Nepal Cookstove Intervention Trials

James M. Tielsch, Ph.D.
Departments of Global Health
George Washington University
Milken Institute School of Public Health

CUGH Meeting
April 2016
Air Pollution & Health

• ~3 billion people cook and heat homes using open fires and simple stoves burning biomass (wood, animal dung and crop waste) and coal.
• >4 million people die prematurely from illness attributable to the household air pollution from cooking with solid fuels.
• >50% of premature deaths among children under 5 are due to pneumonia caused by PM inhaled from household air pollution. Changing rapidly due to vaccine rollout.
• >3.8 million premature deaths annually from NCDs including stroke, ischaemic heart disease, COPD and lung cancer attributed to household air pollution.

WHO. WHO guidelines for indoor air quality: household fuel combustion. 2014.
Figure 4.3: Global black carbon emissions from combustion, in gigagrams (Gg). This includes emissions from fossil fuels and biofuels such as household biomass (i.e. wood charcoal, dung, crop waste) used for cooking.

Asian Brown Cloud
# Experimental Trials Underway

<table>
<thead>
<tr>
<th>Trial location</th>
<th>Main investigating institution (PI)</th>
<th>Intervention technologies/fuels</th>
<th>Main health outcomes</th>
<th>Trial registration number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ghana</td>
<td>Columbia University (Kinney P.)</td>
<td>2 intervention arms: Biolite fan stove; LPG</td>
<td>Incidence of ALRI in children under 12 months; birth weight</td>
<td>NCT01335490</td>
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<td>Nepal</td>
<td>Johns Hopkins (Tielsch J.)</td>
<td>2 intervention arms: Envirofit rocket stove; LPG</td>
<td>Incidence of ALRI in children under 36 months; birth weight</td>
<td>NCT00786877</td>
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<td>Malawi</td>
<td>Liverpool School of Tropical Medicine (Mortimer K.)</td>
<td>Philips fan stove</td>
<td>Incidence of ALRI in children under 60 months</td>
<td>ISRCTN59448623</td>
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<td>Nigeria</td>
<td>University of Chicago (Olopade C.)</td>
<td>Ethanol clean cook stove</td>
<td>Incidence of adverse pregnancy outcomes</td>
<td>Awaited</td>
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</tbody>
</table>
Nepal Cookstove Intervention Trials: Phase 1 & 2

Phase 1
• Modified step-wedge cluster randomized trial comparing traditional open-burning biomass to improved biomass stove with chimney.

Phase 2
• Individually randomized trial comparing improved biomass stove with chimney to LPG.
Nepal Cookstove Intervention Trials: Primary Specific Aims: Phase 1

1. Compare the incidence of ARI among children <36 months of age in households before and after replacement of cookstove with high efficiency, vented model.

2. Compare the rate of low birthweight (<2500 g) among newborn infants...

3. Compare the rate of pre-term birth (<37 wk) among newborn infants...
Cookstove Trial Study Site: Sarlahi District
## Enhanced Step-Wedge Design Plus

### Original Step-Wedge Trial: Phase 1 (months)

| Group | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
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| 2     | S | E | S | S | S | S | S | S | S | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  |
| 3     | S | S | E | S | S | S | S | S | S | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  |
| 4     | S | S | S | S | E | S | S | S | S | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  |
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| 9     | S | S | S | S | S | S | S | S | S | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  |
| 10    | S | S | S | S | S | S | S | S | S | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  |
| 11    | S | S | S | S | S | S | S | S | S | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  |
| 12    | S | S | S | S | S | S | S | S | S | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  | S  |

### Phase 2

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**Randomize 1600 Eligible Households**

*S* = Surveillance for ALRI

**E** = Environmental Assessment and Surveillance for ALRI

**I** = Cookstove replacement for this group of sectors.

**I** = LPG stove installation for households randomized to this intervention.
Flow Chart for Participation
Nepal Cookstove Intervention Trial, Phase 1

Previously Known
Potentially Eligible HH
(n = 2331)

New Potentially Eligible HH
(n = 1409)

Households Potentially Eligible
(n = 3740)

Not Eligible for Pre-Installation Surveillance
200 = Not met/moved
39 = No eligible woman or child
1 = Refused
7 = LPG/kerosene stove
117 = No Household Info

Not Eligible for Post-Installation Surveillance
89 = Not met/moved
18 = Refused
5 = LPG/kerosene stove
62 = Structurally ineligible

Baseline

Additions prior to New Stove Install

Total prior to New Stove Install

Children <36 Months

3024

1122

4146

Married Women 15-30 Years

4055

184

4239

1453 = Aged out
66 = Moved/Lost
57 = Died
16 = Refused
49 = HH ineligible
69 = Never Met

168 = Moved/Lost
11 = Died
22 = Refused
61 = HH ineligible
760 = Never Met

At Time of New Stove Install

2436

1108

3544

Additions after New Stove Install

Total after New Stove Install

227

3444

3217

54 = Moved/Lost
5 = Died
24 = Refused
3361 = Censored, not pregnant
128 = Censored while pregnant

1296 = Aged out
95 = Moved/Lost
62 = Died
2091 = Censored
Key question: Which “improved” cookstove?

- Built test house in Sarlahi. Tested 3 stove models.
- Chose manufactured product from Envirofit. Only product “available” in quantities needed and designed with chimney and at least 2 cooking positions.
Measurement of Key Outcomes – ALRI

• Visit once per week. Ask about signs / symptoms for each day in preceding week.
• If meet case definition (difficulty breathing plus fever): supervisor visits same/next day to conduct exam.
  • Temperature
  • Resp. rate
  • Danger signs
  • Oxygen saturation, & carboxyhemoglobin
  • Digital chest auscultation
Measurement of Key Exposures

- Measuring 2 key exposures before and after improved stove installation.
- Ambient particulate concentration
  - Thermo Scientific MIE device. Laser light scattering. Logs every 10s
  - Chose not to use filter-based measures due to cost and logistics.
- Carbon monoxide concentration
  - Ambient measures using logging device every 10 sec.
  - Physiologic measure of carboxyhemoglobin in pregnant women and sick children.
### Kitchen Concentrations of PM$_{2.5}$ & CO from Pre and Post Stove Installation, Phase 1

<table>
<thead>
<tr>
<th></th>
<th><strong>Pre-stove</strong></th>
<th></th>
<th><strong>Post-stove</strong></th>
<th></th>
<th><strong>Pre - post</strong></th>
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<tbody>
<tr>
<td></td>
<td>N</td>
<td>$LL^+$</td>
<td>Mean</td>
<td>$UL^+$</td>
<td>N</td>
<td>$LL^+$</td>
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<tr>
<td><strong>PM$_{2.5}$</strong></td>
<td></td>
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<td></td>
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<tr>
<td>Total daily average ($\mu$g/m$^3$)</td>
<td>2963</td>
<td>1336</td>
<td>1380</td>
<td>1425</td>
<td>2752</td>
<td>895</td>
</tr>
<tr>
<td>SI* daily average ($\mu$g/m$^3$)</td>
<td>2949</td>
<td>3364</td>
<td>3475</td>
<td>3587</td>
<td>2716</td>
<td>2175</td>
</tr>
<tr>
<td>Non-SI daily average ($\mu$g/m$^3$)</td>
<td>2963</td>
<td>254</td>
<td>269</td>
<td>283</td>
<td>2752</td>
<td>180</td>
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<tr>
<td>95$^{th}$ percentile ($\mu$g/m$^3$)</td>
<td>2963</td>
<td>6202</td>
<td>6441</td>
<td>6680</td>
<td>2752</td>
<td>4062</td>
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<tr>
<td>Time above 100 $\mu$g/m$^3$ (h)</td>
<td>2963</td>
<td>14.1</td>
<td>14.4</td>
<td>14.6</td>
<td>2752</td>
<td>11.8</td>
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<tr>
<td>Time above 1000 $\mu$g/m$^3$ (h)</td>
<td>2963</td>
<td>5.2</td>
<td>5.3</td>
<td>5.4</td>
<td>2752</td>
<td>3.8</td>
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<tr>
<td><strong>CO</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Total daily average (ppm)</td>
<td>2011</td>
<td>10.6</td>
<td>11.0</td>
<td>11.4</td>
<td>1848</td>
<td>6.4</td>
</tr>
<tr>
<td>SI* daily average (ppm)</td>
<td>2005</td>
<td>21.1</td>
<td>21.9</td>
<td>22.7</td>
<td>1840</td>
<td>14.0</td>
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<td>Non-SI daily average (ppm)</td>
<td>2011</td>
<td>1.8</td>
<td>1.9</td>
<td>2.0</td>
<td>1840</td>
<td>1.1</td>
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<tr>
<td>95$^{th}$ percentile (ppm)</td>
<td>2011</td>
<td>48.3</td>
<td>50.3</td>
<td>52.3</td>
<td>1848</td>
<td>29.2</td>
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<td>Time above 6 ppm (h)</td>
<td>2011</td>
<td>6.4</td>
<td>6.6</td>
<td>6.8</td>
<td>1845</td>
<td>4.1</td>
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<td>Time above 9 ppm (h)</td>
<td>2011</td>
<td>4.7</td>
<td>4.9</td>
<td>5.0</td>
<td>1845</td>
<td>3.1</td>
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</tbody>
</table>

* SI for stove-influenced;

+ Lower and upper 95% CI of regression coefficient estimate.
An episode of ALRI is defined as:

- a consecutive set of 2 or more days with fever and difficult breathing with both symptoms being reported on at least 1 day during the episode and in which at least 1 symptom occurs on each day.
- Episodes must be separated by 7 or more symptom free days.
ALRI Incidence

Incidence per person year

- March 2010: 4.17
- Apr-Jun: 0.78
- Jul-Sep: 0.60
- Oct-Dec: 0.60
- Jan-Mar 2011: 0.15
- Apr-Jun: 0.18
- Jul-Sep: 0.17
- Oct-Dec: 0.25
- Jan-Mar 2012: 0.22
- Apr-Jun: 0.06
- Jul-Sep: 0.07
- Oct-Dec: 0.06
- Nov-Dec: 0.14

Yellow bars represent pre-install incidence, and blue bars represent post-install incidence.
Cough Incidence

Incidences per person year:
- Pre-install:
  - March 2010: 23.17
  - Apr-Jun: 7.42
  - Jul-Sep: 7.26
  - Oct-Dec: 9.02
  - Jan-Mar 2011: 8.52
  - Apr-Jun: 6.80
  - Jul-Sep: 6.51
  - Oct-Dec: 5.11
  - Jan-Mar 2012: 5.41
  - Apr-Jun: 4.87
  - Jul-Sep: 4.57
  - Oct-Dec: 3.21
- Post-install:
  - March 2010: 23.17
  - Apr-Jun: 7.42
  - Jul-Sep: 7.26
  - Oct-Dec: 9.02
  - Jan-Mar 2011: 8.52
  - Apr-Jun: 6.80
  - Jul-Sep: 6.51
  - Oct-Dec: 5.11
  - Jan-Mar 2012: 5.41
  - Apr-Jun: 4.87
  - Jul-Sep: 4.57
  - Oct-Dec: 3.21

Legend:
- Yellow bars: pre-install
- Blue bars: post-install
Challenges to Analysis

• Traditional step-wedge designs assume no secular trend.
• Clear secular trend for almost all morbidities.
• Therefore accounting for secular trend, season, and child age are all important to isolate the effect of the new stove on health outcomes.
### OR of Incidence Post vs. Pre Stove Installation, Phase 1

<table>
<thead>
<tr>
<th>Morbidity</th>
<th>aOR*</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>ALRI</td>
<td>0.87</td>
<td>0.67</td>
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<td>fever</td>
<td>1.01</td>
<td>0.96</td>
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<td>cough</td>
<td>0.91</td>
<td>0.85</td>
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<tr>
<td>wheezing</td>
<td>0.87</td>
<td>0.78</td>
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*Adjusted for child age, child sex, calendar time
Odds Ratio of Prevalence Post vs. Pre Stove Installation, Phase 1

<table>
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<td>0.96</td>
<td>0.93</td>
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<td>cough</td>
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<td>0.83</td>
</tr>
<tr>
<td>wheezing</td>
<td>0.97</td>
<td>0.92</td>
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</table>

*Adjusted for child age, child sex, calendar time
**Kitchen Concentrations**

- Modest decline in PM concentrations (40%) with Envirofit biomass stove with chimney.
- PM$_{2.5}$ concentrations remained well above indoor air standards suggesting emission reductions were inadequate AND stove stacking was common.
- We have weekly compliance data: analysis coming....
Health Outcomes: Phase 1

- 13% reduction in ALRI incidence (weak evidence)
- 20% reduction in ALRI prevalent days (modest evidence).
- Significant reductions in incidence of cough & wheeze (~10%).
- No difference in severe ALRI.
Collaborative Institutions

- Nepal Nutrition Intervention Project – Sarlahi
- Johns Hopkins Bloomberg School of Public Health
- Institute of Medicine, Tribhuvan University
- George Washington University
Investigators:
- James Tielsch
- Joanne Katz
- Luke Mullany
- Patrick Breysse
- Scott Zeger
- William Checkley
- Subarna Khatry
- Steven LeClerq
- Laxman Shrestha
- Ramesh Adhikari

Funding:
- National Institute of Environmental Health Sciences (NIH)
- Thrasher Research Fund
- Global Alliance for Clean Cookstoves, UN Foundation (Phase 2)
Stove Testing