

## Evaluation of N95 respirator use as a tuberculosis control measure in a resource-limited setting

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### SUMMARY

**SETTING:** A 150-bed public Brazilian hospital that serves as reference hospital for tuberculosis (TB) patients.

**OBJECTIVE:** To evaluate the use of personal respiratory protection by health care workers (HCWs) as a measure to reduce TB occupational risk.

**DESIGN:** One hundred and forty-five HCWs were randomly observed for the use of a N95 respirator when entering high-risk areas or performing high-risk procedures.

**RESULTS:** N95 respirators were infrequently used, even for high-risk procedures such as endotracheal intubation (25%) and respiratory aspiration (12%), and in high-risk areas such as the respirology ward (69.2%), emergency department (29.5%), intensive care unit (8.8%), and TB room isolation (39.5%). Facial-seal leakage was

observed in 39% of HCWs due to failure to wear the mask with a tight facial fit as directed.

**CONCLUSION:** Respirator use as a sole control measure is inadequate in any setting and is not cost-effective in resource-limited settings. Alternative or additional measures are clearly needed in hospitals with a high incidence of active TB admissions, specially following recent recommendations from the WHO, which consider personal respiratory protection as the third line of defense for TB control, indicated when TB risk cannot be adequately reduced by administrative and engineering controls.

**KEY WORDS:** tuberculosis control; N95 respirators; health care workers

THE OCCUPATIONAL RISK of tuberculosis (TB) in the hospital setting has been well-recognized, particularly in the last decade. It is estimated that 1% to 10% of health care workers (HCWs) may be infected annually in hospitals with more than 200 admissions per year for TB.<sup>1</sup> Several patient care-related factors can facilitate or predispose to occupational spread of the disease, such as close contact with infectious patients, bronchoscopy, intubation, endotracheal suctioning during mechanical ventilation and procedures that stimulate coughing.<sup>2</sup> TB patient characteristics, such as disease of the lungs, airways or larynx, the presence of acid-fast bacilli in sputum, absence of therapy or recently started therapy, lack of response to therapy or presence of cavitation on chest radiograph, may also enhance transmission.<sup>3</sup> Finally, the risk of transmission may be influenced by the prevalence of active TB in the community and in particular areas of the hospital.<sup>4-7</sup> For example, exposure to *Mycobacterium tuberculosis* is higher among staff working in emergency rooms (ER) and units that admit patients with active TB.

The risk of TB transmission has caused understandable alarm among HCWs about the safety of working in institutions with a large number of admissions for active TB, especially in areas with a high prevalence of multidrug-resistant TB (MDR-TB).<sup>8</sup> These concerns have led to a renewed interest in measures designed to prevent TB infection in HCWs.<sup>9</sup> Several guidelines have been developed to prevent the transmission of TB in health care facilities. The guidelines from the World Health Organization (WHO)<sup>10</sup> and the Centers for Disease Control and Prevention (CDC)<sup>11</sup> are based on a hierarchy of control measures, with emphasis on administrative measures, followed by environmental control through engineering measures. In areas where the concentrations of droplet nuclei cannot be adequately reduced by these two measures (e.g., TB patient isolation room, bronchoscopy suite), personal respiratory protection through the use of respirators is recommended.

At Julia Kubitscheck Hospital (JKH) in Belo Horizonte, Minas Gerais, Brazil, a high annual tuberculin skin test (TST) conversion rate among HCWs led to

demands for hospital administration to provide personal respirators for hospital staff. The overall TST conversion rate is 4% per year, with higher rates in the intensive care unit (ICU) (15%) and ER (16%) (unpublished data). In comparison, the TST conversion rate in the general population is about 1% per year. JKH is a 150-bed public hospital that serves as a tertiary care referral centre and a reference hospital for TB patients for the state of Minas Gerais. Approximately 50 patients are admitted with active pulmonary TB (PTB) each month. In addition, human immunodeficiency virus (HIV) infected patients are commonly cared for in the same wards, ER department and clinics as TB patients. The percentage of admitted TB patients who are HIV-infected are not known, because these patients are not routinely submitted to enzyme-linked immunosorbent assay (ELISA) for HIV testing. No administrative or engineering control measures to prevent the transmission of TB were in place before or during this study besides personal respiratory protection.

## METHODS

A cross-sectional observational study was conducted to evaluate N95 respirator use as a TB control measure in a resource-limited setting. In response to high annual HCW TST conversion rates, the administration of JKH purchased disposable, National Institute for Occupational Safety and Health (NIOSH) certified, N95 respirators with the ability to filter particles 0.3  $\mu\text{m}$  in diameter with a filter efficiency of at least 95%. In October 2000, all HCWs with direct TB patient contact were given a respirator, instructed on proper use according to the manufacturers' instructions, and fit-tested with the saccharose test.<sup>11</sup> HCWs were told that masks could be reused, but that they must be replaced if they became dirty, crushed, torn or moist. HCWs were instructed to replace their respirators at least every 30 days; however, there was no administrative procedure in place to ensure their replacement.

Between December 2000 and March 2001, HCWs were randomly observed for the use of a respirator when entering and exiting high-risk areas or performing high-risk procedures. High-risk areas were defined as units where patients with diagnosed or suspected TB are initially assessed (e.g., ER), admitted (e.g., pneumology ward), or undergo high-risk procedures (e.g., ICU). High-risk procedures were defined as procedures that produce infectious aerosols, namely endotracheal intubation, respiratory aspiration and bronchoscopy. All observed HCWs were aware of this research study.

After leaving the patient room or completing a high-risk procedure, those HCWs wearing a respirator were examined for adequacy of facial fit and possible facial-seal leakage. The correct use of the head straps, incorrect head strap tension or position, and

the presence of moustache or beard, according to the manufacturers' instructions for wearing the respirator, were observed. All HCWs were asked to produce their mask to determine whether it was soiled, moist or damaged, and were interviewed regarding mask storage conditions and length of storage. Two observers conducted the observations and HCW interviews using a standardised data collection form.

The sample size calculation, data entry and analysis were conducted using Epi Info, version 6 (CDC, Atlanta, GA). The  $\chi^2$  test or Fisher's exact test were used where appropriate, to compare proportions and rates.<sup>12</sup>

## RESULTS

Between December 2000 and March 2001, 145 HCWs were observed in the following units: ER (44), ICU (34), respiratory (26) and other units, including medical and surgical wards, ambulatory-care facilities, medical offices, dental settings (41). Seventy-six observations involved HCWs caring for patients on TB isolation. The profession of the observed HCWs included 86 nurses (59.3%), 44 physicians (30.3%), and 15 others (10.3%), including pharmacists, social workers, dentists and ward clerks (Table). Respirators were worn for 37 (25.5%) patient encounters. For patients on TB isolation, respirators were worn for 30 (39.5%) of 76 encounters. Respirators were used for 8 (20.0%) of 40 high-risk procedures, 25 (24.3%) of 103 routine patient care encounters, 15 (26.8%) of 56 medication administrations, and 2 (15.4%) of 13 instances where HCWs entered the room without providing direct care (Table).

**Table** N95 respirator use by health care workers in a TB referral hospital, Brazil

	Respirator use		Odds ratio (95%CI)	P value
	n	n (%)		
Unit				
Respirology	26	16 (61.5)	Referent	—
Emergency	44	12 (27.3)	0.23 (0.07–0.74)	0.005
Intensive care	34	2 (5.9)	0.04 (0.01–0.23)	<0.001
Other	41	7 (17.1)	0.13 (0.03–0.45)	<0.001
Shift				
Morning	67	22 (32.8)	Referent	—
Afternoon	40	6 (15.8)	0.38 (0.12–1.15)	0.06
Night	38	9 (22.5)	0.59 (0.22–1.59)	0.25
Patient on TB isolation				
Yes	76	30 (39.5)	6.85 (2.45–20.09)	<0.001
No	69	6 (8.7)		
Profession				
Nurse	86	21 (24.4)	Referent	—
Physician	44	12 (27.3)	1.16 (0.47–2.86)	0.723
Other	15	4 (26.6)	1.13 (0.27–4.42)	0.852
High-risk procedure				
Yes	40	8 (20.0)		
No	105	29 (27.6)	1.53 (0.58–4.11)	0.367

TB = tuberculosis; CI = confidence interval.

The correlation between respirator use and unit, shift, profession, TB isolation, and high-risk procedures is shown in the Table. Respirators were more frequently used in the respirology unit compared to other areas in the hospital. The use of respirators was lowest in the ICU. There was a trend toward increased respirator use for the morning shift compared to the afternoon shift, but this was not statistically significant. Respirator use was significantly higher for HCWs caring for patients on TB isolation. The frequency of respirator use was similar between nurses, physicians and other professions. HCWs were not more likely to wear a respirator when performing a high-risk procedure. During endotracheal intubation, three (25%) of 12 physicians wore a respirator. For intubations in the ICU, none of the five physicians wore respirators for the procedure, compared to three (42.8%) of seven observed intubations in the ER.

Possible face-seal leakage was observed in 16 (39.4%) of the 37 HCWs who wore respirators according to the manufacturer's instructions. The most common cause was failure to use all the head straps or incorrect head strap tension or position. One HCW had an inadequate fit due to the presence of facial hair. Masks were available for examination in 93 instances: none was in optimal condition; 84 (90.3%) were dirty, 18 (19.4%) were crushed or torn, and 1 (1.1%) was moist. In 52 instances, masks were not available for examination. Masks were commonly not available because they had been lost (30.7%), left in another location in the hospital (26.9%) or left at home (11.5%).

Storage conditions were deemed inadequate in 9 (9.7%) of 106 cases in which this information was available because the respirator was not stored in a plastic sack according to the manufacturer's instructions, although this is not considered the ideal method of respirator storage.<sup>11</sup> In addition, 4 (4.3%) HCWs kept their respirators beyond the recommended 30-day period.

## DISCUSSION

Personal respiratory protection is rarely used by HCWs at JKH. Respirator use was very low among HCWs working in TB isolation rooms or those performing high-risk procedures, two of the main indications for respiratory protection according to WHO and CDC guidelines.<sup>10,11</sup> The rate of respirator use was lowest among HCWs who entered the room but did not provide direct hands-on care, possibly due to a lack of understanding of airborne transmission. Respirator use was more common on the respirology ward compared to other areas. This finding may reflect a better awareness of the risks of TB transmission or a greater number of active PTB admissions to this unit. Compliance was lowest in the ICU, although this is a high-risk setting due to production of infectious

aerosols during respiratory aspiration and endotracheal intubation. The reasons for low compliance in the ICU are not clear, although inadequate time for HCWs to locate and put on a respirator during life-threatening emergencies may be a contributing factor.<sup>13</sup>

A proper seal between the respirator and the face of the wearer is essential for effective, reliable protection. In this study, the main cause of possible face-seal leakage was failure to wear the respirator as directed, despite intensive training on proper use. The HCWs using a HEPA filter complained of discomfort and interference with breathing if they wore the respirator to produce a tight facial fit. HEPA filter use increases resistance to breathing, dead space and physical load. Increased resistance to inspiratory and expiratory flow can reduce maximal work performance by approximately 10%.<sup>14,15</sup> If HCWs wear their HEPA filters or N95 respirators improperly to reduce the work of breathing, the use of these expensive respirators will provide no benefit in TB prevention and may result in a false sense of security.<sup>16</sup>

There are some limitations to this study. HCW compliance with respirator use was determined by direct observation over a defined period of time. Compliance may have been influenced by the presence of the study personnel, although it is expected that compliance was increased during the period of observation. In addition, compliance rates may have been different if measured at shorter or longer intervals after mask distribution and training.

Besides the use of respirators, no administrative or engineering control measures were in place at JKH at the time of the study to prevent occupational acquisition of TB. The doors of the isolation rooms are always open, and furthermore some of the rooms have no doors and patients can circulate throughout the hospital without surgical masks; when there is no isolation room available most TB patients are admitted to medical rooms. Smear results can take 2 to 3 days to arrive. Sometimes treatment is initiated before the results, but this is not always possible, due to limited hospital resources. HCWs at this hospital must enter TB isolation rooms routinely and work in close proximity to infectious patients. Thus, a combination of effective administrative controls, engineering measures and personal protective devices may be needed to provide adequate protection.<sup>17</sup> No studies have compared the relative efficacy of different interventions in reducing the occupational risk of TB. This information would be invaluable in resource-limited settings so that efforts can be directed toward those that have the greatest impact.<sup>18</sup> The use of respirators as a sole control measure is inadequate in any setting, as TB transmission may occur when contagious patients are not identified promptly, isolated and treated.<sup>19</sup> Furthermore, although respirator use may offer some protection to HCWs, this measure alone will not protect other patients or visitors.

In the absence of conclusive data to support or refute the effectiveness of individual respiratory protection in preventing TB transmission in the health care setting, medical prudence suggests that respirators are a reasonable approach to promote additional protection to exposed workers when administrative and engineering measures are inadequate.<sup>20</sup> Although there is clearly a need for data on the effectiveness of respirators, ideal studies to resolve this question will probably never be conducted due to ethical reasons. The optimal study would compare TST conversion rates in health care facilities in high-prevalence areas with and without the use of respirators while other TB control measures remain unchanged.<sup>21</sup>

This study and others have shown that HCW acceptance is an important factor limiting the effectiveness of respirators against inhalation hazards.<sup>15</sup> Furthermore, respirators that are not worn as recommended or cared for in a manner that maintains their integrity afford little protection. Hospitals should consider these factors before spending limited resources on purchasing respirators when planning TB control programs. Respirators should not be relied on as the primary method of TB control, and alternative or additional measures must be taken to prevent occupational TB transmission in hospitals with a high incidence of active TB patient admissions.

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## RÉSUMÉ

**CONTEXTE :** Un hôpital public brésilien de 150 lits qui sert d'hôpital de référence pour les patients tuberculeux (TB). **OBJECTIF :** Évaluer l'emploi d'une protection respiratoire personnelle par les travailleurs de soins de santé (HCW) comme mesure de réduction du risque professionnel de tuberculose (TB).

**SCHEMA :** On a observé l'utilisation par 145 HCW randomisés du masque respiratoire N95 pour pénétrer dans des zones à haut risque ou pendant des procédures entraînant des risques élevés.

**RÉSULTATS :** Les masques respiratoires N95 ont été utilisés peu fréquemment, même pour les procédures à haut risque comme l'intubation endotrachéale (25%), l'aspiration respiratoire (12%) et dans des zones à haut risque comme la salle de pneumologie (69,2%), le département des urgences (29,5%), l'unité de soins intensifs (8,8%) et la chambre d'isolement TB (39,5%). On a observé des fuites au niveau du masque facial chez 39% des HCW par suite du défaut de respect des indications, c'est-à-dire un arrimage facial étanche.

**CONCLUSION :** L'utilisation d'un masque respiratoire comme mesure unique est inadéquate dans n'importe quel contexte et a un mauvais rapport coût/efficacité dans des contextes à ressources limitées. Des mesures alternatives ou additionnelles sont manifestement nécessaires dans les hôpitaux où les admissions pour TB active ont une

forte incidence, particulièrement en concordance avec les recommandations récentes de l'OMS, qui considère que la protection respiratoire individuelle est la troisième ligne de défense de la lutte antituberculeuse, indiquée lorsque le risque de TB ne peut pas être réduit de façon correcte par des mesures administratives ou techniques.

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## RESUMEN

**MARCO DE REFERENCIA :** Un hospital público de 150 camas, a su vez hospital de referencia para pacientes con tuberculosis (TB), en Brasil.

**OBJETIVO :** Evaluar el uso de la protección respiratoria personal por parte de los profesionales de la salud (HCW), como medio para reducir el riesgo profesional de TB.

**MÉTODO :** Se observaron aleatoriamente 145 profesionales de la salud para analizar su utilización de un respirador o máscara N95 cuando ingresaban en zonas de alto riesgo o cuando realizaban procedimientos de alto riesgo.

**RESULTADOS :** El uso de la máscara N95 fue infrecuente, incluso durante procedimientos de alto riesgo como la intubación endotraqueal (25%) y la aspiración de las vías respiratorias (12%) y en las zonas de alto riesgo como el servicio de neumología (69,2%), el servicio de urgencias (29,5%), la unidad de cuidado intensivo

(8,8%) y las habitaciones de aislamiento para TB (39,5%). Se observaron fugas al nivel de los bordes de la máscara en el 39% de los HCW, debido a la falta de un buen ajuste facial, recomendado para un buen uso de la máscara.

**CONCLUSIÓN :** El uso de la máscara como única medida de protección es inadecuado en todos los ambientes y no es rentable en medios con limitación de recursos. Es evidente que en hospitales con un alto número de ingresos por TB se precisan medidas alternativas o adicionales. Según las recomendaciones recientes de la OMS la protección respiratoria personal constituye la tercera línea de defensa en la lucha contra la TB, y está indicada cuando el riesgo de TB no puede reducirse adecuadamente mediante medidas administrativas, ni de ingeniería.

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