A position statement and practical guide to the use of particulate filtering facepiece (N95, FFP2, or equivalent) respirators for South African health care workers exposed to respiratory pathogens including *M. tuberculosis* and SARS-CoV-2

Keertan Dheda,^{1,2} Salome Charalambous,^{3,4} Aaron S Karat,⁵ Arne von Delft,^{6,7} Umesh G Laloo,^{8,9} Richard van Zyl Smit,¹⁰ Rubeshan Perumal,¹ Brian W Allwood,¹¹ Aliasgar Esmail,¹² Michelle L Wong,¹³ Adriano G Duse,¹⁴ Guy Richards,¹⁵ Charles Feldman,¹⁶ Mervyn Mer,¹⁷ Kennedy Nyamande,¹⁸ Usha Lalla,¹¹ Coenraad FN Koegelenberg,¹¹ Francois Venter,¹⁹ Halima Dawood,²⁰ Shahieda Adams,²¹ Ntobeko AB Ntusi,²² Helene-Mari van der Westhuizen,^{7,23} Mahomed-Yunus S Moosa,^{24,25} Neil A Martinson,^{26,27} Harry Moultrie,^{28,29} Jeremy Nel,³⁰ Harry Hausler,³¹ Wolfgang Preiser,³² Lance Lasersohn,^{33,34,35} Heather J Zar,³⁶ Gavin J Churchyard^{3,4,37}

***A position statement endorsed by the
South African Thoracic Society, Infection Control Society of South Africa,
South African Society of Anaesthesiologists, Critical Care Society of Southern Africa,
South African Medical Association, South African HIV Clinicians Society,
Infectious Diseases Society of South Africa, South African Heart Association, TB Proof, and Free of TB***

Affiliations

1. Centre for Lung Infection and Immunity, Division of Pulmonology, Department of Medicine and UCT Lung Institute & South African MRC/UCT Centre for the Study of Antimicrobial Resistance, University of Cape Town, Cape Town, South Africa.
2. Faculty of Infectious and Tropical Diseases, Department of Immunology and Infection, London School of Hygiene & Tropical Medicine, London, United Kingdom
3. The Aurum Institute, Johannesburg, South Africa
4. School of Public Health, University of the Witwatersrand, Johannesburg, South Africa
5. TB Centre, London School of Hygiene & Tropical Medicine, London, United Kingdom
6. School of Public Health and Family Medicine, University of Cape Town, Cape Town, South Africa
7. TB Proof, South Africa
8. Gateway Private Hospital Medical Centre, Umhlanga Ridge, South Africa
9. Principal Investigator Durban International Clinical Research Site
10. Division of Pulmonology and Department of Medicine, University of Cape Town & Groote Schuur Hospital
11. Division of Pulmonology, Department of Medicine, Stellenbosch University and Tygerberg Hospital, Cape Town, South Africa
12. Clinical Trials Unit, University of Cape Town Lung Institute, South Africa
13. Division of Pulmonology, Department of Medicine, School of Clinical Medicine, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa
14. Clinical Microbiology & Infectious Diseases, School of Pathology of the NHLS & University of the Witwatersrand, Johannesburg, South Africa
15. Dept of Critical Care, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa

16. Department of Internal Medicine, School of Clinical Medicine, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa
17. Department of Medicine, Divisions of Pulmonology and Critical Care, Charlotte Maxeke Johannesburg Academic Hospital and Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa.
18. Department of Pulmonology, Nelson R Mandela School of Medicine, College of Health Sciences, University of KwaZulu Natal, Durban, South Africa
19. Ezintsha, Faculty of Health Sciences, University of the Witwatersrand
20. Greys Hospital, Pietermaritzburg, South Africa
21. Division of Occupational Medicine, School of Public Health and Family Medicine, University of Cape Town, South Africa
22. Division of Cardiology, Department of Medicine, University of Cape Town and Groote Schuur Hospital, Cape Town, South Africa
23. Nuffield Department of Primary Care Health Sciences, University of Oxford, United Kingdom
24. Department of Infectious Diseases, Division of Internal Medicine, Nelson R Mandela School of Medicine, University of KwaZulu-Natal, Durban, South Africa
25. Southern African HIV Clinicians Society
26. Perinatal HIV Research Unit (PHRU), University of the Witwatersrand, South Africa.
27. Johns Hopkins University Center for TB Research, Baltimore MD
28. National Institute for Communicable Diseases, Division of the National Health Laboratory Service, Johannesburg, South Africa
29. Clinical Microbiology & Infectious Diseases, School of Pathology, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa
30. Division of Infectious Diseases, Department of Medicine, University of the Witwatersrand
31. TB HIV Care, Cape Town, South Africa
32. Division of Medical Virology, Faculty of Medicine and Health Sciences, Stellenbosch University and National Health Laboratory Service Tygerberg
33. South African Society of Anaesthesiologists
34. Department of Anaesthesia, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa
35. Division of Critical Care, Chris Hani Baragwanath Hospital and University of the Witwatersrand, Johannesburg, South Africa.
36. Dept of Paediatrics & Child Health, Red Cross Children's Hospital and SA-MRC unit on Child & Adolescent Health, University of Cape Town, South Africa
37. Department of Medicine, Vanderbilt University, Nashville, TN, USA

Corresponding author

Keertan Dheda, Centre for Lung Infection and Immunity, Division of Pulmonology, Department of Medicine and UCT Lung Institute, Groote Schuur Hospital, Old Main Building, Observatory Cape Town, 7925

Email: keertan.dheda@uct.ac.za

Executive summary

Initial recommendations for protecting health care workers (HCWs) against COVID-19 were based on an early and incomplete understanding of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission; namely, that it occurred mainly via large respiratory droplets ($>10\text{ }\mu\text{m}$) that were inhaled into the nasopharynx, directly inoculated onto mucous membranes, deposited on the skin and transferred by direct contact, or transferred indirectly by infected fomites. There is now substantial evidence to show that transmission by aerosol (particles $<10\text{ }\mu\text{m}$ that can remain suspended for hours before being inhaled) is likely the predominant mode, with skin- and fomite-based transmission thought to play a lesser role. Many international organisations have updated their personal protective equipment (PPE) guidelines accordingly. Because N95 or equivalent particulate filtering facepiece respirators (henceforth referred to as 'respirators') are more effective than surgical masks against bioaerosols, the World Health Organization, United States Centers for Disease Control and Prevention, and European Centre for Disease Control and Prevention all now recommend that HCWs wear a respirator when caring for individuals thought to have COVID-19. In South Africa, however, surgical masks are still recommended for the routine care of individuals with possible or confirmed COVID-19, with respirators reserved for so-called aerosol-generating procedures. In contrast, South African guidelines recommend the use of respirators for routine care of all individuals with possible or confirmed tuberculosis (TB), which is transmitted almost exclusively via aerosol.

In health facilities in South Africa, TB and COVID-19 have similar presentations, may occur together, and often have overlapping risk factors and imaging characteristics. Distinguishing between TB and COVID-19 in individual patients is challenging without examination and investigation, both of which may entail prolonged exposure of HCWs to potentially infectious individuals. Symptom-based triage has limited utility in identifying risk: asymptomatic transmission of SARS-CoV-2 is well recognised, and a high proportion of individuals with pulmonary TB also may not have symptoms. The prevalence of undiagnosed respiratory disease is therefore likely to be significant in many general clinical areas (e.g., waiting areas). HCWs are known to be at higher risk of TB than the general population and thousands of HCWs have developed COVID-

19 since the start of the pandemic. A proportion of South African HCWs are also HIV positive, placing them at increased risk of severe COVID-19 disease, hospital admission, and death.

Improving infection prevention and control involves implementing a package of administrative, environmental, and personal protection measures, along with substantial reorganisation of systems, care processes, and guidelines to prioritise HCW and patient safety. While this will take time, it is unacceptable to expose HCWs to increased risk until such changes are made. We propose that the South African health system adopts a target of 'zero harm', aiming to completely eliminate transmission of respiratory pathogens to all individuals in every health care setting. Accordingly, in line with the precautionary principle, we recommend the use of high quality, fit-tested respirators by all frontline or non-frontline staff (clinical and non-clinical) during activities that involve contact or sharing air in indoor spaces with individuals who (i) have not yet been clinically evaluated or (ii) are thought or known to have TB and/or COVID-19, or other potentially harmful respiratory infections including influenza, measles, and varicella.

We recognise that this will be challenging, not least due to global and national shortages of PPE. The National Department of Health's policy for the regulation of respiratory protective equipment enables a robust framework for manufacture, assessment, and quality control and has been well supported by local manufacture and the South African Department of Trade, Industry and Competition. Manufacturers should explore adaptations to improve comfort of respirators and reduce barriers to communication. The wider use of respirators does not replace the need for structural changes to improve the safety of health facilities: persistent advocacy and research around potential systems change remain essential.

Introduction

Almost 2.5 million South Africans have tested positive for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) since March 2020, and around 70,000 have died in hospitals from COVID-19.^[1] Although SARS-CoV-2 was initially thought to be spread predominantly through droplet or direct contact, there is strong evidence now that aerosol-based transmission is likely the dominant route of spread.^[2] This is especially important in the light of the circulation (at the time of writing) of the Delta variant, which is more transmissible than the original virus or Beta variant.^[3] Because many people infected with SARS-CoV-2 are asymptomatic, and because any respiratory symptoms experienced are often non-specific, clinically distinguishing people with COVID-19 from other respiratory infections is impossible.^[4] Frontline health care workers (HCWs) are highly exposed and at high risk of infection, as shown by the thousands who have been infected, developed illness, and died.^[5]

HCWs in high tuberculosis (TB) burden countries are already at high risk of TB infection and disease.^[6-9] Despite significant progress, TB incidence in South Africa remains high at over 600 per 100,000 population (around 360,000 new cases per year), and it has consistently been the country's leading cause of death, responsible for ~60,000 deaths every year.^[10] Management of a respiratory pandemic is more complex in high TB burden countries such as South Africa: in addition to previous or current TB, individuals seeking care often have a history of one or more of HIV, tobacco smoking, biomass fuel exposure, outdoor air pollution, or exposure to mining dust, which considerably expands the differential diagnosis in those presenting with respiratory symptoms.^[11-13] Presentations and risk factors can be difficult to differentiate without additional time and investigation, both of which can increase the likelihood and duration of HCW exposure to infectious individuals. TB may also be a specific factor placing people at increased risk of developing COVID-19.^[14]

International guidelines recommend that HCWs should be wearing N95 or equivalent particulate filtering facepiece respirators ("respirators") for routine care of individuals with possible TB or COVID-19 (though World Health Organization [WHO] COVID-19 guidelines are not entirely consistent).^[15,16] At the time of

70 writing, however, South African COVID-19 guidelines state that this level of protection is needed only for
71 ‘aerosol-generating’ procedures (AGPs), such as intubation and bronchoscopy.^[16–18] Recent studies suggest
72 that coughing – common in both TB and COVID-19 pneumonitis – may produce as much (or more) aerosol
73 than some AGPs.^[19–21] There is also strong evidence that, like *Mycobacterium tuberculosis* (*M.tb*),^[2,22] SARS-
74 CoV-2 is transmitted also by aerosol; this includes a wealth of epidemiological data (recently summarised by
75 Greenhalgh and colleagues),^[2] laboratory experiments showing that the virus remains viable in aerosols for
76 up to 3 hours,^[23] detection of viable virus in air samples from COVID-19 infected persons and animals,^[24–26]
77 and identification of SARS-CoV-2 in hospital air filters and building ducts.^[27] In other experiments, activities
78 like speaking, shouting, and singing have been shown to produce substantial amounts of infectious aerosol,
79 as has the use of oxygen.^[28] The definition of aerosol-generating procedure in South African guidelines is
80 therefore overly restrictive^[18] and there is a pressing need to ensure that HCWs are adequately protected
81 from both *M.tb* and SARS-CoV-2.

82 In this article, we aim to build the case for national policies to support more widespread and consistent use
83 of respirators by HCWs in high TB burden countries like South Africa, both in the context of the ongoing
84 COVID-19 pandemic and beyond. We make specific recommendations for situations in which respirators
85 should be worn by HCWs in South Africa and discuss some of the additional efforts needed to sustain this
86 policy.

87 **Making the argument**

88 **Health care workers are left unprotected**

89 Effective implementation of infection prevention and control (IPC) in health facilities is important to avoid
90 ‘institutional amplification’ of epidemics,^[29] to protect the people who attend and work there, and to
91 preserve the health workforce – a critical issue at all times, and more so during a pandemic. TB in HCWs is a
92 persistent problem: numerous studies over the last 30 years have shown that HCWs in high TB burden
93 countries are more likely than the general population to develop both latent TB infection and active TB
94 disease, largely because of occupational exposure.^[6,7,30–33] Many HCWs may have underlying vulnerability to

severe disease, for which optimal protection is essential,^[34] and, in addition to the risk to HCWs themselves, there are also risks of transmission to their families, vulnerable household members, and patients. The thousands of HCWs who have developed and died from COVID-19 in the last 18 months clearly demonstrates both the risks faced by HCWs and the insufficient priority given to HCW safety.^[5,35–38]

HCWs, like all other South African workers, have a right to a safe working environment.^[39] HCWs worldwide have paid a disproportionate price for governments' and health systems' lack of foresight, lack of preparation, and underinvestment in pandemic preparedness;^[40] this has manifested, among other things, as inadequate or insufficient personal protective equipment (PPE) for frontline and other staff.^[41,42] Indeed, it was shown recently that none of the tested "KN95" respirators evaluated in South Africa met stipulated safety standards for HCW protection.^[43] We echo calls by other authors for urgent research, funding, and prioritisation of IPC and HCW protection^[44] and for more comprehensive approaches to occupational health.^[45,46] Though we recognise that systemic changes will take time to enact, it is unacceptable that HCWs remain at risk until such changes are made.

On the frontline it is impossible to differentiate between TB, SARS-CoV2 and other infections

Because of the multitude of possible presentations, non-specific symptoms (e.g., fever, cough), overlapping risk factors, and likelihood of dual infection,^[11–14,47,48] it is impossible to make a specific diagnosis of TB, COVID-19, or other respiratory infection in most South African health facilities without detailed clinical assessment and laboratory investigation, usually over a period of at least 24–72 hours (the turnaround time of most diagnostic tests). If the HCW is not adequately protected, this represents a major opportunity for transmission to occur. Transmission of SARS-CoV-2 by asymptomatic individuals has been widely documented,^[4] and the burden of 'subclinical' TB^[49] in South Africa is increasingly evident. The recent national TB prevalence survey found that around half of the people in the community with confirmed pulmonary TB did not have symptoms suggestive of TB^[50] and a recent study in KwaZulu-Natal showed similar findings among adults attending primary health care clinics.^[51]

Symptom screening cannot differentiate between TB and other respiratory infections. TB can often present as acute pneumonia or acute lower respiratory tract infection (LRTI), and *M.tb* may be amongst the most common pathogens isolated in this context in Asian and African settings (reviewed in detail in a recent article).^[47] In a large study from South Africa (n ≈ 2500 patients), a symptom duration threshold of >14 days was unable to distinguish between TB and other respiratory pathogens, and, in those with LRTI of less than 14 days duration, TB was the microbiologically-proven diagnosis in a staggering ~18% of patients.^[52] This figure is remarkable, considering that in patients with acute LRTI a microbiological diagnosis is made in only ~50% of cases.

Triage, based on symptom screening, is challenging to perform consistently and has been shown to be sub-optimally implemented at PHC clinics across the country.^[53,54] In addition, adults accompanying children or other vulnerable individuals may not be screened and may be undetected sources of *M.tb* or SARS-CoV-2. This means that potentially infectious individuals with undetected disease (with or without symptoms) may remain in general patient streams in perceived 'lower risk' areas, with subsequent inappropriate use of less effective PPE by HCWs.

As discussed below, current guidance recommends use of different PPE for different 'types' of patients (e.g., respirators only when in contact with individuals with 'possible' or 'known' TB or COVID-19). However, as we have emphasised, it is almost impossible to estimate who is likely to have TB or COVID-19 (or another respiratory infection, such as influenza or bacterial or fungal pneumonia). Additionally, without information on infectiousness, ventilation, occupancy of rooms, and duration of exposure,^[55] it is difficult to reliably estimate the risk of transmission in any given space at any given time. It is therefore unrealistic to expect individual HCWs to make repeated assessments of risk during the course of a working day and adjust their PPE accordingly, particularly at a time when the health system is under pressure.^[56,57]

SARS-CoV-2 and *M.tb* are transmitted by aerosol: particulate filtering facepiece respirators offer better protection

143 Person-to-person transmission of SARS-CoV-2 is currently understood to occur predominantly by two routes.
144 First, via larger respiratory droplets (size $>10\text{ }\mu\text{m}$), which fall rapidly to the ground or onto surfaces –
145 droplets of size $10\text{ }\mu\text{m}$ and $100\text{ }\mu\text{m}$ take ~ 10 minutes and ~ 6 seconds, respectively, to fall to the ground.^[58]
146 Such droplets may be inhaled or deposited into the nasopharynx or directly inoculated onto mucous
147 membranes (eyes, mouth, upper pharynx) or the skin, with subsequent person-to-person transfer by via
148 direct contact or infected fomites. Second, via aerosol: particles produced through coughing, speech, singing,
149 and “aerosol-generating procedures”, which, after desiccation, are usually up to $10\text{ }\mu\text{m}$ in diameter, can
150 remain suspended in the air for several hours, and may be inhaled into the lungs (small airways and alveoli)
151 of another person.^[22,59–62] The second route, sometimes referred to as airborne transmission, is also the
152 main route of transmission of the measles virus and *M.tb*.^[55,63] However, is important to note that
153 terminology (airborne vs. aerosol vs. respiratory droplets) is not standardised or well defined, and thus
154 airborne spread is likely due to production of a continuum of virus-containing droplet sizes that may be
155 deposited in the upper and/or lower respiratory tract of susceptible individuals.^[22]

156 Early in the pandemic, SARS-CoV-2 was thought to be transmissible only via large droplets/fomites, and
157 precautions therefore centred on restricting close contact, cleaning surfaces, and handwashing.^[64,65]
158 However, research on aerosolisation has shown that respiratory particle sizes vary widely, and that smaller
159 particles ($<5\text{ }\mu\text{m}$) are more likely to contain pathogen.^[22] The high likelihood of considerable aerosol
160 transmission of SARS-CoV-2^[2,66–68] has now been acknowledged by the WHO and the United States Centers
161 for Disease Control and Prevention (US CDC), which recently made recommendations around improving
162 ventilation of indoor spaces as part of coronavirus-related IPC.^[69,70] Ventilation is important for mitigating
163 aerosol transmission: increasing the number of air changes per hour means that suspended particles are
164 more likely to be removed before they can be inhaled.^[71,72] Ten cogent reasons, including underlying
165 evidence, as to why aerosol-based transmission is an important and co-dominant route of SARS-CoV-2
166 transmission were recently elegantly summarised in the *Lancet*.^[2]

167 The evidence around the relative efficacy of masks and respirators against aerosols is also reasonably clear.
168 In laboratory studies, respirators (filtering face piece [FFP] 2 or FFP3) were shown to be 16–108 times more
169 effective than fluid repellent surgical masks (FRSMs) in filtering aerosolised sodium chloride.^[73] Clinical
170 studies are less definitive, in part because of variation in methodologies and definitions of exposure,
171 confounding, and issues with powering of studies. At least two studies, however, have shown statistically
172 important reductions in risk with quality respirator use compared with surgical masks, particularly when
173 used continuously (as opposed to ‘targeted’ use) and when individuals were exposed to clinical respiratory
174 illness.^[73–77]

175 **Current South African guidance is at odds with international recommendations**

176 Table 1 summarises South African and global guidance around respirator use for personal protection against
177 *M.tb* and SARS-CoV-2. The majority of national and international bodies (other than Public Health
178 England)^[78] recommend the use of respirators for routine care of individuals with possible or confirmed
179 COVID-19 or TB. South Africa, at present, recommends an N95 respirator for care of individuals with possible
180 or confirmed TB, but only a surgical mask for routine care of individuals with possible or confirmed COVID-
181 19.^[18,79] This does not offer individuals protection against aerosol transmission of SARS-CoV-2 and,
182 importantly, requires HCWs to differentiate between those who may have TB and those who may have
183 COVID-19, which, as outlined above, is difficult if not impossible to do.

Table 1. International and South African recommendations for use of masks and respirators by health care workers (note the mask terminology used is concordant with what was used in the relevant guideline document)*.

Source	Scope	Tuberculosis		COVID-19	
		Routine care*	AGPs†	Routine care*	AGPs†
South Africa DoH/NICD ^[18,79]	South Africa	N95 respirator	N95 respirator	Surgical mask	N95 respirator
WHO ^[16,17]	Global	Particulate respirator (high TB burden settings)‡	Particulate respirator	N95/FFP2/FFP3 respirator§	N95/FFP2/FFP3 respirator
US CDC ^[80,81]	United States	N95 respirator (at least)	N95 respirator at least. Consider elastomeric full-facepiece respirator or PAPR	N95 or equivalent or higher-level respirator	N95 respirator or respirators that offer a higher level of protection
PHE ^[78] / NICE ^[82]	England/United Kingdom	FFP2 respirator	FFP2 or FFP3 respirator	Fluid-resistant surgical face mask (Type IIR)	FFP3 respirator or hood
ECDC ^[83,84]	Europe	Respirator	Respirator	Respirator	Respirator
India MoHFW ^[85,86]	India	N95 respirator	N95 respirator	N95 respirator	N95 respirator

#Terms used for mask/respirator types are consistent with those used in the respective guidelines. WHO defines 'particulate respirators' as those meeting N95 or FFP2 standards. ECDC defines 'respirators' as those meeting FFP2 or FFP3 standards.

*Routine care of people with possible or confirmed TB or COVID-19

†AGPs (aerosol-generating procedures) include endotracheal intubation/extubation; respiratory tract suctioning; manual ventilation; tracheotomy; tracheostomy; bronchoscopy; surgery or post mortems involving high-speed cutting (of the respiratory tract); certain dental procedures; non-invasive and high-frequency oscillating ventilation; use of high flow nasal oxygen, sputum induction; chest physiotherapy; cardiopulmonary resuscitation; and collection of naso- and oropharyngeal swabs

‡"...to reduce *M. tuberculosis* transmission to health workers, persons attending health care facilities or other persons in settings with a high risk of transmission"

§"...for work with infected people in indoor, crowded places without adequate ventilation"

||"...in all patient care areas, while providing patient care"

AGP: aerosol-generating procedure; CDC: Centers for Disease Control and Prevention; COVID-19: coronavirus disease 2019; ECDC: European Centre for Disease Control and Prevention; FFP: filtering face piece; HCW: health care worker; IDSA: Infectious Diseases Society of America; MoHFW: Ministry of Health and Family Welfare; n/s: not specified; NICD: National Institute for Communicable Diseases; NICE: National institute for Health and Care Excellence; PAPR: powered air-purifying respirator; PHE: Public Health England; TB: tuberculosis; US: United States; WHO: World Health Organization

In summary (and sidestepping controversies about whether surgical masks or respirators are essential for protection against SARS-CoV-2), the high risk of HCW exposure to and infection with *M.tb* and inability to differentiate TB from other acute LRTIs mandates the consistent use of respirators by HCWs in high TB burden settings. It is impractical and not clinically meaningful to provide pathogen-specific guidance on masking. We have therefore provided guidance below in the context of routine exposure to acute respiratory infections.

Recommendations

Zero transmission, zero harm: our recommendations for the widespread consistent use of particulate respirators in high TB burden settings

We propose that the health system should aim for a target of ‘zero transmission, zero harm’: a position that builds on the precautionary principle^[87] and the foundational ethical value of ‘do no harm’ to suggest that the health system’s duty of care extends beyond patients to include its workforce. The principle of ‘zero harm’ has been used most widely to refer to efforts to improve patient safety,^[88] but here we use the term specifically around disease transmission. It is unacceptable that any person should be infected with *M.tb* or SARS-CoV-2 as a result of exposure in a health care facility, and the health system should aim to eliminate transmission in all health care settings. Clearly this will require prioritisation and significant long-term investment in a range of IPC measures, including consideration of building design, ventilation, ultraviolet germicidal irradiation (UVGI) systems, and organisation of services to reduce overcrowding and enable consistent implementation of administrative measures such as triage, respiratory isolation, prompt treatment, and disinfection of surfaces and equipment. This also means that HCWs are entitled to, and should have access to, high quality PPE sufficient to protect against both droplet and aerosol transmission, with efforts made to minimise exposure.

We therefore make the following recommendations.

1. Particulate filtering facepiece respirators should be worn by:
 - a. all staff (clinical and non-clinical) during activities that involve contact or sharing air in indoor spaces (more so if poorly ventilated) with individuals who (i) have not yet been clinically evaluated or (ii) are thought or known to have TB and/or COVID-19 (this will likely include waiting areas, emergency departments, clinic consultation rooms, and certain inpatient wards and high care/intensive care units);
 - b. frontline staff in clinical areas who are in contact with patients thought or known to have TB, COVID-19, or other respiratory infection, including influenza, measles, and varicella (likely

236 areas include emergency departments, medical admissions units, and 'patients under
237 investigation' [PUI] wards); and

- 238 c. any staff involved in high risk or aerosolising procedures involving individuals thought or
239 known to have TB or COVID-19 (e.g., bronchoscopy, open or closed suctioning of the airway,
240 non-invasive ventilation, oxygen, and dental procedures, among others).

- 241 2. Respirators (N95, FFP2, and other equivalent respirators, e.g., quality-assured KN95 masks) should
242 fulfil the following requirements, per criteria set out by South Africa's National Department of
243 Health^[89] and the National Institute for Occupational Safety and Health (NIOSH; see Box 1).^[90]

- 244 a. All respirators should be accompanied by Homologation Certificates, proof of international
245 compliance, and quality certificates. The filter designation, manufacturer, model number,
246 and certification approval number should be displayed on the body of the respirator.
- 247 b. All respirators require a clear physical marking with 1) the manufacturer/brand
248 name/registered trademark; 2) an alphanumeric rating as recognised (e.g., FFP2, FFP3, N95,
249 KN95); 3) a standard compliance label showing the standard/s the device has met; 4) the size
250 of the respirator, model number, and lot number; and 5) any other mandatory markings.
- 251

252 **Box 1. Quality requirements for particulate filtering facepiece respirators in South Africa**

Certification

All particulate filtering facepiece respirators sold should be accompanied by Homologation Certificates, proof of international compliance (in the case of imported RPE including NIOSH approvals, European Union certifications, CE marking reports, and complete FDA registrations) and quality certificates. The minimum required stipulation is:

1. Total inward leakage using quantitative and/or qualitative Fit tests (performed at facility level on individuals);
2. Determination of particulate filter penetration (PFP) with the minimum testing requirement being to NaCl filtration (and only where possible to paraffin oil and latex particles);
3. Determination of flow resistance (inhalation resistance at a minimum, but preferably inhalation and exhalation resistance with the latter mandatory for valved respirators);
4. Flammability testing;
5. Fluid resistance test (this test is not mandatory at this time owing to capacity and development constraints in lab testing in South Africa). Where fluid resistance testing has not been conducted by a verified international lab but all other local tests pass, the recommendation is for mandatory visor usage to protect against respirator fluid exposure.

Metrology Notification

All filtering facepiece respirators (SAHPRA Class B device) in the interests of identification, safety and to ensure that homologation is possible and accurate should have a clear physical marking/stamp on each mask or respirator with the mandatory (in bold) minimum information being:

1. **Manufacturer/brand name/registered trademark** or easily understood abbreviation
2. **The mask or respirator efficiency classification**; an alphanumeric rating as recognised (e.g., FFP2, FFP3, N95, KN95)
3. **Standard Compliance Label** that indicates the local SANS standard showing the device has been tested against and passed
4. **Size of the respirator, model number and lot number**;
5. **Any other mandatory markings** as required by SANAS, NRCS, SAHPRA, other national regulator or standard and as may be required by the Legal Metrology Act, 2014 (Act 9 of 2014).

253 Adapted from the South Africa National Department of Health's Policy for the Regulation of Quality Respiratory
254 Protective Equipment (RPE) Supply in Healthcare (2020)^[89]

255 FDA: United States Food and Drug Administration; NRCS: National Regulator for Compulsory Specifications; RPE:
256 respiratory protective equipment; SAHPRA: South African Health Products Regulatory Authority; SANAS: South African
257 National Accreditation System; SANS: South African Bureau of Standards

- 259 3. The respirator should, at minimum, be evaluated by qualitative fit testing.^[91] Fit testing forms an
260 indispensable part of achieving the objective filtration of virus and bacteria and should be carried
261 out at least annually for every HCW required to wear a respirator, in accordance with the
262 respirator's brand and size. Additional fit testing is generally recommended if the subject
263 experiences a weight change of ≥ 10 kg or has significant dental changes, reconstructive surgery, or

facial disfigurement.^[89] We recommend that health care facilities have access to low-cost qualitative fit testing equipment (e.g., the 3M Qualitative Fit Test Apparatus FT-10)^[43] so that respirators and wearers can be evaluated. Qualitative fit testing is simpler and cheaper than quantitative testing. This may be at individual health care facilities or through local or regional centres. This will also provide regulatory bodies an opportunity to evaluate masks that claim to meet N95 or FFP2 standards and will go towards establishing a 'respiratory protection programme' for HCWs, in line with international guidance.^[17] To meet new recommendations by the South African Health Products Regulatory Authority (SAHPRA),^[92] regional or national comprehensive testing nodes should be established to perform more rigorous quantitative fit testing (for example, using the ambient aerosol condensation nuclei counter protocol)^[91] and evaluation of filtration integrity. There is currently negligible access to such facilities in the South African public or private sectors.

4. It is critical to emphasise that particulate respirators alone are less likely to be effective if other IPC measures are not implemented. Therefore, in line with international IPC guidelines,^[16,17] a 'package of care' approach should be adopted, involving administrative controls (e.g., triage and separation of people with infectious or potentially infectious TB, COVID-19, and/or influenza, etc.), environmental controls (minimising crowding, use of UVGI, ensuring good ventilation [at least 6–12 air changes per hour equivalent]), use of other forms of high quality PPE when appropriate (eye protection, gloves, aprons), source control (face coverings for all attendees), physical distancing, and hand hygiene. Attention to IPC must also be maintained in non-clinical areas where transmission potential remains high, for example, staff canteens, rest areas, and changing rooms. Because of the risk of transmission from HCWs to patients, HCWs should also be made aware of their responsibilities to maintain precautions outside of health facilities, for example, during use of public transport; by minimising time spent in poorly ventilated, densely occupied areas; and by maintaining physical distancing, hand hygiene, and use of face coverings.

We note also that the practice of wearing a surgical mask over a fit tested quality respirator to prevent contamination or improve efficacy is not evidence based, has not been evaluated scientifically, and may unnecessarily increase the work of breathing. Wearing a surgical mask underneath a respirator is not recommended as it is likely to compromise fit and therefore the efficacy of the respirator. In addition, given the occurrence of breakthrough infections with SARS-CoV-2 in individuals who have received a partial or even full vaccination course,^[93] no differentiation should be made according to vaccination status as regards use of PPE.

Hurdles and challenges

Our aim is to make recommendations for measures that will provide the highest level of protection to HCWs and patients, regardless of the logistical obstacles. We recognise, however, that these recommendations may not be straightforward to implement. Health systems have been severely affected by the global shortage of quality respirators and are facing challenges with procurement and manufacturing. The Department of Health should work with manufacturers, regulatory bodies, and other relevant parties to find ways to overcome challenges to better serve HCWs. We also urge manufacturers to explore improving the comfort of respirators and to take measures to reduce barriers to communication (e.g., by using transparent materials to allow lipreading). Innovative methods should be explored to produce new masks (e.g., 3D printing) without compromising on quality.^[94,95]

The US CDC states that respirators are “*meant to be disposed after each use*”, but also describes contingency strategies in the case of acute shortages or crisis, including ‘decontamination’ (e.g., with UVGI, hydrogen peroxide, or moist heat; also known as ‘reprocessing’), ‘extended use’ (continuous use of the same respirator for encounters with multiple patients), and ‘limited reuse’ (use of the same respirator for encounters with multiple patients, with the respirator donned and doffed between encounters).^[96] Each approach carries risks, most importantly of reductions in respirator fit and filtration performance, but also of contamination and self-contamination through repeated donning and doffing.^[97–99] As such, SAHPRA and Department of Health currently prohibit decontamination/reprocessing of respirators by any method but, in

the case of shortages or if supply optimisation is required, do support extended use (with no attempts at cleaning or decontaminating and ideally without repeated donning and doffing) of single use respirators for up to 6–8 hours, depending on the manufacturer.^[89]

From a long-term IPC perspective, a focus on respirator use risks over-emphasising individual protection, shifting responsibility back to individual HCWs and lessening pressure on the health system to make the structural changes needed to improve the safety of the working environment. We recognise that persistent advocacy and research to support broader systems change is needed.^[100,101] As previously suggested,^[6] improved routine reporting of the incidence of TB, COVID-19, and other occupationally-acquired illnesses among HCWs will help monitor the longer-term effects of preventive measures and help drive advocacy.

Conclusions

SARS-CoV-2 and *M.tb* are transmitted via aerosol. HCWs are at high risk of infection. The use of surgical masks in frontline settings is inappropriate. Fit-tested particulate filtering facepiece respirators provide better protection against infectious aerosols than surgical masks, are already recommended for use by all HCWs in high TB burden countries and many COVID-19 pandemic settings, and should be worn routinely to protect HCWs against TB and COVID-19.

Acknowledgments/ Funding

KD acknowledges funding from the SA MRC (RFA-EMU-02-2017), EDCTP (TMA-2015SF-1043, TMA-1051-TESAII, TMA-CDF2015), UK Medical Research Council (MR/S03563X/1) and the Wellcome Trust (MR/S027777/1). HJZ is funded by the SA-MRC and the UK MRC (GEC1111). FV's unit acknowledges funding from the Bill & Melinda Gates Foundation (BMGF), South African Medical Research Council, National Institutes for Health, AIDS Fonds, Unitaid, Foundation for Innovative New Diagnostics and the Children's Investment Fund Foundation, amongst others. GJC is funded by NIH/DAIDS, Unitaid, BMGF, CEPI, and ViiV. NN gratefully acknowledges funding from the NRF, SA-MRC, UK MRC, and the Lily and Ernst Haussmann Trust.

Declaration of interests

Dr Martinson's institution receives grants from Pfizer for research into pneumonia. All other authors have no interests to declare.

References

- 1 National Institute for Communicable Diseases SA. Latest confirmed cases of COVID-19 in South Africa (25 July 2021). NICD. 2021. <https://www.nicd.ac.za/latest-confirmed-cases-of-covid-19-in-south-africa-25-july-2021/> (accessed 2021 Jul 26)
- 2 Greenhalgh T, Jimenez JL, Prather KA, Tufekci Z, Fisman D, Schooley R. Ten scientific reasons in support of airborne transmission of SARS-CoV-2. *Lancet*. 2021;397(10285):1603–5.
- 3 Network for Genomic Surveillance South Africa. SARS-CoV-2 Sequencing Update (19 July 2021). 2021. <https://www.nicd.ac.za/wp-content/uploads/2021/07/Update-of-SA-sequencing-data-from-GISAID-19-July-2021.pdf> (accessed 2021 Jul 27)
- 4 Qiu X, Nergiz AI, Maraolo AE, Bogoch II, Low N, Cevik M. The role of asymptomatic and pre-symptomatic infection in SARS-CoV-2 transmission-a living systematic review. *Clin Microbiol Infect Off Publ Eur Soc Clin Microbiol Infect Dis*. 2021;27(4):511–9.
- 5 Bandyopadhyay S, Baticulon RE, Kadhum M, et al. Infection and mortality of healthcare workers worldwide from COVID-19: a systematic review. *BMJ Glob Health*. 2020;5(12):e003097.
- 6 Grobler L, Mehtar S, Dheda K, et al. The epidemiology of tuberculosis in health care workers in South Africa: a systematic review. *BMC Health Serv Res*. 2016;16(1):416.
- 7 Uden L, Barber E, Ford N, Cooke GS. Risk of Tuberculosis Infection and Disease for Health Care Workers: An Updated Meta-Analysis. *Open Forum Infect Dis*. 2017;4(3):ofx137.
- 8 Adams S, Ehrlich R, Baatjies R, et al. Incidence of occupational latent tuberculosis infection in South African healthcare workers. *Eur Respir J*. 2015;45(5):1364–73.
- 9 Jarand J, Shean K, O'Donnell M, et al. Extensively drug-resistant tuberculosis (XDR-TB) among health care workers in South Africa. *Trop Med Int Health*. 2010;15(10):1179–84.
- 10 World Health Organization. Tuberculosis profile: South Africa (2019). https://worldhealthorg.shinyapps.io/tb_profiles/?_inputs_entity_type=%22country%22&lan=%22EN%22&iso2=%22ZA%22 (accessed 2021 Jun 6)
- 11 Brunet L, Pai M, Davids V, et al. High prevalence of smoking among patients with suspected tuberculosis in South Africa. *Eur Respir J*. 2011;38(1):139–46.
- 12 van Zyl Smit RN, Pai M, Yew WW, et al. Global lung health: the colliding epidemics of tuberculosis, tobacco smoking, HIV and COPD. *Eur Respir J*. 2010;35(1):27–33.
- 13 Lin H-H, Ezzati M, Murray M. Tobacco smoke, indoor air pollution and tuberculosis: a systematic review and meta-analysis. *PLoS Med*. 2007;4(1):e20.
- 14 Boule A, Davies M-A, Hussey H, et al. Risk factors for COVID-19 death in a population cohort study from the Western Cape Province, South Africa. *Clin Infect Dis Off Publ Infect Dis Soc Am*. 2020;
- 15 World Health Organization. Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed (interim guidance - 12 July 2021). 2021. <https://apps.who.int/iris/rest/bitstreams/1356030/retrieve> (accessed 2021 Jul 27)

- 376 16 World Health Organization. COVID-19: Occupational health and safety for health workers. Interim guidance - 2
377 February 2021. 2021. <https://apps.who.int/iris/rest/bitstreams/1329986/retrieve> (accessed 2021 May 2)
- 378 17 World Health Organization. WHO guidelines on tuberculosis infection prevention and control: 2019 update. 2019.
379 <https://apps.who.int/iris/bitstream/handle/10665/311259/9789241550512-eng.pdf?ua=1> (accessed 2019 Dec 1)
- 380 18 South Africa National Department of Health. COVID-19 Disease: Infection Prevention and Control Guidelines.
381 Version 2 (21st May 2020). 2020. [https://www.nicd.ac.za/wp-content/uploads/2020/05/ipc-guidelines-covid-19-](https://www.nicd.ac.za/wp-content/uploads/2020/05/ipc-guidelines-covid-19-version-2-21-may-2020.pdf)
382 [version-2-21-may-2020.pdf](https://www.nicd.ac.za/wp-content/uploads/2020/05/ipc-guidelines-covid-19-version-2-21-may-2020.pdf)
- 383 19 Brown J, Gregson FKA, Shrimpton A, et al. A quantitative evaluation of aerosol generation during tracheal
384 intubation and extubation. *Anaesthesia*. 2020;10.1111/anae.15292.
- 385 20 Shrimpton A, Gregson FKA, Cook TM, et al. A quantitative evaluation of aerosol generation during tracheal
386 intubation and extubation: a reply. *Anaesthesia*. 2021;76(S3):16–8.
- 387 21 Chanpong B, Tang M, Rosenczweig A, Lok P, Tang R. Aerosol-Generating Procedures and Simulated Cough in
388 Dental Anesthesia. *Anesth Prog*. 2020;67(3):127–34.
- 389 22 Fennelly KP. Particle sizes of infectious aerosols: implications for infection control. *Lancet Respir Med*.
390 2020;8(9):914–24.
- 391 23 van Doremalen N, Bushmaker T, Morris DH, et al. Aerosol and Surface Stability of SARS-CoV-2 as Compared with
392 SARS-CoV-1. *N Engl J Med*. 2020;382(16):1564–7.
- 393 24 Lednicky JA, Lauzardo M, Fan ZH, et al. Viable SARS-CoV-2 in the air of a hospital room with COVID-19 patients. *Int*
394 *J Infect Dis IJID Off Publ Int Soc Infect Dis*. 2020;100:476–82.
- 395 25 Lednicky JA, Lauzardo M, Alam MM, et al. Isolation of SARS-CoV-2 from the air in a car driven by a COVID patient
396 with mild illness. *Int J Infect Dis IJID Off Publ Int Soc Infect Dis*. 2021;108:212–6.
- 397 26 Kutter JS, de Meulder D, Bestebroer TM, et al. SARS-CoV and SARS-CoV-2 are transmitted through the air between
398 ferrets over more than one meter distance. *Nat Commun*. 2021;12(1):1653.
- 399 27 Nissen K, Krambrich J, Akaberi D, et al. Long-distance airborne dispersal of SARS-CoV-2 in COVID-19 wards. *Sci*
400 *Rep*. 2020;10(1):19589.
- 401 28 Schijven J, Vermeulen LC, Swart A, Meijer A, Duizer E, de Roda Husman AM. Quantitative Microbial Risk
402 Assessment for Airborne Transmission of SARS-CoV-2 via Breathing, Speaking, Singing, Coughing, and Sneezing.
403 *Environ Health Perspect*. 2021;129(4):47002.
- 404 29 Basu S, Stuckler D, McKee M. Addressing Institutional Amplifiers in the Dynamics and Control of Tuberculosis
405 Epidemics. *Am J Trop Med Hyg*. 2011;84(1):30–7.
- 406 30 Menzies D, Fanning A, Yuan L, Fitzgerald M. Tuberculosis among health care workers. *N Engl J Med*.
407 1995;332(2):92–8.
- 408 31 Menzies D, Joshi R, Pai M. Risk of tuberculosis infection and disease associated with work in health care settings.
409 *Int J Tuberc Lung Dis*. 2007;11(6):593–605.
- 410 32 Joshi R, Reingold AL, Menzies D, Pai M. Tuberculosis among health-care workers in low- and middle-income
411 countries: A systematic review. *PLoS Med*. 2006;3(12):2376–91.
- 412 33 Baussano I, Nunn P, Williams B, Pivetta E, Bugiani M, Scano F. Tuberculosis among health care workers. *Emerg*
413 *Infect Dis*. 2011;17(3):488–94.
- 414 34 Ambrosioni J, Blanco JL, Reyes-Urueña JM, et al. Overview of SARS-CoV-2 infection in adults living with HIV. *Lancet*
415 *HIV*. 2021;8(5):e294–305.
- 416 35 South Africa Ministry of Health. Statement on Health Care Workers that have Acquired COVID-19. 2020.
417 [https://storage.googleapis.com/stateless-bhekisisa-website/wordpress-uploads/2020/08/fda38e56-hcw-13-](https://storage.googleapis.com/stateless-bhekisisa-website/wordpress-uploads/2020/08/fda38e56-hcw-13-august-2020.pdf)
418 [august-2020.pdf](https://storage.googleapis.com/stateless-bhekisisa-website/wordpress-uploads/2020/08/fda38e56-hcw-13-august-2020.pdf) (accessed 2021 May 4)

- 36 Jordan B. Covid-19 killed 339 state health-care workers between March and November. TimesLIVE. 2021. <https://www.timeslive.co.za/news/south-africa/2021-01-06-covid-19-killed-339-state-health-care-workers-between-march-and-november/> (accessed 2021 May 4)
- 37 Kambhampati AK. COVID-19—Associated Hospitalizations Among Health Care Personnel — COVID-NET, 13 States, March 1–May 31, 2020. *MMWR Morb Mortal Wkly Rep*. 2020;69.
- 38 Spencer J, Jewett C. Twelve months of trauma: more than 3,600 US health workers died in Covid’s first year. The Guardian. 2021. <https://www.theguardian.com/us-news/2021/apr/08/us-health-workers-deaths-covid-lost-on-the-frontline> (accessed 2021 May 4)
- 39 Government of the Republic of South Africa. Occupational Health and Safety Act 85 of 1993. Jul 2, 1993.
- 40 De Raeve P, Adams E, Xyrichis A. The impact of the COVID-19 pandemic on nurses in Europe: A critical discussion of policy failures and opportunities for future preparedness. *Int J Nurs Stud Adv*. 2021;3:100032.
- 41 Saba A, Jika T. Eastern Cape’s PPE shortage endangers healthcare workers. The Mail & Guardian. 2020.
- 42 World Health Organization. Shortage of personal protective equipment endangering health workers worldwide. 2020. <https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide> (accessed 2021 Jun 8)
- 43 Mottay L, Le Roux J, Perumal R, et al. KN95 filtering facepiece respirators distributed in South Africa fail safety testing protocols. *S Afr Med J*. 2020;111(3):234.
- 44 Griffith DE, Cegielski JP. Tuberculosis Healthcare Workers: There Goes My Hero. *Clin Infect Dis Off Publ Infect Dis Soc Am*. 2020;
- 45 Ehrlich R, Spiegel JM, Adu P, Yassi A. Current Guidelines for Protecting Health Workers from Occupational Tuberculosis Are Necessary, but Not Sufficient: Towards a Comprehensive Occupational Health Approach. *Int J Environ Res Public Health*. 2020;17(11):3957.
- 46 Bourgeault IL, Maier CB, Dieleman M, et al. The COVID-19 pandemic presents an opportunity to develop more sustainable health workforces. *Hum Resour Health*. 2020;18.
- 47 Dheda K, Makambwa E, Esmail A. The Great Masquerader: Tuberculosis Presenting as Community-Acquired Pneumonia. *Semin Respir Crit Care Med*. 2020;41(4):592–604.
- 48 Aston SJ, Rylance J. Community-Acquired Pneumonia in Sub-Saharan Africa. *Semin Respir Crit Care Med*. 2016;37(6):855–67.
- 49 Frascella B, Richards AS, Sossen B, et al. Subclinical tuberculosis disease - a review and analysis of prevalence surveys to inform definitions, burden, associations and screening methodology. *Clin Infect Dis*. 2020;ciaa1402.
- 50 Mvusi L. First National TB Prevalence Survey, South Africa, 2017-19. In: *The 51st Union World Conference on Lung Health*. 2020.
- 51 Govender I, Karat AS, Baisley K, et al. Prevalence of Mycobacterium tuberculosis in sputum among adult clinic attendees compared with the surrounding community in rural South Africa: implications for finding the missing millions. *51st World Conf Lung Health Int Union Tuberc Lung Dis*. 2020;Abstract EP32-410-24.
- 52 Walaza S, Tempia S, Dreyer A, et al. The Burden and Clinical Presentation of Pulmonary Tuberculosis in Adults With Severe Respiratory Illness in a High Human Immunodeficiency Virus Prevalence Setting, 2012-2014. *Open Forum Infect Dis*. 2017;4(3).
- 53 Chihota VN, Ginindza S, McCarthy KM, Grant AD, Churchyard GJ, Fielding KL. Missed Opportunities for TB Investigation in Primary Care Clinics in South Africa: Experience from the XTEND Trial. *Plos One*. 2015;10(9):e0138149.

- 460 54 Kweza PF, Van Schalkwyk C, Abraham N, Uys M, Claassens MM, Medina-Marino A. Estimating the magnitude of
461 pulmonary tuberculosis patients missed by primary health care clinics in South Africa. *Int J Tuberc Lung Dis Off J*
462 *Int Union Tuberc Lung Dis*. 2018;22(3):264–72.
- 463 55 Yates TA, Khan PY, Knight GM, et al. The transmission of Mycobacterium tuberculosis in high burden settings.
464 *Lancet Infect Dis*. 2016;16(2):227–38.
- 465 56 Amalberti R, Vincent C. Managing risk in hazardous conditions: improvisation is not enough. *BMJ Qual Saf*.
466 2020;29(1):60–3.
- 467 57 Wizner K, Nasarwanji M, Fisher E, Steege AL, Boiano JM. Exploring respiratory protection practices for prominent
468 hazards in healthcare settings. *J Occup Environ Hyg*. 2018;15(8):588–97.
- 469 58 Wells W. On air-borne infection: Study II. Droplets and droplet nuclei. *Am J Epidemiol*. 1934;20(3):611–8.
- 470 59 Loudon RG, Roberts RM. Droplet expulsion from the respiratory tract. *Am Rev Respir Dis*. 1967;95(3):435–42.
- 471 60 Leung NHL. Transmissibility and transmission of respiratory viruses. *Nat Rev Microbiol*. 2021;
- 472 61 Asadi S, Wexler AS, Cappa CD, Barreda S, Bouvier NM, Ristenpart WD. Aerosol emission and superemission during
473 human speech increase with voice loudness. *Sci Rep*. 2019;9(1):2348.
- 474 62 Stadnytskyi V, Anfinrud P, Bax A. Breathing, speaking, coughing or sneezing: What drives transmission of SARS-
475 CoV-2? *J Intern Med*. n/a(n/a).
- 476 63 Churchyard G, Kim P, Shah NS, et al. What We Know About Tuberculosis Transmission: An Overview. *J Infect Dis*.
477 2017;216(suppl_6):S629–35.
- 478 64 World Health Organization. Infection prevention and control during health care when coronavirus disease (COVID-
479 19) is suspected or confirmed. (Interim guidance, 29 June 2020). 2020.
480 <https://apps.who.int/iris/rest/bitstreams/1284718/retrieve> (accessed 2021 May 3)
- 481 65 South Africa National Department of Health. COVID-19 Disease: Infection Prevention and Control Guidelines.
482 Version 1 (April 2020). 2020.
- 483 66 MacIntyre CR, Ananda-Rajah MR. Scientific evidence supports aerosol transmission of SARS-COV-2. *Antimicrob*
484 *Resist Infect Control*. 2020;9.
- 485 67 Tang JW, Bahnfleth WP, Bluysen PM, et al. Dismantling myths on the airborne transmission of severe acute
486 respiratory syndrome coronavirus-2 (SARS-CoV-2). *J Hosp Infect*. 2021;110:89–96.
- 487 68 Dancer SJ, Tang JW, Marr LC, Miller S, Morawska L, Jimenez JL. Putting a balance on the aerosolization debate
488 around SARS-CoV-2. *J Hosp Infect*. 2020;105(3):569–70.
- 489 69 World Health Organization. Roadmap to improve and ensure good indoor ventilation in the context of COVID-19.
490 1 March 2021. 2021. <https://apps.who.int/iris/rest/bitstreams/1333991/retrieve> (accessed 2021 May 2)
- 491 70 Centers for Disease Control and Prevention. COVID-19: Ventilation in Buildings [Updated 2 June 2021]. 2021.
492 <https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html> (accessed 2021 Jun 8)
- 493 71 Stockwell RE, Ballard EL, O'Rourke P, Knibbs LD, Morawska L, Bell SC. Indoor hospital air and the impact of
494 ventilation on bioaerosols: a systematic review. *J Hosp Infect*. 2019;103(2):175–84.
- 495 72 Chan P-C, Fang C-T. The role of ventilation in tuberculosis control. *J Formos Med Assoc*. 2021;120(6):1293–5.
- 496 73 Ramaraj P, Super J, Doyle R, Aylwin C, Hettiaratchy S. Triaging of respiratory protective equipment on the
497 assumed risk of SARS-CoV-2 aerosol exposure in patient-facing healthcare workers delivering secondary care: a
498 rapid review. *BMJ Open*. 2020;10(10).
- 499 74 Iannone P, Castellini G, Coclite D, et al. The need of health policy perspective to protect Healthcare Workers
500 during COVID-19 pandemic. A GRADE rapid review on the N95 respirators effectiveness. *PloS One*.
501 2020;15(6):e0234025.

- 502 75 MacIntyre CR, Chughtai AA. A rapid systematic review of the efficacy of face masks and respirators against
503 coronaviruses and other respiratory transmissible viruses for the community, healthcare workers and sick
504 patients. *Int J Nurs Stud*. 2020;108:103629.
- 505 76 MacIntyre CR, Wang Q, Seale H, et al. A randomized clinical trial of three options for N95 respirators and medical
506 masks in health workers. *Am J Respir Crit Care Med*. 2013;187(9):960–6.
- 507 77 Chu DK, Akl EA, Duda S, et al. Physical distancing, face masks, and eye protection to prevent person-to-person
508 transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. *Lancet Lond Engl*.
509 2020;395(10242):1973–87.
- 510 78 Public Health England. COVID-19: infection prevention and control (IPC) (version 1.2, updated 1 June 2021). 2021.
511 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/990923/20210602_Infection_Prevention_and_Control_Guidance_for_maintaining_services_with_H_and_C_settings__1_.pdf
512 (accessed 2021 Jun 8)
- 513 79 South Africa National Department of Health. Practical Manual for Implementation of the National Infection
514 Prevention and Control Strategic Framework. 2020. [https://www.nicd.ac.za/wp-](https://www.nicd.ac.za/wp-content/uploads/2020/04/Practical-Manual-for-implementation-of-the-National-IPC-Strategic-Framework-March-2020-1.pdf)
515 [content/uploads/2020/04/Practical-Manual-for-implementation-of-the-National-IPC-Strategic-Framework-March-](https://www.nicd.ac.za/wp-content/uploads/2020/04/Practical-Manual-for-implementation-of-the-National-IPC-Strategic-Framework-March-2020-1.pdf)
516 [2020-1.pdf](https://www.nicd.ac.za/wp-content/uploads/2020/04/Practical-Manual-for-implementation-of-the-National-IPC-Strategic-Framework-March-2020-1.pdf) (accessed 2021 May 2)
- 517 80 Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of Mycobacterium
518 tuberculosis in Health-Care Settings, 2005. 2005.
519 https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=rr5417a1_e (accessed 2021 Jun 8)
- 520 81 Centers for Disease Control and Prevention. Interim Infection Prevention and Control Recommendations for
521 Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic (updated Feb. 23, 2021). 2021.
522 <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html> (accessed 2021 Jun 8)
- 523 82 Diel R, Nienhaus A, Witte P, Ziegler R. Protection of healthcare workers against transmission of Mycobacterium
524 tuberculosis in hospitals: a review of the evidence. *ERJ Open Res*. 2020;6(1).
- 525 83 European Centre for Disease Prevention and Control. European Union Standards for Tuberculosis Care - 2017
526 update. 2017. <https://www.ecdc.europa.eu/sites/default/files/documents/ESTC-leaflet-September-2018.pdf>
527 (accessed 2021 Jun 8)
- 528 84 European Centre for Disease Prevention and Control. Infection prevention and control and preparedness for
529 COVID-19 in healthcare settings (Sixth update – 9 February 2021). 2021.
530 [https://www.ecdc.europa.eu/sites/default/files/documents/Infection-prevention-and-control-in-healthcare-](https://www.ecdc.europa.eu/sites/default/files/documents/Infection-prevention-and-control-in-healthcare-settings-COVID-19_6th_update_9_Feb_2021.pdf)
531 [settings-COVID-19_6th_update_9_Feb_2021.pdf](https://www.ecdc.europa.eu/sites/default/files/documents/Infection-prevention-and-control-in-healthcare-settings-COVID-19_6th_update_9_Feb_2021.pdf) (accessed 2021 Jun 8)
- 532 85 National Centre for Disease Control, Directorate General of Health Services, Ministry of Health and Family
533 Welfare, Government of India. National Guidelines for Infection Prevention and Control in Healthcare Facilities.
534 2020. [https://main.mohfw.gov.in/sites/default/files/National%20Guidelines%20for%20IPC%20in%20HCF%20-](https://main.mohfw.gov.in/sites/default/files/National%20Guidelines%20for%20IPC%20in%20HCF%20-%20final%281%29.pdf)
535 [%20final%281%29.pdf](https://main.mohfw.gov.in/sites/default/files/National%20Guidelines%20for%20IPC%20in%20HCF%20-%20final%281%29.pdf) (accessed 2021 Jun 8)
- 536 86 Government of India: Ministry of Health and Family Welfare. Clinical management protocol for COVID-19 (in
537 adults) - version 6, 24 May 2021. 2021.
538 <https://www.mohfw.gov.in/pdf/COVID19ClinicalManagementProtocolAlgorithmAdults19thMay2021.pdf>
539 (accessed 2021 Jun 8)
- 540 87 Richter ED, Laster R. The Precautionary Principle, epidemiology and the ethics of delay. *Int J Occup Med Environ*
541 *Health*. 2004;17(1):9–16.
- 542 88 Davis DJ. Going beyond benchmarks: zero harm for every patient, every time. *J Nurs Adm*. 2015;45(4):183–4.
- 543 89 South Africa National Department of Health. Policy for the regulation of quality respiratory protective equipment
544 (RPE) supply in healthcare (August 2020). 2020. [https://www.nicd.ac.za/wp-content/uploads/2020/11/RPE-Policy-](https://www.nicd.ac.za/wp-content/uploads/2020/11/RPE-Policy-20-August-2020-Signed.pdf)
545 [20-August-2020-Signed.pdf](https://www.nicd.ac.za/wp-content/uploads/2020/11/RPE-Policy-20-August-2020-Signed.pdf) (accessed 2021 Jul 27)
- 546

- 547 90 The National Institute for Occupational Safety and Health. Approved Particulate Filtering Facepiece Respirators.
548 2020. https://www.cdc.gov/niosh/nppt/topics/respirators/disp_part/default.html
- 549 91 Occupational Safety and Health Administration. Fit Testing Procedures (Mandatory). 2004.
550 <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA> (accessed 2021 Jun 6)
- 551 92 South African Health Products Regulatory Authority. Communication to Stakeholders. MD025: Licensing and
552 Regulatory requirements for the manufacture and distribution of medical and respirator masks during COVID-19.
553 2020. [https://www.sahpra.org.za/wp-content/uploads/2020/09/MD025_Alternative-licensing-and-regulatory-](https://www.sahpra.org.za/wp-content/uploads/2020/09/MD025_Alternative-licensing-and-regulatory-pathway-for-masks_September2020_vF.pdf)
554 [pathway-for-masks_September2020_vF.pdf](https://www.sahpra.org.za/wp-content/uploads/2020/09/MD025_Alternative-licensing-and-regulatory-pathway-for-masks_September2020_vF.pdf) (accessed 2021 Jun 8)
- 555 93 Bergwerk M, Gonen T, Lustig Y, et al. Covid-19 Breakthrough Infections in Vaccinated Health Care Workers. *N Engl*
556 *J Med*. 2021;0(0):null.
- 557 94 McAvoy M, Bui A-TN, Hansen C, et al. 3D Printed frames to enable reuse and improve the fit of N95 and KN95
558 respirators. *MedRxiv Prepr Serv Health Sci*. 2020;
- 559 95 Imbrie-Moore AM, Park MH, Zhu Y, Paulsen MJ, Wang H, Woo YJ. Quadrupling the N95 Supply during the COVID-
560 19 Crisis with an Innovative 3D-Printed Mask Adaptor. *Healthcare*. 2020;8(3).
- 561 96 Centers for Disease Control and Prevention. Implementing Filtering Facepiece Respirator (FFR) Reuse, Including
562 Reuse after Decontamination, When There Are Known Shortages of N95 Respirators (updated 19 October 2020_ .
563 Centers for Disease Control and Prevention. 2020. [https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-](https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html)
564 [strategy/decontamination-reuse-respirators.html](https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html) (accessed 2021 Jul 30)
- 565 97 Bergman MS, Viscusi DJ, Zhuang Z, Palmiero AJ, Powell JB, Shaffer RE. Impact of multiple consecutive donnings on
566 filtering facepiece respirator fit. *Am J Infect Control*. 2012;40(4):375–80.
- 567 98 Degesys NF, Wang RC, Kwan E, Fahimi J, Noble JA, Raven MC. Correlation Between N95 Extended Use and Reuse
568 and Fit Failure in an Emergency Department. *JAMA*. 2020;324(1):94–6.
- 569 99 Brady TM, Strauch AL, Almaguer CM, et al. Transfer of bacteriophage MS2 and fluorescein from N95 filtering
570 facepiece respirators to hands: Measuring fomite potential. *J Occup Environ Hyg*. 2017;14(11):898–906.
- 571 100 Kielmann K, Karat AS, Zwama G, et al. Tuberculosis infection prevention and control: why we need a whole
572 systems approach. *BMC Infect Dis Poverty*. 2020;9(1):56.
- 573 101 van der Westhuizen H-M, Nathavitharana RR, Pillay C, Schoeman I, Ehrlich R. The high-quality health system
574 ‘revolution’: Re-imagining tuberculosis infection prevention and control. *J Clin Tuberc Mycobact Dis*.
575 2019;17:100118.