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Original Article

A cluster randomized clinical trial comparing fit-tested and non-fit-tested N95 respirators to medical masks to prevent respiratory virus infection in health care workers

Chandini Raina MacIntyre,^a Quanyi Wang,^b Simon Cauchemez,^c Holly Seale,^a Dominic E. Dwyer,^d Peng Yang,^b Weixian Shi,^b Zhanhai Gao,^a Xinghuo Pang,^b Yi Zhang,^b Xiaoli Wang,^b Wei Duan,^b Bayzidur Rahman,^a Neil Ferguson^c

^aSchool of Public Health and Community Medicine, Faculty of Medicine, University of New South Wales, Sydney, Australia. ^bThe Beijing Center for Disease Prevention and Control, Beijing, China. ^cMRC Center for Outbreak Analysis and Modelling, Department of Infectious Disease Epidemiology, Imperial College London, London, UK. ^dInstitute for Clinical Pathology and Medical Research, Westmead Hospital, Sydney, Australia.

Correspondence: Professor C. Raina MacIntyre, Professor of Infectious Diseases Epidemiology and Head of School, School of Public Health and Community Medicine, Faculty of Medicine, University of New South Wales, Samuels Building, Room 325, Sydney, 2052 NSW, Australia. E-mail: r.macintyre@unsw.edu.au

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Background We compared the efficacy of medical masks, N95 respirators (fit tested and non fit tested), in health care workers (HCWs).

Methods A cluster randomized clinical trial (RCT) of 1441 HCWs in 15 Beijing hospitals was performed during the 2008/2009 winter. Participants wore masks or respirators during the entire work shift for 4 weeks. Outcomes included clinical respiratory illness (CRI), influenza-like illness (ILI), laboratory-confirmed respiratory virus infection and influenza. A convenience no-mask/respirator group of 481 health workers from nine hospitals was compared.

Findings The rates of CRI (3.9% versus 6.7%), ILI (0.3% versus 0.6%), laboratory-confirmed respiratory virus (1.4% versus 2.6%) and influenza (0.3% versus 1%) infection were consistently lower for the N95 group compared to medical masks. By intention-to-treat analysis, when *P* values were adjusted for clustering, non-fit-tested N95 respirators were significantly more protective than medical masks against CRI, but no other outcomes

were significant. The rates of all outcomes were higher in the convenience no-mask group compared to the intervention arms. There was no significant difference in outcomes between the N95 arms with and without fit testing. Rates of fit test failure were low. In a *post hoc* analysis adjusted for potential confounders, N95 masks and hospital level were significant, but medical masks, vaccination, handwashing and high-risk procedures were not.

Interpretation Rates of infection in the medical mask group were double that in the N95 group. A benefit of respirators is suggested but would need to be confirmed by a larger trial, as this study may have been underpowered. The finding on fit testing is specific to the type of respirator used in the study and cannot be generalized to other respirators.

Trial registration Australian New Zealand Clinical Trials Registry (ANZCTR), ACTRN: ACTRN12609000257268 (<http://www.anzctr.org.au>).

Keywords Health workers, influenza, masks, PPE.

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Introduction

The current influenza A H1N1 2009 virus pandemic,¹ the ongoing zoonotic transmission of influenza A H5N1 and

tion is one of the key non-pharmaceutical interventions for protection of HCWs.

Nosocomial influenza and other outbreaks result in significant morbidity and costs^{2,3} and can occur in the absence

the emergence of oseltamivir-resistant seasonal influenza A H1N1 are threats to human health. Hospital health care workers (HCWs) are key to effective pandemic response and the capacity of health care systems. Respiratory protec-

of community epidemics.⁴ During outbreaks of infectious diseases, hospitals may amplify virus transmission, as demonstrated during severe acute respiratory syndrome (SARS).⁵ Furthermore, anticipated antiviral shortages and