

# Personal respiratory protection and tuberculosis: national evidence-based guidelines in England and Wales

Pratt RJ<sup>1</sup>, Curran ET<sup>2</sup>

1. Professor of Nursing, Director, Richard Wells Research Centre, Thames Valley University London, 32-38 Uxbridge Road, London W5 2BS
2. Lead Nurse for Infection Control, North Glasgow Sector, NHS Greater Glasgow and Clyde, Glasgow Royal Infirmary, Bacteriology Department, Glasgow G4 0SF and Honorary Lecturer, Glasgow University, Glasgow G12 8LW

Accepted for publication: 17 May 2006

Key words: Tuberculosis, personal respiratory protection, infection control, evidence-based guidelines

## Abstract

**I**n our review published in the previous issue, we noted that contradictory infection prevention and control recommendations have resulted in confusion in practice and inconsistent use of personal respiratory protection when caring for patients with infectious respiratory tuberculosis in hospitals and other healthcare facilities. Recent national evidence-based guidelines in England and Wales have sought to clarify this issue by making firm recommendations for tuberculosis infection prevention and control. We describe and discuss this guidance, focusing on our concerns over the illogical recommendations for the use of personal respiratory protection.

## Introduction

In the previous issue of this journal, we reviewed the evidence for the effectiveness of various infection control measures frequently recommended for reducing the risk of nosocomial transmission of *Mycobacterium tuberculosis* when caring for patients with infectious respiratory tuberculosis (Curran et al, 2006). We described the underpinning evidence for a hierarchy of tuberculosis control strategies that are incorporated into a single effective evidence-based tuberculosis control programme in hospitals and other healthcare facilities. These control strategies include administrative and engineering controls and personal respiratory protection (PRP). We stressed that administrative and engineering controls, i.e. having efficient and reliable systems in place to identify, isolate, investigate, and treat patients who may have infectious respiratory tuberculosis, were the most effective control measures available to prevent nosocomial transmission in healthcare settings. We then described the indications for the appropriate use of PRP in certain clinical situations. We concluded that the evidence for using PRP was ambiguous and that there should be clear and authoritative national guidance on the role for PRP in the protection of healthcare workers from occupational exposure to tuberculosis.

The National Collaborating Centre for Chronic Conditions (Royal College of Physicians) has now produced this guidance on behalf of the National Institute for Health and Clinical Excellence (NICE) in England and Wales (National Collaborating Centre for Chronic Conditions, 2006). As this guidance has already been reviewed (Bell, 2006), in this brief article we focus on using the NICE guideline recommendations to clarify the use of PRP when caring for patients with known or suspected infectious respiratory tuberculosis.

## Personal respiratory protection (PRP)

PRP involves the use of filtering half-mask respirators or powered air-purifying respirators (PAPR) to minimise the risk to healthcare workers from potentially harmful air contaminants, such as *M. tuberculosis*. We have previously described in detail the types of filtering half-mask

respirators (meeting the European standard EN 149: 2001) that are approved for use in the UK (Curran et al, 2006). All of these leak to some extent and they are graded accordingly: FFP1 masks are allowed a total inward leakage in simulated use of 25%; FFP2 masks are allowed a simulated leakage of 11%, while FFP3 masks (the highest grade in this category of PRP) are allowed a 5% total leakage rate. We have also previously described the use in some clinical circumstances of PAPR (Curran et al, 2006), but in this article we are concentrating on trying to clarify the use of filtering half-mask respirators in view of the new NICE guideline.

## Background

Historically, nurses and other healthcare workers have used a variety of face masks, e.g. surgical masks, to minimise the risk of becoming exposed to *M. tuberculosis* when caring for patients with infectious respiratory tuberculosis (sputum microscopy smear positive for acid-fast bacilli (AFB)). In more recent times, it has been recognised that any face mask worn for protection against tuberculosis must be capable of filtering out particles as minute as evaporated respiratory droplets (droplet nuclei) containing tubercle bacilli, i.e. less than five micrometres in aerodynamic diameter. During the last decade, particulate filter respirators capable of doing this, such as the current range of half-mask filtering respirators, have been introduced into infection control practice.

Although nurses have recognised that administrative and engineering controls are the most effective means of preventing nosocomial exposure when caring for patients with infectious respiratory tuberculosis, PRP has continued to be used as part of an overall tuberculosis control programme. Authoritative guidelines (Centers for Disease Control and Prevention, 2005) and various statutory health and safety regulations (Health and Safety Executive, 2002) have recommended and required the use of PRP when caring for patients known or suspected of having infectious respiratory tuberculosis. The rationale for this has been that healthcare workers need to avoid any exposure to biological agents such as bacteria, viruses or fungi that create a hazard to human health. While accepting that administrative and engineering controls most efficiently protect against this, these measures are not fail-safe and at any rate do not completely eliminate the risk of preventable exposure. Indeed, one notable outbreak of multi-drug resistant respiratory tuberculosis (MDR-TB) occurred in a London teaching hospital, because of a failure of engineering controls (Breathnach et al, 1998) and other examples of inadequate engineering controls were cited in our review (Wiggam et al, 2000; Pavelchak et al, 2001; Sutton et al, 2000). In addition, there are reports in the literature of the failure of administrative controls where patients admitted with respiratory signs and symptoms suggestive of respiratory tuberculosis are initially misdiagnosed on admission. This has

**Table 1. Hierarchy of evidence and recommendation classification (National Collaborating Centre for Chronic Conditions, 2006)**

Level of evidence		Classification of recommendation	
Level	Type of evidence	Class	Evidence
<b>1+ +</b>	High-quality meta-analysis (MA) systematic reviews (SR) of randomised controlled trials (RCTs), or RCTs with a very low risk of bias.	<b>A</b>	Level 1+ + and directly applicable to the target population <i>or</i> Level 1+ and directly applicable to the target population AND consistency of results Evidence from NICE technology appraisal
<b>1+</b>	Well-conducted MA, SR or RCTs, or RCTs with a low risk of bias		
<b>1-</b>	MA, SR or RCTs, or RCTs with a high risk of bias		
<b>2+ +</b>	High-quality SR of case-control studies. High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal	<b>B</b>	Level 2+ +, directly applicable to the target population and demonstrating overall consistency of results <i>or</i> extrapolated evidence from 1+ + or 1+
<b>2+</b>	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal		
<b>2-</b>	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant probability that the relationship is not causal		
<b>3</b>	Non-analytic studies (for example case reports, case series)	<b>C</b>	Level 2+, directly applicable to the target population and demonstrating overall consistency of results <i>or</i> extrapolated evidence from 2+ +
<b>4</b>	Expert opinion, for consensus		
		<b>D(GPP)</b>	A good practice point (GPP) is a recommendation based on the experience of the GDG

resulted in delays in initiating appropriate infection control measures and in starting effective antituberculosis therapy that can render the patient non-infectious. In fact, an outbreak of MRD-TB in another London hospital was caused by just such a failure in administrative controls, compounded by aerosol generating diagnostic procedures being used on the source patient in an open bay on a ward with other immunocompromised patients (Kent et al, 1994).

### Supporting evidence

The new NICE guideline (National Collaborating Centre for Chronic Conditions, 2006) acknowledges that as infection control measures are often implemented together, it is difficult to assess the contribution of each measure. Additionally, the guideline development group (GDG) was unable to identify studies of sufficient methodological quality to support many current infection control practices and concluded that 'there was no good evidence to support measures for infection control in patients with smear-positive disease not suspected to have MDR-TB, whether or not HIV positive, and endorsed the guidance given in the British Thoracic Society guideline' (Joint Tuberculosis Committee of the BTS, 1998). The GDG further noted that 'masks are only required for MDR-TB or during close contact in cough-inducing procedures, for example bronchoscopy and sputum induction'.

The recommendations for PRP were classified according to the level of evidence which influenced the recommendation (see Table 1).

### Evidence to recommendations

The GDG made a range of comprehensive recommendations (see Box 1 for those focused on PRP). The recommendations for PRP were derived from the experiences of the GDG and classified as good practice points, i.e. based on acceptable evidence, but the lowest category

of evidence. It is important to remember that all evidence-based guidelines are based on the best available evidence, not the best possible evidence (Pratt et al, 2001).

In the NICE guidelines, PRP is only recommended when caring for patients with suspected or diagnosed MDR-TB or when being present during aerosol-generating procedures (being conducted on any patient with suspected or known infectious respiratory tuberculosis). The GDG further recommend that all patients with tuberculosis be assessed for drug resistance and further advise that when PRP is recommended, FFP3 respirators are used (National Collaborating Centre for Chronic Conditions, 2006) (see Box 2).

### Discussion

Evidence-based guidelines are produced by National Collaboration Centres on behalf of NICE to facilitate clinical effectiveness, i.e. to ensure that practice decisions are based on best evidence of efficacy. The guideline developed by the National Collaborating Centre for Chronic Conditions provides comprehensive evidence-based practice recommendations spanning all of the salient issues of clinical diagnosis, medical management and measures for prevention and control of tuberculosis. The methodological approach to developing this guidance is sound and congruent with best practice in guideline developments. The recommendations have been widely consulted on and enjoy the approval of the key stakeholders, professional organisations and societies, including the Infection Control Nurses Association, whose members served on the GDG.

Some infection control practitioners will be surprised to see recommendations for using PRP for MDR-TB, but not for drug-sensitive tuberculosis. As PRP is intended to form part of a 'protective package' (along with administrative and engineering controls) of measures to minimise the risk of preventable exposure to infectious

**Box 1. Guidelines for personal respiratory protection from the National Institute for Health and Clinical Excellence (National Collaborating Centre for Chronic Conditions, 2006)**

- (Recommendation 23) Healthcare workers caring for people with tuberculosis should not use masks, gowns or barrier nursing techniques unless:
  - MDR-TB is suspected
  - Aerosol-generating procedures are being performed
- (Recommendation 16) All patients with tuberculosis should have risk assessments for drug resistance and for HIV (see Box 2)
- (Recommendation 57) Staff and visitors should wear FFP3 masks during contact with a patient with suspected or known MDR-TB while the patient is considered infectious.

[All recommendations are classified as **D(GPP)** (see Table 1)]

**Box 2. Risk factors for drug resistance (National Collaborating Centre for Chronic Conditions, 2006)**

Recommendation 52 – A risk assessment for drug resistance should be made for each patient with tuberculosis, based on the risk factors listed below:

- History of prior tuberculosis drug treatment; prior tuberculosis treatment failure
- Contact with a known case of drug-resistant tuberculosis
- Birth in a foreign country, particularly high-incidence countries as defined on the Health Protection Agency website. See: [www.hpa.org.uk](http://www.hpa.org.uk) (search for 'World Health Organization country data TB')
- HIV infection
- Residence in London
- Age profile, with highest rates between ages 25 and 44
- Male gender.

[Recommendation classified as **C** (see Table 1)]

micro-organisms, why, some may wonder, is it permissible to allow exposure to drug-sensitive tuberculosis, but extra precautions are required to minimise exposure to drug-resistant tuberculosis? After all, drug-resistant tuberculosis is no more and no less infectious than is drug-sensitive tuberculosis. It is just that the consequences of drug-resistant tuberculosis, e.g. prolonged period of therapy and isolation, treatment expense and poor clinical outcomes, are more severe with drug-resistant disease. However, it could be argued that this does not justify allowing nurses to be exposed to preventable drug-sensitive micro-organisms simply because if they become ill as a result of this exposure they can be treated. If a particulate filter respirator will provide some protection against exposure to drug-resistant tubercle bacilli, surely it will provide the same protection against drug-sensitive tubercle bacilli. The authors do not know too many nurses who would be comfortable in being unnecessarily exposed to any level of tubercle bacilli when caring for a patient with infectious respiratory tuberculosis, drug-resistant or drug-sensitive, when it could be prevented by the use of PRP.

Triage assessment for risk factors for drug-resistance may not be reliable and additionally, we have already identified that failures in both administrative and engineering controls may result in nurses and other healthcare workers becoming exposed to MDR-TB.

What are the moral and legal consequences of a nurse following these guidelines, i.e. not using PRP, who becomes occupationally exposed to a patient with infectious respiratory tuberculosis and acquires active respiratory tuberculosis, regardless of whether or not it is drug-resistant? How will NHS trust chief executives and trust infection control teams in England and Wales rationalise a two-tier approach to using PRP, if it results in exposing healthcare workers to preventable infectious agents that may cause disease?

Guidelines serve to facilitate good clinical decision-making and provoke further discussion on the most clinically effective approaches to patient care. Often a lack of evidence becomes apparent during the guideline development process and this is reflected in an agenda for further research. A hallmark of evidence-based guidelines is that they are reviewed and updated on a timely basis. Let us hope that when these guidelines are revised, there is better evidence with which to support or refute the use of PRP when caring for patients with tuberculosis, whether the strains are drug-resistant or sensitive. The question is, however... can we wait?

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