Cholera Vaccine and Behavior Change Trial
Outcome Measurements

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Study Objectives

1. Conduct and evaluate the feasibility and effectiveness in reducing diarrhea due to *Vibrio cholerae* of a mass cholera vaccination program in a high incidence urban area.

2. Evaluate the feasibility of adding a household hand washing and safe drinking water promotion intervention to a cholera vaccine program and the overall impact of this combination on decreasing the incidence of diarrhea due to *Vibrio cholerae*.

3. Analyze cost-effectiveness and cost-benefit of the interventions
Study setting

• Mirpur
  – Urban
  – 25% migration per year

• High risk areas
  • Poor housing construction
  • High density of population
  • Poor sanitary condition
  • Water scarcity
  • Unhealthy environment
  • Narrow and dark lane/street:
  • Sharing of kitchen/toilet water
Pictorial view of the GIS database

Slide from Mohammad Ali
Design and arms of the study

- Design: Cluster randomized
- Cluster type: Geographic, separated by at least 30 meters from the other cluster(s)
- Arms of the study:
  - Vaccine arm
  - Vaccine plus hygiene and safe water arm
  - Non-intervention arm
The study clusters by arms

Slide from Mohammad Ali
### Cluster size by arms (baseline census)

<table>
<thead>
<tr>
<th>Arms of the study</th>
<th>Total population</th>
<th>Cluster size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Average</td>
</tr>
<tr>
<td>Vaccine</td>
<td>82,699</td>
<td>2,757</td>
</tr>
<tr>
<td>Vaccine plus hygiene and safe water</td>
<td>82,391</td>
<td>2,746</td>
</tr>
<tr>
<td>Non-intervention</td>
<td>82,301</td>
<td>2,743</td>
</tr>
<tr>
<td>Total</td>
<td>247,391</td>
<td>2,749</td>
</tr>
</tbody>
</table>

Slide from Mohammad Ali
Shanchol Cholera Vaccine

- Whole killed vaccine
- Administration
  - Non-pregnant persons > 12 months of age
  - Requires 2 doses one month apart
  - No buffer required
- $1.85 per dose
- 67% effective in preventing cholera in the 2 years after vaccination in a phase 3 trial in Kolkata
New Hardware
Soapy water preparation (Tk1/bottle)
Chlorine Dispenser

• Intervene at shared water source
• One turn of the valve dispenses appropriate dose of chlorine for 5 liters water
• Option for reservoirs of treated water
Supportive Environment

**Levels**
- Household
- Compound
- Community

**Dimensions**
- Physical Environment
- Resources & subsidies
- Norms & social support
- Leadership & advocacy

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**Individual**

- Perceived benefits & barriers of hardware & behavior
- Knowledge & skills
- Subjective norms
- Self-efficacy
- Threat perception
- Disgust
- Habits

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**Formation of new habits**

- CUES TO ACTION
- REPETITION
- STABLE ENVIRONMENT TO PRACTICE BEHAVIOR
- NEW BEHAVIORS BECOME HABITUAL

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**Technical attributes of product/hardware**
- Effectiveness
- Tangible effects
- Complexity
- Cost
- Availability

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Slide from Peter Winch
Promoting handwashing and water treatment

- Comprehensive communication plan
- Promotional messages based on research findings
- Initial focus on the household (and courtyard)
  - Flipcharts, cue cards
- Focus on ‘non health’ benefits
Promoting handwashing - the promoters

- From same community
- Courtyard meetings (introduction of promotion)
- **NEW** Trained in negotiation and interactive techniques
  - number and location of HW stations
  - Who will be the caretaker
- **NEW** Regular visits with varied activities
- **NEW** Using interactive rather than didactic approach

Slide from Leanne Unicomb
Primary Outcome

• Persons with diarrhea, severe enough to visit a health care provider and who have *Vibrio cholerae* isolated from their stool.
  – Most patients will come from 2 ICDDRB operated facilities
  – Some surveillance and referral at other facilities in the area
Primary Analysis

- Closed cohort
- Intention to treat
- Incidence of diarrhea due to *V. cholerae*
  - Vaccine versus control
  - Vaccine + behavior change versus control
Secondary outcomes

- Diarrhea, severe enough to require hospitalization, that is not caused by cholera
- Self reported diarrhea
  - 48 hour recall
  - Part of 6 monthly census update
- Self reported respiratory disease
Hospitalized diarrhea not from *V. cholerae*
Secondary analysis

- **Hypothesis:** Persons living in communities that receive the behavior change intervention or at lower risk of severe diarrhea from causes other than cholera compared with persons living in control communities.
- **Study population**
  - Open cohort
  - People who live in intervention areas.
  - Among persons who move in, we will begin to count their person time after 28 days of residence.
- **Intention to treat**
Self reported diarrhea and respiratory illness
Secondary analysis

• Hypothesis: Persons living in communities that receive the behavior change intervention will have less self reported diarrhea and respiratory compared with persons living in control communities.

• Study population
  – Open cohort
  – People who live in intervention areas.
  – Among persons who move in, we will begin to count their person time after 28 days of residence.

• Intention to treat
Tertiary Outcomes uptake measures

- Presence of soap and water in the most convenient place to wash hands
- Presence of residual chlorine in drinking water
- Microbiological water quality using H2S testing
- Presence of soapy water in the compound
- Presence of chlorine dispenser
- Use of soap when asked to demonstrate how they usually wash hands after defecation
Tertiary Measurements

• Monthly assessments
  – 200 randomly selected intervention households
  – 100 households from cholera vaccine only neighborhoods
  – 100 households from control

• Track uptake over time
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