prevalence of pH1N1 was 0.2% (n = 1) among 519 arriving pilgrims and 0.1% (n = 2) among 2699 departing pilgrims [6], probably because of heightened infection control and preexisting cross-immunity among pilgrims, most of whom would have been exposed to H1N1 before 1957 [7].

Experience from an ear, nose, and throat (ENT) clinic in Makkah suggested that only 77 of 3087 patients (2.5%) who attended with ENT symptoms had suspected pH1N1 based on history of contact with a patient with pH1N1 and clinical symptoms of influenza-like illness (ILI); however, laboratory testing for influenza virus was not undertaken [8]. The efficacy of influenza vaccine is dependent on matching the vaccine and circulating influenza strains. Because the pH1N1 vaccine was not largely available in time for Hajj 2009, protection was dependent on previous exposure to H1N1 influenza A virus and nonpharmaceutical interventions such as face masks [2].

Historically, face masks have been used to prevent or reduce nosocomial transmission of pandemic influenza since, at least, the time of Spanish influenza in 1918. Nurses who wore specially designed face masks and changed them every 2 hours experienced lower infection rates than those who did not [9]. Recent experiments confirm that surgical masks and respirators can filter influenza virus, although observational studies or clinical trials have not yet clearly demonstrated the effectiveness of plain surgical masks in household or healthcare settings [10–16].

The role of surgical masks, respirators, and/or hand hygiene in preventing ILI has been examined in at least 15 studies including 5 randomized controlled trials (RCTs). These compared “plain surgical mask” with “no intervention” against ILI [10–14]. In 4 of these RCTs influenza was laboratory confirmed [10–13]. Metadata from these studies indicated that wearing surgical masks did not change the frequency of laboratory-confirmed influenza (Figure 1). The findings may have been due to limitations and biases in study design [10–14]. A common limitation of all studies was small sample size. Despite similar study design, the sample-size calculations were based on different assumptions, and the studies lacked the power to detect a difference in incidence of laboratory-confirmed influenza.

At least 2 observational studies at the Hajj have examined the role of masks in preventing acute respiratory infection. One of these studies evaluated the role of face masks among pilgrims at the 2002 Hajj [15], when a protective effect was shown in men but not in women. The other study evaluated the use of face masks worn by healthcare workers at the 2005 Hajj in preventing acquisition of acute respiratory infection when protective effectiveness was non-significant [16].

The Hajj congregation of more than 2 million people who stay for 5 days in 25,000 tents in Mina, a valley within Makkah city, provides a unique opportunity to conduct RCTs of mask effectiveness to avoid sample size and design limitations.

During Hajj 2011 the 5-day stay in Mina is from 4 to 8 November. We are undertaking a pilot study to examine the feasibility of a cluster RCT of mask use among Australian pilgrims. Assuming success of this pilot trial, we plan to set up large RCT involving pilgrims from several countries in subsequent years. We are seeking expressions of interest for a multinational collaboration and would be pleased to hear from possible collaborators.

Note

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