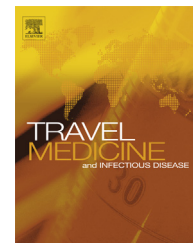


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A cohort study of the impact and acquisition of nasopharyngeal carriage of *Streptococcus pneumoniae* during the Hajj

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Summary *Background:* The annual Muslim pilgrimage attracts over two million pilgrims who gather in a limited time and space. The pilgrimage carries the potential risk of increase risk of the acquisition of *Streptococcus pneumoniae*. In this cohort study, we evaluate the effect of the Hajj on the prevalence of pneumococcal serotype nasopharyngeal carriage in the Hajj pilgrim population. The secondary objective is to evaluate the effects of the mass gathering on carriage of invasive pneumococcal serotypes.

Methods: This is a prospective cohort study with two data collection periods: at the beginning and at the end of the Hajj. Nasopharyngeal samples were taken via a standardized swabbing method.

Results: A total of 1175 pilgrims were enrolled at the beginning of the study and 1155 (98.3%) were included at the second part of the study. The pre-Hajj samples were obtained at a mean of 0 days and the post-Hajj sampling occurred at a mean of 15 days after arrival to Saudi Arabia. The overall carriage rate of *Streptococcus pneumoniae* in the pre- and post-Hajj was 1.8% and 7.1% ($P = 0.0016$). The potential coverage of the 7-valent pneumococcal conjugate vaccine (PCV7), PCV10 and PCV13 were 15.5%, 19.1%; and 35.5%, respectively. The coverage for the 23-valent pneumococcal polysaccharide vaccine (PPV23) was 40%.

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Conclusion: Although there was an increase in the acquisition of *S. pneumoniae*, its magnitude is low which does not support public health recommendations for general pneumococcal vaccination of pilgrims except those at risk.

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1. Introduction

Streptococcus pneumoniae is one of the leading causes of pneumonia and meningitis globally, causing approximately 800,000 deaths per year in children less than 5 years of age [1]. More than 90 pneumococcal serotypes have been identified; their incidence and virulence vary by age, clinical syndromes, and geographic region [2]. The burden of pneumococcal disease in adults is insufficiently understood. In developed countries, community-acquired pneumonia is a major cause of hospital admission and mortality in individuals over 65 years of age [3–7]. A large fraction of these cases are likely due to *S. pneumoniae*, but the lack of sensitive and specific diagnostic tools limits our ability to determine the exact contribution of this pathogen to disease [8–15].

Each year, over 2,000,000 Muslim pilgrims assemble in Makkah, Saudi Arabia to complete the Hajj, one of the five pillars of Islam. This event brings people from around the world into crowded conditions where the potential for illness and disease transmission is high. Little research has been performed on pneumococcal disease per se in the context of the Hajj pilgrimage. A recent review of health risks at the Hajj does not identify data on pneumococcus specifically, but notes that the American Advisory Committee on Immunization Practices recommends pneumococcal conjugate vaccine 13 (PCV13) followed by pneumococcal polysaccharide vaccination for persons with underlying illness or over the age of 65 years [16]. Several possibilities exist for the Hajj to increase global pneumococcal transmission and illness. First, pilgrims may experience more acute respiratory illness and other pneumococcal disease by coming into contact with potentially virulent clones. Second, transmission of potentially virulent clones among pilgrims may lead to more disease globally. Third, transmission of antibiotic resistant clones may increase the prevalence of antibiotic resistant pneumococcal disease globally. Finally, the great mix of pneumococcal serotypes likely present among pilgrims may facilitate serotype replacement in countries that have implemented routine infant PCV vaccine. A recently completed study evaluated pneumococcal carriage in groups of pilgrims tested on arrival to and departure from the Hajj [17]. Preliminary investigation found that carriage at the end of the Hajj was several-fold higher than upon arrival. However, interpretation of results was limited by the study design [17]. In that study, specimens were collected in a series of cross-sectional studies rather than a cohort study. Subsequently, paired and parried cohorts were examined for the presence of *S. pneumoniae* [18]. In

this study, we describe a follow-up pneumococcal nasopharyngeal carriage using a cohort design, testing the same participants on arrival and again upon departure. The primary objective of this study is to evaluate the effect of the Hajj mass gathering on the prevalence of overall pneumococcal and PCV-13-serotype pneumococcal nasopharyngeal carriage in the Hajj pilgrim population. The secondary objective is to evaluate the effects of the mass gathering on carriage of invasive pneumococcal serotypes and to explore risk factors for acquisition of carriage during the Hajj. The medium-term objective was to determine whether pneumococcal vaccine recommendations should be made to reduce disease spread and burden during the Hajj event.

2. Materials and methods

In this study, we describe the results of the in-depth characterization of 111 pneumococcal isolates collected from pilgrims performing the Hajj in the Kingdom of Saudi Arabia in 2013. The study is a prospective cohort study with two data collection periods: at the beginning and at the end of the Hajj. Nasopharyngeal specimens and demographic and epidemiological data were collected from all study subjects. Nasal samples were taken via a standardized swabbing method, as described [17,18]. Beginning-Hajj epidemiological data and samples were collected at King Abdul Aziz International (KAAI) airport, Jeddah, as pilgrims arrive. End-Hajj epidemiological data and samples were collected during the last days of the pilgrimage in Mina.

2.1. Sample size

The sample size is based on the 2011–2012 pilot study data that found overall beginning-Hajj *S. pneumoniae* carriage prevalence of around 5% and an end-Hajj/beginning-Hajj prevalence ratio of 1.5–2 depending on the outcome [17]. Based on these data, approximately 1100 subjects are needed to have 80% power to detect a prevalence ratio of 1.6 with a two-sided type 1 error of 5%.

2.2. Specimen collection

A dedicated laboratory technician using Dacron tipped swabs according to a standardized swabbing technique collected nasopharyngeal specimens. Swabs were immediately inoculated into Skim milk, tryptone, glucose and glycerol transport medium (STGG) and transported daily in ice boxes to a mobile

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