2012). However, determinants of optimal hospital staffing for mass-gathering events depends on the volume and nature of cases presenting during the events. The Saudi MOH intentionally overstaffs healthcare professionals at Hajj hospitals to ensure adequate service, requiring massive resources. The current study described the inpatient all-cause mortality based on physician and nurse staffing. Analytical studies examining the association between medical staffing and mortality, while accounting for differences in patients' requirements for specific doctor specialties and nursing care, shift-to-shift variations in staffing at the unit level, and controlling for potential confounders would aid the Saudi MOH in making evidence-based decisions regarding the necessary levels of staffing at Hajj hospitals. Flexible staffing practices that consistently match staffing needs throughout the season is important to ensure high-quality services with efficient resource allocation.

It has been reported that spirituality can improve quality of life, decrease anxiety and depression in cancer patients, enhance physical and mental health; furthermore, religious participation is a powerful social determinant of health (Chaar et al., 2018; Miller & Thoresen, 1999; Seybold & Hill, 2001; VanderWeele, 2017). Similar protective associations between spirituality measured by service attendance and all-cause mortality have been found in Denmark (la Cour, Avlund, & Schultz-Larsen, 2006), Finland (Teinonen, Vahlberg, Isoaho, & Kivela, 2005), Taiwan (Yeager et al., 2006), and Israel (Litwin, 2007), with different religious groups constituting the majority among these countries. The association between spirituality and mortality during the Hajj, and for Muslims in general, has yet to be established. Further research is needed to query these relationships and determine if spirituality in Muslim populations outweighs other social determinants of health, such as gender, race, and income. Studies would require relatively large sample sizes, longitudinal data, and adequate controls for potential confounding factors. These data have the potential to inform interventions that could contribute to the well-being of Hajj and Muslim populations.

This study was restricted to all-cause mortality within a hospital setting. Mortality taking place outside the hospital still needs to be assessed for the Hajj. A mortality surveillance system should be initiated to ensure that the data are collected in a manner that permits public health studies aimed at reducing pilgrim mortality. However, the current study will assist the Saudi authorities in making more informed decisions to prepare for upcoming seasons. Over the past few years, it has become increasingly apparent that more information about healthcare during the Hajj is needed to more efficiently manage such events. This study provided detailed information about inpatient all-cause mortality in the hospitals serving the Hajj. The majority of patients were elderly with a high prevalence of chronic medical disorders. Noninfectious diseases were the most significant contributors to mortality. The study highlights the importance of surveillance during the Hajj to understand its health risks and strengthen the evidence upon which policy can be developed.

Table 2.1
Number ***of total death*** (mortality rate) by year and city during the Hajj (2012 – 2017).*

Year	Makkah		Sacred Sites		Total	
	Death Number	(%)	Death Number	(%)	Death Number	MR**
2012	839	(64)	476	(36)	1,315	(42)
2013	446	(70)	191	(30)	637	(32)
2014	463	(70)	194	(30)	657	(32)
2016	486	(68)	228	(32)	714	(38)
2017	437	(67)	220	(33)	657	(28)
Total	2,671	(67)	1309	(33)	3980	(30)

*Hajj 2015 was excluded.
** per 100,000 pilgrims.

Table 2.2
Number of ***inpatient all-cause mortality*** (mortality rate) by year and city during the Hajj (2012 – 2017).*

Year	Makkah			Sacred Sites			Total		
	Death Number	(%)	MR**	Death Number	(%)	MR**	Death Number	(%)	MR**
2012	345	(65.6)	64	181	(34.4)	65	526	(23.5)	64
2013	299	(76.7)	76	91	(23.3)	53	390	(17.4)	69
2014	297	(75.6)	68	96	(24.4)	45	393	(17.6)	60
2016	352	(74.0)	71	124	(26.0)	64	476	(21.3)	69
2017	325	(77.0)	68	127	(33.0)	59	452	(20.0)	65
Total	1,618	(72.3)	69	619	(27.7)	57	2,237	(100.0)	65

*Hajj 2015 was excluded.
** per 1000 discharged patients.

Table 2.3
Demographic characteristics of inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj (2012 - 2017).*

Demographic data	Makkah	Sacred sites	Total
	n (%)	n (%)	N (%)
	1,618 (72.3)	619 (27.7)	2,237
Sex			
Male	1,008 (62.3)	390 (63.0)	1,398 (62.5)
Female	610 (37.7)	229 (37.0)	839 (37.5)
Age Group			
≤ 40	113 (7.0)	16 (2.6)	129 (5.8)
41 – 50	151 (9.3)	54 (8.7)	205 (9.1)
51 – 60	345 (21.3)	141 (22.8)	486 (21.8)
61 – 70	563 (34.8)	216 (34.9)	779 (34.8)
71 – 80	323 (20.0)	147 (23.7)	470 (21.0)
> 80	123 (7.6)	45 (7.3)	168 (7.5)
Hajj (Pilgrimage) Status			
Domestic	268 (16.6)	22 (3.6)	290 (12.9)
International	1,350 (83.4)	597 (96.4)	1,947 (87.1)
Nationality			
Indonesia	391 (24.2)	97 (15.7)	488 (21.8)
India	203 (12.5)	80 (12.9)	283 (12.7)
Pakistan	153 (9.5)	61 (9.9)	214 (9.6)
Egypt	86 (5.3)	107 (17.3)	193 (8.6)
Bangladesh	98 (6.1)	39 (6.3)	137 (6.1)
Myanmar (Burma)	67 (4.1)	2 (0.3)	69 (3.1)
Saudi Arabia	44 (2.7)	23 (3.7)	67 (3.0)
Turkey	57 (3.5)	10 (1.6)	67 (3.0)
Nigeria	48 (3.0)	10 (1.6)	58 (2.6)
Morocco	31 (1.9)	25 (4.0)	56 (2.5)
Malaysia	51 (3.2)	4 (0.6)	55 (2.4)
Other**	389 (24.0)	161 (26.0)	550 (24.6)

*Hajj 2015 was excluded.
**Other included 15 patients of unknown origin.

Table 2.4
Distribution of inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj by geographic region (2012 – 2017). *

Region	**n (%) ****
Southeast Asia	656 (29.03)
South Asia	646 (28.9)
Arabic countries	569 (25.4)
Africa	165 (7.4)
Europe	91 (4.1)
Central and East Asia	90 (4.0)
North America	5 (0.2)

*Hajj 2015 was excluded.
** 15 patients were of unknown origin.

Table 2.5
Mode of admission of inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj (2012 – 2017).*

Mode of admission	**Makkah**	**Sacred sites**	**Total**
	n (%)	n (%)	N (%)
Emergency department	1,367 (84.5)	565 (91.3)	1,932 (86.4)
Other**	251 (15.5)	54 (8.7)	305 (13.6)

*Hajj 2015 excluded
** Other modes of admission included patients who admitted through outpatient clinic and patients who transferred from another hospital.

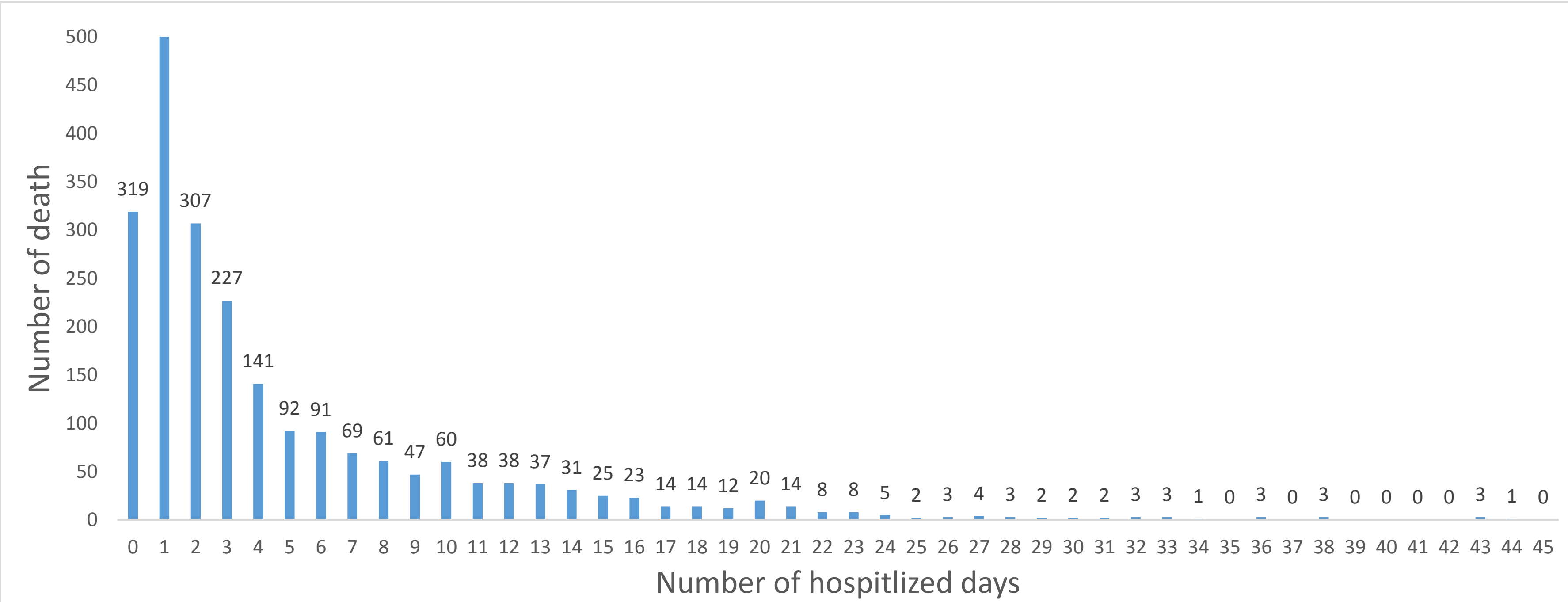


Figure 2.1: Distribution of inpatient all-cause mortality in Makkah and sacred sites hospitals during Hajj by length of stay (2012 – 2017).
*Hajj 2015 was excluded

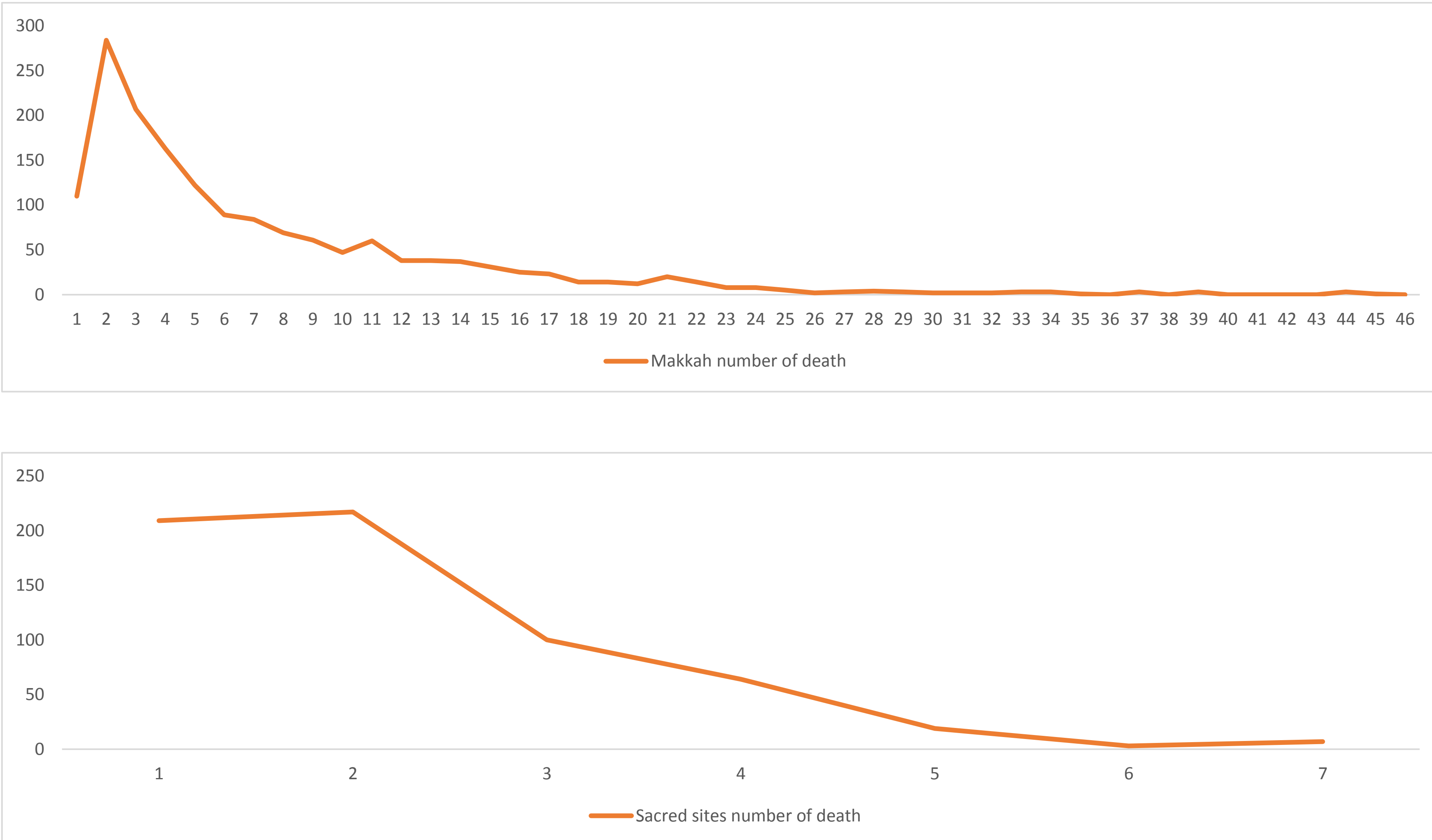


Figure 2.2.a,b: Distribution of inpatient all-cause mortality in Makkah and sacred sites hospitals during Hajj by length of stay and city (2012 – 2017). *Hajj 2015 was excluded.

Table 2.6
Distribution of inpatient all-cause mortality in Makkah and sacred sites hospitals by Hajj time phases (2012 – 2017).*

Phase	**n (%)**
Pre-event	498 (22.3)
Event	1,010 (45.1)
Post-event	729 (32.6)

*Hajj 2015 was excluded.

Table 2.7
Discharge diagnoses in inpatients all-cause mortality in Makkah and sacred sites hospitals during the Hajj (2012 – 2017).*

Discharge diagnosis	**Makkah**	**Sacred sites**	**Total**
	n (%)	**n (%)**	**N (%)**
Cardiovascular diseases	387 (23.9)	306 (49.4)	693 (31.0)
Pulmonary diseases	328 (20.3)	82 (13.2)	410 (18.3)
Infectious diseases	247 (15.3)	29 (4.7)	276 (12.3)
Gastrointestinal diseases	163 (10.1)	29 (4.7)	192 (8.6)
Endocrine diseases	145 (9.0)	33 (5.3)	178 (8.0)
Renal diseases	124 (7.7)	47 (7.6)	171 (7.6)
Neurological diseases	86 (5.3)	42 (6.8)	128 (5.7)
Injury and external causes	45 (2.8)	29 (4.7)	74 (3.3)
Tumors	41 (2.5)	13 (2.1)	54 (2.4)
Diseases of blood origin	39 (2.4)	1 (0.2)	40 (1.8)
Other**	13 (0.8)	8 (1.3)	21 (1.0)

* Hajj 2015 was excluded.
**Age-related diseases, diseases of the musculoskeletal system and connective tissue, maternal and child diseases, and diseases of the genitourinary system.

Table 2.8
Preexisting chronic diseases in inpatients all-cause mortality in Makkah and sacred sites hospitals during the Hajj (2012 – 2017).*

Preexisting chronic diseases	**Makkah**	**Sacred sites**	**Total****
	n (%)	**n (%)**	**N (%)**
Diabetes mellitus	504 (31.0)	206 (33.3)	710 (31.6)
Hypertension	384 (23.7)	170 (27.5)	554 (24.8)
Cardiovascular disease ***	301 (18.6)	140 (22.6)	441 (19.7)

* Hajj 2015 was excluded.
**A total of 1242 (55.5%) patients had co-morbid conditions. Some patients had more than one preexisting chronic diseases. Hence the total number of preexisting chronic diseases adds up to more than 1242 patients.
*** Cardiovascular diseases included cerebrovascular diseases.

Table 2.9
Medical services provided to inpatients all-cause mortality in Makkah and sacred sites hospitals during the Hajj (2012 – 2017).*

Medical services	**Makkah**	**Sacred sites**	**Total**
	n (%)**	**n (%)****	**N (%)*****
ICU admission	731 (45.2)	191 (31.0)	922 (41.2)
Intubation	212 (13.1)	98 (15.8)	310 (13.9)
Endoscopy	124 (7.7)	16 (2.6)	140 (6.3)
Radiology imaging	289 (17.9)	99 (16.0)	388 (17.3)
Blood transfusion	82 (5.1)	18 (3.0)	100 (4.5)

*Hajj 2015 was excluded.
** Percentage of inpatient all-cause mortality occurred in Makkah (1,618) and sacred city (619).
*** Out of total inpatient all-cause mortality (2,237)

Table 2.10
Medical services provided to inpatients all-cause mortality in Makkah and sacred sites hospitals during the Hajj by event phases (2012 – 2017).*

Phase	Medical care services				
	ICU	**Intubation**	**Endoscopy**	**Radiology imaging**	**Blood transfusion**
	n (%)	n (%)	n (%)	n (%)	n (%)
Pre-event	187 (20.3)	52 (16.8)	40 (28.6)	77 (19.8)	25 (25.0)
Event	379 (41.1)	156 (50.3)	48 (34.3)	173 (44.6)	38 (38.0)
Post-event	356 (38.6)	102 (32.9)	52 (37.1)	138 (35.6)	37 (37.0)
Total	922 (41.2)	310 (13.9)	140 (6.3)	388 (17.3)	100 (4.5)

*Hajj 2015 was excluded.

Table 2.11
Distribution of inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj by bed-to-nurse ratio and bed-to-doctor ratio grades (2012 - 2017). *

Bed-to-nurse ratio grade	Bed-to-doctor ratio grade			
	1	**2**	**3**	**Total**
	n (%)	**n (%)**	**n (%)**	**N (%)**
1	588 (26.3)	33 (1.5)	0 (0.0)	621 (27.8)
2	503 (22.5)	122 (5.4)	4 (0.2)	629 (28.1)
3	0 (0.0)	628 (28.1)	359 (16.0)	987 (44.1)
Total	1,091 (48.8)	783 (35.0)	363 (16.2)	2,237 (100.0)

*Hajj 2015 was excluded.

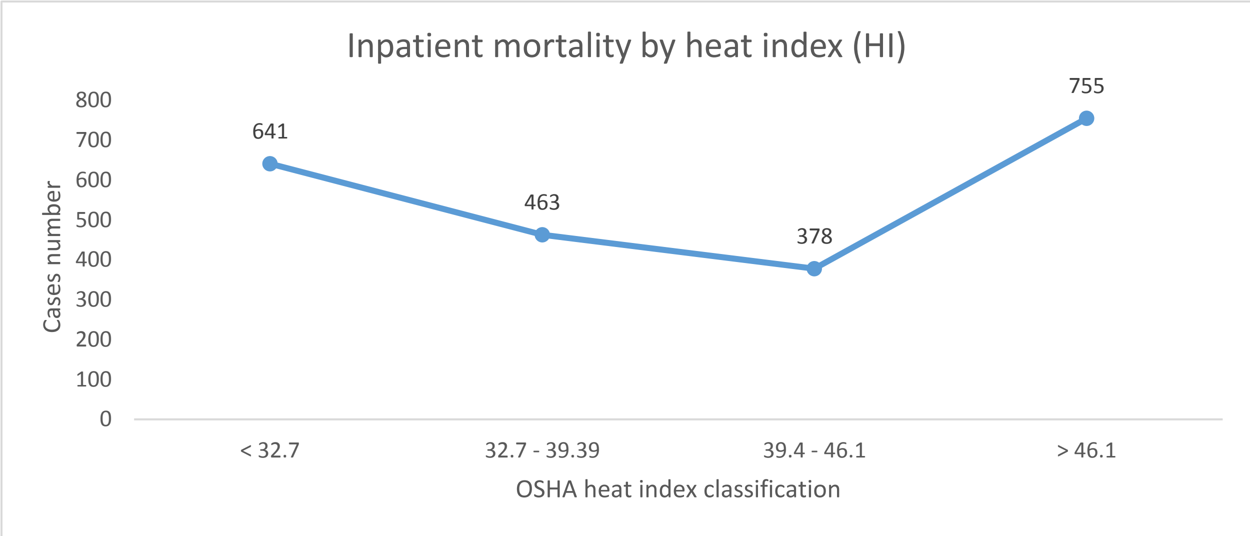


Figure 2.3: Distribution of inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj by Heat index categorizations (2012 – 2017).*
*Hajj 2015 was excluded.

3 Impact of Preexisting Chronic Diseases on Inpatient All-Cause Mortality in Hajj Hospitals

3.1 Introduction

Pilgrims come from varied backgrounds with diverse ethnicities, socioeconomic statuses, and ages. However, the majority of pilgrims will be middle-aged or older before they can afford the journey. Annually, nearly 200,000 pilgrims arrive from low-income countries, many of whom have had little, if any, pre-Hajj healthcare, which has huge public health implications (Yezli et al., 2017). Further complicating health management during the Hajj, comorbidities among pilgrims are common. The actual rituals of Hajj take place over approximately 10 days, from the 7th to 16th day of Dhul-Hijjah. For pilgrims, this is a time of extraordinary physical and mental stress.

Due to the associated disruptions in the normal life of patients with chronic diseases (e.g., geography, weather, diet, and physical activities), their physical abilities are subjected to significant challenges. In addition to severe heat, long walking distances, direct health hazards, and excessive exertion, there are a number of further logistical challenges for patients with preexisting chronic diseases. Managing temperature-sensitive medications can be complicated by waiting for long hours in the sun for transportation and difficulties in accessing refrigeration for medication storage. Overall, pilgrims with preexisting chronic diseases are at increased risk for morbidity and mortality from their preexisting disease, itself, as well as increased risks for the illnesses that threaten all pilgrims during the Hajj.

Considering the high global prevalence of diabetes mellitus, hypertension, and cardiovascular diseases (ranging between 8.5% and 40%) coupled with the number of Muslims performing the Hajj (approximately 2.5 million adults), it is estimated that the number of

Muslims with chronic diseases performing the Hajj could exceed 300,000 per year. This may be an underestimate, though, as the prevalence of chronic diseases in Arab and Muslim countries is above that of non-Muslim countries (Roth et al., 2017; Stevens, Mascarenhas & Mathers, 2009; WHO, 2016). Additionally, a large proportion of Hajj participants are over 60 years of age. With the greater prevalence of chronic diseases in older individuals, the number of people with chronic diseases during the Hajj could be considerably higher than estimates (Siavash & Haghighi, 2012).

Historically, communicable diseases have been the most abundant causes of morbidity and mortality during the Hajj (WHO, 2015b); but over the past few years, noncommunicable diseases have emerged as an important contributor to adverse outcomes. For instance, cardiovascular diseases now causes up to 64% of ICU admissions and 46-66% of deaths among pilgrims during the Hajj (Al Shimemeri, 2012; Madani, 2007; Pane et al., 2013). Cardiovascular disease-related conditions (e.g., diabetes mellitus and hypertension) represent significant comorbidities among Hajj pilgrims, particularly in 65 to 75 year old, among whom, 31% are diabetic, 27.5% are hypertensive, and 11.4% have hypercholesterolemia (Gautret et al., 2009). This age group would, therefore, be expected to constitute the highest number of hospitalizations during the Hajj. However, despite these shifting in health priority, the health requirements to obtain entry for the Hajj remain unchanged and are focused only on communicable disease prevention with no measures to reduce the influx of individuals with noncommunicable comorbidities. This emphasis can be explained by the fact that public health professionals often consider the significant global impact of communicable diseases compared to noncommunicable diseases.

Lack of standard, formal guidelines has been one of the most significant problems for providers of mass gathering medical care (Milsten et al., 2002). Several groups have attempted to address this by publishing consensus recommendations, including the American College of Emergency Physicians and the National Association of Emergency Medical Services Physicians (Leonard, Petrilli, Noji, & Calabro, 1990; "Mass Gathering Medical Care", 2015). However, the complex interaction between the multitude of variables associated with mass-gathering events has made developing formal guidelines difficult.

Many reports recommended pre-Hajj health screening for individuals to only provide entry to those deemed fit to undertake Hajj based on medically informed, evidence-based, and well-formulated criteria (Afshin-Nia, Dehkordi, Fadel, & Ghanei, 1999; Al Shimemeri, 2012; Pane et al., 2013). For instance, Yezli, Alotaibi, & Saeed (2016) recommend a health assessment that would screen pilgrims for risk factors, determine how well their chronic diseases are managed, and identify and exclude those with severe health conditions from undertaking the pilgrimage. As a matter of fact, some countries have already implemented health screening for pilgrims exiting their home countries, which has substantially reduced the rate of both hospital admissions and mortality during the Hajj (Al Shimemeri, 2012; Pane et al., 2013). Such health screenings, though, would impose restriction on many of the Muslims seeking to complete the Hajj (Memish et al., 2016). Two-thirds of Hajj pilgrims originate from developing countries who must save money throughout their lives in order to achieve their spiritual objectives. Because the Hajj is only feasible for these individuals later in their lives when chronic conditions are more likely, such restrictions would likely deny as many as half of all pilgrims the opportunity to complete the Hajj (Ahmed et al., 2006; El Bcheraoui et al., 2014). Unfortunately, no rigorous study has yet been completed to clarify the implications of such recommendations. Much of the current work is anecdotal or descriptive, often limited to a single Hajj season or a specific condition. More robust studies are needed to enable evidence-based planning and healthcare management.

The Donabedian model, first described by Avedis Donabedian in 1966, provides a framework for conducting evidence-based service evaluation. This model separates structures, processes, and outcomes into their constituent parts, giving a more complete picture of a service by focusing not only on outcomes, but also on the elements of care that are responsible for producing such outcomes (Berwick & Fox, 2016; Donabedian, 1966, 2005). As such, this model has been widely used to assess the quality of healthcare services (McDonald et al., 2007; Rai & Wood, 2017). According to this model, improvements in the structure of care should lead to improvements in clinical processes that should, in turn, improve patient outcomes.

In this chapter, I aim to evaluate the impact of preexisting chronic diseases (structure) on inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj while considering the possible Effect Measure Modifications (EMMs) in cases with multiple chronic diseases. This study supports the Saudi MOH's effort to understand the underlying risk factors for mortality during the Hajj, which will help policymakers develop a consensus health screening program to decrease mortality and morbidity. Also, it assists in understanding the associated burden imposed by the unique populations present during the Hajj and how such populations can affect the quality of services provided in Makkah and sacred sites hospitals.

3.2 Methods

3.2.1 Study design and population

This retrospective, matched, case-control study audited medical records and discharge information obtained from the admission offices of each Hajj hospital for pilgrims who were admitted to Makkah and sacred sites hospitals during the 45-day period between 15th of Dhul-Qa'dah and 30th of Dhul-Hijja during the five included Hajj seasons (2012, 2013, 2014, 2016, and 2017). As discussed above, the 2015 Hajj was excluded because of two major events that significantly increased the number of deaths that year. Data collection was explained in section 2.2.1 pages 27. Briefly, four hospitals in Makkah and eight hospitals at the sacred sites were visited to collect administrative data from the admissions offices. Medical students were recruited and trained to review the patient medical records for inpatient all-cause mortality cases and selected control subjects. The administrative datasets were examined, and two lists of patients (males and females) who were discharged alive from the same hospitals during the same time period was created and sorted by age. For each mortality case, two discharged control subjects were randomly matched to the cases based on age and sex. All eligible controls met the same inclusion and exclusion criteria as the cases except that no death location was needed. Access to medical records and the data collected by the admission offices was approved by the Saudi MOH, and the study was approved by the Ethical Committee at King Fahad Medical City in Riyadh, Saudi Arabia.

3.2.2 Study variables

Case recruitment

Eligible cases included inpatient deaths occurring in one of the hospitals serving the Hajj during the study period. Administrative information collected by all twelve hospitals in Makkah and sacred sites were examined, and total in-hospital mortality file numbers were identified to confirm the date and location of death. Discharge status has three categories: died, improved, or transferred. Improved and transferred patients were combined to create a binary variable: died versus alive, with patients who died serving as the index cases. A total of inpatient 2,237 deaths were included.

Control group selection

Individual fixed-ratio variable caliper matching was utilized for control group selection. Gender was coded into two categories: male or female. Age was measured in years, and available comparison subjects whose age was closest to the index subjects were selected. This was done to get the best possible match while avoiding not obtaining a match for certain index subjects because some of the index cases were much older than the pool of control subjects (Rothman, Greenland, & Lash, 2008). Populations tended towards advanced age and male gender in the index cases relative to the control cases. Matching those two confounders increased the study efficiency by preventing an extreme departure from the optimal control distribution for estimating a common odds ratio (Rothman et al., 2008). One stage sampling was preferred over multistage sampling by year and hospital as it prevented an imposed selection bias on the study and permits the subsequent study of the effect of hospital characteristics on inpatient all-cause mortality.

Exposure variables

Preexisting chronic diseases were defined as conditions that were diagnosed previously and require ongoing medical attention and/or limit the activities of daily living (Warshaw, 2006). Preexisting chronic diseases were binary (yes or no) variables collected at the second stage of the data collection process. Keywords indicating the presence of the preexisting chronic diseases were searched for in the selected patient medical records. Both type 1 and type 2 diabetes were included in the diagnosis of diabetes. History of cardiovascular diseases variable included any patient with cardiovascular or cerebrovascular diseases. Patient medical records that do not indicate preexisting chronic diseases were classified as absent.

Other variables.

The dataset included several variables that were used to describe the population. These included age, gender, nationality, patient status, and location of discharge. Age was used in two forms. It was used as a continuous variable to control for confounding factors and as a categorical variable stratified into six categories to describe the population. Gender was coded into two categories: male or female. Nationality was an individually assigned categorical variable. If nationality was not specified, the subject was classified as unknown. However, this applied to only thirty subjects (0.4%) who were included under the nationality category of others. Patient type was categorized into three categories: Saudi citizen, a resident of Saudi Arabia, and pilgrims from outside Saudi Arabia. Because only few patients were Saudi citizens or residents, the variable was dichotomized to domestic patients versus international patients. Location of discharge was a binary variable: Makkah versus sacred sites.

3.2.3 Statistical analysis

Appropriate descriptive statistics were conducted to summarize the demographic characteristics of the study population for which raw number and percentage are presented. For each preexisting chronic disease, the prevalence by age group for cases and controls was calculated.

To examine the association between inpatient all-cause mortality with preexisting chronic diseases, multivariate logistic regression analysis was conducted using inpatient all-cause mortality as the dependent variable and preexisting chronic diseases as the independent variables. All preexisting chronic diseases variables were included in one model along with nationality, age, and gender, which were controlled for because of their possible confounding effect.

As matching in the design does not control for confounding by the matching factors, yet it can introduce confounding even when it did not exist in the source population, age and gender were included in the analysis as potential confounding factors (Rothman et al., 2008). Selection of potential confounders for adjustment was based on previous literature as well as exploring the associations present in my data revealed by the directed acyclic graphs (Greenland, Pearl, & Robins, 1999; Pearl, 1995 Appendix B, Figure B8). The use of graphical tools to illustrate the association between variables allows researchers to show theoretical relationships among variables of interest, summarize their qualitative knowledge, and state assumptions about the associations that will be analyzed (Hernán, Robins, 2018; Rothman et al., 2008). The magnitudes of association between inpatient all-cause mortality and each of the preexisting chronic diseases were estimated using odds ratios (ORs) with 95% confidence intervals (CIs).

Because previous research suggests an EMM relationship between diabetes, hypertension, and cardiovascular diseases, the EMM of each of the preexisting chronic diseases on the association with inpatient all-cause mortality during the Hajj and each of the other preexisting chronic diseases was examined (Adler et al., 2000; Adlerberth, Rosengren & Wilhelmsen, 1998; Almdal, Scharling, Jensen & Vestergaard, 2004; Barrett-Connor & Khaw, 1988; Gress et al., 2000; Hu, Jousilahti & Tuomilehto, 2007; Kannel & McGee, 1979; Meng, Zhou, Zhang & Tang, 2015). The stratified regression approach was used by conducting stratum-specific logistic regression analyses for each binary, preexisting chronic disease variable while controlling for measured potential confounders (Van Ness & Allore, 2006). For example, hypertension stratum-specific ORs of the association of inpatient all-cause mortality, and diabetes was examined while controlling for age, gender, and nationality. The differences between the stratum-specific ORs would suggest EMM by hypertension.

To better present the EMM results, the separate effects of the two risk factors and their joint effect using one reference category were reported. ORs with CIs and p-values for the joint and separated effect of both exposures under investigation were estimated using the subgroup with the lowest risk for mortality as a reference. Using the same subgroup as the reference permitted the assessment of the overall interaction measures (Knol & VanderWeele, 2012; VanderWeele, 2015; Von Elm et al., 2008). Also, the EMM on both additive (the relative excess risk due to interaction [RERI]) and multiplicative scales with CIs and p-values were reported (Hosmer & Lemeshow, 1992; Lundberg, Fredlund, Hallqvist & Diderichsen, 1996; Rothman, 2002). Given that inpatient all-cause mortality is a rare outcome among inpatient pilgrims, ORs would approximate risk ratios. Hence, the additive interaction can be performed by directly substituting ORs for risk ratios (Kalilani & Atashili, 2006).

Sensitivity analyses to assess how substantial residual, unmeasured confounding would need to be to explain away the observed associations were conducted (Arah, Chiba, & Greenland, 2008; VanderWeele, & Arah, 2011). Also, to identify either consistency of or large differences in the magnitude of effect estimates among different categories of patients, subgroup analysis was performed among international pilgrims, domestic pilgrims, pilgrims who were admitted to the ICU, and those who came from certain well represented countries (including Indonesia, India, Pakistan, Egypt, Bangladesh, and Saudi Arabia). Finally, nondifferential misclassification of preexisting chronic diseases was assessed (Greenland, 1996). All analyses were performed using SAS 9.4 (Statistical Analysis Systems, Inc, Cary, NC), with an α cutoff of 0.05.

3.2.4 Power calculation

SAS PROC POWER statement was used to estimate the power of the logistic regression models. A logistic regression of a binary response variable Y (inpatient all-cause mortality) on a binary independent variable X (e.g., history of diabetes mellitus) with a sample size of 6,711 observations (2,237 cases and 4,474 controls) achieves 99% power at a 0.05 significance level to detect a change in Pr(Y=1) corresponding to an OR of 1.5. (Appendix D, Table D1)

3.3 Results

Selected demographic and risk factors were compared between cases and controls as shown in Table 3.1. Due to the matched design, cases and controls shared similar demographic characteristics with regards to age, and gender. Deaths occurred more in Makkah and among international pilgrims compared to sacred sites and among domestic pilgrims. Overall, 1,715 patients were diabetic (25.6%), 1,344 had hypertension (20.0%), and 1,049 had cardiovascular diseases (15.6%). Also, the distribution of the preexisting chronic diseases by age was similar for cases and controls with the greatest number detected between 60 and 70 years of age (Table 3.2).

Table 3.3 shows the distribution of preexisting chronic diseases among the study population as well as the risk of inpatient all-cause mortality associated with the conditions under study. Among mortality cases, 710 were diabetic (31.7%), 554 had hypertension (24.8%), and 439 had cardiovascular diseases (19.6%). In Hajj hospitals, diabetic patients had a 44% increased risk of mortality during their hospitalization compared to non-diabetic patients (OR: 1.44, 95% CI: 1.27-1.63). Also, hypertension was associated with an increased risk of inpatient all-cause mortality with an OR of 1.34 (95% CI: 1.17-1.53). As with hypertension, cardiovascular diseases were associated with an increased risk of inpatient all-cause mortality (OR: 1.32, 95% CI: 1.14-1.53).

For EMM, the separate and joint effects of the coexistence of two preexisting chronic diseases on inpatient all-cause mortality are reported in Tables 3.4, 3.5, and 3.6. The inpatient all-cause mortality risk for pilgrims with diabetes and hypertension was equivalent to the expectation based on the absence of interaction on a multiplicative scale (observed OR: 1.86, 95% CI: 1.53-2.25; expected OR: 1.79 [1.30 x 1.38]). Diabetes mellitus in combination with cardiovascular diseases gave a lower inpatient all-cause mortality risk than expected on the basis of independent effects (observed OR: 1.64, 95% CI: 1.34-2.00; expected OR: 2.27 [1.51 x 1.50]). Similarly, the joint effect of hypertension and cardiovascular diseases was lower than expected on the basis of independent effects (observed OR: 1.40, 95% CI: 1.12-1.75; expected OR: 2.35 [1.56 x 1.49]).

In addition, stratifying logistic regression analysis provided different conclusions about the association between each of the preexisting chronic diseases and inpatient all-cause mortality. Results pertaining to diabetes and hypertension suggested a positive association between the existence of each chronic disease and inpatient all-cause mortality in each stratum (Table 3.4). The similarity in diabetes-specific and hypertension-specific odds ratio estimates suggested that an EMM for the association of each condition with the outcome by the other condition was not detected. The test for interaction on the multiplicative scale was not statistically significant (ratio of OR: 1.03, 95% CI: 0.77-1.29, $p = 0.84$). However, diabetes mellitus significantly interacted with hypertension on the additive scale (RERI: 0.25, 95% CI: -0.19-0.69).

There was no evidence of EMM in the relationship between diabetes and cardiovascular diseases as the stratum-specific estimates differ from one another, and the Mantel-Haenszel OR was similar to the crude estimates (Table 3.5). However, the test for multiplicative interaction was statistically significant (ratio of OR: 0.73, 95% CI: 0.45-1.01; $p = 0.03$) as was the test for additive interaction (RERI= -0.32, 95% CI: -0.80-0.15). These results indicated a negative EMM on both the additive and multiplicative scales.

The same association between diabetes and cardiovascular diseases was observed in testing the EMM of the association between hypertension and cardiovascular diseases (Table 3.6). Again, the test of interaction was statistically and negatively significant on the additive and multiplicative scales (RERI: -0.61, 95% CI: -1.09 to -0.12, ratio of OR: 0.62, 95% CI: 0.33-0.91, $p = 0.001$). The difference in cardiovascular-diseases-specific and hypertension-specific OR estimates suggested that an EMM for the association of each condition with the outcome by the other condition was detected.

Subgroups analyses indicated different results. While the magnitude of associations among international pilgrims were similar to the magnitude of associations among the total population for all preexisting chronic diseases, domestic diabetic and hypertensive patients had a lower risk of inpatient all-cause mortality and a protective effect for patients who had cardiovascular diseases (Table 3.7). Also, the risk of inpatient all-cause mortality due to preexisting chronic diseases among ICU patients was lower than the risk for the total population (Table 3.8). Hypertension and cardiovascular diseases were inversely associated with inpatient all-cause mortality (hypertension OR: 0.98, 95% CI: 0.71-1.37; cardiovascular diseases OR: 0.73, 95% CI: 0.51-1.04) and diabetic patients had a lower risk (OR: 1.24, 95% CI: 0.89-1.69). Moreover, pilgrims who came from Indonesia, India, Pakistan, and Egypt had a similar effect sizes as the total population (Table 3.9). However, patients who came from Bangladesh and Saudi Arabia had a different effect size of diabetes and hypertension on inpatient all-cause mortality and an inverse association between cardiovascular diseases and inpatient all-cause mortality (Table 3.9).

3.4 Discussion

The prevalence of preexisting chronic diseases among pilgrims has been well established in the literature (Afshin-Nia et al, 1999; Al Ghamdi et al, 2003; Al Shimemeri, 2012; Alomi & Zahran, 2016; Bakhsh et al, 2015; Gautret et al, 2009; Khan et al; 2006; Madani et al, 2006; Meysamie et al, 2006; Pane et al, 2013). However, the relationship between preexisting chronic diseases and inpatient all-cause mortality during the Hajj and the interactions between multiple preexisting chronic diseases has not been established. This current study provides significant insight into the effects of selected preexisting chronic diseases on inpatient all-cause mortality. The separate and joint effects of different combinations of the preexisting chronic diseases on inpatient all-cause mortality during the Hajj were examined using the same reference groups for each analysis to assess the overall interaction measures.

In the studied population, history of diabetes mellitus was present in 1,715 cases (25.5%), hypertension in 1,334 cases (19.9%), and cardiovascular diseases in 1,049 cases (15.6%). Those numbers are consistent with a previous study within a similar Hajj setting (Khan et al., 2006). Results from the logistic regression analysis of preexisting chronic diseases in the current study showed a strong association between each of the conditions under study with inpatient all-cause mortality in Hajj hospitals. Diabetes, hypertension, and cardiovascular diseases risk was in line with previous reports examining the same association in a hospital setting or similar population that shared the same baseline characteristics as the Hajj population, such as advanced age and high male-to-female ratio (Barnett, McMurdo, Ogston, Morris, & Evans, 2006; Bethel, Sloan, Belsky, & Feinglos, 2007; Emerging Risk Factors Collaboration, 2011; Gordon-Dseagu, Shelton

& Mindell, 2011; Granger et al, 2003; Hirakawa et al, 2017; Huang et al, 2011; Huang et al, 2014; Isomma et al, 2001; Knaus et al., 1991; Targher et al., 2017; Win, Hussain, Hebl, Dunlay, & Redfield, 2017).

The current study did not observe the expected trend of having higher odds for inpatient all-cause mortality compared to the normal setting. It was expected that the odds of inpatient all-cause mortality would be increased given the hardship that pilgrims undergo while performing the rituals of the Hajj. Pilgrims exposed to many factors, which could be unique to the Hajj duty. These factors include, but are not limited to, infections originating from their home countries, overcrowding, inadequate nutrition, hot weather, and physical exertion. People with preexisting chronic diseases are at a greater risk of illness due to the nature of the disease and also the altered daily routine.

Another important finding is the possible EMM by one of the preexisting chronic diseases on the association with inpatient all-cause mortality when multiple chronic diseases coexist. Consistent with many reports in other countries, findings from the current study suggest that coexistence of diabetes and hypertension was associated with increased odds of inpatient all-cause mortality (Kolawole, & Ajayi, 2000; Manson et al., 1991; Oyewo, Ajayi, & Ladipo, 1989; Redelings, Sorvillo, & Simon, 2006). In contrast to the majority of previous studies examining the EMM of cardiovascular diseases on the association between diabetes and inpatient all-cause mortality, the current study found that the risk of inpatient all-cause mortality associated with diabetes among patients with cardiovascular diseases was less than that of patients without cardiovascular disease (Table 3.5). Also, there was no evidence of an association between hypertension with inpatient all-cause mortality among patients with cardiovascular diseases (Table 3.6; Gheorghiade et al, 2006; Gustafsson et al, 2004; Lee et al, 2003; Mebazaa et al, 2013;

Parissis et al, 2011; Sarma et al, 2013; Targher et al, 2016, 2017; Yancy et al, 2006). However, a limited number of previous studies found a similar conclusion as the current study (Cleland et al., 2014; Greenberg et al., 2007; Kosiborod et al., 2009).

Surprisingly, the current study showed no association between cardiovascular disease and inpatient all-cause mortality among diabetic or hypertensive patients (Table 3.5 and Table 3.6). One explanation could be that the presence of diabetes and hypertension explained the risk of inpatient all-cause mortality among these subgroups. Another explanation is that some of the critical conditions, such as renal failure, are highly associated with the preexisting chronic diseases under the study and are, indeed, important predictors of mortality. However, there was evidence of an EMM of diabetes and hypertension on the association between cardiovascular diseases and inpatient all-cause mortality on both the multiplicative and the additive scale (Table 3.5 and Table 3.6).

This work relied on administrative data and brief patient medical records, which are never complete or detailed enough to provide a clinically precise method for identifying preexisting chronic diseases. The most important shortcoming of using administrative data for this study is the lack of the data regarding the severity of the illness as well as data regarding different treatment regimens both at admission and during the hospital stay. Another limitation of the data used in this study is the ability to distinguish between primary and secondary diagnoses. It is possible that my estimates overestimated the contribution of preexisting chronic diseases because of the difficulty in distinguishing between these two diagnoses. Moreover, the data excluded primary healthcare centers, other hospitals operated by sectors apart from the MOH and visiting medical missions. Therefore, generalizing these results to the entire Hajj population should only be done with great caution. However, the majority of death occurring during the Hajj can be captured by the data retrieved from Hajj hospitals.

A complete database that includes detailed information regarding the severity of the illness, such as fasting glucose test, hemoglobin A1C, systolic and diastolic blood pressure, specific cardiac disease, time of diagnosis, and treatment regimens, could distinguish between complicated and controlled cases (Huang et al., 2011). Despite these limitations, the use of administrative data and patient medical records is supported by many types of studies and has been validated for estimating the prevalence of chronic diseases, especially diabetes and hypertension (Robinson, Young, Roos, & Gelskey, 1997). Extracting clinical details for more precise measurement is not only prohibitively expensive on the scale needed to develop a pre-Hajj health screening tool, but also would not be broadly applicable to the type of data that are common for mass-gathering events. The nature of the Hajj and the travel patterns allowed for only minimal interaction with the patients. While effective in treating their immediate problem, this is not an appropriate setting for continuous follow up. This precluded comprehensive treatment but allowed for referral.

In addition, as stated in the previous chapter, nondifferential, independent misclassification is another threat to the study. Misclassification of the exposure could introduce bias to the study during data insertion into the patient medical records by the healthcare providers or during data extraction by the field data collectors. However, independent, nondifferential misclassification of a binary variables can be predicted. According to Rothman et al. (2008), independent, nondifferential misclassification of a binary variable always biases the measure of the effect towards the null value.

Although all measured confounders for the association between preexisting chronic diseases and all-cause mortality were adjusted for, the results may still be subject to unmeasured confounders and residual confounding. Pilgrims' social, psychological, socioeconomic status, tobacco use, lifestyle, body mass index and diet may confound the association. In addition, over-adjustment due to chronic diseases is possible given that diabetes and hypertension variables may be mediators on the pathway whenever one of them modeled. It has also been argued that adjusting for socioeconomic status may underestimate true effect estimates (Schisterman, Cole & Platt, 2009). To account for these concerns, sensitivity analysis to assess how strong unmeasured confounding by socioeconomic status would need to be to explain the observed association was performed and resulted in a less than 10% difference in point estimates (Appendix C, Table C1). Such substantial confounding by unmeasured factors seems unlikely, given adjustment for the set of covariates.

Moreover, nondifferential misclassification of preexisting chronic diseases was evaluated with multiple scenarios for sensitivity and specificity (Greenland, 1996). ORs were significantly altered when specificity was reduced by 20% (Appendix C, Tables C.2, C3, and C4). However, it is unlikely that the study would have such a low specificity. Also, a minimally adjusted model that included age and gender, as well as subgroup analyses among international pilgrims, domestic pilgrims, pilgrims who were admitted to ICU, and those who came from certain nationalities, were performed, and the point estimates were similar to or only slightly different from the point estimates reported in the main analysis.

Strengths of the study include a large sample size that reflected many of the pilgrims' characteristics as well as the comprehensive study approach that addressed the effect of preexisting chronic diseases on inpatient all-cause mortality separately and in combination. The results were robust across the statistical method of analysis, subgroup analysis, and sensitivity analysis for unmeasured confounding factors, and nondifferential misclassification. This study provides much needed information about preexisting chronic diseases among the Hajj population and their relationship to inpatient all-cause mortality to some extent, which can help direct future policymaking.

My findings are preliminary but raise a hypothesis worth testing in a larger, population-based, retrospective study in order to generalize these results. In the future, a study based on comprehensive data collection from the Hajj population that includes, at least, the most important potential confounders as well as different outcomes, such as hospital admission, length of hospital stay, and ICU admission, could strengthen the conclusions regarding the current hypothesis. Also, a pilot, prospective, cohort study to examine the effect of a prescreening health test among high-risk pilgrims would support the effort to understand the health risks and strengthen the evidence base upon which policy can be developed. However, the high risk of mortality, especially in older pilgrims with preexisting chronic diseases has been highlighted by this study.

The study results support the previous calls for pre-Hajj health screening for individuals who would like to come to Makkah (Afshin-Nia et al., 1999; Al Shimemeri, 2012; Pane et al., 2013; Yezli et al., 2016). Yet, as Memish et al. (2016) stated, restricting pilgrims due to their medical condition is not an option for many reasons. Rather than restrictions, a serious discussion among all national and international stakeholders should take place to develop risk mitigation strategies to minimize the adverse effects caused by preexisting chronic diseases and improve the quality of the healthcare services provided during the Hajj. To support such planning, epidemiological data concerning noncommunicable diseases should be gathered at the

Hajj. Ongoing disease surveillance and data analysis will provide the necessary data to understand these health risks and, therefore, formulate effective policies regarding these risks.

Table 3.1
Demographic characteristics of inpatient cases and controls in Makkah and sacred sites hospitals during the Hajj (2012 - 2017).*

Demographic data	**Mortality cases**	**Controls**
	N = 2,237 (%)	N = 4,474 (%)
Sex		
Male	1,398 (62.5)	2,796 (62.5)
Female	839 (37.5)	1,678 (37.5)
Age Group		
≤ 40	129 (5.8)	265 (5.9)
41 - 50	205 (9.2)	400 (9.0)
51 - 60	486 (21.7)	979 (21.9)
61 - 70	779 (34.8)	1,581 (35.3)
71 - 80	470 (21.0)	912 (20.4)
> 80	168 (7.5)	337 (7.5)
Hajj (Pilgrimage) Status		
Domestic	290 (13.0)	399 (8.9)
International	1,947 (87.0)	4,075 (91.1)
Location of discharge		
Sacred sites	619 (27.7)	1,191 (26.6)
Makkah	1,618 (72.3)	3,282 (73.4)
Nationality		
Indonesia	488 (21.8)	473 (10.6)
India	283 (12.7)	516 (11.5)
Pakistan	214 (9.6)	457 (10.2)
Egypt	193 (8.6)	351 (7.9)
Bangladesh	137 (6.1)	341 (7.6)
Turkey	67 (3.0)	212 (4.7)
Nigeria	58 (2.3)	172 (3.8)
Morocco	56 (2.5)	154 (3.4)
Saudi Arabia	67 (3.0)	142 (3.2)
Yemen	51 (2.3)	118 (2.6)
Algeria	47 (2.1)	108 (2.4)
Malaysia	55 (2.5)	88 (2.0)
Sudan	30 (1.3)	108 (2.4)
Afghanistan	36 (1.6)	100 (2.2)
Myanmar (Burma)	69 (3.1)	44 (1.0)
Iraq	29 (1.3)	84 (1.9)
Other**	342 (15.3)	991 (22.2)

*Hajj 2015 was excluded.
**30 patients were of unknown origin.

Table 3.2
Distribution of preexisting chronic diseases by age for inpatient cases and controls in Makkah and sacred sites hospitals during the Hajj (2012 – 2017). *

Preexisting chronic disease	Mortality cases	Control	Total
	n (%)	n (%)	N (%)
Diabetes Mellitus			1,715 (25.6)**
$\leq$ 40	28 (3.9)	22 (2.2)	50 (2.9)
41 - 50	54 (7.6)	83 (8.3)	137 (8.0)
51 - 60	152 (21.4)	245 (24.4)	397 (23.1)
61 - 70	256 (36.1)	355 (35.3)	611 (35.6)
71 - 80	159 (22.4)	216 (21.5)	375 (21.9)
> 80	61 (8.6)	84 (8.36)	145 (8.4)
Hypertension			1,344 (20.0)**
$\leq$ 40	20 (3.6)	17 (2.1)	37 (2.7)
41 - 50	53 (9.6)	63 (8.0)	116 (8.6)
51 - 60	104 (18.8)	165 (20.9)	269 (20.0)
61 - 70	200 (36.1)	308 (39.0)	508 (37.8)
71 - 80	129 (23.3)	171 (21.6)	300 (22.3)
> 80	48 (8.7)	66 (8.3)	114 (8.5)
Cardiovascular diseases			1,049 (15.6)**
$\leq$ 40	19 (4.3)	12 (2.0)	31 (3.0)
41 - 50	42 (9.6)	46 (7.5)	88 (8.4)
51 - 60	94 (21.4)	126 (20.7)	220 (21.0)
61 - 70	155 (35.3)	229 (37.5)	384 (36.6)
71 - 80	97 (22.1)	137 (22.5)	234 (22.3)
> 80	32 (7.3)	60 (9.8)	92 (8.8)

*Hajj 2015 was excluded.
** Percentage of pilgrims with preexisting chronic diseases of total study population.

Table 3.3
Prevalence, crude and adjusted odds ratios for inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj by preexisting chronic diseases (2012-2017).*

Preexisting chronic diseases	**Mortality cases**	**Controls**	**Crude OR**	**(95% CI)**	**Adjusted OR*** **	**(95% CI)**
	n (%)	n (%)				
Diabetes mellitus						
Yes	710 (31.7)	1,005 (22.5)	1.60**	(1.43 – 1.80)	1.44**	(1.27 - 1.63)
No	1,527 (68.3)	3,469 (77.5)	1.00		1.00	
Hypertension						
Yes	554 (24.8)	790 (17.7)	1.54**	(1.35 – 1.74)	1.34**	(1.17 - 1.53)
No	1,683 (75.2)	3,684 (82.3)	1.00		1.00	
Cardiovascular disease						
Yes	439 (19.6)	610 (13.6)	1.56**	(1.35 – 1.77)	1.32**	(1.14 - 1.53)
No	1,798 (80.4)	3,864 (86.4)	1.00		1.00	

*Hajj 2015 was excluded
** p-value < 0.05
Note AOR=adjusted odds ratio. CI=confidence interval.
***ORs are adjusted for preexisting chronic diseases, nationality, age, and gender.

Table 3.4
Effect measure modification in the association between diabetes mellitus and hypertension on the risk of inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj (2012 – 2017).*

	Hypertension				OR (95%CI) for Hypertension within strata of DM
	Yes		No		
	N Cases/Controls	AOR*** (95% CI)	N Cases/Controls	AOR*** (95% CI)	
Diabetes mellitus					
Yes	277/312	1.86** (1.53 - 2.25)	433/693	1.38** (1.19 - 1.59)	1.40** (1.12 - 1.74)
No	277/478	1.30** (1.10 - 1.54)	1250/2991	1	1.30** (1.10 - 1.54)
OR (95% CI) for DM within strata of Hypertension		1.61** (1.27 – 2.05)		1.38** (1.19 - 1.60)	

*Hajj 2015 was excluded.
** p-value < 0.05
Measure of interaction on additive scale: RERI (95% CI) = 0.25 (— 0.19, 0.69).
Measure of interaction on multiplicative scale: ratio of ORs (95% CI) = 1.03 (0.77, 1.29); P= 0.84.
Note AOR=adjusted odds ratio. CI=confidence interval. DM= Diabetes mellitus.
***ORs are adjusted for age, gender, cardiovascular diseases, and nationality.

Table 3.5
Effect measure modification in the association between diabetes mellitus and cardiovascular diseases on the risk of inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj (2012 – 2017).*

	Cardiovascular disease				**OR (95%CI) for Cardiovascular disease within strata of DM**
	Yes		**No**		
	N Cases/Controls	**AOR*** (95% CI)**	**N Cases/Controls**	**AOR*** (95% CI)**	
Diabetes mellitus					
Yes	221/282	1.64** (1.34 - 2.00)	489/723	1.50** (1.30 - 1.72)	1.10 (0.87 - 1.38)
No	218/328	1.51** (1.25 - 1.84)	1309/3141	1	1.51** (1.25 - 1.83)
OR (95% CI) for DM within strata of Cardiovascular disease		1.20 (0.92 - 1.57)		1.50** (1.30 - 1.72)	

*Hajj 2015 was excluded.
** p-value < 0.05
Measure of interaction on additive scale: RERI (95% CI) = —0.32 (—0.80, 0.15).
Measure of interaction on multiplicative scale: ratio of ORs (95% CI) = 0.73 (0.45, 1.01); P= 0.03.
Note AOR=adjusted odds ratio. CI=confidence interval. DM= Diabetes mellitus. CVD= Cardiovascular diseases.
***ORs are adjusted for age, gender, nationality, and hypertension.

Table 3.6
Effect measure modification in the association between cardiovascular diseases and hypertension on the risk of inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj (2012 – 2017).*

	Cardiovascular disease				OR (95% CI) for Cardiovascular disease within strata of Hypertension
	Yes		No		
	N Cases/Controls	AOR*** (95% CI)	N Cases/Controls	AOR*** (95% CI)	
Hypertension					
Yes	177/245	1.40** (1.12 - 1.75)	377/545	1.49** (1.29 - 1.73)	0.97 (0.75 - 1.25)
No	262/365	1.58** (1.32 - 1.89)	1421/3319	1	1.56** (1.31 - 1.85)
OR (95%CI) for Hypertension within strata of Cardiovascular disease		1.03 (0.78 - 1.35)		1.49** (1.29 - 1.73)	

*Hajj 2015 was excluded.
** p-value < 0.05
Measure of interaction on additive scale: RERI (95% CI) = — 0.61 (—1.09, —0.12).
Measure of interaction on multiplicative scale: ratio of ORs (95% CI) = 0.62 (0.33, 0.91); P= 0.001.
Note AOR=adjusted odds ratio. CI=confidence interval. CVD= Cardiovascular diseases.
***ORs are adjusted for age, gender, nationality and diabetes mellitus

Table 3.7
Prevalence, crude and adjusted odds ratios for inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj by preexisting chronic diseases for domestic and international pilgrims (2012-2017).*

Preexisting chronic diseases	Mortality cases	Controls	Crude OR	(95% CI)	Adjusted OR***	(95% CI)
	n (%)	n (%)				
International pilgrims						
Diabetes mellitus						
Yes	634 (32.6)	919 (22.6)	1.65**	(1.47 – 1.87)	1.47**	(1.30 – 1.67)
No	1313 (67.4)	3156 (77.4)	1.00		1.00	
Hypertension						
Yes	494 (25.4)	730 (17.9)	1.55**	(1.36 – 1.77)	1.34**	(1.17 – 1.53)
No	1453 (74.6)	3345 (82.1)	1.00		1.00	
Cardiovascular disease						
Yes	403 (20.7)	554 (13.6)	1.65**	(1.43 – 1.90)	1.40**	(1.21 – 1.62)
No	1544 (79.3)	3521 (86.4)	1.00		1.00	
Domestic pilgrims						
Diabetes mellitus						
Yes	76 (26.2)	86 (21.6)	1.29	(0.90 – 1.87)	1.26	(0.86 – 1.85)
No	214 (73.8)	313 (78.5)	1.00		1.00	
Hypertension						
Yes	60 (20.7)	60 (15.0)	1.47**	(0.98 – 2.19)	1.49	(0.97 – 2.29)
No	230 (79.3)	339 (85.0)	1.00		1.00	
Cardiovascular disease						
Yes	36 (12.4)	56 (14.0)	0.87	(0.55 – 1.37)	0.72	(0.44 – 1.17)
No	254 (87.6)	343 (86.0)	1.00		1.00	

*Hajj 2015 was excluded
** p-value < 0.05
Note AOR=adjusted odds ratio. CI=confidence interval.
***ORs are adjusted for preexisting chronic diseases, nationality, age, and gender.

Table 3.8
Prevalence, crude and adjusted odds ratios for inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj by preexisting chronic diseases for ICU patients (2012-2017).*

Preexisting chronic diseases	**Mortality cases**	**Controls**	**Crude OR**	**(95% CI)**	**Adjusted OR*** **	**(95% CI)**
	n (%)	n (%)				
ICU Patients						
Diabetes mellitus						
Yes	303 (32.9)	77 (30.4)	1.14	(0.84 – 1.54)	1.23	(0.89 – 1.69)
No	619 (67.1)	176 (69.6)	1.00		1.00	
Hypertension						
Yes	259 (28.1)	73 (28.8)	0.97	(0.71 – 1.32)	0.98	(0.71 – 1.37)
No	663 (71.9)	180 (71.2)	1.00		1.00	
Cardiovascular disease						
Yes	179 (19.4)	61 (24.1)	0.77	(0.55 – 1.07)	0.73	(0.51 – 1.04)
No	743 (80.6)	192 (75.9)	1.00		1.00	

*Hajj 2015 was excluded
** p-value < 0.05
Note AOR=adjusted odds ratio. CI=confidence interval.
***ORs are adjusted for preexisting chronic diseases, nationality, age, and gender.

Table 3.9
Prevalence, crude and adjusted odds ratios for inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj by preexisting chronic diseases for selected nationalities (2012-2017).*

Preexisting chronic diseases	Mortality cases n (%)	Controls n (%)	Crude OR	(95% CI)	AOR ***	(95% CI)
Indonesia						
Diabetes mellitus						
Yes	159 (32.6)	107 (22.6)	1.65**	(1.24 – 2.19)	1.53**	(1.13 – 2.10)
No	329 (67.4)	366 (77.4)	1		1	
Hypertension						
Yes	131 (27.0)	95 (20.1)	1.46**	(1.08 – 1.97)	1.30	(0.81 – 1.58)
No	357 (73.0)	378 (79.9)	1		1	
Cardiovascular disease						
Yes	103 (21.1)	81 (17.1)	1.29	(0.94 – 1.79)	1.13	(0.81 – 1.58)
No	385 (78.9)	392 (82.9)	1		1	
India						
Diabetes mellitus						
Yes	84 (29.7)	124 (24.0)	1.31	(0.97 – 1.82)	1.20	(0.85 – 1.68)
No	199 (70.3)	392 (76.0)	1		1	
Hypertension						
Yes	61 (21.5)	84 (16.3)	1.42	(0.98 – 2.05)	1.30	(0.88 – 1.97)
No	222 (78.5)	432 (83.7)	1		1	
Cardiovascular disease						
Yes	56 (19.8)	73 (14.1)	1.46	(0.99 – 2.15)	1.32	(0.88 – 1.97)
No	227 (80.2)	443 (85.9)	1		1	
Pakistan						
Diabetes mellitus						
Yes	67 (31.3)	112 (24.5)	1.43	(0.99 – 2.04)	1.43	(0.91 – 1.95)
No	147 (68.7)	345 (75.5)	1		1	
Hypertension						
Yes	45 (21.0)	80 (17.5)	1.28	(0.85 – 1.92)	1.11	(0.72 – 1.73)
No	169 (79.0)	377 (82.5)	1		1	

Cardiovascular disease						
Yes	37 (17.3)	60 (13.1)	1.38	(0.88 – 2.16)	1.22	(0.76 – 1.96)
No	177 (82.7)	397 (86.9)	1		1	
Egypt						
Diabetes mellitus						
Yes	59 (30.6)	78 (22.2)	1.50**	(1.01 – 2.25)	1.44	(0.95 – 2.17)
No	134 (69.4)	273 (77.8)	1		1	
Hypertension						
Yes	52 (27.0)	71 (20.2)	1.41	(0.93 – 2.14)	1.32	(0.85 – 2.05)
No	141 (73.0)	280 (79.8)	1		1	
Cardiovascular disease						
Yes	31 (16.1)	42 (12.0)	1.38	(0.83 – 2.29)	1.14	(0.67 – 1.96)
No	162 (83.9)	309 (88.0)	1		1	
Bangladesh						
Diabetes mellitus						
Yes	48 (35.0)	95 (27.9)	1.37	(0.89 – 2.10)	1.26	(0.81 – 1.98)
No	89 (65.0)	246 (72.1)	1		1	
Hypertension						
Yes	36 (26.3)	67 (19.7)	1.45	(0.91 – 2.32)	1.34	(0.82 – 2.18)
No	101 (73.7)	274 (80.3)	1		1	
Cardiovascular disease						
Yes	31 (22.6)	66 (19.3)	1.21	(0.74 – 1.96)	1.08	(0.66 – 1.79)
No	106 (77.4)	275 (80.7)	1		1	
Saudi Arabia						
Diabetes mellitus						
Yes	22 (32.8)	37 (26.0)	1.40	(0.74 – 2.65)	1.56	(0.79 – 3.08)
No	45 (67.2)	105 (74.0)	1		1	
Hypertension						
Yes	12 (17.9)	33 (23.2)	0.76	(0.36 – 1.60)	0.68	(0.30 – 1.52)
No	55 (82.1)	109 (76.8)	1		1	
Cardiovascular disease						
Yes	13 (19.4)	30 (21.1)	0.92	(0.44 – 1.92)	0.93	(0.42 – 2.05)
No	54 (80.6)	112 (78.9)	1		1	

*Hajj 2015 was excluded.
** p-value < 0.05
***ORs are adjusted for preexisting chronic diseases, nationality, age, and gender.

4 Inpatient All-Cause Mortality and Selected Medical Services as a Proxy for the Quality of the Services in Hajj Hospitals

4.1 Introduction

"The quality of medical care is a highly contextual and a difficult concept to define. Although it reflects values and goals in the medical care system and in the broader society of which it is a part, quality can be defined nearly any way one wishes" (Idvall, 2001). The quality of healthcare remains a significant problem in many settings, including mass-gathering events. However, determining a consensus definition of quality and methods for its evaluation, monitoring, and improvement persist as elusive challenges for research (Donabedian, 1966).

Despite the caveats associated with its use, administrative data can serve as a useful screening tool (Duclos & Lifante, 2018; Groene et al., 2014; Iezzoni, 1997; Zhan, 2016). It provides detailed clinical information and can, therefore, be used to evaluate quality in greater depth. It is able to be accessed and analyzed using computers, inexpensive to analyze, longitudinal, and covers large populations (Zhan, 2016; Zhan & Miller, 2003). Beginning in the 1970s, administrative data has been used to reveal startling variations in healthcare and clinical practice patterns and assess clinical outcomes (Mitchell et al., 1994; Wennberg & Gittelsohn, 1973). Similarly, administrative data has served as a useful tool for quality assessment research, including complication screening and screening for incidences relevant for patient safety (AHRQ, 2003; Iezzoni et al., 1992; Johantgen, Elixhauser, Ball, Goldfarb, & Harris, 1998).

Hospital discharge data, which is a form of administrative data, has been widely used in basic research seeking to improve understanding of health services and improve health policy. Discharge data can reveal how systems for organizing, financing, and delivering health services affect hospital utilization, costs, and outcomes. Such data has been used to study the effect of market competition on hospital cost growth, the impact of enrollment in a managed care plan on resource consumption in ICUs, the effect of provider volume on outcomes after intracranial tumor resection, and the relationship between nurses' educational level and surgical outcomes (Aiken et al., 2003; Angus et al., 1996; Cowan et al. 2003; Zwanziger, Melnick, & Bamezai, 2000).

However, mass-gathering events create a more complicated situation, the understanding of which is vital to appropriately prepare the required health resources. In the absence of other sources of information, hospital discharge data provides valuable insight into health status, use of healthcare resources, and outcomes of care. The continued availability of this information is necessary to ensure continued improvements in our understanding of how healthcare is delivered during these events in order to ensure quality and efficient care for gathering participants.

Long before the advent of electronic health records or computerized healthcare data, Donabedian presaged many of the challenges that persist in current efforts to assess the quality of care (Donabedian, 1966). He underscored the difficulties of assessing quality on the basis of medical records or direct observation of clinical encounters and highlighted the importance of representative samples; clear measurement standards; reliable, reproducible measures of quality; and valid measures of structure and process that could be linked to outcomes (Donabedian, 1982). His work provided healthcare professionals with a framework to evaluate patient care based on categories of health services variables.

As mentioned in chapter 3, a large number of geographically diverse pilgrims, many of whom are elderly with underlying medical conditions, attend the Hajj. Although the prescribed Hajj rituals last only ten days, most pilgrims remain in Makkah for several weeks (Memish et al.

2014; Parker et al., 2018). The Saudi MOH devotes substantial resources to maintaining, equipping, and staffing the temporary Hajj hospitals, enabling them to provide diagnostic and therapeutic medical services such as advanced radiology, mechanical ventilation, intravenous vasoactive medication support, and well-equipped ICU beds.

In the current chapter, the effect of selected inpatient diagnostic and therapeutic procedures (process variables) on inpatient all-cause mortality (outcome variable) was estimated for the unique population of Hajj pilgrims receiving care at Makkah and sacred sites hospitals. Although Saudi Arabia makes every effort to serve the pilgrims, the massive number of visitors during the Hajj period has strained the system. As such, mortality during hospitalization does still occur. A better understanding of the most efficient way to utilize healthcare services would provide useful information for designing targeted interventions to improve healthcare quality in upcoming seasons.

4.2 Methods

4.2.1 Study design and population

This study used the same sample as Chapter 3 in a retrospective, matched, case-control design. A total of 2,237 deaths that occurred during hospitalization were included as the cases of this study. A matching ratio of 1:2 was used to sample the control subjects. A total of 6,711 subjects were included in the study. Data collection and control matching is explained in Chapter 2 Section 2.2.2 pages 28 and 29 and Chapter 3 Section 3.2.1 pages 62 and 63. In addition, indicators of hospital characteristics were extracted from the SARA dataset, which is described in Textbox 1 page 33.

4.2.2 Study variables

Case recruitment and control group selection

A detailed explanation of the case recruitment and control group selection is provided in Chapter 3 Section 3.2.2 page 63 and 64.

Exposure variables – process characteristics.

Diagnostic and therapeutic procedures included ICU admission, intubation, endoscopy, radiology imaging, and blood transfusion. Each was treated as a binary variable (yes or no). While ICU admission was extracted from the administrative dataset, all the other variables were collected from the patients' medical records. As stated in the data collection section (Chapter 2 Section 2.2.2 pages 28 and 29), trained medical students reviewed patient medical records for information about the diagnostic and therapeutic procedures provided during hospitalization. Intubation, radiology imaging, endoscopy, and blood transfusions were reported as performed (yes) if explicitly mentioned in doctor order sheets, ICU forms, or daily nurse notes or if a request form, endoscopy findings report, or radiology report were included in the patient's medical record.

Other variables – patient characteristics

Index subjects were matched to control subjects by age and gender. Preexisting chronic diseases (including diabetes mellitus, hypertension, and cardiovascular diseases), resident status (domestic vs. international), and mode of admission were all binary variables (yes or no). Categorical variables included nationality, time of discharge (pre-event, event, or post-event), and discharge diagnosis (based on the CCS for ICD-10). LOS was the only continuous variable.

LOS was computed by subtracting the date of admission to a hospital from the date of discharge, counting the date of admission as zero.

Other variables - hospital characteristics.

The SARA dataset was used to retrieve the number of physicians, nurses, and beds in the hospitals included in the study. Next, the ratios of bed-to-nurse and bed-to-doctor were calculated, with smaller numbers indicating better staffing. The location of the hospital was a binary variable (Makkah versus sacred sites). While Makkah hospitals are permanent, sacred sites hospitals only operate during the Hajj season. Thus, the location of the hospital can be used as a proxy for hospital type (permanent versus temporary). All variables were treated as macro observations within which the individual variables were embedded.

4.2.3 Statistical analysis

Patient and hospital characteristics were described for the study population based on each of the significant variables. For categorical variables, crude numbers and percentages were reported. Means and SE were calculated for continuous variables. The distribution of the medical services utilized by event phases and location of the services (Makkah vs. sacred sites) were calculated. The study period for each season was divided into three phases: pre-event (days 1 to 21), event (days 22 to 30), and post-event (days 31 to 45). Event was defined as the actual time when pilgrims perform the rituals. Pre-event and post-event were defined as the periods before and after the Hajj rituals. City of admission was used to determine location.

The standard logistic regression model assumes that the observations obtained from each unit are independent, an assumption that would be violated by fitting a standard logistic regression to nested data (Wilson & Lorenz, 2015). This violation could lead to underestimating

SEs, leading to false-positive results. Multilevel, or hierarchical, modeling is an analytic technique designed for complex, nested data structures (Diez-Roux, 2000; Duncan, Jones, & Moon, 1998). It has several advantages for the analysis of hospital-based data, including the ability to include the variability at each level of the hierarchy, and thus allows for the analysis of cluster effects at different levels within the models (Shahian et al., 2001). Hence, the information from different levels can be incorporated into a subject-specific logistic regression model.

A hierarchical logistic regression model with mixed effect was used to account for the nesting of patient data within hospital data (Austin, 2010; Moineddin, Matheson, & Glazier, 2007). The log odds of inpatient all-cause mortality as a function of medical services and a random, hospital-specific effect was modeled. This strategy accounts for within-hospital associations between the observed outcomes and reflects the assumption that underlying differences in quality among the hospitals leads to systematic differences in outcomes. Separate models for each medical service were conducted using inpatient all-cause mortality as the dependent variable and the medical services as independent variables. All hospital variables, including hospital location, bed-to-nurse ratio, and bed-to-doctor ratio, were treated as a random effect. The included patient-level variables were treated as fixed effects and were chosen based on the directed acyclic graph (Greenland, Pearl, & Robins, 1999; Pearl, 1995). These included age; gender; preexisting chronic diseases; mode of admission; time of the discharge; discharge diagnosis; and pilgrim residency status.

To evaluate the associations in more homogenous groups, subgroup analyses were conducted. Subgroup analysis stratified by pilgrims' residency status, type of service, and nationality were performed to investigate the differences in effect among different groups. Residency status was used to account for differences in the services provided to domestic patients compared to international patients. Moreover, medical services included in the study were categorized into diagnostic and therapeutic services to distinguish between the effects of the type of service on inpatient all-cause mortality. Diagnostic services included radiology imaging and endoscopy. Therapeutic services included ICU admission, intubation, and blood transfusion. Also, the risk of inpatient all-cause mortality associated with the medical services among selected nationalities within the large sample size, as well as ICU patients, was conducted.

In addition, sensitivity analysis was conducted to assess the impact of unperformed, requested services (Greenland, 1996). The data only included service orders and those services documented in the medical records, but there was no confirmation that the service was actually performed. This sensitivity analysis tested different scenarios of unperformed services to quantify the impact on the ORs. The magnitudes of association between inpatient all-cause mortality and each process indicator were estimated using ORs with 95% CIs. All analyses were performed in SAS 9.4 (Statistical Analysis Systems, Inc, Cary, NC; Schabenberger, 2005), with an α cutoff of 0.05.

4.2.4 Power calculation

SAS PROC POWER statement was used to estimate the power of the logistic regression model. A logistic regression of a binary response variable Y (all-cause mortality) on a binary independent variable X (e.g., admission to ICU) with a sample size of 6,711 observations (2,237 cases and 4,468 controls) achieves a 90% power at a 0.05 significance level to detect a change in Pr(Y=1) corresponding to an odds ratio of 1.5. Blood transfusion achieves a lower power of 69%. However, a larger population effect size would result greater larger statistical power (Appendix D, Table D2).

4.3 Results

Of the total discharges included in the study, 23,391 occurred at Makkah hospitals (68.5%) and 10,769 occurred at sacred sites hospitals (31.5%; Appendix A, Table A9). Table 4.1 describes the population included in the study. Gender ratio and age mean (63 years old) were similar for mortality and control cases due to the matched design. Among the control group, a higher proportion of patients were international pilgrims rather than domestic pilgrims (91.1% versus 8.9%), with Indian pilgrims the most represented nationality (11.5%). Moreover, on average, mortality cases had a longer length of stay compared to control patients (4.9 days versus 3.5 days), and cardiovascular diseases accounted for the majority of discharge diagnoses among mortality cases (31.0%) followed by pulmonary diseases (18.3%).

Cardiovascular diseases were also the leading diagnosis among patients who were admitted to the ICU (28.6%), intubated (30.0%), and had a CT-scan or MRI (39.8%). Gastrointestinal diseases were the greatest discharge diagnosis among patients who had an endoscopy (82.3%). Additionally, mortality cases received a larger number of medical services during the event period compared to the pre- and post-event periods, except for endoscopy (Table 4.2). Also, Makkah hospitals administered a higher number of medical services compared to sacred sites hospitals in both cases and controls (Table 4.2).

The distribution of medical services included in the study are presented in Table 4.3. ICU admission was the most commonly performed service within mortality cases (41.2%). Intubation was performed in 13.9% of mortality cases, endoscopy in 6.3%, radiology imaging in 17.3%, and blood transfusion in 4.5%. Overall, the proportion of medical services administered to control patients was lower.

Results from the hierarchical logistic regression models were significant for all services except radiology imaging (OR: 1.60, 95% CI: 0.98-2.60). Within the same hospital, ICU admission was associated with an eight-fold higher risk of death during the hospital stay compared to patients not admitted to the ICU (OR: 8.00, 95% CI: 7.8-8.2). Patients who received blood transfusions had an elevated risk of inpatient all-cause mortality (OR: 4.00, 95% CI: 2.59-6.24). Also, the risk of inpatient all-cause mortality was twice as likely for patients who underwent endoscopy compared to patients who did not (OR: 1.99, 95% CI: 1.37-2.88). In contrast, intubation was associated with decreased inpatient all-cause mortality (OR: 0.54, 95% CI: 0.35-0.82). However, when this model was not adjusted for ICU admission, intubation was associated with a four-fold increase in the risk of inpatient all-cause mortality (OR: 4.10, 95% CI: 2.42-6.92).

When stratified by residency status, receiving any of the medical services included in this study associated with an increased risk of death, except for intubation (Table 4.4). While the estimated risks in domestic pilgrims were significantly altered, the associations in international pilgrims were slightly modified. For example, among domestic patients, ICU admission was associated with a 40-fold risk of inpatient all-cause mortality (OR: 40.1, 95% CI: 32.69-49.17). However, the CI was wide due to the small subject number included in the model. Taken in aggregate, the likelihood of death was increased among patients who received any of the included diagnostic or therapeutic procedures compared to patients who did not receive any procedures (Table 4.5).

4.4 Discussion

The goal of a well-performing healthcare system is to deliver care that improves the health of individuals and populations. The Hajj population is exceptional in the fact that it is sicker and older than the general population. In this chapter, a large hospital-based sample covering multiple Hajj seasons revealed an increased risk of inpatient all-cause mortality among pilgrims who received any of the studied medical services, except for intubation, which was consistent in both international and domestic pilgrims. However, the risk was more pronounced in international pilgrims compared to domestic pilgrims, except for ICU admission.

In the current study, cardiovascular disease was the leading cause of ICU admission (28.6% of total ICU admissions) followed by pulmonary disease (23.1% of total ICU admissions). This finding is comparable to a previous report of 29% of total ICU admissions being due to cardiovascular diseases and 23.3% being due to pulmonary diseases (Afessa et al., 2005). The mortality rate among ICU admissions was 41.2%. This result is significantly higher than a previously reported 8.2% mortality rate (Finkielman et al., 2004). However, that study was conducted among the general population, which has a higher proportion of younger and healthier individuals. Moreover, ICU admission was associated with an eight-fold increase in inpatient all-cause mortality compared to patients who were not admitted to the ICU. This result is significantly higher than results from other settings (Afessa et al., 2005; Azevedo, de Souza, Zygun, Stelfox, & Bagshaw, 2015; Barbash et al., 2016; Gabler et al., 2013; Laupland et al., 2011; Soltani et al., 2015; Uusaro, Kari, & Ruokonen 2003; Wagner et al., 2013). For example, Uusaro, Kari, & Ruokonen (2003) found that ICU admission was a significant, independent risk factor for mortality among older patients. However, they reported a lower risk compared to the current study (OR = 1.53; 95% CI 1.29-1.81).

The decision to perform intubation is not an easy one as it is typically made under stressful conditions. In contrast to the current study, a meta-analysis by Fevang et al. (2017) summarized the results of 21 studies comparing the mortality rates of adult trauma patients undergoing prehospital intubation to those undergoing emergency department intubations. In both groups, the mortality rate was high – 48% and 29%, respectively – and the ORs favored emergency department intubation with a crude mortality of 2.56 and an adjusted mortality of 2.59. In another study, Sanchez et al. (2008) found that the mortality rate after an emergency department intubation was as high as 27.0%. This result is almost double the mortality rate reported in the current study (13.9%). The study was a single-center study with a limited number of participants (Sanchez et al., 2008). However, it is comparable to the current study, as the majority of the pilgrim patients were admitted through the emergency department. Although intubation was inversely associated with inpatient all-cause mortality, this required adjustment for ICU admission. A possible, underlying explanation is that most of the intubation cases occurred in patients admitted to the ICU. Adjusting for ICU admission could result in multicollinearity between intubation and ICU admission that might affect the estimate.

Of the patients who received endoscopy in the current study, 6.3% died during their hospital stay. In a previous study predicting mortality in patients with bleeding peptic ulcers after therapeutic endoscopy, 7.1% experienced in-hospital mortality (Chiu et al., 2009). CT-scans and MRI are used for numerous clinical indications, including evaluation for pulmonary embolism, adenopathy, pleural diseases, and pneumonia, among others. The reported use of radiology imaging among the Hajj population in the current study (144 per 1,000 persons) is consistent with previous results showing a rate of advanced radiology imaging among the 2010 Medicare population of 149 per 1,000 persons (Smith-Bindman et al., 2012). Also, the current study reported a 60% increased risk of inpatient mortality among those who underwent CT-scans or MRI. A prior study that evaluated the same association showed similar results. Hughes-Austin et al. (2016) estimated that CT-scans were associated with a 50% higher risk of death. In contrast, further results showed that whole-body CT (WBCT) imaging improved survival in blunt trauma patients (Hajibandeh & Hajibandeh, 2015).

Blood transfusions were found to be associated with an increased risk of inpatient all-cause mortality in the current study. In a meta-analysis of blood transfusions in myocardial infarction patients, transfusion was positively associated with death (OR: 2.91; 95% CI: 2.46-3.44; Chatterjee, Wetterslev, Sharma, Lichstein, & Mukherjee, 2013). However, these findings are limited to myocardial infarction patients and cannot be generalized to other study settings or populations.

Although the overall medical services utilization was not different between the two groups, international pilgrims were at higher risk of inpatient all-cause mortality compared to domestic patients for all services except ICU admission (Table 4.4). Contrary to my results, Al Faleh et al. (2015) found that non-Saudis had a 2.9-fold higher likelihood of death compared to Saudis. The study concluded that these disparities could be explained by patient characteristics as well as system-related shortcomings. However, the study examined a general hospital population that was not similar to the Hajj population. The higher risk of inpatient all-cause mortality in international Hajj pilgrims might be expected given the large percentage between 60 and 80 years old (58%). Prior research has demonstrated that international patients have significantly worse adverse outcomes in US hospitals when compared to their domestic counterparts, with the largest differences occurring in patients with the highest illness severity (Satjapot, Johnson & Garman, 2011). In the current study, domestic patients were more commonly over 80 years old. This could explain the higher risk of inpatient all-cause mortality among domestic patients who were admitted to the ICU. Another possible reason for this discrepancy might be that attending the Hajj is easier and less expensive for domestic pilgrims, which could encourage very old pilgrims to perform the Hajj regardless of their health status. However, Hajj hospitals still face several unique challenges in caring for international patients. Given that most of the pilgrims come from developing countries, some of these challenges include language barriers, cross-cultural differences, lack of local social support while receiving care, mental and physical stress from traveling long distances, and limited medical infrastructure within the patient's home country. Inherent physician bias might, theoretically, be a factor in the observed differences in outcomes between domestic and international pilgrims, but this current study did not assess that.

Subgroup analysis by nationality showed significantly higher ORs for death in patients admitted to the ICU among all nationalities, which could be explained by the fact that such individuals would be sicker. On the other hand, intubation was unexpectedly protective within most of the nationalities when adjusted for ICU admission. Endoscopy, radiology imaging, and blood transfusions were associated with higher risk of death among most of the nationalities. However, the small number of subjects in some of the subgroups resulted in unreliable ORs and 95% CIs (Appendix C, Table C5). Also, when the association was evaluated within ICU patients, the risk was similar to that of the total sample (Appendix C, Table C6).

This study has several limitations. The analysis was based on administrative data, which has inherent biases that cannot be avoided. Comprehensive quality assessment typically demands a tradeoff between the credibility of administrative data versus the expense and feasibility of data collection. Administrative files contain limited clinical insight. Therefore, examining the quality of care at the individual level or evaluating the technical quality of processes of care are precluded. For example, ICU admission was not differentiated by the purpose (medical versus surgical), and intubation was not described as urgent or elective. Furthermore, hospital characteristics data were interpolated using the SARA project, which does not capture the variation within the hospital. Therefore, the effect of these factors on the process of care and outcomes cannot be accounted for, which could confound the results.

Some important variables were not measured. Data collection was not detailed enough to address questions of race, socioeconomic status, tobacco smoking, lifestyle, body mass index, or diet. Therefore, interactions with unmeasured variables might have played a role in patients' adverse outcomes, although this cannot be investigated with the existing data. Moreover, the study is susceptible to nondifferential, independent misclassification which can be introduced during the data insertion by the healthcare providers or by the field data collectors during data collection. However, this bias would favor the null value (Rothman et al., 2008). To determine the impact of nondifferential misclassification and unperformed procedures, sensitivity analyses were conducted to assess changes in the ORs. ICU admission was impacted by any reduction in sensitivity and specificity, while intubation, endoscopy, radiology imaging, and blood transfusion were only altered with a reduced specificity of 10% or more (Appendix C, Tables C7, C8, C9, C10, and C11).

Finally, bias resulting from sparse data may also exaggerate the estimates in stratified analyses (Greenland, Schwartzbaum & Finkle, 2000). ORs of ICU admission and intubation in domestic patients could be biased away from the null value due to the small numbers within the strata of the covariates included in the conditional logistic model. Nonetheless, a simplified fitted model was used to reduce bias and showed similar results (Maldonado & Greenland, 1998; Schaefer, 1983).

A noteworthy strength of this study is that it identified previously unreported differences between domestic and international pilgrims in medical services provided in Hajj hospitals. Despite the concerns discussed above, the study serves as a useful screening tool that highlights areas in which quality should be investigated in greater depth using detailed clinical information. It is possible to examine three potential indicators of quality from this study (Iglehart, 1996): access (whether pilgrims have access to ICU beds), limited outcomes (inpatient all-cause mortality as an outcome), and limited processes (e.g., whether patients with gastrointestinal manifestations underwent endoscopy). To my knowledge, this is the first study to assess the quality of healthcare services provided during the Hajj mass-gathering using the Donabedian model.

Matching the supply of healthcare services with demand is fundamental for the efficient delivery of advanced life support to patients in urgent need. In an emergency setting, the decision to admit patients should be based on their potential to benefit from the care (Arabi & Al-Shimemeri, 2003; Lanken et al., 1997; Swenson, 1992). Mismatch in this relationship between supply and demand strains a hospitals' capacity, which results in a disrupted ability to provide timely and high-quality care to all patients in need. The resulting suboptimal quality of care may directly contribute to increased risk for adverse events including, but not limited to, avoidable deaths.

Although the Saudi MOH provides advanced services during the Hajj, mortality remains relatively high. This suggests that the health status of pilgrims could be significantly improved. The Hajj population has unique demographic profiles that are not accurately reflected in the studies mentioned above. These demographics are accompanied by a greater prevalence of individuals with chronic illnesses, such as diabetes mellitus, hypertension, cardiovascular disease, and chronic kidney disease. As such, the number of potential ICU admissions exceeds the available beds during the Hajj season. In these cases, the decision regarding ICU admission should be made based on the priority model (Hagen, Jopling, Buchman, & Lee, 2013). Madani

(2007) showed that among ICU patients in Hajj hospitals, the risk of complications and death increased with age, with the highest risk observed in pilgrims over 80 years of age. Several studies demonstrated a relationship between ICU bed availability and adverse outcomes, including mortality (Azoulay et al., 2001; Byrick, Mazer, & Caskennette, 1993; Singer, Carr, Mulley, & Thibault, 1983; Sinuff, Kahnamoui, Cook, Luce, & Levy, 2004; Stelfox et al., 2012; Strauss, LoGerfo, Yeltatzie, Temkin, & Hudson, 1986; Walther & Jonasson, 2001).

The importance of these results is highlighted by the lack of studies on the quality of the services provided in Hajj hospitals, particularly the ones evaluated in my study, and relationships with inpatient all-cause mortality risk. Further research should be conducted to confirm my results using data collected firsthand specifically for research purposes. Studies are needed to answer questions regarding the relationship between the adjacent pair in the structure-process-outcome model and whether the effects observed in this study could potentially be attributed to an unknown intermediate variable. Mediation analysis would help to achieve a complete assessment of the quality of the services in Hajj hospitals as well as to develop a strategy to identify the cause of failures in the system and attribute them to structure, process, or both. Moreover, using different outcomes, such as length of stay, the number of outpatient visits, or patient and provider satisfaction with care would provide additional insight into the current study results. Finally, the opportunity to collect large amounts of data during the Hajj is invaluable. Large datasets have the potential to play a critical role in preventing disease. The analysis of these data can be utilized during the Hajj for disease prevention and control as well as be utilized at other times of the year to assist in health policy planning at the global, regional, and country levels.

Table 4.1
Demographic characteristics of inpatient cases and controls in Makkah and sacred sites hospitals during the Hajj (2012 - 2017).*

Demographic data	Mortality cases	Controls
	N = 2,237 (%)	N = 4,474 (%)
Sex		
Male	1,398 (62.5)	2,796 (62.5)
Female	839 (37.5)	1,678 (37.5)
Age Group		
Mean (SE)	63 (13.6)	63 (13.8)
≤ 40	129 (5.8)	265 (5.9)
41 - 50	205 (9.2)	400 (9.0)
51 - 60	486 (21.7)	979 (21.9)
61 - 70	779 (34.8)	1,581 (35.3)
71 - 80	470 (21.0)	912 (20.4)
> 80	168 (7.5)	337 (7.5)
Hajj (Pilgrimage) Status		
Domestic	290 (13.0)	399 (8.9)
International	1,947 (87.0)	4,075 (91.1)
Location of discharge		
Sacred sites	619 (27.7)	1,191 (26.6)
Makkah	1,618 (72.3)	3,282 (73.4)
Nationality		
Indonesia	488 (21.8)	473 (10.6)
India	283 (12.7)	516 (11.5)
Pakistan	214 (9.6)	457 (10.2)
Egypt	193 (8.6)	351 (7.9)
Bangladesh	137 (6.1)	341 (7.6)
Turkey	67 (3.0)	212 (4.7)
Nigeria	58 (2.3)	172 (3.8)
Morocco	56 (2.5)	154 (3.4)
Saudi Arabia	67 (3.0)	142 (3.2)
Yemen	51 (2.3)	118 (2.6)
Algeria	47 (2.1)	108 (2.4)
Malaysia	55 (2.5)	88 (2.0)
Sudan	30 (1.3)	108 (2.4)
Afghanistan	36 (1.6)	100 (2.2)
Myanmar (Burma)	69 (3.1)	44 (1.0)
Iraq	29 (1.3)	84 (1.9)
Other**	342 (15.3)	991 (22.2)
Diabetes mellitus		
Yes	710 (31.7)	1,005 (22.5)
No	1,527 (68.3)	3,469 (77.5)

Hypertension		
Yes	554 (24.8)	790 (17.7)
No	1,683 (75.2)	3,684 (82.3)
Cardiovascular disease		
Yes	439 (19.6)	610 (13.6)
No	1,798 (80.4)	3,864 (86.4)
Hajj time phases		
Pre-event	498 (22.3)	1,016 (22.7)
Event	1,010 (45.1)	2,143 (47.9)
Post-event	729 (32.6)	1,315 (29.4)
Discharge diagnosis		
Cardiovascular diseases	693 (31.0)	796 (17.8)
Pulmonary diseases	410 (18.3)	732 (16.3)
Infectious diseases	276 (12.3)	371 (8.29)
Gastrointestinal diseases	192 (8.6)	557 (12.4)
Endocrine diseases	178 (8.0)	459 (10.3)
Renal diseases	171 (7.6)	190 (4.2)
Neurological diseases	128 (5.7)	351 (7.8)
Injury and external causes	74 (3.3)	728 (16.3)
Tumors	54 (2.4)	46 (1.0)
Diseases of blood origin	40 (1.8)	136 (3.0)
Other ***	31 (1.4)	108 (2.4)
Length of stay (in days)		
Mean (SE)	4.9 (6.1)	3.5 (4.0)
Hospital bed-to-nurse ratio grade		
1	621 (27.8)	1,175 (26.3)
2	629 (28.1)	1,196 (26.7)
3	987 (44.1)	2,103 (47.0)
Hospital bed-to-doctor ratio grade		
1	1,091 (48.8)	2,077 (46.4)
2	783 (35.0)	1,390 (31.1)
3	363 (16.2)	1,007 (22.5)

*Hajj 2015 was excluded. SE: Standard error.
**30 patients were of unknown origin. ***Age-related diseases, diseases of the musculoskeletal system and connective tissue, maternal and child diseases, diseases of the genitourinary system, ophthalmological conditions, and ENT conditions.

Table 4.2
Distribution of cases and control in Makkah and sacred sites hospitals during the Hajj by time, location and diagnosis (2012 - 2017).*

Medical services	Mortality cases	Alive controls	Total
	N = 2,237 (%)	N = 4,474 (%)	
ICU admission	**922 (78.5)**	**253 (21.5)**	**1,175 (%)**
By time			
Pre-event	187 (20.3)	43 (17.0)	230 (19.6)
Event	379 (41.1)	175 (69.1)	554 (47.1)
Post-event	356 (38.6)	35 (13.8)	391 (33.3)
By Location			
Makkah	731 (79.3)	114 (45.0)	845 (71.9)
Sacred sites	191 (20.7)	139 (55.0)	330 (28.1)
By Diagnosis			
Cardiovascular diseases	254 (27.5)	83 (32.8)	337 (28.6)
Pulmonary diseases	200 (21.7)	71 (28.1)	271 (23.1)
Infectious diseases	130 (14.1)	7 (2.8)	137 (11.7)
Gastrointestinal diseases	92 (10.0)	15 (5.9)	107 (9.1)
Renal diseases	78 (8.5)	5 (2.0)	83 (7.1)
Others	168 (18.2)	72 (28.5)	240 (20.4)
Intubation	**310 (67.8)**	**147 (32.2)**	**457 (%)**
By time			
Pre-event	52 (16.8)	24 (16.3)	76 (16.6)
Event	156 (50.3)	92 (62.6)	248 (54.3)
Post-event	102 (32.9)	31 (21.1)	133 (29.1)
By location			
Makkah	212 (68.4)	82 (55.8)	294 (64.3)
Sacred sites	98 (31.6)	65 (44.2)	163 (35.7)
By diagnosis			
Cardiovascular diseases	98 (31.5)	39 (26.5)	137 (30.0)
Pulmonary diseases	65 (21.0)	43 (29.3)	108 (23.5)
Infectious diseases	37 (12.0)	8 (5.4)	45 (9.9)
Gastrointestinal diseases	34 (11.0)	11 (7.5)	45 (9.9)
Renal diseases	21 (6.8)	4 (2.7)	25 (5.5)
Others	55 (17.7)	42 (28.6)	97 (21.2)
Endoscopy	**140 (38.7)**	**222 (61.3)**	**362 (%)**
By time			
Pre-event	40 (28.6)	60 (27.0)	100 (27.6)
Event	48 (34.3)	96 (43.2)	144 (39.8)
Post-event	52 (37.1)	66 (29.7)	118 (32.6)
By location			
Makkah	124 (88.6)	178 (80.2)	302 (83.4)

Sacred sites	16 (11.4)	44 (19.2)	60 (16.6)
By diagnosis			
Gastrointestinal diseases	101 (72.1)	197 (88.7)	298 (82.3)
Others	39 (27.9)	25 (11.3)	64 (17.7)
Radiology imaging	**388 (39.9)**	**585 (60.1)**	**973 (%)**
By time			
Pre-event	77 (19.8)	142 (24.3)	219 (22.5)
Event	173 (44.6)	293 (50.1)	466 (47.9)
Post-event	138 (35.6)	150 (25.6)	288 (29.6)
By location			
Makkah	289 (74.5)	384 (65.6)	673 (69.2)
Sacred sites	99 (25.5)	201 (34.4)	300 (30.8)
By diagnosis			
Cardiovascular diseases	202 (52.1)	185 (31.6)	387 (39.8)
Injuries	42 (10.8)	240 (41.0)	282 (29.0)
Gastrointestinal diseases	42 (10.8)	40 (6.8)	82 (8.4)
Nervous system diseases	6 (1.6)	53 (9.1)	59 (6.1)
Others	96 (24.7)	67 (11.5)	163 (16.7)
Blood transfusion	**100 (55.2)**	**81 (44.8)**	**181 (%)**
By time			
Pre-event	25 (25.0)	23 (28.4)	48 (26.5)
Event	38 (38.0)	36 (44.4)	74 (40.9)
Post-event	37 (37.0)	22 (27.2)	59 (32.6)
By location			
Makkah	82 (82.0)	64 (79.0)	146 (80.7)
Sacred sites	18 (18.0)	17 (21.0)	35 (19.3)
By diagnosis			
Injuries	16 (16.0)	23 (28.4)	39 (21.5)
Gastrointestinal diseases	18 (18.0)	21 (26.0)	39 (21.5)
Hematological diseases	12 (12.0)	13 (16.0)	25 (13.8)
Infectious diseases	14 (14.0)	4 (4.9)	18 (10.0)
Others	40 (40.0)	20 (24.7)	60 (33.2)

*Hajj 2015 was excluded.

Table 4.3
Prevalence, crude and adjusted odds ratios for inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj by medical services (2012-2017).*

Medical services	Mortality cases n (%)	Controls n (%)	Crude OR	(95% CI)	Adjusted OR***	(95% CI)
ICU Admission						
Yes	922 (41.2)	253 (5.7)	11.72**	(10.10 – 13.70)	8.00**	(7.8 – 8.2)
No	1,315 (58.8)	4,221 (94.3)	1.00		1.00	
Intubation						
Yes	310 (13.9)	147 (3.3)	4.74**	(3.87 – 5.80)	0.54**	(0.35 – 0.82)
No	1,927 (86.1)	4,327 (96.7)	1.00		1.00	
Endoscopy						
Yes	140 (6.3)	222 (5.0)	1.28**	(1.03 – 1.59)	1.99**	(1.37 – 2.88)
No	2,097 (93.7)	4,252 (95.0)	1.00		1.00	
Radiology imaging						
Yes	388 (17.3)	585 (13.1)	1.40**	(1.21 – 1.61)	1.60	(0.98 – 2.60)
No	1,849 (82.7)	3,889 (86.9)	1.00		1.00	
Blood transfusion						
Yes	100 (4.5)	81 (1.8)	2.54**	(1.88 – 3.42)	4.00**	(2.59 – 6.24)
No	2,137 (95.5)	4,393 (98.2)	1.00		1.00	

*Hajj 2015 was excluded
** p-value < 0.05
Note AOR=adjusted odds ratio. CI=confidence interval.
***ORs estimates were results of separate logistic regression models, one for each procedure. All models controlled for age, gender, nationality, hypertension, diabetes, discharge diagnosis, length of stay, mode of admission, time of event, patient residency status, hospital location, hospital of discharge, bed-to-doctor ratio, and bed-to-nurse ratio. In addition to that, ICU admission was controlled for when intubation was modeled.

Table 4.4
Prevalence, crude and adjusted odds ratios for inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj by medical services for domestic and international pilgrims (2012-2017).*

Medical services	Mortality cases	Controls	Crude OR	(95% CI)	Adjusted OR***	(95% CI)
	n (%)	n (%)				
International pilgrims						
ICU Admission						
Yes	798 (41.0)	241 (5.9)	11.05**	(9.43 – 12.95)	7.88**	(5.67 – 9.42)
No	1,149 (59.01)	3,834 (94.1)	1.00		1.00	
Intubation						
Yes	274 (14.1)	138 (3.4)	4.66**	(3.77 – 5.76)	0.52**	(0.32 – 0.84)
No	1,673 (85.9)	3,937 (96.6)	1.00		1.00	
Endoscopy						
Yes	117 (6.0)	204 (5.0)	1.21	(0.96 – 1.53)	2.00**	(1.16 – 3.45)
No	1,830 (94.0)	3,871 (95.0)	1.00		1.00	
Radiology imaging						
Yes	334 (17.1)	506 (12.4)	1.46**	(1.26 – 1.70)	1.66**	(1.01 – 2.72)
No	1,613 (82.9)	3,569 (87.6)	1.00		1.00	
Blood transfusion						
Yes	88 (4.5)	72 (1.8)	2.64**	(1.92 – 3.63)	4.07**	(2.53 – 6.54)
No	1,859 (95.5)	4,003 (98.2)	1.00		1.00	
Domestic pilgrims						
ICU Admission						
Yes	124 (42.8)	12 (3.0)	24.79**	(13.30 – 46.21)	40.1**	(32.69 – 49.17)
No	166 (57.2)	387 (97.0)	1.00		1.00	
Intubation						
Yes	36 (12.4)	9 (2.3)	6.04**	(2.86 – 12.77)	0.87	(0.34 – 2.23)
No	254 (87.6)	390 (97.7)	1.00		1.00	
Endoscopy						

Yes	23 (7.9)	18 (4.5)	1.78	(0.94 – 3.37)	1.58	(0.61 – 4.11)
No	267 (92.1)	381 (95.5)	1.00		1.00	
Radiology imaging						
Yes	54 (18.6)	79 (19.8)	0.92	(0.62 – 1.35)	2.01**	(1.65 – 2.45)
No	236 (81.4)	320 (80.2)	1.00		1.00	
Blood transfusion						
Yes	12 (4.1)	9 (2.3)	1.86	(0.77 – 4.48)	2.05	(0.35 – 11.96)
No	278 (95.9)	390 (97.7)	1.00		1.00	

*Hajj 2015 was excluded
** p-value < 0.05
Note AOR=adjusted odds ratio. CI=confidence interval.
***ORs estimates were results of separate logistic regression models, one for each procedure. All models controlled for age, gender, nationality, hypertension, diabetes, discharge diagnosis, length of stay, mode of admission, time of event, patient residency status, hospital location, hospital of discharge, bed-to-doctor ratio, and bed-to-nurse ratio. In addition to that, ICU admission was controlled for when intubation was modeled.

Table 4.5
Prevalence, crude and adjusted odds ratios for inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj by type of the service (2012-2017).*

Medical services	**Mortality cases**	**Controls**	**Crude OR**	**(95% CI)**	**Adjusted OR*** **	**(95% CI)**
	n (%)	**n (%)**				
Diagnostic procedures						
Yes	492 (22.0)	774 (17.3)	1.35**	(1.19 – 1.53)	1.66	(0.42 – 7.10)
No	1,745 (78.0)	3,700 (82.7)	1.00		1.00	
Therapeutic procedures						
Yes	968 (43.3)	343 (7.7)	9.20**	(8.01 – 10.57)	7.03	(0.91 – 8.07)
No	1,269 (56.7)	4,131 (92.3)	1.00		1.00	

*Hajj 2015 was excluded
** p-value < 0.05
Note AOR=adjusted odds ratio. CI=confidence interval.
***ORs estimates were results of two separate logistic regression models. All models controlled for age, gender, nationality, hypertension, diabetes, discharge diagnosis, length of stay, mode of admission, time of event, patient residency status, hospital location, hospital of discharge, bed-to-doctor ratio, and bed-to-nurse.

5 Resources That Could Enhance Medical Care During the Hajj

5.1 Introduction

This dissertation provides a description of mortality during the Hajj and its relationship to preexisting chronic diseases and specific medical services provided in Hajj hospitals. Findings from this dissertation can be summarized by three key points. First, inpatient mortality in Hajj hospitals is relatively high, with a large number occurring in individuals of advanced age. The data also suggest differences in gender, pilgrims' residency status, and mode of admission. Second, preexisting chronic diseases are common among pilgrims, and these patients are at an increased risk of death during the Hajj compared to those without chronic diseases. This effect is even more pronounced in older individuals. Third, although advanced medical services were provided to pilgrims, inpatient all-cause mortality was common, and it was higher in Makkah hospitals compared to sacred sites hospitals. These results have important public health implications for Hajj policymakers.

The following sections provide a suggested information system to capture Hajj-related data; describe a conceptual model to improve the quality of medical services during and research on the Hajj; propose a pre-Hajj health screening exam to quantify pilgrims' preexisting chronic diseases; provide an example of the screening exam resulting from data generated within this dissertation; and recommend the use of technology and innovative interventions to optimize Hajj healthcare services.

5.2 An Information System to Aid Health-Related Decisions Concerning the Hajj

One of the roles of information systems is to support the decision-making process by organizations and help stakeholders determine appropriate evidence-based policies. Additionally, such a system should gather the necessary data to conduct strategic risk assessment, identify risks before the Hajj, manage risks during the Hajj, and plan for future Hajj.

The Saudi MOH provides a vast range of health services during the Hajj. These services generate a vast amount of data that could be managed and utilized to provide a better understanding of disease spread and prevention and improve early warnings and responses to various public health situations, including communicable and noncommunicable diseases. Effective disease prevention can be improved with data, especially to facilitate actions regarding preventable risk factors during the Hajj (Nafea, 2016). The Healthcare Electronic Surveillance Network (HESN) is the MOH-configured system of the Public Health Solution for Disease Surveillance and Management. The HESN is a web-based system developed for communicable disease surveillance and outbreak and public health resource management (Al-Tawfiq, & Memish, 2014). However, no similar system has been created to track data regarding noncommunicable diseases within Hajj hospitals nor the general Hajj population.

An information health system should be in place in order to support the mission of the MOH to reduce the morbidity and mortality associated with preexisting chronic diseases. It should capture pre-Hajj data, such as pilgrims' demographic information and preexisting chronic diseases, among other types of information. Also, a sophisticated surveillance system needs to be developed to track and integrate health-related data in real-time from a variety of sources during the Hajj, such as the Ministry of Hajj, MOH, Ministry of Interior, and crowdsourcing. Such a surveillance system could inform public health authorities and provide the necessary information to detect potential epidemics or other health threats during the Hajj. Moreover, it should enable the collecting of follow-up data regarding high-risk pilgrims to facilitate longitudinal studies of the impact of the Hajj on these pilgrims after they return to their home countries. This type of studies are essential to understand the characteristics of pilgrims, the repercussions of the Hajj on their health, and important risk and preventive factors (Li, Stampfer, Williams, & VanderWeele, 2016). The utility of this information would further be bolstered by collecting related health data such as clinical data from health providers (hospitals, physicians, and laboratories), drug sales from pharmacies, outbreak reports, population demographics, and emergency and urgent care data. The integrated data that would be generated within this system could then be aggregated and analyzed for early detection of diseases and otherwise contribute significantly to public health surveillance.

However, implementing such a system would pose many challenges not typically encountered in a normal setting. First, different types of data from different types of healthcare providers would need to be integrated, including demographics, travel patterns, climate data, spatial data, and health-related data. Second, the extensive size of the data would create challenges in its creation and utilization. Third, complicated strategies are required to manage the spatial data resulting from the diverse geographical distributions of pilgrims' origins and destinations. Finally, the breadth and depth of the data collected raises concerns about managing privacy and ownership of the data (Alshammari & Mikler, 2018). Despite these challenges, creating such an information system is feasible given strong political will and support, appropriate funding, and cooperation between all involved parties. Furthermore, the benefits of such a system should provide the needed motivation, as it would substantially enhance the planning and delivery of health services during the Hajj and protect global health security.

5.3 A Conceptual Model for Healthcare Services During the Hajj

Developing a clear and concise conceptual framework can be valuable in guiding the development of a functional healthcare system to accommodate the influx of pilgrims and ensure that the system is capable of operating at its maximum capacity. Armenian (1986) proposed a three-dimensional model useful in organizing wartime actions. Adapting the same model to Hajj healthcare services would be useful for planning, analysis, and research. The three-dimensional matrix in Figure 5.1 includes the following:

1. Level of action, which includes the ecological and personal levels. The ecological level concerns policy and the government effort to enhance the entire Hajj experience, such as remodeling the Mina Bridge to eliminate any catastrophic events. The personal level pertains to the prevention and rehabilitation activities, such as mandatory pre-Hajj vaccinations.
2. Type of action, which could range from prevention activities to curative activities to rehabilitation. The Hajj has a frame of reference for each of these types of activities.
3. Timing of action, which includes activities prior to, during, and after the Hajj. These can take the form of planning, researching, or providing services.

This dissertation recommends a pre-Hajj screening exam for preexisting chronic diseases for pilgrims in their country of origin. Using the Armenian model, it is an example of a personal, preventive, pre-Hajj intervention. The next section will present an example of a screening exam for preexisting chronic diseases using the data utilized in this dissertation.

5.4 An Example of Proposed Pre-Hajj Health-Screening Exam

As the burden of chronic diseases at the Hajj continues to grow, providing cost-effective healthcare services has become increasingly important. A better understanding of the health status of the pilgrims beforehand could greatly contribute to predicting efficient resource allocation during the Hajj. Utilizing the insights generated within this dissertation, a simple, pre-Hajj, health screening exam to quantify the number of pilgrims with multiple coexisting medical conditions has been developed. An equally weighted, five-level index has been created using age, hospital LOS, diabetes, hypertension, and cardiovascular diseases as indicators of pilgrims' health conditions. Age is dichotomized with a cut-off point of 65 years. LOS also is dichotomized with two days as a cut-off point. Diabetes, hypertension, and cardiovascular diseases are binary variables. Summing the risk factor scores results in a five-point summary score that was further dichotomized. Pilgrims, who scored less than three were categorized as low risk, and those who scored three or more were categorized as high risk.

Odds ratios for inpatient all-cause mortality increased with score up to a score of 4, with a slight reduction in risk for a score of 5 (Table 5.1). Dichotomizing these scores into low-risk (zero to two) and high-risk (three or more) revealed an OR of 1.72 for mortality in high-risk pilgrims compared to low-risk pilgrims (95% CI: 1.51-1.96; Table 5.2). These results indicate that mortality risk associates with the indicators included in the index and highlights its utility.

Applying a pre-Hajj screening exam, such as the one presented above, could provide Hajj authorities with a general picture of the health status of incoming pilgrim, permitting better allocation of medical staff, support staff, and medical equipment to Hajj healthcare facilities. However, a more sophisticated screening exam may better indicate those at the greatest risk of death. For example, weighting each category and stratifying the data by country of origin would provide more detailed information. Also, using a validated index, such as the Charles index, and Activities of Daily Living (ADL) modified for the Hajj population may be beneficial (Bannay et al., 2016; Wallace & Shelkey, 2007).

5.5 Using Technology and Innovative Interventions to Optimize Hajj Healthcare Services Inside and Outside the Hospital

To meet the Vision 2030 goal of hosting 30 million annual pilgrims by 2030 (Saudi Vision 2030, 2017), Saudi authorities are turning to technology. In recent years, advanced technology has been used during the Hajj for many purposes, including providing medical services (Al-Tawfiq, & Memish, 2014; Khan, & Shambour, 2018). Saudi authorities are actively invested in upgrading the Hajj experience. Infrastructure has been remodeled, additional transportation (including a world-class train) have been added, and hundreds of mobile apps have been developed to help people who are performing the Hajj or Umrah (Khan, & Noji, 2016; Khan, & Shambour, 2018; "Hajj pilgrims take the metro to Makkah," 2010). In addition, the country hosted the largest Hackathon event in the Middle East last year where 3,000 developers gathered to tackle difficult challenges by producing usable software (Ali, 2018). The hackathon "is a design sprint-like event in which computer programmers and others involved in software development, including graphic designers, interface designers, project managers, and others, often including domain experts, collaborate intensively on software projects" ("Hackathon," 2000). However, several challenges remain, many of which can be overcome by implementing the latest technologies to make this pilgrimage easier for participants and authorities, alike.

Previously, numerous innovative interventions have been proposed in the literature with the potential to substantially evolve the Hajj (Amro, & Nijem, 2012; Fathnan, Wibowo, Hidayat, Marenda, & Ferdiana, 2010; Hameed, 2010; Ibrahim et al., 2012; Nsoesi et al., 2015; Osman & Shaout, 2014; Yusoff, Zulkifli, & Mohamed, 2011). However, many innovative interventions still could be implemented to enhance the medical services provided during the Hajj. Telemedicine is one type of technology that enables expert medical advice to be delivered remotely to serve those in need. In a mass-gathering setting, telemedicine could cover a variety of services, such as ICU, radiology, pathology, and second opinions. In addition to improving the quality of services and increasing access, telemedicine would reduce the cost associated with providing healthcare during the Hajj (De La Torre-Díez, López-Coronado, Vaca, Aguado, & de Castro, 2015). Artificial intelligence is another technology that could have many applications for the Hajj. The amount of data generated during the Hajj could be used to direct hospital staffing, locate primary health centers, and predict the flow of the crowd movement.

The Mobile Stroke Unit (MSU) is another innovative intervention that could have a substantial effect on the Hajj. The MSU is a specialized ambulance equipped with a CT scanner, clinical laboratory, and medications for in-field treatment of neurologic emergencies (Walter et al., 2012). The development of such units stemmed from improved patient outcomes when the time from the onset of stroke symptom to initiating treatment was reduced. As a result, these units allow field medical personnel to reach a definitive diagnosis for medically complex stroke patients on site to rapidly initiate stroke care. A significant number of pilgrims are admitted to the emergency room due to medical complications (Madani et al., 2006). Strokes have a high incidence of avoidable medical complications during the Hajj. Ischemic Strokes accounted for approximately 80.3% of all strokes during the Hajj (Table 5.3). The high traffic during this event creates an obstacle for ambulances to transport stroke patients to the hospital in a timely manner. The MSU could overcome this issue to confirm the diagnosis and initiate thrombolytic treatment faster, which could significantly reduce the morbidity and mortality associated with stroke cases (Fisher & Saver, 2015).

5.6 Conclusion

In conclusion, preexisting chronic diseases are an important public health problem that warrants proper consideration of associated outcomes. Although quantifying the problem has many challenges, different studies and interventions could be adopted in the future to optimize healthcare services during the Hajj and enhance their quality. Pairing longitudinal studies with a novel epidemiological methodology, such as mediation analysis and computational methods, could estimate total and partial effects of factors related to attending the Hajj. Moreover, adopting existing frameworks, such as the Donabedian or IOM model and using a variety of outcomes in addition to mortality rate (such as morbidity, length of stay, patients' satisfaction, and service accessibility) as indicators of quality is crucial.

Finally, the Saudi authorities, in collaboration with the other Muslim countries' governments and international organizations, can mandate a screening exam in order to issue Hajj entry visas. However, restricting access to the Hajj based on health status is not an option (Memish et al., 2016). Instead, education of pilgrims and preparation by the Saudi authorities can minimize the morbidity and mortality associated with such preexisting chronic diseases during the Hajj.

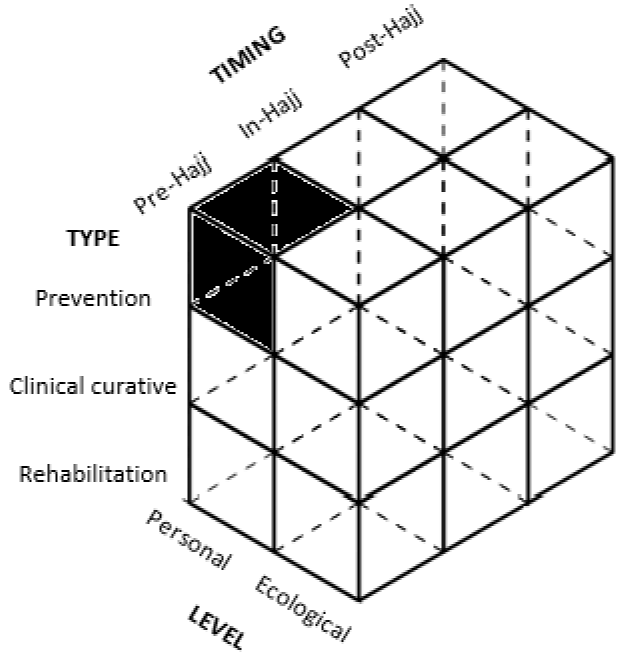


Figure 5.1 Conceptual model for the organization of activities in the Hajj. The Black cube represents the pre-Hajj screening exam for preexisting chronic diseases. Adapted from “In War Time: Options for Epidemiology,” by H. K. Armenian, 1986, *American Journal of Epidemiology*, 124, p. 28. Copyright 1986 by The Johns Hopkins School of Hygiene and Public Health. Reprinted with permission.

Table 5.1
Prevalence, adjusted odds ratios for inpatients all-causes mortality and controls in Makkah and sacred sites hospitals during the Hajj by risk score. (2012 – 2017)*

Score	Mortality cases	Controls	Adjusted OR	(95% CI)
	n (%)	**n (%)**		
0	313 (14.0)	851 (19.0)	1	
1	751 (33.6)	1,691 (37.8)	1.21**	(1.03 – 1.41)
2	663 (29.6)	1,277 (28.5)	1.41	(1.20 – 1.66)
3	353 (15.8)	455 (10.2)	2.11**	(1.74 – 2.55)
4	125 (5.6)	156 (3.5)	2.18**	(1.67 – 2.85)
5	32 (1.4)	44 (1.0)	1.98	(1.23 – 3.18)

*Hajj 2015 was excluded.
** p-value < 0.05
Note. CI=confidence interval.

Table 5.2
Prevalence, adjusted odds ratios for inpatients all-causes mortality and controls in Makkah and sacred sites hospitals during the Hajj by risk category. (2012 – 2017)*

Risk category	Mortality cases	Controls	Adjusted OR	(95% CI)
	n (%)	**n (%)**		
High	510 (43.8)	655 (56.2)	1.72**	(1.51 - 1.96)
Low	1727 (31.1)	3819 (68.9)	1	

*Hajj 2015 was excluded.
** p-value < 0.05
Note. CI=confidence interval.

Table 5.3
Distribution of stroke cases in Makkah and sacred sites hospitals during the Hajj by Stroke type. (2012 – 2017)*

Year	Ischemic Stroke			Hemorrhagic Stroke		
	Makkah	**Sacred sites**	**Total**	**Makkah**	**Sacred sites**	**Total**
2012	92	44	136	27	8	35
2013	66	17	83	23	9	32
2014	73	8	81	11	0	11
2016	61	21	82	19	1	20
2017	108	22	130	28	2	30

*Hajj 2015 was excluded.

Appendix A

Table A1

Total number of pilgrims (percentage) coming to Hajj by year and resident status (2012 – 2017). (Saudi General Authority for Statistics [GAS]).

Year	Total pilgrims	Domestic pilgrims	(%)	International pilgrims	(%)
2012	3,161,573	1,408,641	(45)	1,752,932	(55)
2013	1,980,249	600,718	(30)	1,379,531	(70)
2014	2,085,238	696,185	(33)	1,389,053	(67)
2015	1,952,817	567,876	(29)	1,384,941	(71)
2016	1,862,909	537,537	(29)	1,325,372	(71)
2017	2,352,122	600,108	(26)	1,752,014	(74)
Mean	2,232,485	735,178	-	1,497,307	-

Table A2

International pilgrims coming to the Hajj by year and point of entry (2012 – 2017). (Saudi Ministry of Health [MOH])

Year	Airports	Land-ports	Seaports	Total
	Number of pilgrims (%)			
2012	1,621,982 (92.5)	113,020 (6.5)	17930 (1.0)	1,752,932
2013	1,292,098 (93.6)	72,535 (5.3)	14898 (1.1)	1,379,531
2014	1,315,850 (94.7)	59,204 (4.3)	13.999 (1.0)	1,389,053
2015	1,334,247 (96.4)	37,771 (2.7)	12,923 (0.9)	1,384,941
2016	1,246,883 (94.0)	65,766 (5.0)	12,723 (1.0)	1,325,372
2017	1,648,332 (94.1)	88,855 (5.1)	14,827 (0.8)	1,752,014

Table A3
Domestic pilgrims coming to the Hajj by year, nationality, and gender (2012 – 2017). (Saudi MOH)

Year	Total domestic pilgrims	Saudis		Total Saudis	Non-Saudis		Total non-Saudis
		Females	Males		Females	Males	
2012	1,408,641	120,934	207,589	328,523	207,337	872,781	1,080,118
2013	600,718	68,700	119,943	188,643	113,159	298,916	412,075
2014	696,185	90,928	146,095	237,023	121,373	337,789	459,162
2015	567,876	81,150	112,495	193,645	109,894	264,337	374,231
2016	537,537	71,389	99,103	170,492	107,725	259,320	367,045
2017	600,108	89,052	120,363	209,415	117,345	273,348	390,693
Total	4,411,065	522,153	805,588	1,327,741	776,833	2,306,491	3,083,324

Table A4
International pilgrims coming to the Hajj by year and gender (2012 – 2017). (Saudi MOH)

Years	Total international pilgrims	Females	Males
2012	1,752,932	801,126	951,806
2013	1,379,531	627,107	752,424
2014	1,389,053	631,014	758,039
2015	1,384,941	634,377	750,564
2016	1,325,372	601,567	723,805
2017	1,752,014	811,645	940,369
Total	8,983,843	4,106,836	4,877,007

Table A5
Number of visits to healthcare facilities (rate) during the Hajj by year, type of facility, and city (2012 – 2017). (Saudi MOH)

Year	**Primary healthcare**				**Emergency room**				**Outpatient clinics**			
	Makkah	**Sacred Sites**	**Total**	**Rate***	**Makkah**	**Sacred Sites**	**Total**	**Rate***	**Makkah**	**Sacred Sites**	**Total**	**Rate***
2012	164,333	341,420	505,753	160	33,645	16,486	50,131	16	45,891	90,256	136,147	43
2013	101,158	244,484	345,642	175	16,624	8,556	25,180	13	42,151	81,536	123,687	62
2014	77,733	215,210	292,943	140	9,317	11,341	20,658	10	36,461	92,089	128,550	62
2015	87,785	139,039	226,824	116	14,233	9,153	23,386	12	23,336	46,959	70,295	36
2016	60,689	243,035	303,724	163	9,252	5,590	14,842	8	14,328	52,085	66,413	36
2017	52,825	145,212	225,037	94	8,427	4,834	15,648	7	13,287	48,725	65,921	28
Total	544,523	1,328,400	1,899,923	142	91,498	55,960	149,845	11	175,454	411,650	591,013	44

*Per 1,000 pilgrims

Table A6
Healthcare providers devoted to the Hajj by year and type (2012 – 2017). (Saudi MOH)

Year	Physicians	Nurses	Other HCWs*	Total
2012	3636	6375	11941	21952
2013	4171	6825	12636	23632
2014	4344	6611	13085	24040
2015	4533	7441	14385	26359
2016	4383	8202	13836	26421
2017	4391	8196	14034	26621

* Other healthcare workers included pharmacists, allied health personnel, administrative personnel, engineers, workers, and drivers.

Table A7
Number of beds in the Hajj hospitals by year and city (2012 – 2017). (Saudi MO)

Year	Number of beds		
	Makkah	Sacred Sites	Total
2012	2068	1449	3517
2013	2068	1449	3517
2014	1732	1528	3260
2015	2737	1316	4053
2016	2457	1532	3989
2017	2457	1675	4132

Table A8

Number of healthcare facilities serving the Hajj by year, type, and city (2012 – 2017). (Saudi MOH)

Year	Makkah			Sacred Sites	
	Permanent Hospital	Permanent HCs*	Seasonal HCs*	Seasonal Hospital	Seasonal HCs*
2012	8	31	12	8	96
2013	8	31	12	8	96
2014	8	31	12	8	96
2015	8	31	15	8	112
2016	8	29	12	8	94
2017	8	29	12	8	101

*HCs: Healthcare centers

Table A9

Number of patients discharged from hospitals of the Hajj by year and city (2012 – 2017).*

Year	Makkah	(%)	Sacred sites	(%)	Total
2012	5,408	(65.8)	2,805	(34.2)	8,213
2013	3,927	(69.5)	1,722	(30.5)	5,649
2014	4,387	(67.2)	2,141	(32.8)	6,528
2016	4,913	(71.6)	1,951	(28.4)	6,864
2017	4,756	(68.9)	2,150	(31.1)	6,906
Total	23,391	(68.5)	10,769	(31.5)	34,160

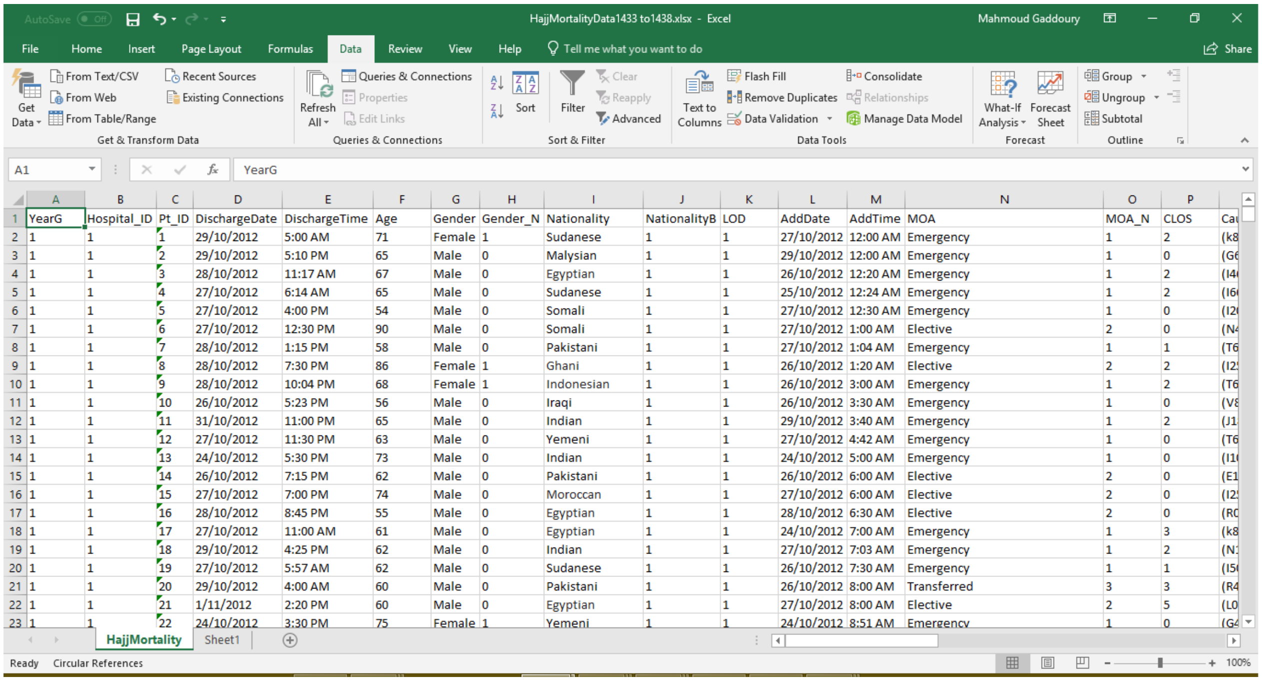
*Hajj 2015 was excluded

Appendix B

Table B1

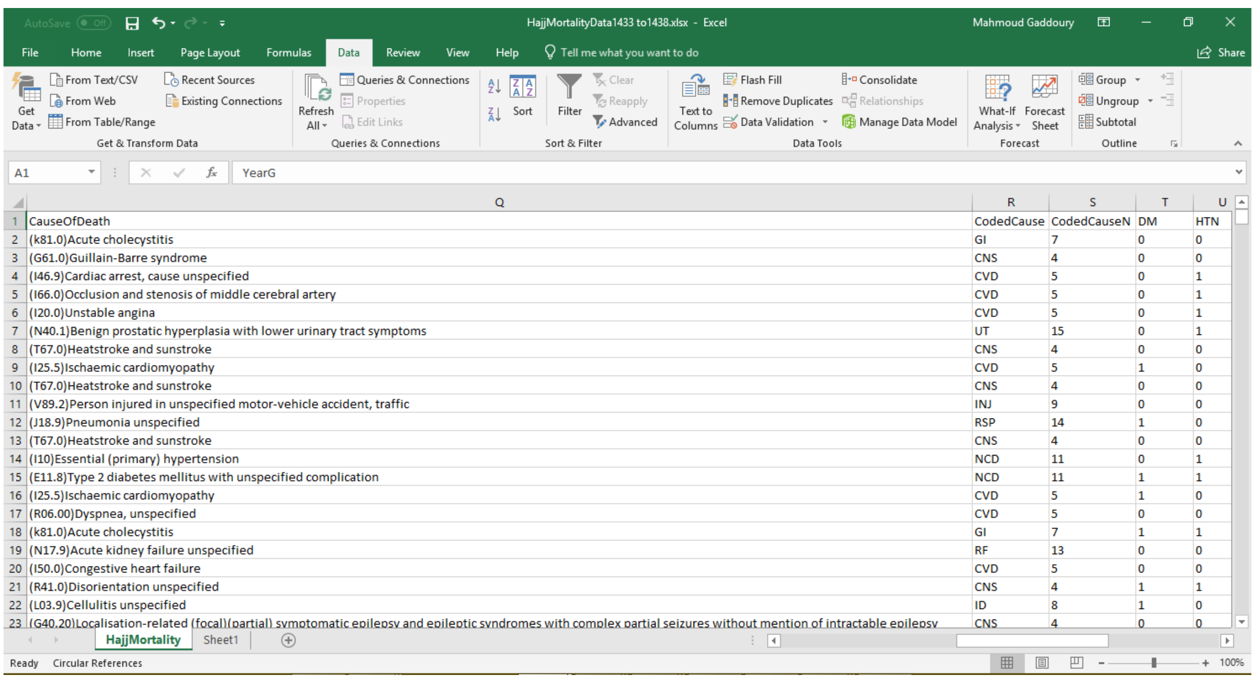
Hospitals included in the study by city.

City	Hospital Name
Makkah	
	Al-Nour Specialty Hospital
	Hera'a General Hospitals
	King Abdulaziz Hospital
	King Faisal Hospital
Arafat	
	Arafat General Hospital
	East Arafat Hospital
	Jabal Alrahmah Hospital
	Namira Hospital
Mina	
	Mina Aljisr Hospital
	Mina Altawarea Hospital
	Mina Alwadi Hospital
	Mina Sharea Jadid Hospital



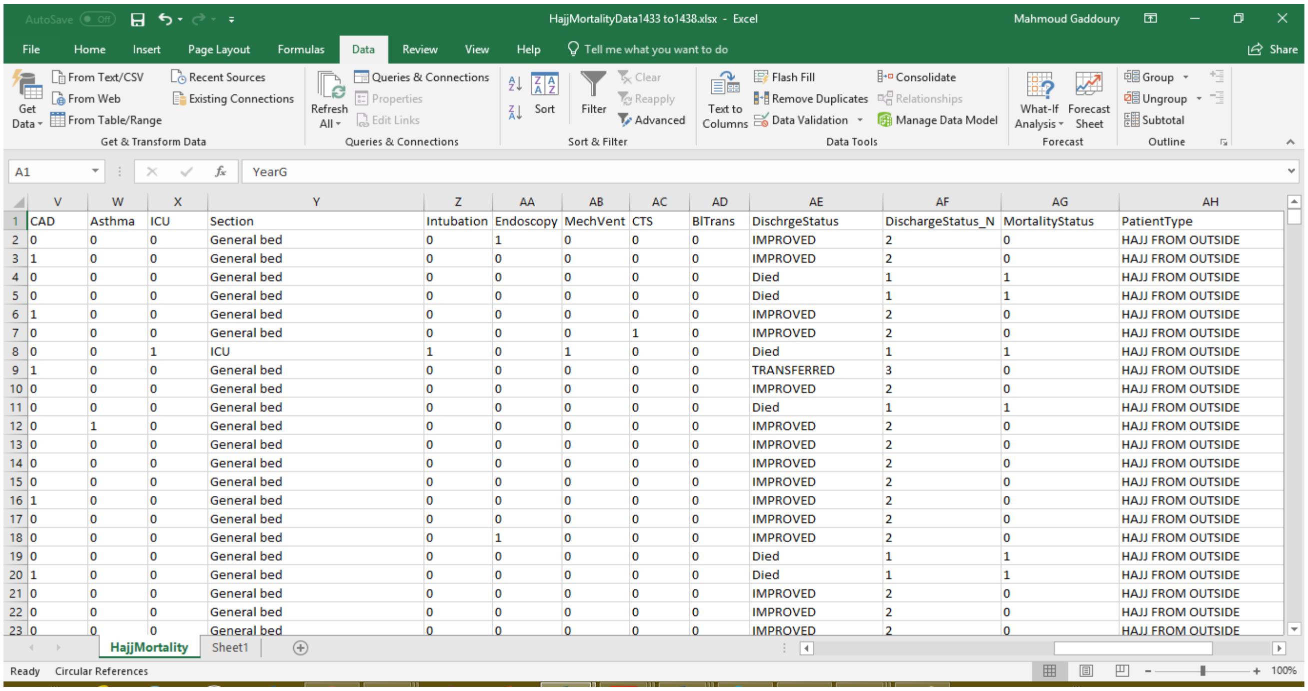
	YearG	Hospital_ID	Pt_ID	DischargeDate	DischargeTime	Age	Gender	Gender_N	Nationality	NationalityB	LOD	AddDate	AddTime	MOA	MOA_N	CLOS	Cau
2	1	1	1	29/10/2012	5:00 AM	71	Female	1	Sudanese	1	1	27/10/2012	12:00 AM	Emergency	1	2	(k8
3	1	1	2	29/10/2012	5:10 PM	65	Male	0	Malysian	1	1	29/10/2012	12:00 AM	Emergency	1	0	(G6
4	1	1	3	28/10/2012	11:17 AM	67	Male	0	Egyptian	1	1	26/10/2012	12:20 AM	Emergency	1	2	(I4
5	1	1	4	27/10/2012	6:14 AM	65	Male	0	Sudanese	1	1	25/10/2012	12:24 AM	Emergency	1	2	(I6
6	1	1	5	27/10/2012	4:00 PM	54	Male	0	Somali	1	1	27/10/2012	12:30 AM	Emergency	1	0	(I2
7	1	1	6	27/10/2012	12:30 PM	90	Male	0	Somali	1	1	27/10/2012	1:00 AM	Elective	2	0	(N4
8	1	1	7	28/10/2012	1:15 PM	58	Male	0	Pakistani	1	1	27/10/2012	1:04 AM	Emergency	1	1	(T6
9	1	1	8	28/10/2012	7:30 PM	86	Female	1	Ghani	1	1	26/10/2012	1:20 AM	Elective	2	2	(I2
10	1	1	9	28/10/2012	10:04 PM	68	Female	1	Indonesian	1	1	26/10/2012	3:00 AM	Emergency	1	2	(T6
11	1	1	10	26/10/2012	5:23 PM	56	Male	0	Iraqi	1	1	26/10/2012	3:30 AM	Emergency	1	0	(V8
12	1	1	11	31/10/2012	11:00 PM	65	Male	0	Indian	1	1	29/10/2012	3:40 AM	Emergency	1	2	(J1
13	1	1	12	27/10/2012	11:30 PM	63	Male	0	Yemeni	1	1	27/10/2012	4:42 AM	Emergency	1	0	(T6
14	1	1	13	24/10/2012	5:30 PM	73	Male	0	Indian	1	1	24/10/2012	5:00 AM	Emergency	1	0	(I1
15	1	1	14	26/10/2012	7:15 PM	62	Male	0	Pakistani	1	1	26/10/2012	6:00 AM	Elective	2	0	(E1
16	1	1	15	27/10/2012	7:00 PM	74	Male	0	Moroccan	1	1	27/10/2012	6:00 AM	Elective	2	0	(I2
17	1	1	16	28/10/2012	8:45 PM	55	Male	0	Egyptian	1	1	28/10/2012	6:30 AM	Elective	2	0	(R0
18	1	1	17	27/10/2012	11:00 AM	61	Male	0	Egyptian	1	1	24/10/2012	7:00 AM	Emergency	1	3	(k8
19	1	1	18	29/10/2012	4:25 PM	62	Male	0	Indian	1	1	27/10/2012	7:03 AM	Emergency	1	2	(N1
20	1	1	19	27/10/2012	5:57 AM	62	Male	0	Sudanese	1	1	26/10/2012	7:30 AM	Emergency	1	1	(I5
21	1	1	20	29/10/2012	4:00 AM	60	Male	0	Pakistani	1	1	26/10/2012	8:00 AM	Transferred	3	3	(R4
22	1	1	21	1/11/2012	2:20 PM	60	Male	0	Egyptian	1	1	27/10/2012	8:00 AM	Elective	2	5	(L0
23	1	1	22	24/10/2012	3:30 PM	75	Female	1	Yemeni	1	1	24/10/2012	8:51 AM	Emergency	1	0	(G4

Figure B2: Snapshot of Microsoft Excel sheet used for data collection.



	CauseOfDeath	CodedCause	CodedCauseN	DM	HTN
2	(k81.0)Acute cholecystitis	GI	7	0	0
3	(G61.0)Guillain-Barre syndrome	CNS	4	0	0
4	(I46.9)Cardiac arrest, cause unspecified	CVD	5	0	1
5	(I66.0)Occlusion and stenosis of middle cerebral artery	CVD	5	0	1
6	(I20.0)Unstable angina	CVD	5	0	1
7	(N40.1)Benign prostatic hyperplasia with lower urinary tract symptoms	UT	15	0	1
8	(T67.0)Heatstroke and sunstroke	CNS	4	0	0
9	(I25.5)Ischaemic cardiomyopathy	CVD	5	1	0
10	(T67.0)Heatstroke and sunstroke	CNS	4	0	0
11	(V89.2)Person injured in unspecified motor-vehicle accident, traffic	INJ	9	0	0
12	(J18.9)Pneumonia unspecified	RSP	14	1	0
13	(T67.0)Heatstroke and sunstroke	CNS	4	0	0
14	(I10)Essential (primary) hypertension	NCD	11	0	1
15	(E11.8)Type 2 diabetes mellitus with unspecified complication	NCD	11	1	1
16	(I25.5)Ischaemic cardiomyopathy	CVD	5	1	0
17	(R06.00)Dyspnea, unspecified	CVD	5	0	0
18	(k81.0)Acute cholecystitis	GI	7	1	1
19	(N17.9)Acute kidney failure unspecified	RF	13	0	0
20	(I50.0)Congestive heart failure	CVD	5	0	0
21	(R41.0)Disorientation unspecified	CNS	4	1	1
22	(L03.9)Cellulitis unspecified	ID	8	1	0
23	(G40.20)Localisation-related (focal)(partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures without mention of intractable epilepsy	CNS	4	0	0

Figure B3: Snapshot of Microsoft Excel sheet used for data collection.



	CAD	Asthma	ICU	Section	Intubation	Endoscopy	MechVent	CTS	BlTrans	DischrgeStatus	DischargeStatus_N	MortalityStatus	PatientType
2	0	0	0	General bed	0	1	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
3	1	0	0	General bed	0	0	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
4	0	0	0	General bed	0	0	0	0	0	Died	1	1	HAJJ FROM OUTSIDE
5	0	0	0	General bed	0	0	0	0	0	Died	1	1	HAJJ FROM OUTSIDE
6	1	0	0	General bed	0	0	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
7	0	0	0	General bed	0	0	0	1	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
8	0	0	1	ICU	1	0	1	0	0	Died	1	1	HAJJ FROM OUTSIDE
9	1	0	0	General bed	0	0	0	0	0	TRANSFERRED	3	0	HAJJ FROM OUTSIDE
10	0	0	0	General bed	0	0	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
11	0	0	0	General bed	0	0	0	0	0	Died	1	1	HAJJ FROM OUTSIDE
12	0	1	0	General bed	0	0	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
13	0	0	0	General bed	0	0	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
14	0	0	0	General bed	0	0	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
15	0	0	0	General bed	0	0	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
16	1	0	0	General bed	0	0	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
17	0	0	0	General bed	0	0	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
18	0	0	0	General bed	0	1	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
19	0	0	0	General bed	0	0	0	0	0	Died	1	1	HAJJ FROM OUTSIDE
20	1	0	0	General bed	0	0	0	0	0	Died	1	1	HAJJ FROM OUTSIDE
21	0	0	0	General bed	0	0	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
22	0	0	0	General bed	0	0	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE
23	0	0	0	General bed	0	0	0	0	0	IMPROVED	2	0	HAJJ FROM OUTSIDE

Figure B4: Snapshot of Microsoft Excel sheet used for data collection.

Table B5
Distribution of pilgrims included in the dataset by Geographic region and Country.

Geographic region	
Arab Countries	**Africa**
Algeria	Benin
Bahrain	Burkina Faso
Egypt	Chad
Iraq	Cameroon
Jordon	Ethiopia
Kuwait	Gambia
Lebanon	Ghana
Libya	Guinea
Mauritania	Ivory Coast
Morocco	Kenya
Oman	Niger
Palestine	Nigeria
Saudi Arabia	Senegal
Somalia	South Africa
Sudan	Tanzania
Syria	Togo
Tunisia	Uganda
Yemen	
Central and East Asia	**South Asia**
Afghanistan	Bangladesh
China	India
Iran	Maldives
Kazakhstan	Nepal
Tajikistan	Pakistan
Turkmenistan	Sri Lanka
Uzbekistan	
Southeast Asia	**Europe**
Indonesia	Belgium
Malaysia	Britain
Myanmar (Burma)	Germany
Philippines	France
Singapore	Netherland
Thailand	Russia
	Turkey
North America	
USA	
Canada	

Table B6
Grading of Makkah and sacred sites hospitals during the Hajj by bed-to-nurse ratio and bed-to-doctor ratio (2012 - 2017). *

Bed-to-nurse ratio hospital grade	**Bed-to-doctor ratio hospital grade**			
	1	**2**	**3**	**Total**
	n (%)	**n (%)**	**n (%)**	**N (%)**
1	20 (33.3)	3 (5.0)	0 (0.0)	23 (38.3)
2	10 (16.6)	9 (15.0)	1 (1.6)	20 (33.3)
3	0 (0.0)	11 (18.3)	6 (10.0)	17 (28.3)
Total	30 (50.0)	23 (38.3)	7 (11.6)	60

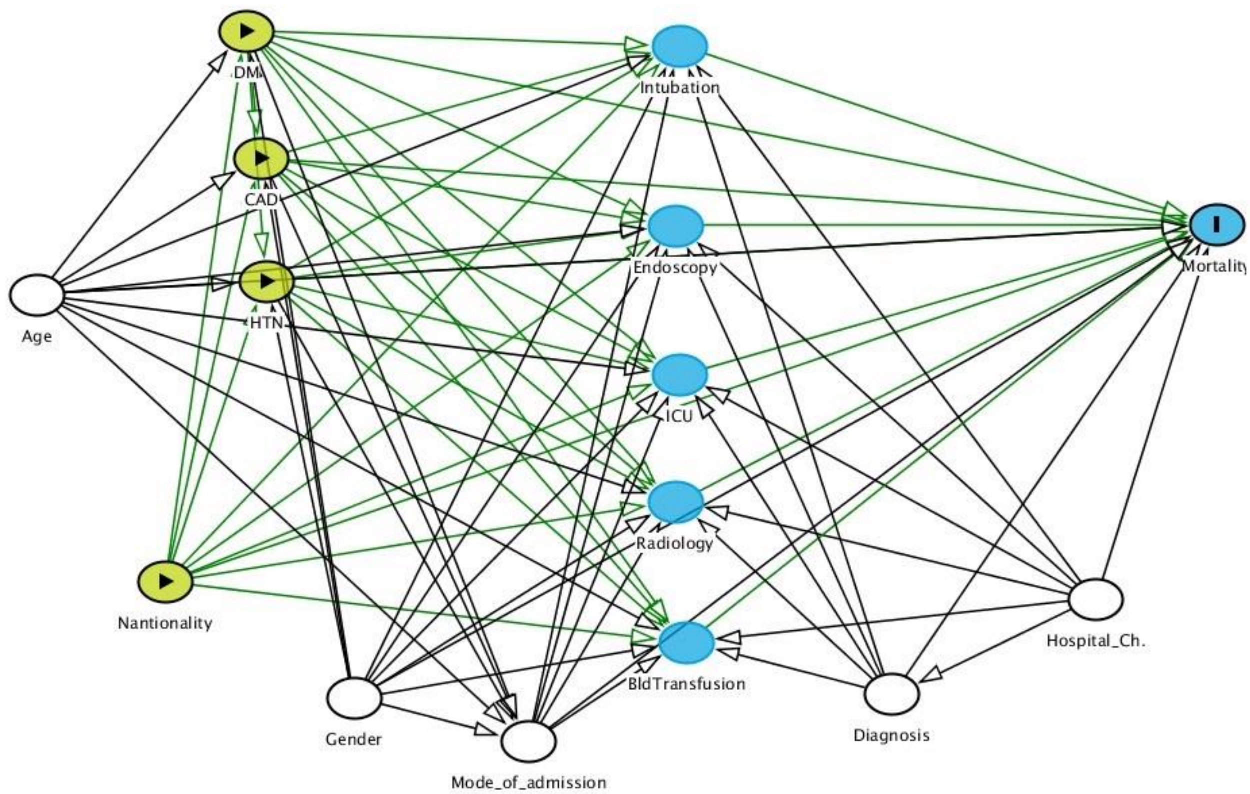
*Hajj 2015 was excluded

- Caution
- Extreme Caution
- Danger
- Extreme Danger

		temperature (°C)																
		27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43
Relative Humidity (%)	40	27	28	29	30	31	32	34	35	37	39	41	43	46	48	51	54	57
	45	27	28	29	30	32	33	35	37	39	41	43	46	49	51	54	57	
	50	27	28	30	31	33	34	36	38	41	43	46	49	52	55	58		
	55	28	29	30	32	34	36	38	40	43	46	48	52	55	58			
	60	28	29	31	33	35	37	40	42	45	48	51	55	59				
	65	28	30	32	34	36	39	41	44	48	51	55	59					
	70	29	31	33	35	38	40	43	47	50	54	58						
	75	29	31	34	36	39	42	46	49	53	58							
	80	30	32	35	38	41	44	48	52	57								
	85	30	33	36	39	43	47	51	55									
	90	31	34	37	41	45	49	54										
	95	31	35	38	42	47	51	57										
	100	32	36	40	44	49	54											

Heat stress Index (ºC)	Category	Dangers
27–32	Caution	Fatigue possible with prolonged exposure and/or physical activity
32–41	Extreme caution	Sunstroke, heat cramps and heat exhaustion possible with prolonged exposure and/or physical activity
41–54	Danger	Sun stroke, heat cramps or heat exhaustions likely, and heatstroke possible with prolonged exposure and/or physical activity
Above 54	Extreme danger	Heat/sunstroke highly likely with continued exposure

Figure B7: NOAA's National Weather Service (NWS) Heat Index Categorization. Adapted from Occupational Safety and Health Administration (OSHA), n.d., Retrieved July 16, 2018, from https://www.osha.gov/SLTC/heatillness/heat_index/pdfs/all_in_one.pdf



CAD: Cardiovascular diseases. HTN: Blood hypertension. DM: Diabetes mellitus. Hospital_Ch: Hospital characteristics.

Figure B8: Diagram of general relations of structure, process and outcome variables included in the study

Appendix C

Table C1
Sensitivity analysis to assess the impact of SES as confounder on the association of preexisting chronic diseases and inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj. (2012-2017).*

Preexisting chronic diseases	**Without adjustment for SES**		**With adjustment for SES**	
	Adjusted OR***	(95% CI)	SES Adjusted OR	(95% CI)
Diabetes mellitus	1.44	(1.27 - 1.63)	1.43	(1.28 - 1.61)
Hypertension	1.34	(1.17 - 1.53)	1.36	(1.20 - 1.57)
Cardiovascular diseases	1.32	(1.14 - 1.53)	1.41	(1.23 - 1.58)

*Hajj 2015 was excluded

Table C2
Sensitivity analysis to assess the impact of non-differential misclassification of diabetes mellitus on its relation inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj. (2012-2017).**

Sensitivity	**Specificity**	**Corrected OR***
0.90	1	1.41
0.80	1	1.41
1	0.90	1.75
1	0.80	4.77
0.90	1	1.41
0.80	1	1.41
0.90	0.90	1.75
0.80	0.80	4.77

*Uncorrected odds ratio estimate is 1.60 (95% confidence interval 1.43–1.80).
**Hajj 2015 was excluded

Table C3
Sensitivity analysis to assess the impact of non-differential misclassification of hypertension on its relation inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj. (2012-2017).**

Sensitivity	Specificity	Corrected OR*
0.90	1	1.40
0.80	1	1.40
1	0.90	1.93
1	0.80	2.04
0.90	1	1.40
0.80	1	1.40
0.90	0.90	1.93
0.80	0.80	2.04

*Uncorrected odds ratio estimate is 1.54 (95% confidence interval 1.35–1.74).
**Hajj 2015 was excluded

Table C4
Sensitivity analysis to assess the impact of non-differential misclassification of cardiovascular diseases on its relation inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj. (2012-2017).**

Sensitivity	Specificity	Corrected OR*
0.90	1	1.44
0.80	1	1.44
1	0.90	2.65
1	0.80	0.06
0.90	1	1.44
0.80	1	1.44
0.90	0.90	2.65
0.80	0.80	0.06

*Uncorrected odds ratio estimate is 1.56 (95% confidence interval 1.35–1.77).
**Hajj 2015 was excluded

Table C5
Prevalence, crude and adjusted odds ratios for inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj by medical services provided for selected nationalities (2012-2017).*

Medical services	Mortality cases n (%)	Controls n (%)	Crude OR	(95% CI)	AOR ***	(95% CI)
Indonesia						
ICU Admission						
Yes	235 (51.8)	38 (8.0)	10.69**	(7.33 – 15.57)	12.31**	(0.34 – 440.93)
No	253 (48.2)	435 (92.0)	1		1	
Intubation						
Yes	80 (16.4)	28 (5.9)	3.14**	(2.00 – 4.94)	0.51	(0.18 – 1.39)
No	408 (83.6)	445 (94.1)	1		1	
Endoscopy						
Yes	33 (6.8)	34 (7.2)	0.94	(0.57 – 1.54)	1.10	(0.61 – 1.94)
No	455 (93.2)	439 (92.8)	1		1	
Radiology imaging						
Yes	100 (20.5)	53 (11.2)	2.03**	(1.41 – 2.92)	2.36**	(1.26 – 4.42)
No	388 (79.5)	420 (88.8)	1		1	
Blood transfusion						
Yes	31 (6.3)	13 (2.8)	2.38**	(1.23 – 4.61)	2.85**	(1.33 – 6.10)
No	457 (93.7)	460 (97.2)	1		1	
India						
ICU Admission						
Yes	114(40.3)	20 (4.0)	16.78**	(10.10 – 27.89)	23.37**	(9.16 – 59.65)
No	169 (59.7)	496 (96.0)	1		1	
Intubation						
Yes	40 (14.1)	12 (2.3)	6.93**	(3.56 – 13.46)	0.39	(0.13 – 1.16)
No	243 (85.9)	504 (97.7)	1		1	
Endoscopy						
Yes	9 (3.2)	28 (5.4)	0.58	(0.27 – 1.26)	1.21	(0.43 – 3.45)
No	274 (96.8)	488 (94.6)	1		1	
Radiology imaging						

Yes	30 (10.6)	64 (12.4)	0.84	(0.52 – 1.33)	1.32	(0.52 – 3.34)
No	253 (89.4)	452 (87.6)	1		1	
Blood transfusion						
Yes	8 (2.8)	4 (0.8)	3.90**	(1.16 – 13.12)	16.53**	(3.19 – 85.65)
No	275 (97.2)	512 (99.2)	1		1	
Pakistan						
ICU Admission						
Yes	78 (36.4)	24 (5.3)	10.21**	(6.21 – 16.79)	13.84**	(4.23 – 45.29)
No	136 (63.6)	433 (94.7)	1		1	
Intubation						
Yes	27 (12.6)	9 (2.0)	7.35**	(3.38 – 15.99)	1.31	(0.34 – 5.06)
No	187 (87.4)	448 (98.0)	1		1	
Endoscopy						
Yes	12 (5.6)	31 (6.8)	0.85	(0.42 – 1.70)	1.02	(0.47 – 2.19)
No	202 (94.4)	426 (93.2)	1		1	
Radiology imaging						
Yes	44 (20.6)	71 (15.5)	1.39	(0.92 – 2.12)	1.46	(0.54 – 3.98)
No	170 (79.4)	386 (84.5)	1		1	
Blood transfusion						
Yes	8 (3.7)	11 (2.4)	1.50	(0.59 -3.80)	2.75**	(1.57 – 4.83)
No	206 (96.3)	446 (97.6)	1		1	
Egypt						
ICU Admission						
Yes	74 (38.3)	20 (5.7)	10.47**	(6.09 – 17.99)	10.61**	(2.20 – 51.10)
No	119 (61.7)	331 (94.3)	1		1	
Intubation						
Yes	30 (15.5)	12 (3.4)	5.36**	(2.67 – 10.86)	0.34**	(0.12 – 0.98)
No	163 (84.5)	339 (96.6)	1		1	
Endoscopy						
Yes	17 (8.8)	17 (4.8)	1.99	(0.98 – 4.01)	3.91**	(2.26 – 6.77)
No	176 (91.2)	334 (95.2)	1		1	
Radiology imaging						
Yes	33 (17.1)	39 (11.1)	1.67**	(1.01 – 2.76)	1.39	(0.71 – 2.73)

No	160 (82.9)	312 (88.9)	1		1	
Blood transfusion						
Yes	7 (3.6)	6 (1.7)	2.31	(0.76 – 7.10)	3.89	(0.73 – 20.63)
No	186 (96.4)	345 (98.3)	1		1	
Bangladesh						
ICU Admission						
Yes	52 (38.0)	31 (9.1)	6.14**	(3.70 – 10.19)	7.11	(1.52 – 33.39)
No	85 (62.0)	310 (90.9)	1		1	
Intubation						
Yes	16 (11.7)	16 (4.7)	2.69**	(1.31 – 5.56)	0.54**	(0.30 – 0.97)
No	121 (88.3)	325 (95.3)	1		1	
Endoscopy						
Yes	5 (3.7)	14 (4.1)	0.89	(0.31 – 2.53)	1.59	(0.46 – 5.51)
No	132 (96.3)	327 (95.9)	1		1	
Radiology imaging						
Yes	20 (14.6)	39 (11.4)	1.36	(0.76 – 2.45)	1.37	(0.79 – 2.38)
No	117 (85.4)	302 (88.7)	1		1	
Blood transfusion						
Yes	4 (2.9)	3 (0.9)	3.42	(0.75 – 15.53)	12.60**	(1.11 – 143.09)
No	133 (97.1)	338 (99.1)	1		1	
Turkey						
ICU Admission						
Yes	25 (37.3)	15 (7.1)	7.90**	(3.83 – 16.30)	15.48**	(9.53 – 25.12)
No	42 (62.7)	197 (92.9)	1		1	
Intubation						
Yes	7 (10.5)	9 (4.3)	2.62	(0.94 – 7.34)	0.46	(0.17 – 1.19)
No	60 (89.5)	203 (95.7)	1		1	
Endoscopy						
Yes	5 (7.5)	11 (5.2)	1.46	(0.49 – 4.36)	2.12	(0.21 – 21.64)
No	62 (92.5)	201 (94.8)	1		1	
Radiology imaging						
Yes	11 (16.4)	23 (10.9)	1.61	(0.73 – 3.51)	2.09	(0.42 – 10.36)
No	56 (83.6)	189 (89.1)	1		1	

Blood transfusion						
Yes	2 (3.0)	1 (0.5)	6.50	(0.56 – 74.88)	7.68	(0.001 – 999.00)
No	65 (97.0)	211 (99.5)	1		1	
Nigeria						
ICU Admission						
Yes	12 (20.7)	4 (2.3)	11.08**	(3.29 – 37.26)	17.34	(1.06 – 285.02)
No	46 (79.3)	168 (97.7)	1		1	
Intubation						
Yes	5 (8.6)	2 (1.2)	7.10	(1.31 – 38.41)	4.01	(0.26 – 60.84)
No	53 (91.4)	170 (98.8)	1		1	
Endoscopy						
Yes	3 (5.2)	7 (4.1)	1.37	(0.34 – 5.56)	2.45	(1.21 – 6.28)
No	55 (94.8)	165 (95.9)	1		1	
Radiology imaging						
Yes	10 (17.2)	28 (16.3)	1.03	(0.47 – 2.30)	1.40	(0.07 – 92.18)
No	48 (82.8)	144 (83.7)	1		1	
Blood transfusion						
Yes	1 (1.7)	3 (1.7)	0.78	(0.08 – 7.79)	0.93	(0.01 – 165.73)
No	57 (98.3)	169 (98.3)	1		1	
Morocco						
ICU Admission						
Yes	14 (25.0)	10 (6.5)	5.29**	(2.15 – 13.03)	4.26	(0.71 – 25.59)
No	42 (75.0)	144 (93.5)	1		1	
Intubation						
Yes	6 (10.7)	2 (1.3)	9.76**	(1.88 – 50.56)	0.64	(0.07 – 5.53)
No	50 (89.3)	152 (98.7)	1		1	
Endoscopy						
Yes	1 (1.8)	5 (3.3)	0.50	(0.06 – 4.46)	1.04	(0.01 – 193.43)
No	55 (98.2)	149 (96.7)	1		1	
Radiology imaging						
Yes	9 (16.1)	18 (11.7)	1.44	(0.60 – 3.43)	2.14	(0.37 – 12.30)
No	47 (83.9)	136 (88.3)	1		1	
Blood transfusion						

Yes	1 (1.8)	2 (1.3)	1.71	(0.15 – 20.18)	0.57	(0.002 – 188.14)
No	55 (98.2)	152 (98.7)	1		1	
Saudi Arabia						
ICU Admission						
Yes	23 (34.3)	4 (2.8)	20.62**	(6.58 – 64.61)	54.50**	(24.36 – 121.93)
No	44 (65.7)	138 (97.2)	1		1	
Intubation						
Yes	9 (13.4)	3 (2.1)	7.05**	(1.82 – 27.29)	3.35	(0.01 – 999.00)
No	58 (86.6)	139 (97.9)	1		1	
Endoscopy						
Yes	2 (3.0)	6 (4.2)	0.88	(0.17 – 4.62)	0.70	(0.02 – 27.13)
No	65 (97.0)	136 (95.8)	1		1	
Radiology imaging						
Yes	12 (17.9)	23 (16.2)	1.18	(0.54 – 2.57)	1.65	(0.78 – 3.50)
No	55 (82.1)	119 (83.8)	1		1	
Blood transfusion						
Yes	3 (4.5)	3 (2.1)	2.00	(0.38 – 10.58)	2.87	(0.32 – 25.53)
No	54 (95.5)	139 (97.9)	1		1	
Yemen						
ICU Admission						
Yes	28 (54.9)	5 (4.2)	30.45**	(10.12 – 91.61)	337.22	(4.64 – 999.99)
No	23 (45.1)	113 (95.8)	1		1	
Intubation						
Yes	7 (13.7)	2 (1.7)	9.44	(1.83 – 48.77)	2.26	(0.06 – 90.56)
No	44 (86.3)	116 (98.3)	1		1	
Endoscopy						
Yes	7 (13.7)	6 (5.1)	3.10	(0.96 – 9.74)	1.77	(0.25 – 12.41)
No	44 (86.3)	112 (94.9)	1		1	
Radiology imaging						
Yes	10 (19.6)	17 (14.4)	1.49	(0.63 – 3.56)	2.21	(0.72 – 6.78)
No	41 (80.4)	101 (85.6)	1		1	
Blood transfusion						
Yes	1 (2.0)	5 (4.2)	0.46	(0.05 – 4.04)	4.43	(0.001 – 999.00)

No	50 (98.0)	113 (95.8)	1		1	
Algeria						
ICU Admission						
Yes	17 (36.2)	11 (10.2)	7.14**	(2.79 – 18.28)	9.87	(0.77 – 127.00)
No	30 (63.8)	97 (89.8)	1		1	
Intubation						
Yes	7 (14.9)	7 (6.5)	2.75	(0.89 – 8.53)	0.02	(0.001 – 0.27)
No	40 (85.1)	101 (93.5)	1		1	
Endoscopy						
Yes	2 (4.3)	4 (3.7)	0.96	(0.16 – 5.59)	999	(0.18 – 999.00)
No	45 (95.7)	104 (96.3)	1		1	
Radiology imaging						
Yes	5 (10.6)	7 (6.5)	1.44	(0.42 – 4.97)	3.88	(0.19 – 78.80)
No	42 (89.4)	101 (93.5)	1		1	
Blood transfusion						
Yes	1 (2.13)	0 (0.0)	999.00	(0.01 – 999)	null	null
No	46 (97.9)	108 (100)	1		1	

*Hajj 2015 was excluded.
** p-value < 0.05
***ORs are adjusted for preexisting chronic diseases, age, and gender.

Table C6
Prevalence, crude and adjusted odds ratios for inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj by medical services for ICU patients (2012-2017). *

Medical services	**Mortality cases**	**Controls**	**Crude OR**	**(95% CI)**	**Adjusted OR*** **	**(95% CI)**
	n (%)	n (%)				
ICU Admission						
Intubation						
Yes	296 (32.1)	127 (50.2)	0.47**	(0.35 – 0.62)	0.70	(0.18 – 2.77)
No	626 (67.9)	126 (49.8)	1.00		1.00	
Endoscopy						
Yes	68 (7.4)	9 (3.6)	2.10**	(1.03 – 4.27)	1.50	(0.74 – 3.00)
No	854 (92.6)	244 (96.4)	1.00		1.00	
Radiology imaging						
Yes	193(20.9)	48 (19.0)	1.13	(0.79 – 1.61)	1.70	(0.75 – 3.83)
No	729 (79.1)	205 (81.0)	1.00		1.00	
Blood transfusion						
Yes	67 (7.3)	9 (3.6)	2.08**	(1.02 – 4.24)	3.42	(0.88 – 13.32)
No	855 (92.7)	244 (96.4)	1.00		1.00	

*Hajj 2015 was excluded
** p-value < 0.05
Note AOR=adjusted odds ratio. CI=confidence interval.
***ORs estimates were results of separate logistic regression models, one for each procedure. All models controlled for age, gender, nationality, hypertension, diabetes, discharge diagnosis, length of stay, mode of admission, time of event, patient residency status, hospital location, hospital of discharge, bed-to-doctor ratio, and bed-to-nurse ratio.

Table C7

Sensitivity analysis to assess the impact of nondifferential misclassification of ICU admission orders on its relation inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj. (2012-2017).**

Sensitivity	Specificity	Corrected OR*
0.90	1	7.32
0.80	1	7.32
1	0.90	7.21
1	0.80	1.49
0.90	1	7.32
0.80	1	7.32
0.90	0.90	7.22
0.80	0.80	1.49

*Uncorrected odds ratio estimate is 7.36 (95% confidence interval 5.74 – 9.34).

**Hajj 2015 was excluded

Table C8

Sensitivity analysis to assess the impact of nondifferential misclassification of intubation orders on its relation inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj. (2012-2017).**

Sensitivity	Specificity	Corrected OR*
0.90	1	4.22
0.80	1	4.22
1	0.90	0.58
1	0.80	0.37
0.90	1	4.22
0.80	1	4.22
0.90	0.90	0.58
0.80	0.80	0.37

*Uncorrected odds ratio estimate is 4.74 (95% confidence interval 3.87–5.80).

**Hajj 2015 was excluded

Table C9
Sensitivity analysis to assess the impact of nondifferential misclassification of endoscopy orders on its relation inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj. (2012-2017).**

Sensitivity	**Specificity**	**Corrected OR***
0.90	1	1.26
0.80	1	1.26
1	0.90	0.74
1	0.80	0.91
0.90	1	1.26
0.80	1	1.26
0.90	0.90	0.74
0.80	0.80	0.91

*Uncorrected odds ratio estimate is 1.26 (95% confidence interval 1.03–1.59).
**Hajj 2015 was excluded

Table C10
Sensitivity analysis to assess the impact of nondifferential misclassification of radiology imaging orders on its relation inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj. (2012-2017).**

Sensitivity	**Specificity**	**Corrected OR***
0.90	1	1.33
0.80	1	1.33
1	0.90	2.39
1	0.80	0.38
0.90	1	1.33
0.80	1	1.33
0.90	0.90	2.39
0.80	0.80	0.38

*Uncorrected odds ratio estimate is 1.40 (95% confidence interval 1.21–1.61).
**Hajj 2015 was excluded

Table C11
Sensitivity analysis to assess the impact of nondifferential misclassification of blood transfusion orders on its relation inpatient all-cause mortality in Makkah and sacred sites hospitals during the Hajj. (2012-2017).**

Sensitivity	Specificity	Corrected OR*
0.90	1	2.47
0.80	1	2.47
1	0.90	0.68
1	0.80	0.85
0.90	1	2.47
0.80	1	2.47
0.90	0.90	0.68
0.80	0.80	0.85

*Uncorrected odds ratio estimate is 2.54 (95% confidence interval 1.88–3.42).
**Hajj 2015 was excluded

Appendix D

Assumptions

Sample size: 6,705
Control to cases ratio 2:1
Detected odd ratios: 1.1 1.3 1.5

Procedure

```
proc power;
twosamplefreq test=pchi
oddsratio = 1.1 1.3 1.5
alpha=0.05
sides=2
refproportion = (exposed controls)
power = .
ntotal = 6705
groupweight = (2 1);
run;
```

Table D1
Power Analysis for Chapter 3: "Inpatient All-Cause Mortality and Selected Medical Services as a Proxy of the Quality of the Services in the Hajj Hospitals"

Exposure variable	**P0**	**Power**		
		OR=1.1	**OR=1.3**	**OR=1.5**
DM	26%	0.367	0.995	0.999
HTN	22%	0.343	0.991	0.999
CAD	15%	0.271	0.963	0.999

Table D2
Power Analysis for Chapter 4: "Inpatient All-Cause Mortality and Selected Medical Services as a Proxy of the Quality of the Services in the Hajj Hospitals."

Exposure variable	**P0**	**Power**		
		OR=1.1	**OR=1.3**	**OR=1.5**
ICU	6%	0.147	0.729	0.982
Intubation	4%	0.115	0.572	0.921
Endoscopy	5%	0.131	0.658	0.962
Radiology imaging	13%	0.247	0.946	0.999
Blood transfusion	2%	0.087	0.344	0.689

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