Institutional ID: 2000028482
Title: Face Masks to Reduce COVID-19 in Bangladesh
ClinicalTrials.gov ID: NCT04630054
Date: 11/11/2020

HRP-503E– Protocol for Social or Behavioral Science or Educational Research
(2017-1)

Protocol Title:
An RCT for Masks to Slow the Spread of COVID-19 in Bangladesh

Principal Investigator: Jason Abaluck

Version Date: November 10th, 2020

(*If applicable*) Clinicaltrials.gov Registration #: Click or tap here to enter text.

INSTRUCTIONS
This template is intended to help investigators prepare a protocol that includes all of the necessary information needed by the IRB to determine whether a study meets approval criteria. **Read the following instructions before proceeding:** 1. Use this protocol template for a PI initiated study that includes direct interactions with research subjects. Additional templates for other types of research protocols are available in the system Library: • If the study involves genetic testing, blood draws, or MRIs, do not use this form. Use the biomedical protocol template. • If the study involves secondary analysis of data, use the Secondary Analysis of Data protocol. • For activities that may qualify as exempt research, use the Request for Exemption form (which includes a decision tree to determine whether or not your study qualifies as exempt). 2. If a section or question does not apply to your research study, type “Not Applicable” underneath. 3. Once completed, upload your protocol in the “Basic Information” screen in IRES IRB system.

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SECTION I: GENERAL INFORMATION

1. **Probable Duration of Project:** State the expected duration of the project, including all follow-up and data analysis activities.

The project was launched on July 24th, 2020, with a pilot of the intervention in 10 villages. The main trial is expected to start on September 23rd and last 12 weeks. An initial participant phone survey will begin on September 23rd , 2020, with follow up phone surveys scheduled for the weeks of October 18th and November 16th, 2020, with the potential for longer-term follow-up surveys. Throughout the 12 weeks of the study duration (September 23rd – December 12th), we will conduct mask distribution and promotion as well as field observations of participants behavior in complying with different COVID-19 mitigation strategies. We expect to complete all data analysis for the project during the month of November. Given the urgent need to provide timely public health recommendations in light of the COVID-19 pandemic, this project will operate under a shorter duration than usual.

2. **Study location:** State where the study will take place and in what setting.

Bangladesh

If international, complete and submit **International checklist** (http://your.yale.edu/policies-procedures/forms/450-ch-1-international-research-checklist) Note: If your research involves interactions with any embargoed countries you should contact the Director of Corporate Contracts and Export Control Licensing (Donald.Deyo@yale.edu or call 203.785.3817) for guidance on how to proceed.

3. **Help us categorize your research**. Are you using any of the following?

☐ Class Project
☒ Participant Observation
☐ Interviews
☒ Surveys
☒ Focus groups (study is not anonymous)
☐ Research in K-12 schools (submit a School Agreement form for the study)
☐ Deception (submit a Debriefing sheet)
☐ Audiotaping, videotaping or photography of individuals (study is not anonymous)
☐ Public viewing of videotapes or photographs
☐ Yale Psychology Pool (study does not qualify for exemption)
☒ International research sites (attach the International Checklist)
☐ Online (web-based) activities
☐ Social networks

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SECTION IV: RESEARCH PLAN

1. **Statement of Purpose:** State the scientific aim(s) of the study, or the hypotheses to be tested.

This study aims to measure the benefits of facemasks in preventing transmission of respiratory infections (especially COVID-19) and to study how different enforcement mechanisms can be used to increase mask use. In particular, this study has six main aims:

1. To develop a scalable intervention that can increase consistent use of a quality mask
2. To assess the impact of appropriately used high-quality masks on the transmission of COVID-19
3. To assess the effect of mask-wearing in reducing the wearer's risk of infection with COVID-19
4. To assess the effectiveness of high-quality cloth vs. "surgical" masks in reducing the spread of COVID-19
5. To evaluate whether increased mask use is associated with risk compensation (an increase in leaving the home or reduced compensation)
6. To assess the protective effect of masks with high filtration and breathability relative to existing face-coverings

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-19, 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 in the study will cost-effectively save lives. The above "theory of change" adds to this direct impact.

2. **Background:** Describe the background information that led to the plan for this project. **Provide references** to support the expectation of obtaining useful scientific data.

a) 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 this

[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

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reason.[2] There is also substantial evidence of asymptomatic or presymptomatic 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]

b) Current Situation

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 requirements and mask take-up can be complex, especially in the developing world. 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

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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).

[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. The regression analysis finds similar results for cases (positive tests) and deaths, and controls for the timing of policies like school, workplace, and transportation closings. But of course, these results are not definitive and many differences in norms and policies cannot be controlled for.

[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/.

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throughout Bangladesh, compliance was high, with 80-95% of respondents reporting that they wore masks in public areas.

Our more recent data, as well as our conversations with officials, 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.

3. Research Plan: Summarize the study design and research procedures using non-technical language that can be readily understood by someone outside the discipline. If working with a Non-Government Organization (NGO) or other organization, be sure to highlight which are research-only activities and which activities would occur regardless of the research. If working with survey firms, please specify what research activities the research firm will be responsible for.

We have four main research questions we seek to answer:

1. Can mask distribution and promotion at mosques, markets, and homes successfully change community mask-wearing norms from the status quo to appropriate wearing of high-quality masks?
2. Can community mask-wearing reduce the transmission of symptomatic respiratory infections and symptomatic COVID-19 infection?
3. Does mask-wearing induce risk-compensation such as an increase in leaving the home or reduced physical distancing?
4. Can mask-wearing reduce the risk of COVID-19 infection for the individual mask wearer?

To answer the first three questions, we will randomize an intervention package at the level of markets and associated villages.

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

Village-level experiment (Research Questions 1, 2 and 3)

Study Design

We will start by identifying 700 markets, along with the most centrally located village and the mosque attended by most residents of that village. We expect this to comprise about 250 households, or 500 adults per village. We will call this entity a “market+” (plural: markets+).

In order to evaluate whether masks prevent the spread of COVID by preventing transmission and/or protecting the wearer, we will randomize markets+ into treatment and control groups. Our intervention will involve distributing masks at no cost at mosques, markets and directly at people’s homes. We will combine the mask distribution with appropriate behavior change communication and messaging involving imams, market committee leadership and community leaders. We will stratify on markets+ within the same upazila, keeping all markets+ at least 5-10 km apart to minimize spillovers.

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Half of the 700 markets+ will be assigned to the treatment group. We intend to stratify to that treatment and control groups are as balanced as possible in terms of ex ante likelihood of COVID-19 infections. To do so, we will: 1) stratify by upazilas and 2) stratify by unions that have similar case rates. For "markets+" that are in the same Upazila and in unions with similar rates of cases, we will list them in order of population and do pairwise stratification by population.

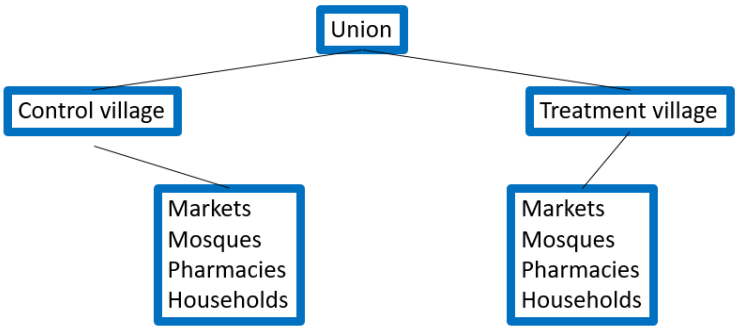

Figure 1: Village-level experiment study design

Outcomes

Primary outcomes:

1. Symptomatic SARS-COV2 Infection assessed at 12 weeks via serological testing

Secondary outcomes:

1. The impact of the intervention on mask use in mosques, markets and other public areas, including the fraction a) appropriately (covering the nose and chin) wearing a mask distributed by our project, b) appropriately wearing a mask that was not distributed by our project, c) inappropriately wearing any a mask or other face covering, or d) are not wearing a face covering at all, and also the fraction specifically wearing our distinctive mask.
2. Prevalence of symptoms of respiratory infection among all individuals for whom we collect phone numbers
3. The prevalence of symptoms of respiratory infection, disaggregated by market vendors, market-goers, imams, mosque-workers, and mosque-goers and none of the above.
4. Number and fraction of pharmacy customers that purchase medicines for symptoms of respiratory infections.
5. Physical distancing behavior measured by direct observation of behavior in mosques.
6. Percentage of adults out of their homes and visiting tea stalls and mosques.
7. Any available data (likely incomplete) on hospitalizations and COVID-19 mortality in each community This data will be aggregate data which is de-identified from local hospitals and clinics. We expect this data to be sparse and incomplete.
8. Effectiveness of pre-intervention masks by examining the effect size of the intervention with respect to the percent of mask-wearing prior to the intervention. For example, the intervention may increase mask use to 30% in both different treatment villages. If the effect of the intervention on COVID-19 infection rate is the same in villages 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.

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This analysis uses the variation generated by the randomization but also requires additional assumptions since the baseline rate of mask use is not randomized.

Intervention activities

In the treatment arm we will conduct the following intervention activities for four weeks:

- Role modeling
  - 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.
- Communities and households:
  - We will encourage local community leaders to endorse a statement mandating that everyone where masks
  - Community mask promoters will go door to door to each household in the market+ and distribute up to 2 masks to each household (one for each household member) and discuss the value of wearing masks in public. During these household visits our surveyors will wear masks and maintain physical distance whenever possible; they will also cleanse their hands with hand sanitizer between each household visit. This will occur immediately after our baseline survey.
- At mosques:
  - Distribute one mask to each worshipper as he enters the mosque for Jummah prayer each Friday.
  - 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 the World Health Organization (WHO) 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 directing 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
  - Have an agreement with the officials managing the market to also encourage people to wear masks on days when our monitors are not present
  - Hand out the aforementioned brochure on the masks
  - An audio recording reminding people to please wear masks will play at markets periodically

Control groups will not be included in mask distribution or mask promotion. We will distribute masks that are manufactured specifically for this project and have a distinctive color and design, so that our enumerators can directly observe whether people are wearing the distributed masks or other masks.

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Data collection

We will conduct the following activities in both control and treatment arms.
Appropriate mask use

- Count the number of mosque-goers (every Friday), market-goers (one day per week), and people in public near the village entrance, indoor restaurants as people enter or exit who are a) appropriately (covering the nose and chin) wearing a mask distributed by our project, b) appropriately wearing a mask that was not distributed by our project, c) inappropriately wearing any a mask or other face covering, or d) are not wearing a face covering at all, and also the fraction specifically wearing our distinctive mask.

Symptoms of respiratory symptoms

- Go to each household and conduct in-person our baseline survey (same questions as telephone survey). We will elicit consent, as well as collecting demographic information such as age, gender, employment status, and household size information.
- Conduct two waves of follow-up phone surveys to elicit respiratory symptoms and ask about mask use: we will conduct these five weeks after the start of the intervention, and nine weeks after the start, with the potential for longer-term follow-up surveys. We will determine the response rate in the pilot, but our initial estimate is at least 70%.
- Monitor differences in response rates between the treatment and control group to assess whether there is possible response bias from people in the treatment group being more likely to complete our full telephone survey (we suggest other ways of mitigating this potential bias below). For 5,000 randomly chosen households, we will draw blood spots from one adult identified as the highest-risk in their household in terms of number of contacts (2,500 in the control group and 2,500 in the treatment group); the blood spots will be collected in the baseline household survey and used for serology tests. This will allow us to see if survey response rates to our telephone survey correlate differently with baseline infectivity in the treatment and control group.
- Recruit and train local pharmacists to collect data on the number, fraction, and gender of customers that report various symptoms of respiratory infection. Pharmacists will also record the count and purpose of the medicines purchase to treat fever, dry cough or sore throat, and the number of family members with each symptom.

Serology tests

- Among adults who report respiratory symptoms in any of our telephone surveys, we will draw blood spots 12 weeks after the initial intervention and conduct serological testing to identify "symptomatic infected". If the number of symptomatic individuals exceeds 20,000, we will randomly choose 20,000 to be tested in this way from all symptomatic individuals.
- Collect bloodspots for serological testing in 5,000 randomly chosen baseline households. At endline (12 weeks after the intervention begins) we will again collect bloodspots for serological testing in these same 5,000 households.

Physical distancing

- Assess if people who are wearing masks are less likely to physically distance themselves from others.

Individual-level experiment (Research Question 4)

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Study design

The goal of the individual experiment is to assess whether mask-wearing reduces the risk of COVID-19 infection for high-risk individuals wearing masks (the "direct effect", albeit in a different population). We distinguish this from the market+ experiment, where the goal is to assess the joint impact of masks on the spread of the virus via both protection and preventing transmission (the "direct" and "indirect" effects). In order to quantify the potential protective effect of a mask reducing the risk that the mask-wearer becomes infected, we will randomly select high-risk individuals in either control markets+, or in additional markets not included in the original experiment to receive masks. We will specifically randomize within markets, ideally selecting indoor vendors who are physically distant from one another. Because these vendors are such a small fraction of the population within markets+, we do not expect this intervention will appreciably impact mask use in the control group of the larger experiment.

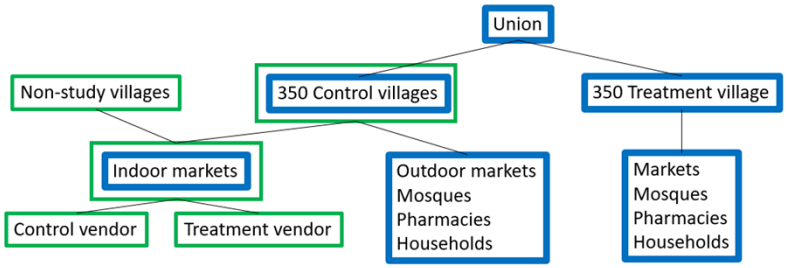

Figure 2: Individual-level experiment study design (in green) embedded in Village-level experiment (in blue)

Intervention activities

- Treatment individuals will be given masks and behavior change communication to motivate proper mask use. They will not be asked to recommend masks to others, but will also not be discouraged from recommending mask use to others.
- Control individuals will receive no masks or behavior change communication

Outcomes

Primary outcome:

1. SARS-CoV-2 infection rates, assessed by comparing baseline to follow-up serology

Secondary outcomes:

1. Prevalence of symptoms of respiratory infection
2. Average body temperature
3. The impact of the intervention on mask wearing by market vendors
4. Physical distancing
5. Hospitalizations and mortality of market vendors

Data collection

We will conduct the following activities among individual-level control and treatment vendors:

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Mask use

- Conduct observations to assess mask use using the same criteria as the above "markets+" experiment

Symptoms of respiratory infection

- Health worker will conduct interviews with participants in the individual randomization arm to gather data on symptoms of respiratory infection at 0, 5 and 9 weeks, as well as collecting blood spots for serological testing at baseline and at 12 weeks

Physical distancing

- Conduct observations to assess physical distancing using the same criteria as the above "markets+" experiment

Mask Production, Distribution, and Promotion

Villages in the treatment arm will be randomized to receive cloth masks or surgical masks. The Standard Group, one of the largest manufacturers of ready-made garments in Bangladesh and part of the Bangladesh Garment Manufacturers and Exporters Association (BGMEA) is prepared to produce 400,000+ cloth masks according to our specifications.[8]

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 outer layer of 100% non-woven polypropylene, a middle layer of 60% cotton/40% polyester interlocking knit, and an inner layer made of the same interlocking knit, and an inner layer made of the same 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 talking. The mask is comfortable, partially because it does not hold hot air over the face. 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]

Surgical masks, made from outer and inner layers of spunbound material and a middle layer of meltblown material, vary in quality but generally have much higher filtration efficiency than cloth masks. Even after surgical masks have been washed 10 times, their filtration efficiency is still higher than most cloth

[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. 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).

[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.

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alternatives. We are speaking to surgical mask manufacturers about producing 400,000+ high-efficiency surgical masks to be distributed for this experiment.

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.

Assessing SARS-CoV-2 infection Via Serologic Testing

In both the market+ 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 market+ 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 market+ 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 addition, we will conduct baseline and endline serologic testing in a random selection of 5,000 households. This is to evaluate factors that could be related to differential reporting between the control and treatment groups.

Dried blood spot samples will be collected at endline from individuals who reported COVID-like symptoms as well as from the 5,000 randomly-selected individuals at baseline and endline. Rapid diagnostic tests will also be performed at endline. Only samples that are positive by rapid diagnostic test and 5% of negative samples will undergo further evaluation by ELISA.

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 by rapid diagnostic testing, plus 5% of negative tests. 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.

The blood drops will be collected by pricking a participant's finger using a sterile, single-use lancet (very small device with a sharp point). The first drop of blood will be wiped away (not used). The next 3 or 5 drops will be put on the collection card, and will be used for the tests. Occasionally it is necessary to stick the finger a second time in order to get enough blood.

The blood will be tested for antibodies against coronavirus. We will be collecting blood samples at the beginning and end of the study for the individual-level experiment and at the end of the study for the market-level experiment. The results from the rapid test will be known at the time of collection, but these

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results must be confirmed with a second test. Results of the confirmatory test will not be returned to participants.

More information on procedures to safely collect the blood samples are outlined in the attachment "SOP for collection of dried blood spots."

Additional serologic infectious disease testing will also be performed to evaluate burden of other diseases in the population. Using the residual sera after performing testing for SARS-CoV-2 antibodies, other serologic infectious disease testing will be performed to evaluate disease burden across the sampled populations. The final list of diseases is yet to be determined but may include dengue, chikungunya, malaria, typhoid, etc. These tests will be conducted using single-plex or multi-plex platforms for IgG detection, depending on test availability.

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. Dried blood spots will be stored in a freezer at North South University (Dhaka, Bangladesh) and stored for future use. Future testing could include additional antibody or PCR testing for SARS-CoV-2 or other infectious diseases. No genetic testing will be performed on these 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 quantitative ELISA assay to evaluate presence of IgM and IgG. Untested samples from the market+ experiment will be stored for possible future testing to evaluate asymptomatic infections.

The ELISA serology test is for research purposes only. It will not guide clinical decision making, and results will not be provided to study participants. We are currently planning to use the InBios IgG ELISA[10], a commercially available test. The subject and biospecimen data collected will not be submitted to or held by the FDA, nor will it be used to determine the safety or efficacy of the test.

4. Genetic Testing N/A ☒

A. Describe

i. the types of future research to be conducted using the materials, specifying if immortalization of cell lines, whole exome or genome sequencing, genome wide association studies, or animal studies are planned *Write here*

ii. the plan for the collection of material or the conditions under which material will be received *Write here*

iii. the types of information about the donor/individual contributors that will be entered into a database *Write here*

iv. the methods to uphold confidentiality *Write here*

B. What are the conditions or procedures for sharing of materials and/or distributing for future research projects? *Write here*

C. Is widespread sharing of materials planned? *Write here*

D. When and under what conditions will materials be stripped of all identifiers? *Write here*

E. Can donor-subjects withdraw their materials at any time, and/or withdraw the identifiers that connect them to their materials? *Write here*

[10] https://inbios.com/scov-2-detect-igg-elisa-kit-2/

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i. How will requests to withdraw materials be handled (e.g., material no longer identified: that is, anonymized) or material destroyed)? *Write here*

F. Describe the provisions for protection of participant privacy *Write here*

G. Describe the methods for the security of storage and sharing of materials *Write here*

5. **Participant Population:** Provide a detailed description of the types of participants who will be recruited into this study.

Participants for the market+ study will consist of individuals residing in each of the villages selected for the study. For the individual-level study, participants will consist of vendors at selected indoor markets.

6. **Describe** how access to the population will be gained in the study.

Our local implementing partners IPA Bangladesh will gain permission and support from all relevant local authorities and community leaders to access the research sites and populations targeted in this study. In particular, they will coordinate with Imams and mosque officials, market managers and authorities, tea stall vendors, indoor market vendors, and village and community leaders in each of the participating research sites.

7. **Participant classification:** Check off all classifications of participants that will be specifically recruited for enrollment in the research project. Will participants who may require additional safeguards or other considerations be enrolled in the study? If so, identify the population of participants requiring special safeguards and provide a justification for their involvement.

☐Children	☐ Healthy	☐Fetal material, placenta, or dead fetus
☒ Non-English Speaking	☐ Prisoners	☐Economically disadvantaged persons
☐Decisionally Impaired	☐ Employees	☐Pregnant women and/or fetuses
☐Yale Students	☐ Females of childbearing potential	

Click or tap here to enter text.

NOTE: Is this research proposal designed to enroll children who are wards of the state as potential participants? ☐Yes ☒ No

8. **Inclusion/Exclusion Criteria:** What are the criteria used to determine participant inclusion or exclusion?

We have collected data on respiratory symptoms throughout Bangladesh using phone surveys since April 2020. These studies were covered by a previous IPA IRB. We are using these data to identify 700 markets+ throughout Bangladesh with high baseline rates of respiratory disease symptoms. Half of the 700 markets+ will be randomly assigned to the treatment and control groups. 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.

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We will also identify around 10,000 indoor market vendors throughout Bangladesh, and randomly assign half of these vendors to each of the treatment and controls arms of the intervention.

SECTION V: RECRUITMENT/CONSENT AND ASSENT PROCEDURES

1. Recruitment Procedures:

a. Describe how potential participants will be identified and contacted, and by whom.

- At participating mosques, worshippers will be given masks as they enter mosques for Friday Jumuaa prayer in the treatment arm, as well as brochures with public health guidelines and recommendations as they exit the mosques. This will be conducted by members of the IPA Bangladesh team. Imams or mosque officials will also communicate with their community members to encourage compliance with the study's public health guidelines.
- At participating markets, we will reach vendors and market-goers as they enter each market in the treatment arm and receive masks handed out by members of the IPA Bangladesh team. We will also hire monitors who will go around each market throughout the study period to encourage people to wear masks.
- In public areas including tea stalls and factories, we will provide individuals with masks handed out by members of the IPA Bangladesh team.
- At participating indoor markets, we will reach vendors at their stalls and provide them with masks handed out by members of the IPA Bangladesh team.
- At participating villages, we will conduct visits inside communities to hand out masks to individual community members.

Are you collecting any information about the individuals prior to their signing a consent form?

Yes ☐ No ☒

If yes, indicate what information you will be collecting and how it will be gathered *(phone screen, paper questionnaire, etc.)* Click or tap here to enter text.

2. Indicate recruitment methods below.

Attach copies of any recruitment materials that will be used.

☐ Flyers
☐ Posters
☐ Letter
☒ Through local NGO or other local contact
☒ Table set-up / in-person recruitment of public
☐ Classroom recruitment
☐ Other:

☐ Internet/web postings
☐ Mass email solicitation
☐ Departmental/Center website
☐ Departmental/Center research boards
☐ Snowball sampling

☐ Social Media (Twitter/Facebook):

☐ Radio
☐ Telephone
☐ Television
☐ Newspaper

3. Targeted Enrollment: Give the number of participants:

a. Targeted for enrollment at Yale for this protocol

Not Applicable

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b. If this is a multi-site study, give the total number of participants targeted across all sites

In the market+ intervention, we expect to successfully survey directly 500 people per market+ per wave across 700 markets+, or 350,000 people for each of the 3 waves of the survey. In the individual intervention, we expect to reach 10,000 indoor market vendors.

4. How was this estimate derived?

These estimates were derived using a set of statistical power calculations for each of the trials.

5. Process of Consent/Assent *(NOTE: When a study includes minors, parent provide permission [not consent] for the child's participation, and the child provides assent for participation)*

Describe the setting and conditions under which consent/assent will be obtained, including parental permission or surrogate permission and the steps taken to ensure participants' independent decision-making.

Prior to all surveys, our implementing partner IPA Bangladesh will present all households with our consent form and record their consent to be surveyed.

6. Evaluation of Participant(s) Capacity to Provide Informed Consent/Assent: Indicate how the personnel obtaining consent will assess the potential participant's ability and capacity to consent to the research being proposed, if applicable.

Our surveyors will communicate with individuals in local languages and will ensure participants are fully aware of all aspects of the study before consenting to participate.

7. Documentation of Consent/Assent: Specify the documents or verbal scripts that will be used during the consent/assent process. Copies of all documents should be appended to the protocol, in the same format that they will be given or spoken to participants.

The study and survey consent forms are attached.

8. Non-English Speaking Participants: Explain provisions in place to ensure comprehension for research involving non-English speaking participants. Translated copies of all consent materials must be submitted for approval prior to use. Do you speak the local language? Will you require a translator? (If so, please elaborate on how the translators will be trained).

All survey enumerators and mask distributors will be native speakers of the local language.

9. Are any of the study procedures likely to yield information subject to mandatory reporting requirements? (e.g. HIV testing – reporting of communicable diseases; parent interview -incidents of child abuse, elderly abuse, etc.). Please verify to whom such instances will need to be reported.

No.

10. Waiver of Consent/Documentation of Consent: In certain circumstances, the IRB may grant a waiver of documentation of consent, or a full waiver of consent, depending on the study. If you will request

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either a waiver of consent, or a waiver of signed consent for this study, complete the appropriate section below.

☐Not Requesting any consent waivers

☒Requesting a waiver of signed consent (e.g., verbal or online consent only):

☐ Recruitment/Screening only *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

☒ Entire Study (Note that an information sheet may be required.)

We will be seeking oral consent for all data collection activities.

For a waiver of signed consent, address the following:

- Would the signed consent form be the only record linking the subject and the research? YES ☒ NO ☐
- Does a breach of confidentiality constitute the principal risk to subjects? YES ☐ NO ☒

OR

- Does the research pose greater than minimal risk? YES ☐ NO☒
- Does the research include any activities that would require signed consent in a non-research context? YES ☐ NO ☒

☐ Requesting a waiver of consent (if you are not obtaining ANY consent):

☐ Recruitment/Screening only *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

☐ Entire Study

For a waiver of consent, please address all of the following:

- Does the research pose greater than minimal risk to subjects?
  ☐ Yes *If you answered yes, stop. A waiver cannot be granted.*
  ☐ No
- Will the waiver adversely affect subjects' rights and welfare? YES ☐ NO☐
- Why would the research be impracticable to conduct without the waiver? Click or tap here to enter text.
- Where appropriate, how will pertinent information be returned to, or shared with subjects at a later date? Click or tap here to enter text.

SECTION VI: PROTECTION OF RESEARCH PARTICIPANTS

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1. Confidentiality & Security of Data: Describe the steps that will be taken to secure the data during storage, use and transmission as outlined in the below sections. NOTE: Data can include paper files, data on the internet or websites, computer files, audio/video files, photographs, etc. and should be considered in the responses to the below sections.

All data will be automatically digitized as it is collected on tablets and sent to password-protected computers at the implementing partner IPA Bangladesh's office. These digital files will then be transferred to a secure directory that only members of the research team can access.

2. What participant information will you be collecting? Describe the identifiers that will be included or associated with the data and/or specimens (e.g., names, addresses, telephone/fax numbers, email addresses, dates (date of birth, admission/discharge dates, etc.), medical record numbers, social security numbers, health plan beneficiary numbers, etc.)Click or tap here to enter text.

We will collect names, GPS locations, and mobile phone numbers. We may also record portions of the phone survey (only the enumerator portion) for quality assurance.

Other potentially identifying information to be collected:
☐Audiotapes
☐Videotapes
☐Faces (focus groups, photographs or other way that an individual would be physically recognized)
☐Potential for identification from the bulk of the information, even if direct identifiers are not collected (deductive disclosure).

3. How will the research data be collected and recorded?

Research data will be collected on tablets utilizing survey software. Data will be transmitted over the internet to an encrypted hard-drive at the office of our implementing partner IPA Bangladesh.

4. If identifiers will be associated with the data and/or specimens, describe whether a record or list containing a code (i.e., code number, pseudonyms) will be used, where the list will be stored, who will have access to the list and when it will be destroyed.

Identifiers will remain on the raw encrypted data for the duration of this study, but will be destroyed after the study's completion by January 2021. Cleaned data that will be used for statistical analysis by the research team will have all identifiers redacted.

5. Describe where, how and for how long the data (hardcopy (paper) and/or electronic data) and/or specimens will be stored.

A digital copy of de-identified data will be preserved after the end of the study. By January 2021 all identifying information described above will be deleted from all data. For the duration of the study, identified data will be stored on an encrypted hard-drive at IPA Bangladesh's office. This data will be kept until the study has finished to allow the possibility for further re-contact of households for additional information if necessary.

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All portable devices must contain encryption software, per University Policy 5100. If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url http://its.yale.edu/egrc or email it.compliance@yale.edu

6. Identify who will have access to the data and/or specimens. *If the data and/or specimens will be transferred to and/or from outside collaborators, identify the collaborator to whom the data and/or specimens will be transferred and how the data and/or specimens will be transferred.*

List of study personnel and roles:

- Jason Abaluck: PI, involved in all aspects of trial design, managing team, and analysis.
- Mohammad Ashraf Haque (Innovations for Poverty Action): trial design, implementation and supervision of the team in Bangladesh.
- Muhamad Maqsud Hossain (North South): laboratory analysis of blood specimens
- Md. Alamgir Kabir (Innovations for Poverty Action): implementation and supervision of the team in Bangladesh.
- Laura Kwong (Stanford): mask design, trial design, analysis and interpretation of de-identified data.
- Steve Luby (Stanford): mask design, trial design, analysis and interpretation of de-identified data.
- Ahmed Mushfiq Mobarak (Yale): trial design, managing team and analysis.
- Ashley Rene Styczynski (Stanford): trial design, analysis and interpretation of de-identified data.
- Salim Benhachmi (Yale): research assistance and support and data analysis.
- Shadman Rahman (Innovations for Poverty Action): research and implementation assistance.
- Shabib Raihan (Innovations for Poverty Action): research and implementation assistance.
- Neeti Zaman (Innovations for Poverty Action): research and implementation assistance.
- Asraul Khan (Innovations for Poverty Action): research and implementation assistance.

7. What will be done with the data when the research is completed? Are there plans to destroy the identifiable data or the link to personal identifiers? If yes, describe how, by whom and when identifiers will be destroyed. If no, describe how the data and/or identifiers will be secured.

Identifiers will be destroyed after the completion of the study by January 2021.

8. Will a Certificate of Confidentiality be needed? (*See also the NIH Certificate of Confidentiality Kiosk, http://grants.nih.gov/grants/policy/coc/index.htm)*

No.

SECTION VII: POTENTIAL RISKS AND BENEFITS

1. **Risks:** Describe the reasonably foreseeable risks, including risks to participant privacy, discomforts, or inconveniences associated with participants participating in the research. *Note: All studies have the potential for risk, if not physical, there may be psychological, reputational, or financial risks or risks to breach of confidentiality.*

There are privacy risks and psychological and reputational risks if members of the households' local community learn about information such as the prevalence of respiratory diseases (including COVID-19) and related symptoms in their households. There might also be stigma attached with participants' choice to wear or not wear the provided masks.

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There is minimal physical risk to participants from the finger stick used during the blood sample collection. The finger stick may cause a small amount of pain and bruising, and the site may bleed slightly for a time after the blood is collected. There is also a very rare chance that the stick site could become infected. If this happens, participants might require medical treatment.

2. **Minimizing Risks:** Describe the manner in which the above-mentioned risks will be minimized.

The data privacy and security measures outlined in Section VI will help minimize the risk of private health information being shared with members of participants' local community. The mask wearing and preventive health measures being communicated to study participants will be in-line with public health measures currently in place in Bangladesh to minimize any potential social stigma associated with mask wearing.

The procedures to safely collect the blood samples are outlined in the attachment "SOP for collection of dried blood spots."

Dried blood spots will be stored in a freezer at North South University (Dhaka, Bangladesh) and stored for future use. Future testing could include additional antibody or PCR testing for SARS-CoV-2 or other infectious diseases. No genetic testing will be performed on these samples. Data attached the biospecimens will be kept in a locked cabinet at North South University, and only members of the study team will have access to the data.

3. **Data and Safety Monitoring Plan:** Include an appropriate Data and Safety Monitoring Plan (DSMP) based on the investigator's risk assessment stated below. (Note: the HSC will make the final determination of the risk to subjects.).
   a. What is your assessment of the overall risk level for subjects participating in this study?

   We believe the risk of participation in this study to be low, because the data being collected is not particularly sensitive and there are no significant risks associated with wearing masks.

   b. If children are involved, what is your assessment of the overall risk level for the children participating in this study?

   Not Applicable.

   c. **Include an appropriate Data and Safety Monitoring Plan. Examples of DSMPs are available here** http://your.yale.edu/policies-procedures/other/data-and-safety-monitoring-plan-template for
      i. Minimal risk
      ii. Greater than minimal/moderate risk

   d. For multi-site studies for which the Yale PI serves as the lead investigator:

      i. How will adverse events and unanticipated problems involving risks to subjects or others be reported, reviewed and managed?

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All field staff of our implementing partner will be asked to report any adverse or risky events at multiple times throughout the project. Any adverse events will be relayed to the Principal Investigator during regular meetings.

ii. What provisions are in place for management of interim results?

Interim results will be stored in directories accessible only to the study team. Any relevant or useful interim findings will be shared when appropriate with policy makers, health practitioners, and the research community at large.

iii. What will the multi-site process be for protocol modifications?

Protocol modifications will be submitted by researchers involved in the study via the IRES system.

4. Potential Benefits: Identify any benefits that may be reasonably expected to result from the research, either to the participant(s) or to society at large. (*Payment of participants is not considered a benefit in this context of the risk benefit assessment.)*

The potential benefits of this project are large. Participants will receive a reusable (after washing) cloth mask and useful information that could help them reduce their exposure to COVID-19 and other respiratory infections, which would benefit them individually as well as the communities they are part of by reducing the spread of respiratory diseases. The study's findings could also benefit society at large by providing reliable causal estimates of the benefits of mask adoption and on the effectiveness of community measures to promote mask wearing, which could inform public health officials and practitioners on the role of widespread mask wearing as a measure to tackle the COVID-19 pandemic.

B. DEVICES ☒**N/A**

1. Are there any investigational devices used or investigational procedures performed at Yale-New Haven Hospital (YNHH) (e.g., in the YNHH Operating Room or YNHH Heart and Vascular Center)? ☐Yes ☐No

***If Yes, please be aware of the following requirements*:**

A YNHH New Product/Trial Request Form must be completed via EPIC: **Pull down the Tools tab in the EPIC Banner, Click on Lawson, Click on "Add new" under the New Technology Request Summary and fill out the forms requested including the "Initial Request Form," "Clinical Evidence Summary", and attach any other pertinent documents. Then select "save and submit" to submit your request**; AND

Your request must be reviewed and approved **in writing** by the appropriate YNHH committee before patients/subjects may be scheduled to receive the investigational device or investigational procedure.

2. **Background Information:** Provide a description of previous human use, known risks, and any other factors that might influence risks. If this is the first time this device is being used in humans, include relevant data on animal models.

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Write here

3. **Source:**
   a) Identify the source of the device to be used. *Write here*
   b) Is the device provided free of charge to subjects? ☐Yes ☐No

4. **Investigational device accountability**: State how the PI, or named designee, ensures that an investigational device is used only in accordance with the research protocol approved by the HIC, and maintains control of the investigational device as follows:

   a) Maintains appropriate records, including receipt of shipment, inventory at the site, dispensation or use by each participant, and final disposition and/or the return of the investigational device (or other disposal if applicable): *Write here*

   b) Documents pertinent information assigned to the investigational device (e.g., date, quantity, batch or serial number, expiration date if applicable, and unique code number): *Write here*

   c) Stores the investigational device according to the manufacturer's recommendations with respect to temperature, humidity, lighting, and other environmental considerations: *Write here*

   d) Ensures that the device is stored in a secure area with limited access in accordance with applicable regulatory requirements: *Write here*

Distributes the investigational device to subjects enrolled in the IRB-approved protocol: *Write here*

SECTION VIII: RESEARCH ALTERNATIVES AND ECONOMIC CONSIDERATIONS

1. Alternatives: What other alternatives, if any, are available to the study participants outside of the research?

Study participants (including those in the control groups) may decide to wear other locally available masks or face coverings besides the ones provided through this project.

2. Payments for Participation (Economic Considerations): Describe payments that will be made to participants, if any, the amount and timing of payments, and the conditions for receiving this compensation (if applicable). If you plan to hold a drawing, be sure to include the following on any consent or recruitment materials mentioning the lottery: 1) the value of the prize; 2) the sponsor of the prize (this cannot be a federal funding source); 3) the odds of winning; and 4) that there are no restrictions to winning.

Study participants will receive face masks at no cost. There will be a small monetary reward for individuals and communities who wear masks regularly.

3. Costs for Participation (Economic Considerations): Clearly describe the participant's costs associated with participation in the research, if any, and the interventions or procedures of the study that will be provided at no cost to participants.

Study participants will receive face masks at no cost.

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