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Analyses of Foodborne Disease Outbreaks during Hajj, Makkah, Kingdom of Saudi Arabia, 2009 – 2011

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An abstract of

A thesis submitted to the Faculty of the

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ABSTRACT

PURPOSE: The Hajj is an annual mass gathering where > 1.8 million Muslim pilgrims from 183 countries come to Makkah, Kingdom of Saudi Arabia (KSA) for approximately two weeks. The KSA Ministry of Health (MOH) is responsible for ensuring the early detection and prevention of infectious diseases that can be transmitted among the markedly great number of pilgrims, such as foodborne illnesses. Foodborne illnesses are especially significant public health problems during mass gatherings. From 2009 – 2011, the Hajj Food Safety Unit (FSU) gathered data on all foodborne outbreaks, yet these data have yet to be fully analyzed to determine the underlining risk factors and the best methods for prevention and control of further outbreaks.

METHODS: A review was made of foodborne disease outbreaks (FBDOs) using data gathered by the FSU in Makkah from 2009 – 2011.

RESULTS: During the three Hajj seasons of 2009 through 2011, a total of seven FBDOs were reported with a range of 2 – 45 cases per outbreak, totaling 107 cases. Among these cases, 74 were female (70%) and 33 were male (30%). Egyptians were the most common nationality affected (69%), followed by Saudis, Malaysians, and Turks (23%, 6%, and 2% respectively). The mean age among cases was 46 years with a SD of 16 years.

CONCLUSIONS: This study found a strong relationship between the three largest FBDOs during Hajj and storage conditions and food handling methods reported over the study period. We recommend improving compliance with the Hazard Analysis Critical Control Point program and establish training programs in food safety. The FSU's work should be expanded through the electronic notification system and the reassessment of lab methods used during FBDO investigations.

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Chapter 1: Introduction

Islam originated in the Kingdom of Saudi Arabia (KSA), which is located in the Arabian Peninsula. It has a total area of 2,149,690 sq km and a population of 26,534,504 (1). The country's unique position in the heart of each Muslim individual comes from the fact that it is the home of the two holiest mosques, which are in Makkah and Medina.

The Hajj, the fifth pillar of Islam, is the pilgrimage to Makkah. Performing the Hajj is a religious obligation for all adult Muslims at least once in their lives, provided that they are both physically and financially able to perform it. Every year, millions of Muslims perform Hajj over a 6-day period from the eighth to the thirteenth of Dhul Al-Hijjah, the twelfth month of the Muslim lunar calendar. On the other hand, Umrah (another Muslim ritual to Makkah) can be performed at any time of the year. In 2011, the total number of pilgrims who came from outside the Kingdom was over 1.8 million from 183 counties, most of them arriving by air (2). Every year, these large numbers of Muslims perform their Hajj duties and move between several Hajj sites at approximately the same time in a small area.

Pilgrims generally stay in large groups; this, together with physical exhaustion, extreme heat, and crowded accommodations can lead to an increase in infectious disease, public health hazards, and environmental health issues (3).

A mass gathering (MG) is defined as an event attended by a sufficient number of people at a specific location for a specific purpose for a defined period of time, which mandates a specific planning and availability of certain resources in the community (4). Hajj, the pilgrimage to Makkah in Saudi Arabia, is one of the largest annual MG with unique characteristics, such as

changing seasonal dates based on the lunar Islamic Calendar and a diversity of attendees who come from different parts of the world with different biopsychosocial backgrounds.

Every year, the Saudi Ministry of Health (SMOH) is responsible for ensuring the early detection and prevention of infectious diseases that can be transmitted among the markedly great number of pilgrims. The SMOH has equipped seven hospitals and 74 health care centers at Hajj sites with essential emergency management resources and has staffed them with specialized, well-trained personnel to provide health care to all pilgrims free of charge (5).

Furthermore, as one of the most important health prevention measures, SMOH established requirements for receiving an entry visa to KSA for Hajj or Umra. Visitors from all over the world arriving for the purpose of Umra or Hajj are required to have a certificate of vaccination with the quadrivalent (ACYW135) vaccine against meningitis issued no more than three years prior and not fewer than 10 days before arrival in KSA. In addition, for visitors arriving from countries in the African meningitis belt, ciprofloxacin tablets (500 mg) chemoprophylaxis are administered at the port of entry to reduce the carrier status. The SMOH also recommends that pilgrims be vaccinated against seasonal influenza before arrival, particularly those at higher risk of complications (e.g., the elderly, people with chronic chest or heart diseases, hepatic or renal failure). Finally, certain vaccinations are required for those coming from countries where certain infectious diseases are highly endemic (e.g., yellow fever, poliomyelitis) (6).

1.1 Preventive Medicine Program for Hajj

SMOH has established the Preventive Medicine Program for Hajj, which is composed of two committees:

The Supervisory Committee is a standing committee located in the SMOH that moves its headquarters to Makkah's Public Health Administration, whose duties and functions include:

- Leading the Preventive Medicine Program for Hajj; determining requirements; nominating employees to the program; and implementing field visits to Hajj areas, including the ports before and during Hajj season;
- Preparation of daily reports on the activities of the program during the season and provision of a copy of these reports to the SMOH on a daily basis;
- Preparation of a final report on the Preventive Medicine Hajj Program and submission to the Minister on the morning of Dhu al-Hijah twelfth each year; and
- Evaluation of the program, assessing the needs for the next Hajj season and making recommendations.

The Executive Committee operates for one month from the 15th of Dhul Al-Qedah until the 15th of Dhul Al-Hijjah each year, and is located at the Public Health Administration in Makkah. It consists of 12 units, one of which is the

Food Safety Unit (FSU). The FSU has been a separate unit in the Executive Committee since 2009. The responsibilities of the FSU include the following (7):

- Respond to foodborne disease outbreaks resulting from the ingestion of food from common sources.

- Receive foodborne disease outbreak (FBDO) notifications through the notification channels (e.g., hospitals, polyclinics, the Executive Committee).
- Inspect and evaluate the food preparation sites that belong to each Hamla[1].
- Prepare daily reports on FBDO, including zero reporting and submitting these reports to the Executive Committee.
- Respond to notifications immediately through field visits and interview suspected cases, create case definitions and construct epidemiologic surveillance using tools (e.g., FBDO forms and questionnaire in Epi Info™). Furthermore, the FSU team collects samples from suspected food, water, and food handlers.
- Write a final report for each FBDO and a final report for FSU activities by the end of Hajj season.
- Participate in the training program for the different units working in the Preventive Medicine Program for Hajj.
- Provide health education regarding food safety and healthy food handling.

The SMOH uses national guidelines for detecting, confirming, reporting, and responding to incidents of FBDO. Furthermore, the SMOH uses a translated version of Frank Bryan's book *Procedures to Investigate Foodborne Illness, Fifth Edition* (personal communication, Dr. Tamadur Kurdi, SMOH).

[1] Hamla is the group of campsites under the management of the Ministry of Hajj.

1.2 Rationale

Although acute diarrheal diseases are one of the most common acute medical problems during Hajj, very few studies have described their incidence or etiology. In 2002, a study showed that diarrhea during Hajj ranked as the third most common cause of hospitalization (3). Different definitions for diarrheal illness, underreporting of cases, and the fact that not all cases can be linked to food contribute to an underestimation of FBDOs (8). Furthermore, the increase in FBDOs in the KSA in the summer and during Hajj seasons (9), in which many outbreaks are attributed to poor food handling and storage, reinforces the need for improving healthy behaviors among food handlers and consumers.

1.3 Aim

The purpose of this study is to improve the prevention and control of FBDOs during the Hajj season.

1.4 Objectives

The objectives of the research are to:

1) Describe all foodborne outbreaks investigated by the FSU from 2009 – 2011;
2) Identify risk factors (e.g., type of food, food handling, and storage) for foodborne outbreaks; and
3) Make evidence-based recommendations for improved prevention and control

Chapter 2: Literature Review

Foodborne illnesses are defined as diseases, infectious or toxic, caused by consuming contaminated food. If two or more individuals have this disease as a consequence of consuming food in common, this is considered a foodborne disease outbreak (FBDO). Globally, there are no clear data regarding incidence of foodborne illnesses; however, most of these cases present with acute diarrheal illness, and in 2005, an estimated 1.8 million died from diarrheal illness. Most of the illnesses were caused by consuming contaminated food or drinking water (8). In the United States, approximately 76 million cases of foodborne disease, resulting in 325,000 hospitalizations and 5,000 deaths, occur each year (10). In the KSA, FBDO has become a very important health concern, as the number of cases increases especially during the summer months and Hajj season (11). Salmonella is the pathogen responsible for most outbreaks (12). Furthermore, meat and chicken are the food items causing these outbreaks (11).

There are several factors contributing to the global burden of foodborne illness. The growing proportion of at-risk populations, such as the elderly and the immunosuppressed, suffer severely from foodborne illnesses. In the era of modern international trade, rapid and widespread food distribution has become inevitable. Furthermore, travellers, such as most pilgrims, may be exposed to unfamiliar pathogens. Finally, there is an increase in food consumption from commercial foodservice settings with poor environmental standards including poor hygiene (8). Though most foodborne diseases are sporadic and most FBDOs are not reported to the Public Health department, FBDO surveillance remains the first step in prevention (8).

2.1 FBDO Investigation

Developing the case definition of an outbreak is of paramount importance for the detection of cases of FBDO. This must be accomplished early in the course of an outbreak investigation. Developing the case definition is an effective tool in the prevention of further infectious diseases spread among pilgrims. The case definition can facilitate the determination of suspected or probable cases of the FBDO. A standard questionnaire can be used for interviewing cases as early as possible, therefore limiting the chance of recall bias (i.e., inability of the patients to remember what they ate). At this stage, specimens can be collected from the patients (i.e., stool, rectal swabs, vomitus). Depending on interviews and clinical judgment at the time of the initial assessment, an action plan can be developed. At the same time the presence of a common source of contaminated food, food preparation, and distribution sites can be immediately assessed by expert personnel.

An early hypothesis, which can be revised later in the course of an outbreak, can help the decision maker set forth a plan for action concerning the outbreak. Describing a FBDO in relation to person, place, and time is an important tool to provide important information for disease prevention and control of the outbreak. By interviewing suspected cases using a standard questionnaire, the time of exposure (ingestion) to the suspected meal, and the time of appearance of clinical manifestations (i.e., symptoms and signs of the disease) can be detected, which can be used to determine the Incubation Period (IP). In addition, a standard questionnaire helps the investigative team to determine the geographic distribution of cases in a given place, which can be plotted using certain types of maps, such as the Plot Map. The place determination is of great importance for infectious disease containment. Finally, describing an outbreak by “person” provides valuable knowledge regarding patients’ characteristics (e.g., age, sex, and occupation).

While patients are being interviewed, data from a group of healthy individuals having some characteristics in common with the patients are collected that can be analyzed to confirm an association between specific exposure to certain types of food and the disease under investigation. Retrospective cohort studies and case-control studies are the most commonly used for FBDOs(8). However, during Hajj, because no clearly defined "cohort" of all exposed and non-exposed individuals can be identified, case-control studies are the most commonly used for analyzing the data.

The Hazard Analysis Critical Control Point (HACCP) is the best preventive program in food safety. It is used to determine the possible point of food contamination at each stage of food preparation, processing, and handling. HACCP has proved to be an effective program in food safety and now considered as an important national regulation in the food safety program in the KSA (13).

Food can be contaminated at any stage of preparation: processing; handling; storage; or transportation. It can be contaminate by many organisms: bacteria, virus, fungi, or parasites. Several vectors can be involved: insects or reptiles. In fact, most FBDOs result from bacterial contamination due to the ability of bacteria to proliferate within a short time if food were kept in certain environmental conditions (i.e., temperature, humidity). Furthermore, most of the bacterial food illnesses occur a short time after food ingestion, ranging from 2 – 48 hours after eating a suspected food (13). Most well-known bacterial foodborne pathogens colonize a wide range of hosts, such as cattle and poultry. Over the past two decades, Salmonella spp., Campylobacter spp., and *E. coli* have dominated research and surveillance activities in many parts of the world, particularly in regard to food manufacturing (14).

While most of the viral causes of foodborne diseases, such as norovirus, hepatitis A, and

hepatitis E, are highly infectious and can present with a clinical manifestation indistinguishable from bacterial causes, most of them are exclusively human pathogens. As such, there is no systematic surveillance for foodborne viral illnesses (14).

2.2 Most Important Bacterial Pathogens Involved in FBDO

2.2.1 *Salmonella enteritidis*

Salmonella enteritidis is gram-negative bacterium that can infect humans through the consumption of contaminated food. Clinically, patients can present with fever, abdominal pain, and diarrhea after an IP of 12 – 72 hours after the consumption of contaminated food. Salmonella contains more than 2,500 pathogenic serotypes (15). In the United States, Salmonella is the most common etiologic agent of foodborne illness (16). Annually, around 1.3 million cases of foodborne illness and more than 500 deaths are attributed to Salmonella (17). Salmonella normally live in the intestines of humans, animals including cattle and birds, and can be excreted later in feces. Contamination of these excreta or infected animals can lead to infection (15).

In the KSA, cross sectional studies were carried out to determine the prevalence of pathogenic Salmonella serotypes among poultry farms. Among the 25,759 samples that were taken from the poultry and their environment, 1,052 (4%) of them were Salmonella positive (18). Improper thawing and undercooking of frozen chicken products can be a source of acquiring a Salmonella-associated foodborne illness; this can be attributed to the ability of Salmonella to survive in freezing temperatures (19). Ground beef was the main suspected source of contamination with a multidrug resistant Salmonella serotype that resulted in FBDOs in four American states in 2007, with a total of 42 cases (20).

With the change toward healthier lifestyles and the increasing consumption of fresh, leafy, green vegetables, current FBDOs in Europe and in the United States show an association with ingestion of certain green, leafy vegetables, particularly lettuce and spinach and their ready to eat (RTE) salads. Contamination can occur at any stage of collection, storage, handling, and packaging. The most commonly reported pathogens are *Escherichia coli* O157:H7, Salmonella spp., and *Listeria monocytogenes* (21). In the United States, in 2008, contaminated raw crops including tomatoes, jalapeno peppers, and Serrano peppers were identified as the main vehicles for the Salmonella strain responsible for the FBDO (22). Furthermore, Salmonella serotype contamination of peanut products and raw almonds have been associated with several FBDOs in the US (23, 24).

In 2006, 31 FBDOs, with a total of 251 cases, were reported to the Public Health Authority in the Qassim region in KSA. Some cases (21.1%) were linked to a microbiologic agent as the suspected pathogen. Salmonella spp. was accountable for 81% of these cases; furthermore, egg, meat and milk and dairy products were the main suspected food items (25). In July 2010, an FBDO was reported to the Public Health Authority in Alhsa region in KSA, with a total of 33 cases. All of them had a clinical presentation of gastroenteritis (abdominal pain 97%, diarrhea 90.9%, fever 78.8%, vomiting 75.8% and nausea 30.3%). The IP ranged between five and twenty hours (26).

The outbreak investigation revealed that the main vehicle was a meat kabob prepared with a mixture of raw eggs two days prior to consumption. Furthermore, on the day of the outbreak, the partially cooked kabob was stored at an improper temperature before the final barbeque at the time of consumption. Salmonella serotype was isolated in samples of the suspected meat kabobs taken from the restaurant under investigation and in the stool samples of eight patients.

Statistical analysis of the data collected showed a statistically significant association between illness and eating the meat kabobs (OR=22.96; 95% CI = 4.73, 151.65) (26).

2.2.2 *Staphylococcus aureus*

Staphylococcus aureus is a gram-positive bacterium that can infect humans through the consumption of contaminated food items usually caused by food handlers carrying the bacterium. Furthermore, contaminated dairy products can be a source of infection. Clinically, patients present with upper gastrointestinal symptoms (nausea and vomiting), after a short IP of 1 – 6 hours (15). Clinical manifestations are linked to *S. aureus* enterotoxins (SEs). More than 20 SEs have been defined (27). Globally, *S. aureus* is one of the most common etiologic agents of FBDOs (28). It causes a self-limited illness of short duration in most cases. However, it can spread widely causing large outbreaks in a short period (29).

2.2.3 *Bacillus cereus*

Bacillus cereus is a gram-positive, spore-forming bacterium. Its propensity to form heat-stable endospores in a short period makes it difficult to control this pathogen. It can be classified into two types: diarrheal and emetic (30). Clinically, the diarrheal type is usually acute; nausea and abdominal pain with an IP ranging from 8 – 16 hours. The emetic type presents with acute nausea, vomiting, and abdominal pain (and in some cases diarrhea). However, the emetic type is characterized by a shorter IP (1 – 5 hours) (8). *B. cereus* is extensively distributed in the environment. Raw grains and dairy products were the main vehicles in several outbreaks (30-32). Most cases of foodborne illness associated with *B. cereus* are mild; however some severe cases of emetic type are associated with severe hepatic impairment, resulting in death (33-35).

2.2.4 *Clostridium perfringens*

Clostridium perfringens is a gram-positive, spore-forming bacterium. An important factor of this bacterium is its ability to produce enterotoxins that can contribute further to the virulence of gastrointestinal diseases in affected patients (36). *Clostridium perfringens* is considered the third most common cause for foodborne illness in the US (37); in addition, it is among the six most common causes of foodborne illnesses in Japan (38). Sources of these bacteria include soil, sewage, and feces of animals and humans. *Clostridium perfringens* can grow in food, especially meat and poultry (15). After an IP of 8 – 24 hours, most patients present with abdominal pain and diarrhea, and most will have mild and self-limited symptoms (8). Improper food handling – particularly in heating, cooling, or reheating – is a major risk factor for acquiring this bacterium. In 2010, a FBDO among patients and staff of a state psychiatric hospital in Louisiana resulted in a total of 50 cases (42 residents and 12 staff). All cases developed vomiting, abdominal pain, and diarrhea. Unfortunately, three patients died after developing necrotizing colitis. Epidemiologic investigations found that improperly stored chicken meal was the suspected food for this outbreak. The chicken was cooked 24 hours before the final consumption and stored at an improper temperature that facilitated the growth and multiplication of *clostridium perfringens* (37).

2.2.5 *Escherichia coli*

Escherichia coli is a gram negative, non-spore forming enteric bacterium. Several strains are known to cause clinical illness to humans (8). Enterohaemorrhagic *E. coli* (EHEC) is a highly pathogenic strain associated with several FBDOs (39). Cattle are the main reservoir for this particular strain. EHEC can be transmitted by contaminated food particularly meat, green

leafy vegetables, or raw milk from infected animals (40). Poor food handling can lead to cross contamination with this bacterium. Drinking water contaminated with fecal matter is another well-known mode of transmitting *E. coli* (8).

E. coli O157 is the most commonly known EHEC. *E. coli* O157, a Shiga-toxin producing *E. coli*, can present clinically with abdominal pain usually severe, bloody diarrhea, and in some cases fever and vomiting (8). In 2006, a multistate FBDO of *E. coli* O157 was reported to the CDC. A total of 183 patients were infected with *E. coli* O157 from 26 states in the US, 29 cases (16%) were complicated by haemolytic uraemic syndrome (HUS), and one death was reported. This outbreak was attributed to fresh spinach (41-43). In 2009, 77 patients were involved in an FBDO of *E. coli* O157, and ten of them (13%) developed HUS. A ready-to-bake prepackaged cookie dough was the main suspected vehicle for this outbreak (44). Other multi state outbreaks were attributed to *E. coli* O157 contaminated aged raw milk cheese and beef tacos produced by fast food chain restaurants (45, 46).

E. coli O104, first isolated in Germany in 2001, is a highly virulent strain that combines virulent characteristics of different strains. It tends to be more resistant to antibiotics; furthermore, the risk of HUS is higher in infected adult patients (39). In Germany, in 2011, a total of 3816 persons were infected with *E. coli* O104 and 845 (22%) of them developed HUS; 54 patients died. Bean sprouts were the source of the contamination (47).

2.2.6 *Listeria monocytogenes*

Listeria monocytogenes is a gram positive, non-spore-forming bacterium. After an IP ranging from days to several weeks, Listeriosis can clinically present with influenza-like illness (fever, headache, and gastrointestinal symptoms). However, a more severe illness can occur in

susceptible individuals (pregnant women, the elderly, and newborns). Infection can occur through ingestion of contaminated food, including raw milk and vegetables. The pasteurization of milk and good hygiene habits can reduce the risk of infection (8).

In the United States, data from the Foodborne Diseases Active Surveillance Network (FoodNet) collected between 2004 and 2009 showed that high-risk populations had a higher risk of the invasive form of Listeriosis. Pregnant women had a greater relative risk (RR) than non-pregnant women (RR=114.6;95% CI=68.9, 205.1). Furthermore, using the age group 14-44 as a reference, older age is associated with a higher risk (45-59 years: RR=4.7;95%CI=3.3, 6.8) (>85 years: RR=53.8;95%CI=37.3, 78.9). In both situations, Hispanics showed a higher RR compared to non-Hispanics (48).

2.2.7 Shigellosis (bacillary dysentery)

Shigella spps. are gram positive, non spore-forming bacteria. After an IP of 1 – 3 days (7 days for bacillary dysentery), shigellosis can clinically present with abdominal pain, vomiting, diarrhea (watery to dysenteric with bloody stool), and fever. Moreover, the clinical disease could last for days to several weeks. Two to three percent of cases are complicated by HUS, Reiter disease, or splenic abscess. The fecal-oral route is the main mode of acquiring this infection. Eating food (salads and vegetables) and drinking water and raw milk that have been contaminated due to poor food handling and low personal hygiene are the most common ways of acquiring this infection (8).

Overall in the United States, with improvements in hand hygiene and waste disposal, *Shigella* contamination has become a rare cause of foodborne illness; when FBDOs are linked to

Shigella, they are most likely due to *Shigella sonnei*, which has largely replaced the *Shigella flexneri* as the most frequently encountered subgroup (49). However, during the period between May 22 and 28, 2001, there was a large FBDO involving 886 cases among the customers of five restaurants located in New York belonging to the same owner. Nearly all of the cases presented with a gastrointestinal illness (abdominal pain, vomiting, diarrhea -- which in some cases was bloody -- fever, and muscle pain). A univariate analysis of exposures to 132 food items at those restaurants reported by 306 diseased and 167 healthy individuals established that several foods were significantly associated with illness. Eating tomato and yogurt sauce were significantly associated with illness in one multivariable model; however, only exposure to tomatoes continued to be significant in all reduced models. An epidemiologic investigation of this outbreak concluded that handling of blemished and rancid tomatoes by the final distributor before arrival to the five restaurants was the likely source of contamination by *Shigella flexneri*. In addition, the poor storage of tomatoes at relatively high temperatures facilitated the growth of the bacteria (50).

2.3 Food Handlers and FBDO

The association of many FBDOs with improper food handling or food storage methods is well known (51). Food handlers have a role in contaminating food with pathogenic organisms through hand contact with their own pathogens excreted through their gastrointestinal tracts, through cross contamination of food items (raw food and ready-to-eat food), and during cleaning of contaminated surfaces. Improving food handlers' behavior through hand washing throughout the food handling process will reduce the risk of FBDOs (51).

In 2000, a survey carried out in different counties in Oregon evaluated the knowledge and

practices of 407 food handlers distributed throughout 67 randomly selected restaurants. The survey found a low score in food safety knowledge among food handlers, which could be an important predictor of increased risk of foodborne illness. Furthermore, this study highlighted the demand for an educational training program targeting the food handlers in order to improve their knowledge and behaviors in food safety (52). According to the Food and Drug Administration (FDA), food handlers were involved in a large number of foodborne illnesses. This led the FDA to adopt stringent interference actions that include: excluding sick food handlers from the working environment; ensuring removal of infectious organisms from the hands of food handlers through proper hand hygiene (effective hand washing); and increasing the use of barrier methods (gloves) in dealing with ready-to-serve food (53).

Food safety training programs not only benefit food handlers, but also food managers who are involved in the training process. This can have a positive impact in improving the overall working environment, which in turn can lead to a reduction in FBDOs (54). On the other hand, in 2011, Pajot and Aubin found in their critical review of literature that there was insufficient evidence that either mandatory or elective food handler training programs will result in improved food-handling safety practices or food handler knowledge (55).

The Public Health Department in the Health Directorate in Makkah, in collaboration with the Municipality of Makkah, performs regular checks of all restaurants and food preparation sites throughout the year. These inspections occur more often during the Hajj season. The inspection includes: ensuring eligibility of the site; confirming the presence of valid health certificates for all food handlers; assessing the work environment; and taking samples of suspected food items, water samples or sometimes samples from the food handlers themselves (e.g., nasal swab).

In a cross sectional study in 2007, conducted during the Hajj season, a sample of food

preparation sites (38 restaurants and 23 fast food establishments) were included for assessing the hygienic quality of the food, the food handlers and the restaurant environments in Makkah. The study area was in the central part of Makkah, one kilometer in each direction from the Holy Mosque, which is the most crowded area almost every day of the Hajj season. The study found that all of these food preparation sites had a valid license, 90% of the food handlers had valid health certificates, and 80% of these sites had a hand-washing facility available to the food handlers. However, the fact that 20% did not have a hand-washing facility in place was an alarming finding. Furthermore, the general level of cleanliness in the work environment at these sites was poor. The fact that 67% of food handlers had not been wearing gloves while handling raw food, plus the finding that 45% had poor nail hygiene, 14% had boils or cuts on their hands, and 10% had history of diarrhea within 24 hours of the study were also causes of concern. These illustrate potential risks for FBDOs in the mass gatherings during Hajj. However, no cultures (food or nails swabs) were found positive for foodborne pathogens (56).

Hamla is the group of campsites under the management of the Ministry of Hajj. In Hajj, Hamlas serve two groups of pilgrims: domestic and international ones. The administration of each Hamla plays a major role in ensuring food safety to prevent FBDOs in its campsites. Furthermore, having medical facilities to detect suspected cases of foodborne illness and report to higher authorities allows early containment of an impending outbreak and timely corrective actions (57).

Chapter 3: Manuscript

Analyses of Foodborne Disease Outbreaks during Hajj, Makkah, Kingdom of Saudi Arabia, 2009 – 2011

ABSTRACT

PURPOSE: The Hajj is an annual mass gathering where > 1.8 million Muslim pilgrims from 183 countries come to Makkah, Kingdom of Saudi Arabia (KSA) for approximately two weeks. The KSA Ministry of Health (MOH) is responsible for ensuring the early detection and prevention of infectious diseases that can be transmitted among the markedly great number of pilgrims, such as foodborne illnesses. Foodborne illnesses are especially significant public health problems during mass gatherings. From 2009 – 2011, the Hajj Food Safety Unit (FSU) gathered data on all foodborne outbreaks, yet these data have yet to be fully analyzed to determine the underlining risk factors and the best methods for prevention and control of further outbreaks.

METHODS: A review was made of foodborne disease outbreaks (FBDOs) using data gathered by the FSU in Makkah from 2009 – 2011.

RESULTS: During the three Hajj seasons of 2009 through 2011, a total of seven FBDOs were reported with a range of 2 – 45 cases per outbreak, totaling 107 cases. Among these cases, 74 were female (70%) and 33 were male (30%). Egyptians were the most common nationality affected (69%), followed by Saudis, Malaysians, and Turks (23%, 6%, and 2% respectively). The mean age among cases was 46 years with a SD of 16 years.

CONCLUSIONS: This study found a strong relationship between the three largest FBDOs during Hajj and storage conditions and food handling methods reported over the study period. We recommend improving compliance with the Hazard Analysis Critical Control Point program and establish training programs in food safety. The FSU's work should be expanded through the electronic notification system and the reassessment of lab methods used during FBDO investigations.

Introduction

The Kingdom of Saudi Arabia (KSA) has the unique position in the heart of each Muslim individual. This comes from the fact that it is the home of the two holiest mosques, located in Makkah and Medina. The Hajj – the fifth pillar of Islam – is the pilgrimage to Makkah. Performing Hajj is a religious obligation for all adult Muslims at least once in their lives, provided that they are both physically and financially able to perform it. Every year, millions of Muslims perform Hajj over a 6-day period. Umrah, another ritual pilgrimage to Makkah, can be performed at any time of the year. In 2011, > 1.8 million pilgrims came to KSA from 183 counties (2). Every year at approximately the same time and within a small area, these large numbers of Muslims perform their Hajj duties and move between several Hajj sites. Pilgrims generally stay in large groups; this, together with physical exhaustion, extreme heat, and crowded accommodations can lead to an increase in public health hazards (e.g., infectious diseases, environmental health concerns) (3).

A mass gathering (MG) is defined as an event attended by a sufficient number of people at a specific location for a specific purpose for a defined period of time, which mandates a specific planning and availability of certain resources in the community (4). The Hajj is one of the largest annual MGs, with diversity of attendees with different biopsychosocial backgrounds who come from different parts of the world.

Every year, the Saudi Ministry of Health (SMOH) is responsible for ensuring the early detection and prevention of infectious diseases that can be transmitted among the markedly great number of pilgrims. The SMOH has equipped seven hospitals and 74 health care centers at Hajj sites with essential emergency management resources and has staffed them with specialized,

well-trained personnel to provide health care to all pilgrims free of charge (5).

SMOH has established the Preventive Medicine Program for Hajj, which is composed of two committees. The Supervisory Committee is a standing committee located in the SMOH that moves its headquarters to Makkah's Public Health Administration during Hajj. The Executive Committee operates for one month from the 15th of Dhul Al-Qedah until the 15th of Dhul Al-Hijjah each year, and is located at the Public Health Administration in Makkah. It consists of 12 units, one of which is the Food Safety Unit (FSU). The FSU has been a separate unit in the Executive Committee since 2009. The responsibilities of the FSU include (7):

- Respond to foodborne disease outbreaks.
- Receive foodborne disease outbreak (FBDO) notifications through the notification channels (e.g., hospitals, polyclinics, the Executive Committee).
- Inspect and evaluate the food preparation sites that belong to each Hamla.[2]
- Prepare daily reports on FBDOs, including zero reporting, and submitting these reports to the Executive Committee.
- Respond to notifications immediately through field visits and interviewing suspected cases, creating case definitions and constructing epidemiologic surveillance using tools (e.g., FBDO forms and questionnaires in Epi Info™).
- Collect samples from suspected food, water, and food handlers.
- Write a final report for each FBDO and a final report for FSU activities by the end of each Hajj season.

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[2] Hamla is the group of campsites under the management of the Ministry of Hajj.

- Participate in the training program for the different units working in the Preventive Medicine Program for Hajj.
- Provide health education regarding food safety and healthy food handling.

The SMOH uses national guidelines for detecting, confirming, reporting, and responding to incidents of FBDO. Furthermore, the SMOH uses a translated version of Frank Bryan's book *Procedures to Investigate Foodborne Illness, Fifth Edition* (personal communication, Dr. Tamadur Kurdi, SMOH).

Although acute diarrheal diseases are one of the most common acute medical problems during Hajj, very few studies have described their incidence or etiology. In 2002, a study showed that diarrhea during Hajj ranked as the third most common cause of hospitalization (3). FBDOs are underreported; reasons for this include the existence of different definitions for diarrheal illness, the underreporting of cases, and the fact that not all cases can be linked to food (8). The increase in FBDOs in the KSA during the summer and Hajj seasons (9), many of which were attributed to poor food handling and storage, reinforced the need for improving healthy behaviors among food handlers and consumers.

Foodborne illnesses are defined as diseases, infectious or toxic, caused by consuming contaminated food. If two or more individuals have this disease as a consequence of consuming food in common, this is considered a foodborne disease outbreak (FBDO). Globally, there are no clear data regarding the incidence of foodborne illnesses; however, most cases present with acute diarrheal illness, and in 2005, an estimated 1.8 million died from diarrheal illness. Most of the illnesses were caused by consuming contaminated food or drinking water (8).

Salmonella is the pathogen responsible for most outbreaks (12). In the KSA, cross sectional studies were carried out to determine the prevalence of pathogenic *Salmonella*

serotypes among poultry farms. Among the 25,759 samples that were taken from the poultry and their environment, 1,052 (4%) of them were *Salmonella* positive (18). Improper thawing and undercooking of frozen chicken products can be a source of acquiring a *Salmonella*-associated foodborne illness; this can be attributed to the ability of *Salmonella* to survive in freezing temperatures (19). Ground beef contaminated with a multidrug-resistant Salmonella serotype was the main suspected source of the FBDOs that occurred in four American states in 2007, with a total of 42 cases (20). *Staphylococcus aureus,* another one of the most common etiologic agents of FBDOs (28), causes a self-limited illness of short duration in most cases. However, it can spread widely causing large outbreaks in a short period (29).There are several factors contributing to the global burden of foodborne illness. The growing proportion of at-risk populations, such as the elderly and the immunosuppressed, suffer severely from foodborne illnesses. In the era of modern international trade, rapid and widespread food distribution has become inevitable. Furthermore, travellers, such as most pilgrims, may be exposed to unfamiliar pathogens. Finally, there is an increase in food consumption from commercial foodservice settings with poor environmental standards, including poor hygiene (8). Though most foodborne diseases are sporadic and most FBDOs are not reported to the Public Health department, FBDO surveillance remains the first step in prevention (8).

Most of the bacterial food illnesses occur a short time after food ingestion, ranging from 2 – 48 hours after eating a suspected food (13). Most well-known bacterial foodborne pathogens colonize a wide range of hosts, such as cattle and poultry. Over the past two decades, *Salmonella* spp., *Campylobacter* spp., and *E. coli* have dominated research and surveillance activities in many parts of the world, particularly in regard to food manufacturing (14).

While most of the viral causes of foodborne diseases, such as norovirus, hepatitis A, and

hepatitis E, are highly infectious and can present with a clinical manifestation indistinguishable from bacterial causes, most of them are exclusively human pathogens. As such, there is no systematic surveillance for foodborne viral illnesses (14).

Food handlers have a role in contaminating food with pathogenic organisms by way of hand contact with their own pathogens excreted through their gastrointestinal tracts, cross contamination of food items (raw food and ready-to-eat food), and during cleaning of contaminated surfaces. Improving food handlers' behavior by training them to wash their hands throughout the food handling process will reduce the risk of FBDOs (51).

According to the Food and Drug Administration (FDA), food handlers were involved in a large number of foodborne illnesses. This led the FDA to adopt stringent interference actions that include: excluding sick food handlers from the working environment; ensuring the removal of infectious organisms from the hands of food handlers through proper hand hygiene (effective hand washing); and increasing the use of barrier methods (gloves) in dealing with ready-to-serve food (53).

Food safety training programs not only benefit food handlers, but also food managers who are involved in the training process. This can have a positive impact in improving the overall working environment, which in turn can lead to a reduction in FBDOs (54).

Methods

Data Sources and Statistical Analyses

Data were collected using the FSU reports of foodborne illness outbreaks during Hajj in Makkah, KSA, from 2009 – 2011. All reports were written in Arabic, so they were translated. The data from 2009 – 2011 outbreaks were concatenated and statistically analyzed using SAS.

Ethics

Since this study was based on secondary data without personal identifiers, it was determined to be exempt from Human Subjects Research by the Emory University Institutional Review Board.

Results

During the three Hajj seasons 2009 through 2011, a total of 7 FBDOs were reported with a range of 2 – 45 cases per outbreak, totaling 107 cases. Among these cases, 74 were female (69%) and 33 were male (31%). Egyptians were the most common nationality affected (69%), followed by Saudis, Malaysians, and Turks (23%, 6%, and 2% respectively). The mean age among cases was 46 years with a SD of 16 years. The middle-aged group (45 - 65 years) was the most commonly affected age group (67%). Those older than 65 years were rarely reported (<1%) nor were children under five (<2%) (Table1).

Table 1. Demographic Characteristics of Cases in Hajj Foodborne Disease Outbreaks, Kingdom of Saudi Arabia, 2009 – 2011

Characteristic		2009	2010	2011	Total (%)
Gender	Male	0	7	26	33 (31)
	Female	29	4	41	74 (69)
Nationality	Egyptian	29	NA	45	74 (69)
	Saudi	NA	3	22	25 (23)
	Malaysian	NA	6	NA	6 (6)
	Turkish	NA	2	NA	2 (2)
Age Group	< 5	0	1	1	2 (2)
	5 – 18 years	0	2	3	5 (5)
	18 – 45 years	5	6	16	27 (25)
	45 – 65 years	23	2	47	72 (67)
	> 65	1	0	0	1 (1)

Abdominal pain and diarrhea were the most common reported symptoms (93%, 85% respectively), followed by nausea and vomiting (43%, 44%). Fever was reported in only 15% of the cases, and < 1% of the cases had bloody diarrhea. All symptoms were typically associated with the most frequently encountered bacterial causes of FBDOs (Table 2).

Table 2. Symptoms of Cases in Hajj Foodborne Disease Outbreaks, 2009 – 2011

Symptoms	2009	2010	2011	Total (%)
Abdominal pain	29	9	61	**99 (93)**
Diarrhea	20	11	60	**91 (85)**
Vomiting	21	11	15	**47 (44)**
Nausea	16	4	26	**46 (43)**
Fever	NA	6	10	**16 (15)**
Headache	NA	6	2	**8 (7)**
Itching	NA	4	NA	**4 (4)**
Chills	NA	2	NA	**2 (2)**
Bloody diarrhea	NA	1	NA	**1 (1)**

A total of 15 cases were admitted to the hospitals; all the cases were stable with no complications and no reported mortality. Of the total, 8 cases were male and 7 were female. Moreover, 8 cases were Saudis and the remaining were Egyptians (Table 3).

Table 3. Demographic Characteristics of Cases Admitted to Hospitals During Hajj Foodborne Outbreaks, Kingdom of Saudi Arabia, 2009 – 2011

Characteristic		2009	2010	2011	Total (%)
Gender	Male	0	0	8	8 (53%)
	Female	0	2	5	7 (47%)
Nationality	Egyptian	NA	NA	7	7 (47%)
	Saudi	NA	2	6	8 (53%)
	Malaysian	NA	NA	NA	NA
	Turkish	NA	NA	NA	NA
Age Group	< 5	NA	0	1	1 (7%)
	5 – 18 years	NA	2	2	2 (13%)
	18 – 45 years	NA	0	3	3 (20%)
	45 – 65 years	NA	0	7	7 (47%)
	> 65	NA	0	0	0 (0%)

This study found a strong relationship between the three largest FBDOs during Hajj (#1, #6, and #7) and storage conditions and food handling methods. In the 2009 FBDO, the kitchen responsible for preparing meals for the pilgrims in the involved camps was found to have poor environmental standards; the main risk factor was poor storage methods for potentially high-risk food items like meat and poultry. Likewise, poor storage methods for cooked food were the risk factor for two outbreaks in 2011 (#6 and #7); in addition, poor food handling methods were also suspected in these two outbreaks. *Salmonella, Staphylococcus aureus* and *Bacillus cereus* were the most commonly suspected pathogens in these outbreaks based on the epidemiological data collected, including IP (Table 4 & Figures 1, 2 & 3).

Table 4. Number of Cases Reported during Hajj Foodborne Outbreaks and Suspected Pathogens, Kingdom of Saudi Arabia, 2009 – 2011

	2009	2010				2011		Total
	FBDO#1	**FBDO#2**	**FBDO#3**	**FBDO#4**	**FBDO#5**	**FBDO#6**	**FBDO#7**	
Number of cases	29	3	2	6	3	45	19	107
Suspected Pathogen	*Staphylococcus aureus*	Unknown	Unknown	Unknown	Unknown	*Staphylococcus aureus* or *Bacillus cereus*	*Salmonella* or *Bacillus cereus*	

Figure 1. Epidemic Curve for Hajj Foodborne Disease Outbreak #1, Kingdom of Saudi Arabia, 2009

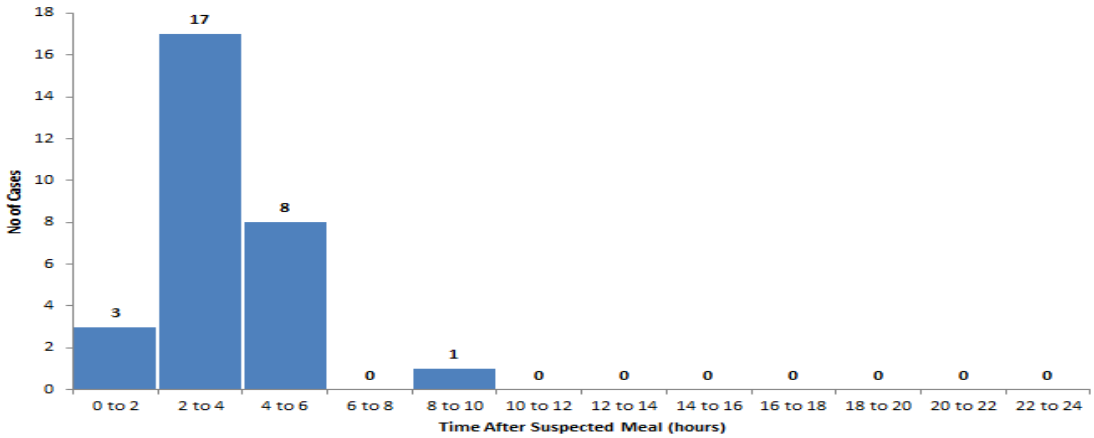


Figure 2. Epidemic Curve for Hajj Foodborne Disease Outbreak #6, Kingdom of Saudi Arabia, 2011

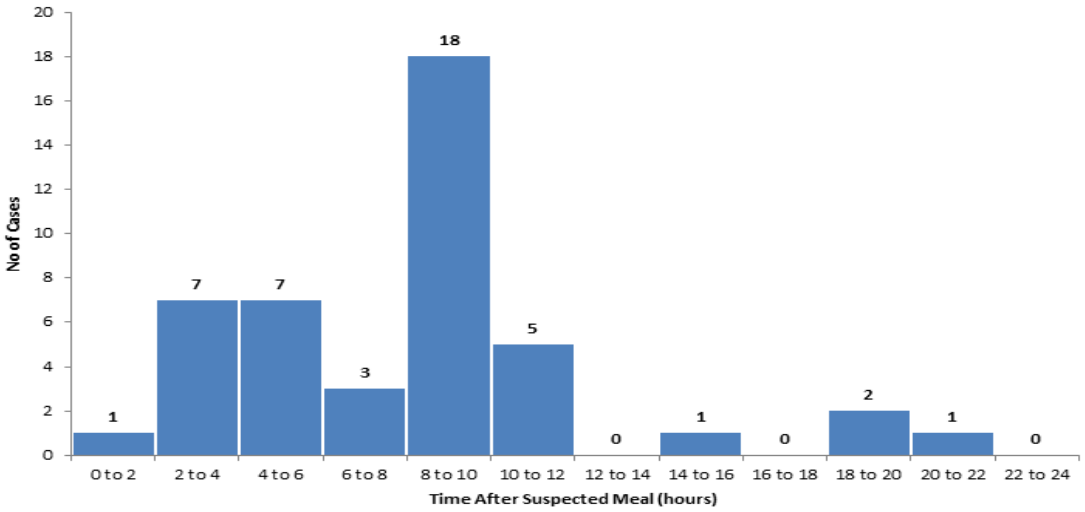
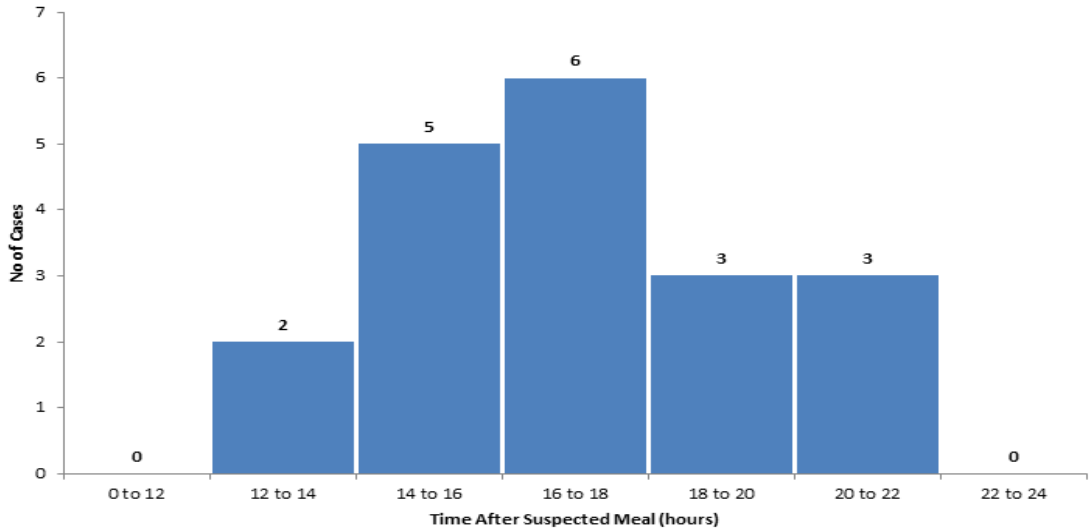


Figure 3. Epidemic Curve for Hajj Foodborne Disease Outbreak #7, Kingdom of Saudi Arabia, 2011



Conclusion and Recommendations

A total of seven FBDOs were reported from 2009 – 2011; three were fully investigated. Due to the dynamics of the Hajj and the fact that most cases were mild and self-limited, some patients chose to withdraw from the investigation. This, in association with the fact that foodborne illnesses are underreported, should be kept in mind when considering FBDO data interpretation (8).

All cases had a typical presentation of foodborne illness: abdominal pain and diarrhea (93% and 85%, respectively), followed by nausea and vomiting (43% and 44%, respectively).

Improving the work environments at food preparation sites is an important factor in reducing food contamination and subsequently reducing the risk of FBDOs; in fact, this study found a strong relationship between the three largest FBDOs during Hajj and the storage conditions and food handling methods at the source preparation sites. In the 2009 FBDO, the kitchen responsible for preparing meals for the pilgrims in the involved camps was found to have poor environmental standards; the main risk factor was poor storage methods for potentially high-risk food items like meat and poultry. Likewise, poor storage methods for cooked food were the risk factor for two outbreaks in 2011 (#6 and #7); poor food handling methods were also suspected in these two outbreaks.

Food handlers can contaminate food with pathogenic organisms by way of hand contact with their own pathogens excreted through their gastrointestinal tracts, through cross contamination of food items (raw food and ready-to-eat food), and during cleaning of contaminated surfaces. The FSU reports support the link between certain FBDOs with improper food handling behaviors. In 2007, Al-Honazil, *et* al. assessed the hygienic quality of the food, food handlers, and the restaurant environments in Makkah during Hajj; they found a generally

low level of cleanliness at the preparation sites. Among food handlers, 67% had not been wearing gloves while handling raw food; 45% of them had poor nail hygiene; 14% had boils or cuts on their hands; and 10% had a history of diarrhea within 24 hours of the study. They concluded that this poses a risk for disastrous FBDOs in the huge mass gathering during Hajj. Notably, none of the cultures from food and nails swabs collected at 61 food preparation sites was found to be positive. This, combined with the fact that none of the seven outbreaks was bacteriologically linked to microbiological causes, raises the need for urgent assessment of the laboratory methods and procedures used for sample collection, transportation, storage, and examination.

Pajot and Aubin found in their critical review of the literature up to 2010 that there was insufficient evidence to show that either mandatory or elective food handler training programs would result in improving food-handling safety practices or food handler knowledge (55). However, this study was done in the Peel region of Ontario, Canada. In the KSA, most of the food handlers come from different developing and relatively poor countries with a relatively low level of food safety knowledge and behaviors. This, in addition to the increased demand on commercial food facilities in Makkah during Hajj, can further exacerbate the risk of FBDOs. Food safety training programs not only benefit food handlers, but also food managers who are involved in the training process; overall, these programs can have a positive impact on improving the overall food preparation environment, which in turn can lead to a reduction in FBDOs (54).

No study has been undertaken in the KSA to evaluate the effectiveness of a food-safety training program targeting food handlers or their managers, particularly in Makkah around the time of the Hajj season. Supporting research that evaluates the effectiveness of a food-safety

training program can provide valuable results and recommendations during the very critical Hajj period.

To improve food safety and reduce the risk of FBDOs in KSA, especially during Hajj, we recommend improving compliance with the Hazard Analysis Critical Control Point (HACCP) program, which is regarded as the best preventive program in food safety, used in determining the possible point of food contamination in each stage of food preparation, processing and handling (13).

We also recommend establishing training programs in food safety for the food handlers and food managers. These can have a positive impact in improving the overall working environments at food preparation sites, which in turn can lead to a reduction in FBDOs (54). Food-handlers working in food establishments in Makkah, particularly in the crowded places around the holy mosque of Makkah, as well as those working in Mina and Arafat should be trained. The training program should be directed to all employees and be conducted in their own languages as much as possible in order to better deliver the knowledge and improve their food handling behaviors. This training should be considered a prerequisite for the food handlers and the establishment for obtaining a work license, and it should also be ongoing, with additional training required for the license renewal.

In reviewing the FSU reports, no single outbreak among the reported FBDOs was linked bacteriologically by lab tests to a certain pathogen. This might indicate the need to reassess the lab methods used in FBDO investigations, down to examining the process of taking, transporting and storing samples.

In the field, although the outbreak notification system has started to shift from the older paper-based communication methods to the newer electronic methods (via smartphones), the

system is still mainly paper-based. Expanding the use of electronic communication would enable the more timely intervention of FSU members, who would function most effectively via a highly organized, well-established communication system that connects different levels in the notification sequence.

Chapter 4: Conclusion and Recommendations

4.1 Conclusion

A total of seven FBDOs were reported from 2009 – 2011; three were fully investigated. Due to the dynamics of the Hajj and the fact that most cases were mild and self-limited, some patients chose to withdraw from the investigation. This, in association with the fact that foodborne illnesses are underreported, should be kept in mind when considering FBDO data interpretation (8). .

All the cases had the typical presentation of foodborne illness, with abdominal pain and diarrhea as the most common symptoms (93% and 85% respectively), followed by nausea and vomiting (43% and 44%).

The work environment at food preparation sites is an important factor in reducing food contamination and subsequently reducing the risk of FBDOs; in fact, this study found a strong relationship between the three largest FBDOs during Hajj and the storage conditions and food handling methods. In the 2009 FBDO, the kitchen responsible for preparing meals for the pilgrims in the involved camps was found to have poor environmental standards; the main risk factor was poor storage methods for potentially high-risk food items like meat and poultry. Likewise, poor storage methods for cooked food were the risk factor for two outbreaks in 2011 (#6 and #7); poor food handling methods were also suspected in these two outbreaks.

As mentioned, food handlers can contaminate food with pathogenic organisms through hand contact with their own pathogens excreted through their gastrointestinal tracts, through cross contamination of food items (raw food and ready-to-eat food), and during cleaning of contaminated surfaces. The FSU reports confirm the link between certain FBDOs with improper

food handling behaviors. In 2007, Al-Honazil et al. assessed the hygienic quality of the food, the food handlers and the restaurant environments in Makkah during Hajj; they found a generally low level of cleanliness at these sites. Moreover, 67% of the food handlers had not been wearing gloves while handling raw food; 45% of them had poor nail hygiene; 14% had boils or cuts on their hands and 10% had history of diarrhea within 24 hours of the study; they concluded that this poses a risk for disastrous FBDOs in the huge mass gathering during Hajj. Notably, though the study was carried out at 61 food preparation sites, none of the cultures from food and nails swabs was positive. This, combined with the fact that none of the seven outbreaks was bacteriologically linked to microbiological causes, raises the need for urgent assessment of the laboratory methods and procedures used for sample collection, transportation, storage, and examination.

Pajot and Aubin found in their critical review of literature searched in 2010 that there was insufficient evidence that either mandatory or elective food handler training programs will result in improving food-handling safety practices or food handler knowledge (55). However, this study was done in the Peel region of Ontario, Canada. In the KSA, most of the food handlers come from different developing and relatively poor countries with a relatively low level of food safety knowledge and behaviors. This, in addition to the increased demand on commercial food facilities in Makkah during Hajj, can further exacerbate the risk of FBDOs. Food safety training programs not only benefit food handlers, but also food managers who are involved in the training process; overall, these programs can have a positive impact in improving the overall food working environment, which in turn can lead to a reduction in FBDOs (54). No study has been undertaken in the KSA to evaluate the effectiveness of a food-safety training program targeting food handlers or their managers, particularly in Makkah around the time of the Hajj season.

Supporting research that evaluates the effectiveness of a food-safety training program can provide valuable results and recommendations during a very critical period of Hajj.

4.2 Recommendations

4.2.1 Improving compliance with the Hazard Analysis Critical Control Point (HACCP) program

The Hazard Analysis Critical Control Point (HACCP) is the best preventive program in food safety, used in determining the possible point of food contamination in each stage of food preparation, processing and handling. HACCP has proved to be an effective program in food safety and is now considered an important national set of regulations in the food safety program in the KSA (13). To be effective, HACCP requires compliance in the following three main areas.

4.2.1.1 Food establishment infrastructure and its surrounding environment

The general cleanliness, shape and design of the facility that increases work efficiency and reduces the risk of food contamination, improving the food safety and reducing the risk of food borne illness; however, many food establishments lack this infrastructure. Food preparation sites in holy places in Arafat and Mina can be evaluated in advance with the collaboration between SMOH, the Ministry of Municipal and Rural Affairs (MOMRA), and Ministry of Hajj. Adequate lighting, aeration and a sufficient and well-organized storage area set at an appropriate storage temperature should be strictly ensured. An adequate safe water supply for the establishment is another important priority for food safety. Kitchen floors, walls, surfaces and even roofs should be easily accessible for cleaning. Raw food storage areas should be separate

from ready-to-eat food items. Furthermore, hand-cleaning facilities should be readily available to the food handlers and should be different from those used for raw food cleaning.

4.2.1.2 Food-handler behavior

Proper hand washing before, during and in between food handlings is an important preventive procedure. Every single food handler should memorize clear steps of proper hand washing according to the recommendations; moreover, these steps should be written and kept in highly visible places inside the food establishment to remind them. Using gloves dose not exclude the need for proper hand washing. The personal hygiene of the food handler, including daily bathing, cutting nails and wearing clean cloths, is of paramount importance. Foods handlers should avoid work if they feel unwell, especially if they have diarrhea, jaundice or fever. If food handlers have any skin abrasions, cut wounds or boils, they should be cleaned and covered properly to avoid food contamination.

4.2.1.3 Food preparation methods

Food should be sourced from known distributors accredited by MOMRA and should fulfill its health requirements. At the food preparation sites, any contamination between raw food and fresh fruits or vegetables should be avoided by using different cutting boards, utensils and surfaces for preparing each. The proper thawing procedure should be conducted either by placing the meat under running water or cooking it and using the probe thermometer to ensure that the deeper parts are cooked thoroughly. Food should be cooked at the proper temperature, at not less than 74 C (165.2F). When food is cooked, its early consumption should be encouraged, as this will decrease the risk of food contamination; however, if food storage is the only option,

the food should be cooled properly by distributing it in small shallow pots, and then once cooled, storing it in a refrigerator at a temperature of 4C or less (39.2F). The golden rule for food safety is to keep hot food hot and cold food cold.

4.2.2 Training programs in food safety

Establishing training programs in food safety is not only beneficial for the food handlers, but also for the food managers who are involved in the training process. It can have a positive impact in improving the overall working environment, which in turn can lead to a reduction in FBDOs (54). Food-handlers working in food establishments in Makkah, particularly in the crowded places around the holy mosque of Makkah and those working in Mina and Arafat, should be trained. The training program should cover all employees and be conducted in their own languages as much as possible in order to better deliver the knowledge and improve their food handling behaviors. This training should be considered a prerequisite for obtaining a working license for the food handlers and the establishment, and also it should be ongoing, with additional training required for the license renewal.

Managers of the food establishment should be involved in the training program to help in evaluating their employees during their work. The FSU should regularly reevaluate its training program so that health workers improve their skills in monitoring the food establishments and completing the FBDO surveillance process. This includes improving their skills in using Epi-Info and other statistical programs that can help bring about the early detection of a suspected etiology and consequently improve early outbreak containment.

Finally, an educational program can be delivered to pilgrims through sending short clear

messages in food safety and proper food storage and handling. Furthermore, the program should increase pilgrims' awareness regarding symptoms of probable food illness for early detection and reporting of FBDOs. The media can facilitate the spread of these messages to large groups of pilgrims.

4.2.3 Reassessing the lab methods used in FBDO investigations

In reviewing the FSU reports, it was observed that no single outbreak among the reported FBDOs was linked bacteriologically by lab tests to a certain pathogen. This might indicate the need to conduct further research and investigations to reassess the lab methods used in FBDO investigations and even the process of taking, transporting and storing samples.

4.2.4 Expanding the electronic notification system

In the field, although the notification system has started to shift from the older paper-based to the newer electronic-based communication system "smart phones", the notification methods are still based mainly on the paper-based ones. Extending the electronic system would ensure FSU members' timely intervention through a highly organized, well-established communication system between different levels in the notification sequence including health facilities, epidemiologists and stakeholders.

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