

## Masking lack of evidence with politics

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The increasing polarised and [politicised views](#)<sup>1</sup> on whether to wear masks in public during the current COVID-19 crisis hides a bitter truth on the state of contemporary research and the value we pose on clinical evidence to guide our decisions.

In 2010, at the end of the last influenza pandemic, there were six published randomised controlled trials with 4,147 participants focusing on the benefits of [different types of masks](#).<sup>2</sup> Two were done in healthcare workers and four in family or student clusters. The face mask trials for influenza-like illness (ILI) reported poor compliance, rarely reported harms and revealed the pressing need for future trials.

Despite the clear requirement to carry out further large, pragmatic trials a decade later, [only six had been published](#): five in healthcare workers and one in pilgrims.<sup>3</sup> This recent crop of trials added 9,112 participants to the total randomised denominator of 13,259 and showed that masks alone have no significant effect in interrupting the spread of ILI or influenza in the general population, nor in healthcare workers.

The design of these twelve trials differed: viral circulation was usually variable; none had been conducted during a pandemic. Outcomes were defined and reported in seven different ways, making comparison difficult. It is debatable whether any of these results could be applied to the transmission of SARs-CoV-2. [Only one randomised trial](#) (n=569) included cloth masks. This trial found ILI rates were 13 times higher in Vietnamese hospital workers allocated to cloth masks compared to medical/surgical masks, RR 13.25, (95%CI 1.74 to 100.97) and over three times higher when compared to no masks, RR 3.49 (95%CI 1.00 to 12.17).<sup>4</sup>

In the study, the control group was asked to continue with their normal practices, which may or may not have included mask-wearing. Mask wearing was measured and documented for all participants, including the control arm. 170/458 (37%) used medical masks in the control arm, 38/458 (8%) used cloth masks, and 245/458 (53%) used a combination of both medical and cloth masks during the study period. \*

After adjusting for other factors, ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) remained significantly higher in the cloth masks group compared with the medical masks group.

It would appear that despite two decades of pandemic preparedness, there is considerable uncertainty as to the value of wearing masks. For instance, high rates of infection with cloth masks could be due to harms caused by cloth masks, or benefits of medical masks. The numerous systematic reviews that have been recently published all include the same evidence base so unsurprisingly broadly reach the same conclusions. <sup>2</sup> However, [recent reviews](#) using lower quality evidence found masks to be effective. Whilst also recommending robust randomised trials to inform the evidence for these interventions. <sup>5</sup>

Many countries have gone onto mandate masks for the public in various settings. Several others – Denmark, and Norway – generally do not. [Norway's Institute for Public Health](#) reported that if masks did work then any difference in infection rates would be small when infection rates are low: assuming 20% asymptomatics and a risk reduction of 40% for wearing masks, 200 000 people would need to wear one to prevent one new infection per week. <sup>6</sup>

What do scientists do in the face of uncertainty on the value of global interventions? Usually, they seek an answer with adequately designed and swiftly implemented clinical studies as has been partly achieved with pharmaceuticals. We consider it is unwise to infer causation based on regional geographical observations as several proponents of masks have done. Spikes in cases can easily refute correlations, compliance with masks and other measures is often variable, and confounders cannot be accounted for in such observational research.

A search of the [COVID trials tracker](#) reveals nine registered trials of which five are currently recruiting participants and one enrolling participants by invitation. <sup>7</sup> In Denmark, where masks are advised for those who break self-isolation to go out to take a test, a randomised trial including 6,000 participants is assessing reductions in COVID-19 Infection Using Surgical Facial Masks Outside the Healthcare System. [In Guinea-Bissau in West Africa](#), the Bandim Health Project is leading a 66,000 person trial – although not yet recruiting – on cloth face masks.

The small number of trials and lateness in the pandemic cycle is unlikely to give us reasonably clear answers and guide decision-makers. This abandonment of the scientific modus operandi and lack of foresight has left the field wide open for the play of opinions, radical views and political influence.

Ongoing trials on trials tracker

trial_id	sponsor	recruitment_status	countries	title	enrollment
NCT04296643	McMaster University	Not Recruiting	No Country Given	Medical Masks vs N95 Respirators for COVID-19	576
NCT04337541	Rigshospitalet, Denmark	Recruiting	Denmark	Reduction in COVID-19 Infection Using Surgical Facial Masks Outside the Healthcare System	6000
ChiCTR2000032213	The First Affiliated Hospital of Chongqing Medical University	Recruiting	China	A medical records based study for the impact of wearing medical masks on oxygen saturation in adult surgical patients after general anaesthesia during novel coronavirus pneumonia (COVID-19) pandemic	151
NCT04375774	University Clinic, UCLouvain	Recruiting	Belgium	Verification of Alternative Do-it-yourself Equipment Respirators for the COVID-19 Personal Protective Equipment (PPE)	10
NCT04415879	The Cleveland Clinic	Recruiting	United States	Effects of a N95 Respirator vs Cloth Mask on Exercise Capacity During Treadmill Exercise.	20
ACTRN12620000688987	The Royal Melbourne Hospital	Not Recruiting	Australia	Comparing the user seal check and fit test between two types of N95 respirators – the Halyard N95 Particulate Filter Respirators and the ProShield-Æ N-95 masks	80
NCT04416919	University of Oklahoma	Recruiting	United States	Assessment of N-95 Facemask for Use in COVID-19 Pandemic in Case of Shortage of Personal Protective Equipment	20
NCT04427176	CHU de Saint Etienne	Not Recruiting	France	Evaluation of ARFC Masks Equipped With CF5 Filter in the Care Unit to Allow a Wider Distribution of FFP2 Masks (Covid-19).	15
NCT04471766	Bandim Health Project	Enrolling by invitation	Guinea-Bissau	Locally Produced Cloth Face Mask and COVID-19 Like Illness Prevention	66000

\* The remaining 1% either reported using a N95 respirator (n=3) or did not use any masks (n=2).

Disclosure:

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(Full bio and disclosure statement [here](#))

The views expressed in this viewpoint represent the views of the authors and not necessarily those of the host institution, the NHS, the NIHR, or the Department of Health.

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