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# Preliminary Observations in RCT Study Investigating Impact of Bioethanol Stove on Pregnancy Outcomes in Nigeria

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# Presentation Outline

- Provide overview of study design of first RCT evaluating impact of the CleanCook stove and bioethanol on pregnancy outcome
- Discuss preliminary results
  - Baseline distributions by intervention arm
  - Personal exposures
  - Adoption
  - Intra uterine growth curves
  - Birth outcomes



# HAP and Pregnancy Outcome Study Objectives

- Investigate ability of ethanol stove and bioethanol to reduce personal exposure to  $PM_{2.5}$ , CO and PAH and improve pregnancy outcome in women who cook primarily with firewood
- Establish exposure-response relationship between pollutants and health outcomes
- To evaluate stove use/likability of the ethanol stoves by temperature based monitoring and compare with health outcomes



# HAP and Pregnancy Outcome Hypothesis

- Ethanol stove and bioethanol fuel use will reduce pregnant women's exposures to  $PM_{2.5}$ , PAH, and CO relative to kerosene and firewood and reduce adverse pregnancy outcomes.



# The CleanCook Tier 4 Stove\*



**Local Primary Health Center**



**Clinic Visit 1: Recruitment, Consent, Questionnaire, Diet Survey, Spirometry**



**Clinic Visit 2: Ultrasound, Blood Draw**

*CBC, Biomarkers of  
Nutrition and  
Malaria*



**Home Visit 1: Initial Home Visit**



**Randomized  
16-18 weeks**



**Control (kerosene/Wood\*)  
(N = 150)**



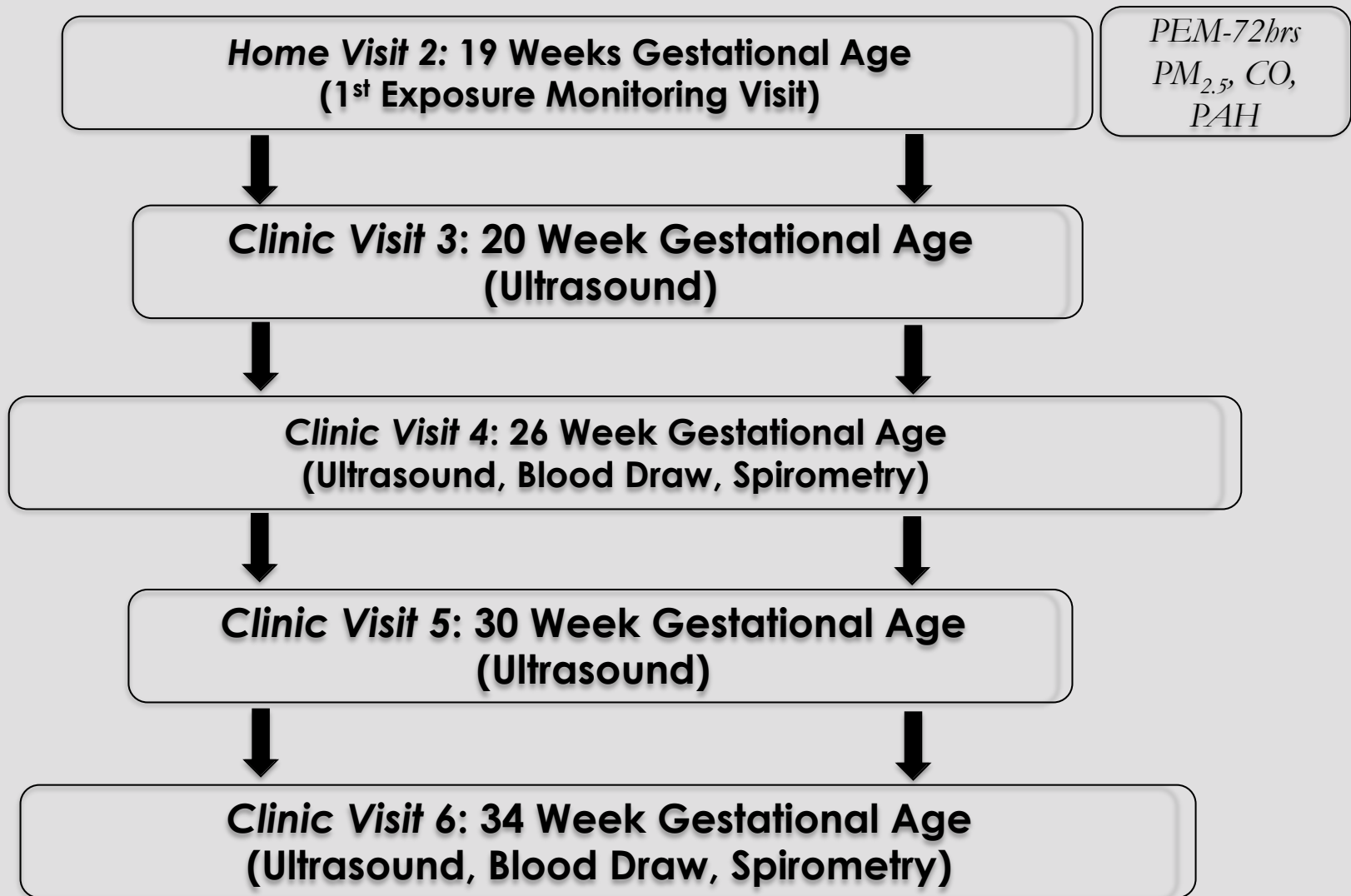
**CleanCook Stove  
(N = 150)**

\*Original design was Ethanol vs. Wood



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**Home Visit 3: 35 Week Gestational Age  
(2<sup>nd</sup> Exposure Monitoring Visit)**



**Clinic Visit 7: 38 Week Gestational Age  
(Ultrasound)**



**Clinic Visit 8: Delivery  
(Pregnancy Outcomes)  
Cord Blood and Placenta Collection\***

\*



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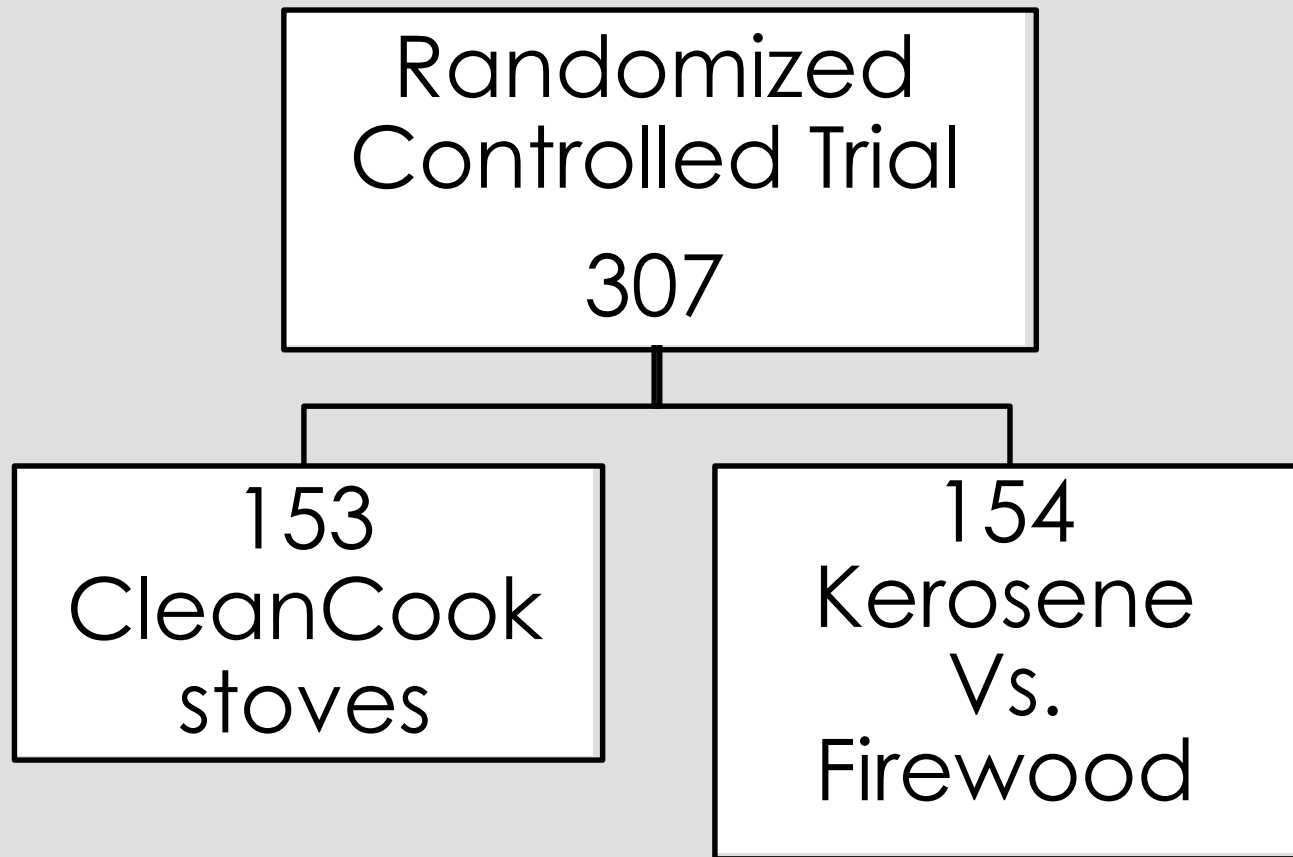


# Exposure and Cookstove Monitoring

- 2<sup>nd</sup> and 3<sup>rd</sup> trimester
  - 72-hr continuous  $PM_{2.5}$  & CO
  - 72-hr integrated PAH (subset)
  - 12-20-hr GPS
- 
- SUMs placed on all homes in study homes
  - SUMs record temperature every 10 minutes



\*SUMs = Stove Use Monitors



Last delivery expected by August 2015



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# Pregnancy Outcome Measures

- Miscarriage
- Preterm delivery
- Intrauterine growth rate
  - Head and abdominal circumference, femur length, crown rump length etc
- Birth weight, length and head circumference
- Apgar scores
- Stillbirth



# Other Outcome Measures

- Pulmonary function
- BP changes
- Biomarkers
  - Nutrition
  - Oxidative damage
  - Systemic inflammation



# Baseline Distribution by Intervention Arm

	Ethanol (153)	Control (150)
<b>Clinic</b>		
Agbongbon	72 (47.4%)	68 (45.3%)
Oranyan	43 (28.3%)	45 (30.0%)
Olorisaoko	37 (24.3%)	37 (24.7%)
Missing	1	
<b>Parity</b>		
<4 children	143 (94%)	140 (93.3%)
>4 children	9 (5.9%)	10 (6.7%)
Missing	1	



# Baseline Distribution by Intervention Arm

	Ethanol (n=153)	Control (n=150)
<b>Gestational age at entry</b>		
Mean, SD	13.1, 3.0	13.2, 3.2
(range)	(6.7-18)	(2.6-18)
Missing	3	2
<b>Education Level</b>		
None	43 (28.3%)	46 (32.2%)
Primary	15 (9.9%)	16 (11.0%)
Senior Secondary	67 (44.1%)	56 (38.5%)



# Obstetrics History at Baseline

	Ethanol n=153	Control n=150
<b>Prior miscarriage</b>		
Yes	43 (28.5%)	42 (28.8%)
No	109 (71.7%)	104 (71.2%)
Missing	1	4
<b>Miscarriages Nos.</b>		
None	109 (71.7%)	104 (71.2%)
1	32 (21%)	33 (22.6%)
2	8 (5.3%)	6 (4.1%)
3	3 (2%)	3 (2%)



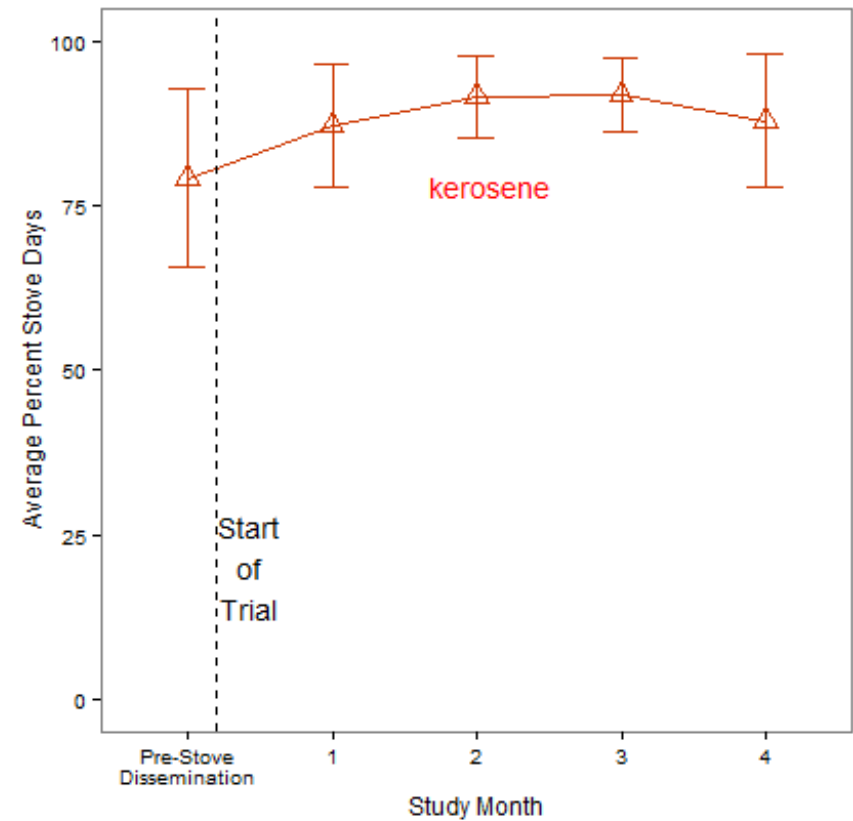
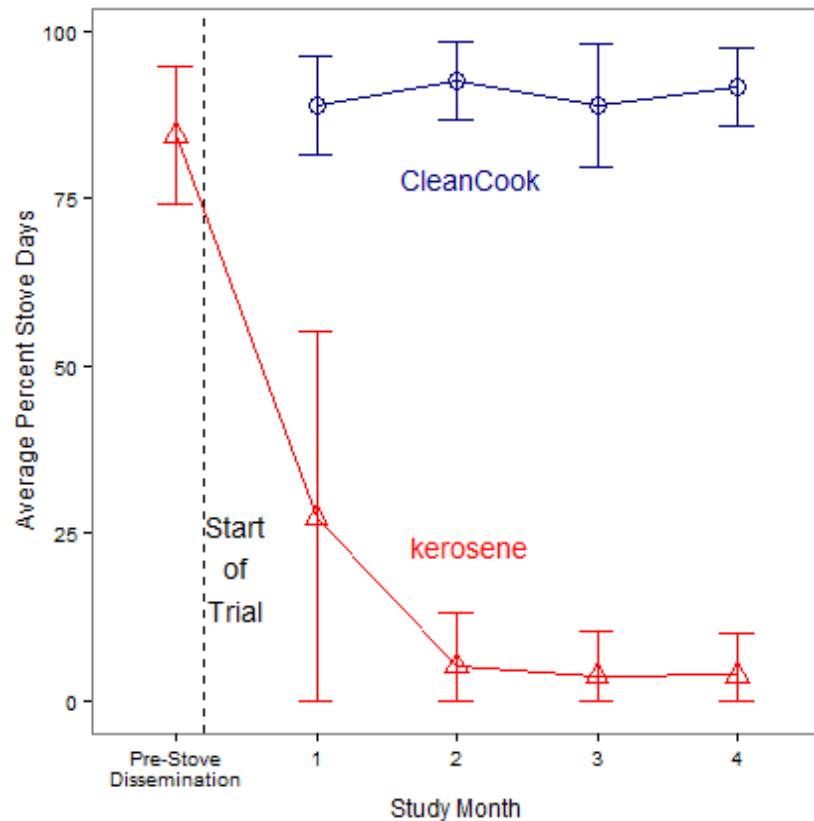
# Main Type of Stove at Entry

Variable	Ethanol (n=153)	Control (n=150)
Three stone	42 (29.2%)	43 (30.7%)
Kerosene	98 (68.1%)	95 (67.9%)
Charcoal	3 (3%)	2 (1.4%)
Electric	1 (0.7%)	0
Missing	9	10





# Adoption of CleanCook Stove



# Personal CO Exposure

	<b>Control (ppm)</b>	<b>Intervention (ppm)</b>	<b>p-value</b>
72 hour mean (SD)	3(4)	1(1)	0.06
Max 15 minute	41(38)	34(18)	0.05
Range	0 - 23	0 - 6	



# Personal PM<sub>2.5</sub> Exposure

	<b>Intervention (Ethanol)</b>	<b>Control (Kerosene)</b>
<b>PM<sub>2.5</sub> 72 hr mean mg/m<sup>3</sup></b>	66.3 [21] (n=83)	87.4 [20] (n=88)



# Preliminary Birth Outcome Data

Variable	Ethanol (N=77)	Control* (N=70)	p-value
<b>Preterm delivery</b>			
Yes	5 (6.5%)	7 (10%)	0.55
No	72 (93.5%)	63 (90%)	
<b>Stillbirths</b>			
Yes	2 (2.6%)	2 (2.9%)	0.40
No	75 (97.4%)	68 (97.1%)	
<b>Miscarriage</b>			
Yes	0	1 (1.4%)	0.48

\* Kerosene/Firewood



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# Birth Outcome Collection Based on Delivery Location

Site	Deliveries as % of total	Outcome data collected
Primary Health Center	170 (69.3%)	149 (87.6%)
Home	34 (13.8%)	25 (73.5%)
Church	21 (8.57%)	19 (90.4%)
TBA	10 (4.08%)	7 (70%)
Mosque	2 (0.81%)	2 (100%)
Unknown	3 (1.22%)	0
Miscarriages	5 (2.04%)	0



# Preliminary Conclusions

- The CleanCook and bioethanol combination appears to reduce PM<sub>2.5</sub> and CO exposures relative to Kerosene
- CleanCook stove is liked and being and is being adopted by Nigerian women.
- Preliminary exposure data indicates ethanol is less pollutant than Kerosene and biomass
- No appreciable difference in preliminary birth outcomes between ethanol and control group but over 50% of deliveries are still pending



# Research Team and Partners

- Obstetrics and Gynecology
  - Prof. Ojengbede and M Bello (Univ. of Ibadan)
- Exposure monitoring
  - Amanda Northcross, PhD (GWU),
  - Godson Ana, PhD and Donee Alexander, PhD (GACC)
- Healthy Life for All Foundation
  - T Ibigbami, J Olajumilo, D Adepoju and D Adu
- Laboratory studies
  - Prof Arinola, A Odetunde (Nigeria), Niu Qun (Chicago)
- Project Gaia (USA), HLF (Nigeria), Shell Foundation







# Mother-Child Exposure to Biomass Smoke in Nigeria



WHO Conference for Life: 2006



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