Will Masks Reduce Transmission of SARS-CoV-2 in Bangladesh? A Cluster Randomized Controlled Trial

Jason Abaluck (Yale SOM), Judy Chevalier (Yale SOM), Mohammad Ashraful Haque (Poverty Action), Muhamad Maqsud Hossain (North South), Md. Alamgir Kabir (Poverty Action), Laura Kwong (Stanford), Steve Luby (Stanford Medical School), Ahmed Mushfiq Mobarak (Yale), Ashley Rene Styczynski (Stanford),

Contact: ahmed.mobarak@yale.edu

The specifics of SARS-CoV-2 transmission and our current scientific understanding of the protective benefits of facemasks are such that modest amounts of spending on mask distribution coupled with a behavior change program to encourage consistent mask usage can produce very large returns in terms of reduced mortality risk.

In this note:

1. We briefly review the case for mask adoption

2. We discuss the current state of mask use globally and the "theory of change" for our proposed intervention

3. We discuss our capacity for (a) procuring high filtration efficiency masks that are mass produced in local garment factories at low cost, and (b) implementing context-appropriate interventions designed to encourage consistent mask usage.

4. We describe a randomized trial to measure the benefits of facemasks in preventing transmission of respiratory infections (especially COVID-19) and to test the success of the behavior change program in increasing proper mask use.

1) The Case for Mask Adoption

There is substantial evidence from laboratory studies that masks can reduce exhaled viral load,[1] and all major public health organizations recommend that those with symptoms of COVID-19 wear masks for

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[1] See, for example:
Leung, N.H.L., Chu, D.K.W., Shiu, E.Y.C. et al. Respiratory virus shedding in exhaled breath and efficacy of face masks. Nat Med (2020). https://doi.org/10.1038/s41591-020-0843-2
Davies, A., Thompson, K.A., Giri, K., Kafatos, G., Walker, J. and Bennett, A., 2013. Testing the efficacy of homemade masks: would they protect in an influenza pandemic? Disaster medicine and public health preparedness, 7(4), pp.413-418.
Ferguson, N.M., Laydon, D., Nedjati-Gilani, G., Imai, N., Ainslie, K., Baguelin, M., Bhatia, S., Boonyasiri, A., Cucunubá, Z., Cuomo-Dannenburg, G. and Dighe, A., 2020. Impact of non-pharmaceutical interventions (NPIs) to reduce COVID-19 mortality and healthcare demand. Imperial College, London. DOI: https://doi. org/10.25561/77482.
Jefferson, T., Foxlee, R., Del Mar, C., Dooley, L., Ferroni, E., Hewak, B., Prabhala, A., Nair, S. and Rivetti, A., 2008. Physical interventions to interrupt or reduce the spread of respiratory viruses: systematic review. Bmj, 336(7635), pp.77-80.
Rengasamy, S., Eimer, B. and Shaffer, R.E., 2010. Simple respiratory protection—evaluation of the filtration performance of cloth masks and common fabric materials against 20–1000 nm size particles. Annals of occupational hygiene, 54(7), pp.789-798.
van der Sande, M., Teunis, P. and Sabel, R., 2008. Professional and home-made face masks reduce exposure to respiratory infections among the general population. PLoS One, 3(7).

this reason.[2] There is also substantial evidence of asymptomatic or pre-symptomatic transmission of COVID-19.[3] This suggests that universal adoption of cloth masks (if used regularly and properly) – including by those who appear healthy–may substantially reduce the transmission rate of the virus.

However, to date, there are few estimates of the degree to which mask adoption actually reduces *transmission* of the virus in the field.[4] Non-experimental estimates suggest that masks lower transmission by 40-50%.[5]

2) The Status Quo

Take-up of masks is highly variable across countries, ranging from 0-20% in the UK, Norway, Finland and Denmark to close to 100% in several Asian countries with historic norms of mask use.[6] As of July 5th, 2020, 4.3 billion people live in countries that do not formally mandate mask use,[7] and 240 million live in countries where mask use is not recommended in any way.

The relationship between mask recommendations, requirements, and mask take-up is complex. In Bangladesh, the government has strongly recommended mask use since early April. This policy was initially accompanied by consistent public messaging, as well as attempts by police and NGOs to confront those who were seen in public without masks. Our surveys from this period indicate that throughout Bangladesh, compliance was high, with 80-95% of respondents reporting that they wore masks in public areas.

Our more recent data suggests that this trend has now reversed. The Bangladeshi government formally mandated mask use in late May and began fining non-compliers; nonetheless, in our latest survey of mask use, we observed 100,000 people in public areas throughout Bangladesh and found that only 26% were wearing masks despite the severity of the epidemic continuing to increase.

Our study has four main aims:

- To develop a scalable intervention that can increase consistent use of a quality mask

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[2] E.g. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/when-and-how-to-use-masks.

[3] Japanese National Institute of Infectious Diseases. Field Briefing: Diamond Princess COVID-19 Cases, 20 Feb Update. https://www.niid.go.jp/niid/en/2019-ncov-e/9417-covid-dp-fe-02.html (Accessed on March 01, 2020).

[4] The gap between the laboratory evidence that masks create a partial physical barrier to viruses and the unknown extent to which masks impede transmission and illness from COVID-19 in the field stems from a variety of factors including (1) the viral exposure required for infection is not known and (2) the relationship between viral exposure and, other things equal, the severity of illness is not known.

[5] Abaluck, Jason and Chevalier, Judith A. and Christakis, Nicholas A. and Forman, Howard Paul and Kaplan, Edward H. and Ko, Albert and Vermund, Sten H., The Case for Universal Cloth Mask Adoption and Policies to Increase Supply of Medical Masks for Health Workers (April 2, 2020). Available at SSRN: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3567438.
Chernozhukov, Victor, Hiroyuki Kasaha, and Paul Schrimpf. "Causal impact of masks, policies, behavior on early COVID-19 pandemic in the US." arXiv preprint arXiv:2005.14168 (2020).
Lyu, Wei, and George L. Wehby. "Community Use Of Face Masks And COVID-19: Evidence From A Natural Experiment Of State Mandates In The US: Study examines impact on COVID-19 growth rates associated with state government mandates requiring face mask use in public." Health Affairs (2020): 10-1377.

[6] https://today.yougov.com/topics/international/articles-reports/2020/03/17/personal-measures-taken-avoid-covid-19

[7] Data from https://masks4all.co/what-countries-require-masks-in-public/.

- To assess the impact of mask use on the spread of respiratory illnesses and especially COVID-19
- To assess the protective value of scientifically designed and validated masks relative to existing face-coverings
- To evaluate whether promoting mask use creates unintended consequences, such as people becoming more likely to engage in otherwise riskier behaviors

We believe that a successful study could influence decision-makers through several channels:

- Our intervention would evaluate whether mask distribution combined with consistent messaging is sufficient to create norms of mask use in places where current mask use is low. Context-appropriate variations of the program we design to increase mask take-up could be replicated in other Asian and African countries with similar implementation and enforcement challenges as Bangladesh.
- Most people in the world still live in countries that do not mandate mask use despite community spread of COVID, and mandates may not go far enough. Direct evidence that masks reduce transmission of the virus would strengthen the hand of those pushing for action in those countries.
- Direct evidence of this type would shift the priorities of public health agencies with limited resources if masks are proven effective.
- With direct evidence of the additional protective value of scientifically-validated masks, many individuals, NGOs and governments would invest more in producing such masks.

Additionally, if successful, the intervention we directly implement in this study will cost-effectively save lives. The above “theory of change” adds to this direct impact.

3) Mask Production, Distribution and Encouragement

We spoke to the head of the Bangladesh Garment Manufacturers and Exporters Association (BGMEA), who connected us to a few reliable factories that are now eager to produce cloth masks for this project in bulk.[8] We are in discussion with sales agents at factories to sew masks to the exact scientific specifications that our team specifies.

After an extensive review of the literature on fabrics for low-cost masks and testing at Stanford University, we have selected to use a mask that has inner and outer layer made of Pellon 931 polyester fusible interface ironed onto interlocking knit and a middle layer of interlocking knit. The fabric will be sewn into a mask with a flat front panel that bunches near the ears and is affixed to the head with ear straps and a metal wire nose brace. The mask fully covers the nose and mouth even with animated

[8] Producing masks locally in Bangladesh yields an ancillary benefit in that it protects the livelihoods of garment factory workers. The ready-made garment industry is the sector hardest hit by the global COVID-19 shock, with a spate of order cancellations from importers in the US and EU. .[8] This disproportionately benefits women and children, as previous research shows that factory jobs allow young women in Bangladesh to delay marriage and childbirth. The BGMEA is itself extremely cognizant of infection risk and is taking numerous measures to reduce employee risk at all facilities, including: maintaining social distancing protocols whenever possible, requiring all employees to wear masks, making available handwashing facilities inside and outside the building, creating an entry plan which allows for each individual to spend 30 seconds washing their hands, and checking temperatures with an infrared thermometer (sending home anyone with a fever) among other procedures (BGMEA Factory Opening Protocol, available on request).

talking. The mask is comfortable and does not hold hot air over the face, which discourages use. We estimate this mask is approximately 60% efficient at blocking particles 300 nm in size at a flow velocity of 10 cm/s (the particle size and approximate flow velocity specified by the U.S. National Institute of Occupational Safety and Health). This compares to bandanas that are <10% effective at a similar flow velocity and surgical masks which have filtration efficacies ranging from 40-70%.[9]

The Yale and IPA research teams have substantial experience implementing behavior change programs in rural Bangladesh over the last 12 years, in partnership with many different local implementers. We have marketed improved cookstoves, encouraged seasonal migration, and implemented community-led total sanitation (CLTS) programs to encourage investments in new hygienic latrines. The CLTS program and the latrine construction subsidies we distributed via lottery were much more logistically complicated and challenging than mask distribution and monitoring of mask-wearing.

4) The Proposed Randomized Controlled Trial

We have three main questions we seek to answer:

1. Can we successfully change community mask-wearing norms?
2. Can community mask-wearing reduce the spread of respiratory disease and (symptomatic) COVID-19 infection?
3. Can individual mask-wearing provide protection against COVID-19 infection?

To answer the first two questions, we will randomize an intervention package at the *mouza* ("group-of villages") level in both "sadar upazilas/municipalities" (small towns) and "non sadar upazilas" (rural sub-districts).

To answer the third question, we will randomly choose a small fraction of high-risk *individuals* in control mouzas and provide them masks and instructions for proper mask-use to assess whether masks protect against infection.

In both the *mouza* and individual mask interventions, one important outcome will be COVID-19 infection rates assessed via serology testing. We discuss this outcome separately in each case.

Mouza Randomization

In order to evaluate whether masks prevent the spread of COVID via either preventing transmission or protecting the wearer, we will randomize *mouzas* into treatment and control groups. *Mouzas* are the smallest official administrative units in Bangladesh and can be identified using Bangladesh Bureau of Statistics sampling frames. Each mouza is a group of contiguous villages that vary in size, but typically contain about 1000 households. Our intervention will involve distributing masks at no cost at the universe of several key distribution points within treatment mouzas: Mosques, markets and tea stalls, and through visits inside communities. We will combine the mask distribution with appropriate behavior change communication and messaging involving imams, market committee leadership and community

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9 Bałazy, A., Toivola, M., Adhikari, A., Sivasubramani, S.K., Reponen, T. and Grinshpun, S.A., 2006. Do N95 respirators provide 95% protection level against airborne viruses, and how adequate are surgical masks?. American journal of infection control, 34(2), pp.51-57.

leaders. We will stratify on *mouzas* within the same upazila, keeping all *mouzas* at least 5-10 km apart to minimize spillovers.

We have collected data on respiratory symptoms throughout Bangladesh using phone surveys since April 2020. We are using these data to identify 700 *mouzas* throughout Bangladesh with high baseline rates of respiratory disease symptoms. Half of the 700 *mouzas* will be assigned to the treatment group. In treatment *mouzas*, we will conduct intervention activities for four weeks. These activities include:

- Ask imams, public officials and community leaders to commit to wearing masks whenever they leave the house, including while imams deliver prayer at the mosque. It's important to get all influential role-models engaged with our intervention.
- At mosques:
    - Distribute masks to each worshipper as he enters the mosque for Jummah prayer each Friday. We will allow worshippers to take more than one mask, but we will emphasize that masks are in limited supply and not to take masks that will not be worn. Specifically, we will encourage them to only to take one mask for each member of their household, and likewise encourage them not to take masks as "backups". We will also instruct our mask distributors to exercise discretion if people appear to be taking an unreasonable number of masks. We will re-evaluate this strategy as implementation proceeds if we feel that hoarding is a problem.
    - Provide imams with behavior change communication to encourage regular and appropriate mask use in public areas, both in the mosque and elsewhere. Imams will variously appeal to men as guardians of their family's health, men as individuals who want to stay healthy so they can continue working, as respected business owners and leaders in the community, and as business owners who want to continue to keep their businesses open. They will also reinforce that men should share the messages about the importance of wearing masks with their families in order to help keep them safe.
    - Hand out a visual brochure produced by Bangladesh's Institute for Epidemiology, Disease Control and Research that underscores the value of mask wearing and shows how to properly wear and clean a mask.
- At markets:
    - Speak to the committee of shop owners at each treated market, explain the importance of mask use, and ask them to commit to wearing masks, as well as direct their employees (the market vendors) to wear a mask at all times.
    - Every other day, distribute one mask to each person who visits the markets and hire one mask promoter to encourage all people at the market to wear masks by emphasizing the individual's duty and ability to keep their community safe
    - Hand out the aforementioned brochure on the masks
- Other locations
    - On days when they are not in markets, mask promoters will be present in each treatment *mouza* at public areas including tea stalls and factories distributing masks and encouraging those not wearing masks to wear them.

In both control and treatment arms, we will:

- Collect names and phone numbers for mosque attendees who volunteer this information (at baseline, prior to the start of the intervention)
- Collect names and phone numbers for market-goers who volunteer this information as they exit (at baseline, prior to the start of the intervention)
- Conduct a phone survey of mosque and market-goers (expected reach: 50%) to ask about mask use at mosques and markets and elsewhere, as well as measure respiratory disease for themselves and their household
- Count the number of mosque-goers (every Friday) and market-goers (one day a week) who are properly wearing masks (a mask that covers the nose and chin), are wearing a mask or other face covering but improperly, or are not wearing a face covering at all
- The masks we manufacture as part of this project will have distinctive color and design, so that our enumerators can directly observe whether the masks we distribute are the ones getting used.
- Use infrared thermometer to evaluate temperature for mosque- and market-goers as they exit
- Conduct health worker interviews with market vendors, plus imams and mosque workers

Our primary outcomes will be:

- Symptoms of respiratory infections among all individuals for whom we collect phone numbers

Auxiliary outcome measures:

- The impact of the intervention on mask-use in mosques, markets and tea stall, including the fraction wearing any mask and the fraction wearing masks appropriately (e.g. masks that cover the mouth, chin and nose)
- The prevalence of symptoms of respiratory infection, disaggregated by markets and mosques
- The prevalence of symptoms of respiratory infection among vendors (monitored by health workers)
- Infrared temperature readings for market goers
- Social distancing behavior measured from phone surveys, cell phone data, and direct observation of behavior at the market and at tea stalls and other social gatherings.
- Any available data (likely incomplete) on hospitalizations and COVID-19 mortality

We intend to conduct three waves of surveys to elicit respiratory symptoms: a baseline survey, three weeks after the start of the intervention, and 6 weeks after the start, with the potential for longer-term follow-up surveys. We expect to be able to survey 50% of mosque and market go-ers.

We can also use the study to evaluate the effect of pre-intervention mask use on effect sizes, which tells us the efficacy of pre-intervention masks. For example, the intervention may increase mask use to 60% in both treatment and control groups. If the effect of the intervention is the same in *mouzas* where people 0% of people were wearing face coverings pre-intervention and where 50% of people were wearing face coverings pre-intervention, this would suggest that the type of face coverings worn prior to the intervention were ineffective.

<u>Individual Randomization</u>

The goal of the individual randomization is to assess whether individual mask-wearing reduces the risk of COVID-19 infection. We distinguish this from the *mouza*-level experiment, where the goal is to assess the joint impact of masks on the spread of the virus via both protection and preventing transmission. In order to separate out the potential protective benefit of avoiding infection to the mask wearer, we will randomly select some high-risk individuals in the control arm to receive masks. Specifically, we will target vendors at indoor markets. Our randomization will be stratified within market, so that control and treatment groups for the individual randomization are otherwise as comparable as possible (the experiment is entirely among the control *mouzas* from the *mouza* level experiment). Because these vendors are such a small fraction of the population within *mouzas*, we do not expect this intervention will appreciably impact mask use in the control group of the larger experiment.

Treatment individuals will be given masks, and instructed about proper mask use.

In both control and treatment arms, we will:

- Do health worker interviews to elicit respiratory symptoms
- Use infrared temperature screening to evaluate temperature

Our primary outcome will be:

- Respiratory disease assessed via health worker interviews

Auxiliary outcome measures include differences between treatment and control groups for the following:

- The impact of the intervention on mask wearing
- Social distancing behavior measured from cell phone data and through direct observation
- Hospitalizations and mortality should they occur

Power for Mouza Randomization

Respiratory Disease

We expect to successfully survey directly 500 people per *mouza* per wave across 700 *mouzas*, or 350,000 people for each of the 3 waves of the survey. We solve for the clinically detectable effect size Δ as a function of the number of individuals per treatment arm (*m = 175,000*), the desired significance level (5%), the desired power level (80%), the expected rates of respiratory symptoms in the treatment and control groups, the number of individuals per cluster (*n = 500*) and the intracluster correlation (rho = .0022).[10] We estimate the intracluster coefficient using our baseline data on respiratory symptoms from a nation-wide telephone survey, and variation across subdistricts in our survey, typically between 50 and 150 surveyed members per upazila. *These power calculations are also conservative because they ignore the possibility of controlling for baseline rates from our initial survey and of stratifying, both of which could lead to substantial increases in power.*

[10] We are specifically using equation (5) from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4521133/ with P_1 = P_2.

The below table recalculates the minimum detectable effect under different assumptions about the fraction of the population infected with COVID-19 over our sample period. The first Column gives possible (true) COVID-19 infection rates in the population. The second column gives the resulting rates of respiratory disease we expect to observe in our survey assuming 2% rates with no COVID-19 and that 50% of COVID-19 patients are symptomatic. Column 3 reports the minimum detectable effect as an absolute reduction in respiratory symptoms, and Column 4 the implied effectiveness of masks in reducing respiratory disease, computed by dividing column 3 by column 2. Column 5 computes a "per mask" detectable effect assuming that we increase mask use by 30% (column 4 divided by 0.3).

Cumulative COVID 19 Incidence	Resp Disease	Detectable Effect	Total Impact of Masks	Impact per mask (30 pp increase)
5%	4.50%	0.0033	7.34%	24.47%
10%	7.00%	0.0041	5.81%	19.37%
15%	9.50%	0.0047	4.92%	16.40%
20%	12.00%	0.0052	4.31%	14.37%

Power for Individual Randomization

To determine the needed sample size for the individual experiment, we perform the same calculation as above, fixing the cluster size to 1 (since randomization is at the individual level) and assuming a desired power of 80% and significance level of 5% in a two-tailed test. Instead of reporting the detectable effect as a function of the sample size, we report the needed sample size associated with three different effect sizes {20%, 30%, 40%}. This is the additional effectiveness of the mask over the status quo in the control group. We will prioritize urban communities with moderate levels of community transmission to avoid having a heavily pre-exposed population that may not be susceptible to infection.

Studies have suggested that increasing mask wearing from 25% to 75% would reduce the reproductive number by 30-50%, even if the mask only provides 50% protection (Stutt R, et al. Royal Society, 2020). Similarly, individual efficacy of cloth or surgical mask wearing in community settings has been found to be around 40% (Chu D, et al. The Lancet, 2020). We will conservatively estimate 20-40% efficacy of the intervention, assuming a more marginal increase in mask use. Although the true incidence of SARS-CoV-2 infections in the communities is unknown, we can approximate cumulative incidence in the control group using evidence from the Diamond Princess Cruise, which has a similar population density to most urban environments in Bangladesh. Over 30 days with partial implementation of interventions, 16.6% of individuals developed laboratory-confirmed infections (Rocklov J, et al. J Trav Med, 2020). This was starting with a population of naïve individuals, so actual incidence rates could be lower (if more pre-exposed individuals) or higher (if efficacy of pre-existing interventions is less). Thus, a range of incidences are considered.

In the table below, "Proportional mask effectiveness" is the proportional reduction in cumulative respiratory disease incidence induced by masks and "Absolute mask effectiveness" is the resulting drop in cumulative incidence (e.g. 20% effectiveness for 5% baseline incidence leads to a 1 percentage point drop in incidence). "Sample size per arm" is the required sample size for each of the control and treatment groups

Proportional mask effectiveness	Respiratory Disease Rates in the Control Group	Absolute Mask Effectiveness	Sample size per group
0.2	0.05	0.0100	7448
0.2	0.1	0.0200	3528
0.2	0.15	0.0300	2221
0.2	0.2	0.0400	1568
0.3	0.05	0.0150	3310
0.3	0.1	0.0300	1568
0.3	0.15	0.0450	987
0.3	0.2	0.0600	697
0.4	0.05	0.0200	1862
0.4	0.1	0.0400	882
0.4	0.15	0.0600	555
0.4	0.2	0.0800	392

Based on this calculation, we think that an experiment with 10,000 indoor market vendors will be well-powered across a range of scenarios.

COVID-19 Rates Assessed Via Serological Testing

In both the *mouza* and individual-level experiment, we are interested in assessing the impacts of mask use on COVID-19 infections separately from respiratory disease. To do so, we will use serological testing.

In the *mouza* experiment, serological tests will be conducted 12 weeks after baseline for individuals who reported respiratory disease symptoms during our intervention. We will follow-up with these individuals using household interviews and conduct serology tests using blood spots obtained from finger pricks. The number of positive serology tests in this population will tell us rates of "symptomatic COVID-19". We will then compare rates of symptomatic COVID-19 between the treatment and control group. For example, if 5% of the 350,000 respondents in the *mouza* experiment report respiratory symptoms, we will conduct 17,500 such tests. Symptomatic COVID-19 will be a subset of cases of respiratory disease. Power will be similar to our respiratory disease calculation above, especially if most respiratory disease cases are COVID-19. If infection rates are higher than expected, we will cap the number of serology tests at 20,000, which should be sufficient to have ample power based on the calculation above.

In the individual experiment, we will conduct both baseline serology tests and serology tests after 12 weeks. In both cases, these will use blood spots obtained via finger pricks administered by health workers. We will start by testing endline blood spots and only perform baseline testing on those individuals who test positive at endline. This will be slightly under 20,000 tests, depending on rates of serologic positivity. The baseline test in the individual experiment will increase power by allowing us to control for COVID-19 infections that occurred pre-intervention.

All testing will be carried out at North South University in Dhaka. Samples will be delivered to the lab weekly where they will be stored until testing. No special handling or storage requirements are needed for dried blood spot samples. If seropositivity rates are low, samples may undergo pooled testing in batches of 5-10 to reduce the total number of tests required. All samples will be run using a Stanford-developed quantitative ELISA assay to evaluate presence of IgM and IgG. Untested samples from the mouza experiment will be stored for possible future testing to evaluate asymptomatic infections.