Quantitative fit testing with limited supplies of respirator masks in hospital personnel during the COVID-19 pandemic

Shanel Cameron 1 BMedSc, MBBS(Hons), FANZCA, Staff Specialist Anaesthetist
Winston Cheung 1,2,3,5 MBChB, FCICM, FRACP, Staff Specialist Intensivist, Clinical Associate Professor
Nigel Cronin 4 BN, BComm, MN, Programs Manager
Karina Griffiths 4 BN, GradCertCritCare, Senior Nurse Educator
Rhiannon Hunt 1 RN, MICNurs, Nurse Unit Manager
Lesley Innes 4 BScPhys, MHlthLaw, Director
Mark Kol 1,2 BA, MBBS(Hons), FRACP, FCICM, ICU Director, Clinical Senior Lecturer
Amy Lawrence 1 BMedSci(Hons), MBBS, FANZCA, Staff Specialist Anaesthetist
Asim Shah 1,2 MBChB, MSc, FACEM, FCICM, FRCEM, Staff Specialist Intensivist, Clinical Senior Lecturer
Katina Skylas 1 RN, MClinNurs(CritCare), Clinical Nurse Consultant Intensive Care
Atul Wagh 1,2 MBBS, MD, DNB, EDIC, FCICM, Staff Specialist Intensivist

The Sydney Local Health District Mask Fit Investigators (in alphabetical order)

1Concord Repatriation General Hospital, Hospital Road, Concord, NSW 2139, Australia. Email: shanel.cameron@health.nsw.gov.au; Rhiannon.Hunt@health.nsw.gov.au; Mark.Kol@health.nsw.gov.au; Amy.Lawrence@health.nsw.gov.au; Asim.Shah@health.nsw.gov.au; Katina.Skylas@health.nsw.gov.au; Atul.Wagh@health.nsw.gov.au
2Sydney Medical School – Concord, University of Sydney, Hospital Road, Concord, NSW 2139, Australia.
3The George Institute for Global Health – Australia, Level 5, 1 King Street, Newtown, NSW 2050, Australia.
4Centre for Education and Workforce Development, Sydney Local Health District, Rozelle Campus, Building 301, Callan Park, Balmain Road, Lilyfield, NSW 2039, Australia. Email: Nigel.Cronin@health.nsw.gov.au; Karina.Griffiths@health.nsw.gov.au; Lesley.Innes@health.nsw.gov.au
5Corresponding author. Email: winston.cheung@health.nsw.gov.au

Received 25 June 2020, accepted 30 June 2020, published online 28 July 2020

There is currently little robust evidence to guide the use of personal protective equipment (PPE) and N95 respirator masks to protect hospital personnel from developing COVID-19 through hospital-associated transmission. 1–4 Studies comparing qualitative mask fit testing (QLFT), using self-examination to identify air leakage, to quantitative mask fit testing (QNFT), using an electronic device to numerically measure air leakage, demonstrate significant differences in leak detection, but have not conclusively shown that QNFT reduces infection rates in healthcare workers. 5

Because of the limited supplies of PPE during the early stages of the COVID-19 pandemic in Australia and the lack of robust evidence that QNFT improves outcomes, there have been suggestions that QNFT not be performed in healthcare workers, predominantly to conserve PPE supplies. This study was therefore conducted, to help inform decision-making, by determining the QNFT failure rates in the respirator masks commonly provided to hospitals in Australia at the start of the COVID-19 pandemic.

QNFT was conducted in medical, nursing and allied health staff from areas deemed high risk for SARS-CoV-2 exposure, at Concord Repatriation General Hospital between 2 April and 22 May 2020. The project was granted exemption from ethical review by the hospital Human Research Ethics Committee. In order to conserve limited supplies, the following four masks were fit tested on staff, in order of priority, until the test was passed: 3M 1860 and 1860S N95 masks, ProShield TN01–11 and TN01–12 N95 masks. Only staff which failed QNFT using these four masks were tested using the 3M Aura 1870þ mask, which was in lowest supply (Fig. 1).

A maximum of 48 h of lower facial hair growth was allowed. No other PPE was worn. QNFT was performed using the TSI...
PortaCount Pro+ Respirator Fit Tester 8038 (TSI, USA) and FitPro+ 3.2.0 (2015, TSI, USA) analysis software. The device directly measured the concentration of particles inside and outside of a mask, and calculated the ratio, called the fit-factor. Staff performed the following exercise protocol: normal breathing, deep breathing, side/side and up/down head movement, talking, and bending over, for 60 s each, and grimacing (OSHA 29CFR1910.134, available at https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134, accessed 2 July 2020). Failure of fit testing was defined as an overall fit-factor ratio of less than 100, or a ratio for an individual exercise of less than 50.

Of the 371 staff who completed QNFT, 23 (6.2% (95% confidence interval (CI) 3.7, 8.7)) failed the first four masks, and 6 (1.6% (95% CI 0.3, 3.0)) failed all five masks. The mask with the lowest failure rate was the 3M 1860S (18.2% (95% CI 13.2, 23.2)).

Our study demonstrates that only a small proportion of healthcare workers fail QNFT using five commonly used respirator masks provided to hospitals in Australia, however, in comparison, the failure rates for individual masks were relatively high. The main limitation was the inability to test workers using all respirator masks due to limited supplies. We believe that QNFT of respirators during the COVID-19 pandemic should continue, to determine the optimal fit for individual healthcare personnel, until more robust evidence becomes available that a particular respirator outperforms the others at an acceptable level, or that QNFT does not reduce infection acquisition rates.

Competing interests
Winston Cheung declares that he has convened educational events that have received financial assistance from 3M, AB Applied Biosystems, AB Sciex, Abbott Medical Optics, Actelion, Advanze Pharma, Alcon, Amgen, Aquatic Solutions, Aspen, Avant Mutual, Bayer Healthcare, BD, Bioline, Boehringer-Ingelheim, B Braun, Celgene, Charcot-Marie-Tooth Association of Australia, CSL Biotherapies, Fresenius Kabi, Glaxo Smith Kline, Genzyme, Immune System Therapeutics, Infusion 360, Invitrogen, Ipsen, Janssen-Cilag, Johnson and Johnson, Leica Microsystems, Life Technologies, Lilly, Macrogen, Medtronic, MACS Miltenyi Biotec, Merck Sharpe and Dohme, National Home Doctor Service, Novartis, Pfizer, PPS Mutual, Roche, Sanofi-Aventis, Schering Plough, Servier, and Wyeth. 3M had no involvement in the design, conduct, analysis of results or manuscript preparation of this study, or decision to submit for publication. None of the other authors have any relevant competing interests.

Acknowledgement
This research did not receive any specific funding.

References
1 Verbeek JH, Rajamaki B, Ijaz S, Sauna R, Toomey E, Blackwood B, Tikka C, Ruotsalainen JH, Kilinc Balci FS. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. Cochrane Database Syst Rev 2020; (5), CD011621.
2 Wang D, Hu B, Hu C, Zhu F, Liu X, Zhang J, Wang B, Xiang H, Cheng Z, Xiong Y, Zhao Y, Li Y, Wang X, Peng Z. Clinical characteristics of 138 hospitalised patients with 2019 novel coronavirus-infected pneumonia in Wuhan, China. JAMA 2020; 323(11), 1061–9. doi:10.1001/jama.2020.1585
3 Radonovich LJ, Simberkoff MS, Bessesen MT, Brown AC, Cummings DAT, Gaydos CA, Los JG, Krosche AE, Gilbert CL, Gorse GJ, Nyquist A-C, Reich NG, Rodriguez-Barradas MC, Savor Price C, Perl TM. N95 respirators vs medical masks for preventing influenza among health care personnel. JAMA 2019; 322: 824–33. doi:10.1001/jama.2019.11645
4 MacIntyre CR, Wang Q, Cauchemez S, Seale H, Dwyer DE, Yang P, Shi W, Gao Z, Pang X, Zhang Y, Wang X, Duan W, Rahman B, Ferguson N. A cluster randomized clinical trial comparing fit-tested and non-fit-tested N9 respirators to medical masks to prevent respiratory virus infection in health care workers. Influenza Other Respir Viruses 2011; 5: 170–9. doi:10.1111/j.1755-2699.2011.00198.x
5 Lam SC, Lui AKF, Lee KYK, Lee JKL, Wong KF, Lee CNY. Evaluation of the user seal check on gross leakage detection of 3 different designs of N95 filtering facepiece respirators. Am J Infect Control 2016; 44: 579–86. doi:10.1016/j.ajic.2015.12.013