Health Protection Scotland

NHS National Services Scotland

HPS Position Statement August 2018

SBAR: National guidance on the use of RPE for healthcare staff caring for patients with *Mycobacterium tuberculosis* complex

Situation	Some respiratory/Infectious Disease physicians and Health Protection Team (HPT) clinicians have expressed concerns with the National Infection Prevention and Control Manual (NIPCM) guidance with regard to the wearing of Respiratory Protective Equipment (RPE) i.e. a filtering face piece (FFP3) respirator, when clinically caring for a patient(s) who is considered infectious with *Mycobacterium tuberculosis* complex. This paper explains the evidence underpinning the guidance to seek support and identifies potential topics for shared review to further improve the RPE guidance.
Background	The NIPCM was developed to support the consistent application of Standard Infection Control Precautions (SICPs) and Transmission Based Precautions (TBPs) .[1] The content of the NIPCM is approved by the multidisciplinary National Policy, Guidance and Outbreak (NPGO) Steering Group. The content of the NIPCM Appendix 11, regarding those infectious agents spread by the airborne route (i.e. *Mycobacterium tuberculosis* complex, *Varicella-Zoster* virus and *Measles* virus) has been a focus of much debate amongst clinicians from various specialities since it was first drafted in 2016. Following previous face-to-face and electronic consultation, a further meeting has been called to explain the reasoning for the current guidance and to gain the support for the national guidance from respiratory/Infectious Disease clinicians working in this area. It is worth noting that this topic has been the subject of much vexed discussion outwith Scotland. For example, as described in the HPS TBPs Literature review on RPE, whilst there is consensus in the literature that *'healthcare workers should use an approved respirator when caring for patients with known or suspected infection transmissible by the airborne (aerosol) route i.e. MDR-TB and XDR-TB and SARS, while the patient is considered infectious.'*;[2] evidence-based guidance on the use of respiratory and facial protection equipment published by the Healthcare Infection Society (HIS) states that a respirator should be worn when caring for patients with active respiratory TB until MDR or XDR disease has been excluded.[3] This recommendation differs from recommendations in other UK guidance such as that made by the National Institute for Health and Care Excellence (formerly the National Institute for Health and Clinical Excellence), that healthcare workers are only required to wear a respirator when caring for a patient with TB if MDR TB is suspected.[4] The HIS guidance also differs from Scottish guidance published by the Health Protection Network (SHPN) which states that healthcare workers should wear a respirator when caring for a patient with TB if MDR TB is suspected, but

	outlines the additional requirement for healthcare workers to wear a respirator when: *'intensive nursing intervention is required if the healthcare worker is likely to have close contact (equivalent to household contact) for a cumulative total for eight hours or more'*. With regards to the evidence underpinning the '8-hour exposure rule' NICE advised (email 27th November 2017) that this is specific to contact tracing exercises and not intended to guide Personal Protective Equipment (PPE)/RPE use*: 'The guideline development group (GDG) recognised the need to limit contact tracing exercises to instances where there is a genuine risk of TB transmission, and chose eight hours as a time threshold for exposure. There is no evidence to support this, but it is in line with the threshold given elsewhere for contact tracing.'* Therefore, the aim of the NIPCM has been to clarify a very confusing topic area, providing Scottish advice in clear and simple terms so as to facilitate the consistent application of SICPs and TBPs. It is the view of the HPS HAI team that what is preventing Tuberculosis outbreaks in our healthcare settings today is not excellence in infection prevention and control practice, but a low incidence of TB in the UK population. Curran (2018) however reminds us that the world population is continuously on the move, with >3 billion air passengers travelling the globe each year, and many people fleeing from countries which have the highest rates of disease - living in refugee camps/asylum centres, unable or declined access to healthcare, providing optimal conditions for disease transmission;[5] and although drug sensitive disease is decreasing worldwide, drug resistant disease is increasing, of which only 20% are being treated.[6]
Assessment	Firstly, regarding the NIPCM, it is important to note that the aim of the manual is to: • Embed the importance of SICPs into everyday practice • Reduce variation in infection prevention and control practice and standardise care processes across all care settings in Scotland • Improve the consistent application of SICPs and understanding when TBPs are required in addition • Release individual board Infection Prevention and Control Team (IP&CT) time from local guidance production to instead ensure the nationally agreed policy and guidance is implemented; and improve staff knowledge and patient confidence in the eradication of avoidable HAIs The content development of the NIPCM is based on an assessment of the extant professional literature and, where evidence is lacking based on expert consensus. Consultation and collaboration with key stakeholders seeks to ensure the guidance produced is risk based and proportionate and in a format that is applicable and accessible to all care staff. The advantages of this standardised guidance approach include a common (NHS Scotland) understanding of PPE requirements for pathogens spread via the contact, droplet and airborne routes; simple rules for all staff (specialist and generalist) leading to improved understanding and consistency of application - which is the underlying principle of the NIPCM. This approach seeks to support the development of a NHS Scotland workforce that is PPE knowledgeable and prepared to effectively respond to current and emerging infection threats. Conversely, it can be expected that a lack of clear, concise and consistent advice

	with regard to PPE use will lead to inconsistent practice and hence a potential increased risk of disease transmission. It is important to point out that the content of the NIPCM is not fixed; it is updated real time; the HPS NPGO Programme Team continuously monitor the published literature for any new evidence, revising the literature review(s) and practice guide accordingly. All of the NIPCM literature reviews (of which there are currently 29) also highlight gaps in infection prevention and control evidence and are accessible to all interested researchers. Secondly, specifically in relation to the recommendation to wear a FFP3 respirator, when clinically caring for a patient who is considered infectious with *Mycobacterium tuberculosis* complex, the key points to note are: 1. Tuberculosis is an airborne pathogen to which, depending on its prevalence and our exposure, we are all vulnerable.[7-9] Accordingly, with regards to infection prevention and control in the healthcare setting, page 277 of the updated NICE guideline (2016) recommend: *'Health care workers and others in contact with patients with pulmonary, or 'infectious', tuberculosis should use appropriate infection control measures, such as FFP3 masks, to protect themselves against transmission until drug susceptibility is demonstrated.'*[4] This 'precautionary principle' is consistent with that recommended in the NIPCM TBPs: '*Respiratory Protective Equipment (RPE) i.e. FFP3 and facial protection, must be considered when a patient is admitted with a known/suspected infectious agent/disease spread wholly by the airborne or droplet route and when carrying out aerosol generating procedures (AGPs) on patients with a known/suspected infectious agent spread wholly or partly by the airborne or droplet route.'*[1] 2. With regard to the level of risk posed, the NPGO Steering Group considered the scoring system developed by Jones and Brosseau[7] as a useful tool to objectively assess the threat. The group agreed with those authors where they stated that '*Mycobacterium tuberculosis is currently recognised as transmitted through the airborne route'* and also agreed with their assessment where they stated, '*Specifically, viable M. tuberculosis bacilli are emitted in cough, the bacilli survive in air over tens of minutes, and infection of animals by bacilli carried in air from tuberculosis hospital wards has been demonstrated experimentally, which are strong, strong, and moderate levels of evidence for conditions 1 to 3, respectively (Table 2). As a risk group 3 organism with an overall weight of evidence score equal to 8, there should be a high level of concern for aerosol transmission as a route of exposure (Table 3). This is supported by the current Centers for Disease Control and Prevention guidance for managing tuberculosis.'* 3. The NPGO Steering Group also discussed the implications of drug resistant versus drug susceptible disease and agreed that RPE requirements should not vary based on drug-resistance. To summarise the discussion, if a high level of RPE is required for drug resistant disease, then logically and ethically it must also be required for drug-sensitive disease; given that the current evidence suggest that the transmissibility and pathogenicity remain unchanged

	regardless of the organisms' drug resistance. The difference based on drug-resistance is the ability to treat, and the cost, toxicity and duration of treatment. Given all of the above, the multidisciplinary NPGO Steering Group endorsed the subsequently published document. To move on, with regard to potential for future refinement of the RPE guidance, some points to consider where joint discussion could be useful are listed below: 1) It has also been reported that: Patients who are smear-positive are most infectious; but smear-negative patients can transmit the disease;[10] people with the highest exposure more often become infected; but some people with minimal exposure become infected;[11] even people with extra-pulmonary disease have transmitted TB disease e.g. aspiration of a tuberculosis abscess;[12] one recent report confirmed transmission of a patient with extra-pulmonary disease through whole-genome sequencing.[13] 2) It maybe useful to discuss whether further clarification as to what are the key indicators for cessation of respirator usage could be for subsequent consideration by the NPGO Steering Group. Finally, as stated in the NIPCM TBPs literature review,[2] although there is no direct legislative requirement for healthcare staff to wear a respirator when delivering care, UK legislation does require employers to provide PPE that affords adequate protection against the risks associated with the task being undertaken: The Health and Safety at Work etc. Act (HSWA) requires a safe working environment and sets the precedent from which all other health and safety regulations follow;[14] the Management of Health and Safety at Work Regulations (MHSWR) place the legal responsibility for health and safety primarily with the employer;[15] under the Control of Substances Hazardous to Health (COSHH) Regulations, where it is not reasonably practicable to prevent exposure to a substance hazardous to health via elimination or substitution (as is the case where healthcare workers are caring for individuals known, or suspected, to be infected with a microorganism spread by the airborne (aerosol) route), then the hazard must be adequately controlled by "applying protection measures appropriate to the activity and consistent with the risk assessment";[16] healthcare staff have a responsibility to ensure that suitable PPE is worn correctly for the task being undertaken.
Recommendations	HPS recommendations: 1. Given the evidence described and the legal responsibility to ensure patient and staff safety, the currently described NIPCM guidance for RPE use for *Mycobacterium tuberculosis* complex should be endorsed. 2. There may be some additions that could be made to the guidance that could improve its application and further advice on these points from Respiratory/Infectious Disease physician colleagues would be helpful to agree recommendations for the consideration of the NPGO Steering Group.

Reference List

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