

Presentation summary for “The First Randomised, Controlled Clinical Trial Of Surgical Masks Compared To Fit-tested And Non-fit Tested N95 Masks In The Prevention Of Respiratory Virus Infection In Hospital Health Care Workers In Beijing, China” (Session 224, Paper K-1918)

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Surgical masks do not protect health workers against influenza and respiratory viruses, and should not be offered to health care workers as protection. N95 masks offer significant protection and should be the standard personal protective equipment offered to health workers. Health workers are at the front line of an effective pandemic response, and their protection is crucial to maintenance of essential health services. During a pandemic, antivirals may be in short supply, resistance to antivirals may develop, and vaccine production will be delayed. Masks are therefore a key available means of protecting health workers. The commonly used masks are surgical masks, but specialized respirators (N95 masks) are also available. These come with a recommendation for “fit testing”, which is a time consuming process designed to ensure proper fit of the mask around the contour of the face. N95 masks cost more than surgical masks but have a higher filtration capacity as tested in laboratory settings. No previous study has been done to determine the clinical efficacy of one type of mask compared to the other. We conducted a randomized clinical trial conducted in 24 hospitals and 1936 hospital health care workers in Beijing, China. We compared surgical masks with N95 masks (fit tested), N95 masks (not fit-tested) and no masks. We found that surgical masks did not offer protection to health care workers. N95 masks, however, offered 75% protective efficacy against proven influenza infection, as well as 56% efficacy against any proven respiratory viral infection. We also showed that formal fit-testing did not improve the efficacy of N95 masks, which is an important benefit during a pandemic, given the time and logistic difficulty associated with fit-testing. It would be indefensible to offer surgical masks to health care workers as protection - N95 masks should be the standard protection offered to health workers, and do not need to be formally fit-tested.

ABSTRACT

Background: There are no published RCTs on the efficacy of surgical masks compared to N95 masks, and no clinical trials of any masks in health care workers. This is a critical gap in evidence, with relevance for pandemic planning.

Aims: To compare the clinical efficacy of surgical masks, N95 masks (fit tested) and N95 masks (non fit tested) compared to control in front line health care workers.

Methods: A cluster RCT of 24 hospitals and 1936 front line hospital health care workers in Beijing, China. Participants wore the masks for 4 weeks during the winter and were followed for development of respiratory illness for 5 weeks. Symptomatic participants were tested for respiratory viruses including influenza. Outcomes included clinical respiratory illness (CRI), influenza-like illness (ILI), any laboratory confirmed respiratory virus infection, and laboratory confirmed influenza.

Results: By intention to treat analysis, surgical masks had no efficacy for any of the outcomes. N95 masks were significantly more protective than control. Fit testing did not appear to improve the efficacy of N95 masks, which as a group had statistically significant efficacy of 60% against CRI, 75% against ILI, 56% against laboratory confirmed respiratory viral infection, and 75% against confirmed influenza infection.

Conclusions: This is the first RCT to compare N95 masks with surgical masks, and has major implications for infection and pandemic control. While N95 masks are superior to surgical masks in clinical efficacy, fit testing does not improve their efficacy. Given the logistic difficulties of fit testing, particularly during an infectious diseases emergency, this is an advantage for public health control.