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Management of hospitalized drug sensitive pulmonary tuberculosis patients during the Hajj mass gathering: A cross sectional study

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ABSTRACT

Background: To document the management of drug-sensitive TB patients during the Hajj and assess compliance with the Saudi TB management guidelines.

Method: The study was conducted in hospitals in Makkah during the 2016 and 2017 Hajj seasons. Structured questionnaire was used to collect data on relevant indices on TB management and a scoring system was developed to assess compliance with guidelines.

Results: Data was collected from 31 TB cases, 65.4% (17/26) were Saudi residents. Sputum culture was the only diagnostic test applied in 67.7% (21/31) of patients. Most (96.8%, 30/31) confirmed TB cases were isolated, but only 12.9% (4/28) were tested for HIV and merely 37% (10/27) received the recommended four 1st-line *anti*-TB drugs. Guideline compliance scores were highest for infection prevention and control and surveillance (9.6/10) and identifying TB suspects (7.2/10). The least scores were obtained for treating TB (5.0/10) and diagnosing TB (3.0/10).

Conclusions: Healthcare providers training and supervision are paramount to improve their knowledge and skill and ensure their compliance with existing TB management guidelines. However, there may be a need for the introduction of an international policy/guideline for TB control and management during mass gatherings such as the Hajj to guide providers' choices and facilitate monitoring.

1. Introduction

Tuberculosis (TB) remains a global public health problem with significant morbidity and mortality. In 2017, the World Health Organisation (WHO) estimated that 10 million people developed active TB causing up to 1.6 million deaths [1]. The WHO's End-TB strategy aims to reduce the overall number of TB deaths by 95% and the TB incidence rate by 90% in 2035 compared with the 2015 baseline incidence and mortality figures [2]. Key to achieving these targets is the early diagnosis and appropriate management of TB cases worldwide according to national and international guidelines [3–6]. This includes in the context of mass gatherings such as the annual Hajj in Makkah, Kingdom of Saudi Arabia (KSA), where over 2 million pilgrims, many originating from TB endemic areas, congregate in crowded settings and worship under conditions that increase the risk of TB transmission [7,8].

In the context of the Hajj, respiratory tract infection including those caused by viruses have been researched in detail [9]. However, while TB cases have been reported during the event [10,11], TB management approaches during this unique event remained largely undocumented, and it is unknown whether these are consistent with the KSA and international TB management guidelines. Hospitals in Makkah serve both Hajj pilgrims as well as local residents and the Hajj workforce during the mass gathering free of charge. The additional stress on these health facilities during Hajj may compromise the services provided for all patients during the event, including those diagnosed with TB. This study documents the management of drug-sensitive TB patients during Hajj and explores the compliance of healthcare providers with the KSA TB management guidelines in the Ministry of Health (MOH) hospitals in Makkah during the mass gathering.

2. Methods

2.1. Study design, setting and population

This cross sectional study took place in Makkah, Saudi Arabia, and included 13 hospitals comprising those serving pilgrims in Hajj holy

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sites. The study was conducted during the Hajj lunar month (1st-30th DulHija) during the 2016 and 2017 Hajj seasons, corresponding to 2nd Sep-1st Oct 2016 and 22nd Aug-21st Sep 2017, respectively. All hospitalized adults (>18 years old) diagnosed with drug-sensitive pulmonary TB (PTB) during the study period were enrolled in the study if they consented. These patients are referred to in the manuscript as "suspected TB patients" until the time they were confirmed to have TB by the healthcare facility there were admitted to.

2.2. Data collection and analysis

The management of TB patients was documented using a specifically designed data collection form which included patients' demographics data, underlying health conditions and TB risk factors as well as clinical data including various aspects of TB management such as patients' screening, infection prevention and control (IPC), TB diagnosis and treatment and case notification and outcome. Data was collected by the study team from patient's records, attending physician and through interviews with patients.

All analyses were done using SPSS 22.0 (SPSS Inc., Chicago, USA) and SAS 9.4 (SAS Institute Inc., NC, USA) software program. Variables were characterized using frequencies and mean for the respective categorical and continuous variables. A scoring system was developed, having identified four key themes from the questionnaire and literature review which were relevant to TB management in Hajj. The themes were 1) identifying TB suspect, 2) IPC and surveillance, 3) diagnosing TB and 4) treating drug-sensitive TB. For each theme, relevant indicators were identified from the questionnaire (Tables 2–5). A score of 1 was assigned for each indicator/variable that was consistent with the 2014 KSA TB management guideline [6] (latest version during study period) and 0 for inconsistency with the guideline. The indicator subscore (x) for guideline consistency was obtained as follows:

X = Number of cases consistent with guidelines (c)/ Total number eligible of cases (d) * 10

The eligible cases summed the consistent and inconsistent responses with TB guideline and strictly excluded missing data and unknown responses. The guideline consistency score for each theme was obtained by calculating the mean of the indicator sub-scores for each theme.

2.3. Ethics

The study was approved by the King Fahad Medical City Ethics Committee and the Institutional Review Board (IRB log: 16-329E) and conducted in accordance with the Ethics Committee's guidelines.

3. Results

3.1. Characteristics of the study population

Characteristics of the study population are presented in Table 1. For the two-year period, 31 confirmed drug-sensitive PTB patients were recruited for the study. The mean age of the study population was 52 years (SD = 18.1 years, range 21–83 years). Most (80.6%, 25/31) were males and over half were over 50 years old (60.7%, 17/28), with only primary or no formal education (55.1%, 16/29). The TB patients were nationals of 10 countries but the majority (65.4%, 17/26) had been residing in KSA for at least one year (Table 1). Over one third of the cases (37.5%, 9/24) did not complete their Hajj rituals while the status of 50% (12/24) of the cases was not known. Three confirmed TB cases (12.5%, 3/24) did complete their Hajj rituals in individual ambulances. No mortality was recorded among the TB patients at the time when the study ended with half (14/28) having been discharged (Table 1).

Table 1
Characteristics of the drug-sensitive tuberculosis cases.

Variable	Frequency n (%)
Gender, N = 31	
Male	25 (80.6)
Age group, N = 28	
21–30	6 (21.4)
31–40	3 (10.7)
41–50	2 (7.1)
51–60	7 (25.0)
61–70	6 (21.4)
>70	4 (14.3)
Level of education, N = 29	
No Formal Education	11 (37.9)
Primary Education	5 (17.2)
Secondary Education	10 (34.5)
University/Higher Education	3 (10.3)
Nationality, N = 31	
Saudi Arabia	11 (35.5)
Philippine	3 (9.7)
Indonesia	2 (6.5)
India	3 (9.7)
Mali	2 (6.5)
Sudan	2 (6.5)
Somalia	2 (6.5)
Pakistan	3 (9.7)
Myanmar	2 (6.5)
Chad	1 (3.2)
Residence in the past year, N = 26	
Saudi Arabia	17 (65.4)
India	3 (11.5)
Pakistan	1 (3.8)
Philippine	1 (3.8)
Indonesia	1 (3.8)
Somalia	1 (3.8)
Chad	1 (3.8)
Myanmar	1 (3.8)
Travel outside current residential area in the past year? N = 30	
Yes	9 (30.0)
• Saudi Arabia	5 (55.6)
• Indonesia	1 (11.1)
• Pakistan	1 (11.1)
• Morocco	1 (11.1)
• Sri Lanka	1 (11.1)
Performed Hajj or Umrah in the past year, N = 29	
Yes	8 (27.6)
No	20 (69.0)
Don't recall	1 (3.4)
Current or past smoker of tobacco products, N = 29	
Yes	13 (44.8)
Have a chronic health condition, N = 27	
Yes	17 (63.0)
• Diabetes	12 (44.4)
• Chronic kidney disease	1 (3.7)
• Chronic lung disease	3 (11.1)
• Cardiovascular disease	4 (14.8)
• Hypertension	7 (25.9)
Case outcome[a], N = 28	
Discharged	14 (50.0)
Inpatient	12 (42.9)
Referred	2 (7.1)
Deceased	0 (0.0)

N; total number of patients with available data.
[a] Outcome at the end of the study period.

In relation to TB risk factors, only 6.6% (2/30) of respondents reported prior travel to high TB burden countries (Pakistan and Indonesia) and 27.6% (8/29) stated that they had performed Hajj or Umrah within the past 1 year. The majority (75%, 6/8) of the previous Hajj or Umrah pilgrims were Saudi residents. A sizable proportion of TB cases declared that they had smoked or were current smokers of tobacco products (44.8%, 13/29) or had chronic diseases (63.0%, 17/27) especially diabetes and hypertension (Table 1).

Table 2
Results of variables related to tuberculosis infection prevention and control.

Infection prevention and control	Frequency n (%)
Was the patient separated from other patients during registration (triaging)? N = 31	
Yes	15 (48.4)
No	2 (6.5)
Don't Know	14 (45.2)
Where was the TB suspected patient admitted while awaiting diagnosis? N = 31	
General Ward	1 (3.2)
ER	4 (12.9)
Isolation ward/room	24 (77.4)
ICU	1 (3.2)
Neurosurgery ward	1 (3.2)
Where was the confirmed PTB patient admitted in the healthcare facility? N = 31	
ER	1 (3.2)
Isolation ward/room	30 (96.8)
How long was the confirmed PTB patient in the healthcare facility from arrival to isolation? N = 29	
<1 day	27 (93.1)
1–2 days	0 (0.0)
3–7 days	1 (3.4)
>7 days	1 (3.4)

TB; tuberculosis, PTB; pulmonary tuberculosis, ER; emergency room, ICU; intensive care unit, N; total number of patients with available data.

3.2. Infection prevention and control

Upon registration, most (76.6%, 23/30) suspected TB patients were admitted to an isolation room or ward. Otherwise, the patients were either admitted into the emergency room (ER [6.7%, 2/30]), ICU (6.7%, 2/30), neurosurgery ward (3.3%, 1/30), orthopedic ward (3.3%, 1/30) or general ward (3.3%, 1/30). While a proportion (48.4%, 15/31) of suspected TB patients was separated from other patients during registration, the triaging status of 45.2% (14/31) of suspected TB patients was not reported (Table 2). The proportion of suspected TB patients put in isolation while waiting diagnosis was 77.4% (24/31) and rose to 96.8% (30/31) once drug-susceptible TB was confirmed. Only 1 (3.2%) confirmed TB patient was managed in the ER. Generally, most (93.1%, 27/29) confirmed TB patients spent less than 1 day in the health facilities before they were isolated.

3.3. Early detection of drug-susceptible TB through systematic screening

In all cases, appropriate symptoms were sought from TB suspects, in particular, cough ≥2 weeks (64.5%, 20/31) and fever with chills/night sweat (67.7%, 21/31). The history of contact with active TB cases was obtained from 45.2% (14/31) of suspected TB cases, although the status of this variable was unknown in a further 41.9% (13/31) of the cases (Table 3). In general, 44.8% (13/29) of the TB suspects were questioned about other TB risk factors. Specifically, their country of residence, HIV status and potential occupational exposure to TB (Table 3). Furthermore, in the majority of cases (67.7%, 21/31) providers used recommended screening test for active TB (chest X-ray) in case management.

3.4. Diagnosing drug-susceptible TB

In terms of diagnostic period, 50% (5/10) of TB suspected patients within known health facilities visits status had >2 visits to health facilities before appropriate screening/diagnostic tests were ordered (Table 4). However, the period between patient registration/arrival in health facilities and order of TB screening/diagnostic test(s) was ≤12 h in 77.4% (24/31) of cases. Similarly, in most cases (83.4%, 25/30), the period between ordering screening/diagnostic test(s) and confirmation of TB diagnosis was ≥2 days. In general, 62.5% (15/24) of cases were diagnosed within 2 days of arrival/registration to healthcare facilities.

Sputum culture was the diagnostic test utilized in the majority (67.7%, 21/31) of cases (Table 4). Xpert MTB/RIF assay was not utilized for TB diagnosis. In one instance, none of the recommended diagnostic tests were ordered for the TB suspected patient. Only 12.9% (4/25) of suspected/confirmed TB cases were screened for HIV.

Table 3
Results of variables related to early TB detection through systematic screening of patients.

Early TB detection through systematic screening	Frequency n (%)
History of contact with active TB cases obtained from suspected TB case, N = 31	
Yes	14 (45.2)
No	4 (12.9)
Don't Know	13 (41.9)
Suspected TB case questioned about other TB risk factors, N = 29	
• HIV status	6 (20.7)
• Occupational risk	8 (27.6)
• Country of residence	8 (27.6)
Symptom that warranted the suspicion of PTB, N = 31	
• Cough ≥ 2 weeks	20 (64.5)
• Hemoptysis	2 (6.5)
• Any productive cough	7 (22.6)
• Chest pain	5 (16.1)
• Fever/Night sweats/chills	21 (67.7)
• Weight loss	10 (32.3)
• Other symptoms	9 (29.0)
Appropriate screening test for active TB conducted, N = 31	
Yes	21 (67.7)
No	10 (32.3)

TB; tuberculosis, PTB; pulmonary tuberculosis, HIV; human immunodeficiency virus, N; total number of patients with available data.

Table 4
Results of variables related to tuberculosis diagnosis.

Diagnosing TB	Frequency n (%)
Number of visits to the healthcare facility before screening/diagnosis tests were ordered for the patient, N = 10	
1 visit	3 (30.0)
2 visits	2 (20.0)
>2 visits	5 (50.0)
Diagnostic test(s) ordered for the TB suspected patient, N = 31	
Sputum culture	21 (67.7)
Smear microscopy	3 (9.7)
Sputum culture + smear microscopy	6 (19.4)
None	1 (3.2)
Time between patient registration/arrival and order of screening/diagnostic tests, N = 31	
<1 h	3 (9.7)
1–12 h	21 (67.7)
>12–24 h	2 (6.5)
>24 h	3 (9.7)
Time between order of screening/diagnostic tests and confirmation of active PTB, N = 30	
<1 day	11 (36.7)
1–2 days	14 (46.7)
3–7 days	5 (16.7)
Suspected/confirmed TB patient screened for HIV, N = 25	
Yes	4 (12.9)
No	21 (87.1)

TB; tuberculosis, PTB, pulmonary tuberculosis, HIV; human immunodeficiency virus, N; total number of patients with available data.

3.5. Treating drug-susceptible TB

In over half of cases (58.1%, 18/31), the TB suspected patients were questioned about their TB history, although for a further 25.5% (8/31), response to this variable was unknown (Table 5). The majority of confirmed TB patients (77.7%, 21/27) received either four 1st-line *anti*-TB drugs (Isoniazid [INH]-Rifampicin [RIF]-Pyrazinamide [PZA]-Ethambutol [EMB]) in 37.0% (10/27) of the cases or three 1st-line *anti*-TB drugs (40.7% 11/27). Among the latter, 54.5% (6/11) received RIF-

Table 5
Results of variables related to tuberculosis treatment.

Treating TB	Frequency n (%)
TB suspected patient questioned about his/her TB history? (i.e previous TB diagnosis, previous TB treatment), N = 31	
Yes	18 (58.1)
No	5 (16.1)
Don't know	8 (25.8)
The confirmed TB patient prescribed treatment regimen, N = 27	
Four 1st-line agents	10 (37.0)
Three 1st-line agents	11 (40.7)
Two 1st-line agents	3 (11.1)
One 1st-line agents	2 (7.4)
None	1 (3.7)
The confirmed TB patient given enough TB treatment to last until arrival to his/her country of origin, N = 18	
Yes	6 (33.3)
No	1 (5.6)
Don't know	11 (61.1)
The confirmed PTB patient referred for further treatment after Hajj, N = 22	
Yes	1 (4.5)
No	4 (18.2)
Don't know	17 (77.3)

TB; tuberculosis, PTB, pulmonary tuberculosis.
N; total number of patients with available data.

PZA-EMB, 36.6% (4/11) had RIF–INH–EMB and 9.0% (1/11) were given INH-EMB-PZA. For the remaining patients, 11.1% (3/27) received two 1st-line *anti*-TB drugs (66.6% INH-RIF, 33.4% RIF-EMB), 7.4% (2/27) received one *anti*-TB drug (RIF) and one case was recorded to have received no *anti*-TB drugs. In general, RIF was the most subscribed *anti*-TB drug (in 92.6% [25/27] of cases), followed by EMB (81.5%, 22/27) and INH (63%, 17/27) and PZA (63%, 17/27).

Based on the duration of Hajj season (around one month), the possibility of monitoring treatment completion is unfeasible in a Hajj study. Thus, appropriate post-Hajj referral and provision of drugs to last during the referral period were proxies for estimating possible continuity of care. In most cases it was not known whether confirmed TB patients were referred for further treatment after completion of Hajj (77.3%, 17/22) or were given enough *anti*-TB drugs to last until they arrive in their country of residence (61.6%, 11/18).

3.6. TB case notification

In 76.7% (23/30) of cases, the confirmed TB cases were reported to the KSA MOH preventive medicine department. The reporting status of the rest of the cases (23.3%, 7/30) was unknown. A proportion (44.8%, 13/29) of the confirmed TB cases was reported to the appropriate country medical missions' office. This excludes the 48.3% (14/29) of cases with unknown medical missions' reporting status. Among the latter, 57.1% (8/14) were Saudi residents. The confirmed TB case status of two residents of Pakistan and Myanmar were not reported to their respective country medical mission's office.

3.7. TB management guideline compliance scores

The TB management guidelines compliance scores across the 4 identified themes are presented in Table 6. Out of a maximum possible score of 10, the overall guideline compliance score was highest for the themes IPC and surveillance (9.6) and identifying TB suspects (7.2). The least scores were obtained for the themes treating TB (5.0) and diagnosing TB (3.0). Some notable variations in theme's sub-scores were observed. For instance, while the overall score for the identifying TB suspects theme was high, a low score was documented for obtaining history of TB risk factors from patients. Inversely, while the overall score for treating TB was average, high score was seen in relation to not starting TB treatment for patient before TB diagnosis.

4. Discussion

This study exemplifies the compliance of tertiary healthcare providers with the Saudi national guidelines for TB management during the Hajj. The result showed high level of compliance with the assessed TB management guidelines indices for systematic screening of TB suspects as well as IPC and surveillance, but low compliance scores were obtained for prompt TB diagnosis and use of standardized treatment regimen for drug-susceptible TB.

Most TB cases in the current study were males and over half were above 50 years old with primary or no formal education. This is in accordance with global and Hajj-related data and established risk factors for TB [1,7,10,12]. However, the prevalence of coexisting chronic diseases (63%, 17/27) among TB patients, especially diabetes, was higher than that reported internationally as well as previous studies among Hajj pilgrims with TB [7,12–14]. The presence of chronic diseases, increases the risk of TB disease, predisposes to severe illness and complicates TB treatment [1,12]. As such, the management of comorbidities is now a key focus of the integrated, patient-centered care and prevention strategy of global TB control [2].

Around 28% (8/29) of the TB cases reported being current smokers and a similar proportion (5/18) indicated that they did smoke in the past. This is higher than that reported in another study among Hajj pilgrims with TB (13.3%) [7] but lower than figures from some international reports [15,16]. Other risk factors for TB such as visit to, or residence in high-burden countries and occupational exposure were uncommon among TB patients in the study and so was previous Hajj or Umrah performance. While the latter events are not an established risk factor for TB transmission, Hajj is a risk of TB infection and both clinically-recognized or undiagnosed active TB have been reported at the pilgrimage [7,10,17].

The majority (65.4%, 17/26) of TB patients in this study were KSA residents. This may be explained by the fact that the study included both pilgrims and non-pilgrims and that healthcare facilities in Makkah provide healthcare to pilgrims and non-pilgrims during the Hajj. Although Saudi Arabia is not a high TB burden country, TB incidence in the country show significant regional variation with the Makkah region showing much higher TB incidence rates than the rest of the country and rising trend [18,19]. In addition to the hosting of the Hajj and Umrah mass gatherings, this high TB incidence may also be related to the fact that around 40% of the Makkah region population are non-Saudis, many originate from and frequently visit high TB burden countries [18,19]. Regardless, it is evident that in addition to strategies to control imported active TB [7], interventions to prevent transmission during Hajj from locals and internal pilgrims with TB should also be developed and implemented.

Generally, home-based care for TB is preferred to methods of care that are based on strict hospitalization. In the KSA context, medical or mental instability and residence in congregate settings are among factors that may warrant hospitalization [6]. In this study, most of the suspected and confirmed TB patients were admitted and isolated for TB management. To the best of our knowledge, there is no standardized global protocol guiding the choice of suitable models of care-whether home based or hospitalized care-during international mass gatherings. However, considering the potential of TB transmission in such crowded settings, the constant mobility of pilgrims and challenges in verifiable or stable residences for pilgrims during Hajj, hospitalization, although undesirable, seems a logical and practical choice for TB management during the mass gathering.

IPC in healthcare settings is one of the key strategies for TB control [20]. However, implementation of IPC recommendations seems to be inadequate with several studies reporting poor TB infection control measures in health facilities [21–24]. Further, many HCWs are practicing without adequate infection control training and often lack knowledge on TB infection control strategies and guidelines [24,25]. In the current study, we report high compliance with the aspects of TB IPC

Table 6
TB management guidelines compliance scores for the TB cases.

TB management theme/subtheme	Total number of eligible cases	Number of cases consistent with guidelines	Guideline compliance score
IPC and surveillance			**9.6**
• Pre-diagnosis admission ward	31	31	10.0
• Post-diagnosis admission ward	31	30	9.7
• Triage management	17	15	8.8
• Case notification	23	23	10.0
Identifying TB suspects			**7.2**
• Implementing symptom-based screening	31	31	10.0
• Obtaining relevant history of TB close-contact	18	14	7.8
• Obtaining history of TB risk factors	29	13	4.5
• Conducting appropriate TB screening tests	31	21	6.8
Diagnosing TB			**3.0**
• Number of diagnostic visit	10	5	5.0
• Appropriate diagnostic tests	31	9	2.9
• HIV testing	31	4	1.3
Treating TB			**5.0**
• Pre-diagnosis TB treatment	18	17	9.4
• Appropriate TB treatment regimen for confirmed cases	27	10	3.7
• Linkage to continuous care (transfer-out)	5	1	2.0

TB; tuberculosis, HIV; human immunodeficiency virus, IPC; infection prevention and control.

measures investigated. Effective separation of patients presenting with symptoms and signs consistent with TB as well as isolation of confirmed TB cases was reported. The high compliance scores for IPC may be partly related to the rigorous measures taken by the KSA MOH to prevent and control Middle East Respiratory Syndrome (MERS) in the Kingdom which, as TB, also does spread through infected person's respiratory secretions such as via coughing and sneezing [26].

Early detection through systematic screening of TB suspects is key to improving TB case detection. The WHO recommends that persons with signs and symptoms consistent with TB should be evaluated for TB to ensure prompt diagnosis and treatment [3,5]. Similarly, the Saudi TB guideline recommends that healthcare workers (HCWs) should be knowledgeable about TB symptoms to facilitate the efficient identification of TB suspects for diagnosis and treatment [6]. In the current study, providers utilized presenting symptoms to correctly identify suspected TB patients in all cases. Cough and fever with chills/night sweat were the most frequent symptoms among patients. This finding corroborates existing evidence that identifies cough as the most common symptom of PTB [3,27]. Further, in majority of cases (67.7%, 21/31), chest X-ray, a recommended screening tool for active TB, was conducted for the TB suspects. Chest X-ray is particularly more sensitive for TB screening after a positive symptom screening [27]. However, we also found that less than half of the TB suspected cases were questioned about TB risk factors. Adequate knowledge of TB symptoms and risk factors among providers are prerequisites for correct and prompt identification of suspected TB patients for screening and diagnosis [5,6]. In view of the significant use of both symptom-based and radiological screening methods in this study, a total guideline compliance score of 7.2 out of 10 was obtained for the prompt identification and screening of TB suspects theme for TB management.

Delayed diagnosis of TB can enhance the transmission of infection, worsen the disease and increase the risk of death [28,29]. In the current study, half of the TB cases had more than 2 visits to healthcare facilities before TB screening/diagnosis tests were ordered for the patients. While studies from other settings reported similar findings [30,31], our results are concerning, as delays in diagnosing TB during Hajj may lead to significant transmission given the crowded setting during the event. Similarly, sputum culture (which takes at least 2–3 weeks to produce results) was the only recommended diagnostic test applied in about 70% (21/31) of cases. The application of sputum culture as the singular diagnostic test is not consistent with approved standards for TB diagnosis [6]. As 75% (18/24) of suspected cases were confirmed to have TB by the third day of arrival in the health facility, it appears that providers relied on screening tests, such as chest X-ray, for the confirmation of TB diagnosis. This practice is inconsistent with both national and international guidelines; chest radiography is only recommended for screening purposes.

The 2014 KSA TB guidelines recommended the use of Xpert MTB/RIF as an initial TB diagnostic test on a conditional basis [6]. As such, the latter was not included in the scoring criteria for this study. Nonetheless, Xpert MTB/RIF, which could detect TB and MDR-TB by proxy in the same day [32], was not applied for TB diagnosis in this study. Although available in a number of Saudi hospitals and reference labs, the roll out of Xpert MTB/RIF has been slow and its use for point-of-care testing is limited [7,33]. Access to same day diagnosis of TB could prove valuable in a highly mobile Hajj population where follow-up visits to the same health facility may not be guaranteed and where delays in diagnosis may increase the risk of transmission in such crowded settings. As such, KSA authorities should consider the provision of TB molecular testing capability in health facilities within the Hajj areas to facilitate rapid (same-day) diagnosis of TB during the mass gatherings.

Due to the synergistic relationship between HIV and TB, it is recommended that all TB patients should be screened for HIV [5]. Yet, only a fraction of TB patients were questioned about their HIV status (20.7%, 6/29) or tested for HIV (12.9%, 4/28) in this study. This is much lower than what is reported globally [1]. As a low prevalence setting, knowledge of HIV among healthcare workers is low in Saudi Arabia [34]. Yet, HIV could be a more frequent comorbidity among pilgrims who arrive with active TB from areas with high HIV disease prevalence [1]. More so, a missed or delayed HIV diagnosis in a TB patient stalls the commencement of appropriate treatment and results in poor outcomes for the patient, community and health system [35]. Therefore, healthcare providers in KSA ought to be trained and guided to conduct screening for HIV and other comorbidities in all suspected TB patients irrespective of their nationality. In general, because of delays in diagnosis, infrequency of HIV testing and failure to utilize the appropriate diagnostic tests for suspect TB patients, the combined score for the TB diagnosis theme was 3 out of a maximum of 10, the lowest score of all TB management themes in the current study.

Treatment of TB in KSA is free of charge for pilgrims and other patients and both the KSA and WHO guidelines for TB management recommend the use of four 1st-line *anti*-TB drugs in the treatment of drug-susceptible TB [5,6]. The guideline compliance score for TB treatment in this study was average; partly because 63% (17/27) of TB patients received fewer than four 1st-line *anti*-TB drugs. In general, inappropriate treatment of TB is common worldwide. In a systematic review that included 37 studies from 22 countries, inappropriate

treatment regimens were prescribed in 67% of the studies and the percentage of patients on inappropriate regimens varied between 0.4% and 100% [36]. Poor knowledge of national and international TB management guidelines contributes to inappropriate prescription of *anti*-TB drugs by healthcare providers, and the use of inappropriate regimen drives the occurrence of relapse and the emergence of drug-resistant TB [37,38].

Both the WHO and KSA TB guidelines recommend that all patients with PTB being treated with the 1st-line regimen should have their sputum samples tested by the end of the 2nd, 5th and 6th month of treatment [6,39]. In the current study, all confirmed TB cases with known notification status were reported to the Saudi health authorities. However, it is unknown whether the continuum of care was maintained for TB cases who were international pilgrims and who had to return to their home countries soon after the pilgrimage (before the end of the treatment period). Any travel-related treatment interruptions could breed treatment relapse and drug-resistance and propagate community spread of TB. Both national and international TB guidelines fall short of providing guidance on TB control at international mass gatherings, including procedures for ensuring access to care and support services during travel. Thus, the development and dissemination of a multi-national Hajj and Umrah and/or mass gatherings-specific TB management protocols are needed. These protocols should also include pathways for the safe transfer across borders and follow up of TB patients involved in mass gatherings.

The current study is among the foremost surveys of TB management at international mass gatherings. While the small number of cases and high proportion of unknown responses for some variables constituted limitations, the TB management indices obtained was a fair representation of the compliance of providers with national and international TB guidelines in MOH hospitals during the Hajj. The findings provides a basis for the review of existing practices across settings-private and public sector vs national and foreign health facilities- and serves as a reference for the development of appropriate guideline and protocol for TB management at the Hajj and Umrah, as well as other settings with similar health system resources and population dynamics hosting recurrent international mass gatherings. In the short term, availability of rapid molecular diagnostic techniques for TB as we all improving HCWs' knowledge regarding TB management guidelines and monitoring compliance are needed to ensure TB patients are management appropriately during Hajj and that TB transmission is prevented.

Conflicts of interest statement

No conflicts of interest to declare.

Funding sources

None to declare.

Ethical approval and consent to participate

The study was approved by the King Fahad Medical City Ethics Committee and the Institutional Review Board (IRB log: 16-329E) and conducted in accordance with the Ethics Committee's guidelines. All participants gave verbal consent before enrolment.

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