

**The Role of Hand Hygiene in the Prevention of Emerging
Respiratory Tract Infections among Attendees of Religious
Mass Gatherings in Saudi Arabia**

*A thesis submitted in fulfilment of the requirements for the degree of
Doctor of Philosophy*

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STATEMENT OF ORIGINALITY

This is to certify that, to the best of my knowledge, the content of this thesis is my own work. This thesis has not been submitted for any degree or other purpose.

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AUTHORSHIP ATTRIBUTION STATEMENT

This PhD thesis consists of seven published manuscripts as follows:

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- My contribution: I am the first and corresponding author of this paper. I undertook an independent literature search, data extraction, and quality assessment. I also wrote the original draft, received comments from co-authors, and edited subsequent versions of the manuscript.

Publication #2, Chapter 2: Mahdi H, Alqahtani A, Barasheed O, Alemam A, Alhakami M, Gadah I, et al. Hand Hygiene Knowledge and Practices among Domestic Hajj Pilgrims: Implications for Future Mass Gatherings Amidst COVID-19. Trop Med Infect Dis. 2020;5(4):160.

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- My contribution: I am the first and corresponding author of this paper. I contributed to the concept and design of the study, data collection, formal analysis, and interpretation of the results. I also wrote the original draft, received comments from the co-authors, and edited subsequent versions of the manuscript.

Publication #4, Chapter 4: Mahdi HA, Rashid H, Qashqari FS, Hariri SH, Marglani OA, Barasheed O, et al. Syndromic surveillance of respiratory-tract infections and hand hygiene practice among pilgrims attended Hajj in 2021: a cohort study. BMC Infect Dis. 2022;22(1):578.

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In addition to the statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

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As a supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

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ETHICS CLEARANCE

Ethics approval was obtained from the following committees/boards.

- The Institutional Review Board of King Abdullah Medical City, Makkah, Saudi Arabia (IRB number: 19-558), dated 03-Aug-2019 (**Publication #2**).
- The Institutional Review Board of King Abdullah Medical City, Makkah, Saudi Arabia (IRB number: 20-661), dated 09-Jul-2020 (**Publication #3**).
- The Biomedical Ethics Committee, Umm Al-Qura University, Makkah, Saudi Arabia (Approval no. HAPO-02-K-012-2021-07-708), dated 18-Jul-2021 (**Publications #4, 5 and 7**).
- The Institutional Review Board of King Abdullah Medical City, Makkah, Saudi Arabia (IRB number: 21-772), dated 11-Apr-2021 (**Publications #6 and 7**).

ABSTRACT

Background

Religious mass gatherings (MGs) in the Kingdom of Saudi Arabia (KSA), the Hajj and Umrah pilgrimages, attract millions of participants annually, posing a high risk of transmission of respiratory tract infections (RTIs) due to dense populations, close contact, and shared accommodation. Hand hygiene (HH) is a fundamental infection control measure, but its preventive role against RTIs during MGs lacks focused research. Therefore, this PhD thesis aimed to assess knowledge, perceptions, and practices regarding HH and its role in preventing viral RTIs among attendees of religious MGs in KSA, including Hajj and Umrah pilgrims and visitors to the Prophet's Mosque, during the COVID-19 pandemic while also exploring the burden and epidemiological patterns of RTIs among pilgrims.

Methods

To achieve the study objectives, I embarked on five observational studies and a pilot randomised control trial (RCT) conducted between 2019 and 2021 among domestic Hajj and Umrah pilgrims in Makkah and visitors to the Prophet's Mosque in Al Madinah. A cross-sectional study was conducted during the 2019 Hajj season to assess HH knowledge and practices before the pandemic. Following that, another cross-sectional study was carried out among visitors to the Prophet's Mosque during the last four days of Hajj in 2020, exploring HH knowledge, perception, and practice during the pandemic. Building upon these studies, one cohort study evaluated HH behaviour and symptomatic viral RTI rates during the 2021 Hajj, followed by a post-Hajj cross-sectional study. In the same year (2021), amid the pandemic, a parallel RCT examined the relationship between HH and RTI rates during the peak period of the Umrah season. Subsequently, using the collected data, I compared the health behaviours and RTI rates between the 2021 Hajj

and Umrah pilgrims. In addition, I conducted a systematised review to compare airborne infection patterns among Hajj pilgrims from different countries with varying circumstances, including income status.

Results

The systematised review identified a high risk of RTIs during Hajj, regardless of pilgrims' nationality. However, my studies found an overall low prevalence of RTIs among both Hajj and Umrah pilgrims (5% and 2%, respectively) during the pandemic, with even lower rates of 'possible COVID-19' (1% and 0.4%, respectively). Nonetheless, Hajj pilgrims had significantly higher RTI rates than Umrah pilgrims ($p = 0.05$). Nearly half of symptomatic pilgrims (46%) in the post-Hajj study reported that at least one of their close contacts had experienced similar respiratory symptoms, implying a high risk of contact transmission following the pilgrimage.

Participants demonstrated moderate HH knowledge, with no apparent improvement during the pandemic (pre-pandemic: 6.7 ± 1.9 of a total score of 12 among Hajj pilgrims in 2019 versus amidst the pandemic: 6.4 ± 1.35 of a total score of 12 among visitors to the Prophet's Mosque in 2020 and 4.15 ± 1.22 of a total score of 6 among Hajj pilgrims in 2021). However, the majority of participants believed in HH methods' effectiveness against viruses like influenza and COVID-19. Compliance with HH practices was generally good, with handwashing with soap and water being the preferred method. Nonetheless, Hajj participants demonstrated higher compliance with alcohol-based hand rubs (ABHR) than Umrah participants (53% vs. 36%, respectively, $p < 0.001$).

The compliance rate with the HH intervention (ABHR) did not significantly differ between the intervention and control groups in our trial (37% vs. 36%, respectively, $p = 0.8$). Also, no statistically significant difference in RTI rates was found between the intervention and control groups during the pandemic (OR = 1.1; 95% CI 0.3–4.0), suggesting inconclusive evidence of

HH's protective role during Umrah. The pilot trial successfully demonstrated the feasibility of a future full-scale trial within the Umrah setting and similar MG settings.

Conclusion

This thesis highlighted the importance of HH during religious MGs in KSA amidst a pandemic, revealing a high risk of RTIs during the Hajj and underscoring the need for preventive measures. Although RTI prevalence decreased during the pandemic, monitoring the risk of RTI following MGs remains critical. Establishing a future RCT on HH's role in preventing RTIs during Umrah is feasible, and the outcome currently remains inconclusive. Ongoing efforts to improve HH knowledge and compliance among pilgrims are essential, along with further research to refine preventive measures in MG contexts. These findings have significant implications for global public health policy, not only in KSA but also in similar MG settings globally.

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LIST OF ABBREVIATIONS

ABHR	Alcohol-based hand rub
ARI	Acute respiratory infection
CAP	Community-acquired pneumonia
CATI	Computer-assisted telephone interview technique
CHG	Chlorhexidine-based cleanser
CI	Confidence interval
COVID-19	Novel coronavirus disease 2019
CSF	Cerebrospinal fluid
FIFA	Fédération Internationale de Football Association
HH	Hand hygiene
HIC	High-income country
ICU	Intensive care unit
ILI	Influenza-like illness
KSA	Kingdom of Saudi Arabia
LMIC	Low and middle-income countries
MERS-CoV	Middle East respiratory syndrome coronavirus
MG	Mass gathering
NOS	Newcastle-Ottawa Scale
OR	Odds ratio
PCR	Polymerase chain reaction
PCV13	13-Valent pneumococcal conjugate vaccine
PoCT	Point-of-care testing
PPE	Personal protective equipment

PPSV23	23-Valent pneumococcal polysaccharide vaccine
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomised controlled trial
RR	Relative risk
RTI	Respiratory tract infection
SARS	Severe acute respiratory syndrome
SARS-CoV-2	Severe acute respiratory syndrome coronavirus-2
SD	Standard deviation
SPSS	Statistical Package for Social Sciences
WHO	World Health Organization

DEFINITION OF TERMINOLOGIES RELATED TO RESPIRATORY TRACT INFECTIONS

Respiratory tract infections: This is a general term that refers to respiratory infections caused by either viral or bacterial agents.

Viral respiratory tract infections: This refers to infections exclusively caused by viral aetiology; more specifically, this term may refer to influenza or COVID-19, but may not include other viral diseases such as respiratory syncytial virus (RSV), parainfluenza, etc.

Emerging respiratory tract infections: This refers to infections that are newly recognised in a population or have existed but are rapidly increasing in incidence or geographic range. These include severe acute respiratory syndrome (SARS), influenza A/(H1N1)pdm09, Middle East respiratory syndrome coronavirus (MERS-CoV), and COVID-19.

Symptomatic/syndromic respiratory tract infections: This refers to infections, including influenza and COVID-19, that are diagnosed based on an assessment of clinical symptoms rather than laboratory tests.

Airborne infections: This refers to pathogens transmitted through air droplets/respiratory route, including those not predominantly causing respiratory tract infections, such as meningococcal diseases.

INTRODUCTION

1. Religious mass gatherings in the Kingdom of Saudi Arabia

A mass gathering (MG) is defined as "an organised or unplanned event attended by a sufficient number of people to strain the planning and response resources of a community, state, or nation hosting the event".¹ MGs can vary in their purpose, duration, size, and location. Religious congregations, political rallies, sports competitions, scientific and business conventions, and conferences are some examples of MG events that could be held worldwide at national, regional, or local levels. The duration of MGs may vary from several hours, e.g., music concerts and the Umrah pilgrimage, to days or weeks, e.g., the Hajj pilgrimage and the FIFA World Cup. Some organised MG events occur at different sites, e.g., the FIFA World Cup, or at a specific location, e.g., Hajj.² Although these MGs may bring several benefits to a host country, particularly in the form of financial revenues and cultural exchange, they have the potential to amplify health and safety issues. The greatest challenge for a city hosting an MG event is meeting the need for demand in the healthcare system's capacity to serve populations notably larger than its local population.¹ This is accompanied by outbreaks of communicable diseases and an increased incidence of non-communicable diseases, stampedes, alcohol and substance abuse, and terrorist incidents.³

The Kingdom of Saudi Arabia (KSA) is the custodian of two holy mosques: the Grand Mosque (Al-Masjid Al-Haram) in the city of Makkah (Figure 1) and the Prophet's Mosque (Al-Masjid Al-Nabawi) in the city of Al Madinah (Figure 2), which are the global destinations for millions of Muslims.² Makkah, known as Islam's holiest city, hosts 'Hajj' and 'Umrah', the two major religious MGs in Islam. Hajj (the major pilgrimage) is one of the five basic pillars of Islam and is thus obligatory for every physically and financially able practising Muslim. This Islamic pilgrimage is important because it is one of the world's largest annual religious MGs. Up to three

million Muslims from more than 180 nations gather to spend specified days in the last month of the Islamic lunar calendar year (called Dhul-Hijjah) at specific sacred sites within and on the outskirts of Makkah, including Mina (an unpopulated valley a few kilometres east of Makkah), the Plain of Arafat (a nearby hillside in Makkah), and Muzdalifah (a place located between Mina and Arafat).⁴

Unlike Hajj, Umrah (the minor pilgrimage) is not obligatory, and its rituals can be accomplished in a few hours at any time throughout the year within the Grand Mosque in Makkah.⁵ The fasting month of Ramadan is the peak season for Umrah, as it has almost similar spiritual significance to Hajj for the devotees; the Prophet Mohammad (peace be upon him) said, "Umrah in Ramadan is equivalent to Hajj (in religious reward)".⁵

Many Hajj and Umrah pilgrims visit the Prophet's Mosque, which houses the mausoleum of the Prophet Muhammad (peace be upon him). This visitation (known as Ziyarah) is not required as part of Hajj or Umrah, but it is a unique and revered optional opportunity that should not be missed; therefore, the majority of pilgrims include this visit in their itinerary and spend several days in Al Madinah city, which becomes the second most crowded city in KSA during Hajj and Umrah seasons.² Even during the peak period of Hajj when pilgrims stay in Makkah, many non-pilgrims celebrate Eid Al-Adha (the Feast of Sacrifice), which corresponds to the 10th of Dhul-Hijjah, by visiting the Prophet's Mosque and performing a special prayer. Figure 3 illustrates the detailed major differences between these religious MGs in KSA.

As an integral part of Saudi Arabia's Vision for 2030, the "Pilgrim Experience Program" seeks to enable the greatest number of pilgrims to perform these pilgrimages to the fullest extent and to enhance their experience by preparing the two holy mosques and providing the finest services to pilgrims before, during, and after visiting Makkah and Al Madinah.⁶

Figure 1. The Grand Mosque (Al-Masjid Al-Haram) in Makkah city.



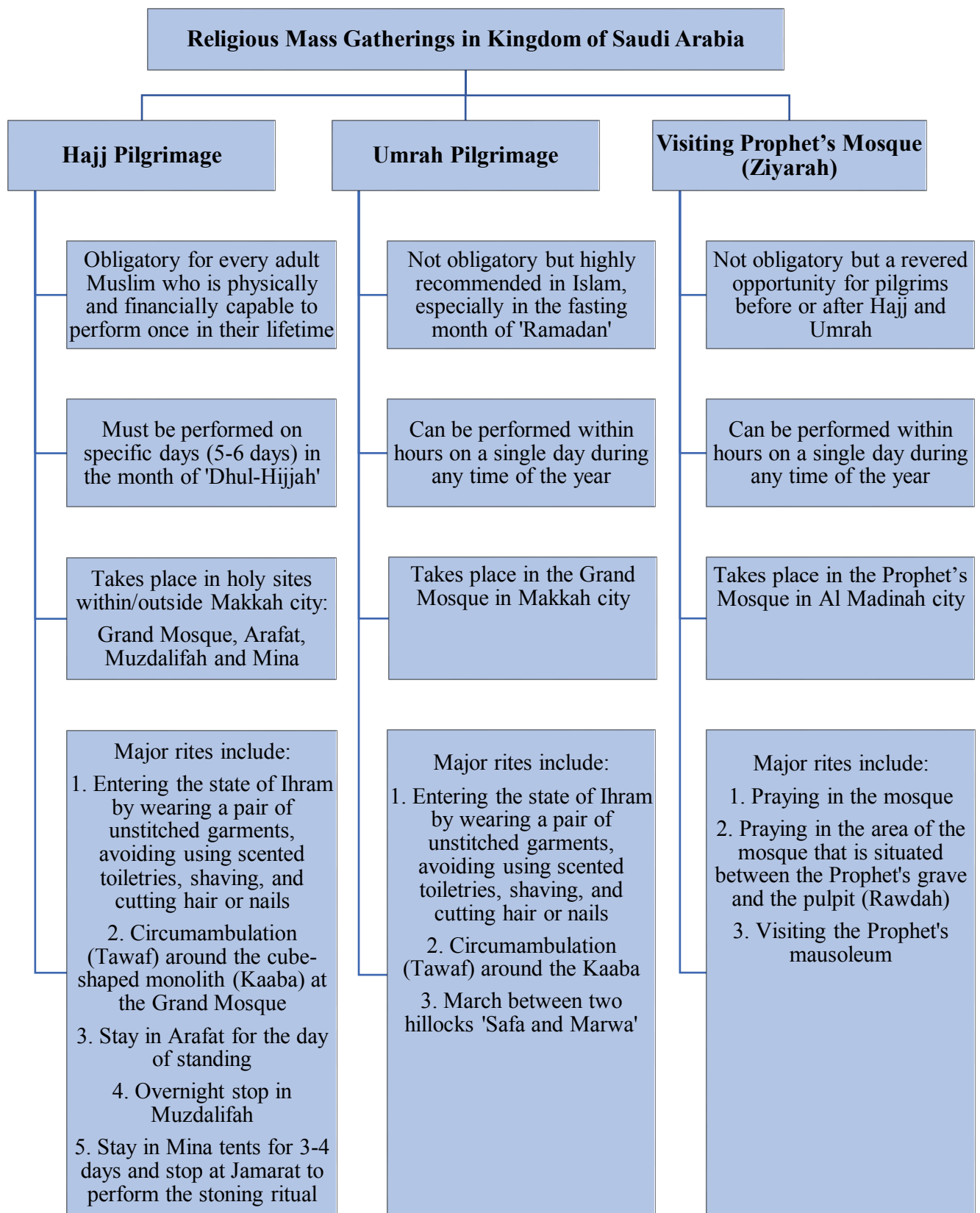
Image used with permission from Mr Emad Alhusayni, Saudi Arabia. ©Copyright of Emad Alhusayni Photography (emadphoto.com) [Accessed on 22 May 2023].

Figure 2. The Prophet's Mosque (Al-Masjid Al-Nabawi) in Al Madinah city.



Image used with permission from Mr Emad Alhusayni, Saudi Arabia. ©Copyright of Emad Alhusayni Photography (emadphoto.com) [Accessed on 22 May 2023].

Figure 3. Major differences between religious mass gatherings in Saudi Arabia.



Such religious events associated with MG have a confluence of special characteristics and potential risks. The potential for transmission of infectious diseases among attendees is a significant concern due to the inevitable severe congestion of participants in confined spaces and prolonged close contact in ritual sites with minimal physical distancing.^{7, 8} For instance, the tents in Mina, where Hajj pilgrims are required to stay for a minimum of three to four nights, have the capacity to house up to 100 to 150 individuals. This high density of individuals within the tents, coupled with prolonged close contact, may increase the likelihood of transmission of infections among pilgrims.⁹

The Hajj pilgrimage has been observed to impose significant ritual and physical demands on participants, which can result in a heightened vulnerability to severe morbidity and mortality.¹⁰ A major proportion of individuals who undertake this Islamic pilgrimage are older adults, with about 50% of them aged over 50 years and roughly 25% aged at least 65 years, who attain the necessary resources to perform Hajj after years of saving.¹¹ Among those pilgrims, many of them suffer from pre-existing health conditions such as diabetes mellitus, chronic lung disease, cardiovascular disease, or other chronic illnesses.¹² In addition, the Islamic lunar calendar experiences a lag of approximately 10 to 11 days in relation to the Gregorian calendar on an annual basis; hence, the timing of the Hajj pilgrimage may vary across different seasons, ranging from the winter influenza peak in the northern hemisphere to the meningitis season in sub-Saharan Africa.¹³

2. Risk of respiratory tract infections at Hajj and Umrah

A series of major health issues have long been documented at Hajj throughout its 1,400-year history. Historical documents recorded instances of cholera outbreaks afflicting pilgrims prior to 1989, alongside the widespread prevalence of meningococcal disease, including the major Serogroup A outbreak in 1987.¹⁴ This historical narrative sets the backdrop for the evolving landscape of health concerns at these MGs.

Over time, the focus has increasingly shifted towards respiratory tract infections (RTIs) as the most prevalent health issue encountered by pilgrims during Hajj and Umrah. A series of recent clinical and microbiological studies have investigated RTIs among pilgrims (summarised in Table 1). The prevalence of RTIs varied across the studies. A 2016 Malaysian surveillance found that 71% of Hajj pilgrims were confirmed to have at least one positive respiratory pathogen¹⁵; conversely, another study between the 2013 and 2015 Hajj seasons showed that 7% of Chinese pilgrims had a viral RTI.¹⁶ Foremost among the clinical symptoms reported by affected pilgrims is cough, with rates varying from 40% to 100%,^{15, 17} followed by a sore throat from 46% to 78%,^{15, 18} rhinitis from 27% to 65%,^{15, 19} and fever from 2% to 41%.^{16, 20} The results of laboratory-based studies detected multiple viral and bacterial agents causing RTIs. Concerning viral aetiology, human rhinovirus was the most commonly isolated virus among pilgrims, with a prevalence ranging from 0.5% to 42%,^{21, 22} followed by influenza from 3% to 40%,^{19, 23} and human coronavirus from 0.3% to 19%.^{16, 24} *Haemophilus influenzae* was the most prevalent bacteria, with a range of 5% to 43%,^{15, 22} followed by *Staphylococcus aureus* (1–36%),^{18, 19} *Klebsiella pneumoniae* (0.5–21%),^{15, 25} and *Streptococcus pneumoniae* (0.5–18%).^{22, 25}

Table 1. Summary of recent studies that reported the burden of respiratory tract infections among Hajj and Umrah pilgrims.

Author ^{ref}	Hajj/Umrah	Nationality (study year)	Clinical symptoms (%)	RTI burden (%)	Detected Pathogens (%)
Memish et al ²⁴	Hajj	Different nationalities (2013)	NR	62	Rhinovirus (34) Influenza (4) Coronavirus (19) <i>S. pneumoniae</i> (13) <i>K. pneumoniae</i> (4) <i>S. aureus</i> (8) <i>H. influenzae</i> (12)
Barasheed et al ¹⁷	Hajj	Saudi, Australian and Qatari (2013)	Cough (40) Rhinitis (34) Sore throat (59)	11	Rhinovirus (25) Influenza (4) Coronavirus (2)
Agustining sih et al ²³	Hajj and Umrah	Indonesian (2013–2014)	NR	40	Influenza (40)
Hashem et al ²⁶	Hajj	Different nationalities (2014)	NR	51	Rhinovirus (12) Influenza (29) Coronavirus (18)
Al-Abdallat et al ²⁰	Hajj	Jordanian (2014)	Cough (76) Rhinitis (37) Sore throat (50) Fever (41)	58	Rhino/enterovirus (47) Coronavirus (13) influenza (5)
Refaey et al ²⁷	Hajj	Egyptian (2012–2015)	NR	30	Influenza (14)
Ma et al ¹⁶	Hajj	Chinese (2013–2015)	Fever (2)	7	Influenza (6) Coronavirus (0.3)
Alfelali et al ²⁸	Hajj	Saudi, Australian and Qatari (2013–2015)	NR	43	Rhinovirus (35) Influenza (4)
Erdem et al ²²	Hajj and Umrah	Turkish (2013–2015)	NR	33	Influenza (8) Coronavirus (0.5) Rhinovirus (0.5) <i>S. pneumoniae</i> (0.5) <i>H. influenzae</i> (0.5)
Koul et al ²⁹	Hajj and Umrah	Indian (2014–2015)	NR	32	Influenza (11) Coronavirus (17) Rhinovirus (6)

Muraduzza man et al ³⁰	Hajj	Bangladeshi (2013–2016)	NR	30	Influenza (22)
Noor Nik Zuraina et al ¹⁵	Hajj	Malaysian (2016)	Cough (100) Rhinitis (27) Sore throat (46) Fever (32)	71	<i>H. influenzae</i> (43) <i>S. pneumoniae</i> (1) <i>K. pneumoniae</i> (0.5)
Hoang et al ²⁵	Hajj	French (2014–2017)	Cough (72) Rhinitis (55) Sore throat (46) Fever (25)	17	Rhinovirus (27) Coronavirus (8) Influenza (4) <i>H. influenzae</i> (32) <i>K. pneumoniae</i> (21) <i>S. pneumoniae</i> (18) <i>S. aureus</i> (14)
Alasmari et al ³¹	Hajj	Different nationalities (2017)	Cough (44)	39	NR
Hoang et al ¹⁹	Hajj	French (2014–2016 and 2018)	Cough (43) Rhinitis (65) Sore throat (63) Fever (39)	25	Rhinovirus (40) Coronavirus (15) Influenza (3) <i>S. aureus</i> (36) <i>H. influenzae</i> (30) <i>K. pneumoniae</i> (17) <i>S. pneumoniae</i> (4)
Bokhary et al ¹⁸	Hajj	Different nationalities (2018)	Cough (74) Rhinitis (61) Sore throat (78) Fever (40)	7	<i>H. influenzae</i> (5) <i>S. pneumoniae</i> (2) <i>S. aureus</i> (1)
Alsayed et al ²¹	Hajj	Different nationalities (2019)	NR	68	Rhinovirus (42) Influenza (29) Coronavirus (19)

NR = not reported

Pneumonia has been identified as the leading cause of hospitalisation and admission to intensive care units (ICU) during Hajj. For instance, it was the primary cause contributing to critical illness among pilgrims requiring ICU admission in 15 hospitals in Makkah and Al Madinah consecutively over two Hajj years (2009 and 2010).³² A study investigated the burden of community-acquired pneumonia (CAP) during Hajj 2016, revealing that the majority of cases (71%) were admitted in hospitals in Makkah, with 53% post-Hajj, of whom 45% required ICU care, resulting in an overall case-fatality rate of 10%.³³ A retrospective analysis of all patients diagnosed with pneumonia and admitted to a hospital in Al Madinah during the Hajj period of 2004–2013 revealed that 37.4% had positive sputum cultures, with primary organisms including *S. aureus* (36.1%), *K. pneumoniae* (29%), *H. influenzae* (24.3%), community-acquired MRSA (6.5%), *Pseudomonas aeruginosa* (3.1%), and *S. pneumoniae* (1%), while the mortality rates were 2% in the hospital ward and significantly higher at 21% in the ICU.³⁴ In a recently published cross-sectional study focusing on pneumonia cases among Hajj and Umrah participants, 38 clinical samples were examined for bacterial pathogens: 66% of samples tested positive for bacteria, with *H. influenzae* (26.4%), *Moraxella catarrhalis* (20.8%), *K. pneumoniae* (13.2%), *S. pneumoniae* (9.4%), and *S. aureus* (5.7%) being the detected causative agents.³⁵

Emerging infectious diseases are of particular concern at MGs, which have a high epidemic potential and could lead to an unprecedented intercontinental outbreak. Several viral RTIs have emerged in recent years, such as severe acute respiratory syndrome (SARS) in 2003, the influenza A H1N1 (H1N1pdm09) pandemic in 2009, the Middle East respiratory syndrome coronavirus (MERS-CoV) in 2012, and more recently the coronavirus disease (COVID-19) pandemic.^{36, 37, 38} Many studies have investigated the emerging viral RTIs among pilgrims over the past few years. For instance, a few studies examined the 2009 H1N1 pandemic among Hajj pilgrims: Ashshi et al³⁹ reported 9 (0.6%) cases; Moattari et al⁴⁰ reported 5 (1.8%) cases; Ziyaeyan et al⁴¹ reported 5 (1.6%) cases; Memish et al⁴² reported 2 (0.1%) cases; Kandeel et al³⁸ did not report any cases

among the participants studied. Since 2012, surveillance studies on the incidence of MERS-CoV infection among Hajj pilgrims have been conducted, but no cases have been reported⁴³; however, several cases have been recorded among Umrah pilgrims and other travellers to KSA.⁴⁴ A few recent studies estimated the rates of COVID-19 among Hajj and Umrah pilgrims in the midst of the pandemic. During Hajj in 2021, a retrospective surveillance study revealed that 41 out of 58,428 pilgrims tested positive for COVID-19 via real-time polymerase chain reaction (PCR) tests performed before, during, and after the event.⁴⁵ Another study was conducted at Cairo International Airport to determine the incidence of COVID-19 among Egyptian pilgrims who had completed their Umrah during the month of Ramadan in 2022: 6.7% (n = 67) of 1003 participants tested were positive for COVID-19.⁴⁶

Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) can spread through droplet or droplet nuclei so behaviours like coughing, sneezing, speaking, singing or breathing can spread person-to-person transmission.⁴⁷ This infection has affected more than 770 million people worldwide, with over six million casualties, and in KSA there have been 841,469 confirmed cases and 9,646 mortalities (as of 10 September 2023).⁴⁸ The first official case of COVID-19 in KSA was detected in March 2020, about five months before the 2020 Hajj.⁴⁹ The authorities in KSA implemented multiple drastic preventive and mitigation measures at the holy mosques to stop the spread of the virus during Hajj and Umrah congregations (2020, 2021, and 2022) (Figure 4). In the early stage of the pandemic, the KSA government decided to impose a lockdown at the holy mosques and entirely suspend Umrah and Ziyarah.⁵⁰ The number of pilgrims for the 2020 Hajj, which took place in late July and early August, was drastically downscaled to only 1,000 residents of all nationalities inside KSA who were closely observed and accompanied by medical personnel.⁴⁹ By the end of 2020, some of these stringent restriction measures were gradually lifted, and Umrah resumed, although a limited number of COVID-19-vaccinated domestic pilgrims were permitted to participate in Umrah and Ziyarah under strict health precautions.⁵¹ When the next

Hajj season was held in July 2021, the number of participating pilgrims was raised to 60,000 pre-selected residents of KSA who obtained two doses of the COVID-19 vaccine, in addition to a strictly implemented bundle of COVID-19 personal protective measures (e.g., wearing facemasks, observing personal hygiene, and maintaining social distancing).⁴⁵ As of October 2021, nearly a year and a half since the initial closure, the full capacity of the Grand Mosque began to be re-utilised, and further prayers and more Umrah pilgrims were permitted.⁵² As a result of the success of the Hajj 2020 and 2021, as well as the excellent coverage of the COVID-19 vaccination, the KSA government escalated the number of pilgrims to nearly one million and allowed international pilgrims to attend Hajj 2022.⁵³ In a significant decision, the government of KSA permitted an unrestricted Hajj pilgrimage in 2023, drawing over 1.8 million Muslims, including one and a half million international pilgrims from 150 countries. This marked the largest Hajj season post-COVID-19, proceeding seamlessly without noticeable outbreaks or public health threats.⁵⁴

Figure 4. Pilgrims at the Grand Mosque amidst the COVID-19 pandemic.

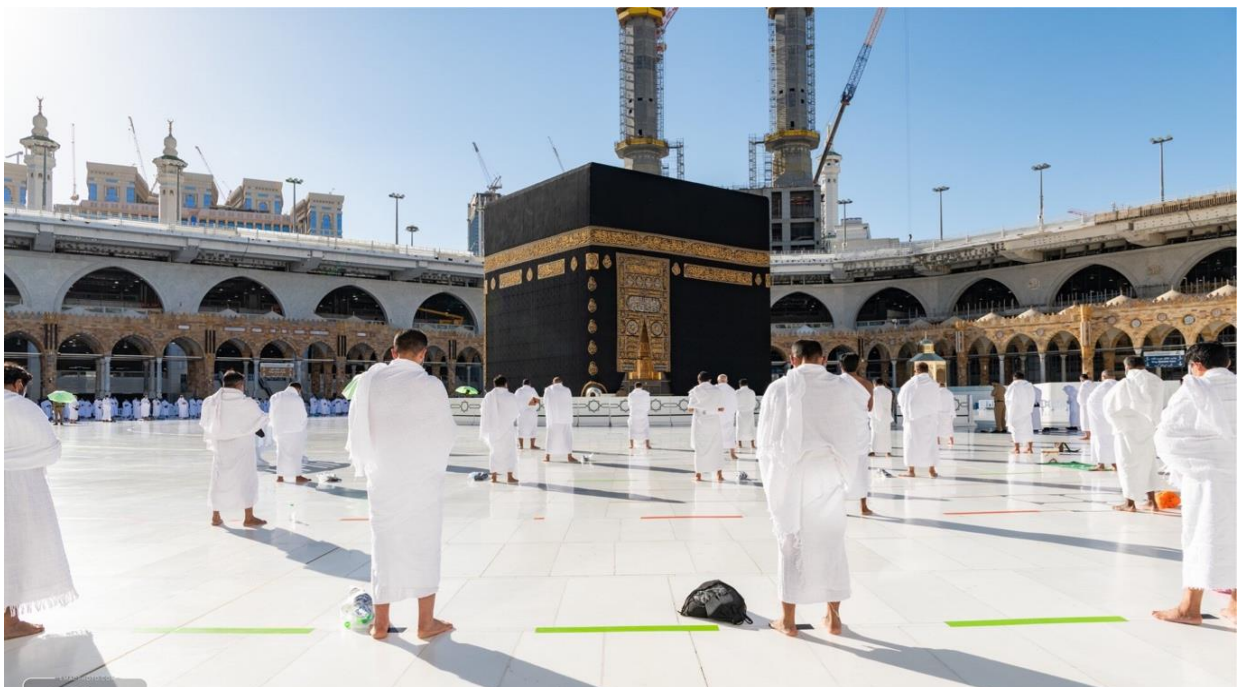


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3. Hand hygiene interventions to prevent respiratory tract infections

Various pharmaceutical and non-pharmaceutical interventions have been recommended and implemented to interrupt or reduce the spread of infectious diseases among the attendees of MGs; these interventions have been refined annually based on the global epidemiological scenario.⁵⁵ Pharmaceutical measures such as vaccinations and antiviral drugs are considered the key preventive and control measures against RTIs but may not be sufficient to prevent the spread of all viral RTIs potentially caused by a few hundred different viruses, particularly in the context of a pandemic; hence, non-pharmaceutical interventions such as hand hygiene (HH), facemasks, cough etiquette, and social distancing complement these pharmacological interventions. However, evidence on the preventive role of most non-pharmaceutical interventions against RTIs among participants in MG settings is inconclusive or unproven. For example, a large randomised controlled trial (RCT) among Hajj pilgrims found that using a facemask seemed to be ineffective against viral RTIs.²⁸

Using HH methods frequently and thoroughly is one of the most fundamental infection control and prevention measures. Handwashing with soap and water for at least 20 seconds or hand sanitisation with a 60% alcohol-based hand rub (ABHR) can help prevent viral RTIs in events where people are more likely to mix, contract, and disseminate infections.⁵⁶ Systematic reviews in a variety of settings have demonstrated the role of HH in reducing the burden of RTIs,^{57, 58, 59} but there is very limited focused research on the role of HH in MGs. In a recent systematic review to evaluate the efficacy of HH and other physical interventions against respiratory viruses in settings such as schools, childcare centres, and households, the pooled data from 19 RCTs (Table 2) revealed that HH interventions may be beneficial with an 11% relative reduction in RTIs (relative risk [RR] = 0.89; 95% confidence interval [CI] 0.83–0.95); this benefit would result in a reduction from 200 to 178 events per 1000 persons (95% CI 166–188).⁶⁰

Table 2. Summary of randomised controlled trials on the efficacy of hand hygiene in non-mass gathering settings.

Author ^{ref}	Study population (Year)	Intervention	Outcome
Ashraf et al ⁶¹	Young children in rural communities in Bangladesh (2012–2013)	Handwashing with soap and water	Handwashing reduced ARI cases by 32% (RR = 0.68; 95% CI 0.52–0.88).
Azor-Martinez et al ⁶²	Children in day care centres in Spain (2013–2014)	Educational intervention and HH products (soap and sanitiser)	The soap group had less risk of RTI episodes (RR = 0.77; 95% CI 0.68–0.88) than the control group. The sanitiser group had a higher risk of RTI episodes (IRR = 1.21; 95% CI 1.06–1.39) than the soap group.
Biswas et al ⁶³	Primary schoolchildren, Bangladesh (2015)	Hand sanitiser and a respiratory hygiene education	Incidence of laboratory-confirmed influenza was 53% lower in the intervention arm (3/1,000 person-weeks) than in the control arm (6/1,000 person-weeks) ($p = 0.01$).
Correa et al ⁶⁴	Children 1–5 years in childcare centres in Colombia (2008)	Hand sanitiser plus handwashing	Significant risk reductions for ARI in the intervention compared to control arm $p < 0.001$.
Cowling et al ⁶⁵	Household members in Hong Kong (2008)	HH education and products (liquid soap and ABHR)	HH seemed to reduce influenza transmission, but the differences compared with the control group (only education) were not significant.
Cowling et al ⁶⁶	Household members in Hong Kong (2007)	HH education and products (liquid soap and ABHR)	6% secondary attack ratio of household contacts with laboratory confirmed influenza, but it did not significantly differ across the intervention arms.
Hubner et al ⁶⁷	Employees at workplaces in Germany (2005–2006)	ABHR	ABHR significantly reduced the episodes of common cold (OR = 0.35; 95% CI 0.17–0.71), fever (OR = 0.38; 95% CI 0.14–0.99) and coughing (OR = 0.45; 95% CI 0.22–0.91).
Larson et al ⁶⁸	Hispanic households in USA (2006–2008)	HH education with ABHR	ABHR group was significantly more likely to report that no household member had symptoms ($p = 0.01$), but there were no significant differences in rates of infection by intervention group in multivariate analyses.

Little et al ⁶⁹	Individuals sharing a household in UK (2011–2013)	Internet-based intervention to maximise handwashing intention and monitor behaviour	51% of individuals in the intervention group reported at least RTI episodes vs. 59% in the control group (RR = 0.86; 95% CI 0.83–0.89; $p < 0.0001$).
Millar et al ⁷⁰	Military Trainees in USA	Enhanced promotion vs. promotion plus a chlorhexidine-based cleanser (CHG)	ARI rates were lower in the enhanced standard group (RR = 0.82; 95% CI 0.80–0.87) and marginally higher in the CHG group (RR = 1.07; 95% CI 1.03–1.11) when compared with the standard group.
Nicholson et al ⁷¹	Community children aged 5 years in India (2007–2008)	Combination of HH promotion with provision of free soap	Intervention group 5-year-olds had fewer episodes of ARI (15%; 95% CI 30–8).
Ram et al ⁷²	Index case-patients in communities in Bangladesh (2009–2010)	Soap and daily handwashing promotion	Intervention was not associated with lower rates of ILI or laboratory-confirmed influenza among compound or household members; secondary attack ratio for intervention to control for ILI 1.24 (95% CI 0.93–1.65) and Laboratory-confirmed influenza 2.40 (95% CI 0.68–8.47).
Roberts et al ⁷³	Staff in childcare centres in Australia (1996)	Training on infection control, handwashing, and aseptic nose-wiping technique	No significant reduction in colds in intervention group across the full age range; Incidence rate ratio for ARI 0.92 for intervention to control (95% CI 0.86–0.99).
Sandora et al ⁷⁴	Homes of families with children in USA (2002–2003)	Campaign to increase using ABHR and HH education	Overall rate of secondary respiratory illness was not significantly different between groups (IRR = 0.97; 95% CI 0.72–1.30).
Simmerman et al ⁷⁵	Households with a febrile, influenza-positive child in Thailand (2008–2009)	HH education and standard unscented liquid soap	Secondary influenza infection was not significantly different in the handwashing group (OR = 1.20; 95% CI 0.76–1.88; $p = 0.44$).
Stebbins et al ⁷⁶	Children in elementary schools in USA (2007–2008)	Training in hand and respiratory hygiene plus hand sanitiser	No significant effect of the intervention on all laboratory confirmed influenza cases (IRR = 0.81; 95% CI 0.54–1.23).

Swarthout et al ⁷⁷	Pregnant women from Kenyan villages (2012–2014)	Handwashing with soap	No evidence of an effect of intervention on prevalence of ARIs in children (RR = 0.97; 95% CI 0.90–1.04).
Teesing et al ⁷⁸	Nursing staff in nursing home in Netherlands (2016–2017)	HH enhancement activities: an e-learning, live lessons, posters, and a photo competition	HH reduced risk of ILI (RR 0.51; 95% CI 0.31–0.83) in the intervention arm vs. the control arm.
Zomer et al ⁷⁹	Caregivers and children in day care centres in Netherlands (2011–2012)	HH products, training sessions, and posters/stickers	No evidence for an effect of the intervention on the incidence of episodes of common cold (IRR = 1.07; 95% CI 0.97–1.19).

ABHR: alcohol-based hand rub; ARI: acute respiratory infection; HH: hand hygiene; ILI: influenza-like illness; RTI: respiratory tract infection.

Regarding the use of HH in MG settings, limited observational studies conducted before the COVID-19 pandemic resulted in inconsistent evidence about the role of HH in preventing viral and bacterial RTIs among Hajj pilgrims.⁸⁰ Surveys conducted among pilgrims from the USA in 2009, Malaysia in 2013, and Australia in 2015 demonstrated that practising HH effectively reduced symptomatic RTIs.^{81, 82, 83} Interestingly, a study observed that French pilgrims who engaged in more frequent handwashing were more likely to experience fever and respiratory symptoms during the 2012 Hajj compared to those with typical handwashing habits.⁸⁴ Conversely, in 2013, the same team found that participants who used ABHR had a lower prevalence of *S. pneumoniae* in throat swab specimens compared to those who did not use ABHR, yet participants who reported frequent handwashing with soap only had a non-significantly lower prevalence of the bacteria.⁸⁵ Nevertheless, another two studies did not find any association between HH and a decreased risk of RTIs among French pilgrims.^{86, 87}

Practising HH methods is one of the most preferred infection prevention and control measures during these Islamic pilgrimages. Several studies indicated a good uptake of HH among Hajj pilgrims; for example, most Australian pilgrims in 2014 and 2015 (94% and 69%, respectively) frequently cleaned their hands with soap and with ABHR,^{83, 88} and a significant proportion of French pilgrims in 2012 and 2013 (40% and 50%, respectively) reported frequent handwashing and, respectively, 46% and 67% used ABHR.^{84, 85} A good practice of HH was also found among Umrah pilgrims; for instance, more than half of Malaysian pilgrims in 2018 practised HH interventions, including washing their hands after handshakes, touching doorknobs, sneezing, and coughing,⁸⁹ as well as the vast majority of pilgrims (82%) who participated in a 2019 study at an international airport in KSA washed their hands with soap and water or used ABHR after coughing or sneezing.⁹⁰

Notably, handwashing with soap and water was the most frequently reported method for hand cleaning by pilgrims, followed by ABHR, as evidenced by a previous systematic review by Alqahtani and colleagues, which concluded that the compliance rate of washing hands with soap and water among Hajj participants ranged from 32% to 90% (a pooled estimate of 69%), whereas the use of ABHR ranged from 31% to 77% (a pooled estimate of 51%).⁸⁰

Hajj and Umrah are unique settings to explore the role of HH in preventing the transmission associated with such MG events. However, there is a paucity of focused studies investigating the preventive role of HH against viral RTIs and other key research questions around HH use among attendees of these MGs, particularly amidst a global pandemic.

4. Thesis aims and objectives

This PhD thesis aims to assess knowledge, perceptions, and practices regarding HH and its role in preventing viral RTIs among attendees of religious MGs in KSA, including Hajj and Umrah pilgrims and visitors to the Prophet's Mosque, amidst the COVID-19 pandemic while also exploring the burden and epidemiological patterns of RTIs among pilgrims.

The thesis addresses the following six research objectives:

- | | |
|----------------------------|--|
| <u>Objective #1</u> | Investigate the epidemiological patterns of airborne infections among Hajj pilgrims. |
| <u>Objective #2</u> | Assess HH knowledge and practices among Hajj pilgrims prior to the COVID-19 pandemic. |
| <u>Objective #3</u> | Assess HH knowledge and practices among Hajj pilgrims and visitors to the Prophet's Mosque at different stages during the COVID-19 pandemic. |
| <u>Objective #4</u> | Estimate the rates of syndromic viral RTIs among Hajj pilgrims during the COVID-19 pandemic. |
| <u>Objective #5</u> | Explore the relationship between practising HH and rates of RTIs in Umrah amidst the COVID-19 pandemic. |
| <u>Objective #6</u> | Compare pilgrims' HH knowledge, practices, and rates of RTIs during the peak periods of Umrah and Hajj. |

5. Thesis structure

This thesis contains a total of six chapters, and each of these chapters covers at least one of the six research objectives and comprises one to two of the seven published manuscripts.

The thesis chapters and their linked objectives and publications are presented as follows:

Chapter 1: A review of epidemiological patterns of Hajj-acquired airborne infections among pilgrims

Linked objective:

- Objective #1: Investigate the epidemiological patterns of airborne infections among Hajj pilgrims.

Linked publication:

- Publication #1: Epidemiological differences in Hajj-acquired airborne infections in pilgrims arriving from low and middle-income versus high-income countries: A systematised review.

Chapter 2: Hand hygiene knowledge and practices among domestic Hajj pilgrims before the COVID-19 pandemic hit

Linked objective:

- Objective #2: Assess HH knowledge and practices among Hajj pilgrims prior to the COVID-19 pandemic.

Linked publication:

- Publication #2: Hand hygiene knowledge and practices among domestic Hajj pilgrims: Implications for future mass gatherings amidst COVID-19.

Chapter 3: Hand hygiene knowledge, perception, and practices among domestic visitors to the Prophet's Mosque amid the COVID-19 pandemic

Linked objective:

- Objective #3: Assess HH knowledge and practices among Hajj pilgrims and visitors to the Prophet's Mosque at different stages during the COVID-19 pandemic.

Linked publication:

- Publication #3: Hand hygiene knowledge, perception, and practices among domestic visitors to the Prophet's Mosque in Al Madinah city amid the COVID-19 pandemic: A cross-sectional study.

Chapter 4: Surveillance of respiratory tract infections and hand hygiene among pilgrims who attended the 2021 Hajj season

Linked objectives:

- Objective #3: Assess HH knowledge and practices among Hajj pilgrims and visitors to the Prophet's Mosque at different stages during the COVID-19 pandemic.
- Objective #4: Estimate the rates of syndromic viral RTIs among Hajj pilgrims during the COVID-19 pandemic.

Linked publications:

- Publication #4: Syndromic surveillance of respiratory tract infections and hand hygiene practice among pilgrims attended Hajj in 2021: A cohort study.
- Publication #5: Low prevalence of syndromic respiratory tract infections among returning Hajj pilgrims amidst the COVID-19 pandemic: A post-Hajj survey.

Chapter 5: Feasibility of establishing a large trial among pilgrims amidst a pandemic to explore the relationship between practising hand hygiene and rates of respiratory tract infections

Linked objective:

- Objective #5: Explore the relationship between practising HH and rates of RTIs in Umrah amidst the COVID-19 pandemic.

Linked publication:

- Publication #6: The relationship between hand hygiene and rates of acute respiratory infections among Umrah pilgrims: A pilot randomised controlled trial.

Chapter 6: A comparison of pilgrims' hand hygiene knowledge, practices, and rates of respiratory tract infections during the peak of Umrah and Hajj

Linked objective:

- Objective #6: Compare pilgrims' HH knowledge, practices, and rates of RTIs during the peak periods of Umrah and Hajj.

Linked publication:

- Publication #7: Hand hygiene knowledge and practices, and rates of respiratory tract infections between Hajj and Umrah pilgrims: A comparative study.

CHAPTER 1: A review of epidemiological patterns of Hajj-acquired airborne infections among pilgrims

Hajj pilgrims come from different regions with distinct cultural and health profiles. Pilgrims from countries with a low burden of disease are at risk of contracting an infection from those from countries with a high burden due to their proximity in confined spaces during rituals.⁹¹ Before commencing the journey, many pilgrims, especially those from developing countries, may lack access to sufficient public health measures, e.g., vaccinations.¹² Such diversity may result in influencing the burden of health risks associated with this pilgrimage. However, the burden of infections acquired during Hajj among participants from low and middle-income countries (LMIC) and high-income countries (HIC) was not compared, and thus I was prompted to conduct a systematised review comparing the epidemiological patterns of Hajj-acquired airborne infections among pilgrims from LMIC versus HIC (Publication #1).

The data synthesis from studies on the burden of laboratory-confirmed airborne diseases during Hajj revealed that pilgrims from both regions are susceptible to contracting airborne infections, but there appear to be variations in the prevalence of certain infections among pilgrims from LMIC or HIC compared to the other group. Studies presenting data on pilgrims' vaccination uptake revealed considerable variability among both LMIC and HIC pilgrims, reflecting differing uptake rates of recommended vaccines possibly due to variations in vaccine availability and policies between nations. Enhanced vaccination coverage and effective protective methods are required to interrupt the transmission of airborne diseases during Hajj, regardless of pilgrims' socioeconomic background or nation of origin.

Publication #1: Mahdi HA, Alluhidan M, Almohammed AB, Alfelali M, Shaban RZ, Booy R, et al. Epidemiological Differences in Hajj-Acquired Airborne Infections in Pilgrims Arriving from Low and Middle-Income versus High-Income Countries: A Systematised Review. *Trop Med Infect Dis.* 2023;8(8):418. <https://doi.org/10.3390/tropicalmed8080418>.



Systematic Review

Epidemiological Differences in Hajj-Acquired Airborne Infections in Pilgrims Arriving from Low and Middle-Income versus High-Income Countries: A Systematised Review

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Abstract: This systematised review aims to compare the epidemiological patterns of Hajj-acquired airborne infections among pilgrims from low and middle-income countries (LMIC) versus those from high-income countries (HIC). A PubMed search was carried out for all published articles before February 2023, using a combination of MeSH terms and text words. The Newcastle–Ottawa Scale (NOS) was used to assess data quality. From a total of 453 titles identified, 58 studies were included in the review (LMIC = 32, and HIC = 26). In the pooled sample, there were 27,799 pilgrims aged 2 days to 105 years (male: female = 1.3:1) from LMIC and 70,865 pilgrims aged 2 months to 95 years (male: female = 1:1) from HIC. Pilgrims from both HIC and LMIC had viral and bacterial infections, but pilgrims from HIC tended to have higher attack rates of viral infections than their LMIC counterparts. However, the attack rates of bacterial infections were variable: for instance, pilgrims from LMIC seemed to have higher rates of meningococcal infections (0.015–82% in LMIC vs. 0.002–40% in HIC) based on the study population, but not *Mycobacterium tuberculosis* (0.7–20.3% in LMIC vs. 38% in HIC). Targeted measures are needed to prevent the spread of airborne infections at Hajj.

Keywords: airborne infections; Hajj; high-income countries; low and middle-income countries; pilgrims

1. Introduction

Hajj is an annual religious mass gathering (MG) held in Makkah, the Kingdom of Saudi Arabia (KSA), which, during a non-pandemic year, attracts more than two million pilgrims to attend the pilgrimage [1]. During the Hajj pilgrimage, the climatic conditions and inevitable overcrowding of pilgrims in Makkah and the surrounding holy sites significantly increase the likelihood of contracting and transmitting infectious diseases [2]. Pilgrims come from over 180 countries, including both high-income and low-income nations, with various

unique cultural, nutritional and health behaviour backgrounds. Pilgrims originating from regions with variable disease profiles present one of the most significant challenges to the host country. Certain diseases or infectious agents may be prevalent in some regions but not in others [3], which makes it difficult for the host country to apply a uniform preventive guideline. Additionally, pilgrims from countries with a low burden of disease may acquire infection from pilgrims from countries with a high burden of disease, due to their close contact in confined spaces in accommodation and during rituals [2]. Also, many pilgrims, particularly those from developing countries, may have limited access to adequate healthcare services and preventative measures, e.g., vaccinations before they commence their journey [4]. Such diversity in the pilgrim population might determine the burden of health risks acquired during this MG event.

In particular, airborne infections are a major public health issue and a significant cause of morbidity at Hajj. Pneumonia is the leading cause of hospitalisation during Hajj and the second or third most common cause of admission to the intensive care unit (ICU) during Hajj [5]. Furthermore, many airborne infections have emerged in recent decades, including severe acute respiratory syndrome (SARS) in 2003, the influenza A (H1N1)pdm09, the Middle East respiratory syndrome coronavirus (MERS-CoV) in 2012, and, more recently, the novel coronavirus disease 2019 (COVID-19) in 2019, presenting a major public health and infection control challenge for both the authorities in KSA and the national authorities in the pilgrims' countries of origin [6,7].

A handful of systematic reviews have provided a comprehensive overview of available evidence on the burden of respiratory infections in Hajj [5,8–11]; however, no study was undertaken to compare the burden of infections at Hajj among participants from low and middle-income countries (LMIC) and high-income countries (HIC). This comparison is important, as it can inform future public health policy and identify potential prevention and control strategies. Therefore, this systematised review aims to compare the epidemiological patterns of Hajj-acquired airborne infections among pilgrims from LMIC versus HIC. By the term 'airborne infection', we mean any infection transmitted by respiratory route, irrespective of whether it primarily causes respiratory infection or not, so infections like 'meningococcal disease' were also included.

2. Materials and Methods

2.1. Search Strategy and Study Selection

This review was conducted and reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [12]. However, we did not attempt to register this systematised review with PROSPERO or other registry databases as the process takes much longer during the COVID-19/post-COVID-19 period, and we did not intend to delay this important systematic review.

The PubMed electronic database was comprehensively searched for all relevant articles published from inception to February 2023. Also, a manual search was conducted to identify additional potentially eligible articles by reviewing the reference lists of the included studies. The search strategy was developed using a combination of MeSH terms and keywords, including: 'Hadj' OR 'Hadz' OR 'Hajj' OR 'Mecca' OR 'Makkah' OR 'pilgrimage' OR 'pilgrims' AND 'respiratory tract infection' OR 'airborne infection' OR 'acute respiratory infection'.

Three independent reviewers (HAM, M. Alluhidan, and HR) evaluated the retrieved studies for eligibility by screening titles and abstracts, selected relevant manuscripts based on the inclusion criteria, and then reviewed the full texts of each paper potentially meeting the inclusion criteria. If any discrepancies or disagreements arose, they were resolved through discussion among the researchers. The inclusion criteria included primary studies reporting microbiological data on viral or bacterial respiratory infections involving Hajj pilgrims of any age, gender, or country of origin that employed a laboratory-based diagnostic method. Only English language articles were considered for this review. Studies conducted outside the Hajj setting or involving non-pilgrim participants rather than

Hajj pilgrims or reporting only clinical or self-reported respiratory symptoms or infections without laboratory-confirmed data were excluded. The pilgrims' countries of origin were classified based on the 2021–2022 World Bank Classification for countries by income (<https://datatopics.worldbank.org/world-development-indicators/the-world-by-income-and-region.html> accessed on 2 March 2023).

2.2. Data Extraction and Synthesis

The data were independently extracted from each included article by two authors (HAM and M. Alluhidan) into an extraction spreadsheet. The extracted data were then cross-checked for accuracy by another reviewer (HR). The extracted data included the year of study, selection method/case ascertainment, testing methods, study sample, nationality, age and gender of participants, risk factors, influenza and pneumococcal vaccine uptake, and burden of airborne infections.

The studies were heterogeneous in terms of study sites, diagnostic tests applied, and research outcomes assessed; hence, a meta-analysis or correlation analysis has not been attempted. However, a narrative synthesis was carried out by providing the upper and lower ranges of proportions for comparative variables and attack rates of airborne infections.

The study quality was assessed by two authors (HAM and HR) using the Newcastle–Ottawa Scale (NOS), in which an observational study is scored based on a 'star system' across three broad domains: the selection of the study groups; the comparability of the groups; and the ascertainment of either the exposure or outcome of interest. Conventionally, a score of 6–9 is considered good quality, a score of 3–5 as average and a score of 0–2 as poor (http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp accessed on 5 April 2023).

3. Results

3.1. General Description of Included Studies and Quality Assessment

As shown in the PRISMA flowchart (Figure 1) database searches and hand searching resulted in a total of 453 hits; these 79 full texts were reviewed, of which 58 studies finally met the inclusion criteria: 32 involved pilgrims from LMIC (Table 1) and 26 from HIC (Table 2). The studies involved pilgrims who attended Hajj from 1987 to 2021, with study sample sizes varying widely from 7 to 58,428 participants. The studies were heterogeneous in terms of study sites, diagnostic tests applied to identify the causative agents of infections (such as polymerase chain reaction (PCR) or viral/bacterial culture), and outcomes assessed.

Pilgrims were recruited from a variety of settings, including healthcare facilities in Makkah and/or Al Madinah during Hajj [13–30], tents in Mina [31–35], entry or exit points in Saudi Arabia [36–40], arrival or departure lounges/waiting rooms of pilgrims' home country airports [41–54], hospitals in pilgrims' home countries immediately after their return [55–59], or travel clinics before their departure from home countries [60–64]. The burden of viral respiratory infections alone was reported by 28 studies [14,18,20,22,28,29,31,33,34,36,37,41–47,51–53,55,57,58,61,65–67]; bacterial respiratory infections alone by 22 studies [13,15–17,19,23,24,27,30,32,35,40,48–50,54,56,63,64,68,69]; and both viral and bacterial airborne infections by 8 studies [21,26,38,39,59,60,62,70].

Table 1. Summary of included studies involving participants from low and middle-income countries.

Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
AlBarrak et al., 2018 [13]	2016	Majority from LMIC: Indonesian (22.3) Egyptian (10.2) Indian (9.8)	Adults with radiologically confirmed pneumonia admitted in general hospitals in Makkah and Al Madinah	Urine antigen test was used in addition to culture-based methods	266	65.3 (30–90)	2:1	Diabetes (36)	NR	Community-acquired pneumonia	<i>S. pneumoniae</i> 48 (18)
Alborzi et al., 2009 [41]	2006–2007	Iranian	Pilgrims with symptoms of ARI at Shiraz airport on return from the Hajj	Direct fluorescent staining and viral culture were performed on nasal wash specimens. Rhinovirus and enterovirus tested by RT-PCR	255	52.4 (19–82)	1:1.1	NR	Influenza vaccine (85.5)	Viral respiratory infections	Influenza 25 (9.8) Rhinovirus 15 (5.9) Other viruses 42 (16.4)
Alsayed et al., 2021 [14]	2019	Asian (64) African (30.3) European (2.7) North American (2.2) Oceanian (0.5)	Pilgrims with severe ARI symptoms who were initially hospitalised at seven healthcare facilities in Makkah, Arafat, and Mina at Hajj	Nasopharyngeal swabs were collected and tested using multiplex RT-PCR	185	58 (2 d–88 y)	1.9:1	NR	NR	Viral respiratory infections	Rhinovirus 53 (42) Influenza 54 (29.2) Coronaviruses 35 (18.9) Other viruses 19 (10.2) MERS-CoV 0 (0)
Alzeer et al., 1998 [32]	1994	Middle Eastern (34) South-East Asian (31) Indian (23) African (11)	All pilgrims admitted with pneumonia to Al-Noor Specialist Hospital and King Abdulaziz Hospital, Makkah	Sputum samples or fibre optic bronchoscopy samples for microscopy and culture, blood chemistry	64	63	2.6:1	NR	NR	Pneumonia	Viruses: Influenza 3 (4.7) Parainfluenza 1 (1.6) Bacteria: <i>M. tuberculosis</i> 13 (20.3) <i>S. pneumoniae</i> 6 (9.4) <i>K. pneumoniae</i> 5 (7.8) <i>H. influenzae</i> 3 (4.7) <i>S. aureus</i> 2 (3.1) Other bacteria 11 (17.3)

Table 1. Cont.

Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Annan et al., 2015 [42]	2013	Ghanaian	Adult pilgrims at the Kotoka International Airport after Hajj	Nasopharyngeal specimens were tested by RT-PCR	839	52 (21–85)	1:1.2	NR	NR	Viral respiratory infections	Rhinovirus 141 (16.8) RSV 43 (5.1) Influenza viruses 11 (1.3) MERS-CoV 0 (0)
Asghar et al., 2011 [15]	2005	Indonesian (18.4) Saudi (17.1) Pakistani (11.8) Indian (9.2) Egyptian (6.6) Malaysian (5.3) Syrian (4) Others (27.6)	Hajj pilgrims with suspected pneumonia who were admitted to hospitals in Makkah	Sputum samples were tested by routine culture, acid fast bacilli examination, and culture	141	>94% of cases were >50 y	1.3:1	Diabetes (55)	NR	Pneumonia	<i>M. tuberculosis</i> 1 (0.7) <i>S. pneumoniae</i> 5 (3.5) <i>K. pneumoniae</i> 8 (5.7) <i>S. aureus</i> 7 (5) Others 70 (50)
Ashshi et al., 2014 [36]	2010	280 Indonesian 157 Algerian 188 Indian 101 Syrian 128 Ivorian 104 Sierra Leonean 113 Somalian 123 Nigerian 112 Turkish 89 Australian 99 American 97 British	Pilgrims entering Saudi Arabia via King Abdulaziz International Airport, Jeddah city	Throat swab analysed using RT-PCR	1600	1309 aged > 40 291 aged ≤ 40	1.6:1	NR	Influenza vaccine (93.4)	Influenza A	Influenza A 120 (7.5)
Baharoon et al., 2009 [16]	2004	Majority were South Asian	All pilgrims admitted with severe sepsis and septic shock among Hajj pilgrims in two major ICUs in Makkah: King Faisal and King Abdulaziz Hospitals	Clinical diagnosis of severe sepsis/septic shock. Confirmation of source of infection with X-ray and/or positive culture	42	65.4	1.8:1	Lung diseases (71) Hypertension/Cardiac (43) Diabetes (29) Kidney diseases (2)	NR	Bacterial sepsis	Community-acquired pneumonia 23 (54.8)

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Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Bokhary et al., 2022 [17]	2018	Egyptian (22.3) Sudanese (14.9) Algerian (11.6) Moroccan (9.1) Libyan (2.6) Saudi (14.9) Indian (7.4) Pakistani (6.6)	Adult pilgrims who sought medical care for upper RTIs during Hajj	Oropharyngeal swabs were taken and tested by bacteriological culture method and automated VITEK 2 COMPACT system	121	45	8.3:1	NR	NR	Bacterial respiratory infections	<i>H. influenzae</i> 6 (4.9) <i>S. pneumoniae</i> 2 (1.6) <i>S. aureus</i> 1 (0.8) Others 1 (0.8)
El-Gamal et al., 1988 [19]	1987	Pakistani, Indian and Indonesian (50)	Suspected cases of meningitis were presented to the outpatient clinic at King Abdulaziz Hospital in Al Madinah city	CSF, blood and skin samples were examined. CSF samples were examined under microscope and by latex test	229	(30–70)	2.3:1	NR	NR	Meningococcal	Meningitis 188 (82) (177 serogroup A and 11 serogroup C)
El-Kafrawy et al., 2022 [20]	2019	15 Indonesian 9 Indian 4 Moroccan 3 Somalian and Sudanese (each) 2 Saudi, Bangladeshi, and Nigerian (each) 13 others	Pilgrims with RTIs who presented to the healthcare facilities at Hajj sites in Makkah	Nasopharyngeal swabs were collected and tested by multiplex RT-PCR	53	Majority (58%) >60 years old	NR	NR	NR	Human rhinoviruses	Rhinoviruses 19 (36.8)

Table 1. Cont.

Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
El-Sheikh et al., 1998 [21]	1991–1992	30 different nationalities	Pilgrims who were referred to either Ajyad hospital or three dispensaries in Jeddah. Upon enrolment, all patients were diagnosed with upper or lower RTIs	Sputa were collected and examined microscopically. Throat swabs were collected for cell culture and virus identification by immunofluorescence	1156	(10–80)	NR	NR	NR	Viral and bacterial respiratory infections	Viruses: RSV 18 (2.4) Influenza 49 (6.4) Parainfluenza virus 45 (5.9) Adenovirus 36 (4.7) Bacteria: <i>H. influenzae</i> 42 (10.6) <i>K. pneumoniae</i> 31 (7.8) <i>S. pneumoniae</i> 27 (6.8) <i>S. pyogenes</i> 7 (2.4) <i>S. aureus</i> 11 (3.8)
Hashem et al., 2019 [22]	2014	Majority Indian and Indonesian	During the 5 days of Hajj, samples were collected from all pilgrims presenting with ARI symptoms and suspected of MERS-CoV infection at seven healthcare facilities in Makkah, Mina, and Arafat	Nasopharyngeal samples were collected and tested using RT-PCR and microarray	132	61.85 (26–95)	2:1	NR	NR	Viral respiratory infections	Influenza 39 (29.5) Rhinoviruses 17 (12.1) Coronaviruses 24 (18.2) Other viruses 18 (13.6) MERS-CoV 0 (0)
Harimurti et al., 2021 [54]	2015	Indonesian	A multi-site longitudinal study collected data before the departure from Indonesia, and immediately upon arrival	Nasopharyngeal samples were collected pre- and post-Hajj and tested by culturing onto blood agar	813	53.1	1:1	Lung disease (2) Cardiovascular disease (0.8) Liver disease (0.2) Diabetes (5.8)	Pneumococcal vaccine (2)	Pneumococcal infection	<i>S. pneumoniae</i> (8.2)

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Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Kandeel et al., 2011 [43]	2009	Egyptian	Random selection of pilgrims who returned by ship to Port Tawfiq. Non-random selection of returning pilgrims at Cairo International airport	Throat swabs analysed by RT-PCR	551	(12–65)	1.3:1	NR	Influenza vaccination (98)	Viral respiratory infections	Influenza A/H3N2 6 (1)
Karima et al., 2003 [23]	2000	Majority Pakistani (18) Indian (15) Indonesian (12)	All suspected and microbiologically confirmed cases of meningococcal disease referred to public and private hospitals and health centres in Makkah	CSF examination: Gram stain smears, latex agglutination and culture	105	23% (61–70) 22% (41–50)	1.9:1	fourteen diabetes one ischemic heart disease one renal failure three hyper-tension	NR	Meningococcal	Meningitis A, B, W 67 (64)
Koul et al., 2018 [44]	2014–2015	Indian	Pilgrims were interviewed for respiratory symptoms and tested for respiratory viruses in Srinagar International Airport, Jammu and Kashmir, India	Nasopharyngeal and throat swabs tested by RT-PCR	300	60 (26–60)	1:1.1	NR	Influenza vaccine (72)	Viral respiratory infections	Influenza 33 (11) Coronaviruses 52 (17.3) Rhinovirus 20 (6) Other viruses 20 (6) MERS-CoV 0 (0)

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Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Lingappa et al., 2003 [24]	2000	African (35) Asian (42) Southwest Asian (26) European (4) Middle Eastern (19)	Case data from Ministry of Health surveillance records, regional health directories, clinical laboratory records and inpatient charts from all hospitals in Makkah, Al Madinah and Jeddah	Blood and CSF culture, latex agglutination of CSF	253	40 (0.2–80)	1.1:1	NR	NR	Meningococcal	253 confirmed cases among approx. 1.7 million pilgrims (0.015). Serogroups W 93 (37), A 60 (24), B 4 (2), C 4 (2)
Mandourah et al., 2012 [25]	2009–2010	Over 40 nationalities	All patients admitted to 15 hospitals in Makkah and Al Madinah	Sputum culture and blood culture	452	64	1.8:1	Diabetes (32.5) Lung diseases (17.1)	NR	Pneumonia	<i>S. pneumoniae</i> 3 (0.7) <i>K. pneumoniae</i> 5 (1.1) <i>S. aureus</i> 3 (0.7) Other bacteria 21 (4.6)
Mandourah et al., 2012 [26]	2009	East Asian (29.1) South Asian (24.6) Arab (30.9) Black (12.7) White (2.7)	All pilgrims admitted to ICUs of four key hospitals in Makkah	Nasal-swab specimens were tested by RT-PCR	110	60.5	1.7:1	Cardiovascular disease (28.2) Lung disease (20.9) Liver disease (6.4) Diabetes (28.2) Hypertension (31.8)	NR	Viral and bacterial respiratory infections	Influenza A/H1N1 * 24 (21.8) Community-acquired pneumonia 21 (19.3) Tuberculosis 1 (0.9)

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Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Memish et al., 2012 [37]	2009	Middle Eastern (63) Asian or African (37)	On arrival of pilgrims just before Hajj, and before departure after Hajj at King Abdulaziz International Airport, Jeddah	Nasopharyngeal and throat swabs tested by xTAG Respiratory Viral Panel FAST assay. Specimens positive for influenza A but negative for seasonal H1 and H3 were subjected to additional PCR amplification to detect pandemic H1 and avian H5	3550	49.4	1.4:1	NR	Influenza vaccine (53.3)	Viral respiratory infections	Influenza 11 (0.5) RSV 8 (0.3) Coronaviruses 10 (0.4) Enterorhinovirus 351 (13) Other viruses 14 (0.7)
Memish et al., 2014 [38]	2013	Majority from Indonesia (32.4) Pakistan (18.9) India (10.8)	All pilgrims admitted to 15 healthcare facilities in Makkah and Al Madinah, who were diagnosed with pneumonia	Sputum samples screened for MERS-CoV by RT-PCR and respiratory multiplex array was used to detect up to 22 other viral and bacterial respiratory pathogens	38	58.6 (25–83)	2.2:1	NR	NR	Viral and Bacterial respiratory infections	Viruses: Influenza 6 (15.8) Rhinoviruses 15 (39.5) Coronaviruses 5 (13.3) Others 2 (5.2) MERS-CoV 0 (0) Bacteria: <i>S. pneumoniae</i> 13 (34.2) <i>H. influenzae</i> 5 (13.2) Others 10 (26.3)
Memish et al., 2014 [39]	2013	Majority Indian (17.1) Indonesian (12.9) Pakistani (11.9) Turkish (10.7)	A random selection at the Hajj terminal of King Abdulaziz International Airport, Jeddah, of arriving and departing pilgrims	Nasal swabs analysed by RT-PCR	5235	51.8 (18–93)	1.2:1	Diabetes (6.8), Hypertension (13.1)	Influenza vaccine (22), pneumococcal vaccine (4.4)	MERS-CoV	MERS-CoV 0 (0)

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Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Memish et al., 2015 [66]	2013	African (44.2) Asian (40.2) American (8.4) European (7.2)	Pilgrims recruited upon entering Saudi Arabia at Jeddah International Airport and at Mina camps before leaving Saudi Arabia	Nasal swabs analysed by RT-PCR	1206	50 (18–88)	1.9:1	NR	Influenza vaccine (21.9) Pneumococcal vaccine (1.2)	Viral and Bacterial respiratory infections	Viruses: Influenza (3.6) Rhinovirus (34.4) Coronaviruses (19.5) Others (2.4) Bacteria: Meningococcal (0.3) <i>S. pneumoniae</i> (12.7) <i>K. pneumoniae</i> (3.9) <i>S. aureus</i> (7.9) <i>H. influenzae</i> (11.7)
Moattari et al., 2012 [46]	2009	Iranian	Symptomatic Iranian pilgrims who arrived at Shiraz Airport Iran from Hajj	Throat swabs were collected and tested by virus culture and RT-PCR	275	46 (20–70)	1:1	NR	Influenza vaccine (100)	Influenza viruses	Influenza A/H3N2 8 (2.9) Influenza A/H1N1 5 (1.8) Influenza B 20 (7.3)
Muraduzzaman et al., 2018 [47]	2013–2016	Bangladeshi	Pilgrims and other people returning from the Middle East presented with respiratory symptoms were recruited via active screening at the point of entry	Nasal and throat swabs and sputum tested by RT-PCR	81	49 (14 m–81 y)	1.2:1	NR	NR	Viral respiratory infections	Influenza viruses 18 (22.2) Other viruses 6 (7.4) MERS-CoV 0 (0)
Refaey et al., 2017 [51]	2012–2015	Egyptian	A convenience sample of about 10% of pilgrims from each flight who returned at Cairo International Airport from Hajj	Nasopharyngeal swabs were collected from all participants while sputum specimens collected only from those with respiratory symptoms. Specimens were tested by RT-PCR	3364	56 (0–105)	(1:1.1)	NR	Influenza vaccine (19.7)	Viral respiratory infections	All influenza viruses 484 (14.4) Influenza A/H1N1 117 (3.5) Influenza A/H3N2 187 (5.6) Influenza B 180 (5.4) MERS-CoV 0 (0)

Table 1. Cont.

Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Shirah et al., 2017 [30]	2004–2013	African (43.9) Asian (51.2) European (3.3) North African (0.7) South American (0.47) Oceanian (0.47)	Clinical data of pilgrims with confirmed pneumonia who attended emergency department of a general hospital in Al Madinah during Hajj	Chest X-ray, throat and nose swabs, sputum and blood culture	1059	56.8 (48–64)	2.9:1	Lung disease (15) Diabetes (34.8) Cardiovascular disease (23.3)	NR	Pneumonia	<i>K. pneumoniae</i> 307 (29) <i>S. pneumoniae</i> 1 (1) <i>S. aureus</i> 382 (36) <i>H. influenzae</i> 257 (24) Other bacteria 102 (10)
Yavarian et al., 2018 [52]	2013–2016	Iranian	Specimens were taken from arriving pilgrims at Emam Khomeini Airport in Tehran	Throat swabs were collected and tested by using one-step RT-PCR	3840	NR	NR	NR	NR	Influenza viruses	All influenza viruses 499 (13) Influenza A/H1N1 258 (51.7) Influenza A/H3N2 100 (20) Influenza B 135 (27) MERS-CoV 0 (0)
Yezli et al., 2017 [35]	2015	Afghan (27.1) Pakistani (25.9) Bangladeshi (19.1) Nigerian (15.1) South African (12.7)	Non-hospitalised adult pilgrims were enrolled during Hajj who had coughs and could voluntarily produce sputum samples	Sputum samples were processed using the Xpert MTB-RIF assay	1164	54.5 (18–94)	2.6:1	Hypertension (58.8) Diabetes (42.2) Kidney disease (2) Lung disease (4.4) Liver disease (2.4) Cardiovascular disease (15.9)	NR	Tuberculosis	<i>M. tuberculosis</i> 15 (1.4)

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Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Yousuf et al., 2000 [40]	1992–1993	Pakistani (53.3) Algerian (13.3) Indonesian, Thai, Syrian, American, and Congolese (6.7)	All patients admitted to King Abdulaziz Hospital, Al Madinah with a diagnosis of meningococcal disease	CSF culture and smear	15	NR	2.7:1	NR	NR	Meningococcal	Meningococcal infection A and C 8 (53.3)
Ziyaeyan et al., 2012 [53]	2009	Iranian	One in ten individuals passing through the passport checkout at Shiraz International Airport was selected	Pharyngeal swabs were collected and tested by using RT-PCR	305	49.2 (24–65)	1:1.3	NR	Influenza vaccine (97.7)	Influenza viruses	Influenza A/H1N1 4 (1.6) Other influenza A viruses 8 (2.6)

ARI: Acute respiratory infection; CSF: cerebrospinal fluid; ICU: intensive care unit; LMIC: low and middle-income countries; MERS-CoV: Middle East respiratory syndrome coronavirus; NR: not reported; PCR: polymerase chain reaction; RSV: respiratory syncytial virus; RTI: respiratory infection. * Likely influenza A (H1N1)pdm09.

Table 2. Summary of included studies involving participants from high-income countries.

Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Aberle et al., 2015 [55]	2014	Austrian	Returning Hajj pilgrims who had sought medical care in different Austrian hospitals/medical centres	Sera, sputa, throat swabs, or bronchoalveolar lavage samples were collected and tested by RT-PCR	7	54 (47–66)	(2.5:1)	Diabetes (43) Hypertension (43) Cardiovascular diseases (12.5) Lung disease (12.5)	NR	Viral respiratory infections	Influenza B 3 (43) Influenza A 2 (29) Rhinovirus 2 (29) MERS-CoV 0 (0)
Aguilera et al., 2002 [56]	2000	French and British	Hospitalised cases identified by National Surveillance Centres in Europe: only cases in France and UK were used for analysis	Cases were diagnosed by soluble antigen detection or PCR	90	51	(1:1.1)	NR	NR	Meningococcal	90 cases of meningococcal W135 disease: pilgrims 12 (13)
Al-Abdallat et al., 2017 [57]	2014	Jordanian	Returning Hajj pilgrims with symptoms of RTIs were instructed to present to sentinel health facilities in the south, north, and central regions of Jordan	Nasopharyngeal and oropharyngeal swabs were collected and tested by RT-PCR	125	51.5 (25–86)	(1.6:1)	Hypertension (22) Diabetes (14) Cardiovascular disease (8) Kidney disease (1) Lung disease (2)	NR	Viral respiratory infections	Rhino/enterovirus 59 (47) Coronavirus 16 (13) Influenza 6 (5) Other viruses 5 (4) MERS-CoV 0 (0)
Alahmari et al., 2022 [67]	2021	100 different nationalities	Records of pilgrims who did the PCR test were collected from the official database of the Saudi Ministry of Health	PCR-based surveillance with paired-swab samples (pre-Hajj and post-Hajj)	58428	NR	(1:1)	NR	NR	COVID-19 infection	SARS-CoV-2 41 (0.1)
Alfelali et al., 2020 [31]	2013–2015	Saudi and Qatari (91) Australian (9)	Pilgrims were randomised to 'facemask' or 'no facemask' by tents in Mina, Makkah	Nasal swabs were collected and tested using a multiplex RT-PCR	7687	34 (18–95)	(1:1.1)	NR	Influenza vaccine: intervention group (49.9) vs. control group (49.4)	Viral respiratory infections	Rhinovirus (35.1) Influenza A/H1N1 and H3N2 (4.5) Parainfluenza (1.7)

Table 2. Cont.

Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Alzeer et al., 2023 [70]	2018	NR	Samples were collected voluntarily from pilgrims who resided in the study tents	Nasopharyngeal swabs were collected and tested by multiplex RT-PCR	32	NR	NR	NR	NR	Viral and bacterial respiratory infections	Viruses: Rhinovirus 5 (15.62) Coronavirus 3 (9.4) Influenza 3 (9.4) Other viruses 7 (21.9) Bacteria: <i>K. pneumoniae</i> 20 (62.5) <i>S. aureus</i> 10 (31.3) <i>S. pneumoniae</i> 5 (15.6) <i>H. influenzae</i> 1 (3.1) Other bacteria 3 (9.4)
Atabani et al., 2016 [58]	2013–2015	British	UK travellers/pilgrims who returned from the Middle East and presented to hospitals in the Midlands, the Southwest, and North of England with RTI symptoms were actively investigated	Nose and throat swabs, nasopharyngeal aspirates, sputum and bronchoalveolar lavage samples were collected and tested by RT-PCR	202	54 (4 m–85 y)	(1.4:1)	NR	NR	Viral respiratory infections	Influenza 41 (20.3) Rhinovirus 29 (14.4) Other viruses 20 (9.9) MERS-CoV 0 (0)
Balkhy et al., 2004 [18]	2003	Saudi (46.8)	Patients presented to the National Guard Mina hospital outpatient clinic, on days 10 and 11 of Hajj	Throat swabs were inoculated onto MDCK, A549 and LL19Ks cell lines using conventional methodology, and screened by immunofluorescence for viruses	500	Majority (20–40)	(1.1:1)	NR	Influenza vaccine (4.4)	Viral respiratory infections	Influenza 30 (7) Other viruses 24 (4.8)

Table 2. Cont.

Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Barasheed et al., 2014 [33]	2013	Australian, Saudi, and Qatari	Pilgrims were recruited during the first day of Hajj and followed closely for four days	Nasopharyngeal swabs were collected and tested by multiplex RT-PCR	112	35 (18–75)	(1:1.3)	Lung disease (68) Diabetes (41) Cardiovascular disease (4) Kidney disease (4)	Influenza vaccine (68.8)	Viral respiratory infections	Rhinovirus 28 (25) Influenza 5 (4) Coronavirus 2 (2) Other viruses 5 (4)
Barasheed et al., 2014 [34]	2011	Australian	Tents were randomised to 'supervised mask use' versus 'no supervised mask use'. Pilgrims with ILI symptoms for ≤3 days were recruited as 'cases' and those who slept within 2 m of them as 'contacts'	Nasal swabs were taken and tested using Quick-Vue A+B point-of-care test and NAT for influenza viruses	164	44.1 (17–80)	(1:1.3)	NR	NR	Viral respiratory infections	Rhinovirus 39 (23.8) Influenza 7 (4.3) Other viruses 2 (1.2)
Benkouiten et al., 2013 [60]	2012	French	A prospective survey among a cohort of pilgrims departing from Marseille, France, to Makkah for Hajj	Nasal swabs were collected and tested by RT-PCR	154	59.3 (21–83)	(1:1.6)	Diabetes (27.5) Hypertension (26.3) Lung disease (7.8) Cardiovascular disease (7.2)	Influenza vaccine (45.6) Pneumococcal vaccine (35.9)	Viral respiratory infections	Rhinovirus 13 (8.4) Influenza 2 (1.3) Other viruses 4 (2.6)
Benkouiten et al., 2014 [61]	2013	French	Pilgrims were recruited at a private specialised travel agency in Marseille, France. participants were sampled and followed up before departing from France and before leaving Saudi Arabia	Paired nasal and throat swab specimens were collected and tested by RT-PCR	129	61.7 (34–85)	(1:1.5)	NR	Influenza vaccine (0) Pneumococcal vaccine (51.2)	Viral and bacterial respiratory infections	Viruses: Influenza 10 (7.8) Coronavirus 27 (20.9) Rhinovirus 19 (14.7) MERS-CoV 0(0) Bacteria: <i>S. pneumoniae</i> 80 (62)

Table 2. Cont.

Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
El Bashir et al., 2004 [65]	2003	British	A cohort of pilgrims from the East End of London who participated in Hajj	Blood samples were collected pre-and post-Hajj, and tested by haemagglutination inhibition	115	NR	NR	NR	Influenza vaccine (26)	Influenza viruses	All influenza viruses 44 (38) Influenza A/H3N2 42 (37) Influenza A/H1N1 1 (0.9) Influenza B 1 (0.9)
Erdem et al., 2016 [59]	201–2015	Turkish	In patients with a diagnosis of a travel-associated infection needing hospitalisation after returning from the Arabian Peninsula. Data were collected retrospectively from infectious diseases departments of 15 Turkish referral centres	Microbiological cultures were used for bacteria and Multiplex/RT-PCR was used for viruses	185	60.3	(1:1.1)	Diabetes (24.3) Hypertension (8.6) Cardiovascular disease (10.8) Liver disease (1.1) Kidney disease (0.54) Lung disease (14.1)	NR	Viral and bacterial respiratory infections	Viruses: Influenza 15 (8.1) Coronavirus 1 (0.5) Rhinovirus 1 (0.5) Other viruses 3 (1.6) Bacteria: <i>S. pneumoniae</i> 1 (0.5) <i>H. influenzae</i> 1 (0.5) Other bacteria 1 (0.5)
Hoang et al., 2022 [62]	2014–2018	French	Hajj pilgrims from Marseille, France, were recruited through a private specialised travel agency and were systematically sampled before departing and upon their return from Hajj	Nasopharyngeal swabs were collected and tested by RT-PCR	207	NR	NR	Diabetes (32.4) Hypertension (28) Lung disease (15) Cardiovascular disease (9.7) Kidney disease (1.9)	Influenza vaccine (29.5) Pneumococcal vaccine (30.9)	Viral and bacterial respiratory infections	Viruses: Rhinovirus (40.6) Coronavirus (15.5) Influenza (2.9) Bacteria: <i>S. aureus</i> (35.8) <i>H. influenzae</i> (30.4) <i>K. pneumoniae</i> (17.4) <i>S. pneumoniae</i> (3.9)

Table 2. Cont.

Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Jones et al., 1990 [68]	1987–1988	British	Meningococcal Reference Laboratory	Nasal swabs were cultured	39	NR	NR	NR	NR	Meningococcal	Meningococcal A (0.18)
Ma et al., 2017 [45]	2013–2015	Chinese	Randomly selected returning pilgrims arriving at Xinjiang and Gansu airports	Viral infection samples collected and tested by RT-PCR	847	2.24	(1.4:1)	NR	Influenza vaccine (100)	Viral respiratory infections	Influenza 48 (5.7) Coronavirus 3 (0.3) MERS-CoV 0 (0)
Marghani et al., 2016 [27]	2014	Gulf (58) Asian (12.4) South Asian (11.9) North African (11.5) African (3.5) European (2.2) American (0.5)	Patients presented to the emergency or outpatient departments of Alnoor Specialised Hospital in Makkah	Bacteriological culture and isolation, and antimicrobial susceptibility testing (AST) were performed using MicroScan Walk Away System ID/AST	226	34.6 (9–77)	(3.5:1)	NR	NR	Bacterial acute rhinosinusitis	<i>S. aureus</i> 46 (20.3)
Matsika-Claquin et al., 2001 [69]	2000	French	Standardised questionnaire used to interrogate study subjects	A case was considered to be confirmed when the strain isolated from usually sterile media was found to be identical to the epidemic strain (W135, 2a: P1-2.5--clonal complex ET37)	27	(2 m–87 y)	(1:1.2)	NR	NR	Meningococcal	Meningococcal W (0.002)

Table 2. Cont.

Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Nik Zuraina et al., 2018 [48]	2016	Malaysian	Hajj pilgrims who returned to the arrival hall of Sultan Ismail Airport, Kota Bharu, Kelantan, Malaysia with RTI symptoms, including productive cough	Bacteriological culture method and Vitek II system	297	57.4 (27–82)	(1:1)	NR	NR	Bacterial respiratory infections	<i>H. influenzae</i> 123 (44.4) <i>K. pneumoniae</i> 11 (3.7) <i>S. pneumoniae</i> 2 (0.7) Other bacteria 28 (9.4)
Nik Zuraina et al., 2022 [49]	2016	Malaysian	Hajj pilgrims who returned to Sultan Ismail Petra Airport, Kelantan, Malaysia with RTI symptoms during Hajj	Sputum specimens were collected and tested by culture and thermostabilized, multiplex PCR	202	56.7 (26–80)	(1:1.1)	NR	NR	Bacterial respiratory infections	<i>H. influenzae</i> 88 (43.5) <i>K. pneumoniae</i> 1 (0.5) <i>S. pneumoniae</i> 2 (1) Other bacteria 20 (9.9)
Novelli et al., 1987 [50]	1987	Qatari	Returning pilgrims or their contacts admitted to Hamad General Hospital, Doha, Qatar	Blood and/or CSF culture and/or latex test for meningococcal antigen in CSF	15	40	NR	NR	NR	Meningococcal	Meningococcal A 6 (40)
Rashid et al., 2008 [28]	2005	British	Pilgrims attending the British Hajj Delegation Medical Clinic in Makkah and in tents in Mina with symptoms of upper RTI	Two nasal swabs taken and tested by testing using PoCT and RT-PCR	202	44 (1.5–83)	(9.1:1)	Diabetes, chronic heart, lung or kidney disease, all high-risk conditions together (26)	Influenza vaccine (28)	Viral respiratory infections	Influenza 28 (13.9) RSV 9 (4)
Rashid et al., 2008 [29]	2006	British	Hajj pilgrims with upper RTI who attended British Hajj Delegation Clinic in Makkah and Mina	Two nasal swabs taken and tested by testing using PoCT and RT-PCR	150	41 (14–81)	(11.5:1)	Diabetes (62) Lung disease (23) Cardiovascular disease (12)	Influenza vaccine (37.3)	Viral respiratory infections	Influenza 17 (11) Rhinovirus 19 (12.7) Other viruses 2 (1.3)

Table 2. Cont.

Author, Publication Year	Study Year	Participants' Nationalities (%)	Selection Method/Case Ascertainment	Testing Method	Sample Size	Mean/Median Age (Range)	Male:Female	Risk Factors (%)	Vaccine Uptake (%)	Detected Diseases Name	Disease Burden n (%)
Wilder-Smith et al., 2003 [63]	2002	Singaporean	Referred by travel agencies, pilgrims were recruited at a Muslim centre in Singapore that performs mass vaccinations and following a few months after Hajj	Paired blood samples were collected pre- and post-Hajj, and IgG antibodies for pertussis whole-cell antigen were measured	358	48 (16–75)	(1:1.7)	NR	NR	Pertussis	<i>Bordetella pertussis</i> 5 (1.4)
Wilder-Smith et al., 2005 [64]	2002	Singaporean	Pilgrims were consecutively recruited at mass pre-travel vaccination sites before Hajj and following a few months after Hajj	A whole-blood assay (Quantiferon TB assay) prior to departure and 3 months after return from Hajj	365	49.2 (18–75)	(1:1.6)	Diabetes (8.8)	NR	Tuberculosis	<i>M. tuberculosis</i> 139 (38)

CSF: cerebrospinal fluid; MERS-CoV: Middle East respiratory syndrome coronavirus; NR: not reported; PCR: polymerase chain reaction; RTI: respiratory tract infection; RSV: respiratory syncytial virus; UK: United Kingdom. PoCT: point-of-care testing.

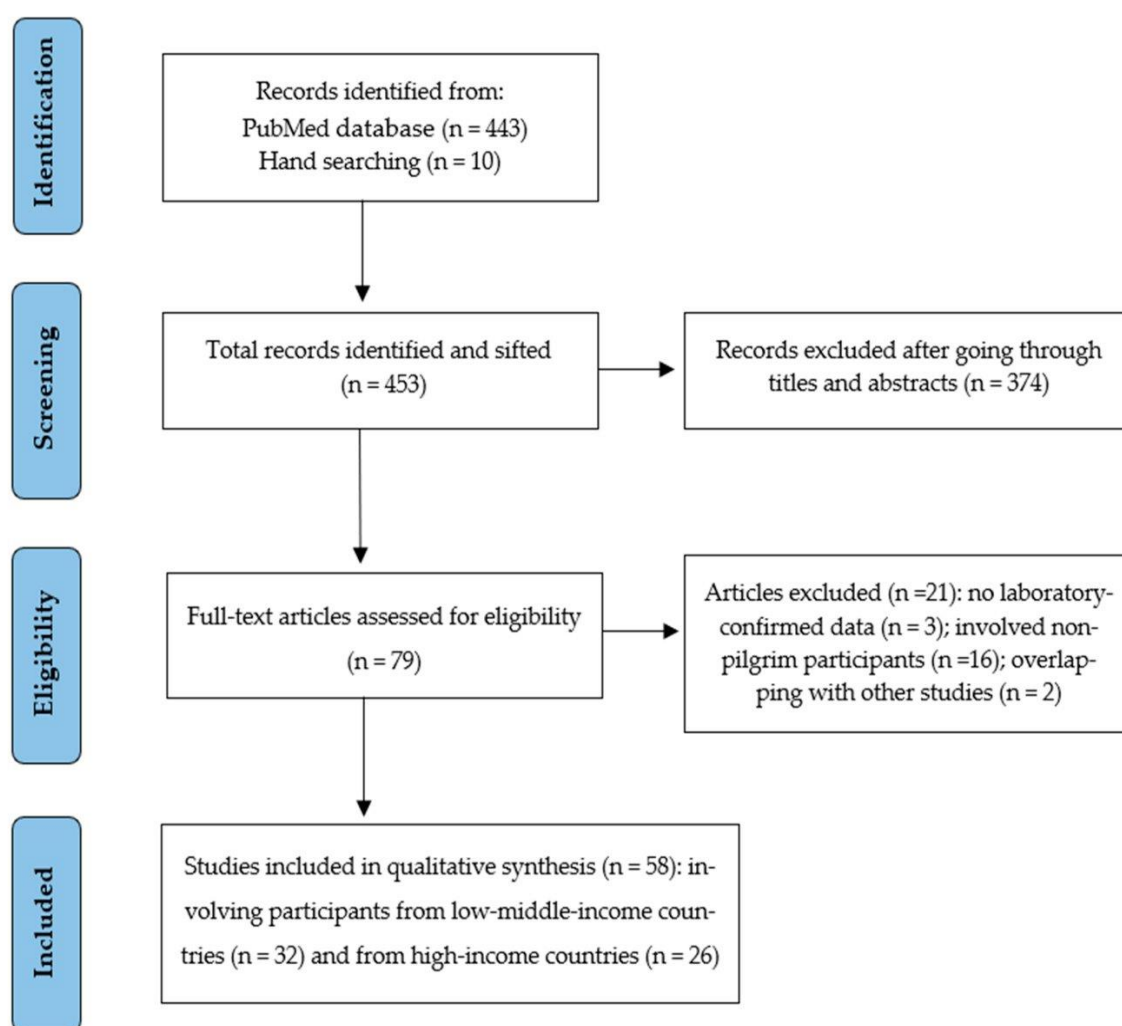


Figure 1. PRISMA flowchart of the search strategy.

3.2. Comparative Variables and Attack Rates of Hajj-Acquired Airborne Infections

Table 3 provides a detailed comparison of the demographic data, risk factors, vaccination uptake, and burden of confirmed airborne infections between pilgrims from LMIC and HIC. In the pooled sample, there were 27,799 pilgrims from LMIC with ages ranging from 2 days to 105 years and a male-to-female ratio of 1.3:1, and 70,865 pilgrims from HIC with ages between 2 months and 95 years and an equal gender ratio of 1:1. Most pilgrims from LMIC arrived from Africa, Southeast Asia, and the Eastern Mediterranean, whereas most pilgrims from HIC mainly arrived from Europe, the Eastern Mediterranean, and the Western Pacific.

Table 3. Comparative variables and attack rates of airborne infections between low and middle-income and high-income countries.

Variables	Low and Middle-Income Countries	High-Income Countries
Demographics		
Pooled study sample	27,799	70,865
Age (range)	2 d–105 y	2 m–95 y
Male: Female	1.3:1	1:1
Vaccination uptake (%)		
Influenza vaccination	19.7–100	0–100
Pneumococcal vaccination	1.2–4.4	30.9–51.2
Risk factors (%)		
Diabetes	5.8–36	0.9–32.4
Hypertension	2.9–43	8.6–28
Cardiovascular disease	0.8–43	0.1–10.8
Chronic lung disease	1.1–71	1.4–15
Chronic kidney disease	0.5–2	0.1–1.9
Chronic liver disease	0.2–6.4	1.1
Attack rate of viral airborne infections (%)		
Influenza	0.5–29.5	1.3–38
Human rhinovirus	5.9–39.5	0.5–47
Human coronavirus	0.4–19.5	0.1–20.9
Other viruses	0.7–16.4	0.7–21.9
Attack rate of bacterial airborne infections (%)		
Meningococci	0.015–82	0.002–40
<i>M. tuberculosis</i>	0.7–20.3	38
<i>S. pneumoniae</i>	1–54.8	0.5–62
<i>K. pneumoniae</i>	1.1–29	0.5–62.5
<i>H. influenza</i>	4.7–24	0.5–44.4
<i>S. aureus</i>	0.7–36	20.3–35.8
Other bacteria	0.8–50	0.5–9.9

The most commonly reported chronic medical conditions among pilgrims from LMIC were chronic lung and cardiovascular diseases; noting that, the highest proportions of these conditions (71% and 43%, respectively) were observed in one study that studied a highly selective cohort of pilgrims admitted to ICU with severe sepsis and septic shock [16]. On the other hand, the most frequently observed chronic medical conditions among pilgrims arriving from HIC were variable, with diabetes ranging from 1% among pilgrims from Australia [34] to 32% among pilgrims from France [62], and hypertension ranging from 9% among pilgrims from Turkey [59] to 28% among pilgrims from France [62].

Studies that reported the pilgrims' vaccination uptake revealed a wide variation in uptake both among LMIC and HIC pilgrims. Influenza vaccine uptake rates in LMIC ranged from 20% among Egyptian Hajj pilgrims in the years 2012 to 2015 [51] to 100% among Iranian pilgrims in 2009 [46]. As for HIC, a study involving French pilgrims in 2013 found that none of them had received an influenza vaccine before departing for Hajj, due to the unavailability of the vaccine at that time [60], while another study involving Chinese pilgrims indicated that all of them had received the vaccine in the years 2013 and 2015 [45]. The uptake rates of the pneumococcal vaccine in LMIC varied between 1% and 4% among Hajj pilgrims during the year 2013 [38,39]. Regarding HIC, a study conducted among French pilgrims between 2014 and 2018 revealed that 31% of them received the vaccine before embarking on their Hajj journey [62]; in contrast, a separate study conducted on French pilgrims in 2013 reported that 51% of them had received the vaccine [60].

Epidemiological patterns of proven viral airborne infections seemed to show higher attack rates of viral infections among HIC pilgrims than among LMIC pilgrims. Human rhinoviruses were the most prevalent viral agent among pilgrims in both groups, followed

by influenza and human coronaviruses, including SARS-CoV-2. On the other hand, the attack rate of confirmed bacterial airborne infections varied more widely across the groups. For instance, pilgrims from LMIC tended to have higher rates of meningococcal and *Staphylococcus aureus* infections, whereas pilgrims from HIC seemed to have higher rates of other bacterial infections such as *M. tuberculosis*, *Streptococcus pneumoniae*, *Klebsiella pneumoniae*, and *Haemophilus influenza* infections (see Table 3 for detailed comparative results).

Multiple studies have investigated the emerging viral airborne infections during Hajj over the past few years. For instance, five studies investigated influenza A (H1N1)pdm09: Ashshi et al. [36] reported nine (0.6%) confirmed cases; Kandeel et al. [43] reported not detecting any case; Memish et al. [37] reported two (0.1%) cases; Moattari et al. [46] recorded five (1.8%) cases; and Ziyaeyan et al. [53] reported another five (1.6%) cases. Furthermore, 12 studies were conducted between 2013 and 2015 to identify the occurrence of MERS-CoV during the pilgrimage; nonetheless, no case of MERS-CoV virus was confirmed [22,38,42,44,45,47,51,52,55,57,58,60]. Recently, only one retrospective surveillance study assessed the rate of COVID-19 among Hajj pilgrims amidst the pandemic in 2021, which found that 41 pilgrims out of a total of 58,428 tested positive for COVID-19 during and after Hajj [67].

In terms of quality assessment of the included studies, most LMIC and HIC studies were average in quality, as defined by a NOS score of total stars of between three and five; however, four LMIC studies [37–39,54] and nine HIC studies [31,33,34,56,60–62,65,67] received a good quality rating of between six and nine stars (Table 4).

Table 4. Newcastle and Ottawa Scale (NOS) scores for the included studies.

Studies	Selection (Max 4 Stars)	Comparability (Max 2 Stars)	Outcome/Exposure (Max 3 Stars)	Total Score
High-income countries (HIC)				
Aberle et al., 2015 [55]	**	—	**	4
Aguilera et al., 2002 [56]	***	—	***	6
Al-Abdallat et al., 2017 [57]	**	—	**	4
Alahmari et al., 2022 [67]	***	—	***	6
Alfelali et al., 2020 [31]	***	*	**	6
Alzeer et al., 2023 [70]	***	—	**	5
Atabani et al., 2016 [58]	**	—	**	4
Balkhy et al., 2004 [18]	**	—	**	4
Barasheed et al., 2014 [33]	***	*	**	6
Barasheed et al., 2014 [34]	***	*	**	6
Benkouiten et al., 2013 [60]	***	—	***	6
Benkouiten et al., 2014 [61]	***	—	***	6
El Bashir et al., 2004 [65]	***	—	***	6
Erdem et al., 2016 [59]	**	—	***	5
Hoang et al., 2022 [62]	***	—	***	6
Jones et al., 1990 [68]	**	—	**	4
Ma et al., 2017 [45]	**	—	***	5
Marglani et al., 2016 [27]	**	—	**	4
Matsika-Claquin et al., 2001 [69]	**	—	**	4
Nik Zuraina et al., 2018 [48]	**	—	**	4
Nik Zuraina et al., 2022 [49]	**	—	**	4
Novelli et al., 1987 [50]	**	—	**	4
Rashid et al., 2008 [28]	**	—	***	5
Rashid et al., 2008 [29]	**	—	***	5
Wilder-Smith et al., 2003 [63]	***	—	**	5
Wilder-Smith et al., 2005 [64]	***	—	**	5

Table 4. Cont.

Studies	Selection (Max 4 Stars)	Comparability (Max 2 Stars)	Outcome/Exposure (Max 3 Stars)	Total Score
Low and middle-income countries (LMIC)				
AlBarrak et al., 2018 [13]	**	—	**	4
Alborzi et al., 2009 [41]	**	—	**	4
Alsayed et al., 2021 [14]	**	—	**	4
Alzeer et al., 1998 [32]	**	—	**	4
Annan et al., 2015 [42]	**	—	**	4
Asghar et al., 2011 [15]	**	—	**	4
Ashshi et al., 2014 [36]	**	—	**	4
Baharoon et al., 2009 [16]	**	—	**	4
Bokhary et al., 2022 [17]	**	—	*	3
El-Gamal et al., 1988 [19]	**	—	**	4
El-Kafrawy et al., 2022 [20]	**	—	**	4
El-Sheikh et al., 1998 [21]	**	—	**	4
Hashem et al., 2019 [22]	**	—	**	4
Harimurti et al., 2021 [54]	***	—	***	6
Kandeel et al., 2011 [43]	**	—	**	4
Karima et al., 2003 [23]	**	—	**	4
Koul et al., 2018 [44]	**	—	**	4
Lingappa et al., 2003 [24]	**	—	**	4
Mandourah et al., 2012 [25]	**	—	**	4
Mandourah et al., 2012 [26]	**	—	**	4
Memish et al., 2012 [37]	***	—	***	6
Memish et al., 2014 [38]	**	—	**	4
Memish et al., 2014 [66]	***	—	***	6
Memish et al., 2015 [39]	***	—	***	6
Moattari et al., 2012 [46]	**	—	**	4
Muraduzzaman et al., 2018 [47]	**	—	**	4
Refaey et al., 2017 [51]	***	—	**	5
Shirah et al., 2017 [30]	**	—	**	4
Yavarian et al., 2018 [52]	**	—	**	4
Yezli et al., 2017 [35]	**	—	**	4
Yousuf et al., 2000 [40]	**	—	**	4
Ziyaeyan et al., 2012 [53]	**	—	**	4

Asterisks represent score points.

4. Discussion

This systematised review presented the epidemiological patterns of airborne infections acquired during Hajj among pilgrims from LMIC and HIC. The qualitatively synthesised data showed that pilgrims from both resource-rich and resource-poor settings are at risk of acquiring airborne diseases during Hajj, but some infections are more common in LMIC or HIC than others, and vice versa. Hajj is an overcrowded event, and the proximity of participants, along with environmental conditions, amplifies the risk of transmitting respiratory pathogens, thus contributing to outbreaks of airborne infections [2]. Previously published systematic reviews also reported the occurrence of airborne/respiratory infections to be common among pilgrims. For instance, in a review of studies published prior to February 2018 reporting the prevalence of symptomatic respiratory infections among Hajj pilgrims, Benkouiten et al. found that influenza-like illness (ILI) ranged from 8% to 78% and pneumonia from 0.2% to 55% [9]. Safarpour et al. demonstrated in a meta-analysis that all serotypes of influenza viruses were identified among pilgrims, with estimated prevalence rates of 3.6%, 2.9%, and 0.9% for influenza types A, B, and C, respectively [10].

This systematised review uniquely shows wide variations in the burden of airborne infections between LMIC and HIC pilgrims. Despite the fact that Hajj pilgrims hail from resource-rich salubrious countries and therefore have better compliance with, and awareness about, the preventive measures, and access to more advanced public health services,

the microbiological data paradoxically show that they may be at a higher (or at least at an equal) risk of developing viral infections compared to those from LMIC. On the other hand, the attack rates of bacterial infections demonstrated a more varied pattern. Pilgrims from LMIC seemed to have higher rates of certain bacterial infections, such as meningococcal infection, as was found among 82% of pilgrims with suspected infection at the time of an outbreak during the 1987 Hajj season [19], whereas some other bacterial infections were more prevalent among HIC pilgrims, for instance, *M. tuberculosis* infection, as was recorded among 38% of Singaporean Hajj pilgrims after the year 2002 pilgrimage [64].

This wide range of yielded rates may have been attributed to disparities in study settings, sample types, pilgrims' pre-existing immunity including previous infection, and diagnostic methods used. A number of other factors may have also contributed to these differences. For instance, pilgrims participating in Hajj either from developed or developing countries share equally the same rituals as instructed by Islam; there is no discrimination between pilgrims based on their gender, income, or ethnicity, so HIC pilgrims were not actually at an advantage compared to their LMIC counterparts. Furthermore, differences in hygiene practices, living conditions, and sociodemographic factors may have influenced the transmission dynamics of such infections among pilgrims. Due to disparities in health-care expenses, infrastructure, and resources, including diagnostic capacity, there could be variations in diagnostic yields for infectious pathogens between HIC and LMIC. For instance, HIC may employ more sophisticated and expensive diagnostic protocols, leading to more accurate and comprehensive data, while LMIC may rely on less-advanced diagnostic methods, potentially resulting in variations in the reported incidence of infections.

Although vaccination against influenza is strongly encouraged as part of pre-Hajj health preparations for all pilgrims, the results showed a wide variability in vaccination uptake, likely due to differences in seasonal vaccine availability and vaccination policies across countries. This was clearly noticed among pilgrims from France during the 2013 Hajj season, where none of them managed to receive an influenza vaccine before departing for Hajj, because they needed to set out on Hajj before the seasonal vaccine was available in their jurisdictions [60]. The Scientific Committee for Influenza and Pneumococcal Vaccination guidelines as part of the Saudi Thoracic Society recommends the following for Hajj pilgrims: all persons of ≥ 50 years are recommended to receive a combined vaccination with a 23-valent pneumococcal polysaccharide vaccine (PPSV23) and a 13-valent pneumococcal conjugate vaccine (PCV13) before Hajj (for those planning immediately before Hajj, at least one dose of PPSV23), immunocompetent persons of < 50 years with risk factors are recommended to receive a single dose of PPSV23 at least 3 weeks before Hajj, and it is not recommended that the vaccine be routinely provided to healthy persons aged < 50 years [71]. However, the uptake of a pneumococcal vaccine is suboptimal among the general population of KSA and other Gulf countries. For example, only 6% of Saudi adults have received the vaccination amidst the COVID-19 pandemic [72]. It is common for HIC to implement a policy that suggests or provides pneumococcal vaccination for elderly individuals and those with pre-existing medical conditions [73]; consequently, a significant number of pilgrims from these countries would likely have received the pneumococcal vaccine [5].

These findings emphasise the need for targeted interventions, such as enhanced pre-Hajj vaccination and awareness programs for all pilgrims, regardless of their income status. Non-pharmaceutical interventions (e.g., facemasks, hand hygiene, cough etiquette, and physical distancing) have been used to prevent airborne infections at Hajj, but these interventions are underutilised, or at least the evidence of their effectiveness among Hajj pilgrims is inconclusive or unproven. For instance, a large-scale randomised controlled trial (RCT) among pilgrims found that the efficacy of using a facemask against viral respiratory infections was inconclusive [31]. Similarly, a recent pilot RCT conducted during the COVID-19 pandemic among Umrah participants (the abbreviated pilgrimage that Muslims can take year-round) failed to yield conclusive evidence regarding the protective effects of hand hygiene [74].

As the host country of this MG event, KSA has demonstrated notable success in safeguarding the well-being and safety of participants in the modern era through advance planning, comprehensive healthcare plans, preventive strategies, and risk-based infection control measures to contain the health risks associated with this pilgrimage [75]. The significant contribution of KSA in preventing and controlling the dissemination of emerging infectious diseases in recent Hajj seasons has been lauded worldwide and proven by some of the studies included in this review. The low prevalence of pandemic infections like COVID-19 and influenza A (H1N1)pdm09, and the absence of MERS-CoV at Hajj are testament to this.

A key limitation of this review is limiting the search strategy to only English language articles, but because most original Hajj-related manuscripts are generally published in English, the possibility of missing any important publication is very remote. An additional limitation was the clinical heterogeneity of the included studies, meaning that a meta-analysis was not feasible. Also, the way the results were presented in the included papers precluded us from carrying out any quantitative synthesis. We presented the results as lower and upper ranges of proportions and rates. We have called this a 'systematised review' because not all standard steps of a 'systematic review' could be followed; for instance, this review was not registered in PROSPERO, although it utilised a rigorous and comprehensive study design, including adherence to the PRISMA statement and the use of the NOS quality assessment tool. Furthermore, databases other than PubMed were not searched because from our experience most good-quality Hajj-related manuscripts are indexed in PubMed. There could be some manuscripts that are published in non-PubMed-indexed journals. Finally, we could not focus on other parallel information about the identified pathogens including their genetic characteristics, virulence, or drug resistance. Despite these limitations, this study significantly contributed by shedding light on the epidemiological patterns of airborne infections among attendees of MG events, which hold substantial implications for policymakers in host countries and offer valuable information that can inform decision-making processes. Given the recent announcement by the World Health Organization (WHO) that COVID-19 no longer constitutes a public health emergency of international concern, coupled with the anticipated increase in the number of Hajj participants in 2023 [76,77], it becomes important to direct future studies to provide a head-to-head comparison of the epidemiological patterns of Hajj-acquired airborne infections among pilgrims from LMIC and HIC using similar (if not identical) study settings.

5. Conclusions

This review comprehensively assessed the burden and epidemiological patterns of airborne infections among Hajj pilgrims from LMIC and HIC. The findings showed that pilgrims from both regions are at risk of acquiring airborne diseases during Hajj. More Hajj pilgrims from HIC seemed to develop viral respiratory infections compared to those from LMIC; however, such a difference did not seem to exist for bacterial respiratory infections. The findings highlight the need for improved vaccination coverage and effective infection control measures to prevent the spread of airborne infections during the Hajj pilgrimage and ensure the safety and well-being of all pilgrims, irrespective of their socioeconomic status or country of origin.

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CHAPTER 2: Hand hygiene knowledge and practices among domestic Hajj pilgrims before the COVID-19 pandemic hit

The qualitative data synthesis of the burden of airborne infections among Hajj pilgrims from the previous review (Publication #1) showed that pilgrims are at risk of acquiring viral and bacterial RTIs during the pilgrimage, emphasising the need to implement effective infection control methods. Practising HH, along with other non-pharmaceutical interventions, has been used to prevent RTIs at Hajj, but there were insufficient studies examining the knowledge and practises of HH among Hajj pilgrims, even before the emergence of SARS-CoV-2.

I conducted a survey (Publication #2) during the 2019 Hajj season to assess domestic Saudi pilgrims' knowledge about HH and reported compliance rates. In this cross-sectional study, the data were collected in Mina, Makkah, KSA, using a self-administered questionnaire. The findings indicated that pilgrims achieved a moderate level of knowledge about HH. Most pilgrims correctly identified that HH prevents RTIs; however, a large proportion of them were unaware that it can prevent hand-foot-mouth disease, and many incorrectly reported that it prevents HIV/AIDS. Using soap and water was the predominant HH method practised, yet pilgrims showed relatively poor HH behaviour following certain high-risk actions such as touching a patient, sneezing, coughing, and handshaking.

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Article

Hand Hygiene Knowledge and Practices among Domestic Hajj Pilgrims: Implications for Future Mass Gatherings Amidst COVID-19

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Abstract: This study examined Hajj pilgrims' knowledge and reported practice of hand hygiene. In Hajj 2019, a cross-sectional survey was undertaken in Mina, Makkah, Saudi Arabia, of domestic Saudi pilgrims aged ≥ 18 years by using a self-administered Arabic questionnaire that captured data on pilgrims' socio-demographics, hand hygiene knowledge, and reported practices of hand cleaning following certain actions. A total of 348 respondents aged 18 to 63 (median 32) years completed the survey, of whom 200 (57.5%) were female. The mean ($\pm$ standard deviation (SD)) hand hygiene knowledge score was 6.7 ($\pm$ SD 1.9). Two hundred and seventy one (77.9%) and 286 (82.2%) of respondents correctly identified that hand hygiene can prevent respiratory and gastrointestinal infections respectively, but 146 (42%) were not aware that it prevents hand-foot-mouth disease. Eighty-eight (25.3%) respondents erroneously reported that hand hygiene prevents HIV. Washing hands with water and soap was the most preferred method practiced before a meal (67.5% (235/348)), after a meal (80.2% (279/348)), after toilet action (81.6% (284/348)), when hands were visibly

soiled (86.2% (300/348)), and after waste disposal (61.5% (214/348)). Hajj pilgrims demonstrated a good knowledge and practice of hand hygiene, but there are gaps that are vital to control outbreaks such as COVID-19.

Keywords: COVID-19; Hajj; hand hygiene; infection prevention and control; infectious disease; mass gathering

1. Introduction

COVID-19 pandemic has affecting about 38 million individuals with over one million deaths around the world (as of 13 October 2020) [1]. The disease is believed to transmit from human to human primarily via respiratory droplets, direct contact and indirect contact. Most mass gatherings (MGs), therefore, have been cancelled during this pandemic. MGs are defined as the concentration of people at a specific location for a specific purpose over a set period of time and which has the potential to strain the planning and response resources of the country or community [2]. MGs are known to accelerate the progression of a pandemic. A MG of two million people in Mexico, the Iztapalapa Passion Play that took place in 5–11 April 2009 is believed to have accelerated the spread of the last pandemic caused by influenza A(H1N1)pdm09 [3]. Each year, Hajj pilgrimage to Makkah, in Saudi Arabia, attracts two to three million people from around the world making it one of the largest annual MGs. Respiratory tract infections are the leading illnesses during Hajj affecting 40–90% of pilgrims [4]. Such religious and other MGs pose a significant risk for the spread of infectious diseases, as currently the case with the global pandemic of COVID-19. Saudi Arabia has reported about 338 confirmed cases with about 5000 fatalities [1], and despite banning of Umrah (minor pilgrimage to holy cities in Saudi Arabia) and subsequently downscaling the Hajj of 2020, there have been clusters of COVID-19 in Makkah and Medina, the two important pilgrimage cities [5].

MG-related confirmed cases of COVID-19 have been reported in South East Asian countries like Malaysia [6], and South Korea [7]. In the Middle East, the virus spread from a religious MG in Qom, a Shi'ite holy city (120 km south of the capital Tehran), Iran [8]. Intense crowding during Hajj is highly likely to amplify the risk of transmission of COVID-19. Approximately a third of Hajj attendees are elderly or have pre-existing health conditions, rendering them highly vulnerable to severe form of disease and fatality from infection [9].

In the absence of a definitive preventive measure, non-pharmaceutical measures such as social distancing, isolation, quarantine, and hand hygiene remain the mainstay of infection prevention and control against respiratory infections including COVID-19 [10].

The Saudi Arabian Ministry of Health (MoH) recommends an array of preventive measures annually to minimize the risk of transmission of respiratory infections during Hajj season, including hand washing, respiratory hygiene, and vaccinations [9]. Despite this advice, research demonstrates that the uptake of preventive measures varies among pilgrims [11].

Hand hygiene was found to be the most favored infection preventive measure for Hajj attendees [11]. It is significantly associated with a reduction in self-reported respiratory infections including influenza-like illnesses (ILI) [12], frequency of sputum production, myalgia [13], and fever [14]. Use of an alcohol-based hand sanitizer significantly reduces *Streptococcus pneumoniae* detection in respiratory samples [15]. There is a paucity of focused research that has examined knowledge and practice of hand hygiene among domestic Hajj attendees. This study examined hand hygiene knowledge and reported behaviors among Saudi Hajj pilgrims in 2019 and attempts to inform policy for the other MGs amidst COVID-19.

2. Materials and Methods

A cross-sectional study using a paper-based anonymous survey was conducted among Saudi pilgrims aged ≥ 18 years who attended Hajj in 2019 in Mina tent city, Greater Makkah, Saudi Arabia, a place where pilgrims spend at least four nights during Hajj. A convenient sampling strategy was used to recruit participants. The data collectors went to Mina and randomly approached the nearest two domestic tour groups (Hamlahs) who agreed to cooperate with the study. From these selected Hamlahs the sample was drawn by randomly asking pilgrims to participate in the study.

This paper-based self-administered anonymous survey was conducted in Arabic. Initially, a survey questionnaire in English was drafted using some exemplary questions used in published surveys [16,17]. Two public health researchers and one epidemiologist translated the questionnaire to Arabic independently. Subsequently, two professional translators performed backward translation separately (who have not seen the original survey or material). The survey underwent pilot testing via a focus group of eight respondents to discuss and answer the survey to ensure readability, personal interpretation of individual question and solving any problems in answering the questions. Following revision, the final version was prepared by the authors that addressed grammatical discrepancies.

The questionnaire consisted of three parts. Part 1 collected non-identifying participant sociodemographic data. Part 2 collected data about the participant's knowledge of hand hygiene using true/false questions. Additionally, there were questions on common myths and fallacies of hand hygiene reported in the literature, such as the misconceptions that hands should be held under water while lathering with soap and the adequate time used for hands rubbing before rinsing. This was assessed using a Likert scale that uses scoring from 0 to 12, with a higher score indicating considerable knowledge level on hand hygiene and a lower score indicating insufficient knowledge. Part 3 comprised of items related to self-reported hand washing behavior. Respondents were asked whether they washed their hands, and by what methods, in different situations during their Hajj journey. These included hand washing before and after eating, after using toilet, after caring a sick person, when hands are visibly dirty, after disposal of a garbage bag, after sneezing or coughing, and after handshaking.

Seven senior medical students (four males and three females) were selected as volunteers and trained as data collectors. The volunteers approached and explained the study purpose and methodology to domestic Saudi Hajj pilgrims residing in camps in Mina on 11th and 12th of August 2019. Pilgrims who agreed to participate were then given the questionnaires to complete, and respondents' queries, if any, were answered. This being an anonymous survey, no signed consent was obtained, and respondents' completion of the survey was considered as their implied consent. Ethics approval was obtained from King Abdullah Medical City, Makkah, Saudi Arabia (IRB ref 19-558).

To ensure correct and uniform entry of data, the collected data from hard copy questionnaires were entered into an electronic form using the Google Forms software (Google LLC, Mountain View, CA, USA) (<https://forms.gle/syQt5ouVzJ5usr318>). Subsequently, all the data were exported to a master Excel spreadsheet (Microsoft Office 356, version 2002, Redmond, WA, USA) for cleaning and coding before importing to Statistical Package for Social Sciences (SPSS) software (IBM SPSS Statistics for Windows, version 25.0, IBM Corp, Armonk, NY, USA). Descriptive statistics for socio-demographic characteristics, hand hygiene knowledge level, and hand hygiene practices of the respondents were reported. Where appropriate the difference between categorical variables was examined using the chi-squared test, and independent t-test was used to compare the gender differences in the knowledge score on hand hygiene. Binary logistic regression, using the backward Wald method, controlling for factors, such as age, gender, chronic medical conditions, educational level, employment status and the number of times respondents attended Hajj, was used to investigate variables related to hand hygiene knowledge and practices. Previous researchers found that at least 60% of respondents were practicing hand hygiene at Hajj; considering an error margin of 5% to be acceptable for this anonymous survey, a sample of 370 respondents was considered sufficient for this study.

3. Results

Volunteers approached and invited 380 pilgrims to participate in the study, and 348 (91.6%) agreed. The median age of respondents was 32 (range 18–63) years, 200 (57.5%) were female. Of all 348 respondents, 208 (59.8%) had a bachelor's degree or above, 108 (51.7%) were employed, and 43 (12.4%) reported having at least one chronic disease. Just over three-quarters (270, 77.6%) of the respondents reported attending Hajj that year for the first time, with the rest (78, 22.4%) reporting attending Hajj previously at least once (Table 1).

Table 1. Demographic characteristics of respondents (N = 348).

Variables	n (%)
<i>Age, years</i>	
Median (range)	32 (18–63)
<i>Gender</i>	
Male: Female	148:200 (42.5:57.5)
<i>Education</i>	
None	11 (3.2)
Primary/elementary school certificate	22 (6.3)
High school certificate	73 (21)
Diploma	34 (9.8)
University degree	182 (52.4)
Higher degree	26 (7.5)
<i>Employment stats</i>	
Unemployed	126 (36.3)
Student	42 (12)
Employed	180 (51.7)
Self-employed	19 (5.5)
Full time worker	148 (42.5)
Casual/part-time worker	13 (3.7)
<i>Number of times attending Hajj</i>	
Once	270 (77.6)
More than one	78 (22.4)

Of the 348 respondents, there were 230 (66.3%) who reported being aware of the annual Saudi MoH health recommendations for Hajj travelers issued, 262 (75.5%) who reported seeking some form of health advice before Hajj journey, 286 (82.2%) reported receiving the compulsory meningococcal vaccine, and 288 (82.8%) reported receiving other recommended vaccines (Table 2).

With respect to knowledge about hand hygiene, the mean ($\pm$ standard deviation (SD)) of total scores (0 to 12) was 6.7 ($\pm$ 1.9). Less than half (155, 44.5%) of the respondents had a low knowledge score (defined as total score of ≤ 6), over half (175, 50.3%) had a medium score (defined as total score of between 7 and 9), and the rest (18, 5.2%) had a high score (defined as total score of ≥ 10). In multivariate logistic regression analysis, there was no significant association between the level of hand hygiene knowledge and possible factors, including gender, age, having chronic diseases, number of Hajj times, education, and employment status (all p values > 0.05). Nonetheless, both gender and employment status showed a near statistical significance (odds ratio (OR) = 1.73, 95% CI = 0.98–3.07, $p = 0.06$ and OR = 1.76, 95% CI = 0.97–3.16, $p = 0.06$, respectively) with females and employed respondents

having higher knowledge level compared to males and unemployed individuals. The results of the respondents' level of hand hygiene are detailed in Table 3.

Table 2. Awareness of Saudi Arabian Ministry of Health (MoH) recommendations, pre-Hajj health advice, and vaccination status (N = 348).

Variables	n (%)
<i>Awareness of MoH recommendations</i>	
No	117 (33.6)
Yes	231 (66.4)
<i>Sought pre-Hajj health advice</i>	
No	85 (24.4)
Yes	263 (75.6)
<i>Sources of Hajj health advice</i>	
Doctors	48 (11.1)
Special Hajj websites (e.g., MoH)	81 (18.8)
Tour groups	80 (18.5)
Family and friends	130 (30.1)
General websites	93 (21.5)
<i>Vaccination status</i>	
Mandatory meningococcal vaccine	286 (82.2)
Recommended influenza vaccine	280 (80.5)

Table 3. Hand hygiene knowledge level among respondents (N = 348).

Questions	Answered n (%)
Which of the following diseases can be transmitted by poor hand hygiene?	
<i>Diarrhoeal diseases</i>	
True §	286 (82.2)
False	62 (17.8)
<i>Flu, cough (upper respiratory infection or ILI)</i>	
True §	271 (77.9)
False	77 (22.1)
<i>Hand-foot-mouth disease</i>	
True §	202 (58)
False	146 (42)
<i>HIV/AIDS</i>	
True	88 (25.3)
False §	260 (74.7)
<i>Skin infections</i>	
True §	195 (56)
False	153 (44)

Table 3. Cont.

Questions	Answered n (%)
<i>Eye infections</i>	
True §	258 (74.1)
False	90 (25.9)
<i>Diabetes</i>	
True	16 (4.6)
False §	332 (95.4)
Are the following statements correct?	
<i>Always keeping your hands clean may lower our body defence mechanism</i>	
True	181 (52)
False §	167 (48)
<i>Hands should be held under water while lathering with soap</i>	
True	120 (34.5)
False §	228 (65.5)
<i>An alcohol-based hand sanitiser that contains 40% alcohol is sufficient for hands disinfection</i>	
True	119 (34.2)
False §	229 (65.8)
<i>Rubbing my hands until soap forms a lather for 10 s before rinsing is enough for hand disinfection</i>	
True	202 (58)
False §	146 (42)
<i>Temperature of water makes no difference in terms of the cleansing effect of hand cleaning</i>	
True §	147 (42.2)
False	201 (57.8)
Mean (±SD) of Total Scores (0 to 12)	6.7 (±1.92)

§ Correct answer.

Table 4 summarizes the results of whether pilgrims practiced hand hygiene or not and by what methods in different situations during Hajj. Except for cleaning hands following handshakes, which was reported by just over half (177, 51.9%) respondents, an overwhelming majority of respondents reported cleaning their hands following other tasks. Hand washing using water and soap was the most commonly reported hand hygiene method among pilgrims across all situations. A small number (58, 16.7%) of the respondents reported barriers to using hand hygiene during Hajj season, notably unavailability of soap and hand rub (60.5% (31/58)), limited access to washrooms (23.3% (18/58)) and intense crowding (16.3% (14/58)).

Table 4. Respondents' hand hygiene practices and methods used in different situations during Hajj (N = 348).

Types of Hand Hygiene	Before Meal n (%)	After Meal n (%)	After Toilet Action n (%)	After Touch a Sick Person n (%)	When Hands Visibly Dirty n (%)	After Waste Disposal n (%)	After Sneeze/Cough n (%)	After Handshakes n (%)
Water only	60 (17.2)	29 (8.3)	33 (9.5)	33 (9.5)	12 (3.4)	44 (12.6)	60 (17.2)	30 (8.6)
Water and soap	235 (67.5)	279 (80.2)	284 (81.6)	138 (39.7)	300 (86.2)	214 (61.5)	89 (25.6)	68 (19.5)
Alcohol hand rubs	22 (6.3)	19 (5.5)	23 (6.6)	111 (31.9)	31 (8.9)	44 (12.6)	68 (19.5)	63 (18.1)
Water wipes	16 (4.6)	14 (4.0)	5 (1.4)	14 (4.0)	3 (0.9)	12 (3.4)	51 (14.7)	16 (4.6)
Did not practice hand hygiene	15 (4.3)	7 (2.0)	3 (0.9)	52 (14.9)	2 (0.6)	34 (9.8)	80 (23.0)	171 (49.1)

4. Discussion

This study explored hand hygiene knowledge and reported practices of domestic Saudi Hajj pilgrims. There is a paucity of research that has examined hand hygiene knowledge among Hajj pilgrims. In this study the pilgrims had a moderate knowledge of hand hygiene (6.7 ± 1.9). Most respondents had an accurate knowledge of the protective role of hand hygiene against common infectious diseases such as respiratory and gastrointestinal infections, but some were not aware of its role against some less common but nonetheless important infections. Concerningly, about 40% of respondents were not aware that hand hygiene can prevent hand-foot-mouth disease for which hand hygiene is strictly advised, and a quarter of respondents mistakenly thought hand hygiene prevented HIV infection. Pilgrims' knowledge also varied for responses pertaining to questions relating to common myths surrounding hand hygiene and knowledge on correct hand hygiene procedure. For instance, half of the respondents reported that persistent hand washing lowers immunity, half thought that temperature of the water makes a difference in terms of the cleansing effect of hand washing, a third did not know that hands should not be placed under water while lathering, about 58% erroneously thought rubbing hands just for 10 s is enough to ensure disinfection while it should be 20 s, and about a third thought 40% alcohol is sufficient for disinfecting hands whereas the correct answer should be minimum 60% alcohol [10].

A study conducted among Malaysian pilgrims during the 2018 Hajj showed 87.1% pilgrims knew that washing one's hands with hand sanitizers can protect one from flu-like illness, which compares with only 77.9% pilgrims in our study knowing the role of hand hygiene against flu/cough/ILI [18]. The lower proportion in our study could be explained by the fact that foreign pilgrims are generally better informed and better prepared for Hajj travel since health authorities in their countries of origin are mandated to ensure health advice to pilgrims on communicable diseases prompting months of preparation including attendance at pre-travel health seminar (usually more than once) before embarking on Hajj journey [9]. It is also encouraging to see that more domestic pilgrims sought pre-Hajj advice in the present study compared to the previous year (three-quarters versus half) [19]. In this study, there was no significant difference in knowledge level by gender or age as was found in other studies involving Saudi healthcare workers and trainees [20]. It is unsurprising that some pilgrims lacked knowledge in some more specialist themes like alcohol concentration needs to be in disinfectants, duration of time required for hand rubbing, prohibition of placing hands under water while lathering and insignificance of water temperature, yet the pilgrims seem to have similar or even better knowledge in some domains compared to community dwellers in another developed country in Asia [17].

Hand washing with soap and water was the most common type of hand cleaning reportedly used by the study respondents in almost all the situations followed by alcohol hand rubbing. The results of this study are consistent with, and corroborate, the findings of other studies, including a systematic review, which found among Hajj pilgrims hand washing with soap was more popular than hand gel or sanitizers [18,21]. In contrast, a study explored domestic pilgrims' uptake of health preventive measures during the peak Hajj days found the proportion of respondents washing their hands with soap and cleaning hands with hand sanitizers was same (65%); however, pilgrims who were concerned about food poisoning were more likely to clean their hands with hand sanitizers (adjusted OR 2.5, 95% CI 1.1–5.4) indicating pilgrims' degree of concern may dictate the mode of hand hygiene [19].

The results of the present study also showed a relatively poor hand hygiene behavior after touching a patient with only 39.7% washing hands with soap–water and 31.9% using alcoholic hand rub, after sneezing and coughing (respectively 25.6% and 19.5%) and following handshakes (respectively 19.5% and 18.1%). Similarly, low compliance with hand hygiene following these actions in previous studies, for instance 15% Australian pilgrims washed hands after touching a patient while at Hajj, despite the fact that 86% made an intention before Hajj to wash hands after touching an ill person, indicating there were practical issues that barred them [22], e.g., unavailability of soap and hand rub, limited access to washrooms and intense crowding reported as barriers to hand hygiene in this study. Another study conducted among members of public across Gulf countries showed that only 39% individuals washed their hands with soap after handshakes which may indicate that in a non-epidemic setting most people

would not wash hands following handshake [23]. Regardless of what products are being used by pilgrims, hand hygiene in general has been proven to be an effective measure against respiratory infections at Hajj [12–14] and is practiced by pilgrims from different nationalities [18,19].

The patchy knowledge gap and non-compliance on certain occasions warrant improvement. This is indicated by the findings from this and a previous study that showed pilgrims with a university-level education had a higher hand hygiene compliance compared to those with a lower education, and several other studies reporting lack of awareness as an important hindrance to hand hygiene, meaning education may improve the hand hygiene uptake [24]. Through a pre- and post-intervention survey conducted during the Hajj 2011, Turkestani and colleagues showed that direct health education to pilgrims is effective in improving hand hygiene compliance rate from 79.1% to 95.5% [25]. During a pandemic era, such as the current COVID-19 outburst, intensive pre-travel health education perhaps through a certification program following a short course on hygiene may be made compulsory for all pilgrims. Tour operators may conduct the course and should have, as a pre-requisite of running Hajj tours, more advanced knowledge of hygiene, health, and safety. This can be buttressed by direct health education and a random quick knowledge test at the points of entries supplemented by multi-lingual health messages on billboard with graphical illustration on how to perform hand hygiene, map a direction of hand hygiene facilities and resources. Effective pandemic health messaging during the Hajj 2009 was associated with higher compliance with protective measures and with shorter duration of respiratory illnesses [12]. Furthermore, giving advice by Islamic scholars about the importance of alcohol-based hand rubs use and reinforce how this practice does not harm pilgrims could potentially eliminate taboos surrounding the use of alcohol-based hygienic products and in turn enhance compliance [26].

Although a small number of respondents reported some barriers in practicing hand hygiene during Hajj such as unavailability of soap and hand rub, limited access to washrooms, and intense crowding, solutions, for example, providing supplementary hand hygiene products to pilgrims, could potentially increase the uptake. However, in Hajj setting, such improvements are not always feasible; therefore, pilgrims are encouraged to carry their own personal hygiene products.

Considering the continuance of the COVID-19 pandemic and its risks of spreading in mass gatherings, and the increase in average infections globally, the Saudi Government decided to downscale Hajj for this year 2020 allowing only a thousand local and resident foreigners perform the pilgrimage [27].

This study had some limitations. Firstly, the survey was conducted only among domestic Saudi pilgrims who unlike international pilgrims bypass many vicissitudes of travel hence these findings may not be generalizable. Secondly, the reported barriers were not qualitatively gauged, and finally, being anecdotal in nature some data (e.g., vaccination history) could be at risk of recall bias. These limitations can be addressed by a mixed-method study involving an extended sample from multiple nationalities with different health, education and cultural backgrounds.

5. Conclusions

There is a paucity of research that has examined infection prevention and control measures in MGs. Hand hygiene was generally acceptable among domestic Saudi pilgrims but there were variable knowledge gaps in some aspects that may be improved by intensive health education and awareness-raising strategies. Hajj pilgrims demonstrated a good knowledge and reported practice of hand hygiene, although there were some gaps in their key areas that are vital to containing and mitigating outbreaks, particularly in the context of MGs and the current global COVID-19 pandemic.

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CHAPTER 3: Hand hygiene knowledge, perception, and practices among domestic visitors to the Prophet's Mosque amid the COVID-19 pandemic

A few months following the 2019 Hajj season, COVID-19 was declared a global pandemic. I found from the preceding chapter (Publication #2) that although Hajj pilgrims showed an overall good knowledge and practice of HH, it was crucially important to address some of the identified key gaps at the time of such a global pandemic, especially in settings of MG. Due to the limited literature regarding the practice of public health measures among MGs participants in KSA amidst the pandemic, I conducted an anonymous survey among visitors to the Prophet's mosque in Al Madinah city corresponding to the last four days of Hajj starting from July 31 to August 3, 2020 (Publication #3).

To the best of my knowledge, this was the first survey that explored the HH knowledge, perception, and practice of the visitors to the Prophet's Mosque amidst the COVID-19 pandemic. The study revealed that the domestic visitors had a moderate level of knowledge about HH, with variable levels of knowledge gaps. Even though the pilgrims reported sound practices of HH during the COVID-19 outbreak, negligence in compliance that could potentially lead to contracting and spreading RTIs persisted.

Publication #3: Mahdi HA, Assaggaf HM, Alfelali M, Ahmed OB, Alsafi R, Shaban RZ, et al. Hand Hygiene Knowledge, Perception, and Practices among Domestic Visitors to the Prophet's Mosque in Al Madinah City Amid the COVID-19 Pandemic: A Cross-Sectional Study. *Int J Environ Res Public Health*. 2021;18(2):673. <https://doi.org/10.3390/ijerph18020673>.



Article

Hand Hygiene Knowledge, Perception, and Practices among Domestic Visitors to the Prophet's Mosque in Al Madinah City Amid the COVID-19 Pandemic: A Cross-Sectional Study

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Abstract: This study aimed to assess hand hygiene knowledge, perception, and practices of visitors to the Prophet's Mosque in Al Madinah City, Saudi Arabia. Using a self-administered electronic questionnaire, a cross-sectional survey was conducted among domestic residents, who visited the mosque between 31 July and 3 August 2020. Participants' demographic data, hand hygiene knowledge, perception, and practices were collected. Four hundred participants aged 18–65 (median 36) years completed the survey, of which 215 (53.8%) were female. The visitors' mean knowledge score about hand hygiene was 6.4 ($\pm$ standard deviation (SD) 1.35) of total 12. Most participants (392, 98%) were aware of the role of hand hygiene in preventing Coronavirus Disease 2019 (COVID-19); nevertheless, 384 (96%) said hand hygiene lowers body immunity and 316 (79%) thought <60% alcohol is sufficient for hand disinfection. Males had a higher knowledge score than females (6.46 ($\pm$ 1.41) vs. 6.14 ($\pm$ 1.27), $p = 0.02$) and, visitors who had no formal education scored higher than those with post-graduate education (6.88 ($\pm$ 1.45) vs 5.73 ($\pm$ 1.12), $p = 0.01$). Washing hands with soap and water was the predominant method practiced after a meal (365, 91.7%), after toilet visit (354, 88.5%), after touching a surface (262, 65.7%), after waste disposal (332, 83.2%), and when hands were visibly dirty (357, 89.5%). Al Madinah visitors had moderate knowledge about hand hygiene, but demonstrated some knowledge gaps and negligence in practice that are crucial to curb the spread of COVID-19.

Keywords: COVID-19; hand hygiene; knowledge; practice; visitors to the Prophet's Mosque

1. Introduction

A mass gathering (MG) is defined as a congregation of attendees at a specific location for a specific purpose over a period of time, and that has the potential to strain the planning and response resources of the host country or community [1]. Millions of Muslims from around the world travel every year to the Two Holy Mosques in Kingdom of Saudi Arabia (KSA): The Grand Mosque in the city of Makkah for Hajj and Umrah, and the Prophet's Mosque (Al-Masjid al-Nabawi) in the city of Al Madinah that houses the shrine of the Prophet Mohammad (peace be upon him). This visitation to the Prophet's Mosque, called 'Ziyarah' in Arabic, is not an integral part of Hajj, but is considered by pilgrims to be a unique revered optional opportunity that should not be missed. Hence, most Hajj and Umrah pilgrims' itineraries include this Ziyarah [2], and they stay in Al Madinah for several days.

The global pandemic of the novel Coronavirus Disease 2019 (COVID-19) has affected more than 89 million individuals with fatalities exceeding 1.9 million around the world, and over 363,000 confirmed cases with over 6000 deaths in Saudi Arabia (as of 9 January 2021) [3]. Religious MGs pose a significant risk for the spread of respiratory tracts infections, as is currently the case with the COVID-19 pandemic [4,5]. Multiple outbreaks of COVID-19 in different countries have been traced to attending such religious events [6–8]. In order to prevent the spread of the virus among attendees of Hajj and Umrah MGs, several sectors in KSA have taken immediate and drastic measures from the beginning of this pandemic; for example, the Saudi Arabian authorities immediately imposed a lockdown in these holy sites and suspended Umrah and Ziyarah [9]. Since early June 2020, restrictions on the Prophet's Mosque were eased gradually and a limited number of current residents of Saudi Arabia (domestic and expatriates) were permitted to pray with a strict public health protocol to follow, including observing hand hygiene [10].

Frequently and thoroughly washing hands with soap and water for at least 20 s or sterilising hands with a 60% alcohol-based hand sanitiser, when soap and water are not available, can help prevent respiratory viral infections in settings where people are more likely to mix, contract, and spread infections [11]. As COVID-19 can spread through contact with contaminated surfaces, hand hygiene remains a fundamental control and prevention measure and is strongly recommended to curb its transmission, especially in the absence of a clinically approved vaccine or antiviral prophylaxis [11].

Studies found that hand hygiene was the most favoured infection prevention method among Hajj pilgrims prior to the COVID-19 crisis [12–14]. A survey conducted by our team during the Hajj 2019 demonstrated that domestic Hajj pilgrims had sound hand hygiene knowledge and practice, but there are gaps in areas that are now considered vital to contain and mitigate outbreaks such as the COVID-19 pandemic [15]; however, anecdotally, it is believed that COVID-19 campaigns may have improved the situation. The Saudi general population have shown acceptable awareness and practices towards COVID-19 [16–19]. Nonetheless, there is no focused published study that has examined the knowledge and practice of hand hygiene among visitors to the Prophet's Mosque in Al Madinah City during the pandemic or earlier. Therefore, this study aims to assess hand hygiene knowledge, perception, and practice among visitors to the Prophet's Mosque amidst the COVID-19 pandemic.

2. Materials and Methods

Using a convenient sampling strategy, a cross-sectional survey was conducted among Saudi Arabian residents who visited the Prophet's Mosque in Madinah, Saudi Arabia, during Eid al-Adha (the feast of sacrifice), corresponding to the last days of Hajj over four days starting from 31 July to 3 August 2020. Visitors of both genders aged ≥ 18 years were invited to participate, while the minors (i.e., persons under 18 years of age) and individuals not having a full mental capacity to comprehend the consent form in Arabic or English were excluded.

For the health and safety of the research team members and study participants amidst the ongoing outbreak of COVID19, a self-administered electronic questionnaire in Arabic or English was deemed preferable to a pen-paper based survey. Four trained data collectors approached the potential participants at the mosque and explained the study purpose and methodology. Visitors who agreed to participate were then given a tablet device where the questionnaire was completed, and the responses were recorded through an online survey development cloud-based software (Rased) (The Custodian of the Two Holy Mosques Institute for Hajj and Umrah Research, Makkah, Saudi Arabia). This being an anonymous survey, no signed consent was obtained, and respondents' completion of the survey was considered as their implied consent. Ethics approval was obtained from King Abdullah Medical City (KAMC), Makkah, Saudi Arabia (IRB reference number: 20-661).

The questionnaire was devised using some exemplary questions used in a published survey conducted in 2019 by the study authors [15] and was revised by taking the COVID-19 pandemic into consideration and feedback from MG and infectious disease experts. Following the revision, the final version was prepared and grammatical discrepancies in both Arabic and English were fixed. The questionnaire consisted of three major parts. Part 1 collected non-identifiable socio-demographic information about the participant including gender, age, education, and nationality. Part 2 collected data about the participants' knowledge of hand hygiene using true/false statements about risks, practice, and common myths and fallacies associated with hand hygiene reported in the literature and global public health institutes (the World Health Organization and the U.S. Centers for Disease Control and Prevention) [20,21]. The sum of knowledge scores was calculated for each participant using a scale from 0 to 12, with a higher score indicating considerable knowledge level on hand hygiene and a lower score indicating poor knowledge. Additionally, participants' perception regarding the germicidal effects of different hand hygiene methods including against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was also captured in Section 2. Part 3 comprised items related to self-reported hand hygiene behaviour. Participants were asked how often they used different hand hygiene products (water only, soap and water, and alcohol-based hand rubs (ABHRs)) to clean their hands per day in the past two weeks prior to data collection. They were also asked which of these products they used for cleaning hands during key situations when they are most likely to be exposed to germs such as before and after eating, after toileting, and so on. Finally, participants were asked to report what possible reasons may have hindered them from practising regular hand hygiene and what side effects they experienced from using hand hygiene products.

All the collected data in the software were exported to a master Excel spreadsheet (Microsoft Office 356, version 2002, Redmond, WA, USA) for cleaning and coding before importing to Statistical Package for Social Sciences (SPSS) software (IBM SPSS Statistics for Windows, version 26.0, IBM Corp, Armonk, NY, USA). Frequencies and percentages were used to present the categorical variables including most demographic data, hand hygiene knowledge level, perception, and practices, while the mean (or median with range) $\pm$ standard deviation (SD) was used to summarise continuous variables including total hand hygiene knowledge score. Pearson correlation test was used to indicate the strength of association between visitors' age and their level of hand hygiene knowledge, while one-way analysis of variance (ANOVA) was applied to determine the significant differences of the sample categorical characteristics in association with the knowledge score. Pearson's chi-squared test was applied to assess differences among the sample characteristics and participants' practice of hand hygiene. A p -value ≤ 0.05 was considered to be statistically significant.

3. Results

Of total 412 individuals approached, all (100%) agreed to take part in the study, of whom 400 (97%) participants aged 18–65 (median of 36) years completed the online questionnaire, of whom 215 (53.8%) were female. The local Saudi citizens accounted for 83 (21.7%) of the sample, with the leading expatriates being Pakistanis 84 (22%); further,

284 (71.7%) resided in Madinah, 146 (36.7%) had a high school level education, and 52 (13%) reported having at least one comorbidity (Table 1).

Table 1. Demographic characteristics of respondents ($n = 400$).

Characteristics	Findings
Median (range) of age in years	36 (18–65)
Male: Female n (%)	185: 215 (46.3: 53.8)
Nationality n (%)	
Saudi Arabia	83 (21.7)
Pakistan	84 (21.9)
Afghanistan	23 (6)
Bangladesh	19 (5)
Egypt	28 (7.3)
India	35 (9.1)
Sudan	23 (6)
Yemen	19 (5)
Others	69 (18)
Residence in Saudi Arabia n (%)	
Al Madinah	284 (71.7)
Jeddah	43 (10.9)
Yanbu	9 (2.3)
Riyadh	31 (7.8)
Al-Qassim	6 (1.5)
Hail	6 (1.5)
Others	17 (4.3)
Education n (%)	
None	26 (6.5)
Primary/elementary school certificate	68 (17.1)
High school certificate	146 (36.7)
Diploma	43 (10.8)
University degree	78 (19.6)
Higher university degree	37 (9.3)
Presence of pre-existing medical conditions n (%)	
Absent	348 (87)
Present	
Hypertension	35 (8.8)
Chronic heart diseases	6 (1.5)
Diabetes	17 (4.3)
Chronic kidney disease	4 (1)
Chronic gastrointestinal disease	8 (2)

The findings of the participants' knowledge level of hand hygiene are detailed in Table 2. The mean ($\pm$ SD) hand hygiene knowledge score was 6.4 ($\pm$ 1.35), a quarter (98, 24.5%) of the participants had a poor knowledge score of <6 , nearly three-quarters (297, 74.3%) had a medium score of 6 to 9, and a small proportion (5, 1.3%) had a high score of ≥ 10 . Men had a significantly higher hand hygiene knowledge mean score than women (6.46 ($\pm$ 1.41) vs 6.14 ($\pm$ 1.27), $p = 0.02$); however, participants with no formal education had a higher hand hygiene knowledge score than those with post-graduate level education (6.88 ($\pm$ 1.45) vs 5.73 ($\pm$ 1.12), $p = 0.01$). Fewer participants correctly responded to the following knowledge statements: HIV/AIDS does not transmit through poor hand hygiene (34.5%), keeping hands clean does not effect on immunity system (4%), ABHRs should contain at least 60% of alcohol for disinfection of hands (21%), antiseptic/antibacterial soaps are not more effective at preventing infections than washing with plain soap (2.5%), and water temperature does not make a difference in the cleansing effect of washing of hands (45.8%).

Table 2. Hand hygiene knowledge level among participants ($n = 400$).

Statements	Correct Answer n (%)
1. Respiratory infections including “COVID-19” can be transmitted by poor hand hygiene	392 (98)
2. HIV/AIDS can be transmitted by poor hand hygiene	138 (34.5)
3. Always keeping your hands clean may lower our body defence mechanism	16 (4)
4. ABHR containing less than 60% of alcohol is sufficient for hands disinfection	84 (21)
5. Washing of and with soap and water from 20 to 40 s is sufficient for hands disinfection	376 (94)
6. Hands should be held under water while lathering with soap	249 (62.3)
7. The temperature of water does not make difference in terms of the cleansing effect of hand washing	183 (45.8)
8. Antiseptic/antibacterial soaps are more effective at preventing illness than washing with plain soap and water	10 (2.5)
9. Using ABHR may not be as effective as the use of soap and water when hands are visibly dirty	359 (89.8)
10. There is no need to clean our hands after sneezing, coughing, or shaking hands	291 (72.8)
11. Ultra-violet (UV) lamps should not be used to disinfect our hands or other areas of our skin	187 (46.8)
12. Spraying and introducing bleach or another surface disinfectant into our hands is safe and it will protect us against COVID-19 and other infections	231 (57.8)
Mean ($\pm$ SD) of total scores (0 to 12)	6.4 ($\pm$ 1.35)

ABHR = alcohol-based hand rub; COVID-19 = Coronavirus Disease 2019.

Table 3 shows that most participants believed cleansing hands with antiseptic/antibacterial soap and water (263, 65.8%), plain soap and water (195, 48.8%), and alcohol-based hand rubs (224, 56%) were very effective hand hygiene methods, and 60 (15%) thought even plain water is very effective.

Table 3. Perceptions of the effectiveness of hand hygiene methods ($n = 400$).

Participants' Perception of Effectiveness	n (%)
Water only	
Not effective	67 (17)
Somewhat effective	272 (68)
Very effective	60 (15)
Plain soap and water	
Not effective	3 (0.8)
Somewhat effective	202 (50.5)
Very effective	195 (48.8)
Antiseptic/antibacterial soap and water	
Not effective	1 (0.3)
Somewhat effective	136 (34)
Very effective	263 (65.8)
ABHR	
Not effective	2 (0.5)
Somewhat effective	174 (43.5)
Very effective	224 (56)

ABHR = alcohol-based hand rub.

Table 4 presents the frequency of hand hygiene practice methods across both genders, showing that males used soap and water more frequently than females ($p = 0.05$). Table 5

summarises participants' hand hygiene practices and methods used before and after nine key actions showing water alone or soap and water was the predominant hand hygiene method practised before a meal, by 215 (53.9%) and 165 (41.4%) participants, respectively, while soap and water was the main method used after a meal (365, 91.7%), after toilet visit (354, 88.5%), after touching a surface (262, 65.7%), after caring for a patient (213, 53.4%), when hands were visibly dirty (357, 89.5%), after waste disposal (332, 83.2%), and after handshakes (112, 28%). More people used disposable handkerchiefs (110, 27.6%) and soap and water (102, 25.6%) following a sneeze or cough.

Table 4. Frequency of reported practice of hand hygiene methods in both gender groups ($n = 400$).

Hand Hygiene Practices by Gender Groups	Never <i>n</i> (%)	Less Frequently (≤5 Times/Day) <i>n</i> (%)	More Frequently (>5 Times/Day) <i>n</i> (%)	<i>p</i> -Value ^a
Water only				
Male (<i>n</i> = 185)	4 (2)	52 (28)	129 (70)	0.08
Female (<i>n</i> = 214)	1 (0.5)	78 (36.5)	135 (63)	
Soap and water				
Male (<i>n</i> = 185)	1 (0.5)	146 (79)	38 (20.5)	0.05 *
Female (<i>n</i> = 215)	1 (0.5)	189 (88)	25 (11.5)	
ABHR				
Male (<i>n</i> = 184)	11 (6)	170 (92.4)	3 (1.6)	0.30
Female (<i>n</i> = 215)	22 (10)	190 (88.4)	3 (1.6)	

^a By chi-square test; asterisks * indicate a significant difference; ABHR = alcohol-based hand rub.

Table 5. Participants' hand hygiene practices and methods used in the nine key actions ($n = 400$).

Types of Hand Hygiene	Before Meal n (%)	After Meal n (%)	After Toileting n (%)	After Touching a Surface n (%)	After Caring for a Patient n (%)	When Hands Visibly Dirty n (%)	After Waste Disposal n (%)	After Sneeze/Cough n (%)	After Handshake n (%)
Water only	165 (41.4)	9 (2.3)	5 (1.3)	31 (7.8)	3 (0.8)	5 (1.3)	18 (4.5)	60 (15.1)	80 (20)
Soap and water	215 (53.9)	365 (91.7)	354 (88.5)	262 (65.7)	213 (53.4)	357 (89.5)	332 (83.2)	102 (25.6)	112 (28)
ABHR	16 (4)	20 (5)	40 (10)	87 (21.8)	175 (43.9)	36 (9)	47 (11.8)	50 (12.6)	107 (26.8)
Disposable handkerchiefs	1 (0.3)	2 (0.5)	1 (0.3)	2 (0.5)	1 (0.3)	1 (0.3)	0 (0)	110 (27.6)	0 (0)
Did not practice	2 (0.5)	2 (0.5)	0 (0)	17 (4.3)	7 (1.8)	0 (0)	2 (0.5)	76 (19.1)	101 (25.3)

ABHR = alcohol-based hand rub.

The main reported reasons that might have hindered the visitors from complying with regular hand hygiene were failure to remember (210, 52.5%), being too busy (96, 24%), and difficulty in accessing hand cleaning products (91, 22.8%). A small number (92, 23.1%) of participants experienced adverse dermatologic effects of adopting frequent hand hygiene, such as skin dryness, peeling skin, allergy, or eczema, which of whom 64 (70%) were female.

4. Discussion

To the best of our knowledge, this is the first study that focused on evaluating knowledge, perception, and reported practices of hand hygiene among domestic visitors to the Prophet's mosque in Al Madinah City amidst the COVID-19 pandemic. As elaborated below, the key findings of this survey may inform future policy.

4.1. Knowledge about Hand Hygiene

The participants in this study achieved a moderate level of the knowledge about hand hygiene, with an average score of 6.4 (± 1.35), and nearly three-quarters (297, 74.25%) obtained a medium score. This finding indicates that most study participants (392, 98%) were knowledgeable about the protective role of a good hand hygiene practice against the COVID-19 and other respiratory infections, yet only one-third correctly reported that HIV/AIDS does not transmit through poor hand hygiene. According to the visitors' responses, poor knowledge was detected in numerous aspects associated with the common myths surrounding hand hygiene and a proper hand hygiene procedure. For example, 96% of participants mistakenly reported that consistent hand washing negatively impacts body immunity, almost 80% were unaware of the correct concentration of alcohol hand washing solutions should contain to ensure optimum disinfection, and more than half thought the temperature of the water makes a difference in terms of the cleansing effect of hand washing. Concerningly, many visitors were unaware that engaging in high-risk practices, such as applying bleach or other household disinfectant products to bare hands and using ultra-violet lamps to disinfect hands, can damage skin tissues [20,22]. Anticipating such high-risk practices with the intention to combat COVID-19 was observed in a survey conducted among U.S. residents [22].

Despite the intensive awareness-raising COVID-19 campaigns, the hand hygiene knowledge score in this survey did not significantly improve—rather, it slightly worsened—compared with our previous survey conducted among Hajj pilgrims in 2019 (average knowledge score in this survey 6.4 compared with 6.7 in the previous year) [15]. Nonetheless, some statements in the current study received higher correct responses like the essential role of cleaning of hands in preventing respiratory illnesses transmission (98% versus 78%) and the accurate time (at least 20 s) of scrubbing hands with soap (94% versus 42%). These higher rates of correct responses probably indicate that people have become more aware of the protective role of hand hygiene and its correct practices amidst the ongoing COVID-19 pandemic. This fact is supported by several recent surveys that determined the awareness level and practice toward COVID-19 among the Saudi Arabian population. For instance, an online survey involving 6000 members of Saudi public showed 22.4% of respondents indicated that washing hands with soap and water was important to avoid transmission of COVID-19 [16]; in another survey of 3388, 87.7% strongly agreed and 10.8% just agreed that hand hygiene was essential to protect oneself from COVID-19; and in a third survey involving 443 respondents [17], 96% of respondents reported they knew they had to wash their hands with soap and water for 20 s, however, 16.2% were not compliant with this knowledge [18].

Gender and education level were identified to be predictive factors in this study. Male participants tended to have a higher level of hand hygiene knowledge and were more likely to wash their hands with soap and water more frequently (>5 times/day). This could be because males are mostly outdoor, and hence are more exposed to healthcare messages, or maybe because males are more careful about their health as COVID-19 is worse in males [23]. Surprisingly, education level was negatively associated with knowledge, where participants who did not attain any academic certificate were more likely to score higher in the knowledge level than postgraduate degree holders. On the contrary, some recent findings among the Saudi population suggested that females and highly educated people are more adherent to and knowledgeable about COVID-19 prevention and control measures [17,19]. This could be a chance finding, and hence needs further investigation. This also hints that perhaps more focused health education is needed to improve public health, irrespective of background educational status of a person.

4.2. Perception of Hand Hygiene

Most of the visitors to the mosque had a positive perception of the effectiveness of hand hygiene in killing viruses existing in our hands, including COVID-19, and this matched the results of studies involving the Saudi general population and healthcare workers,

which found that over 90% agreed that washing hands is essential to protect themselves and others from COVID-19 transmission [17,24]. Noticeably, participants had a strong belief that antiseptic/antibacterial soaps are more effective than plain soap in preventing infectious illnesses, while evidence to date has not proven that there is a difference between the use of these products on the effectiveness of hand cleansing. In addition, long-term exposure to antibacterial substances in hand hygiene products may increase the risk of developing antimicrobial resistance [25].

4.3. Practice of Hand Hygiene

When participants were asked about their hand hygiene practices at specific high-risk situations, soap and water was the most preferred method reportedly used, followed by alcohol-based hand rubs. This finding is in parallel with the results of formerly conducted studies among attendees of Hajj and Umrah pilgrimage that found hand washing with soap and water was more prevalent than other hand hygiene methods [15,26–28]. It is also noteworthy that Saudi Arabian citizens have a preference for using soap and water to ABHR as a preventive measure against COVID-19 [19]. In spite of the recommendations of washing hands after sneezing or coughing and following handshakes to prevent contracting and spreading infections, it seems that the low compliance of hand hygiene during these situations is an issue that persists even during the pandemic. This survey shows a relatively poor hand hygiene behaviour after sneezing or coughing, with only 25.6% washing hands with soap and water and 12.6% using alcoholic hand sanitiser, as well as following handshakes (28% and 26.8%, respectively), and the largest proportion (27.6%) used a handkerchief following a sneeze, while previously, they washed hands with water and soap [15]. Similarly, approximately 27% of the Saudi Arabian citizens did not wash their hands after nose-blowing, coughing, or sneezing amidst the COVID-19 pandemic [17]. Conversely, hand hygiene compliance in this study improved slightly following other high-risk actions, e.g., about 98% of visitors of the mosque cleaned their hands after touching a patient and 99% cleaned hands following waste disposal, whereas 85% and 90% of pilgrims, respectively, during the 2019 Hajj complied [15]. Another survey involving Umrah pilgrims conducted in 2019 showed that over 90% of pilgrims washed their hands with soap and water or sanitisers after coughing and sneezing, before eating or preparing food, and after using the bathroom [29]. The fact that fewer participants were complying with ABHR compared with using soap and water may have stemmed from the religious and cultural preference of Muslims to avoid alcoholic substances when equivalent alternates are available [30].

4.4. Barriers and Side Effects of Hand Hygiene

Visitors reported that being busy, forgetting to clean hands when they should, and inaccessibility sometimes to hygienic products were the main obstacles, among others, to regular hand hygiene. Hence, people intending to participate in MG events are encouraged to carry their personal hygiene products to overcome these problems and increase the uptake. Few visitors (92, 23.1%), mostly women, reported having abnormal skin reactions as a result of frequent hands washing. Some advisable tips, such as applying moisturizers after hand cleaning, are helpful in preventing further side effects [31].

4.5. Implications for the Upcoming Religious Mass Gatherings

The Saudi Arabian health authorities have launched a nationwide COVID-19 awareness campaign using various sources (e.g., social media platforms) to disseminate information about the disease route of transmission, signs and symptoms, and preventive strategies; in turn, this effort, along with other drastic measures, has helped significantly in reducing the newly acquired cases and controlling the spread of the disease in the country [32]. More people have been attending the Two Holy Mosques, since October 2020, following the Saudi government decision to ease more restrictions on visiting of the Prophet's mosque, and gradually reopening Umrah season to pilgrims in Makkah after a lockdown that lasted

for seven months [10]. Therefore, COVID-19 precautionary messages should continue to target this population with an emphasis on evidence-based instructions about the best and safe hygiene practices.

4.6. Study Limitations and Future Recommendations

The major limitation of this study was that it only captured the knowledge and practices of visitors to the Prophet's mosque in a certain stage of the pandemic (between 31 July and 3 August 2020); consequently, the results may not be generalizable outside the domain of the defined population and scope of the current study. We recommend implementing an additional survey involving participants of another religious MG setting in Saudi Arabia (such as Umrah) to assess hand hygiene awareness and practices at a different stage of the pandemic.

5. Conclusions

There is a lack of research investigating hand hygiene at religious mass events during the COVID-19 pandemic. This study showed that the domestic visitors to the Prophet's mosque had a moderate knowledge score of hand hygiene with consideration of variable knowledge gaps, specifically in some aspects related to accurate hand hygiene techniques and involvement in high-risk practices. The participants reported better practices of hand hygiene during the current COVID-19 disaster, yet negligence in the compliance has been observed in some situations that could lead to contracting and disseminating infections. Sustained improvements through intensive awareness-raising interventions to enhance knowledge and practice of hand hygiene are essential for MG participants from different sociodemographic backgrounds amidst the ongoing COVID-19 pandemic.

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Conflicts of Interest: The authors declare no conflict of interest.

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CHAPTER 4: Surveillance of respiratory tract infections and hand hygiene among pilgrims who attended the 2021 Hajj season

As highlighted in the earlier chapter (Publication #3), I found some knowledge gaps and non-compliance in HH among the visitors, which prompted me to conduct additional research involving participants of other religious MGs that entail more prolonged and intense rituals, aiming to gain a comprehensive understanding of HH awareness and practices across various stages during the pandemic. Hence, I carried out a surveillance study (Publication #4) targeting pilgrims in the subsequent Hajj year (2021), following the decision of the Saudi government to lift more COVID-19 restrictions on the pilgrimage.

To this end, a prospective cohort study was designed to evaluate pilgrims' HH behaviour during the peak week of Hajj assembly and to estimate the rate of symptomatic viral RTIs among pilgrims. A baseline questionnaire was administered to pilgrims, who were then followed up after seven days using a questionnaire about the onset of symptoms and their HH practises. This surveillance study found that the incidence of syndromic RTIs was lower among Hajj pilgrims compared to studies conducted before the pandemic, possibly as a result of COVID-19-related measures. The findings did not seem to show improvements in the pilgrims' HH knowledge, although a higher level of knowledge was found to be correlated with improved HH practice. Finally, the study did not demonstrate a significant effect of practising HH on reducing the rates of RTI during the pilgrimage; thus, it was decided to conduct an RCT to provide a more definitive answer.

Publication #4: Mahdi HA, Rashid H, Qashqari FS, Hariri SH, Marglani OA, Barasheed O, et al. Syndromic surveillance of respiratory-tract infections and hand hygiene practice among pilgrims attended Hajj in 2021: a cohort study. BMC Infect Dis. 2022;22(1):578. <https://doi.org/10.1186/s12879-022-07559-0>.

RESEARCH

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Syndromic surveillance of respiratory-tract infections and hand hygiene practice among pilgrims attended Hajj in 2021: a cohort study

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Abstract

Background: The risk of transmission of viral respiratory tract infections (RTIs) is high in mass gatherings including Hajj. This cohort study estimated the incidence of symptomatic RTIs and hand hygiene compliance with its impact among Hajj pilgrims during the COVID-19 pandemic.

Methods: During the week of Hajj rituals in 2021, domestic pilgrims were recruited by phone and asked to complete a baseline questionnaire. Pilgrims were followed up after seven days using a questionnaire about the development of symptoms, and practices of hand hygiene. Syndromic definitions were used to clinically diagnose 'possible' influenza-like illnesses (ILI) and COVID-19 infection.

Results: A total of 510 pilgrims aged between 18 and 69 (median of 50) years completed the questionnaire, 280 (54.9%) of whom were female, and all of them (except for one) were vaccinated against COVID-19 with at least one dose. The mean ($\pm$ SD) of pilgrims' hand hygiene knowledge score (on a scale of 0 to 6) was 4.15 ($\pm$ 1.22), and a higher level of knowledge was correlated with a higher frequency of handwashing using soap and water. Among those 445 pilgrims who completed the follow-up form, 21 (4.7%) developed one or more respiratory symptoms, of which sore throat and cough were the commonest (respectively 76.2% and 42.8%); 'possible ILI' and 'possible COVID-19' were present in 1.1% and 0.9% of pilgrims. Obesity was found to be a significant factor associated with the risk of developing RTIs (odds ratio = 4.45, 95% confidence interval 1.15–17.13).

Conclusions: Hajj pilgrims are still at risk of respiratory infections. Further larger and controlled investigations are needed to assess the efficacy of hand hygiene during Hajj.

Keywords: COVID-19, Hajj, Hand hygiene, Influenza-like illnesses, Respiratory-tract infections

Background

Hajj is an annual Islamic pilgrimage where pilgrims gather in sacred sites in the city of Holy Makkah, Kingdom of Saudi Arabia, to perform certain rituals at specific times. The rites of Hajj include assembly at the Holy Mosque where pilgrims make circumambulations around the monolith called 'Kaaba', march between two hillocks

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and stay in tents at specific locations on the outskirts of Makkah. On designated days of Hajj, all pilgrims stay in tents Mina, a valley at the outskirts of Makkah, when they remain in intense religious contemplation and seclusion (called state of 'Ihram') by wearing a pair of unstitched sheets, and by avoiding stitched garbs (including gowns, caps and gloves) and scented toiletries. The inevitable over-crowding with minimal physical distancing between pilgrims amplifies the risks of contracting and disseminating viral respiratory tract infections (RTIs) [1, 2]. Respiratory symptoms are common among Hajj pilgrims, with cough being the predominant symptom reaching as high as 90% among some pilgrims [3]. The rate of influenza-like illnesses (ILI) among Hajj pilgrims varied by nationality of pilgrims and study year [1]. However, the overall prevalence of ILI among pilgrims was high in the past decade; for example, more than 80% among French pilgrims from 2014 to 2017 [4], 63.4% among Australian pilgrims in 2011 [5], and 30.4% among Egyptian pilgrims between 2012 and 2015 [6].

Using hand hygiene intervention properly and frequently is one of the most important infection control and prevention methods against viral RTIs. Only limited studies have explored the practice and effectiveness of hand hygiene intervention among Hajj pilgrims [7–10]. A previous systematic review assessed the practice and effectiveness of hand hygiene among Hajj pilgrims but provided inconsistent and inconclusive evidence on the role of hand hygiene in preventing viral RTIs [7]. A study conducted by our team during the Hajj in 2019 showed that while pilgrims have good knowledge and practice of hand hygiene, only a minority used recommended hand hygiene products and most preferred to use soap and water; overall hand hygiene to prevent contact transmission of RTIs is underutilised [11].

Since the World Health Organization (WHO) declared coronavirus disease-19 (COVID-19) as a global pandemic in March 2020, the government of Saudi Arabia has imposed multiple stringent public health measures and restrictions to curb the spread of COVID-19 during the pilgrimage [2]. Consequently, the number of Hajj pilgrims was considerably downscaled from millions of Muslims globally in normal times to only a few thousand local pilgrims in 2020 and 60,000 pilgrims who were resident in Saudi Arabia at the time of Hajj in 2021 [12].

We are not aware of any study has been conducted to estimate the incidence of RTIs among Hajj pilgrims during the COVID-19 pandemic. Also, pilgrims' hand hygiene compliance and its effectiveness against RTIs have not been well explored. Therefore, the primary objective of this study was to estimate the incidence of symptomatic viral RTIs among pilgrims who attended the 2021 Hajj season. Additionally, we assessed pilgrims'

hand hygiene behaviour during the pilgrimage and its impact on preventing RTIs.

Methods

A prospective cohort study was undertaken among Hajj pilgrims in the year 2021. Domestic pilgrims aged ≥ 18 years of both genders who spoke Arabic or English not having any ILI symptoms at the time of recruitment were eligible to take part in this cohort study, while those who reported any ILI symptoms at the time of recruitment or refused to participate were excluded. As a result of COVID-19 restrictions and for the health and safety of pilgrims, the study was conducted distantly via phone calls by the research team. An ethics approval was obtained from the biomedical ethics committee, Umm Al-Qura University, Makkah, Saudi Arabia (Approval no. HAPO-02-K-012-2021-07-708), and other necessary permissions to perform the study were also sought. The informed consent was obtained from all subjects.

The recruitment took place during the week of Hajj rituals, from 8 to 13 of Dhul-Hijjah month of the Arabic calendar corresponding to 19 to 23 July 2021. A convenience sample was drawn from a list of around 1000 pilgrims with their names and contact information, provided by Hajj Hamlahs (tour operators). Among those pilgrims from the list who responded to the phone calls were invited to the study and provided with the study's objectives and procedures, and those who met the eligibility criteria and gave their consent to participate were asked to be interviewed and complete the baseline questionnaire.

The baseline questionnaire contained questions about participants' socio-demographic information, presence of pre-existing comorbidities, smoking status, and source of pre-Hajj health information. Pilgrims were asked if they received influenza vaccine within the previous year, and the COVID-19 vaccine before attending Hajj. More specific details related to COVID-19 vaccination were captured such as type/brand of vaccine received, and occurrence of adverse reactions (if any) following vaccination. The final part of the baseline questionnaire captured data related to pilgrims' knowledge about hand hygiene and perception regarding the effects of different hand hygiene products against RTIs. The questionnaire was devised by using exemplary questions used in a previously published survey [13]. It was then modified based on the 2021 global epidemiological scenario and feedback from leading MG and infectious disease experts.

Seven days after the recruitment, pilgrims who completed the baseline questionnaire were contacted again individually via a phone call to participate in the second phase of the study, which focused on following up pilgrims' health and hand hygiene behaviour. The

follow-up questionnaire contained questions about the presence or absence of constitutional symptoms (subjective fever, fatigue, myalgia, and headache), respiratory symptoms (cough, sore throat, rhinitis, dyspnoea, and smell or taste dysfunction) and gastrointestinal symptoms (diarrhoea, and vomiting). Details about these symptoms including onset date, duration and whether they sought treatment were obtained. Lastly, pilgrims were asked about their hand hygiene behaviour during the Hajj journey; for instance, how frequently they used soap and water, and alcohol-based hand sanitisers to clean their hands, and if they cleaned their hands before or after specific high-risk situations, such as before eating, after toilet action, after nose blowing, sneezing, or coughing and so forth.

This study used a broad definition of a case of RTI; it was defined as the development of one or more respiratory symptoms during the follow-up phase. In order to clinically diagnose a possible case of viral RTIs among our study cohorts, syndromic definitions for 'possible' ILI and COVID-19 were applied as per the criteria described and evaluated elsewhere [14, 15]. ILI was defined as 'a triad of cough, sore throat and subjective fever' as described by Rashid et al. [14]. The triad had a sensitivity and specificity of respectively 67% and 64% against influenza confirmed by reverse transcriptase-polymerase chain reaction. The COVID-19 infection criterion was defined as the 'concomitant presence of three or more of the following symptoms: fever, myalgia, cough, and olfactory and taste disorders' as defined by Fulvio et al. [15], which was found to be highly significantly correlated with a positive molecular diagnosis of COVID-19 (adjusted odds ratio [OR] 18.55, 95% CI 13.77–24.97) and a specificity of 91.2%.

The participant's responses were directly entered into an online questionnaire through "Microsoft Forms", a development cloud-based software (Microsoft Office 356, version 2002, Redmond, WA, USA). Subsequently, these responses were exported to a master Excel spreadsheet (Microsoft Office 356, version 2002, Redmond, WA, USA) for data translation, cleaning, and coding before importing into Statistical Package for Social Sciences (SPSS) software (IBM SPSS Statistics for Windows, version 26.0, IBM Corp, Armonk, NY, USA) for analysis. For descriptive analysis, frequencies and percentages were applied to present categorical variables, the incidence of symptoms, and 'possible ILI' and 'possible COVID-19'. The mean (or median with range) $\pm$ standard deviation (SD) was used to summarise continuous data. The associations of potential factors with the practices of hand hygiene, and with the estimated incidence of RTIs were analysed using simple logistic regression. The risk estimation was carried out using OR with 95%

confidence interval (CI) and a p value of ≤ 0.05 was considered statistically significant.

With an estimated incidence of symptomatic RTIs associated with Hajj of 30% in a previous study [6] and an error margin of 5% at a confidence level of 97%, a sample of 400 participants was needed for the study. Considering a high dropout rate, we decided to inflate the sample by 125% and targeted to recruit at least 500 subjects.

Results

A total of 800 Hajj pilgrims were approached for cohort recruitment, of those 510 (63.75%) agreed to take part in the study and completed the baseline questionnaire. During the second phase, 65 (12.75%) were lost to follow-up (37 did not answer the call and 28 refused to proceed with the study) leaving 445 completing the follow-up.

The participants were aged between 18 and 69 (median of 50) years and 280 (54.9%) were female. Native Saudi pilgrims accounted for 437 (85.7%) of the cohort; further, 276 (54.1%) of the participants held a bachelor's certificate, 126 (24.7%) were public sector employees and 120 (23.5%) were private sector employees. Of all, 167 (32.7%) reported having one or more pre-existing health conditions, 60 (11.8%) reported being tested positive for COVID-19 before Hajj, and 77 (15.1%) were current smokers. Concerning the vaccinations received by pilgrims before attending the pilgrimage, 297 (58.2%) reported receiving the influenza vaccine, and all of them (except for one pilgrim) were vaccinated with a single dose of COVID-19 vaccine, while 472 (92.5%) received both doses (Table 1).

Pilgrims sought some form of health information on preventative methods from various sources: 319 (62.5%) acquired information from social media and internet websites, 283 (55.5%) from the Saudi Ministry of Health campaigns, 205 (40.2%) from Hajj tour operators, 152 (29.8%) from friends and relatives and 82 (16.1%) from health professionals. The mean ($\pm$ SD) of total knowledge scores (on a scale of 0–6) was 4.15 ($\pm$ 1.22), nearly half (49%) had a medium score of 3–4, another 41% had a high score of 5–6 and a small proportion (10%) of the pilgrims had a poor knowledge score of 1–2. Most pilgrims (416, 81.6%) believed that soap and water were very effective hand hygiene methods against RTIs, and many others (308, 60.4%) believed alcohol-based hand sanitiser was so effective.

The pilgrims' hand hygiene practices during the Hajj in the follow-up phase illustrated that 311 (70%) reported washing their hands with soap and water more than five times per day, whereas just over half of them (236, 53%) reported using alcohol-based hand sanitisers more than five times a day. Compared to those with a poor knowledge level about hand hygiene, pilgrims

Table 1 Pilgrims' socio-demographics, medical history and vaccination status (n = 510)

Characteristic	n (%)
Age (years)	
18–25	55 (10.8)
26–39	109 (21.3)
40–55	209 (41)
56–64	127 (24.9)
≥ 65	10 (2)
Gender	
Male: female	230: 280 (45:55)
Nationality	
Saudi Arabia	437 (85.7)
Egypt	28 (5.5)
Yemen	8 (1.6)
Tunis	4 (0.8)
Syria	4 (0.8)
Sudan	4 (0.8)
Others	25 (4.8)
Education	
No education	9 (1.8)
Primary/elementary school certificate	20 (3.9)
High school certificate	64 (12.5)
Diploma	27 (5.3)
Bachelor's certificate	276 (54.1)
Higher university degree	114 (22.4)
Occupation	
Unemployed	107 (21.0)
Student	31 (6.1)
Retired	94 (18.4)
Public sector worker	126 (24.7)
Private sector worker	120 (23.5)
Self-employed	32 (6.3)
Presence of chronic medical conditions	
Hypertension	66 (12.9)
Diabetes	46 (9.0)
Obesity	19 (3.7)
Chronic lung disease	19 (3.7)
Chronic heart disease	10 (2.0)
Smoking status	
Non-smoker	375 (73.5)
Current smoker	77 (15.1)
Past smoker	37 (7.3)
Passive smoker	21 (4.1)
Received influenza (flu) vaccine	
No	213 (41.8)
Yes	297 (58.2)
Received first dose of COVID-19 vaccine	
Oxford/AstraZeneca	98 (19.2)
Pfizer	410 (80.4)
Moderna	1 (0.2)

Table 1 (continued)

Characteristic	n (%)
Received second dose of COVID-19 vaccine	
Oxford/AstraZeneca	38 (7.5)
Pfizer	433 (84.8)
Moderna	1 (0.2)
Reported COVID-19 vaccine adverse reactions	
Pain/redness at injection site	149 (29.2)
Fatigue and headache	153 (30)
Muscle pain	123 (24.1)
Fever/chills	116 (22.7)
Difficulty in breathing	5 (1)
Nausea/vomiting	5 (1)
Diarrhoea	7 (1.4)

The denominator is the number of recruited pilgrims in the study irrespective of whether they completed the follow-up or not

with higher knowledge level had a higher frequency of washing hands using soap and water (77.3% [140/181] vs. 61.5% [24/39], $p = 0.02$). Most pilgrims cleaned their hands after toilet action (417, 93.7%) followed by hand washing before eating (405, 91%) and after eating (391, 88%) (Table 2).

The main reported motivators to comply with regular hand hygiene during Hajj were a strong belief that cleansing hands would protect from infections (281, 63.1%), and an awareness of the protective role of regular hand hygiene practice (326, 73.3%). In contrast, the barriers to compliance with hand hygiene were failure to remember or being too busy to clean their hands (80,

Table 2 Pilgrims' hand hygiene practices during Hajj (n = 445)

Hand hygiene practices	n (%)
Frequency of washing hands using soap and water	
Less frequently (≤ 5 times/day)	134 (30)
More frequently (> 5 times/day)	311 (70)
Frequency of using alcohol-based hand sanitisers	
Less frequently (≤ 5 times/day)	209 (47)
More frequently (> 5 times/day)	236 (53)
Practising hand hygiene at key actions	
Before eating	405 (91)
After eating	391 (88)
After toileting	417 (93.7)
When hands are visibly dirty	331 (74.4)
After nose-blowing, sneezing or coughing	254 (57.1)
After touching garbage	276 (62)
After shaking hands	236 (53)
After touching frequently used surfaces	352 (79.1)

The denominator is the number of pilgrims who completed the follow-up

18%) and avoiding scented or alcoholic hands cleaning products (48, 10.8%)

The incidence of RTIs was 4.7% (21 of 445) among pilgrims who self-reported developing one or more symptoms of RTIs during follow-up; of 21 symptomatic pilgrims, 16 (76.2%) had a sore throat, nine (42.8%) had cough, eight (38%) had rhinitis, four (19%) had smell or taste dysfunction, and three (14.2%) had dyspnoea (Table 3). The onset date of symptoms ranged from 23 to 31 July 2021 (i.e., from the last day to one week after the conclusion of Hajj rituals), and the duration was between one to seven (median of five) days. Only one-third of those cases (7 of 21) had visited a hospital or clinic to treat the symptoms. The estimated incidence of 'possible ILI' was 1.1% (5 of 445), and the incidence of 'possible COVID-19' infection was 0.9% (4 of 445)

Table 4 illustrates the relationship of potential factors with the incidence of RTIs among pilgrims using simple logistic regression analysis. The analyses showed that apart from obesity, no other socio-demographic characteristics were significantly associated with the risk of RTIs. Being obese significantly increased the increased risk of RTIs (OR 4.45, 95% CI 1.15–17.13, $p=0.03$). Neither washing hands using soap and water (OR 0.71, 95% CI 0.25–1.99) nor using alcohol-based hand sanitisers (OR 1.02, 95% CI 0.42–2.47) had a significant impact on reducing the risk of developing RTIs. Practising hand hygiene when hands are visibly dirty, after shaking hands, and after touching frequently used surfaces or objects were not significantly protective. Receipt of influenza vaccine tended to be protective against ILI although the difference was not statistically significant (OR 5.77, 95% CI 0.64–52.12, $p=0.07$).

Table 3 Reported clinical symptoms of RTIs among pilgrims (n = 21)

Reported symptoms	n (%)
Sore throat	16 (76.2)
Cough	9 (42.8)
Fatigue	9 (42.8)
Rhinitis	8 (38)
Subjective fever	7 (33.3)
Myalgia	5 (23.8)
Headache	4 (19)
Smell/taste dysfunction	4 (19)
Diarrhoea	4 (19)
Short of breath (Dyspnoea)	3 (14.2)

Discussion

This appears to be the first study that estimated the incidence of symptomatic RTIs among Hajj pilgrims amidst the ongoing global COVID-19 pandemic, which found that 4.7% of the total pilgrims who completed the study reported having one or more respiratory symptoms, and 'possible' ILI and COVID-19 cases were identified in 1.1% and 0.9% of pilgrims, respectively. Sore throat and cough were the most common clinical manifestations presented in this study, and this was similar to what other studies recorded among pilgrims from Australia [5, 8, 16], France [4, 17, 18], and Malaysia [19] who attended Hajj years prior to the pandemic. On the contrary, compared to what was found in our study, the previous studies documented relatively higher rates of ILI ranging from 10% among Australian pilgrims in 2015 [8] to 47.3% among French pilgrims in 2013 [18]. The estimated incidence of 'possible COVID-19' among Hajj pilgrims in the current study of 0.9% indicates religious MGs carry an important risk of pandemic despite the high vaccination rate. However, this rate was much lower when compared with the Saudi Arabian nationwide data. A serosurveillance study showed that the overall prevalence of COVID-19 among the Saudi population to be about 11% [20], and another study involving Saudi healthcare workers showed that 10% of them had the disease [21]. A high vaccination rate among pilgrims may have made the difference. During the influenza pandemic of 2009, a prospective survey of 551 vaccinated Egyptian pilgrims reported no influenza A(H1N1)pdm09 among returned travellers. Without vaccination, a much higher incidence would be expected [22]. Very large outbreaks of COVID-19 occurred in religious MGs where vaccination was not mandatory. During the Kumbh Mela (Hindu religious MG) in India in April 2021 a large super-spreader event accelerated waves of COVID-19 throughout India spread via unvaccinated pilgrims [23].

The Saudi Government's preparedness and response for controlling the COVID-19 outbreak at the recent two Hajj years undoubtedly played a crucial role in controlling the RTIs among pilgrims. For the Hajj 2021, only 60 thousand pre-selected Saudi Arabian residents were permitted to take part, while overseas pilgrims, those with chronic diseases, children (less than 18 years) or elderlies (above 65 years) were not allowed [9]. Besides, the Saudi health authority implemented a bundle of control measures that included pharmaceutical and non-pharmaceutical interventions, mass testing and triaging. In addition, pilgrims' adherence to preventative measures including maintaining physical distancing and wearing face masks, was monitored stringently [24].

Obesity was identified to be a significant risk factor in this study, and obese pilgrims had a more than four-fold

Table 4 Potential factors associated with RTIs among pilgrims (n = 21)

Variable	Number of cases (%)	OR (95% CI)	p-value
Age (years)			
18–25	1 (2.1)	Reference	0.37
26–39	8 (8.2)	4.18 (0.50–34.41)	
40–55	6 (3.4)	1.68 (0.19–14.29)	
56–64	5 (4.3)	2.13 (0.24–18.78)	
≥ 65	1 (10)	5.22 (0.29–91.37)	
Gender			
Male	10 (5)	Reference	0.80
Female	11 (4.5)	0.89 (0.37–2.15)	
Nationality			
Saudi	18 (4.7)	Reference	0.91
Non-Saudi	3 (5)	1.07 (0.30–3.76)	
Education level			
No education	0 (0)	0.00 (0.00–0.00)	0.82
Primary/elementary school certificate	0 (0)	0.00 (0.00–0.00)	
High school certificate	4 (7.4)	1.73 (0.55–5.43)	
Diploma	2 (8.7)	2.06 (0.44–9.62)	
University degree	15 (4.4)	Reference	
Chronic medical conditions			
Obesity	3 (16.7)	4.45 (1.15–17.13)	0.03
Smoking Status			
Non-smoker	18 (4.8)	Reference	0.91
Current smoker	3 (4.5)	0.94 (0.26–3.27)	
Using soap and water			
Less frequently (≤ 5 times/day)	5 (3.7)	0.71 (0.25–1.99)	0.52
More frequently (> 5 times/day)	16 (5.1)	Reference	
Using Alcohol-based hand sanitisers			
Less frequently (≤ 5 times/day)	10 (4.8)	1.02 (0.42–2.47)	0.95
More frequently (> 5 times/day)	11 (4.7)	Reference	
Hand hygiene practices in key occasions*			
Before eating	18 (4.4)	2.45 (0.56–10.63)	0.23
After eating	18 (4.6)	1.48 (0.34–6.33)	0.59
After toileting	21 (5)	0.00 (0.00–0.00)	0.99
When hands are visibly dirty	17 (5.1)	0.52 (0.14–1.95)	0.33
After nose-blowing, sneezing or coughing	11 (4.3)	1.42 (0.42–4.81)	0.57
After touching garbage	12 (4.3)	1.58 (0.45–5.53)	0.47
After shaking hands	12 (5.1)	0.61 (0.20–1.90)	0.40
After touching frequently used surfaces	17 (4.8)	0.86 (0.25–2.95)	0.81

Significant results are highlighted in bold *Practising hand hygiene in key occasions set as a comparison reference

increased risk of RTIs. Review studies that explored the relationship between obesity and viral RTIs concluded that obesity raises the risk of contracting and having severe complications from ILI and COVID-19 [25–27]. Another study that investigated the correlation between the prevalence of obesity and COVID-19 infection rate in 54 countries detected that the residents of Saudi Arabia have the highest prevalence of obesity of 35% and it was significantly associated with the susceptibility to

COVID-19 [28]. Furthermore, the increased body mass index (BMI) was observed to have a strong association with hospital admission among patients with COVID-19 infection [29, 30].

Nearly half of the pilgrims in this cohort achieved a moderate level of hand hygiene knowledge, and the mean score on a scale of 0 to 6 was 4.15 (± 1.22). Although the awareness level was expected to improve significantly in this study compared to previous years as

a result of the intensive public health campaigns about COVID-19, similar moderate levels of awareness were observed in our formerly conducted surveys involving domestic Hajj pilgrims in 2019 and visitors to the Prophet's Mosque in 2020, the average scores in a scale of 0 to 12 were 6.7 and 6.4, respectively [7, 13]. More pilgrims in the current study agreed that hand hygiene methods are essential for protection against viral RTIs in comparison to the visitors to the Prophet's Mosque in 2020: 81.6% of pilgrims believed that the use of soap and water was a very effective method to ward off RTIs while 60.4% pilgrims believed alcohol-based hand sanitiser was effective, these compare with respectively 48.8% and 56% visitors to the Prophet's Mosque believing the effectiveness of the measures [13]. This may indicate that more pilgrims have now become aware of the importance of hand hygiene possibly an effect of the widespread health education campaigns against COVID-19.

In line with the finding of this study, Alqahtani et al. [8, 31] revealed that a strong belief in the effectiveness of hand hygiene in infection prevention was among the main reasons influencing pilgrims' decision to use hand hygiene regularly during Hajj. Conversely, obstacles to adherence to hand hygiene during Hajj were also identified in the study, primarily were failure to remember or being too busy and avoiding scented and alcoholic hygienic products. This was an expected result since pilgrims spend a significant amount of time performing rituals and moving between sites during the pilgrimage. Furthermore, according to the rules of 'Ihram', scented toiletries including scented soaps, perfumes, or deodorant on pilgrim's body or clothing are avoided. The religious and cultural preference of Muslims to avoid products that contain alcohol when alternatives are available may further explain the low compliance of using alcohol-based hand sanitiser among Hajj pilgrims [27]. Unlike the reported barrier in our 2019 Hajj study [7], the unavailability of soap and hand sanitisers was not a major hindrance for pilgrims who attended this Hajj to clean their hands, and this was possibly due to the distribution of a large volume of hygienic products at every Hajj sites.

Our results demonstrated that pilgrims who scored higher knowledge of hand hygiene were more likely to wash their hands more frequently using soap and water during Hajj rituals; however, previous studies have not reported a similar correlation between knowledge and practice of hand hygiene among Hajj pilgrims. It has been evident that delivering pre-Hajj health education is an effective method to improve pilgrims' practices of hand hygiene during the Hajj journey and therefore health promotion and education on hand hygiene should be sustained for Hajj pilgrims [31].

There is still a paucity of data on the effectiveness of hand hygiene practices in preventing RTIs during this Islamic pilgrimage. In this observational study, hand hygiene was not found to be significantly effective against viral RTIs, as was found in a few previous studies involving Hajj pilgrims [9]. In contrast, other studies conducted among US pilgrims in 2009 and Malaysia pilgrims in 2013 confirmed that good hand hygiene was significantly associated with a decreased risk of RTIs [14, 32]. Using a compulsory set of pharmaceutical and non-pharmaceutical interventions during this Hajj may have confounded the real effect of hand hygiene in this study. A randomised controlled trial (RCT) is needed to quantify the role of hand hygiene against RTIs.

This study has added valuable evidence that may be useful for future studies to build, especially the provision of syndromic data for the surveillance of RTIs in the context of a pandemic at such MGs. However, undertaking this study amidst such extraordinary conditions was fraught with some challenges and limitations. We were compelled to investigate only domestic pilgrims from selected Hamlahs which may have restricted the generalisability of the results outside the domain of the defined time and population. Furthermore, we were unable to collect biological samples for virological confirmations due to administrative restrictions and therefore the cases of influenza and COVID-19 were considered possible rather than confirmed. The design of the study was anecdotal in nature; thus, some data could have been at risk of information and recall bias. Other measures in the bundle of infection control such as use of face mask, other personal protective equipment (PPE) and cough etiquette were not explored in this study for the following reasons: first, face mask has been extensively studied at Hajj including through a large RCT [33]; second, facemask use was made compulsory during the Hajj 2021, a penalty was applied for non-compliance; third, it was deemed unlikely pilgrims would use other PPEs (gowns, gloves and eye shields) as they avoid using certain garbs in the state of 'Ihram'; fourth, cough etiquette is a multi-component prevention strategy having three or more elements in it of which this study already covers one component (hand hygiene practice after coughing, nose-blowing and sneezing). Future studies should explore all components of cough etiquette and possibly also explore PPE use.

Conclusions

The incidence of syndromic viral RTIs among Hajj pilgrims during the COVID-19 pandemic was low. Stringent preventive measures against COVID-19 may have contributed to reduced incidence. Even though the findings of this study did not show a substantial improvement in hand hygiene knowledge among the pilgrims, a higher

level of knowledge did improve hand hygiene practice. Our results could not confirm the protective role of hand hygiene against RTIs during Hajj, it is strongly advised to continue to use hand hygiene and health measures to prevent RTIs at MGs, particularly in the context of a pandemic with a highly transmissible variant like Omicron strain of SARS-CoV-2. An RCT study to explore the effect of hand hygiene against RTIs at Hajj is a call of the time.

Abbreviations

RTI: Respiratory-tract infection; ILI: Influenza-like illness; MG: Mass gathering; COVID-19: Coronavirus disease-19.

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Author contributions

HAM, HR, MA, OB and FSQ contributed to the concept and design of the study. HAM, MA, FSQ, SHH, and OB contributed to the acquisition of data, analysis, and interpretation of data. HAM, HR, and MA drafted the manuscript. RB, FSQ, SHH, OAM, OB, AA, ASA and RZS substantively revised the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to containing information that could compromise participants' privacy but are available from the corresponding author HR on reasonable request.

Declarations

Ethics approval and consent to participate

All methods were conducted in accordance with the Declaration of Helsinki. It was approved by the biomedical ethics committee, Umm Al-Qura University, Makkah, Saudi Arabia (Approval number: HAPO-02-K-012-2021-07-708). Informed consent was obtained from all subjects.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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CHAPTER 4 (*continued*)

In the previous study (Publication #4), I considered the need for a post-Hajj survey to report the rate of symptomatic RTIs among returning pilgrims during the COVID-19 pandemic. Previous laboratory-based surveillance studies revealed that returning pilgrims from Hajj with RTI symptoms had a viral aetiology.^{20, 27, 92} Therefore, the aim of the following study (Publication #5) in this chapter was to estimate the prevalence of symptomatic viral RTIs among domestic Hajj pilgrims who returned home after the pilgrimage in 2021 and also to assess the risk of RTIs among pilgrims' contacts.

The study participants were interviewed two weeks after returning to their homes to collect data on the onset of RTI symptoms at any time between the conclusion of Hajj rituals and the day of recruitment. The survey identified a low prevalence of symptomatic RTIs among returning pilgrims, and only a small proportion of them met the syndromic criteria for influenza-like illness (ILI) or COVID-19. Nonetheless, the risk of disseminating RTIs among contacts following this Islamic pilgrimage is still a concern, as a significant proportion (45.5%) of symptomatic pilgrims reported that their close contacts had developed similar symptoms.

Publication #5: Mahdi HA, Qashqari FS, Hariri SH, Bamerdah S, Altayyar SA, Almalki HM, et al. Low Prevalence of Syndromic Respiratory Tract Infections among Returning Hajj Pilgrims Amidst the COVID-19 Pandemic: A Post-Hajj Survey. *Trop Med Infect Dis.* 2022;7(8):182. <https://doi.org/10.3390/tropicalmed7080182>.



Article

Low Prevalence of Syndromic Respiratory Tract Infections among Returning Hajj Pilgrims Amidst the COVID-19 Pandemic: A Post-Hajj Survey

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Abstract: This study estimates the point prevalence of symptomatic respiratory tract infections (RTIs) among returned Hajj pilgrims and their contacts in 2021. Using the computer-assisted telephone interview (CATI) technique, domestic pilgrims were invited to participate in this cross-sectional survey two weeks after their home return from Hajj. Of 600 pilgrims approached, 79.3% agreed to participate and completed the survey. Syndromic definitions were used to clinically diagnose possible influenza-like illnesses (ILI) and COVID-19. Median with range was applied to summarise the continuous data, and frequencies and proportions were used to present the categorical variables. Simple logistic regression was carried out to assess the correlations of potential factors with the prevalence of RTIs. The majority of pilgrims (88.7%) reported receiving at least two doses of the COVID-19 vaccine before Hajj. Eleven (2.3%) pilgrims reported respiratory symptoms with the estimated prevalence of possible ILI being 0.2%, and of possible COVID-19 being 0.4%. Among those who were symptomatic, five (45.5%) reported that one or more of their close contacts had developed similar RTI symptoms after the pilgrims' home return. The prevalence of RTIs among pilgrims who returned home after attending the Hajj 2021 was lower compared with those reported in the pre-pandemic studies; however, the risk of spread of infection among contacts following Hajj is still a concern.

Keywords: COVID-19; Hajj; influenza-like illnesses; pilgrims; respiratory tract infections

1. Introduction

The Hajj pilgrimage is an annual religious mass gathering (MG) event in Makkah city, Kingdom of Saudi Arabia (KSA). During a pre-pandemic year, up to 3 million Muslims spent extended time at multiple sites in Makkah to perform various religious rituals [1]. This Hajj MG is associated with a high burden of infectious diseases, with respiratory tract

infections (RTIs) being the most prevalent infections reported among the pilgrims [2,3]. The prevalence of influenza-like illnesses (ILI) among Hajj pilgrims ranges from 8% to 63% depending on the nationality of pilgrims, the study year and how ILI is defined [4,5].

Several respiratory viruses have emerged over the last several years such as Middle East respiratory syndrome coronavirus (MERS-CoV), which posed a great public health threat to the Hajj pilgrimage; nevertheless, no major outbreaks have been documented to date [6]. For instance, studies revealed no detection of MERS-CoV infection in any samples tested for viral RTIs obtained from 81 returning pilgrims from Bangladesh and 202 from the UK who presented with symptoms of respiratory illness [7,8]. Most recently, COVID-19 has been a major public health and infection control challenge at Hajj [9]. In order to attend the 2021 Hajj amidst the pandemic, definite eligibility criteria were set for residents of all nationalities inside KSA who were aged between 18 and 65 years, and only residents immunised against COVID-19 were permitted [10,11]. Furthermore, various non-pharmaceutical control measures were put in place during the pilgrims' entire Hajj journey to limit the spread of SARS-CoV-2, including obligatory face mask use, advice on practising frequent hand hygiene, providing required hygienic products to pilgrims and maintaining physical distance [10,11].

Hajj and other MGs not only amplify the risk of infections among participants but also accelerate the transmission of these infections among their close contacts, making MGs a significant risk to global health security [6,12]. Only a limited number of studies assessed the prevalence of RTIs among pilgrims after their home return. Among returning UK pilgrims with ILI in 2005, 11% tested positive for a virus on RT-PCR, 9% for respiratory syncytial virus (RSV) type A and 2% for influenza A/H3 [13], while a 2009 survey among 1507 domestic pilgrims from Riyadh, KSA, showed that 97% of pilgrims reported RTI symptoms on their return from Hajj [14].

Data are scarce on the post-Hajj prevalence of RTIs, and to the best of our knowledge, no study has assessed the prevalence of symptomatic RTIs among pilgrims during Hajj amidst the COVID-19 pandemic. A study conducted by our team during the peak period of Hajj in 2021 demonstrates the need for a post-Hajj surveillance study [15]. To this end, this manuscript aims to report the point prevalence of syndromic RTIs among domestic Hajj pilgrims who returned home after the pilgrimage in 2021 and assesses the risk of RTIs among pilgrims' contacts.

2. Materials and Methods

A cross-sectional study was conducted among returning domestic pilgrims (i.e., current residents of KSA) who attended Hajj (18–23 July) in the year 2021. Pilgrims of both genders aged 18 years or above were eligible to participate in the survey, while those who declined to participate or did not speak Arabic or English were excluded. Ethics approval was obtained from the Biomedical Ethics Committee of Umm Al-Qura University, Makkah, KSA (reference number: HAPO-02-K-012-2021-07-708), and all participants provided voluntary informed consent.

The survey was conducted using computer-assisted telephone interviews (CATI). A convenience sample of 600 pilgrims was contacted by phone from a list provided by Hajj hamlaqs (companies that specialise in Hajj services and tourism) two weeks after their return from Hajj. Pilgrims who responded to the calls were interviewed using a structured questionnaire, and their responses were recorded in Microsoft Forms, an electronic survey development cloud-based software (Microsoft Office 365, version 2002, Redmond, WA, USA). The questionnaire consisted of two major parts: part one captured data about participants' non-identifiable socio-demographics including the presence of pre-existing comorbidities, smoking status, and receipts of influenza and COVID-19 vaccinations, while part two focused on collecting information related to the occurrence of respiratory symptoms and some constitutional or gastrointestinal symptoms. In addition, pilgrims who developed symptoms were asked about the onset date and duration of these symptoms, their history of contact with room-/tent-mates suffering from RTIs during Hajj and whether any of

their close contacts at home or work who were not pilgrims developed similar symptoms following any pilgrims' home return.

A case of RTI was clinically defined as any pilgrim who reported having at least one respiratory symptom, including cough, sore throat, rhinitis, dyspnoea or smell or taste dysfunction at any time between the conclusion of Hajj rituals and the day of recruitment (i.e., within two weeks of pilgrims' return to their home cities). The syndromic definitions for possible ILI and possible COVID-19 were applied according to criteria described and assessed elsewhere [16,17]. We used the ILI definition described by Rashid et al. as 'a triad of subjective fever, cough, and sore throat' [16]. The triad has sensitivity and specificity of, respectively, 67% and 64% against influenza confirmed by reverse transcriptase-polymerase chain reaction. For identifying possible COVID-19, we used a definition by Fulvio et al.: 'concomitant presence of three or more of the following symptoms: fever, myalgia, cough, and smell or taste dysfunction' [17]. This constellation of symptoms is highly likely to be associated with a positive molecular diagnosis of COVID-19 (odds ratio [OR] = 18.55; 95% confidence interval [CI]: 13.77–24.97) and has a specificity of 91.2%. Since the study was conducted after the pilgrims' home return, collecting samples for laboratory testing could not be attempted.

The recorded data were analysed using Statistical Package for Social Sciences (SPSS) (IBM SPSS Statistics for Windows, version 26.0, IBM Corp, Armonk, NY, USA). For the descriptive analysis, the median with range was applied to summarise the continuous data, whereas frequencies and proportions were used to present the categorical variables as well as the prevalence of RTIs and possible ILI and possible COVID-19. The correlation of potential factors with the estimated prevalence of RTIs was carried out using simple logistic regression. The potential factors were chosen by reviewing the literature on respiratory infections and COVID-19 in Hajj and community settings [18,19]. The risk estimation was analysed using OR, and 95% CI and a *p*-value less than 0.05 was considered statistically significant.

3. Results

A total of 600 pilgrims were invited to participate, of whom 476 (79.3%) agreed to participate and completed the survey. The median age of the pilgrims was 50 (range 18–70) years (Table 1). About one quarter (25.4%) of pilgrims reported having one or more pre-existing medical conditions, and 422 (88.7%) received both doses of COVID-19 vaccine before commencing the Hajj journey (Table 2).

Eleven pilgrims (2.3%) reported developing one or more RTI symptoms two weeks after Hajj; of those, nine (81.8%) had rhinitis, six (54.5%) had a cough, five (45.5%) had a sore throat and two (18.2%) had dyspnoea with smell or taste dysfunction. Table 3 shows the breakdown of the individual and combinations of symptoms reported by pilgrims with RTIs. Of the symptomatic pilgrims, four (36.4%) sought treatment from a hospital or health clinic, three (27.3%) had come in contact with room-/tent-mates who developed RTIs during Hajj and five (45.5%) seem to have transmitted the infection to their household/workplace contacts after coming back from Hajj. The median duration of the symptoms was four (range 1–21) days, and their onset dates extended from the 23rd of July to the 1st of August 2021, i.e., from the last day to nine days after the consummation of Hajj rituals.

Only one participant met the definition of possible ILI, which translates to an estimated prevalence of 0.2%, and two met the definition of possible COVID-19, translating to an estimated prevalence of 0.4%; both of them were fully vaccinated and had no known history of COVID-19. In a simple logistic regression analysis, as illustrated in Table 4, there was no significant association between the prevalence of RTIs among pilgrims and the potential factors including age, gender, pre-existing medical conditions, education, smoking status, and receipts of influenza and COVID-19 vaccines (all *p* > 0.05).

Table 1. Participants' socio-demographic characteristics (n = 476).

Characteristics	n (%)
Age (years)	
18–25	35 (7.4)
26–39	118 (24.8)
40–55	203 (42.7)
56–64	111 (23.4)
≥65	8 (1.7)
Gender	
Male:Female	257:219 (54:46)
Nationality	
Saudi Arabia	337 (70.8)
Egypt	29 (6.1)
Pakistan	27 (5.7)
India	21 (4.4)
Algeria	10 (2.1)
Others	52 (10.9)
Education	
No education	32 (6.7)
Primary/elementary school certificate	51 (10.7)
High school certificate	83 (17.4)
Diploma	33 (6.9)
Bachelor's degree	206 (43.3)
Higher university degree	71 (14.9)

Table 2. Participants' medical history and vaccination status (n = 476).

Variable	n (%)
Presence of pre-existing comorbidities	
Diabetes	67 (14.1)
Hypertension	62 (13)
Chronic lung diseases	11 (2.3)
Chronic heart diseases	6 (1.3)
Obesity	4 (0.8)
Others	6 (1.3)
Smoking status	
Non-smoker	359 (81.2)
Current smoker	46 (10.4)
Past smoker	29 (6.6)
Passive smoker	8 (1.8)
Influenza vaccine	
No	244 (51.3)
Yes	232 (48.7)
COVID-19 vaccine, dose 1	
No	7 (1.5)
Yes	469 (98.5)
COVID-19 vaccine, dose 2	
No	54 (11.3)
Yes	422 (88.7)

Table 3. Reported symptoms of respiratory tract infections among participants (n = 11).

Individual Symptoms	n (%)
Rhinitis	9 (81.8)
Fatigue	9 (81.8)
Cough	6 (54.5)
Sore throat	5 (45.5)
Subjective fever	4 (36.4)
Headache	4 (36.4)
Smell/taste dysfunction	2 (18.2)
Short of breath (dyspnoea)	2 (18.2)
Myalgia	2 (18.2)
Vomiting	1 (9.1)
Combination of Symptoms	n (%)
Subjective fever, and cough	1 (9.1)
Subjective fever, cough, sore throat, rhinitis, dyspnoea, smell/taste dysfunction, myalgia, fatigue, headache, and vomiting	1 (9.1)
Subjective fever, cough, dyspnoea, smell/taste dysfunction, myalgia, and fatigue	1 (9.1)
Subjective fever, cough, rhinitis, and fatigue	1 (9.1)
Cough, rhinitis, fatigue, and headache	2 (18.2)
Sore throat, rhinitis, and fatigue	2 (18.2)
Sore throat, rhinitis, and headache	1 (9.1)
Sore throat, rhinitis, fatigue, and headache	1 (9.1)
Rhinitis and fatigue	1 (9.1)

Table 4. Associations of potential factors with respiratory tract infections among participants (n = 11).

Variable	n (%)	OR (95% CI)	p-Value
Age (years)			
18–25	2 (5.7)	Reference	0.3
26–39	5 (4.2)	0.7 (0.01–3.9)	
40–55	2 (1)	0.2 (0.02–1.2)	
56–64	2 (1.8)	0.3 (0.04–2.2)	
≥65	0 (0)	0.0 (0.0–0.0)	
Gender			
Male	9 (1.9)	Reference	0.3
Female	6 (2.7)	1.4 (0.4–4.7)	
Education			
No education	1 (3.1)	1.1 (0.1–9)	0.4
Primary/elementary school certificate	0 (0)	0.0 (0.0–0.0)	
High school certificate	1 (1.2)	0.4 (0.1–3.3)	
Diploma	1 (3)	1.0 (0.1–8.7)	
University degree or higher	8 (2.9)	Reference	
Pre-existing medical conditions			
No	7 (2)	Reference	0.4
Yes	4 (3.3)	1.7 (0.5–5.9)	
Smoking status			
Non-smoker	9 (2.3)	Reference	0.4
Current smoker	2 (4.3)	1.9 (0.4–9.3)	
Influenza vaccine			
No	3 (1.2)	Reference	0.1
Yes	8 (3.4)	2.8 (0.7–10.9)	
COVID-19 vaccine			
No	1 (1.9)	Reference	0.8
Yes	10 (2.4)	1.3 (0.2–10.2)	

4. Discussion

This study estimated the post-Hajj prevalence of symptomatic RTIs among pilgrims who attended the 2021 Hajj in the midst of the ongoing COVID-19 pandemic. The current study identified a low prevalence of possible ILI and possible COVID-19 among pilgrims. Rhinitis, cough and sore throat were the commonest clinical respiratory symptoms presented in our survey, and this was similar to what previous studies documented among Hajj pilgrims [4,5,20]. However, a cohort study during the same Hajj year showed greater prevalence rates of syndromic RTIs: 4.7% of the cohorts experienced RTI symptoms, and, respectively, 1.1% and 0.9% were suspected of having ILI and COVID-19. These lower rates were observed in this survey despite fewer pilgrims having university-level or higher education than those in the previous study (58.2% vs. 76.5%), and fewer were vaccinated against influenza (48.7% vs. 58.2%) and COVID-19 (88.7% vs. 92.5%) [15]. In contrast, previous studies found that the level of education was associated with higher compliance with preventive measures [21–23]. This discrepancy may have stemmed from recall bias in the current study, where the follow-up with pilgrims took place two weeks after Hajj, in contrast to the cohort study that was conducted in real-time during Hajj.

Almost half of the symptomatic pilgrims in this survey reported that one or more of their close contacts had developed similar RTI symptoms, which represents a high risk of contact transmission following Hajj. Previous studies that employed molecular diagnosis also showed the role of contact in the propagation of respiratory viral infection among Hajj pilgrims. For instance, a cross-sectional study involving UK pilgrims conducted in 2005 showed that 58% of pilgrims had a history of contact with ill pilgrims, and the frequency of influenza diagnosis was 17% among those who reported contact with URTI compared with 9% who reported no contact [24]. In a comparative study conducted the next year (in 2006), 7% of domestic Saudi pilgrims reported contact with an individual suffering from ILI, one of whom had laboratory-proven influenza, while 19% of UK pilgrims reported contact with individuals with ILI, of whom three had laboratory-proven influenza and two others had rhinovirus infection [25].

A significant proportion of pilgrims carry respiratory viruses and remain symptomatic upon their arrival to their home countries from Hajj, as was evidenced in several laboratory-based surveillance studies. In 2013, a study conducted among returning Hajj pilgrims at Kotoka International Airport in Ghana concluded that of all participants, 651 (77.6%) had respiratory symptoms, and 179 (21.3%) tested positive for one or more respiratory viruses [26]. In another surveillance conducted over two years (2014 and 2015) among returning Indian Hajj and Umrah pilgrims at Srinagar International Airport, Jammu and Kashmir, 300 pilgrims suffered from RTI, and 97 (32.3%) nasopharyngeal swabs were positive for a virus, most commonly influenza [27]. After Hajj 2006, a total of 255 pilgrims from Iran at Shiraz Airport experienced symptoms of RTI, with cough (83.5%) and sore throat (82%) being the commonest symptoms, and 83 (32.5%) had laboratory-proven viral infections [28].

The overall prevalence of RTIs among pilgrims in this Hajj season was markedly lower in comparison with the data reported in the pre-pandemic studies. For instance, a longitudinal survey conducted among domestic pilgrims from Riyadh city (capital of KSA) in 2010 showed that 53% developed RTIs [14]; similarly, ILI was recorded in 30% of Egyptian pilgrims in a survey from 2012 to 2015 [29], in 47.3% of French pilgrims in 2013 [30] and in 10% of Australian pilgrims in 2015 [18]. The previous studies were conducted prior to the pandemic, when up to 3.5 million pilgrims gathered to perform Hajj in inevitably overcrowded condition, with minimal physical distancing, and this may have in turn accelerated the transmission of RTIs [14,18,29,30]. Furthermore, the attendees of the recent Hajj seasons during the global pandemic may have become more aware of the important role of the non-pharmaceutical control measures against infections as a result of the intensive awareness-raising COVID-19 campaigns, although the pilgrims' knowledge and practices of these interventions were not measured in this current survey.

The extent of COVID-19 related to the Hajj setting presented in our study was much lower than the KSA national data. A nationwide seroprevalence cross-sectional study estimated an overall prevalence of COVID-19 of 11% in KSA [31]. The stringent measures applied during Hajj including the disallowance of pilgrims aged ≥ 65 years may have contributed to the observed difference. In contrast, other down-scaled MGs (e.g., Tokyo Olympics 2020, Beijing Winter Olympics 2022) conducted using strict closed-loop and bubble systems in addition to COVID-19 vaccinations resulted only a sizeable outbreak but with no local transmission (Beijing Olympics), while during the Tokyo Olympics there was a high rate of local transmission [32,33]. Therefore, the success stories of the Hajj 2021 and the Beijing Winter Olympics 2022 imply that MGs can still be conducted amidst pandemics if carefully planned and managed with the implementation of stringent public health measures. This year (2022), a larger number of international and domestic pilgrims, roughly one million, performed Hajj safely without recording any outbreak of infectious diseases of global significance including COVID-19 and monkeypox [34].

The strength of this study is that to the best of our knowledge it is the only study that surveyed the health of pilgrims after Hajj amidst the COVID-19 pandemic. This study also has some limitations. It was conducted during an exceptional Hajj season when no overseas pilgrims were allowed unless they were already resident in KSA and pilgrims had to be healthy with no pre-existing diseases; therefore, the generalisability of the results is limited. Since we used the CATI method to collect data from participants, we ensured that we would not have missing data. However, some of the non-sensitive variables such as smoking status have a few missing data which are treated by available case analysis. Given that the study was conducted during COVID-19, the primary focus of this manuscript was on viral infection, but bacterial infection is also a possibility. A study conducted over 4 years (2014–2017) involving 485 French pilgrims showed that 33% of pilgrims acquired at least 1 respiratory virus, and 35% acquired at least 1 respiratory bacterium, suggesting that bacterial infections too are important [4]. Another limitation is that we used a standard definition of COVID-19 which may not capture atypical presentations of novel COVID-19 variants. Additionally, because this was a self-reported study, the participants' responses may have been subjected to information bias. It is difficult to eliminate recall bias fully, but it could be minimised by a more careful selection of research questionnaires, giving intensive training to data collectors and allowing adequate time for participants to recall long-term memory. With the aim of further reducing recall bias, the duration of contact with roommates was not assessed. Since one fourth of SARS-CoV-2 infections remain asymptomatic [35], syndromic surveillance will miss a significant proportion of infections and thus will have limited value in controlling spread unless supplemented by a sensitive and specific diagnostic test. Finally, this was a syndromic survey, and the findings were not verified by microbiological tests. Large multinational follow-up studies are recommended for clinic-based syndromic surveillance, in conjunction with laboratory-based surveillance.

5. Conclusions

The results of this survey indicate that although the 2021 Hajj was conducted during COVID-19 challenges, the prevalence of symptomatic RTIs among the returning Hajj pilgrims was low, and only a small fraction of pilgrims met the syndromic definitions of ILI or COVID-19. Therefore, the COVID-19-related public health countermeasures during the Hajj seem to be a success story for conducting future MGs amidst pandemics, and adopting such changes can play an essential role in mitigating the transmission of COVID-19 and other RTIs as well as ensuring the safety and wellness of participants.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The datasets generated and/or analysed during the current study are not publicly available due to containing information that could compromise participants' privacy but are available from the corresponding author (HAM) on reasonable request.

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CHAPTER 5: Feasibility of establishing a large trial among pilgrims amidst a pandemic to explore the relationship between practising hand hygiene and rates of respiratory tract infections

One of the main purposes of this research work was to investigate the role of HH in the prevention of symptomatic viral RTIs, including COVID-19, in religious MG contexts in KSA. Only limited observational studies have reported that the effectiveness of HH interventions against RTIs during the Hajj pilgrimage has been either conflicting or inconclusive.⁸⁰ In fact, no interventional study was implemented among Hajj or Umrah pilgrims to examine the role of HH in preventing RTIs, specifically during a global pandemic like COVID-19. In light of this, the main objective of this chapter was to estimate the relationship between practising HH and rates of RTI among Umrah pilgrims amidst the COVID-19 pandemic, in addition to assessing the feasibility of establishing a full-scale RCT under such circumstances.

Between April and July of 2021, I completed a parallel RCT (Publication #6) among domestic Umrah pilgrims who were randomly assigned to either the intervention group, who received ABHR and instructions, or the control group, who did not receive ABHR. Seven days later, pilgrims in both groups were followed to record the occurrence of any RTI symptoms. The primary outcome of this pilot RCT suggested that implementing a future large-scale trial in MGs, including Umrah, during a pandemic is feasible, but such a study would need to be extremely large given the low rates of outcomes found here. Several factors may have confounded the protective effect of HH in this trial, including the inadequate sample size as it was designed as a feasibility trial, the study design's dependence on symptomatology which may have overlooked asymptomatic cases, the obligatory application of a bundle of COVID-19 interventions during Umrah including facemask use, maintaining physical distancing and other measures in addition to HH, and the

seasonal variability of influenza activity, alongside other confounding unknown factors.^{60, 80}

Although the preventive effect cannot be demonstrated from this pilot trial, simple HH should still be recommended for Hajj and Umrah pilgrims as it may have other benefits and complements Muslims' practice of routine handwashing five times a day before prayers.

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The relationship between hand hygiene and rates of acute respiratory infections among Umrah pilgrims: A pilot randomised controlled trial

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ABSTRACT

Background: There is a lack of randomised controlled trials (RCTs) investigating the role of hand hygiene in preventing and containing acute respiratory infections (ARIs) in mass gatherings. In this pilot RCT, we assessed the feasibility of establishing a large-scale trial to explore the relationship between practising hand hygiene and rates of ARI in Umrah pilgrimage amidst the COVID-19 pandemic.

Methods: A parallel RCT was conducted in hotels in Makkah, Saudi Arabia, between April and July 2021. Domestic adult pilgrims who consented to participate were randomised 1:1 to the intervention group who received alcohol-based hand rub (ABHR) and instructions, or to the control group who did not receive ABHR or instructions but were free to use their own supplies. Pilgrims in both groups were then followed up for seven days for ARI symptoms. The primary outcome was the difference in the proportions of syndromic ARIs among pilgrims between the randomised groups.

Results: A total of 507 (control: intervention = 267: 240) participants aged between 18 and 75 (median 34) years were randomised; 61 participants were lost to follow-up or withdrew leaving 446 participants (control: intervention = 237:209) for the primary outcome analysis; of whom 10 (2.2 %) had developed at least one respiratory symptom, three (0.7 %) had 'possible ILI' and two (0.4 %) had 'possible COVID-19'. The analysis of the primary outcome found no evidence of difference in the proportions of ARIs between the randomised groups (odds ratio 1.1 [0.3–4.0] for intervention relative to control).

Conclusion: This pilot trial suggests that conducting a future definitive RCT to assess the role of hand

Abbreviations: ABHR, Alcohol-based Hand Rub; ARI, Acute Respiratory Infection; COVID-19, Coronavirus Disease-19; HH, Hand Hygiene; ILI, Influenza-Like Illness; KSA, Kingdom of Saudi Arabia; MG, Mass Gathering; RCT, Randomised Controlled Trial; RT-PCR, Real-Time reverse Transcriptase-Polymerase Chain Reaction

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hygiene in the prevention of ARIs is feasible in Umrah setting amidst such a pandemic; however, outcomes from this trial are inconclusive, and such a study would need to be very large given the low rates of outcomes observed here.

Trial registration: This trial was registered in the Australian New Zealand Clinical Trials Registry (ANZCTR) (ACTRN12622001287729), the full protocol can be accessed there.

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Introduction

Acute respiratory infections (ARIs) are a major public health burden, causing serious morbidity and mortality, especially in vulnerable populations such as travellers. The burden of ARI is very high in the Eastern Mediterranean Region, a region that hosts many of the planet's mass gatherings (MGs). For instance, the incidence of ARI in Pakistan in 2003 was 4403 per 10,000 person-years, and among Omani children under 5 years of age in 2013 was 11,200 per 10,000 person-years, while the prevalence of community-acquired pneumonia among hospitalised patients in the Kingdom of Saudi Arabia (KSA) in 2013 was 30.3 % [1]. Currently, the coronavirus disease of 2019 (COVID-19) pandemic has affected over 600 million people with about 6.5 million fatalities (as of 10 October 2022) [2]. Ever-increasing and faster international travel intensifies the transmission of ARIs, especially in MG settings [3–5].

Saudi Arabia hosts Hajj and Umrah pilgrimages where over 10 million pilgrims travel from around the world every year [6]. Unlike Hajj, which is performed at a specific time of the year within and outside Makkah proper, the rituals of Umrah (the minor pilgrimage) take place in Makkah city and can be performed at any time of the year. The Umrah pilgrims stay in Makkah for a few days to weeks, many also visit the Prophet's Mosque in Madinah [7]. Umrah pilgrimage during the fasting month of Ramadan is very crowded, and outbreaks of airborne infections including ARIs have been reported [8–10]. Only a limited number of local pilgrims who were vaccinated against COVID-19 were allowed to take part in the 2021 Umrah pilgrimage under stringent monitoring of adherence to infection prevention and control measures [11].

Non-pharmacological interventions such as hand hygiene (HH) have been used to complement pharmacological measures such as vaccinations against influenza, and now also against COVID-19, and antiviral use in the prevention and control of viral ARIs [12]. Systematic reviews of observational studies and randomised controlled trials (RCTs) in community and/or healthcare settings have demonstrated the role of HH in reducing the burden of viral ARIs [13–15]. However, the studies were mostly conducted in developed world settings, had some risks of bias and originated from non-MG settings.

Few studies have evaluated the practices and effectiveness of HH interventions among Hajj and Umrah pilgrims. A focused systematic review showed that of 12 observational studies that assessed the practice of HH among Hajj pilgrims, the compliance rate of handwashing with soap and water ranged between 32 % and 90 % (pooled estimate of 69 %), while the uptake of alcohol-based hand rub (ABHR) ranged between 31 % and 77 % (pooled estimate 51 %) [16]. A survey administered by our team during the 2019 Hajj found that while pilgrims have good knowledge and practice of HH, only a minority used recommended HH products and most preferred to use soap and water; overall HH to prevent contact transmission of ARIs was underutilised [17]. The findings of a survey among 225 Malaysian Umrah pilgrims in 2018 demonstrated that more than half of the participants practised HH measures, including cleaning hands after handshaking, touching doorknobs, sneezing, or coughing [18]. A recent syndromic surveillance conducted by our team during the

2021 Hajj amid the COVID-19 pandemic showed that about 70 % of pilgrims washed their hands using soap and water more than five times a day during Hajj, while just over half used ABHR more than five times a day [19].

The effectiveness of HH against ARIs was described in a limited number of studies among Hajj pilgrims. The endpoints employed to assess the effectiveness varied widely: five studies assessed the effect using self-reported clinical respiratory symptoms [19–23], and two studies considered laboratory-confirmed viral or bacterial infections through real-time reverse transcriptase-polymerase chain reaction (RT-PCR) [4,24]. Two studies that used syndromic definitions found handwashing with soap and water to be effective against clinical ARIs [21,22], and one of these additionally found the prevalence of *Streptococcus pneumoniae* was lower among participants using ABHR compared to those who did not [24].

To the best of our knowledge, no focused interventional study has investigated the role of HH in the prevention of ARIs among Hajj or Umrah pilgrims, particularly during a global pandemic such as COVID-19. To this end, the primary objective of this pilot RCT was to assess the feasibility of establishing a large-scale trial to determine the relationship between practising HH and rates of ARI among Umrah pilgrims.

Material and methods

Trial design and participants

A parallel-group pilot RCT was conducted among domestic Umrah pilgrims in Makkah city, KSA during the peak months of Umrah season, Ramadan and Dhul Qi'dah of the Islamic lunar calendar corresponding to April, May and July 2021. Participants were equally randomised 1:1 to either intervention (supervised HH) or control (no supervised HH). The study was conducted according to the RCT protocol and documents that were ethically approved by the Institutional Review Board of King Abdullah Medical City, Makkah, KSA (IRB Ref. No.: 21–772).

After obtaining the necessary approval, the RCT was executed in the pilgrims' accommodations (a total of five hotels) near the Holy Mosque in Makkah. Twenty data collectors, who were given intensive training on the trial procedure, invited participants to join the study, explained to them what the study involved, handed them a participant information sheet, and answered any questions they may have. Informed consent was obtained from the participants who agreed to take part after they had been assessed for eligibility. Umrah pilgrims of all genders were eligible to participate in the study if they were residents of KSA, aged 18 years or above, able to provide informed consent, and did not report any symptoms of ARI at the time of recruitment. Participants who refused to participate or were known to have a contraindication to HH product (e.g., allergy to any component of HH product) were excluded.

Randomisation and intervention

The data collectors randomly assigned participants to the study groups according to random numbers that were generated

beforehand for each hotel by using an online random number allocation software application by an offsite research coordinator who did not take part in the recruitment or assessment of participants [25]. A bottle of 100 ml of ABHR (a locally manufactured hand sanitiser gel that contains 70 % ethanol) that is locally available and approved by the Saudi Food and Drug Authority was supplied for free to each participant in the intervention group to use for 7 days. In addition, the study team members practically demonstrated to the participants the correct method of using the product and helped them clean their hands for the first time. On the other hand, neither ABHR products nor practical instructions were given to anyone in the control group, although they could have used their own supply if they wished. Allocation to the study arms was concealed before randomisation, subsequently, the participants knew to which randomised group they had been assigned as the intervention of using ABHR was visible to them as well as the investigators; hence, the trial could not be blinded.

Data collection and outcomes assessment

A self-administered online baseline questionnaire was sent to participants via text messaging, and they were asked to complete it. The questionnaire captured relevant data related to participants' socio-demographics, medical history, and compliance with HH practice in the past two weeks. Pilgrims were then followed up for one week (7 days) starting from the next day of enrolment by using the computer-assisted telephone interview (CATI) technique. Participants in both groups were asked to report the presence or absence of respiratory symptoms and other systemic or gastrointestinal symptoms, and the practice of the intervention during the study period. The compliance with the intervention was categorised based on the frequency of using ABHR per day: 'less frequently' was defined as < 5 times/day, or 'more frequently' as ≥ 5 times/day. Lastly, information about facilitators of, and barriers to HH practice, and any skin reactions were collected.

The data collection tools (baseline questionnaire and follow-up interviews) were administered through "Microsoft Forms", a development cloud-based software (Microsoft Office 365, version 2209, Redmond, WA, USA) and were devised by using sample questions used in a previously published RCT and a survey by the study team [26,27], and amended, if necessary, based on feedback from leading MG and infectious disease experts. The questionnaires were initially drafted in English; subsequently, two researchers translated them into Arabic independently. Afterwards, professional linguists performed proofreading to carefully check for errors or discrepancies in the text.

To estimate the relationship between HH and rates of ARI among Umrah pilgrims, the primary outcome of the study was the difference in the proportions of pilgrims who developed ARIs between randomised groups. We used broad clinical criteria to define a case of ARI. It was defined as the development of at least one respiratory symptom, including cough, sore throat, rhinitis, dyspnoea, and smell or taste dysfunction, within the study period (i.e., from the next day following the enrolment until the last day of follow-up). Additionally, we estimated the difference between randomised groups in proportions of pilgrims who developed 'possible ILI' and 'possible COVID-19' cases by applying syndromic definitions. The ILI definition was described by Rashid et al. as 'a triad of subjective fever, cough, and sore throat' [28], which has a sensitivity and specificity of correspondingly 67% and 64% against influenza confirmed by RT-PCR. A syndromic definition of COVID-19 used by Adorni et al. as the 'concomitant presence of three or more of the following symptoms: fever, myalgia, cough, and smell or taste dysfunction' was applied; this definition is highly likely to be associated with a positive molecular diagnosis of COVID-19 (adjusted odds ratio [aOR]

18.5, 95 % confidence interval [CI] 13.7–24.9) and has a specificity of 91% [29].

Sample size and statistical analysis

Assuming the prevalence of symptomatic ARIs to be 30 % in the control arm and the prevalence of laboratory proven viral ARIs in controls to be 12 % in the intervention arm, it was considered clinically worthwhile if HH intervention could reduce the prevalence of syndromic ARIs by 50 % [30,31]. Nevertheless, this being a pilot trial we wanted to have a pragmatic sample size of about 400–500 participants and based on our previous experience of conducting another pilot RCT at Hajj we considered that to be good enough [32].

Participants' recorded data were exported to a master Excel spreadsheet (Microsoft Office 365, version 2002, Redmond, WA, USA) for cleaning and coding before importing into Statistical Package for Social Sciences (SPSS) software (IBM SPSS Statistics for Windows, version 26.0, IBM Corp, Armonk, NY, USA) for analysis. For the baseline data, we described the participants' socio-demographic characteristics, medical history, vaccination status, HH knowledge, perception of the effectiveness of HH methods, and frequency of ABHR use in the randomised groups. For descriptive analysis, frequencies and percentages were used to report the categorical variables, while the mean (or median with range) $\pm$ standard deviation (SD) was applied to summarise continuous data.

In the follow-up phase, the analysis was performed on participants who were symptom-free at baseline and completed the follow-up questionnaire (lost to follow-up were excluded from the analysis). The primary outcome was analysed according to the randomised group they were originally assigned, regardless of what treatment they received, by using binary logistic regression. Subgroup analyses were attempted to compare the interaction between the intervention and groups of participants by age, gender, nationality, occupation, smoking status, presence of medical conditions, and the receipt of influenza and COVID-19 vaccinations, and this interaction was tested in a logistic regression model. Differences were described using OR (95 % CI).

Results

As shown in Fig. 1, a total of 507 Umrah pilgrims met the eligibility criteria, consented, and completed the baseline questionnaire, 267 (53 %) of whom were allocated to the control group, and 240 (47 %) were allocated to the intervention group whom all received the ABHR product. Pilgrims' recruitment started in April 2021 and was completed in July 2021. All participants in both groups were followed up, 61 (12 %) were lost to follow-up or withdrew from the study leaving a total of 446 participants (control: intervention = 237: 209) for the primary outcome analysis.

The participants' baseline characteristics are summarised in Table 1. Pilgrims were aged from 18 to 75 (median of 34) years. Of the total participants, 276 (54 %) were female and 444 (88 %) were native Saudi citizens. Of all recruits, 128 (25 %) reported having one or more pre-existing medical conditions, 117 (23 %) were vaccinated against influenza, and 456 (90 %) had received at least one dose of COVID-19 vaccination.

Table 2 demonstrates that the practice of ABHR reported by participants in the intervention group during the study was not different from that reported by those in the control group ($p=0.8$). Although cleaning hands with ABHR more frequently (≥ 5 times a day) among participants in the intervention group during the study seemed to be slightly improved compared to before the study, it was not statistically significant (37 % vs. 32 %, $p=0.20$). Similarly, at the seven-day follow-up, no significant difference was noted in the use of frequent handwashing with soap and water (≥ 5 times a day) between the study arms (68 % [143/209] vs. 66 % [156/237], $p=0.56$).

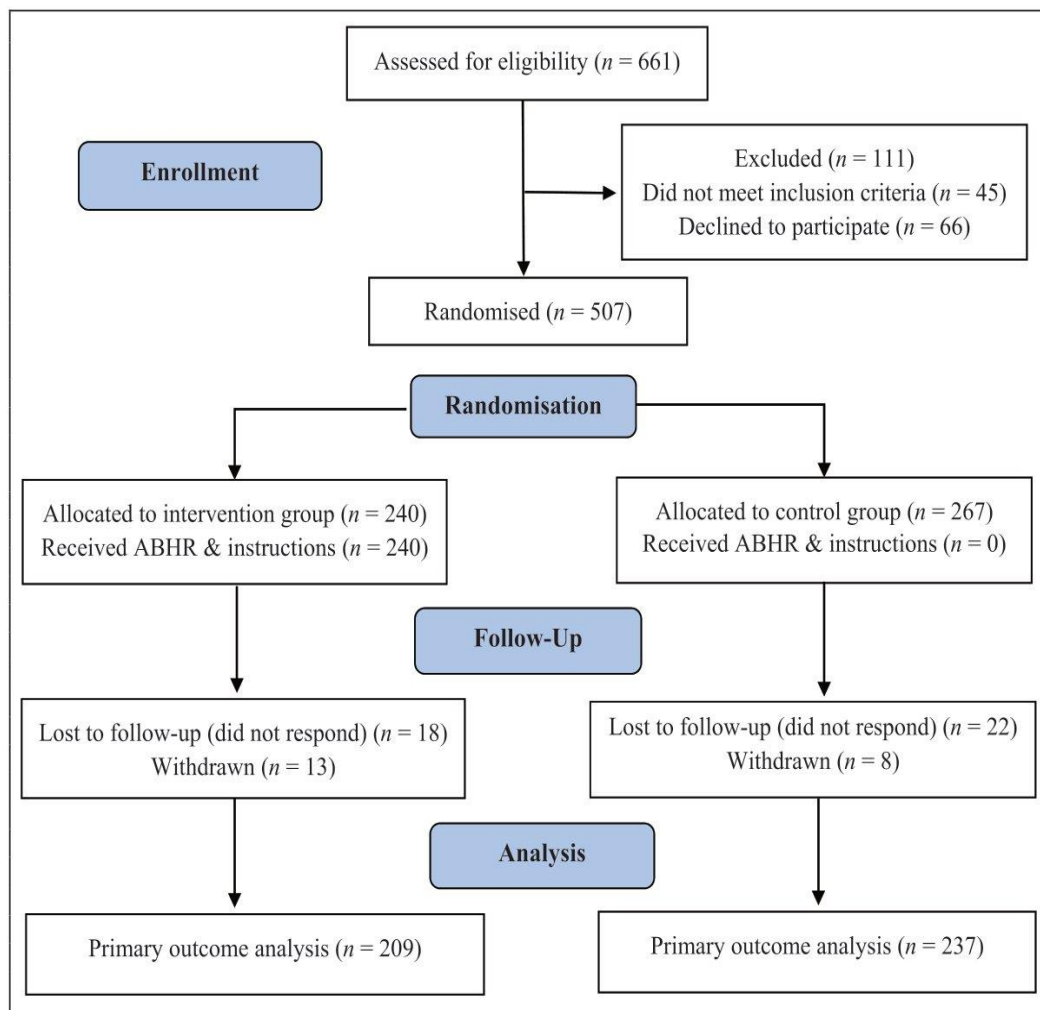


Fig. 1. Flow diagram of enrolment of Umrah pilgrims to trial, group allocation, follow-up and analysis.

Overall, 10 (2.2 %) of the participants had developed at least one respiratory symptom, three (0.7 %) ‘possible ILI’ and two (0.4 %) ‘possible COVID-19’ among those who completed the follow-up questionnaire. In the control group, of five symptomatic participants, two (40%) had cough, one (20 %) had a sore throat, three (60 %) had rhinitis, one (20 %) had smell or taste dysfunction, and one (20 %) had dyspnoea; while in the intervention group, of five symptomatic participants, three (60 %) had cough, five (100 %) had a sore throat, and two (40 %) had rhinitis.

In the analysis of the primary outcome, there was no evidence of a difference in the proportions of syndromic ARIs among pilgrims between the randomised groups (OR 1.1, 95 % CI 0.3–4) (Table 3). The findings from the subgroup analyses showed no evidence of interaction between the intervention and any participant subgroups, including age, gender, occupation, pre-existing medical conditions, smoking status, and receiving influenza and COVID-19 vaccinations (all interaction $p > 0.05$).

A small number of participants (79, 18%) experienced dermatologic side effects of adopting frequent HH, skin dryness was the most common adverse reaction (73, 16 %) followed by hand allergic reactions (18, 4 %). The main motivators of complying with regular HH reported by participants were the strong belief that cleaning hands would protect from illnesses (263, 59 %), and the awareness of the protective role of regular HH practice (249, 56 %); whereas being too busy or failure to remember to clean their hands (168, 38 %) and avoiding scented or alcoholic HH products (67, 15 %) were the major reported barriers.

Discussion

This is the first interventional study that explored the relationship between HH use and ARI rates among Umrah pilgrims during the pandemic of COVID-19. This pilot study showed that a large trial is feasible in Umrah pilgrimage; however, it failed to provide conclusive evidence on the protective role of HH. Inconclusiveness of this pilot study is predictable as it is an underpowered study, the primary aim of which was to assess the feasibility of conducting a definitive trial in Umrah setting.

Inconsistent evidence was found in the literature on the effectiveness of HH against ARIs in MGs [16]. Observational studies conducted at Hajj during the COVID-19 pandemic [19] and before the pandemic did not consistently find an association between HH and decreased ARI prevalence [20,23]. Paradoxically, a study conducted among French pilgrims during the Hajj 2012 found that pilgrims who used frequent HH had higher respiratory symptoms [4]. However, in a prospective cohort study conducted the next year (2013), the prevalence of PCR-confirmed *S. pneumoniae* was significantly lower among French pilgrims who used ABHR than those who did not (55 % vs. 76 %; $p = 0.02$), but not among those who used handwashing with soap and water only [24]. Good practice of HH was identified as a protective measure in minimising symptomatic ARIs in surveys carried out among Hajj pilgrims from the United States (OR 0.36, 95 % CI 0.14–0.94) and Malaysia (OR 0.41, 95 % CI 0.20–0.85) [21,22]. A possible explanation for these conflicting results is the variations in outcome definitions used to measure the effectiveness of HH,

Table 1
Pilgrims' baseline characteristics by randomised groups.

Variable	Control n (%)	Intervention n (%)
Total number of participants at baseline	267 (53)	240 (47)
Age, yr.		
18–25	67 (25)	52 (22)
26–39	97 (36)	104 (43)
40–55	84 (31)	69 (29)
56–64	13 (5)	12 (5)
≥ 65	6 (2)	3 (1)
Gender		
Male	121 (45)	110 (46)
Female	146 (55)	130 (54)
Nationality		
Saudi Arabian	235 (88)	209 (87)
Non-Saudi	32 (12)	32 (13)
Residency in KSA		
Riyadh	78 (29)	70 (29)
Makkah	41 (15)	22 (9)
Jeddah	30 (11)	15 (6)
Abha	18 (7)	27 (11)
Al-Qassim	15 (6)	19 (8)
Al-Madinah	16 (6)	14 (6)
Others	69 (26)	73 (30)
Marital status		
Married	156 (58)	158 (66)
Single	93 (35)	75 (31)
Divorced	11 (4)	4 (2)
Widower	7 (3)	3 (1)
Education		
Higher university degree	27 (10)	28 (12)
Bachelor's certificate	142 (53)	129 (54)
Diploma	21 (8)	26 (11)
High school certificate	62 (23)	41 (17)
Primary/elementary school certificate	13 (5)	11 (5)
No education	2 (1)	5 (2)
Occupation		
Unemployed	74 (28)	73 (30)
Student	43 (16)	38 (16)
Retired	17 (6)	16 (7)
Public sector worker	82 (31)	66 (27)
Private sector worker	39 (15)	35 (15)
Self-employed	12 (4)	12 (5)
Duration of stay in Makkah		
< 1 week	177 (91)	163 (88)
1 week to < 2 weeks	10 (5)	15 (8)
≥ 2 weeks	8 (4)	7 (4)
Presence of chronic medical conditions	67 (25)	61 (25)
Smoking status		
Non-smoker	199 (76)	202 (86)
Current smoker	38 (15)	15 (6)
Past smoker	25 (9)	18 (8)
Received influenza vaccine		
Yes	61 (23)	56 (23)
No	206 (77)	184 (77)
Received COVID-19 vaccine		
Yes	238 (89)	218 (91)
No	29 (11)	22 (9)
Frequency of using soap and water in the past two weeks		
Less frequently (< 5 times/day)	97 (36)	81 (34)
More frequently (≥ 5 times/day)	170 (64)	159 (66)

Table 2
Practice of ABHR by randomised groups.

Variable	Control n (%)	Intervention n (%)	p-value
Frequency of using ABHR pre-study			
Less frequently (< 5 times/day)	149 (63)	143 (68)	0.25
More frequently (≥ 5 times/day)	88 (37)	66 (32)	
Frequency of using ABHR during study			
Less frequently (< 5 times/day)	152 (64)	132 (63)	0.83
More frequently (≥ 5 times/day)	85 (36)	77 (37)	

Table 3
Primary and subgroup analyses by randomised groups.

Variable	Intervention n/ N (%)	Control n/N (%)	Intervention relative to control OR (95% CI)
Rate of ARI	5/209 (2)	5/237 (2)	1.1 (0.3–4)
Rate of 'possible ILI'	3/209 (1)	0/237 (0)	^a
Rate of 'possible COVID-19'	1/209 (0.5)	1/237 (0.4)	1.1 (0.07–18)
Age, yr.			
18–25	2/48 (4)	2/64 (3)	1.3 (0.2–10)
26–39	1/90 (1)	1/88 (1)	1 (0.06–16)
40–55	2/59 (3)	2/68 (3)	1.2 (0.1–8)
56–64	0/10 (0)	0/13 (0)	^a
≥ 65	0/2 (0)	0/4 (0)	^a
Gender			
Male	1/98 (1)	3/106 (3)	0.3 (0.03–3)
Female	4/111 (4)	2/131 (1)	2.4 (0.4–13)
Employment status			
Employed	1/99 (1)	2/117 (2)	0.6 (0.05–7)
Unemployed	4/110 (4)	3/120 (2)	1.5 (0.32–7)
Presence of chronic medical conditions			
Yes	3/52 (6)	2/58 (3)	1.7 (0.3–11)
No	2/157 (1)	3/179 (2)	0.8 (0.1–5)
Smoking status			
Current smoker	0/15 (0)	3/34 (9)	^a
Non-smoker	5/190 (3)	2/198 (1)	2.6 (0.5–14)
Received influenza vaccine			
Yes	0/46 (0)	0/56 (0)	^a
No	5/163 (3)	5/181 (3)	1.1 (0.3–4)
Received COVID-19 vaccine			
Yes	4/195 (2)	5/211 (2)	0.9 (0.2–3)
No	1/14 (7)	0/26 (0)	^a

^a Not calculated due to empty cells.

nationality of pilgrims, modality of HH used and the study year. A well-designed RCT is needed for a definitive answer.

A systematic review of RCTs conducted in settings other than MGs to assess the effectiveness of physical interventions against viral respiratory infections suggested a protective role of HH (RR 0.84, 95 % CI 0.82–0.86) [15]. However, few observational studies investigated the protective role of HH against confirmed COVID-19 among the general population [33]. One study reported that frequent HH either by soap and water or by ABHR was associated with a lower risk of spreading COVID-19 [34], while another study demonstrated only frequent use of ABHR to be effective against COVID-19 [35]. In another study, washing hands with soap and water at least five times per day was found to be protective against COVID-19 [36]. Additionally, cleaning hands after outdoor activities, and before touching the mouth and nose were found to be independent protective factors against COVID-19 [37].

Using a bundle of COVID-19-related interventions during this Umrah season, such as receiving mandatory vaccination against COVID-19, obligatory facemask use, and maintaining physical distance might have confounded the real effect of HH. Moreover, the inadequate sample size, as this study was designed as a feasibility trial, and participants' suboptimal adherence to the assigned HH

intervention or instructions could have been attributed to the lack of relationship observed in this trial. As a result of the intensive campaigns to mitigate COVID-19, pilgrims may have become more aware of the importance of HH and developed stronger beliefs in its effectiveness against infections, which were shown in our findings as the key facilitators of complying with regular HH. Hence, it would have certainly been unethical to advise against HH use during the pandemic.

The frequency of ARIs related to the Umrah setting in the current study was found to be lower than in a Hajj study and similar to that in a post-Hajj study conducted in the same year (2021) [19,38]. The Hajj pilgrimage is ritual-intensive, takes a longer period than Umrah to be performed and involves prolonged exposure to crowds, especially during pilgrims' stay in the tent city of Mina and the Plain of Arafat, which in turn increases the risk of ARIs [12]. Even then, the overall number of ARI events among the domestic Umrah pilgrims in this trial was lower in comparison to the observed rates from the pre-pandemic studies. For example, in a surveillance study conducted among returning Hajj and Umrah pilgrims from India in 2014 and 2015 around 11 % reported symptoms of ARIs [9]. Approximately one-third of respiratory samples (nasopharyngeal and throat swabs) collected from 300 returning Indian pilgrims between 2014 and 2015, who suffered from respiratory infections, tested positive for a virus [10]. The cautious planning along with imposing tight good public health strategies by the KSA government in the recent Hajj and Umrah seasons amidst the pandemic must have played a role in lowering the rates of ARIs including COVID-19 [11].

Hajj and Umrah pilgrims seem to have good overall compliance with HH practice [16]. For instance, the findings of pilgrims' HH practices during the 2021 Hajj showed that the majority washed their hands with soap and water (70%) and used ABHR (53 %) more than five times per day [19]. Moreover, a survey in 2018 reported that more than half of the Umrah pilgrims cleaned their hands after high-risk behaviours such as handshaking, touching doorknobs, and sneezing or coughing [18]. Nonetheless, a pre-pandemic RCT among Malaysian Hajj pilgrims demonstrated a noticeably lower compliance rate of ABHR used in both study groups in contrast to what we found in this trial amidst the pandemic; respectively 15 % and 11 % of Malaysian pilgrims in the control and intervention groups complied with daily ABHR usage [39]. This difference may be a reflection of pilgrims' behavioural changes in response to the pandemic.

Even though Umrah pilgrims in the intervention arm were supplied with HH products and health education, compliance did not differ between intervention and control groups. Therefore, education, provided as practical instructions, may not have an effect. In agreement with our findings, the RCT that investigated the changes in practices of Malaysian pilgrims towards ARI preventive measures before and after Hajj in the year 2013 revealed that HH compliance did not improve following the distribution of ABHR products and educational instructions ($p = 0.37$) [39].

The primary barriers to Umrah pilgrims' compliance with ABHR supplied in this trial were due to forgetfulness and avoidance of using hygienic products containing alcohol. Similar barriers were observed in previously implemented studies among pilgrims of Hajj in 2021 and visitors of the Prophet's Mosque in Al-Madinah in the year before (2020) [19,26]. Muslim pilgrims prefer using non-alcoholic alternatives such as soap and water over ABHR when available [16]. According to Quran, Muslims are forbidden to consume alcohol; however, utilising products with alcohol-based formulations including ABHR is permissible if intended to treat or prevent an illness. Therefore, advice by Islamic scholars about the vital role of ABHR use and explaining how this practice does not compromise pilgrims' religious rites could possibly eliminate this misconception [40].

Prolonged dermal exposure to alcohol-based substances can cause irritation and allergic conditions including dryness, peeling or

itching of the skin [41]. Participants of this trial too reported some skin reactions following HH practice, most frequently skin dryness and hand allergic reactions. In contrast with our findings, a slightly higher proportion of the Prophet's Mosque visitors (23 %) reported dermatologic reactions after frequent HH practice [26]. Simple tips such as using unmedicated hand lotion are advised to minimise side effects.

Implementing such a trial during an exceptional Umrah season was challenging and led to some limitations. Only selective domestic pilgrims were recruited; therefore, the generalisability of the results is restricted. Furthermore, the short stay of Umrah pilgrims in Makkah coupled with COVID-19 restrictions made it difficult to obtain biological samples for laboratory diagnosis of infections, and rather syndromic definitions of ILI and COVID-19 were used. Consequently, a proportion of asymptomatic pilgrims may have been missed out, and atypical presentations of novel COVID-19 variants may not have been identified. Additionally, due to their short stay in Makkah, we had to contemplate concluding the follow-up by seven days. The median incubation periods of the most prevalent respiratory viruses [42], including most circulating variants of SARS-CoV-2 [43], are less than seven days, which means most of the infections were acquired after enrolment. However, a few respiratory viruses that have a maximum incubation period of up to two weeks might have been missed out. Even though the participants were equally randomised (1:1) to study arms, the number of enrollees differed between the groups due to reasons like not meeting eligibility criteria, not consenting and not completing the baseline questionnaires. Finally, although using a structured interview technique to collect data from participants was very beneficial in terms of limiting data loss, obtaining accurate responses, and increasing the response rate, this method required a large number of well-trained data collectors, we are unsure whether it would be manageable to oversee such a large number of data collectors in the actual trial.

To overcome these limitations, a fully powered RCT of multinational participants is needed to investigate the efficacy of HH use against both viral and bacterial infections. Application of molecular diagnostic tests on samples from both symptomatic and asymptomatic pilgrims before leaving Makkah would be most ideal. Despite these difficulties, this study shows that conducting a trial can still be achievable in MGs during a pandemic. This pilot study could be utilised as a model for a definitive trial to test the role of HH and other interventions to counter infectious diseases in Hajj and Umrah settings.

Conclusion

This pilot RCT recommends that implementing a future full-scale RCT to investigate the role of HH in preventing and containing ARIs is feasible in MG settings including Umrah pilgrimage amidst a global pandemic, and such a study would need to be very large given the low rates of outcomes observed here. However, this pilot trial failed to demonstrate any evidence of HH effectiveness against syndromic ARIs.

Authorship contribution statement

AA, HAM, ASA, RZS, RR and HR contributed to the conception and design of the study. OB managed ethical approval. HAM supervised the study. AA, HAM, MA and OB contributed to the acquisition of data. HAM, EHB and HR performed the statistical analysis and interpreted the results. All of the authors drafted the article or revised it critically for important intellectual content and provided final approval of the version for submission.

Ethics approval

All methods were conducted in accordance with the Declaration of Helsinki. The study was approved by the Institutional Review Board of King Abdullah Medical City, Makkah, KSA (IRB Ref. No.: 21–772).

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Declaration of Competing Interest

All authors declare no conflict of interest.

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CHAPTER 6: A comparison of pilgrims' hand hygiene knowledge, practices, and rates of respiratory tract infections during the peak of Umrah and Hajj

No focused study had been carried out to compare the health behaviours and the frequency of symptomatic RTIs among attendees of Hajj and Umrah MGs in KSA, particularly amidst a pandemic. To this end, I sought to embark on a comparative analysis of the data presented in chapters four and five to describe the differences between Hajj and Umrah pilgrims' HH knowledge and behaviours, along with the rates of syndromic RTIs amidst the COVID-19 pandemic.

The datasets for the following comparative study (Publication #7) were retrieved from the two previously published studies in the 2021 Hajj and Umrah seasons (Publications #4 and 6), which utilised comparable assessment instruments to evaluate the knowledge and practice of HH and identical syndromic definitions for RTIs. The results revealed that, despite the fact that Hajj pilgrims showed greater knowledge and practices of HH than Umrah pilgrims, they had a higher rate of symptomatic RTIs during the pandemic. These discrepancies may have resulted from the unique characteristics of these pilgrimages and the distinct risks presented by these MGs.

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Hand hygiene knowledge and practices, and rates of respiratory tract infections between Hajj and Umrah pilgrims: a comparative study

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ABSTRACT

Background: Hajj and Umrah mass gatherings (MGs) in the Kingdom of Saudi Arabia amplify the risk of viral respiratory tract infections (RTIs), but there is a lack of comparative data from these two MGs. This study aims to compare pilgrims' hand hygiene knowledge, practices, and rates of RTIs during the peak periods of Umrah and Hajj in 2021.

Materials and methods: The datasets of this comparative study were obtained from two previously conducted studies that used similar study tools and identical syndromic definitions. The binary logistic regression was applied to compare the categorical variables and, a t-test was used to compare the continuous variables.

Results: A total of 510 Hajj pilgrims and 507 Umrah pilgrims were recruited. The majority of Hajj pilgrims (68%) were ≥ 40 years old, while most Umrah pilgrims (63%) were < 40 years old. The mean total knowledge scores of hand hygiene between the Hajj and Umrah pilgrims differed significantly (4.1 vs. 3.7, respectively, $p < 0.001$) so did their compliance with frequent use of alcohol-based hand rubs (53.0% vs. 36.3%, respectively, $p < 0.001$) and the rates of RTIs (4.7% vs. 2.2%, respectively, $p = 0.05$).

Conclusions: These differences could be attributable to the distinctive characteristics of Hajj and Umrah pilgrimages, and the unique differences in risks posed by those MGs.

(Int Marit Health 2023; 74, 2: 92–97)

Key words: Hajj, Umrah, hand hygiene, mass gathering, pilgrim, respiratory tract infection

INTRODUCTION

The Kingdom of Saudi Arabia (KSA) hosts two major types of religious mass gatherings (MGs): Hajj and Umrah. Hajj is an annual Islamic pilgrimage that attracts up to

three million pilgrims between the 8th and the 13th of Dhul Hijjah, the last month of the Islamic calendar, while Umrah is a minor pilgrimage that can be completed within a short period of time at any time throughout the year,

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although the fasting month of Ramadan is the peak time for Umrah as it holds almost similar spiritual significance to the devotees as Hajj [1]. The common rituals of these pilgrimages include assembly at the Holy Mosque in Makkah City, where pilgrims make circumambulations around the monolith known as the “Kaaba” and march between two hillocks called Safa and Marwa, and Hajj pilgrimage has additional rituals, such as spending the designated Hajj days in tents on the outskirts of Makkah, including Arafat, Mina, and Muzdalifah [2].

During such MGs, the congregation of participants at particular sites for a specific period of rites poses a greater risk of acquiring and transmitting infectious diseases, mainly viral respiratory tract infections (RTIs) [3, 4]. In a survey conducted in 2010, approximately 50% of Hajj pilgrims from the capital city of KSA (Riyadh) developed RTIs [5]. Also, in a surveillance study conducted among returning Hajj and Umrah pilgrims from India in 2014 and 2015, about 11% reported symptoms of RTI [6]. Furthermore, the overall prevalence of influenza-like illnesses (ILI) among Hajj pilgrims is high. For instance, 30% of Egyptian pilgrims studied between 2012 and 2015 [7] and about 80% of French pilgrims studied between 2014 and 2017 had ILI [8].

The practice of proper and frequent hand hygiene (HH), alongside other non-pharmacological interventions, is strongly recommended to control and prevent RTIs during MG events. In the recent Hajj and Umrah seasons, the government of KSA imposed a set of public health measures to prevent the spread of the coronavirus disease 2019 (COVID-19) in the midst of the global pandemic [9]. These measures included the mandatory use of face masks, advice on practising frequent HH, providing necessary hygienic products to pilgrims, and maintaining physical distance [10].

Limited studies have evaluated the knowledge and practices of HH measures among Hajj and Umrah pilgrims. A survey carried out by our researchers during Hajj in 2019 revealed that despite pilgrims' good HH knowledge and practices, only a minority utilised recommended HH products and the majority preferred handwashing with soap and water [11]. The majority of Umrah pilgrims (83%) who participated in a survey in 2019 at the departure lounge at King Abdul Aziz International Airport, Jeddah, KSA, reported cleaning their hands with soap and water or with sanitisers after coughing and sneezing [12].

Nevertheless, no focused study has compared participants' health behaviours and/or symptomatic RTI rates of these pilgrimages specifically amidst the COVID-19 pandemic. To this end, the primary objective of this study was to explore the differences in HH knowledge and practices along with the rates of syndromic RTIs among Hajj and Umrah pilgrims during the pandemic.

MATERIALS AND METHODS

The datasets for this comparative study were retrieved from two studies previously conducted by our team: one of the studies was a pilot randomised controlled trial (RCT) that was conducted among domestic Umrah pilgrims during the peak months of Umrah pilgrimage between 22 April and 8 July 2021 [13], and the other was a prospective cohort study conducted among domestic Hajj pilgrims during the peak week of Hajj festival from 19 to 23 July 2021 [14]. The detailed methodologies of these studies are published elsewhere [13, 14]. In brief, socio-demographic variables, medical and vaccination history, and knowledge about HH of Hajj and Umrah pilgrims were captured in a baseline questionnaire after they agreed to participate in the studies. Subsequently, the study participants were followed up for an equal period of 7 days after recruitment to record the occurrence of RTI symptoms and practices of HH through a follow-up questionnaire.

Similar assessment tools to evaluate knowledge and practice of HH and uniform definitions for RTIs were used in these studies. The level of HH knowledge was assessed based on the sum of the Likert scale of 0–6: ‘low level’ of knowledge was defined as a score of < 3, ‘moderate level’ as a score of 3–< 5, or ‘high level’ as ≥ 5 . HH practice was evaluated according to participants' daily use of soap and water as well as alcohol-based hand rubs (ABHR) to clean their hands during the study period: < 5 times/day indicating ‘less frequently’, or ≥ 5 times/day indicating ‘more frequently’. In order to estimate the rates of RTIs, we applied broad clinical criteria to define a case of RTI, in addition to syndromic definitions for ‘possible ILI’ and ‘possible COVID-19’ that were described and evaluated elsewhere [15, 16]. A case of RTI was defined as the development of at least one respiratory symptom, including cough, sore throat, rhinitis, dyspnoea, and smell or taste dysfunction.

The data recorded from both studies were exported to a single master Excel spreadsheet (Microsoft Office 356, version 2209, Redmond, WA, USA) for cleaning and assigning each line list of data to a code before being imported into Statistical Package for Social Sciences (SPSS) software (IBM SPSS Statistics for Windows, version 29.0, IBM Corp, Armonk, NY, USA) for analysis. The mean (or median with range) $\pm$ standard deviation (SD) was used to report continuous variables, whilst frequencies and percentages were applied to summarise the categorical data. The binary logistic regression was used to test the difference between Hajj and Umrah pilgrims in terms of the reported HH practice and rates of RTIs, while the independent two-sample t-test was used to compare the means of overall HH knowledge score and other continuous variables between Hajj and Umrah pilgrims. A p value of ≤ 0.05 was considered statistically significant.

Table 1. Baseline characteristics by Hajj and Umrah pilgrims

Variable	Hajj pilgrims	Umrah pilgrims	P-value
Age [years]:			
Median (range)	50 (18–69)	34 (18–75)	
18–25	55 (10.8%)	119 (23.5%)	< 0.001*
26–39	109 (21.4%)	201 (39.6%)	< 0.001*
40–55	209 (41%)	153 (30.2%)	< 0.001*
≥ 56	137 (26.9%)	34 (6.7%)	< 0.001*
Male : Female	230 (45.1%) : 280 (54.9%)	231 (45.5%) : 276 (54.5%)	0.88
Nationality:			0.37
Saudi	437 (85.7%)	444 (87.6%)	
Non-Saudi	73 (14.3%)	63 (12.4%)	
Education:			
University-level and higher	390 (76.5%)	326 (64.3%)	< 0.001*
Diploma	27 (5.3%)	47 (9.3%)	0.016*
High school certificate	64 (12.5%)	103 (20.3%)	< 0.001*
Primary/elementary school certificate or no education	29 (5.7%)	31 (6.1%)	0.77
Presence of chronic medical conditions	167 (32.7%)	128 (25.2%)	0.009*
Received influenza vaccine	297 (58.2%)	117 (23.1%)	< 0.001*
Received at least one dose of COVID-19 vaccine	509 (99.8%)	456 (89.9%)	< 0.001*

*These values are statistically significant; COVID-19 – coronavirus disease 2019

Table 2. Comparison of hand hygiene knowledge and practices between Hajj and Umrah pilgrims

Variable	Hajj pilgrims	Umrah pilgrims	P-value
Mean ± SD total knowledge scores	4.1 ± 1.2	3.7 ± 1.3	< 0.001*
Frequency of using soap and water:			
Less frequently (< 5 times/day)	134 (30.1%)	147 (33%)	0.36
More frequently (≥ 5 times/day)	311 (69.9%)	299 (67%)	
Frequency of using ABHR:			
Less frequently (< 5 times/day)	209 (47.0%)	284 (63.7%)	< 0.001*
More frequently (≥ 5 times/day)	236 (53.0%)	162 (36.3%)	

*These values are statistically significant; SD – standard deviation; ABHR – alcohol-based hand rubs

RESULTS

A total of 510 Hajj pilgrims and 507 Umrah pilgrims were enrolled in the studies, of whom 445 participants in the Hajj study and 446 participants in the Umrah study completed the follow-up phase until the end. Table 1 summarises the baseline characteristics of Hajj and Umrah pilgrims and demonstrates significant differences between certain characteristics, including age, pre-existing medical conditions, and receipt of influenza and COVID-19 vaccinations.

Table 2 shows the differences between HH knowledge and practices among Hajj versus Umrah pilgrims. Hajj pilgrims had higher knowledge scores, and significantly more of them used ABHR to clean their hands more frequently compared to Umrah pilgrims. The logistic regression analysis found that there was a statistically significant difference between the rates of RTIs, with Hajj pilgrims having higher RTI rates than Umrah pilgrims; sore throat was the only symptom that significantly varied between participants of the two studies and affected Hajj pilgrims to a greater extent (Table 3).

Table 3. Comparison of respiratory tract infections (RTIs) rates between Hajj and Umrah pilgrims

Variable	Hajj pilgrims	Umrah pilgrims	P-value
Rate of RTI	21 (4.7%)	10 (2.2%)	0.05*
Rate of 'possible ILI'	5 (1.1%)	3 (0.7%)	0.48
Rate of 'possible COVID-19'	4 (0.9%)	2 (0.4%)	0.42
Reported respiratory symptoms:			
Sore throat	16 (3.6%)	6 (1.3%)	0.04*
Cough	9 (2%)	5 (1.1%)	0.29
Rhinitis	8 (1.8%)	5 (1.1%)	0.40
Smell/taste dysfunction	4 (0.9%)	1 (0.2%)	0.21
Shortness of breath (dyspnoea)	3 (0.7%)	1 (0.2%)	0.34

*These values are statistically significant; ILI – influenza-like illnesses; COVID-19 – coronavirus disease 2019

DISCUSSION

This is the first published study to compare health behaviours and rates of symptomatic RTIs among participants from the two largest annual religious MGs in KSA, and its findings indicated that although Hajj pilgrims demonstrated better knowledge and practices of HH than Umrah pilgrims, they reported a higher rate of symptomatic RTIs amidst the COVID-19 pandemic in 2021.

Our findings revealed that the pilgrims who participated in Hajj were significantly older and had more underlying health conditions compared to those who attended Umrah, with *p* values of < 0.001 and 0.009, respectively. The majority of Hajj pilgrims (68%) were ≥ 40 years old, whereas most Umrah pilgrims (63%) were younger than 40 years of age. Other studies also found most Hajj pilgrims to be middle-aged or older. For example, a study conducted in 2021 involving Hajj attendees found that approximately half of the pilgrims were aged between 51 and 60 years [17]. Many Hajj pilgrims are typically elderly as this is a serious commitment considered by most devotees as a once-in-a-lifetime performance and most pilgrims save for years to prepare for the journey [18].

Our study took place between April and July 2021, and the influenza vaccination campaign in KSA was launched in September of the preceding year (2020) [19]. We asked pilgrims if they had received the vaccine in the past 1 year; it is likely that most of the surveyed received the vaccine during the campaign, and some may have received it before the pilgrimages. Nonetheless, Hajj pilgrims showed a significantly higher influenza vaccination rate in comparison to Umrah pilgrims, with respectively 58.2% vs. 23.1% being vaccinated, *p* < 0.001. Similar to our findings, Alfalali et al. [20] reported a vaccination rate of 51.3% among Saudi Hajj pilgrims over 3 years (2013–2015), while Kandeel et al. [21] reported a lower vaccination rate of 26.8% among Egyptian

Umrah pilgrims in 2022. Possible reasons for this variation in vaccination coverage could be a more stringent recommendation for influenza immunisation for Hajj pilgrims, higher rates of pre-existing comorbidities among Hajjis, and thus being medically eligible for the vaccine irrespective of travel. We also observed that Hajj pilgrims had a significantly higher COVID-19 vaccination uptake than Umrah pilgrims, with respective vaccination rates of 99.8% vs. 89.9% (*p* < 0.001). Since Hajj follows Umrah, many more Hajj pilgrims may have been able to receive the mandatory vaccine, which was launched in KSA in phases and prioritised according to occupational category and risk conditions [22].

Overall, our findings indicated that participants in both studies had a moderate level of knowledge about HH, and all of them practised HH. Nevertheless, participants in the Hajj study had better knowledge, and more of them frequently used ABHR to clean their hands than those in the Umrah study, despite the fact that the Umrah study was an RCT to explore the effect of HH on RTIs and at least half of the participants received HH solution free of charge. This discrepancy may reflect the fact that more Hajj pilgrims had a tertiary-level education than their Umrah counterparts (76% vs. 64%, *p* < 0.001). Other studies showed that having a high level of education had a positive role in improving pilgrims' compliance with HH practices [17, 23].

Health education interventions have been demonstrated to improve pilgrims' awareness of and adherence to preventive measures against RTIs [24]. Turkestani et al. [25] demonstrated through a pre-and post-intervention survey conducted during the 2011 Hajj that direct health education to pilgrims is effective in increasing short-term health knowledge as well as the compliance rate of HH (from 79.1% to 95.5%). A cross-sectional study conducted among Australian Hajj pilgrims before and after Hajj to determine what factors influenced their compliance with preventive

measures indicated that pilgrims who sought pre-travel health advice were twice as likely to be vaccinated as those who did not [23]. Additionally, an RCT conducted by Abidin et al. [26] among Hajj pilgrims from Riyadh in 2004 found that in the control group, 33.6% of pilgrims used a face mask during the pilgrimage; among the health education alone group, 51.7% used a face mask (odds ratio [OR] = 2.1; 95% confidence interval [CI] = 1.56–2.86); and among the health education with free face mask group, 81.3% used a face mask (OR = 8.6; 95% CI = 5.93–12.44) [26].

In contrast to Umrah pilgrimage, Hajj is more rite-intensive, takes a longer period to conclude, and entails prolonged exposure to larger crowds, particularly during pilgrims' stays in the tents of Mina and in the plain of Arafat, which in turn poses a higher risk of RTIs; thus, this may have contributed to the higher rates of RTIs observed among Hajj pilgrims in our study. The overall rate of RTIs in both studies was lower than in the pre-pandemic studies that established diagnosis by reverse-transcription polymerase chain reaction (RT-PCR) tests. For instance, approximately one-third of nasopharyngeal and throat samples collected from 300 Indian pilgrims returning from Hajj and Umrah with respiratory infections between 2014 and 2015 were positive for a virus [27]. Although there was no significant difference in the rate of 'possible COVID-19' between Hajj and Umrah studies, the overall rate in this study was lower than that in the general Saudi population and that among attendees of other MGs [10]. A retrospective surveillance study conducted at Hajj in 2021 showed that out of 58,428 pilgrims, 41 tested positive for COVID-19 by RT-PCR conducted before, during and after Hajj [17]. From 11 July to 7 August, the adjusted incidence rate of COVID-19 in KSA ranged from 19 to 24 per 100,000 residents, while the incidence rate among Hajj pilgrims ranged from 3 to 7 per 100,000 pilgrims [17]. Moreover, a low incidence of COVID-19 and influenza was identified in a surveillance study conducted at Cairo airport using RT-PCR on nasopharyngeal swabs among Egyptian pilgrims who returned from Umrah during Ramadan of the year 2022: 67 (6.7%) of the 1003 participants tested positive for COVID-19, and 7 (0.7%) tested positive for influenza [21].

The strength of the current study is that it is the first study to compare the health behaviours and symptomatic RTIs of Hajj and Umrah pilgrims. Also, the comparison was carried out between populations from the same country in the same year amidst the pandemic. Nevertheless, the study has some limitations. We investigated only domestic pilgrims during the COVID-19 pandemic; hence, this may limit the generalisability of our findings beyond the specified population and time frame. A further limitation is the use of distinct research designs; though both studies used similar questionnaires and syndromic criteria to define

ILI and COVID-19 cases, there were differences in methodologies. Lastly, the syndromic RTIs in this study were not confirmed by laboratory tests; therefore, we considered ILI and COVID-19 cases as 'possible' rather than 'confirmed'.

Notably, there are persistent gaps in the health knowledge and behaviours of pilgrims; thus, the application of effective health education programmes and stringent recommendations prior to and during MGs should be sustained, with special consideration for Umrah pilgrims. Using smartphone applications and social media platforms (such as Twitter™, WhatsApp™, Facebook™, etc.) is an ideal medium for communicating health-related messages to a larger audience of Hajj and Umrah pilgrims. Moreover, virtual meeting platforms, such as Zoom, Webex, and Google Meet, have become a significant part of the global education system, particularly so with the unfortunate arrival of COVID-19, and can therefore be utilised by healthcare professionals and health educators to promote health messages and preventive interventions and increase awareness about the potential health risks among attendees of MGs.

CONCLUSIONS

In this comparative study, we sought to describe the differences between Hajj and Umrah pilgrims concerning their HH knowledge and practices in addition to the rates of syndromic RTIs amidst the COVID-19 pandemic. Our findings revealed that Hajj pilgrims had better knowledge about preventive measures and complied more with public health interventions yet had a higher risk of RTIs. These discrepancies could be attributable to the distinctive characteristics of Hajj and Umrah pilgrimages, and the unique differences in risks posed by those MGs.

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CONCLUSIONS

The studies conducted and incorporated into this PhD thesis have provided important insights into the epidemiology of RTIs and the effectiveness of infection prevention interventions among participants in MGs in KSA during the COVID-19 pandemic. Several outcomes were reported regarding the burden and epidemiological patterns of RTIs, as well as knowledge, perceptions, and practices towards HH and its role in preventing syndromic viral RTIs, including COVID-19.

Table 3 provides a summary of the key findings from each publication originating from this thesis, which inform the following conclusions and critical reflections.

Table 3. Key findings from each publication within this thesis.

Publication #1 Epidemiological differences in Hajj-acquired airborne infections in pilgrims arriving from low-middle-income versus high-income countries: A systematised review
<u>Epidemiological patterns of RTIs</u>
• Pilgrims from HIC and LMIC had viral and bacterial infections. • Pilgrims from HIC tended to have higher attack rates for viral infections than those from LMIC. • Pilgrims from LMIC seemed to have higher attack rates of certain bacterial infections, such as meningococcal infections (0.015–82% in LMIC vs. 0.002–40% in HIC), while those from HIC seemed to have higher attack rates of other bacterial infections, such as <i>M. tuberculosis</i> (0.7–20.3% in LMIC vs. 38% in HIC).
Publication #2 Hand hygiene knowledge and practices among domestic Hajj pilgrims: Implications for future mass gatherings amidst COVID-19
<u>HH knowledge</u>
• Moderate knowledge, scoring 6.7 (± 1.9) out of 12.
<u>HH practices</u>
• Using soap and water was the most frequently practised method, followed by ABHR. • Good HH behaviour was reported at certain key actions, such as before and after a meal, after toileting, when hands were visibly dirty, and after waste disposal. • Poor HH behaviour was reported after other key actions, such as handshakes, sneezing, or coughing.

Publication #3 Hand hygiene knowledge, perception, and practices among domestic visitors to the Prophet's Mosque in Al Madinah city amid the COVID-19 pandemic: A cross-sectional study

HH knowledge

- Moderate knowledge, scoring 6.4 (± 1.35) out of 12, it slightly worsened compared to the 2019 Hajj study.

HH perception

- The majority had a positive perception of the effectiveness of HH methods against RTIs.

HH practices

- Using soap and water was the most frequently practised method, followed by ABHR, consistent with the previous year's finding.
- Good HH behaviour was reported at certain key actions, such as before and after a meal, after toileting, when hands were visibly dirty, and after waste disposal.
- Poor HH behaviour was reported at other key actions, such as after handshakes, sneezing, or coughing, consistent with the previous year's finding.
- Compliance slightly improved compared to the 2019 Hajj study, particularly after waste disposal and touching a patient.

Publication #4 Syndromic surveillance of respiratory-tract infections and hand hygiene practice among pilgrims attended Hajj in 2021: A cohort study

HH knowledge

- Moderate knowledge, scoring 4.15 (± 1.22) out of 6, with minor improvement compared to the previous years' findings.

HH perception

- The majority had a positive perception of the effectiveness of HH methods against RTIs and was better than it was in the previous year (2020).

HH practices

- Using soap and water was the most frequently practised method, followed by ABHR, consistent with the previous years' findings.
- Good HH behaviour was reported at almost all key actions.

Burden of symptomatic RTIs

- About 5% reported having one or more respiratory symptoms, and 1% met the syndromic definitions of either ILI or COVID-19, with cough and sore throat being the most common respiratory symptoms.
-

Publication #5 Low prevalence of syndromic respiratory tract infections among returning Hajj pilgrims amidst the COVID-19 pandemic: A post-Hajj survey

Burden of symptomatic RTIs

- About 2% reported having one or more respiratory symptoms, and 0.2% met the syndromic definition of ILI and 0.4% of COVID-19.
- Lower rates of syndromic RTIs and suspected ILI and COVID-19 compared to the study conducted during Hajj.
- About 45% reported that one or more of their close contacts had developed similar RTI symptoms after their home return.

Publication #6 The relationship between hand hygiene and rates of acute respiratory infections among Umrah pilgrims: A pilot randomised controlled trial

HH practices

- No significant difference in using the intervention (ABHR) during the study between the groups (36% in control vs. 37% in intervention, $p = 0.8$).

Burden of symptomatic RTIs

- About 2% reported having one or more respiratory symptoms, 0.7% met the syndromic definition of ILI and 0.4% of COVID-19, with cough and sore throat being the most common respiratory symptoms.

Protectiveness of HH

- Inconclusive evidence on the protective role of HH against viral ARIs.
- No significant difference in the proportions of ARIs (OR = 1.1; 95% CI 0.3–4) and ‘possible COVID-19’ between the groups (OR = 1.1; 95% CI 0.07–18).

Publication #7 Hand hygiene knowledge and practices, and rates of respiratory tract infections between Hajj and Umrah pilgrims: A comparative study

HH knowledge

- Hajj pilgrims had significantly higher knowledge scores than Umrah pilgrims (4.1 vs. 3.7, respectively, $p < 0.001$).

HH practices

- Significantly more Hajj pilgrims used ABHR than Umrah pilgrims (53% vs. 36%, respectively, $p < 0.001$).

Burden of symptomatic RTIs

- Hajj pilgrims had significantly higher RTI rates than Umrah pilgrims (5% vs. 2%, respectively, $p = 0.05$).

ABHR: alcohol-based hand rub; ARI: acute respiratory infection; HH: hand hygiene; HIC: high-income country; ILI: influenza-like illness; LMIC: low and middle-income country; RTI: respiratory tract infection.

1. Burden and epidemiological patterns of respiratory tract infections

The systematised review highlights that regardless of their nationality or income status, Hajj pilgrims are at risk of RTIs. However, the data from the observational studies that I conducted as part of this thesis revealed a significant decrease in the overall prevalence of RTIs among both Hajj and Umrah pilgrims during the pandemic years compared to the pre-pandemic period. For example, systematic reviews and meta-analyses of Hajj-related studies published prior to the pandemic reported that the prevalence of ILI ranged from 8% to 78%, and the overall prevalence of laboratory-proven influenza was 5.9 (95% CI 4.3–8.0) among Hajj pilgrims.^{7, 93} My studies revealed that the rate of ILI ranged from 0.7% to 1% among Umrah and Hajj pilgrims, respectively. Additionally, the comparative analysis of Hajj and Umrah attendees in 2021 demonstrated a significantly lower rate of RTIs among Umrah pilgrims, potentially attributed to smaller crowds and reduced exposure.

Amid global concerns regarding potential COVID-19 outbreaks, the occurrence of suspected COVID-19 cases in this research work among Hajj and Umrah pilgrims (1% and 0.4%, respectively) was lower compared to the seroprevalence of 11% among the general population of KSA but comparable to the incidence in other MGs (e.g., Tokyo Olympics 2020, Beijing Winter Olympics 2022).^{94, 95, 96, 97} Similarly, a retrospective surveillance of the 2021 Hajj found that out of 58,428 pilgrims, only 41 were identified as COVID-19-positive.⁴⁵ Additionally, a surveillance study conducted among pilgrims from Egypt returning from Umrah during Ramadan 2022 revealed an incidence of COVID-19 of 6.7% (67 of 1003 participants testing positive for COVID-19).⁴⁶ A retrospective study conducted during the peri-Hajj period of 2022 to estimate viral aetiology among patients with RTIs admitted to hospitals in Makkah and Al Madinah found an attack rate of COVID-19 of 15%.⁹⁸ This seemingly higher rate of COVID-19 may be attributable to the inclusion of hospitalised citizens and residents living on the Hajj grounds besides Hajj pilgrims, who may be exposed to the same risk during MGs, as well as the extended duration of

the study encompassing pre-, during, and post-Hajj periods. Additionally, more pilgrims were permitted to perform the 2022 Hajj (nearly one million) compared to the previous two years, which may have increased the likelihood of transmission of the virus.

In my studies, I focused solely on syndromic surveillance without virological testing; therefore, a definitive attribution of these symptoms to ILI or COVID-19 cannot be made. However, the observed symptom pattern closely resembled that of earlier research, with a consistent prevalence of clinical symptoms such as sore throat and cough, aligning with findings from previous studies.^{25,}

99, 100

The low prevalence of RTIs and COVID-19 among pilgrims amidst the pandemic may have been attributed to the effective implementation of strict public health measures by the government of KSA.¹⁰¹ Nonetheless, monitoring and assessing the risk of RTI spreading among contacts following Hajj remains critical, as a significant number of symptomatic pilgrims (45%) in our post-Hajj survey in 2021 reported that their close contacts had developed similar symptoms. Implementing a comprehensive set of public health measures, encompassing both pharmaceutical and non-pharmaceutical interventions, is essential for containing and reducing the risk of transmitting respiratory infections among participants of these Islamic pilgrimages, irrespective of their nationality or income status, in both pandemic and non-pandemic scenarios.

2. Knowledge, perception, and practices towards hand hygiene

Our findings revealed persistent gaps in pilgrims' health knowledge and behaviours, indicating areas for improvement. Over the period of three consecutive years (2019–2021), participants in our studies from various religious MGs showed a moderate level of knowledge regarding HH, with only negligible improvement observed during the pandemic despite the extensive COVID-19-related health campaigns. Such COVID-19 campaigns may have positively influenced perceptions about the vital role of HH, as many participants believed in HH methods' effectiveness against respiratory viruses, including SARS-CoV-2.

Pilgrims consistently showed good compliance with HH practices across the study years and settings, with handwashing with soap and water being the most preferred method, followed by the use of ABHR. The overall lower uptake of ABHR in relation to soap and water may be influenced by Muslims' religious and cultural preferences to avoid products containing alcohol when suitable alternatives are available. Additionally, according to the intense religious contemplation and seclusion (known as the state of 'Ihram'), fragrant toiletries, such as scented soaps, perfumes, and deodorants, are not permitted on a pilgrim's body or clothing. Thus, addressing misconceptions and providing guidance about the compatibility of ABHR with religious practices may help improve compliance.

In the pilot HH trial that I led, the compliance rate with ABHR did not significantly differ between the study arms (36% in control vs. 37% in intervention, $p = 0.8$), despite the free provision of ABHR products and education to participants in the intervention arm. However, in a pre-pandemic RCT among Malaysian Hajj pilgrims in 2013 where participants in the intervention group were given health education and ABHR, lower compliance with daily ABHR use was observed in both study arms (control = 15% vs. intervention = 11%),¹⁰² contrasting with our findings and suggesting a possible change in pilgrims' behaviour due to the pandemic.

There was a significant difference in compliance with HH interventions between Hajj and Umrah pilgrims, as evidenced in Publication #7. Despite the Umrah study being an RCT exploring the impact of HH on RTIs and HH solutions being provided freely to at least half of the participants in the intervention arm, fewer Umrah participants compared to Hajj participants complied with HH practices, particularly by use of ABHR, possibly due to the higher proportion of Hajj pilgrims having tertiary-level education compared to their Umrah counterparts. This finding aligns with a previous study that indicated higher education levels positively influenced pilgrims' compliance with HH.⁸⁸ Also, I found in one of my studies that Hajj pilgrims with higher knowledge of HH were more likely to engage in frequent handwashing with soap and water, meaning education may improve HH uptake. It was evident that delivering health education effectively increases pilgrims' awareness and uptake of preventive measures against RTIs.^{103, 104, 105} But the difference could also be due to public health campaigns that are historically more focused on Hajj than Umrah. Consequently, it is crucial to maintain robust health promotion programmes for HH and enforce stringent recommendations before and during such MG events to improve participants' knowledge and practises.

3. The protective role of hand hygiene against viral respiratory tract infections

The pilot RCT included in this thesis was the first interventional study to examine the correlation between HH utilisation and RTI rates among pilgrims attending a religious MG in KSA. The pilot study successfully demonstrated the feasibility of conducting a future large RCT within the context of Umrah, serving as a valuable model for other similar MG settings during pandemic situations. Nevertheless, the findings from this investigation yielded inconclusive evidence on the role of HH against syndromic RTIs during Umrah (OR = 1.1; [95% CI 0.3–4.0] for intervention relative to control). Several factors could have contributed to the lack of an observed relationship: the application of multiple COVID-19-related interventions during Umrah, which may have confounded the true impact of HH practices; the study's limited sample size, as it was designed as a feasibility trial; the participants' poor adherence to the given HH intervention or instructions; and the intensive campaigns promoting HH during the pandemic, which may have improved pilgrims' awareness of its importance and strengthened their belief in its efficacy against infectious diseases. Hence, a fully powered RCT with laboratory-based diagnosis is needed to evaluate the real effectiveness of HH interventions to prevent the spread of viral and bacterial respiratory infections among attendees of MGs.

In a recent systematic review of RCTs, the potential benefit of implementing HH interventions in reducing the risk of viral RTIs in various community settings, such as households, schools, and day care centres, has been demonstrated.⁶⁰ Nevertheless, the evidence regarding the role of HH in preventing RTIs among attendees of MGs remains inconsistent and is primarily based on limited observational studies.⁸⁰ Surveys conducted among pilgrims from the USA in 2009, Malaysia in 2013, and Australia in 2015 consistently showed that practising HH effectively reduced the occurrence of symptomatic RTIs,^{81, 82, 83} whereas two other studies conducted among French pilgrims did not find any significant association.^{86, 87} Another study observed a paradoxical finding that French pilgrims who engaged in frequent handwashing during the 2012 Hajj were more likely

to experience fever and respiratory symptoms compared to those with typical handwashing habits.⁸⁴ In contrast, in 2013, the same French team found that participants who used ABHR had a lower prevalence of *S. pneumoniae* in throat swab specimens compared to those who did not use ABHR, while participants who reported frequent handwashing with soap only had a non-significantly lower rate of bacterial detection.⁸⁵ These conflicting results may be attributed to variations in outcome definitions used to measure the effectiveness of HH, differences in the modality of HH used, as well as variations in pilgrims' backgrounds and the study years that often vary in terms of respiratory activity.

With regard to the protectiveness of HH use against COVID-19, our pilot trial did not find any significant difference between the randomised study groups during the pandemic. On the other hand, several recent studies have demonstrated the protective effects of HH practises against confirmed cases of COVID-19 in the general population. For example, one study found that frequent HH with soap and water or ABHR was associated with a reduced risk of COVID-19 transmission,¹⁰⁶ whereas another study found that only frequent ABHR use was efficacious.¹⁰⁷ Similarly, washing hands a minimum of five times per day with water and soap has been shown to be protective against COVID-19.¹⁰⁸ Also, practising HH at key times was identified as an independent protective factor against COVID-19, such as following outdoor activities (OR = 0.021; 95% CI 0.003–0.134) and before touching the mouth and nose (OR = 0.303; 95% CI 0.114–0.808).⁵⁸

4. Strengths and Limitations

This thesis represents a pioneering research effort to explore the health of attendees during all major religious MG events in KSA during the COVID-19 pandemic. It has several strengths, comprising the inclusion of diverse study designs and the unique conduct of the first pilot RCT during Umrah. My findings offer valuable evidence for future research in similar MG settings, encompassing syndromic data for viral RTI surveillance, assessment of knowledge and adherence to HH practices at different stages of a pandemic, and the potential establishment of a model for a definitive RCT on the effectiveness of HH and other interventions. This knowledge holds significant implications for refining future public health policies, promoting effective health education, and implementing robust measures to control infectious diseases among both local and international participants of MG events in KSA and similar settings globally.

However, conducting this research work during the pandemic presented challenges and imposed several limitations. Firstly, the study population was limited to domestic pilgrims, which may restrict the generalisability of the findings to broader international pilgrim populations and over different time periods. The reliance on self-reported data introduced the risk of information and recall bias, potentially influencing participants' responses. Additionally, due to COVID-19 restrictions, only a pilot RCT could be conducted, not a large-scale RCT, and therefore the evidence remains inconclusive. However, this crucially important pilot trial paves the way for a future large trial. Another limitation was the inability to obtain virological confirmation through biological samples, as administrative restrictions hindered the collection process, and I relied on syndromic surveillance. Consequently, cases were classified as 'possible' rather than confirmed, potentially overlooking asymptomatic pilgrims and atypical presentations of emerging COVID-19 variants and drifted influenza strains.

5. Way forward

Embarking on and completing the proposed large RCT on HH is the best way forward. In the near future, one of my main aims as an academic researcher will be to secure funding for a large HH RCT that will employ laboratory-based surveillance and involve participants from diverse nationalities to assess the efficacy of HH in preventing viral and bacterial infections during Hajj and/or Umrah. The COVID-19 pandemic is no longer classified as a global public health emergency, and Hajj and Umrah pilgrimages have resumed to pre-pandemic levels. The public health challenges of Hajj and Umrah remain as they were before the pandemic. It is therefore essential to prioritise future research on the effectiveness of infection prevention and control measures in reducing the transmission of all RTIs, not solely COVID-19. With Hajj moving to warmer months in recent years, it is important to quantify the frequency of RTIs among pilgrims in the summer, measure the compliance of HH and other preventive measures in hot climates, and explore if the protectiveness level changes in warmer temperatures. Obviously, COVID-19 has not disappeared and remains a disease of public health significance across the globe. Additionally, for KSA, MERS-CoV is still a concern, and although no case has been recorded among Hajj pilgrims, with COVID-19 still circulating, there is a theoretical risk of emerging more transmissible variants of MERS-CoV that may affect Hajj pilgrims. Therefore, it is crucial to investigate the future behaviour of pilgrims in terms of adopting and adhering to non-pharmaceutical preventive measures beyond the COVID-19 pandemic era.

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APPENDICES

Appendix #1. The Institutional Review Board of King Abdullah Medical City ethical approval (IRB number: 19-558)



المملكة العربية السعودية Kingdom of Saudi Arabia
وزارة الصحة Ministry of Health
مدينة الملك عبد الله الطبية في العاصمة المقدسة King Abdulla Medical City in Holy capital
لجنة المراجعة الأخلاقية Institutional Review Board

Institutional Review Board Opinion Letter

Protocol Title	Hand Hygiene knowledge, attitude and uptake among Saudi Hajj pilgrims: Hajj 2019
Version	1.0
Principal investigator	Osamah Barasheed
IRB number	19-558
Sponsor	NA

Dear Dr. Barasheed,

This is to inform you that the above mentioned proposal has been the subject of exemption from review by KAMC IRB registered at the National BioMedical Ethics Committee, King Abdulaziz City for Science and Technology on 14-07-1433 (Registration no. H-02-K-001) and is following the GCP-ICH regulations (OHRP Registration no. IORG0007625).

The decision of **exemption** from review was based on the following submitted documents:

1. protocol version 1.0
2. Data Collection Form - Arabic version 1.0
3. Data Collection Form - English version 1.

Exemption conditions:

- Subject nominative identifiers should be removed from all questionnaires.
- Subject nominative identifiers should be removed on the extraction sheet, and serial number will be used.
- Maintaining patient confidentiality during publication
- Approval timeframe: The study is approved for **one year** from the date of this letter. Extension can be requested one month before the expiry of the approval.
- To conduct research as per the approved documents
- Amendments to the approved documents require IRB approval before implementation
- Research participant confidentiality should be protected at all times and may be subject to audits by KAMC HRPP
- End of study report is expected before expiration of approval
- Document retention for the study should be retained by the PI in safe locked place for three years after the study closure.

General Approval conditions:

- **If your study involves subject consent: Copy of all consents should be submitted to IRB**
- **Final manuscript should be acknowledged by IRB before Journal Submission**
- **If subject's clinical photo would be used for publication or presentation additional patient consent will be required and should be submitted to IRB before publication.**

N.B.: Please note that this letter gives you ethical clearance to perform your study according to the approved documents; you still need to obtain necessary administrative approval from the site/s where the study will be conducted.

Dr. Saad Saeed Alghamdi

(Name of IRB Chair)

(Signature)

03-Aug-2019

DD/MM/YYYY
(Date of approval)

Appendix #2. The Institutional Review Board of King Abdullah Medical City ethical approval (IRB number: 20-661)



المملكة العربية السعودية Kingdom of Saudi Arabia
وزارة الصحة Ministry of Health
مدينة الملك عبد الله الطبية في العاصمة المقدسة King Abdulla Medical City in Holy capital
الجنة الطبية لاختبارات البحث Institutional Review Board

Institutional Review Board Opinion Letter

Protocol Title	Impact of COVID-19 Pandemic on Hand Hygiene Compliance among 2020 Hajj Pilgrims: A Cross-Sectional Study
Version	1.0
Principal investigator	Ms. Wedian O. Al-Mowallad
IRB number	20-661
Sponsor	NA

Dear Ms. Al-Mowallad,

This is to inform you that the above mentioned proposal has been the subject of exemption from review by KAMC IRB registered at the National BioMedical Ethics Committee, King Abdulaziz City for Science and Technology on 14-07-1433 (Registration no. H-02-K-001) and is following the GCP-ICH regulations (OHRP Registration no. IORG0007625).

The decision of **exemption** from review was based on the following submitted documents:

1. Protocol (HH_Hajj_2020_proposal) Version 1
2. Data collection - HH_Hajj_2020_Survey_(Arabic)_v.1
3. Data collection - HH_Hajj_2020_Survey_(English)_v.1

Exemption conditions:

- ☐ Subject nominative identifiers should be removed from all questionnaires.
- ☐ Subject nominative identifiers should be removed on the extraction sheet, and serial number will be used.
- ☐ Maintaining patient confidentiality during publication
- ☐ Approval timeframe: The study is approved for **one year** from the date of this letter. Extension can be requested one month before the expiry of the approval.
- ☐ To conduct research as per the approved documents
- ☐ Amendments to the approved documents require IRB approval before implementation
- ☐ Research participant confidentiality should be protected at all times and may be subject to audits by KAMC HRPP
- ☐ End of study report is expected before expiration of approval
- ☐ Document retention for the study should be retained by the PI in safe locked place for three years after the study closure.

General Approval conditions:

- ☐ **If your study involves subject consent: Copy of all consents should be submitted to IRB**
- ☐ **Final manuscript should be acknowledged by IRB before Journal Submission**
- ☐ **If subject's clinical photo would be used for publication or presentation additional patient consent will be required and should be submitted to IRB before publication.**

N.B.: Please note that this letter gives you ethical clearance to perform your study according to the approved documents; you still need to obtain necessary administrative approval from the site/s where the study will be conducted.

Dr. Saad Saeed Alghamdi

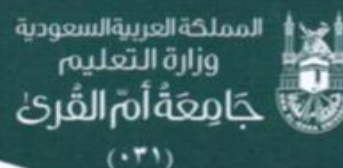
(Name of IRB Chair)

(Signature)

09-Jul-2020

DD/MM/YYYY
(Date of approval)

Appendix #3. The Biomedical Ethics Committee, Umm Al-Qura University ethical approval (Approval no. HAPO-02-K-012-2021-07-708)



Approval No. (HAPO-02-K-012-2021-07-708)

FINAL APPROVAL FROM THE BIOMEDICAL ETHICS COMMITTEE

Principal Investigator: Dr. Fadi Saleh Qashqari	Faculty: Medicine	Date: 18/7/2021
--	--------------------------	------------------------

Proposal Title (in English):

Hajj Pilgrims' Hand Hygiene Practice and Respiratory-Tract Infection Transmission: An Observational Study

The Biomedical Ethics Committee has evaluated and examined the above-mentioned research proposal, and has found it to be in accordance with the specifications and conditions of the ethics of scientific research.

The Committee has accordingly granted the Principal Investigator final approval concerning the ethics of scientific research

Principle Investigator is permitted to:

- Initiate the implementation of scientific research procedures within faculty facilities and laboratories, in addition to the regional research centers and hospitals.
- Publish in scientific journals.

Responsibility of Principal Investigator:

- Must provide a written statement regarding any changes in the research plan, the committee shall decide whether a new approval is needed or not.

Director of Biomedical Ethics Committee
Dr. Aiman M. Momenah



Umm Al-Qura University



Registration No. in National committee of Bio Ethics: HAPO-02-K-012

الرقم : التاريخ : المشغوعات :

Appendix #4. The Institutional Review Board of King Abdullah Medical City ethical approval (IRB number: 21-772)



المملكة العربية السعودية Kingdom of Saudi Arabia
وزارة الصحة Ministry of Health
مدينة الملك عبد الله الطبية في العاصمة المقدسة King Abdulla Medical City in Holy capital
الجنة الطبية أخلاقيات البحث Institutional Review Board

Institutional Review Board Opinion Letter

Protocol Title	Hand hygiene to reducing respiratory-tract infection transmission among Umrah/ Hajj pilgrims: a feasibility trial
Version	1.0
Principal investigator	Dr Osamah Barasheed
IRB number	21-772
Sponsor	NA

Dear Dr. Barasheed,

This is to inform you that the above mentioned proposal has been the subject of exemption from review by KAMC IRB registered at the National BioMedical Ethics Committee, King Abdulaziz City for Science and Technology on 14-07-1433 (Registration no. H-02-K-001) and is following the GCP-ICH regulations (OHRP Registration no. IORG0007625).

The decision of **Expedited** review was based on the following submitted documents:

1. Study protocol V 2 Apr 2021 (Version 2.0)
2. Appendix 1, Arabic baseline questionnaire, V.1, Feb 2021 (Version 1.0)
3. Appendix 1, English baseline questionnaire, V.1, Feb 2021 (Version 1.0)
4. Appendix 2 Arabic instructions of using HH products (Version 1.0)
5. Appendix 2 English instructions of using HH products (Version 1.0)
6. Appendix 3 Arabic Health Dairy V.1 Jan 2021 (Version 1.0)
7. Appendix 3 English Health Dairy V.1 Jan 2021 (Version 1.0)
8. Informed consent, Control group, V.2, April 2021 (Version 2.0)
9. Informed consent, Intervention group, V.2, April 2021 (Version 2.0)

The opinion of the IRB is to **approve** this proposal with its current design:

- The study is approved for one year from the date of this letter. Extension can be requested one month before the expiry of the approval.
- To conduct research as per the approved documents.
- Amendments to the approved documents require IRB approval before implementation.
- End of study report is expected before expiration of approval.
- The study conduct may be subject to audits by KAMC Human Research Protection Program (HRPP).
- Research participant confidentiality should be protected at all times and may be subject to audits by KAMC HRPP.
- Document retention: all study documents should be kept by the principal investigator for a period of three years from study completion.

General Approval conditions:

- **If your study involves subject consent: Copy of all consents should be submitted to IRB**
- **Final manuscript should be acknowledged by IRB before Journal Submission**
- **If subject's clinical photo would be used for publication or presentation additional patient consent will be required and should be submitted to IRB before publication.**

N.B.: Please note that this letter gives you ethical clearance to perform your study according to the approved documents; you still need to obtain necessary administrative approval from the site/s where the study will be conducted.

Dr. Saad Saeed Alghamdi

(Name of IRB Chair)

(Signature)

11-Apr-2021

DD/MM/YYYY
(Date of approval)

Appendix #5. Questionnaire for publication #2

25/06/2020

HAND HYGIENE KNOWLEDGE, ATTITUDE, AND UPTAKE AMONG SAUDI HAJJ PILGRIMS: HAJJ 2019

HAND HYGIENE KNOWLEDGE, ATTITUDE, AND UPTAKE AMONG SAUDI HAJJ PILGRIMS: HAJJ 2019

* Required

1. Participants Code *

2. Date of Participation *

Example: January 7, 2019

Skip to question 3

General information

3. Gender *

Mark only one oval.

☐ Male

☐ Female

4. Age

5. Educational qualification *

Mark only one oval.

- ☐ Non
- ☐ Less than high School certificate
- ☐ High school certificate
- ☐ Certificate/diploma
- ☐ University degree
- ☐ Higher university degree

6. Employment *

Mark only one oval.

- ☐ No
- ☐ Student
- ☐ Full-time
- ☐ Part-time
- ☐ Casual
- ☐ Self-employed

7. Chronic Diseases *

Mark only one oval.

- ☐ No
- ☐ Yes

8. What types of chronic diseases?

9. Number of times you have undertaken the Hajj *

Mark only one oval.

☐ This will be my first time

☐ More than once

10. If "More than once", please specify

Mark only one oval.

☐ 2

☐ 3

☐ 4

☐ 5

☐ More than 5

11. The vaccines that received as preparation for Hajj *

Mark only one oval per row.

	No	Yes	Not Sure
Meningococcal vaccine	☐	☐	☐
Influenza vaccine	☐	☐	☐
Pneumococcal vaccine	☐	☐	☐
Pertussis vaccine	☐	☐	☐
Hepatitis A vaccine	☐	☐	☐
Hepatitis B vaccine	☐	☐	☐
Typhoid vaccine	☐	☐	☐
Polio vaccine	☐	☐	☐
DTP (Diphtheria, Tetanus and Pertussis)	☐	☐	☐

12. Sought of travel health advice before travelling to Hajj *

Mark only one oval.

- ☐ No
- ☐ Yes

13. Where did you get it from?

Check all that apply.

- ☐ A general practitioner/family doctor
- ☐ Hajj tour group leaders and/or travel agents
- ☐ Family and friends
- ☐ Internet "general websites"
- ☐ Internet "special Hajj website" (e.g. Saudi Ministry of Health or Hajj websites)

14. Awareness of the annual health recommendations to Hajj pilgrims issued by Saudi MOH every year? *

Mark only one oval.

☐ No

☐ Yes

15. "Diarrhea" during Hajj *

Mark only one oval.

☐ No

☐ Yes

16. Number of motions per day

Mark only one oval.

☐ 2 or less

☐ 3 or more

17. Duration of Sickness in hours

18. Answer by "Yes" or "No"

Mark only one oval per row.

	No	Yes
Did your stools have blood?	☐	☐
Did your stools have mucus?	☐	☐
Did you have fever at the same time?	☐	☐
Did you take any treatments for diarrhoea or vomiting?	☐	☐

19. Types of Medications if taken

Mark only one oval.

- ☐ Loperamide (Imodium)
- ☐ Antibiotics
- ☐ Oral re-hydration salt/solution
- ☐ Other: _____

Skip to question 20

Hand Hygiene Knowledge, Practice, and Barriers

20. Which of the following diseases can be transmitted by poor hand hygiene? *

Mark only one oval per row.

	True	False	Not sure
Diarrheal disease	☐	☐	☐
Flu, cough (URTI or ILI)	☐	☐	☐
Hand-foot-mouth disease	☐	☐	☐
HIV/AIDS	☐	☐	☐
Skin ulcer	☐	☐	☐
Eye infections	☐	☐	☐
Diabetes	☐	☐	☐

21. Are the following statements correct? *

Mark only one oval per row.

	True	False	Not sure
Always keeping your hands clean may lower our body defense mechanism	☐	☐	☐
An alcohol-based hand sanitizer that contains 40% alcohol is sufficient for hands disinfectant	☐	☐	☐
Hands should be held under water while lathering with soap	☐	☐	☐
Rubbing my hands until soap forms a lather for 10 seconds before rinsing is enough for hand disinfection	☐	☐	☐
Temperature of water makes no difference in terms of the cleansing effect of hand cleaning	☐	☐	☐

22. In the following situations, which methods did you use to clean your hands during Hajj? *

Mark only one oval per row.

	No	Water only	Water and soap	Alcohol-based hand rub	Wet wipes
Before eating	☐	☐	☐	☐	☐
After eating	☐	☐	☐	☐	☐
After using toilet	☐	☐	☐	☐	☐
After caring/shaking a sick person	☐	☐	☐	☐	☐
When your hands are visibly dirty	☐	☐	☐	☐	☐
After sneezing or coughing	☐	☐	☐	☐	☐
After disposal of garbage bag	☐	☐	☐	☐	☐
After shaking hands	☐	☐	☐	☐	☐

23. Have you faced any difficulties in hand washing during Hajj? *

Mark only one oval.

☐ No

☐ Yes

24. Types of Barriers

Appendix #6. Questionnaire for publication #3

Participant serial code	<table border="1"><tr><td></td><td></td><td></td></tr></table>			

Data Collection Form

Impact of COVID-19 Pandemic on Hand Hygiene Compliance among Visitors to Prophet's Mosque in Medina: A Cross-Sectional Study

Dear visitor to Prophet's Mosque,

May Allah accept all your good deeds.

The Custodian of the Two Holy Mosques Institute for Hajj and Umrah Research would like to invite you to participate in this study that aims to measure the extent of the impact of COVID-19 pandemic on the practice and knowledge of hand hygiene. Your participation in this research is voluntary and all data will be confidential and will not be used for any other purpose than for this research. This research has been approved by the Research Ethics Committee of King Abdullah Medical City No. 20-661 dated 9-07-2020. If you agree to participate in this questionnaire, please start filling in the data.

Your participation is highly appreciated and may Allah reward you well.

Participant serial code	
--------------------------------	--

SECTION 1: SOCIODEMOGRAPHIC DATA

Date of Enrolment	<i>Day Month Year</i>		
Age	 <i>Years (e.g. 045)</i>	Gender	☐ Male ☐ Female
Nationality	☐ Saudi ☐ Non-Saudi, specify.....	City of residence in KSA	

1. What is your highest completed educational qualification?		
☐ No education	☐ Less than high school	☐ High school
☐ Diploma	☐ University degree (Bachelor)	☐ Higher university degree (PhD, Masters)

2. Are you employed?	☐ No	☐ Yes
-----------------------------	-----------------------------	------------------------------

3. Do you have any chronic illness?	☐ No (<i>Skip next question</i>)	☐ Yes (<i>Answer next question</i>)
--	---	--

4. What types of chronic diseases you have?		
☐ Diabetes	☐ Chronic heart diseases	☐ Hypertension
☐ Chronic respiratory diseases (including Asthma)	☐ Chronic gastrointestinal disease	☐ Chronic kidney disease
☐ Cancer	☐ Immunosuppression (e.g. HIV, long-term steroid use)	☐ Other:

Participant serial code

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SECTION 2: HAND HYGIENE KNOWLEDGE AND PERCEPTION

5. Please respond to the following statements with 'True' or 'False' or "I don't know".
[1] Respiratory diseases including "COVID-19" can be transmitted by poor hand hygiene ☐ True ☐ False ☐ I don't know
[2] HIV/AIDS can be transmitted by poor hand hygiene ☐ True ☐ False ☐ I don't know
[3] Always keeping your hands clean may lower our body defense mechanism ☐ True ☐ False ☐ I don't know
[4] Alcohol-based hand sanitizer containing less than 60% of alcohol is sufficient for hands disinfection ☐ True ☐ False ☐ I don't know
[5] Hands washing with soap and water from 20 to 40 seconds is sufficient for hands disinfection ☐ True ☐ False ☐ I don't know
[6] Hands should be held under water while lathering with soap ☐ True ☐ False ☐ I don't know
[7] The temperature of water (hot or cold) does not make difference in terms of cleansing effect of hand washing ☐ True ☐ False ☐ I don't know
[8] Antiseptic/antibacterial soaps are more effective at preventing illness than washing with plain soap and water ☐ True ☐ False ☐ I don't know
[9] Use alcohol-based hand sanitizer may not be as effective as use of soap and water when hands are visibly dirty ☐ True ☐ False ☐ I don't know
[10] There is no need to clean our hands after sneezing, coughing, or shaking hands ☐ True ☐ False ☐ I don't know
[11] Ultra-violet (UV) lamps should not be used to disinfect our hands or other areas of our skin ☐ True ☐ False ☐ I don't know
[12] Spraying and introducing bleach or another surface disinfectant into our hands are safe and it will protect us against COVID-19 and other infections ☐ True ☐ False ☐ I don't know

Participant serial code

--	--	--

6. To which extend do you think the following hand hygiene methods would kill microorganisms that may be on our hands including (<i>new Corona Virus</i>).				
	Not effective	Barely effective	Somewhat effective	Very effective
Water only	☐	☐	☐	☐
Plain soap and water	☐	☐	☐	☐
Antiseptic/antibacterial soap and water	☐	☐	☐	☐
Alcohol-based hand sanitizer	☐	☐	☐	☐
Disposable handkerchiefs	☐	☐	☐	☐

SECTION 3: HAND HYGIENE PRACTICE

7. How often have you used the following hand hygiene methods in the past 2 weeks?					
	Never	Seldom 1-3 times/day	Sometimes 4-6 times/day	Frequently 7-9 times/day	At all times
Water only	☐	☐	☐	☐	☐
Soap and water	☐	☐	☐	☐	☐
Alcohol-based hand sanitizer	☐	☐	☐	☐	☐
Disposable handkerchiefs	☐	☐	☐	☐	☐

8. In the following situations, what is the most method have you used to clean your hands in the past 2 weeks?
[1] Before eating ☐ Nothing ☐ Water only ☐ Soap and water ☐ Alcohol-based hand sanitizer ☐ Disposable handkerchiefs
[2] After eating ☐ Nothing ☐ Water only ☐ Soap and water ☐ Alcohol-based hand sanitizer ☐ Disposable handkerchiefs
[3] After using toilet ☐ Nothing ☐ Water only ☐ Soap and water ☐ Alcohol-based hand sanitizer ☐ Disposable handkerchiefs
[4] After touching a surface that may be frequently touched by other people ☐ Nothing ☐ Water only ☐ Soap and water ☐ Alcohol-based hand sanitizer ☐ Disposable handkerchiefs
[5] After taking care of a sick person ☐ Nothing ☐ Water only ☐ Soap and water ☐ Alcohol-based hand sanitizer ☐ Disposable handkerchiefs
[6] When your hands are visibly dirty ☐ Nothing ☐ Water only ☐ Soap and water ☐ Alcohol-based hand sanitizer ☐ Disposable handkerchiefs

Participant serial code	
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[7] After sneezing or coughing ☐ Nothing ☐ Water only ☐ Soap and water ☐ Alcohol-based hand sanitizer ☐ Disposable handkerchiefs
[8] After touching garbage ☐ Nothing ☐ Water only ☐ Soap and water ☐ Alcohol-based hand sanitizer ☐ Disposable handkerchiefs
[9] After shaking hands ☐ Nothing ☐ Water only ☐ Soap and water ☐ Alcohol-based hand sanitizer ☐ Disposable handkerchiefs

9. Select from the following reasons that may hinder your regular hands cleaning in your daily life.	
☐ I am too busy to clean my hands	☐ I always forget to clean my hands
☐ I don't believe that cleaning my hands would protect me from getting sick	☐ I don't need to always clean my hands
☐ I don't know the importance of regular hand hygiene	☐ Lack of or difficult access to hand hygiene products sometimes
☐ I have avoided scented hand hygiene products	☐ I have avoided hand hygiene products that contains alcohol
☐ Other:	

10. Have you recently experienced any side effects from using hand hygiene products?	☐ No (<i>Skip next question</i>) ☐ Yes (<i>Answer next question</i>)
---	--

11. What are these side effects?	
☐ Discomfort	☐ Skin dryness
☐ Peeling skin	☐ Hand allergy
☐ Eczema	☐ Other:

Appendix #7. Baseline questionnaire for publication #4

06/02/2022, 16:30

Microsoft Forms (ممارسة الحجج لنظافة اليدين للوقاية من الأمراض المعدية) (تحرير)

اللغة:English (United Kingdom)

Pilgrims' Hand Hygiene Practice to Reduce Infections Transmission

Dear Hajj pilgrim,

The research team at the College of Medicine - Umm Al-Qura University would like to invite you to participate in this study, which aims to assess the practice of hand hygiene and other preventive measures among Hajj pilgrims and its impact on reducing infectious respiratory diseases. The study was approved by the Research Ethics Committee at Umm Al-Qura University No. (HAPO-02-K-012-2021-07-708).

If you agree to participate, please fill out this questionnaire, which will take about 5 minutes only. We will then contact you after Hajj to check on your health and taking of healthy precautions during the Hajj journey.

Please do not hesitate to contact Dr. Fadi Qashqari or Dr. Hashim Mahdi in case of any inquiries on this mobile number: 

*لتغير الاستبيان الى العربية، اضغط على الأيقونة في اعلى الصفحة

<https://forms.office.com/Pages/DesignPage.aspx?origin=NeoPortalPage#FormId=pzvpe4JE0EmlEnxoGAluM0vRjExpT81CppO-mlDv30FUQUmZnjdNV01UODQ3RjFHQTFINzU4WldVTy4u&Locale=en-gb&TopView...> 1/13

Section 1

Statement of Consent and Approval

I confirm that all aspects related to the study have been explained to me including aims and procedures and that my participation is voluntary with no extra expenses and there is no payment offered to me for participation.

First Name 1.

first and last name

Enter your answer

Last Name 2.

اختياري

Enter your answer

Mobile Number 3.

Enter your answer

Would you like to continue and participate in this study? 4.

☐ Yes

☐ No

Section 2

Demographic Data

Age (years) 5.

Enter your answer

Gender 6.

☐ Man

☐ Woman

Nationality 7.

☐ Saudi

☐ Other

City of residence in Saudi Arabia 8.

Enter your answer

Educational level 9.

☐ No education

☐ Less than high school

☐ High school

☐ Diploma

☐ Bachelor's degree

☐ Postgraduate degree (Masters, PhD)

Current job 10.

☐ Student

☐ Retiree

☐ Not working

☐ Public sector worker

☐ Private sector worker

☐ Self-employed

Section 3

Health Data

Do you have any of the following health conditions? 11.

Mark all that apply of these answers

- ☐ High blood pressure (Hypertension)
- ☐ High blood sugar (Diabetes)
- ☐ Chronic heart disease (e.g. heart attack, heart failure, heart defect)
- ☐ Excess body weight (Obesity)
- ☐ Chronic lung disease (e.g. inflammation or obstruction of lungs airways, asthma)
- ☐ Neurological conditions (e.g. stroke, dementia)
- ☐ Chronic Kidney disease (e.g. chronic renal failure, on dialysis)
- ☐ Chronic Liver disease (e.g. liver damage)
- ☐ Immune suppression (e.g. HIV/AIDS, organ transplantation)
- ☐ Using immune suppression medications
- ☐ Cancer
- ☐ Irritable bowel syndrome

Are you a smoker? 12.

- ☐ No, never smoked
- ☐ Yes, current smoker
- ☐ Ex-smoker

☐ Living with a smoker

Do you have fever, cough, cold, or any other respiratory symptoms? 13.

☐ No

☐ Yes

During the Hajj journey, how many of your roommates/tentmates had a fever, cough, cold, or any other respiratory symptoms? 14.

☐ None

☐ Some

☐ Nearly all

☐ Not sure

Have you got the influenza (flu) vaccine this year? 15.

☐ No

☐ Yes

☐ Not sure

Have you been tested positive for COVID-19? 16.

- ☐ No
- ☐ Yes
- ☐ Not sure

Have you got the COVID-19 vaccine? 17.

- ☐ No
- ☐ Yes

Which type of COVID-19 vaccine have you got in the first dose? 18.

- ☐ Oxford/AstraZeneca
- ☐ Pfizer
- ☐ Moderna
- ☐ Other

Which type of COVID-19 vaccine have you got in the second dose? 19.

☐ I have not got the second dose

☐ Oxford/AstraZeneca

☐ Pfizer

☐ Moderna

☐ Other

Have you experienced any side effects of COVID-19 vaccines? 20.

☐ No

☐ Yes

☐ Not sure

What are these side effects? 21.

Mark all that apply of these answers

☐ Pain or redness at the injection site

☐ Fatigue and headache

☐ Muscle pain

☐ Fever and chills

☐ Difficulty breathing☐ Diarrhoea☐ Other

Section 4

Knowledge and Attitudes about Preventive Health Measures

From which sources did you get the health information about preventive measures before coming for Hajj? 22.

Mark all that apply of these answers

☐ Healthcare Professionals☐ Ministry of Health/Hajj Awareness Campaigns☐ Hajj Company/Hamlah☐ Social Media (Twitter, Facebook, WhatsApp, etc.)☐ Internet Websites☐ Family and Friends

Other

Answer the following questions with "True, False, or Not Sure" 23.

if you are using the phone, please click on the arrows to open answers

	True	False	Not sure
Respiratory tract infections including "COVID-19" can be transmitted by poor hand hygiene	☐	☐	☐
Alcohol hand sanitizer containing less than 60% of alcohol is sufficient for hands disinfection	☐	☐	☐
Hands washing with soap and water from 20 to 40 seconds is sufficient for hands disinfection	☐	☐	☐
Hands should be held under water while lathering with soap	☐	☐	☐

	True	False	Not sure
Water temperature (hot or cold) does not make difference in cleaning effect of hands washing	☐	☐	☐
Use of alcohol hand sanitizer is not as effective as use of soap and water when hands are visibly dirty	☐	☐	☐

To what extent do you think the following hands cleaning methods are effective to kill the germs 24. that we carry on our hands, such as (new coronavirus)?

if you are using the phone, please click on the arrows to open answers

	Not Effective	Somewhat effective	Very Effective
Water only	☐	☐	☐
Soap and water	☐	☐	☐
Alcohol hand sanitizer	☐	☐	☐
Disposable tissues	☐	☐	☐

Appendix #8. Follow-up questionnaire for publication #4

06/02/2022, 16:32

Microsoft Forms (نموذج متابعة الحالة الصحية للحجاج (1) وممارستهم الإجراءات الوقائية خلال رحلة الحج (تحرير

اللغة:English (United Kingdom)

Health Follow-up Form for Hajj Pilgrims and their Practice of Preventive Measures

Dear Hajj pilgrim,

Thank you for your time to fill out this form about your health and hand hygiene practice. The form will take about 5 minutes to complete.

*لتغيير الاستبيان الى العربية، اضغط على الأيقونة في اعلى الصفحة

Section 1

Participant ID

Participant's Name 1.

Enter your answer

Mobile Number 2.

Enter your answer

Section 2

Pilgrims' Health Follow-up

During the last week, have you had cough, cold, sore throat or shortness of breath? 3.

من يوم ١٣ ذو الحجة الى اليوم

☐ No

☐ Yes

Mark all of these symptoms that apply to you 4.

☐ Fever

☐ Cough

☐ Sore throat

☐ Runny nose

☐ Short of breath

☐ Tiredness

☐ Body pain

☐ Headache

☐ Loss of smell or taste

☐ Other

When did you start feeling these symptoms? 5.

Please input date (dd/MM/yyyy)

Did you visit a hospital or clinic to treat these symptoms? 6.

☐ No

☐ Yes

Did you get tested for coronavirus (COVID-19) because of these symptoms? 7.

☐ No

☐ Yes

What was the result of this test of coronavirus (COVID-19)? 8.

☐ Negative (-)

☐ Positive (+)

☐ Not sure

Have you had diarrhea during the last week? 9.

من يوم ١٣ ذو الحجة الى اليوم

☐ No

☐ Yes

Mark all of these symptoms accompanied with diarrhea that apply to you 10.

☐ Fever

☐ Nausea/vomiting

☐ Stomach ache

☐ Dehydration

☐ blood in stool

☐ Mucus in stool

For how many days did you have diarrhea? 11.

☐ One day

☐ Two days

☐ Three days or more

How frequently did diarrhea occur? 12.

☐ Less than 3 times/day

☐ From 3 - 6 times/day

☐ More than 6 time/day

Did you visit a hospital or clinic to treat diarrhea? 13.

☐ No

☐ Yes

Section 3

Practice of Preventive Measures during the Hajj Journey

How often did you use the following hands cleaning methods during Hajj journey? 14.

if you are using the phone, please click on the arrows to open answers

	Never	Rarely (1-3 times/day)	Sometimes (4-6 times/day)	Frequently (7-9 times/day)	All the time (more than 9 times/day)
Water only	☐	☐	☐	☐	☐
Soap and water	☐	☐	☐	☐	☐
Alcohol hand sanitizer	☐	☐	☐	☐	☐
Disposable tissues	☐	☐	☐	☐	☐

At which of these times did you clean your hands regularly during Hajj journey? 15.

Mark all that apply of these times

- ☐ Before eating
- ☐ After eating
- ☐ After using toilet
- ☐ When hands are visibly dirty
- ☐ After nose blowing, sneezing, or coughing
- ☐ After touching garbage
- ☐ After shaking hands
- ☐ After touching frequently used surfaces or objects

Which of these reasons that helped you in cleaning your hands during Hajj journey? 16.

Mark all that apply of these reasons

- ☐ I do not want to get sick
- ☐ I believe that cleaning my hands would protect me from getting sick
- ☐ I know the protective role of regular hand hygiene practice
- ☐ It is easy to use the hands cleaning products

☐ Hands cleaning products were available most of times

☐ Ministry of Health/Hajj awareness campaigns

☐ Other

Which of these reasons that limited you from cleaning your hands during Hajj journey? 17.

Mark all that apply of these reasons

☐ So busy to clean my hands

☐ Always forget to clean my hands

☐ Feeling Lazy to clean my hands

☐ I don't believe that cleaning my hands would protect me from getting sick

☐ I don't not know the protective role of regular hand hygiene practice

☐ Hands cleaning products were not available sometimes

☐ Avoiding scented hands cleaning products

☐ Avoiding alcoholic hands cleaning products

☐ Other

What was your main source of food during Hajj journey? 18.

06/02/2022, 16:32

Microsoft Forms (نموذج متابعة الحالة الصحية للحجاج (1) وممارستهم الإجراءات الوقائية خلال رحلة الحج (تحرير

☐ Canned and dry foods

☐ Restaurants

☐ Food provided by the Hamlah/company

☐ Other

Did you eat raw food or vegetables during Hajj journey? 19.

☐ No

☐ Yes

Appendix #9. Questionnaire for publication #5

اللغة:English (United Kingdom)

A Health Survey on the Transmission of Respiratory Infections among Hajj 2021 Pilgrims

Dear Hajj pilgrim,

The research team at the College of Medicine - Umm Al-Qura University would like to invite you to participate in this health survey, which aims to estimate the incidence of transmission of respiratory infections during the Hajj season 1442 AH. The study was approved by the Research Ethics Committee at Umm Al-Qura University No. (HAPO-02-K-012-2021-07-708).

If you agree to participate, please fill out this questionnaire, which will take few minutes.

Please do not hesitate to contact Dr. Fadi Qashqari or Dr. Hashim Mahdi in case of any inquiries on this mobile number: 

*لتغير الاستبيان الى العربية، اضغط على الأيقونة في اعلى الصفحة

Section 1

Health Status of Hajj Pilgrims

After completing the Hajj, did you suffer from fever, cough, cold, sore throat or shortness of breath?

☐ No

☐ Yes

Mark all of these symptoms that apply to you 2.

☐ Fever

☐ Cough

☐ Sore throat

☐ Runny nose

☐ Short of breath

☐ Tiredness

☐ Body pain

☐ Headache

☐ Loss of smell or taste

☐ Vomiting

☐ Diarrhea

When did you start feeling these symptoms? 3.

Please input date (dd/MM/yyyy)

For how many days did you have these symptoms? 4.

Enter your answer

Did you visit a hospital or clinic to treat these symptoms? 5.

☐ No

☐ Yes

Did you get tested for coronavirus (COVID-19) because of these symptoms? 6.

☐ No

☐ Yes

What was the result of this test of coronavirus (COVID-19)? 7.

☐ Negative (-)

☐ Positive (+)

☐ Not sure

Have any of your contact at home or work, who is not pilgrim, showed similar symptoms? 8.

☐ No

☐ Yes

During the Hajj journey, how many of your roommates/tentmates had a fever, cough, cold, or any other respiratory symptoms?

☐ None

☐ Some

☐ Nearly all

☐ Not sure

Pilgrims' General Information

Age (years) 10.

Enter your answer

Gender 11.

☐ Man

☐ Woman

Nationality 12.

☐ Saudi

☐ Other

Educational level 13.

- ☐ No education
- ☐ Less than high school
- ☐ High school
- ☐ Diploma
- ☐ Bachelor's degree
- ☐ Postgraduate degree (Masters, PhD)

Do you have any of the following health conditions? 14.

Mark all that apply of these answers

- ☐ High blood pressure (Hypertension)
- ☐ High blood sugar (Diabetes)
- ☐ Chronic heart disease (e.g. heart attack, heart failure, heart defect)
- ☐ Excess body weight (Obesity)
- ☐ Chronic lung disease (e.g. inflammation or obstruction of lungs airways, asthma)
- ☐ Neurological conditions (e.g. stroke, dementia)
- ☐ Chronic Kidney disease (e.g. chronic renal failure, on dialysis)
- ☐ Chronic Liver disease (e.g. liver damage)
- ☐ Immune suppression (e.g. HIV/AIDS, organ transplantation)

☐ Using immune suppression medications

☐ Cancer

Are a smoker? 15.

☐ No, never smoke

☐ Yes, current smoker

☐ Ex-Smoker

☐ Live with a smoker

Have you been tested positive for COVID-19? 16.

☐ No

☐ Yes

☐ Not sure

Which type of COVID-19 vaccine have you got in the first dose? 17.

☐ I have not got the first dose

☐ Oxford/AstraZeneca

☐ Pfizer

☐ Moderna

☐ Other

Which type of COVID-19 vaccine have you got in the second dose? 18.

☐ I have not got the second dose

☐ Oxford/AstraZeneca

☐ Pfizer

☐ Moderna

☐ Other

Have you got the influenza (flu) vaccine this year? 19.

☐ No

☐ Yes

☐ Not sure

Appendix #10. Baseline questionnaire for publication #6

اللغة:English (United Kingdom)

Baseline Form of Studying Hand Hygiene among Umrah Pilgrims

Dear Umrah pilgrim,

Thank you for your time to fill out this form. The form will take about 10 minutes to complete.

*لتغير الإستبيان الى العربية، اضغط على الأيقونة في اعلى الصفحة

Section 1

Participant's ID

First name in English 1.

Enter your answer

Last name in English 2.

Enter your answer

Mobile number 3.

Enter your answer

Section 2

Statement of consent and approval

I confirm that all aspects related to the study have been explained to me including aims and procedures and that my participation is voluntary with no extra expenses and there is no payment offered to me for participation. I have been given a copy of the information sheet.

Would you like to continue and participate in this study? 4.

☐ Yes

☐ No

Section 3

Demographic Data

Age (years) 5.

Enter your answer

Gender 6.

☐ Man

☐ Women

Nationality 7.

☐ Saudi

☐ Other

City of residence in Saudi Arabia 8.

Enter your answer

Marital status 9.

☐ Single

☐ Married

☐ Divorced

☐ Widower

Educational level 10.

☐ No education

☐ Less than high school

☐ High school

☐ Diploma

☐ Bachelor's degree

☐ Postgraduate degree (Masters, PhD)

Current job 11.

☐ Student

☐ Retired

☐ Not working

☐ Public sector worker

☐ Private sector worker

☐ Self-employed

Arrival date to Makkah 12.

In Gregorian calendar

Please input date (dd/MM/yyyy)

Leaving date from Makkah 13.

In Gregorian calendar

Please input date (dd/MM/yyyy)

Section 4

Health Data

Do you have any of the following health conditions? 14.

Mark all that apply of these answers

- ☐ High blood pressure (Hypertension)
- ☐ High blood sugar (Diabetes)
- ☐ Chronic heart disease (e.g. heart attack, heart failure, heart defect)
- ☐ Excess body weight (Obesity)
- ☐ Chronic lung disease (e.g. inflammation or obstruction of lungs airways, asthma)
- ☐ Neurological conditions (e.g. stroke, dementia)

☐ Chronic Kidney disease (e.g. chronic renal failure, on dialysis)

☐ Chronic Liver disease (e.g. liver damage)

☐ Immune suppression (e.g. HIV/AIDS, organ transplantation)

☐ Using immune suppression medications

☐ Cancer

Are you a smoker? 15.

☐ No, never smoked

☐ Yes, current smoker

☐ Ex-smoker

Since you have arrived in Makkah, have you visited a hospital or a clinic for cough and fever? 16.

☐ No

☐ Yes

☐ Not sure

Since you have arrived in Makkah, how many of your roommates have had coughs, colds, chest infections or similar symptoms? 17.

- ☐ None
- ☐ Some
- ☐ Nearly all

Have you been tested positive for COVID-19? 18.

- ☐ No
- ☐ Yes
- ☐ Not sure

Have you received the COVID-19 vaccine? 19.

- ☐ No
- ☐ Yes
- ☐ Not sure

Which type of COVID-19 vaccine have you received? 20.

☐ Oxford/AstraZeneca

☐ Pfizer

☐ Moderna

☐ Johnson & Johnson

☐ Not sure

How many doses of the vaccine have you received? 21.

☐ One dose

☐ Two doses

☐ Not sure

Have you received the influenza (flu) vaccine this year? 22.

☐ No

☐ Yes

☐ Not sure

Have you received the pneumococcal vaccine (for pneumonia) in the last 5 years? 23.

☐ No

☐ Yes

☐ Not sure

Have you taken any vitamin supplements in the last month? 24.

☐ No

☐ Yes

☐ Not sure

Have you taken any herbal medicine in the last month? 25.

☐ No

☐ Yes

☐ Not Sure

Section 5

Hand Hygiene Knowledge and Practice

From which sources did you get the information about hand hygiene? 26.

Mark all that apply of these answers

- ☐ Healthcare Professionals
- ☐ Social Media (Twitter, Facebook, WhatsApp, etc.)
- ☐ Internet Websites
- ☐ Ministry of Health Awareness Campaigns
- ☐ Family and Friends
- ☐ Other

Answer the following questions with "True, False, or Not Sure" 27.

if you are using the phone, please click on the arrows to open answers

	True	False	Not sure
Respiratory tract infections including "COVID-19" can be transmitted by poor hand hygiene	☐	☐	☐

	True	False	Not sure
Alcohol hand sanitizer containing less than 60% of alcohol is sufficient for hands disinfection	☐	☐	☐
Hands washing with soap and water from 20 to 40 seconds is sufficient for hands disinfection	☐	☐	☐
Hands should be held under water while lathering with soap	☐	☐	☐
Water temperature (hot or cold) does not make difference in cleaning effect of hands washing	☐	☐	☐
Use of alcohol hand sanitizer is not as effective as use of soap and water when hands are visibly dirty	☐	☐	☐

To what extent do you think the following hands cleaning methods are effective to kill the germs that we carry on our hands, such as (new coronavirus)?

if you are using the phone, please click on the arrows to open answers

	Not Effective	Somewhat effective	Very Effective
Water only	☐	☐	☐
Plain soap and water	☐	☐	☐
Antiseptic/antibacterial soap and water	☐	☐	☐
Alcohol hand sanitizer	☐	☐	☐
Disposable tissues	☐	☐	☐

How often did you use the following hands cleaning methods in the last 2 weeks? 29.

if you are using the phone, please click on the arrows to open answers

	Never	Rarely (1-3 times/day)	Sometimes (4-6 times/day)	Frequently (7-9 times/day)	All the time (more than 9 times/day)
Water only	☐	☐	☐	☐	☐
Soap and water	☐	☐	☐	☐	☐
Alcohol hand sanitizer	☐	☐	☐	☐	☐
Disposable tissues	☐	☐	☐	☐	☐

At which of these times did you clean your hands regularly in the last 2 weeks? 30.

Mark all that apply of these answers

- ☐ Before eating
- ☐ After eating
- ☐ After using toilet
- ☐ When hands are visibly dirty
- ☐ After nose blowing, sneezing, or coughing
- ☐ After touching garbage
- ☐ After shaking hands
- ☐ After touching frequently used surfaces or objects

Customise thank you message

This form has been successfully completed and make sure all your information is confidential.

After one week, we will contact you to follow up on your health and hand hygiene practice.

Greetings from the research team.

اللغة:English (United Kingdom)

Health Follow-up Form of Studying Hand Hygiene among Umrah Pilgrims

Dear Umrah pilgrim,

Thank you for your time to fill out this form about your health and hand hygiene practice. The form will not take more than 5 minutes to complete.

*لتغيير الإستبيان الى العربية، اضغط على الأيقونة في اعلى الصفحة

Section 1

Participant ID

First name in English 1.

Enter your answer

Last name in English 2.

Enter your answer

Mobile number 3.

Enter your answer

Section 2

Information about your health condition

Since performing the Umrah, have you experienced any of the following health symptoms? 4.

if you are using the phone, please click on the arrows to open answers

	No	Yes
Fever	☐	☐
Cough	☐	☐
Sore throat	☐	☐
Runny nose	☐	☐
Tiredness	☐	☐
Body pain	☐	☐
Headache	☐	☐
Short of breath	☐	☐
Loss of smell or taste	☐	☐
Vomiting	☐	☐
Diarrhea	☐	☐

If you have had any of these symptoms, when did you start feeling these symptoms? 5.

In Gregorian calendar

Please input date (dd/MM/yyyy)

If you have had any of these symptoms, have you visited a hospital or clinic to treat them? 6.

☐ No

☐ Yes

☐ Not sure

Did you get tested for coronavirus (COVID-19) during the last week? 7.

☐ No

☐ Yes

☐ Not sure

What was the result of this test for coronavirus (COVID-19)? 8.

☐ Negative (-)

☐ Positive (+)

☐ Not sure

Section 3

Information about your hand hygiene practice

Since you taking part in the study (in the last week), how often have you used the following hands cleaning methods? 9.

if you are using the phone, please click on the arrows to open answers

	Never	Rarely (1-3 times/day)	Sometimes (4-6 times/day)	Frequently (7-9 times/day)	All the time (more than 9 times/day)
Water only	☐	☐	☐	☐	☐
Soap and water	☐	☐	☐	☐	☐
Alcohol hand sanitizer	☐	☐	☐	☐	☐
Disposable tissues	☐	☐	☐	☐	☐

Since you taking part in the study (in the last week), at which of these times have you cleaned your hands regularly or daily? 10.

Mark all that apply of these times

☐ Before eating

☐ After eating

- ☐ After using toilet
- ☐ When hands are visibly dirty
- ☐ After nose blowing, sneezing, or coughing
- ☐ After touching garbage
- ☐ After shaking hands
- ☐ After touching frequently used surfaces or objects

Which of these reasons may help you in cleaning your hands regularly? 11.

Mark all that apply of these reasons

- ☐ I do not want to get sick
- ☐ I believe that cleaning my hands would protect me from getting sick
- ☐ I know the protective role of regular hand hygiene practice
- ☐ Ease of use the hands cleaning products
- ☐ Hands cleaning products are available most of times
- ☐ Ministry of Health awareness campaigns
- ☐ Other

Which of these reasons may limit you from cleaning your hands regularly? 12.

Mark all that apply of these reasons

- ☐ I am too busy to clean my hands
- ☐ I always forget to clean my hands
- ☐ I don't believe that cleaning my hands would protect me from getting sick
- ☐ I don't not know the protective role of regular hand hygiene practice
- ☐ Hands cleaning products are not available sometimes
- ☐ I avoid scented hands cleaning products
- ☐ I avoid alcoholic hands cleaning products
- ☐ Other

Have you had lately any side effects from using hands cleaning products? 13.

- ☐ No
- ☐ Yes

What are these side effects? 14.

Mark all that apply of these side effects

☐ Skin dryness

☐ Peeling of skin

☐ Hand allergy

☐ Sore (painful) hands

☐ Eczema

☐ Other

Customise thank you message

The study has been successfully completed and make sure that all your information is confidential.

Your participation is highly appreciated! We wish you a life-long of health and wellness.

Greetings from the research team