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## Safety of the two-step tuberculin skin test in Indian health care workers

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### ABSTRACT

**Background:** Health care workers (HCW) in low and middle income countries are at high risk of nosocomial tuberculosis infection. Periodic screening of health workers for both TB disease and infection can play a critical role in TB infection control. Occupational health programs that implement serial tuberculin skin testing (TST) are advised to use a two-step baseline TST. This helps to ensure that boosting of waned immune response is not mistaken as new TB infection (i.e. conversion). However, there are no data on safety of the two-step TST in the Indian context where HCWs are repeatedly exposed.

**Materials and methods:** Nursing students were recruited from 2007 to 2009 at the Christian Medical College and Hospital, Vellore, India. Consenting nursing students were screened with a baseline two-step TST at the time of recruitment. From 2007 to 2008 adverse events were recorded when reported during the TST reading (Cohort A). Nurses recruited in the final study year (2009) answered an investigator administered questionnaire assessing all likely side-effects Cohort B). This information was extracted from the case report forms and analysed.

**Results:** Between 2007 and 09, 800 trainees consented to participate in the annual TB screening study and 779 did not have a past history of TB or recall a positive TST and were selected to administer TST. Of these, 755 returned for reading the result and had complete data and were included for the final analysis – 623 subjects in (cohort A) and 132 in (cohort B). These were included for the final analysis. In cohort A only 1.3% reported adverse events. In cohort B, as per the investigator administered questionnaire; 25% reported minor side effects. Itching and local pain were the most common side effects encountered. There were no major adverse events reported. In particular, the adverse events were similar in the second step of the test and not more severe.

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Conclusion: Screening of HCWs with two-step TST for LTBI is simple and safe, and hence suitable for wide scale implementation in high-burden settings such as India.

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## Introduction

For more than a hundred years, the tuberculin skin test (TST) has remained the mainstay for the testing of latent tuberculosis infection (LTBI). A new alternative test for LTBI is now available, the interferon- $\gamma$  assay (IGRA) [1]. In theory, IGRAs have many potential benefits over the conventional TST, but may not necessarily be preferred in high TB incidence settings [2].

The World Health Organization (WHO) has made the following recommendations [3]:

- “There is insufficient data and low quality evidence on the performance of IGRAs in low- and middle-income countries, typically, those with a high TB and/or HIV burden.”
- “IGRAs are more costly and technically complex to do than the TST. Given comparable performance, but increased cost, replacing TST by IGRAs as a public health intervention in resource-constrained settings is not recommended.”

Therefore, TST continues to be recommended for large-scale screening in high TB burden countries, including India.

With the advent of MDR and XDR strains of TB, the high risk of nosocomial TB in high burden settings has regained focus. Until recently, TB infection control (TBIC) has been neglected in TB endemic countries [4]. The stop TB partnership created a subgroup on TBIC, and WHO released guidelines for TBIC in resource-limited settings in 2009 [5]. The estimated prevalence of latent TB infection (LTBI) among HCWs in low- and middle-income countries is 54%, with an annual risk of TB infection (ARTI) ranging from 0.5% to 14.3% [6]. The median annual incidence of TB infection in low- and middle-income countries attributable to health care work has been estimated at 5.8% [6].

Studies conducted on health care trainees in this tertiary care hospital showed the prevalence of LTBI was 47.8% in nursing students [7], with an ARTI of 7.8% [8].

High prevalence of LTBI in health care workers (HCWs) and the very high ARTI is presumably due to the exposure to large numbers of diagnosed and undiagnosed smear-positive pulmonary TB cases, managed at the hospital and worsened by inadequate implementation of TBIC policies. These realities are common across Indian health care facilities [9,10]. Therefore, there is a strong case for the implementation of regular screening for TB infection in HCWs and health care trainees [11]. In a developing country like India, with its high-burden of TB, the simplicity and low cost of the TST makes it a more feasible screening test. Guidelines for occupational serial testing of HCWs suggest that all newly recruited HCWs should undergo a baseline 2-step TST, unless they have documented prior positive TST. In the absence of a baseline two-step TST, distinguishing boosting from conversions (new infection) is

difficult. Boosting of TST upon re-testing in the absence of new infection is due to recall of waned immunity. It is common and is nonspecific as it is associated with remote TB infection, non-tuberculous mycobacterial sensitivity, and BCG vaccination. If serial TST is planned, an initial 2-step TST is required. Otherwise, false positive TST due to boosting might be misinterpreted as conversions. However, there are no data from India on safety of doing a two-step TST in HCWs who are repeatedly exposed.

## Subjects and methods

### Study population

This study, described in previous publications [7,8], was conducted at the Christian Medical College (CMC), Vellore, a large (2200 beds) tertiary referral medical school in Vellore, a town in Southern India. All nursing students were prospectively approached for participation in a cohort study to assess prevalence and risk factors for LTBI and the annual rate of TB infection. The study protocol was approved by the institutional review boards of CMC, Vellore and McGill University Health Centre, Montreal. All clinical investigations were conducted according to the principles expressed in the Declaration of Helsinki.

The College of Nursing at CMC offers several different training programs (Diploma, BSc, Post Diploma courses, Fellowship courses, MSc, Doctoral [PhD]) and, on average, 500–600 students are in training at any given time.

### Methods

All students who provided informed consent to participate in the screening were enrolled. Students completed a written case report form (CRF), providing information on demographics, socio-economic and educational status, previous work in health care, and details on exposure to active TB patients in the hospital and in the community. A symptom screen was done for current active TB, and an assessment for any underlying immune-compromising condition or treatment was made. Examination included inspection for a BCG scar.

Students were tested with TST at baseline using the two step TST protocol [12]. Two tuberculin units (0.1 ml) of RT23 PPD (Staten Serum Institute, Copenhagen) were injected intradermally. After 48–72 h, the induration was measured by a trained reader. An induration of  $\geq 10$  mm was considered positive at baseline [13]. If TST was negative ( $<10$  mm) at baseline, participants underwent the second step of the TST testing at 7–14 days to determine boosting.

After the first TST test in these subjects, those recruited in 2007–2008 were educated about adverse events associated with the TST that could be expected, such as: blistering, fever,

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