

SYNOPSIS

Review of “The impact of community masking on COVID-19: A cluster-randomized trial in Bangladesh”

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One-minute summary

- From November 2020 to April 2021, 600 rural villages in Bangladesh, which included a population of 342,126 adults, were assigned to either no intervention (control, n = 300 villages, n = 163,838 adults) or community-level mask promotion (intervention, n = 300 villages, n = 178,288 adults). The intervention group was cross-randomized to mask promotion strategies at the village and household levels, including cloth (n = 100 villages) and surgical masks (n = 200 villages). The authors used pairwise randomization of unions within the same sub-districts for similarity of Coronavirus Disease 2019 (COVID-19) case data, population size, and population density.
- Mechanisms to increase mask-wearing included the following: providing free masks; providing information about the importance of mask-wearing; having mask promoters reinforce the importance of mask-wearing by stopping individuals in public places who were not wearing masks, reminding them about the importance of mask-wearing, and giving them a mask if they did not have one; partnering with local leaders to encourage mask-wearing at mosques and markets; and in some villages, providing a variety of reminders and explicit commitment signals, as well as incentives for village leaders.
- In the pooled analysis of surgical and cloth mask treatment groups, symptomatic seroprevalence was reduced by 9.3% (adjusted prevalence ratio [aPR] = 0.91; 95% confidence interval [CI]: 0.82–1.00; P = 0.043; control prevalence = 0.76%; treatment prevalence = 0.69%).
 - In the subgroup analysis of surgical masks, the relative reduction of symptomatic seroprevalence was 11.2% (aPR = 0.89; 95% CI: 0.78–1.00; P = 0.043; control prevalence = 0.80%; surgical mask treatment prevalence = 0.71%).
 - The benefit of surgical masks was driven by reduction of symptomatic seroprevalence in persons over 50 years (age 50–60 years: aPR = 0.77; 95% CI: 0.59–0.95; P = 0.011; >60 years: aPR = 0.65; 95% CI: 0.46–0.85; P = 0.001). Wearing a surgical mask did not have a significant effect on reducing symptomatic seroprevalence in persons 40–50 years (unadjusted symptomatic seroprevalence

was 0.95 in controls versus 0.94 in the surgical mask treatment arm; $P = 0.984$) or <40 years (unadjusted symptomatic seroprevalence 0.55 in controls versus 0.52 in the surgical mask treatment arm; $P = 0.618$).

- In the subgroup analysis of cloth masks, the relative reduction of symptomatic seroprevalence was 5.0% (aPR = 0.95; 95% CI: 0.79–1.11; $P = 0.54$; control prevalence = 0.67%; cloth mask treatment prevalence = 0.62%).
- The average proportion of proper mask-wearing in control villages was 13.3% ($n = 806,547$ observations) and 42.3% in intervention villages ($n = 797,715$ observations) (adjusted percentage point difference [aPPD] = 0.29; 95% CI: 0.27–0.31; $P = 0.001$; surgical masks aPPD = 0.3; standard error [SE] = 0.015; cloth masks aPPD = 0.26; SE = 0.019). The increase in mask-wearing was largest in mosques (37.0 percentage points).
 - Proper mask-wearing was sustained during the intervention period and two weeks after, but declined after 5 months where it remained 10 percentage points higher in intervention villages than control villages.
- The average proportion of physical distancing (at least one arm’s length) was 24.1% in control villages and 29.2% in treatment villages (aPPD = 0.05; 95% CI: 0.04–0.06). There was no difference reported between cloth and surgical mask treatment arms. Physical distancing was greatest in markets (aPPD = 0.074), but there was no physical distancing in any mosque, in either treatment or control villages, which relates to a religious norm of standing shoulder-to-shoulder when praying.
- Compared to self-protection messaging alone, altruistic messaging had no greater impact on mask-wearing, and twice-weekly text messages and a verbal commitment had no significant effects on increasing mask-wearing.
- The authors concluded that their “intervention demonstrated a scalable and effective method to promote mask adoption and reduce symptomatic SARS-CoV-2 infections.”

Additional information

- The Government of Bangladesh had strongly recommended mask use from early April 2020, but then switched to mandated mask use in May 2020. Fines were associated with lack of use, but the mandate was predominantly not enforced. When the mandate was first announced, observed masking in previous studies showed portions of masking as high as 51%, which declined to 20-26% a month later.
- The treatment package included:
 1. One-time mask distribution to households, in markets 3-6 days per week, and at mosques on three of four Friday prayers during the first four weeks of the intervention.
 2. Masks were promoted once in households, and weekly or biweekly in public spaces and markets where non-mask wearers were encouraged to wear masks, and by imams at Friday prayers using a scripted speech.
 3. Role-modelling and advocacy by local leaders.

- Cloth masks were manufactured in Bangladesh, had an exterior layer of 100% non-woven polypropylene, two interior layers of 60% cotton/40% polyester interlocking knit, an elastic loop that goes around the head above and below the ears, and a nose bridge. Filtering efficiency was 37% (SD=6%).
- Reusable surgical masks were also manufactured in Bangladesh, had three layers of 100% non-woven polypropylene (the exterior and interior layers were spun-bound and the middle layer was melt-blown), elastic ear loops, and a nose bridge. Filtering efficiency was 95% (SD=1%) but decreased to 76% after washing 10 times with soap and water.
- Village-level and household-level cross-randomizations were not reported to have any significant effect on mask-wearing behaviours, except to some small degree the colour of masks.
 - Village-level cross-randomizations to examine the effect of different social and behaviour change strategies (intervention villages only): cloth versus surgical masks; no incentive, non-monetary incentive, \$190 (USD) monetary incentive for a public project if mask-wearing exceeded 75% after 8 week intervention; signage for households indicating they are a mask-wearing household; and, 0% or 100% households receiving twice-weekly text message reminders about masking importance.
 - Household-level cross-randomizations (intervention villages only): varied colours of masks distributed based on its cross-randomization status in order to infer effect of household-level treatments (blue or green surgical masks at home and promoters blue or green in public, violet or red cloth masks and blue in public) and varied colour per treatment across different villages to avoid mask colour associated with a treatment; messages emphasizing either altruism or self-protection; twice-weekly text reminders or not sent to 0, 50 or 100% of villagers receiving texts; randomized to make verbal commitment to be a mask-wearing household (wear outside and around other people) or not – this assignment could not occur in villages where the public signage was already a commitment.
- Observations of adults were conducted at baseline and once per week for one hour (between 9:00 a.m. and 7:00 p.m.) at each location (markets, restaurant entrances, main road, tea stalls, and mosques) on weeks 1, 2, 4, 6, 8, 10 and 20-27 weeks.
 - Any mask or face covering regardless of it being a distributed mask so long as it was worn properly over mouth and nose.
- Intervention and control groups were balanced on baseline symptomatic seroprevalence, baseline World Health Organization (WHO)-defined COVID-19 symptoms, and baseline mask-wearing rate.
 - WHO case definition of probable COVID-19 given epidemiological risk factors: (a) fever and cough; (b) three or more of the following symptoms (fever, cough, general weakness/fatigue, headache, myalgia, sore throat, coryza, dyspnea, anorexia/nausea/vomiting, diarrhea, altered mental status); or (c) loss of taste or smell.
- There was 98% symptom follow-up (335,382/342,126) via household surveys at weeks 5 and 9 where 27,166 (8.1%) reported COVID-like symptoms during the 8 week intervention period. The proportion of individuals with COVID-like symptoms was 7.6% (cloth mask arm = 7.9%; surgical mask arm = 7.5%; n = 13,273) in the treatment arm and 8.6% (n = 13,893) in the control arm.
- 40.3% (10,952) consented to blood collection (control = 39.9%; treatment = 40.8%; P = 0.24) at 10-12 weeks of follow-up.

- 91.1% (9,977) of blood samples were tested; samples were untested if lacking quantity or could not be matched due to barcode errors. Serology was not conducted if individuals were missing symptom data or did not consent to blood spot collection. Seropositivity was defined by having detectable IgG antibodies against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
- An immunological status ratio (ISR) was calculated as the ratio of optical density divided by the cut-off value. Samples were considered positive if the ISR value was at least 1.1, and negative at 0.9 or less. Equivocal results were retested in duplicate and the average taken.
- Author limitations include that: masks were obviously visible and could affect others' behaviours; no blinding of intervention assignment, but blinding of surveyors to whether they were observing an intervention or control village, and blinding of data analysts; observers could probably be seen despite plain clothes, which may increase adherence to mask-wearing; symptom reporting could be increased in treatment villages due to heightened awareness of COVID-19 and health-seeking behaviours; distance between villages of 2 kilometers may not be adequate to prevent increased mask use in control villages if adults went to treatment villages to get masks, thus diluting the effect of the intervention; symptomatic seroprevalence could be significantly underestimated due to non-consenters; no disease severity measures were captured; no infection confirmation by reverse transcription polymerase chain reaction due to cost; not all symptomatic seroprevalence is necessarily a result of infections occurring during the intervention period since some individuals may already have been infected but became symptomatic during this time; adherence was greater in men than women (mosque data excluded because women generally do not attend prayers at mosques), and promoters were mostly men; outcomes of the study pertains to Alpha (B.1.1.7) but not Delta (B.1.617.2); and, this study does not specifically measure the effects of source control.

PHO reviewer's comments

- This is a preprint article and is subject to change following peer review.
- Overall, this study provides epidemiological evidence to support universal community mask use as an effective public health measure for COVID-19 especially in lower middle-income countries where vaccines may not yet be as readily available. The authors demonstrated the effectiveness of their intervention to increase mask use in rural villages in Bangladesh, and that this increase in mask use was not associated with less physical distancing. They also highlight that ongoing intervention is necessary to maintain mask adherence over time. The authors demonstrated significant population-level protective effects of universal mask-wearing which are likely to be underestimates for jurisdictions with higher mask adherence.
- Study strengths include the large sample size and geographic distribution of villages, and using social and behavioural change communication evidence and a theory-informed approach to develop an intervention and implementation package.
- The authors note that additional retraining of local leaders to promote masks was conducted where mask uptake was low and leadership engagement was low. These villages received targeted treatment to set milestones to be achieved. However, there was no sensitivity analysis conducted to omit these villages from the dataset nor additional description of how many villages and from which treatment arm these were a part of and whether it was balanced between cloth and surgical masks.

- The study did not report on spillover effects from intervention villages to control villages, but discussed in their limitations that due to proximity to intervention villages, masks could have been obtained by adults residing in control villages. There likely would have been the opportunity to document proportions of masks given out in intervention villages observed being worn in control villages given the uniqueness of their colours and logos, but this was not reported. The distance between some control and intervention villages was relatively small, so it would have been valuable to use distance to an intervention village as a regression variable to determine its effect, if any, on control village outcomes.
- Surgical masks were washed with bar soap and water, and reused, which is currently not a recommended practice in Ontario.
- Authors state no adverse events were reported, however, there was no mechanism for reporting or plans to evaluate harms from this study.
- Indoor environments are generally the highest risk for transmission. The study acknowledges that their adherence measurements were predominantly outdoors because few indoor public spaces exist for gatherings. While mask use was measured indoors in mosques, these environments had no physical distancing observed and included predominantly men. Therefore, the results of this study could be confounded by mask use in private indoor environments where observations could not be made, and where most transmission is likely occurring.
- The outcome of symptomatic seropositivity had benefits in terms of efficiency and cost but is limited in that it cannot be definitively linked to symptoms reported in this study.
- It was not specified why the intervention arms were not equally allocated to cloth and surgical masks and instead was a 1:2 ratio. An equal allocation may have allowed for more precise estimates of effect sizes in the cloth mask group, but reduced precision in the surgical mask group.
- There was no age-specific breakdown of the symptomatic seroprevalence data provided for cloth masks, except symptom reporting without serology, despite the analysis having been conducted for surgical masks. Further, there was no age-specific data collected during observations to determine if the effect was related to mask use behaviours. The age differences should be interpreted cautiously as the outcome of *symptomatic* seroprevalence involves substantial bias to detecting older patients who are more likely to be symptomatic and to have more health-seeking behaviours than younger individuals. Furthermore, the results do not suggest mask use is ineffective in younger individuals but that universal adult mask use provides significant protection against symptomatic disease in older adults.
- The cotton mask construction differs from advice from Public Health Agency of Canada that suggests the polypropylene layer be between the cotton layers;¹ in this study polypropylene was the outer layer. The observed differences between surgical and cloth masks should be interpreted cautiously as it may partially be explained by sample size differences, and may not be generalizable to all cloth masks of different construction specifications. Some three-layer cloth masks have similar filtration efficiency to surgical masks.²
- Table S4 indicates that surgical masks were worn more often than cloth masks, although this finding was not statistically significant.
- An ear loop design was used for surgical masks, while an over the head loop design was used for the cloth masks. The loop design could impact convenience, comfort and fit. Ease of wearing

could be a variable that affects wearing and proper use of masks (i.e., easier to don and doff the ear loop design). Loop design may also affect how the mask fits against the face, but face seal leakage was not assessed in this study.

- The intervention was cost-effective, but this conclusion pertains to the economy and value of goods in Bangladesh, which is a lower middle-income country.
- Conclusions from a non-pre-specified analysis comparing data from two different pilots on the effect of in-person reinforcement was not included in this synopsis and caution in interpretation should be made because the results would need to be interpreted with temporal considerations that may not have been accounted for in the authors' conclusions.
- Rates of vaccination are not reported. It is not known whether the same benefit of surgical masks in persons over 50 years would be seen in a highly vaccinated population such as Ontario.

Additional References

1. Public Health Agency of Canada. Non-medical masks: about [Internet]. Ottawa, ON: Government of Canada; 2021 [cited 2021 Sep 10]. Available from: <https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/about-non-medical-masks-face-coverings.html>
2. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Review of “Rapid review on the characteristics of effective non-medical face masks in reducing the risk of SARS-CoV-2 transmission” [Internet]. Toronto, ON: Queen’s Printer for Ontario; 2021 [cited 2021 Sep 10]. Available from: <https://www.publichealthontario.ca/-/media/documents/ncov/research/2021/02/synopsis-young-phac-rapid-review-masks.pdf?la=en>

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