

Impact of pH1N1 influenza A infections on the Otolaryngology, Head and Neck Clinic during Hajj, 2009

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ABSTRACT

الأهداف: بحث تأثير عدوى فيروس أنفلونزا الخنازير البائية على مسار عيادة الأنف والأذن والحنجرة أثناء فريضة الحج في عام 2009م.

الطريقة: أُجريت هذه الدراسة خلال الفترة من نوفمبر إلى ديسمبر 2009م، وشملت المرضى الذين أتوا إلى عيادة الأنف والأذن والحنجرة بمستشفى النور التخصصي، مكة المكرمة، المملكة العربية السعودية. ولقد أجرينا الاختبارات الإحصائية الوصفية من أجل تحليل البيانات.

النتائج: شملت هذه الدراسة ما مجموعه 3087 من المرضى (متوسط العمر: 35 ± 7.8 عاماً)، ولقد بلغ عدد الذكور 2114 مريض (68.5%)، فيما بلغ عدد الإناث 973 مريضة (31.5%) (نسبة الذكور إلى الإناث: 1:2.17). ولقد كان 1467 (47.5%) مريض من الحجاج، و1620 مريض (52.5%) من غير الحجاج، ووصل عدد المرضى السعوديين إلى 1602 مريض (51.8%) من مجموع المرضى المشاركين في الدراسة، فيما كان عدد المرضى غير السعوديين 1485 مريض (48.2%). وقد شكلت التهابات القناة العلوية التنفسية 92% من مجموع التشخيص الكلي، وشملت هذه الالتهابات كلاً من: التهاب البلعوم، والتهابات القناة العلوية التنفسية الفيروسية، وعدوى أنفلونزا الخنازير البائية، والتهاب اللوزتين. ولم يتم الكشف إلا عن 77 (2.5%) حالة مصابة بعدوى أنفلونزا الخنازير البائية في عيادة الأنف والأذن والحنجرة. وعولج 3045 (98.6%) مريض باستخدام المضادات الحيوية وذلك كجزء من العلاج الرئيسي.

خاتمة: أثبتت هذه الدراسة بأن تأثير عدوى فيروس أنفلونزا الخنازير على أداء عيادة الأنف والأذن والحنجرة أثناء فريضة الحج قد كان محدوداً جداً، وكانت هذه العيادة عاملاً مساعداً في تخفيف الضغط على قسم الطوارئ بالمستشفى. كما يستلزم ترشيد استخدام المضادات الحيوية.

Objectives: To examine the possible implications of the 2009 H1N1 influenza A (pandemic flu, pH1N1) on this religious gathering and provide a response plan for the

Otolaryngology, Head and Neck (ENT) clinic during the Hajj pilgrimage.

Methods: This study was conducted between November and December 2009. All patients presenting to the ENT clinic at Al-Noor Specialist Hospital, Makkah, Kingdom of Saudi Arabia were recorded. Descriptive statistics were used to analyze the data.

Results: A total of 3087 patients were included (mean age 35 ± 7.8 years), of which, 2114 were males (68.5%), and 973 females (31.5%, male to female gender ratio=2.17:1). Among them, 1467 patients (47.5%) were Hajji and 1620 patients (52.5%) were non-Hajji. Saudi patients comprised 1602 (51.8%), while non-Saudi's comprised 1485 (48.2%). Upper respiratory tract infections (URTI) including the diagnosis of pharyngitis, viral URTI, pH1N1, and tonsillitis represented (92%) of total diagnoses. Of these, only 77 suspected pH1N1 cases (2.5%) were observed in the ENT clinic. Management of 3045 patients (98.6%) included antimicrobials as part of their main therapy.

Conclusion: The pH1N1 cases presenting to our ENT Hajj clinic had a minimal impact on the clinic operation. The ENT Hajj Clinic helped alleviate pressure from the ER. Excessive use of antibiotic usage should be discouraged.

Saudi Med J 2011; Vol. 32 (9): 933-938

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Received 2nd April 2011. Accepted 18th July 2011.

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Hajj represents an annual holy journey performed by Muslim pilgrims from all around the world to the holy city of Makkah, Kingdom of Saudi Arabia. For most overseas pilgrims, the Hajj celebration is carried out over a whole month, but the most intense rituals last less than a week (from the eighth to the twelfth day of Thul-Hijjah; the twelfth month of the Arabic Hijri calendar). However, from the viewpoint of medical affairs at Hajj, the first twelve days of Thul-Hijjah are the most important period. Of importance, pilgrims move to the holy land of Mina (8 Kilometers from Makkah) on the eighth day of Thul-Hijjah and return back to the city of Makkah after the tenth day. During the 2009 Hajj, more than 2.4 million people participated in this mass migration to a small confined area.¹ The extreme congestion of people and vehicles during this time amplifies health risks, such as those from infectious diseases, especially upper respiratory tract or ear, nose, and throat (ENT) related infections.¹ The possible implications of the 2009 H1N1 influenza A (pandemic flu, pH1N1) infections on this religious gathering had the potential to be unparalleled in scale.²⁻⁷ The purpose of this study was to examine the effect of pH1N1 infections on our practice and provide a response plan for the ENT clinic during the annual Hajj pilgrimage.⁸

Methods. This study was conducted between November and December 2009 (corresponding to 1-17, Thul-Hijjah, 1430 H according to the Arabic Hijri calendar). We used the Makkah ENT-Hajj Database (MENT-HD), which was developed using Microsoft Access 2002 (Microsoft Corporation) as a collaborative project between Umm Al-Qura University and Al-Noor Specialist Hospital, Makkah, Saudi Arabia.⁸ Ethical approval was obtained in accordance with principles of the Declaration of Helsinki as the study involved human subjects. After obtaining appropriate administrative approvals, appropriate patient demographics, diagnosis, and therapy were included in the MENT-HD.

The inclusion criteria of this study included all patients of both genders and all age groups presenting to the ENT clinic at Al-Noor Specialist Hospital, Makkah, Kingdom of Saudi Arabia during the specified period. The pH1N1 diagnosis was suspected based on the following symptoms: fever, cough, sore throat, headache, shortness of breath, myalgia, diarrhea, and occasional vomiting with history of contact to a pH1N1 case.² Exclusion criteria included non-ENT related medical issues. All data were entered directly into the Database during the patient clinic encounter by a registered nurse after evaluation by an ENT physician. Recording of the diagnosis was carried out according to an approved Saudi Ministry of Health (MOH) out-patient data recording

form specially designed for the Hajj; which was based on the International Classification of Diseases (ICD-10).⁹ Data are presented as means \pm SD for continuous variables and as percentages for categorical variables. A *p*-value was calculated using Fisher's Exact Test, and a value of <0.05 was considered as statistically significant. Relative risk (RR) and their 95% confidence interval (CI) were also presented when appropriate. Data analysis was carried out using Microsoft Excel 2002 (Microsoft Corporation, Seattle, WA) and Statistical Package for the Social Sciences Version 11 (SPSS Inc., Chicago, IL, USA).¹⁰

Results. A total of 3087 patients who met our inclusion criteria and presented to our ENT HAJJ clinic were included in this study. The mean age was 35 ± 7.8 years (age range, 2-78 years). The age group distributions are shown on Table 1. There was a statistically significant trend toward young adult age groups presenting to our ENT Hajj clinic with age groups 15-44 years old representing 71.5% of total patients (Chi-squared for trend = 8.36; $p=0.0038$). There were 2114 males (68.5%) and 973 females (31.5%); with a male to female ratio of 2.17:1, a significant statistical difference ($p=0.0001$, RR=0.68, 95% CI: 0.65-0.72).

Among the 3087 patients, 1467 patients (47.5%) were Hajji (Muslims performing Hajj), and 1620 patients (52.5%) were non-Hajji, with no significant statistical difference ($p=0.06$, RR=0.95, 95% CI: 0.90-1.01).

Table 1 - Age group distributions of 3087 patients included in this ENT Hajj clinic study, 2009 (1430 H).

Age Group	Frequency (%)
0-14	109 (3.5)
15-24	597 (19.5)
25-44	1607 (52.0)
45-64	726 (23.5)
+65	48 (1.5)
Total	3087 (100)

Table 2 - Patient's time arrival distributions of 3087 patients included in this ENT Hajj clinic study, 2009 (1430 H).

Time of arrival to clinic	Frequency (%)
8:00 A.M. - 12:00 P.M.	863 (28.0)
12:00 P.M. - 4:00 P.M.	528 (17.0)
4:00 P.M. - 8:00 P.M.	483 (15.7)
8:00 P.M. -12:00 A.M.	717 (23.2)
12:00 A.M. - 4:00 A.M.	376 (12.2)
4:00 A.M. - 8:00 A.M.	120 (3.9)
Total	3087 100

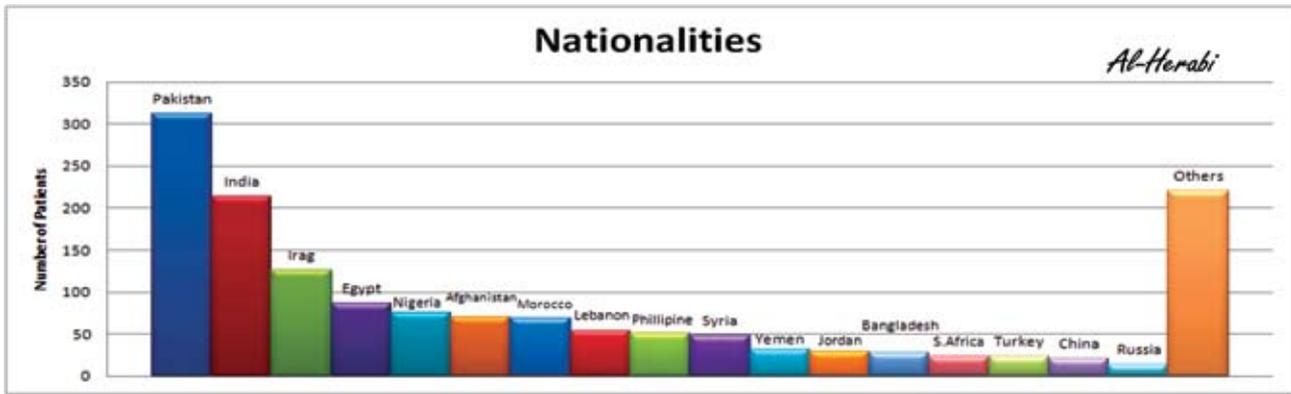


Figure 1 - The distribution of all non-Saudi nationalities of included patients in the ENT Hajj clinic Study.

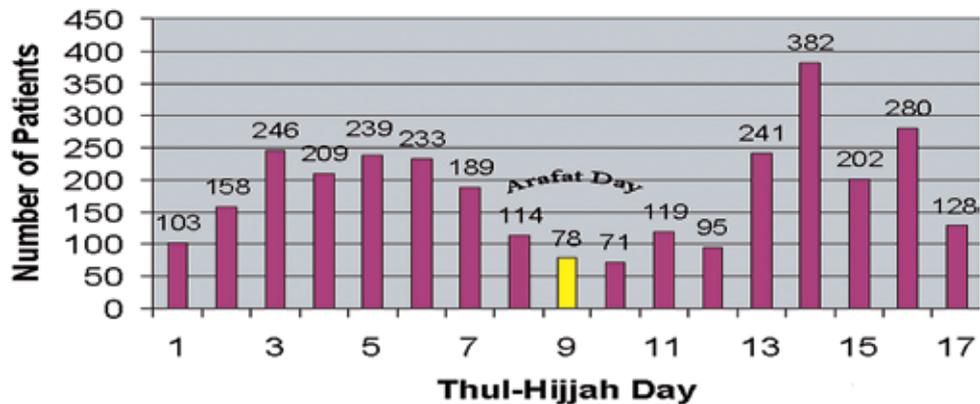


Figure 2 - The distribution of patients arrived daily during the 17 days of the study period to the ENT Hajj clinic 2009.

Table 3 - Diagnosis distributions of 3087 patients included in this ENT Hajj Clinic Study, 2009 (1430 H).

Diagnosis	Frequency (%)
Pharyngitis	1408 (45.7)
Viral URTI	1297 (42.1)
H1N1	77 (2.5)
Tonsillitis	54 (1.7)
Otitis media	37 (1.2)
Vertigo	22 (0.7)
Epistaxis	21 (0.7)
Foreign body Ear	20 (0.6)
Wax	19 (0.6)
Foreign body pharynx	12 (0.4)
Vertigo	11 (0.4)
Nasal trauma	9 (0.3)
Foreign body nose	9 (0.3)
Otitis externa	9 (0.3)
Post operative	8 (0.2)
Sinusitis	8 (0.2)
Laryngitis	7 (0.2)
Free of ENT disease	16 (0.5)
Others	43 (1.4)
Total	3087 (100)

URTI - upper respiratory tract infections, H1N1 - influenza A (H1N1), ENT - ear, nose, and throat

Saudi patients comprised 1602 (51.8 %) and non-Saudi's comprised 1485 (48.2%), with no significant statistical difference ($p=0.17$, $RR=0.96$, 95% CI: 0.91-1.01); non-Saudi Makkah residents comprised only 10 patients (0.3%), and non-Saudi's foreign residents comprised 1475 patients (47.9%). Only 96 patients (3.1%) could not speak Arabic, nor had a companion to help in translation. The distribution of all non-Saudi nationalities is shown on **Figure 1**. The distribution of patients arriving daily during the 17 days of the study period to the ENT Hajj Clinic (November to December 2009 corresponding to 1-17, Thul-Hijjah, 1430 H) is shown on **Figure 2**, with an average daily patients number of 181.

This special ENT Hajj Clinic functioned daily for 24 hours during the Hajj season and operated 2 shifts; twelve hours each. The clinic was operated by 2 personnel and included an ENT physician (specialist or resident) and a nurse. The distribution of patient arrival times during the operational shifts is shown in **Table 2**. The daily averages during those operational shifts are shown in **Figure 3**.

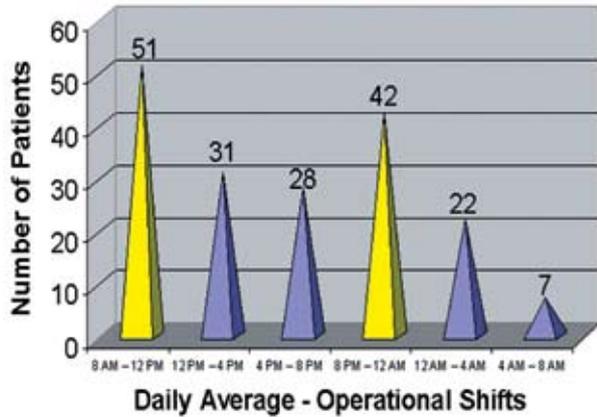


Figure 3 - Patient's time arrival distributions and operational peaks of 3078 patients included in this ENT Hajj clinic study 2009.

Table 4 - Antibiotic therapy distributions of 3087 patients included in this ENT Hajj Clinic Study, 2009 (1430 H).

Main Therapy	Frequency (%)
No antimicrobial	42 (1.4)
Antimicrobial	3045 (98.6)
Augmentin	2328 (76.4)
Amoxil	559 (18.3)
Tamiflu	77 (2.5)
Zithromax	52 (1.7)
Ciprofloxacin	19 (0.7)
Others	10 (0.4)
Total	3087 (100)

The diagnosis was established after the patients had been triaged by the ENT clinic nurse, and then examined by the clinic physician. Recording of the diagnosis was carried out according to an approved Saudi MOH outpatients data recording form specially designed for the Hajj; which was based on the ICD-10.⁹ The distribution of patient diagnoses are shown on Table 3. Bacterial and viral upper respiratory tract infections (URTI) including the diagnose of pharyngitis, viral URTI, pH1N1, and tonsillitis represented (92%) of total diagnoses, with significant statistical difference. (*p*-value=0.0001, RR=2.44, 95% CI=2.33 - 2.55).

Among the 3087 patients seen though the ENT Hajj Clinic, 3045 patients (98.6%) received antimicrobial therapy, with significant statistical difference (*p*-value=0.0001, RR=2.89, 95% CI=2.77 - 3.01). The distribution of antimicrobial medications used is shown in Table 4.

Discussion. The health implications of HAJJ are huge, adding the possible implications of the 2009

H1N1 influenza A pandemic to this religious gathering was potentially unparalleled in scale.⁶ In our institution, we decided to keep the ENT clinic running for 24 hours to help alleviate pressure from the emergency department (ED) and helped providing a specialized service in a timely fashion. An audit from Birmingham, England published recently addressing the feasibility of an ENT emergency clinic demonstrated that such a service significantly reduced patient waiting times and inappropriate referrals. Also, they concluded that such a clinic model provide an effective ENT emergency service.⁸

A total of 3087 Hajj patients were seen in our ENT Hajj clinic with an average age of 35 years old. This young age corresponds in general with the strong physical effort needed to perform the Hajj process. There were 2114 males (68.5%) and 973 females (31.5%); with male to female gender ratio of 2.17:1, which represented a significant deviation toward more male patients. This ratio was seen despite the fact that Hajj, has maintained its usual annual average male to female percentage of 52-55%.^{1,8,11} This was likely contributed to by the surprising fact that only 1467 patients (47.5%) that attended our ENT Hajj Clinic were true Hajji, while 1620 patients (52.5%) were Non-Hajji. This fact has added a significant burden on the clinic outside its intended purpose to serve mainly Hajji patients. Excluding the Saudi patients, 49% of the patients were from Pakistan, India, Iraq, and Egypt; and the rest were distributed over more than 24 other nationalities. These nationalities present a high pilgrimage presence in Makkah every year.^{1,8,11}

This clinic was designed to serve patients during maximal pilgrim's presence in the Holy city of Makkah during the first 17 days of the month of Thul-Hijjah, 1429 H (corresponding to November, 18 and December, 4, 2009). During days 3-7 and 13-16 of the clinic it was working above its daily average of 181⁵ patients, while the clinic slowed down below its daily average during days 8-12 of Thul-Hijjah, which was expected due to pilgrim's presence outside the city of Makkah. During the 24-hour operation of this clinic, it was noted that the busiest shifts were during 8:00 AM – 12:00 PM and 8:00 PM – 12:00 AM shifts; with a shift daily average of 51 and 42 patients representing 51.2% of the total patients. The fundamental purpose of this clinic was to address emergency ENT cases and the possible pH1N1 cases. Two interesting similar experiences with such clinics have been published. The first one from France, by Hervé and colleagues,¹² examined 1237 patients in a similar clinic setup and found that most of the cases did not correspond to true emergencies (53%), and the predominant pathological situations managed were acute external and middle ear otitis, epistaxis, vertigo,

and facial injuries. The second study from England, by Wheatley and colleagues¹³ found that 75% of the patients seen in such open access clinics were suitable for next day evaluation and management.

In our study, the collective diagnosis of bacterial and viral URTI including the diagnosis of pharyngitis, viral URTI, pH1N1, and tonsillitis represented (92%) of the total patients. Of these, only 77 suspected pH1N1 cases (2.5%) were observed in the ENT clinic. The diagnosis was suspected based on the following symptoms: fever, cough, sore throat, headache, shortness of breath, myalgia, diarrhea, and occasional vomiting with history of contact with pH1N1 cases.^{2,14} There was no confirmatory pH1N1 swabs taken as per specific instructions from the MOH; a specific task-force was initiated near the ER to handle all possible pH1N1 cases after an initial triage in the out-patient department. This small number of pH1N1 cases (only 77 possible cases) was far less than anticipated to pass through the ENT Hajj clinic with minimal impact on the operation of the clinic. The issue of infection control is of paramount importance in the Hajj setting; however, it is beyond the subject of this study and it has been addressed before.^{15,16} A pH1N1 vaccination program was rapidly implemented by the Saudi MOH in addition to other preventive measures to control the pandemic, as the pH1N1 vaccine is recognized for rapid protection of individuals who may have little or no prior infection or immunization. This mass vaccination program targeted all medical personnel and vulnerable populations such as older adults, young children, or pregnant women that might suffer the greatest impact from seasonal influenza.^{14,17-19}

In our study, 98.6% of patients received antimicrobial therapy as part of, or their main therapy; this very high percentage is more than expected, especially knowing that 42.1% of the cases were actually diagnosed as viral URTI. Overall, antibiotic use was significantly less among house staff (19.5%) than staff physicians; among staff physicians, antibiotic use was greater among those who work in non-teaching (39.6%) compared with teaching hospitals (32.5%).²⁰ This is actually a well known prescription phenomenon within medical communities. Khamis et al²¹ reported that out of 248 pilgrim patients seen during the 2007 HAJJ season, analgesics and antibiotics were the most commonly prescribed drugs. Another interesting study from the USA including 1952 pediatric patients encountered with a primary diagnosis suggestive of a viral infection found that 33.2% of these patients received antibiotics. Also, a study from the University of Toronto, Canada carried out in 1995²² found that out of 61,165 children, 64% were diagnosed with respiratory infections; of which, 74% of children received antibiotics. A more evidence based medicine model should be applied for

the rational use of antibiotics. The main limitations of this study were essentially related to unavailability of previous similar work to build upon, no clear referral pathway for patients, and minimal coordination between health care agencies, centers, and providers. Also, the clear instruction of the MOH not to confirm the suspected pH1N1 cases and rather treat them empirically or send the patients to a central specialized clinic with no access to its results limited our study. Implications of findings for future research include the use of such an electronic database that can be linked to a computer-based surveillance system central to the MOH to identify any outbreak of infectious diseases. A larger scale institutional electronic database is needed to improve local statistics, and therefore decisions regarding patient care.

The few pH1N1 cases presenting to our ENT Hajj clinic had a minimal impact on the clinic operation. The ENT Hajj Clinic was successful in providing patient care, and in helping alleviate pressure from the ED. Excessive use of antibiotics should be discouraged and preventive measures against URTI including influenza vaccination, hand disinfection, and use of face masks should be encouraged during the Hajj season.

Acknowledgment. Great thanks to Dr. Ail Khan, MD and Regina Akhtar, RN for their help in data collection.

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Related topics

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