International Journal of Infectious Diseases 47 (2016) 105–111

Contents lists available at ScienceDirect

International Journal of Infectious Diseases

journal homepage: www.elsevier.com/locate/ijid

Uptake and effectiveness of facemask against respiratory infections at mass gatherings: a systematic review

Osamah Barasheed [a,b,*], Mohammad Alfelali [b,c], Sami Mushta [d], Hamid Bokhary [e], Jassir Alshehri [a], Ammar A. Attar [f,g,h], Robert Booy [b,i], Harunor Rashid [b,i]

[a] Research Center, King Abdullah Medical City (KAMC), Makkah, P.O. Box: 57657, Saudi Arabia
[b] National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS), The Children's Hospital at Westmead, NSW, Australia
[c] Department of Family and Community Medicine, Faculty of Medicine, King Abdulaziz University, Rabigh, Saudi Arabia
[d] Ministry of Health, Abha, Saudi Arabia
[e] Umm Al-Qura University Medical Center, Umm Al-Qura University, Makkah, Saudi Arabia
[f] Department of Laboratory Medicine, Faculty of Applied Medical Sciences, Umm Al-Qura University, Makkah, Saudi Arabia
[g] Science and technology Unit, General Presidency for the Holy Mosque & Prophet Holy Mosque affairs, Makkah, Saudi Arabia
[h] Department of Innovation & Corporate Integration, King Abdullah Medical City (KAMC), Makkah, Saudi Arabia
[i] Marie Bashir Institute for Infectious Diseases and Biosecurity, School of Biological Sciences and Sydney Medical School, The University of Sydney, Australia

ARTICLE INFO

Article history:
Received 16 February 2016
Received in revised form 18 March 2016
Accepted 24 March 2016

Corresponding Editor: Eskild Petersen, Aarhus, Denmark.

Keywords:
Facemask
Hajj
Influenza-like illness
Mass gathering
Pilgrim
Respiratory infections

ABSTRACT

Objectives: The risk of acquisition and transmission of respiratory infections is high among attendees of mass gatherings (MGs). Currently used interventions have limitations yet the role of facemask in preventing those infections at MG has not been systematically reviewed. We have conducted a systematic review to synthesise evidence about the uptake and effectiveness of facemask against respiratory infections in MGs.

Methods: A comprehensive literature search was conducted according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines using major electronic databases such as, Medline, EMBASE, SCOPUS and CINAHL.

Results: Of 25 studies included, the pooled sample size was 12710 participants from 55 countries aged 11 to 89 years, 37% were female. The overall uptake of facemask ranged from 0.02% to 92.8% with an average of about 50%. Only 13 studies examined the effectiveness of facemask, and their pooled estimate revealed significant protectiveness against respiratory infections (relative risk [RR] = 0.89, 95% CI: 0.84-0.94, $p < 0.01$), but the study end points varied widely.

Conclusion: A modest proportion of attendees of MGs use facemask, the practice is more widespread among health care workers. Facemask use seems to be beneficial against certain respiratory infections at MGs but its effectiveness against specific infection remains unproven.

1. Introduction

The risk of acquisition and transmission of respiratory infections amplifies at mass gatherings (MGs) straining healthcare of the host country. For instance, in Hajj, one of the largest annual MG events in the world, more than 2 million people attend each year in Makkah, and over 90% suffer from at least one respiratory symptom, the risk of viral respiratory infections increases several folds and more severe respiratory infections such as pneumonia are the leading causes of hospital admission.[1–3] Likewise, a number of influenza outbreaks were reported during the World Youth Day 2008, a large catholic gathering in Sydney.[4] MGs are also linked to globalisation of various infections. For instance, the Iztapalapa Play Passion, a religious festival in Mexico, was believed to spark the outbreak of swine flu leading to its accelerated dissemination across the world.[5] Therefore, international public health agencies, including World Health Organization (WHO), have issued guidelines on mass gathering preparedness to minimise the possible risks.[6]

From a public health perspective, one of the key concerns is to prevent global spread of respiratory infections during MGs. Interventions like vaccinations against viral and bacterial respiratory infections, anti-influenza prophylaxis and hand hygiene are

* Corresponding author. Tel.: +966 503 362 068.
E-mail address: barasheed.o@kamc.med.sa (O. Barasheed).

http://dx.doi.org/10.1016/j.ijid.2016.03.023

considered as preventive measures but the measures have limitations. For instance, vaccinations against respiratory infections, such as influenza, are recommended for travellers to MGs such as Hajj,[7] and even though a recent systematic review generally supports its effectiveness against laboratory-confirmed influenza at Hajj,[8] frequent mismatch between vaccine strains and circulating strains is an important concern.[9] Soaring antiviral resistance against both adamantanes and neuraminidase inhibitors is an issue that limits their widespread use in MGs.[4,10] Similarly, while hand hygiene has been recommended as a protective measure for attendees of MGs, its effectiveness is not fully evaluated in a mass gathering setting and the efficacy is debatable.[11] Therefore, the role of another protective measure, facemask, should be explored in the prevention of respiratory infections.[12] Facemask is believed to have a protective role in preventing nosocomial infections since the time of Spanish influenza.[13] Several studies have assessed the usefulness of facemask in household, community and healthcare settings, the findings of which have been summarised in a few reviews.[14–16] Noticeable disparities of facemask effectiveness between these studies were observed. Studies conducted in community or health care settings found facemasks to be generally effective against influenza-like illness (ILI) or even against severe acute respiratory syndrome (SARS) but its effectiveness against respiratory infections at MGs remains unknown.[15,17] A review of non-pharmaceutical interventions against respiratory tract infections among Hajj pilgrims presented data on the uptake of facemask and acknowledged that compliance was generally poor, but did not evaluate its effectiveness during Hajj.[11] Subsequently, further data on the uptake and effectiveness have become available, especially from a pilot randomised controlled trial (RCT).[18] The aim of this systematic review is to explore the uptake and effectiveness of facemask against respiratory infections in MGs.

2. Methods

Studies were identified through searching electronic databases including; Medline (PubMed and Ovid), EMBASE, SCOPUS and CINAHL from database inception to February 8, 2016. We used a combination of MeSH terms and text words including: 'crowding' OR 'mass gathering' OR 'large event' OR 'group assembly' OR 'holiday' OR 'travel' OR 'sport' OR 'Olympic' OR 'FIFA' OR 'festival' OR 'Hajj' (also alternative spelling 'Hadj' or 'Haj') OR 'pilgrimage' AND 'mask' OR 'facemask' OR 'surgical mask' OR 'medical mask' OR 'simple mask' AND 'infection' OR 'respiratory tract diseases' OR 'disease outbreaks' OR 'infectious disease' OR 'respiratory tract infections' OR 'influenza' OR 'pneumonia'. Additionally, an online search of pertinent epidemiology journals, including those not indexed in the mentioned databases (e.g. Saudi Epidemiology Bulletin) was carried out through free hand Google engine search. Finally, manual search was performed reviewing reference lists of included studies to identify additional potentially relevant studies. The search result was presented according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines (Figure 1).[19]

In the first phase, three authors (OB, SM and HB) identified the potential titles, and sifted the titles and abstracts against the inclusion criteria. Titles of all studies published in English language and reported the use or effectiveness of facemask against respiratory infections in MGs were preliminarily included. Studies that dealt with attendees of MGs of any age, gender and country were considered for inclusion. At the end of the screening phase, full texts of potentially relevant studies were retrieved for detailed study. Finally studies that met the inclusion criteria were included for data synthesis. Duplicates were excluded.

Five authors (OB, MA, HB, SM and JA) independently extracted the data from each study into a data extraction sheet which was

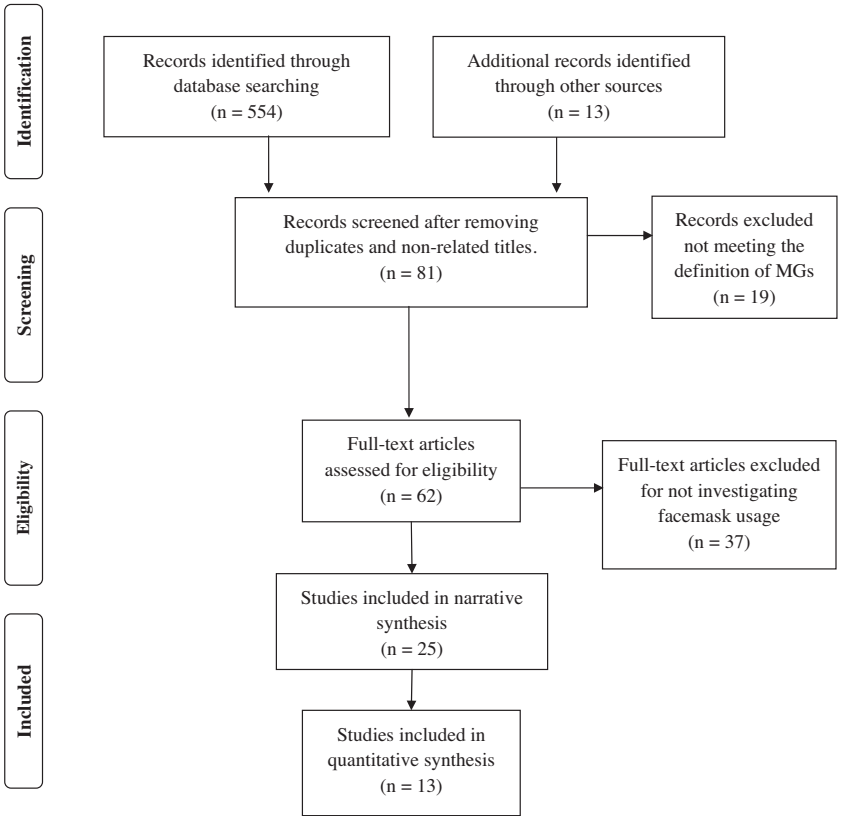

Figure 1. Flow diagram of searching strategy.

divided in two sections, 'facemask uptake' and 'facemask effectiveness' and five authors subsequently cross-checked the entries (OB, AA, HB, SM and JA),while a sixth author (HR) arbitrated when a discrepancy occurred. The following data were abstracted in each extraction sheet: study design, year of conducting the study, sample size, country of origin, age, gender, diagnostic method used, definitions of study end point, and history of participants' chronic diseases, if available.

The quality of the included studies were categorised according to a modified ranking criteria based on Oxford Evidence Based Medicine (http://www.cebm.net/) into groups (e.g., A, B, C, D) where A was for RCTs of adequate sample size, B for observational studies of adequate sample size with good quality or pilot RCTs or non-randomised trial, C for observational studies of inadequate sample size or of poor quality, and D for cases series, such as focus groups or qualitative surveys.

3. Results

3.1. General description

The search results are summarised in Figure 1. Briefly, of 567 abstracts and titles scanned ultimately 25 studies were included. All examined facemask uptake; of them, 13 studies also examined the effectiveness of facemask. The studies were conducted between 1999 and 2014 involving participants from 55 countries. Almost all the included studies involved Hajj pilgrims or other attendees of Hajj pilgrimage such as health care workers (HCWs) at Hajj. Four (out of 25) studies purely focused on the use of facemask against respiratory infections in MGs,[18,20–22] the other 21 studies included facemasks as a part of other intervention measures, or in the context of another research question.

The study sample sizes varied widely ranging from 10 to 1717 participants. The included studies contained the pooled data of 12710 participants aged between 11 and 89 years (mean age ranged from 33.5 to 61.7 years in individual studies). About 37% of the pooled samples were females, in individual studies the proportion of females ranged from 10% to 63%. Excluding three studies, which involved HCWs deployed at Hajj,[23–25] all other included studies involved Hajj pilgrims. The origin of the participants varied depending on the study, seven studies included multinational participants, while the other 18 were exclusive to participants from a single country of origin; seven out of 18 (38.9%) were from Saudi Arabia,[20,23–28] According to study types 11 out of 25 were cohort studies,[1,2,22–24,28–33] another 11 cross-sectional studies,[21,25–27,34–40] two trials (not necessarily RCTs)[18,20] and one case-series conducted as a qualitative study[41] (Table 1).

3.2. Uptake of facemask

The median uptake of facemask in pooled sample was 53.5%. The lowest reported uptake was 0.02% by Elachola et al. among

Table 1
Characteristics of included studies that examined facemask uptake among Hajj attendees in the last decade

Author	Study year	Study type	Study population	Gender female %	Mean age (range) years	Chronic disease %	Facemask uptake %	Reason for non-compliance	Ranking
Al-Shihry et al[35]	1999	Cross-sectional	1707 international pilgrims	NR	NR	NR	24	NR	D
Al-Maghderi et al[34]	2002	Cross-sectional	1374 international pilgrims	13.6	43	13.2	33.2	NR	C
Zein, U[22]	2002	Cohort	447 Indonesian pilgrims	63.1	52.4 (40-64.8)	40.9	48.4	NR	C
Choudhry et al[28]	2002	Cohort	1027 Saudi Arabia pilgrims	27	33.5 (21.8-45.2)	8.1	53.6	NR	C
Aljoudi et al[27]	2003	Cross-sectional	451 Saudi Arabia pilgrims	30.6	NR	NR	35.3	NR	D
Abdin et al[20]	2004	Trial	995 Saudi Arabia pilgrims	43	35.3 (21.6-49)	26	51.3	NR	C
Al-Asmary et al[24]	2005	Case control	250 Saudi Arabia HCWs	12.8	37 (28.3-45.7)	NR	92.8	NR	C
Al-Zahrani et al[36]	2006	Cross-sectional	500 international pilgrims	10	43.5 (11-84)	NR	59.4	NR	C
Khamis et al[38]	2007	Cross-sectional	248 international pilgrims	54.4	40.1 (22.5-57.7)	39.1	12.1	NR	C
Deris et al[37]	2007	Cross-sectional	387 Malaysian pilgrims	43.9	50.4 (39.4-61.4)	NR	72.9	NR	C
Elachola et al[21]	2009	Cross-sectional	international photo frames	23	NR	NR	8.4	NR	D
Balaban et al[30]	2009	Cohort	186 USA pilgrims	50.5	48.9 (16-89)	16.7	48.9	NR	C
Al-Jasser et al[26]	2009	Cross-sectional	1507 Saudi Arabia pilgrims	38.3	37.9 (21-83)	18.4	56.5	NR	B
Ahmed et al[23]	2009	Cohort	126 Saudi Arabia HCWs	20.6	38.7 (28.9-48.5)	-	50	NR	C
Memish et al[25]	2009	Cross-sectional	104 Saudi Arabia HCWs	15	40.9 (23-59)	15	73.1	NR	C
Gautret et al[33]	2009	Cohort	274 French pilgrims	47.7	58 (23-83)	49.3	79.6	NR	C
Maslamani et al[39]	2010	Cross-sectional	1717 international pilgrims	36.3	46.2 (34.7-57.7)	27.1	55.4	NR	C
Emamian et al[31]	2010	Cohort	95 Iranian pilgrims	42.1	NR	48.4	60	NR	D
Barasheed et al[18]	2011	RCT	164 Australian pilgrims	56.7	44.1 (17-80)	22	40.9	Discomfort	B
Benkouiten et al[1]	2012	Cohort	137 French pilgrims	61.7	59.3 (21-83)	57.5	55.1	NR	C
Elachola et al[21]	2013	Cross-sectional	International pilgrims	16	NA	NA	0.02	NR	D
Benkouiten et al[2]	2013	Cohort	129 French pilgrims	59.7	61.7 (34-85)	52.7	53.5	NR	C
Hashim et al[40]	2013	Cross-sectional	468 Malaysian pilgrims	43.8	52.5 (42.4- 62.7)	51	68.8	NR	C
Alqahtani et al[29]	2014	Cohort	25 international pilgrims	41.5	37.1 (21-61)	39	64	Discomfort and breathing difficulties	D
Alqahtani et al[41]	2009-12	Case series	10 Australian pilgrims	40	NR	NR	40	NR	D
Gautret et al[32]	2012-14	Cohort	382 French pilgrims	62	60.6 (22-85)	55.1	53.7	NR	C
Pooled estimate	1999-2014	All studies	12710 participants of 55 nations	37.3	43.5 (11-89)	-	49.7	-	-

HCWs, health care workers; NA, not applicable; NR, not reported; RCT, randomised controlled trial; USA, United States of America.

pilgrims in a unique study that involved quantification of facemasks through photo frames from surveillance camera during the Hajj in 2013, therefor it is considered as an outlier.[21] The highest uptake was 92.8% observed by Al-Asmary et al. among health care workers during Hajj in 2005.[24] Excluding these two studies (Elachola et al[21] and Al-Asmary et al[24]), uptake rate among pilgrims has remained generally steady with gradual increase from 24% in 1999 to 64% in 2014 with minor fluctuations (Figure 2). Studies involving HCWs reported an uptake from 50% in 2009 to 92.8% in 2005. According to the pilgrims' country of origin, Malaysian pilgrims were noticed to be most compliant to using facemasks (70.9%),[37,40] followed by French (60.5%)[1,2,32,33] and Iranians (60%)[31] (Table 1).

Only three studies, all involving Australian pilgrims, evaluated the reasons of compliance (or non-compliance) of using facemask during Hajj.[18,29,41] The most reported reasons for wearing facemask were to avoid transmission of infectious organisms and protection from air pollution.[29] However, discomfort and difficulty in breathing were the most reported reasons for not wearing facemask.[18,41]

3.3. Effectiveness of facemask

Thirteen studies investigated the effectiveness/efficacy of facemask against respiratory infections, but the endpoints varied very widely. Most of these studies (9 out of 13) used a combination of respiratory symptoms (syndromic) as endpoints with varying definitions. For instance, acute respiratory infections (ARI) was used as an endpoint in three studies,[20,24,28] ILI in two,[18,37] upper respiratory tract infection (URTI) in two,[22,26] respiratory illness in two[30,40] and respiratory tract infections in one.[31] However a couple of studies used only one respiratory symptom as an endpoint: fever[39] and cough.[32] Only one study established laboratory-proven viral infections[25] as an endpoint. Definitions for the endpoints are detailed in Table 2.

In regards to the effectiveness of facemask, four out of thirteen studies demonstrated significant effect against respiratory infections,[18,20,22,28] two others showed some effect but did not reach statistical significance.[25,26] One study assessed its effectiveness against fever but ruled out its protectiveness,[39] and the other six studies did not show effectiveness but results were not statistically significant.[24,30–32,37,40] The pooled data from all studies revealed significant protectiveness of facemasks against respiratory infections in general at Hajj (relative risk [RR] = 0.89, 95% CI: 0.84-0.94, $p < 0.01$) (Table 2).

According to the ranking system we used, most of the studies were of average quality (C) whereas two studies were ranked above average (B): a pilot RCT[18] and a large cross-sectional study,[26] the other seven studies were of below average quality (D) either because of small sample size or poor study quality (Table 1).

4. Discussion

This systematic review shows that the use of facemask among the attendees of MGs remains essentially unchanged for decades although exceptionally in one study a very high uptake (about 93%)[24] or a very low uptake rate (0.02%)[21] has been reported but such variability can be explained by their unique study designs or population characteristics. The pooled data of this systematic review suggest that facemask is generally effective against respiratory infections at Hajj, however the endpoints varied widely.

The uptake of facemask among HCWs deployed at Hajj was generally higher than that among ordinary Hajj pilgrims with average compliance among HCWs being 72% compared to 46% among pilgrims. This finding is similar to what have been found in other studies that examined the uptake of facemask in other settings such as health care and community settings. For instance, the uptake of facemask among HCWs in several studies ranged from 56.6% to 84.3% (average 70.7%).[42–45] On the other hand, the uptake of facemask among ordinary population in diverse household and community settings ranged from 38% to 80.7% (average 55%).[46–52] This could be explained by several individual or organisational factors. For example, HCWs have firsthand knowledge about the risk of respiratory infections and the role of preventive measurements in Hajj.[25] Similarly, studies in non-MGs settings showed a positive relationship between HCWs' knowledge about the risk of infectious diseases and their compliance to preventive measures including the use of facemask.[53–55] Organisational factors such as ready availability of facemask in health care settings, proper training programs and supportive policy of health care system could have played an important role in improving the compliance of HCWs to facemask use.[54–57] On the other hand, limited studies explored these individual and organisational

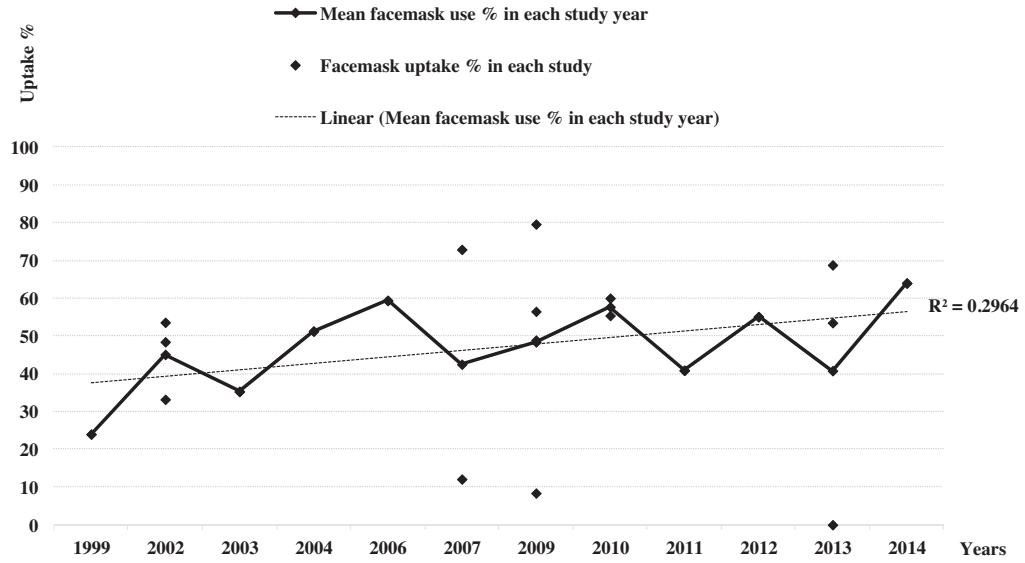

Figure 2. Facemask uptake rate among Hajj pilgrims from 1999 to 2014.

Table 2
Characteristics of included studies that examined facemask effectiveness against respiratory infections in Hajj

Author	Study year	Study type	Sample size	End points; definitions	Relative risk	*p*-Value
Zein, U[22]	2002	Cohort	446	URTI; diagnosed by clinical symptom such as cough, fever, sore throat, hoarseness, cold, and by physical examination	0.30	< 0.01
Choudhry et al[28]	2002	Cohort	1027	ARI; defined as the presence of one of the constitutional symptoms (fever, headache, myalgia) along with one of the local symptoms (running nose, sneezing, throat pain, cough with/without sputum, difficulty breathing)	0.35	< 0.01
Abdin et al[20]	2004	Trial	994	ARI; defined as the presence of one of the constitutional symptoms (fever, headache, myalgia) along with one of the local symptoms (running nose, sneezing, throat pain, cough with/without sputum, difficulty breathing)	0.13	< 0.01
Al-Asmary et al[24]	2005	Cohort	250	ARI; defined as the presence of one of the constitutional symptoms (fever, headache, myalgia) along with one of the local symptoms (running nose, sneezing, throat pain, cough with/without sputum, difficulty breathing)	1.16	0.74
Deris et al[37]	2007	Cross-sectional	387	ILI; defined as the triad of cough, subjective fever and sore throat	1.33	0.07
Balaban et al[30]	2009	Cohort	143	Respiratory illness; defined as the presence of one or more of the following localising signs or symptoms: cough, congestion, sore throat, sneezing, or breathing problems	1.25	0.34
Al-Jasser et al[26]	2009	Cross-sectional	1507	URTI; defined as one of the constitutional symptoms (fever, headache, myalgia) along with one of the local symptoms (running nose, sneezing, throat pain, cough with/without sputum, difficulty breathing)	0.94	0.18
Memish et al[25]	2009	Cross-sectional	104	Laboratory-proven viral infections by using multiplex PCR	0.74	0.54
Maslamani et al[39]	2010	Cross-sectional	1685	Only fever	1.33	< 0.01
Emamian et al[31]	2010	Cohort	95	RTI; defined as all types of respiratory tract infections other than the common cold	1.27	0.43
Barasheed et al[18]	2011	RCT	164	ILI; defined as subjective (or proven) fever plus one respiratory symptom	0.47	0.02
Hashim et al[40]	2013	Cross-sectional	468	Respiratory illness; defined as having ILI or at least one of the non-ILI respiratory symptoms	1.04	0.22
Gautret et al[32]	2012-14	Cohort	382	Only cough	1.04	0.60
Pooled estimate	2002-14	All studies	7652	-	0.82	< 0.01

ARI, acute respiratory infection; ILI, influenza-like illness; PCR, polymerase chain reaction; RCT, randomised controlled trial; RTI, respiratory tract infection; URTI, upper respiratory tract infection.

factors among Hajj pilgrims. A few studies showed that providing educational session on protective measures against respiratory infections (including facemask) before Hajj was associated with significantly higher uptake of facemasks among pilgrims.[18,20,27,36,38] Moreover, adequate accessibility and availability of facemask during Hajj may enhance the compliance of pilgrims. Abdin et al and Barasheed et al revealed a higher uptake of facemask among groups who were provided with sufficient quantity of free facemask (81.3% versus 33.6%, $p < 0.01$, and 76% versus 12%, $p < 0.01$, respectively).[18,20] However, reasons for not using facemask during Hajj have not been explored adequately. While use of facemask at Hajj has been officially recommended by Saudi Ministry of Health since 2014, it is too early to have a significant impact on pilgrims' practice of facemask use.[58]

Although Hajj took place in different seasons (spring, winter and autumn), the uptake of facemask among Hajj pilgrims during the last decade remained generally stable (Figure 2). Findings also showed that there was no significant change in facemask uptake among Hajj pilgrims during the course of influenza A (H1N1) pandemic outburst in 2009, and the Middle East respiratory syndrome corona virus (MERS-CoV) outbreak since 2012. This does not concur with what has been reported in published studies involving the members of general public over the several outbreaks of respiratory infections in non-MG settings.[59–64] Those studies showed an increase in facemask use during the outbreaks due to participants' perceived threat of infection. Poor awareness among many pilgrims of contemporary outbreaks might explain why their uptake of facemask did not increase even during an ongoing outbreak.[65–67] Interestingly, pilgrims of Asian origin (e.g. Malaysians) had higher facemask uptake compared to pilgrims from other regions.[37,40] A polling study that evaluated the uptake of non-pharmaceutical measures during the pandemic influenza A (H1N1) of 2009 found that participants of Asian origin (e.g. Japan) had the higher facemask uptake (71%) compared to the uptake of participants of Western or Latin American origin.[68] Presence of several peaks of influenza seasons in some Asian countries, overcrowding, dense smog and air pollution in many cities may explain the higher uptake of facemask among people from Asian countries;[69,70] additionally, cultural acceptance practice of the population around facemask while in public may make a difference.[68] Focused studies are required to investigate factors influencing facemask compliance among attendees of Hajj and other MGs.

In this systematic review, pooled data of facemask effectiveness showed that participants who used facemask during Hajj are about 20% less likely to suffer from respiratory infections compared to those who do not use it. This effectiveness of facemask is inconclusive due to great heterogeneity in study questions, assessment methods, study designs and qualities, and endpoints. In regards to the research questions, three out of 13 studies investigated facemask effectiveness as the primary research objective: all three studies yielded significant results; whereas only one out of the other 10 studies that assessed facemask as a secondary or indirect outcome, yielded significant results.

Further, there was great heterogeneity in how the frequency and duration of facemask use were assessed. Although, most of the studies used a self-reported questionnaire to quantify facemask uptake among participants, the qualitative descriptive terms that the studies used (e.g. "always", "mostly", "sometimes" or "never")

may have introduced subjective bias, since qualitative description varies depending on participants' perception about the frequency and duration of use. However, only one study used measurable criteria in their questionnaires to quantify the number of facemasks used including the duration (in hours) and frequency of use, finding that using facemask more than eight hours per day was associated with significant decrease in ILI symptoms among Hajj pilgrims.[18] Using surveys with more objective options may decrease bias,[71] and provide more accurate estimate of compliance to facemask use in MGs.

Study designs also may have contributed to variability in results. For instance, two trials, a pilot RCT and a non-randomised trial, reported facemask to be significantly effective against respiratory infections at Hajj, whereas only two out of six cohort studies reported significant results. In contrast, none of the cross-sectional studies yielded significant results. This may indicate that a higher quality study is more likely to produce convincing results.

Finally, facemask effectiveness also differed depending on the study endpoints. For example, studies that examined effectiveness of facemask against a single respiratory symptom (such as cough, sore throat or fever) either ruled out or did not fully support its effectiveness.[32,37,39] This is most likely because singular endpoints are often prone to subjective biases due to their non-specificity. In addition, solitary respiratory symptoms may result from causes other than infections; for instance, cough may result from exposure to dust or smoke during Hajj or may be a manifestation of a chronic respiratory condition of non-infectious aetiology, e.g., bronchial asthma.[29] On the other hand, most of the studies that used syndromic criteria (constellation of symptoms) as an endpoint reported facemasks to be effective against respiratory infections during Hajj.[18,20,22,26,28] This is most likely due to the fact that syndromic endpoints are more specific for an illness than a singular symptom. Only one study used laboratory-confirmed infection as an endpoint, but its sample size was relatively small (n = 104) and it failed to demonstrate statistically significant protectiveness of facemasks against respiratory viral infections among Hajj HCWs.[25] Similarly, in non-MG settings, effectiveness of facemask varied depending on the study endpoint.[42–52,72–74] Meta-analysis of RCTs involving facemask in non-MGs showed efficacy against ILI but not against laboratory-confirmed influenza.[14,15,75]

This study is the first focussed systematic review that describes both the uptake and effectiveness of facemasks against respiratory infections in MGs, and it compiles a data pool of 12710 participants originating from more than 50 countries. However, the main limitation is that most of the studies were of 'average' or 'below average' quality. There was only one RCT but that was a pilot trial of small sample size, and there was another 'trial' published in a non-indexed journal that did not report methodological details including whether and how randomisation was done. As all included studies were conducted only in the context of Hajj, it is not possible to generalise the results to other MGs. A large scale clustered RCT is currently in its final phase that will measure the efficacy of facemasks against both 'syndromic' and laboratory-confirmed viral infections.[75] The full results of the trial, once available, are likely to provide firmer evidence on the usefulness of facemask against respiratory infections among attendees of MGs.

In summary, the use of facemask among attendees of a particular MG (Hajj) remains almost steady with negligible increase throughout the last decade with an average uptake of 50%. Facemasks seem to be beneficial against certain respiratory infections during Hajj but not definitively proven.

Conflicts of interest

Professor Robert Booy has received funding from Baxter, CSL, GSK, Merck, Novartis, Pfizer, Roche, Romark and Sanofi Pasteur for the conduct of sponsored research, travel to present at conferences or consultancy work; all funding received is directed to research accounts at The Children's Hospital at Westmead. Dr Harunor Rashid received fees from Pfizer and Novartis for consulting or serving on an advisory board. The other authors have declared no conflict of interest in relation to this work.

Acknowledgments

The authors would acknowledge the support of Ms. Trish Bennett, Manager, Medical Library, The Children's Hospital at Westmead, NSW, Australia, for help with literature search.

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