ASSESSING THE EFFECT OF IMPROVED RURAL SANITATION ON DIARRHOEA AND INTESTINAL NEMATODES INFECTION: A CLUSTER-RANDOMIZED, CONTROLLED TRIAL IN ORISSA, INDIA

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Orissa Study Objectives

- To assess the impact of improved rural sanitation on:
  - diarrhoeal disease morbidity among of <5s (primary objective) and all ages
  - intestinal nematode infections
  - weight-for-age z-score in <5s
- To assess the impact of improved rural sanitation on expected transmission pathways for oral-faecal transmission (intermediate outcomes):
  - faecal contamination of drinking water
  - environmental exposure to excreta
  - prevalence of mechanical vectors (flies)
  - health-seeking behaviour and expenditures

- To assess the impact of improved sanitation on
  - school attendance (absenteeism)
  - health care seeking behaviour and costs
- To document the delivery of rural sanitation in Eastern India under the Total Sanitation Campaign
- To document uptake, acceptability and use of the intervention over the course of the study.
- To identify determinants of use
- To evaluate the cost-effectiveness of the intervention

Global Distribution of Diarrhoeal Deaths

Table 3. **Countries accounting for three-quarters of deaths due to diarrhoea in the developing regions of the world, 2004**

Country	WHO subregion[a]	Deaths due to diarrhoea (thousands)
India	SEAR D	535
Nigeria	AFR D	175
Democratic Republic of the Congo	AFR E	95
Ethiopia	AFR E	86
Pakistan	EMR D	77
China	WPR B	74
Bangladesh	SEAR D	69
Afghanistan	EMR D	65
Indonesia	SEAR B	39
Angola	AFR D	34
Niger	AFR D	33
Uganda	AFR E	28
Myanmar	SEAR D	26
United Republic of Tanzania	AFR E	25
Mali	AFR D	24
Total of 15 countries		**1384**

Boschi-Pinto 2009

Geographic Distribution of Open Defecation

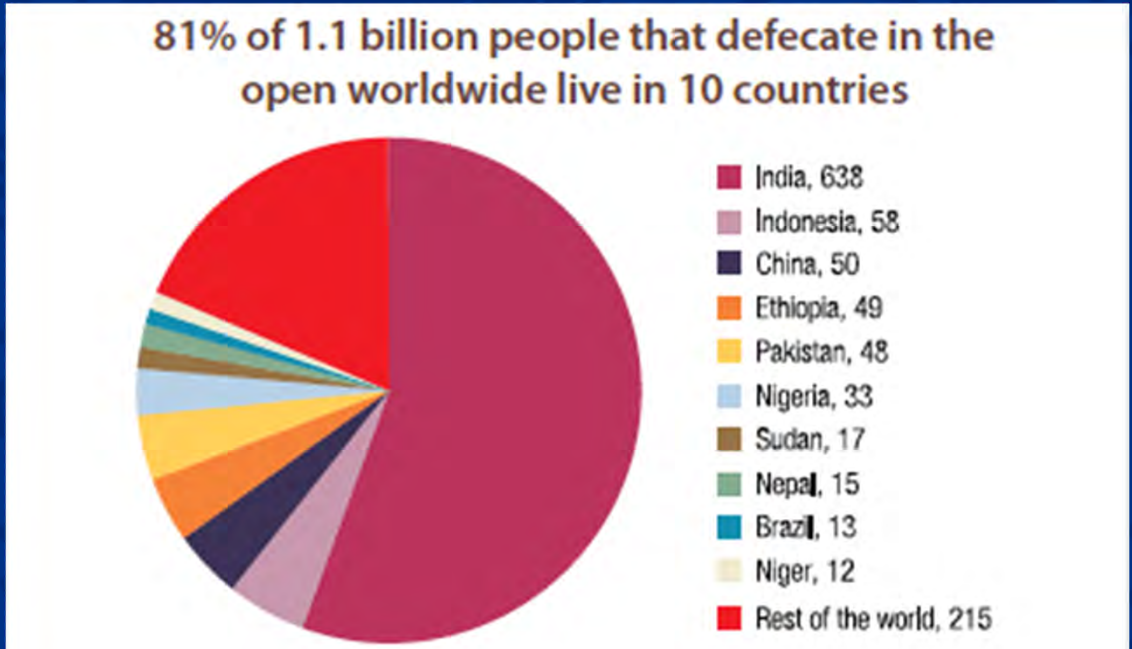


Figure 23 Distribution of 1.1 billion people who practise open defecation, 2008, population (million)

JMP 2010

Study Setting

- 100 villages in Puri District of Orissa. About 50% of the population lives below the poverty line (BPL).
- Scheduled castes and tribes make up 18% and 0.3% of the population, respectively.
- Open defecation is widespread. Sanitation coverage estimated at 23% overall and 15% in rural areas (DLHFS).
- Two-week prevalence of diarrhoea among <5s is 28% (DLHFS).
- High prevalence of STH: ascaris 16%, hookworm 8% and trichuris 4.5% (Chotray GP, 2005).

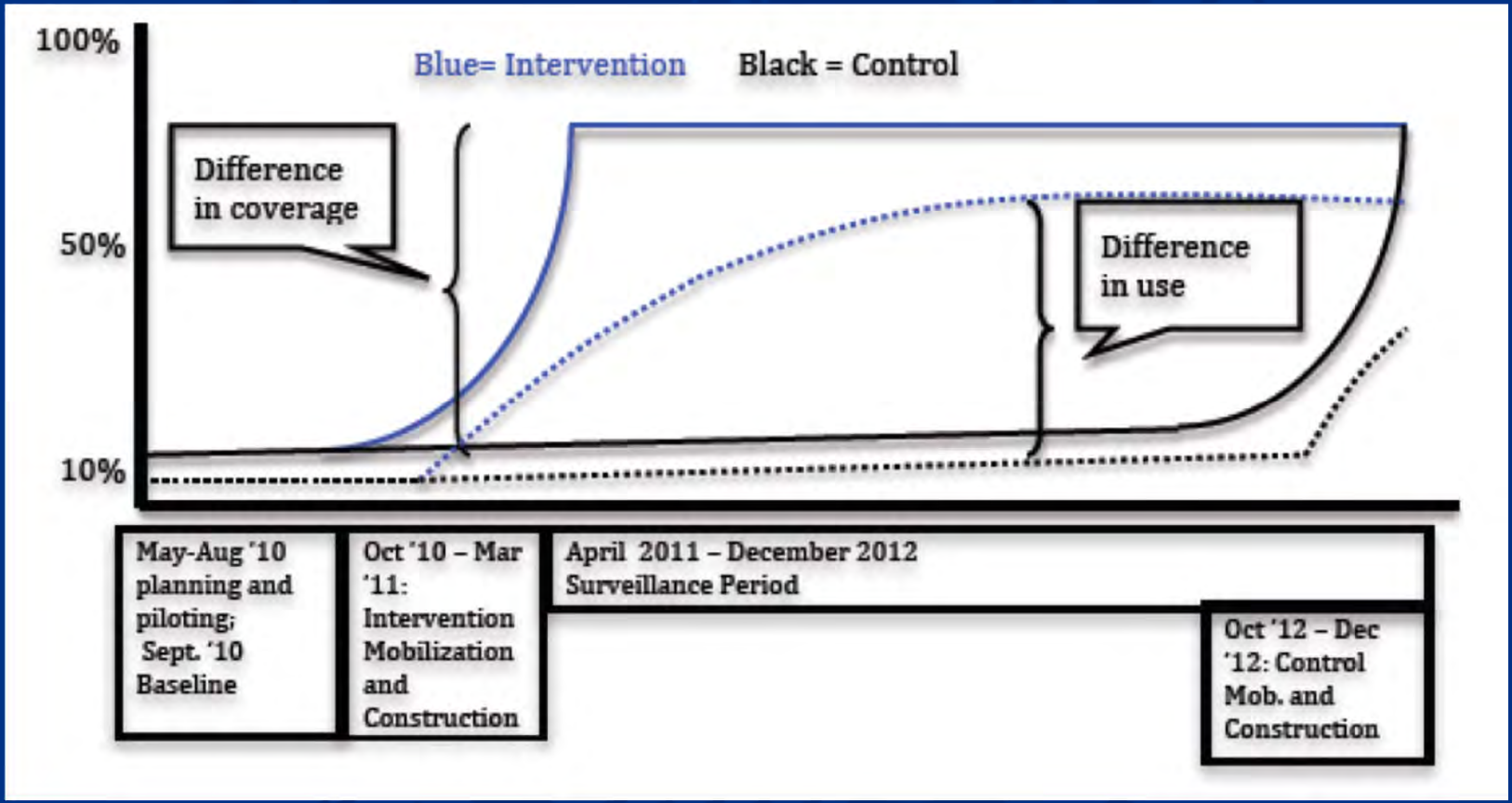
WaterAid Planned Intervention Activities

Activity	Duration	NGO staff*
Village selection	1 week	PD
Rapport building: Village meetings Needs assessment Community Action Plan developed and formation of committees	2 months	PD, CC, GPC
Baseline survey	3 days	GPC
Training of committees	3-day sessions	CC
Exposure visit	1 day	CC, GPC
Door-to-door household visits with IEC cards	2 days	All CC and GCP of NGO
IEC material distribution, wall paintings, street theatre	12 days	GPC
Assessment of campaign using FDG	1 day	CC, GCP
Door-to-door household visits	2 x per month (Total project duration)	GPC +Adolescent girls
Technical training of mechanics and Mason	3-day session	WA, technical

Study Design

- Cluster (community)-randomized controlled field trial
- 100 of 385 candidate villages from Puri District selected for participation in the study.
- Following enrolment and baseline survey, half of the villages were randomly allocated to an intervention group and half to a control group.
- Latrine construction in intervention villages in first 6 months; deferred to control villages for 18 months.

Study Design



Village Eligibility

- Little existing sanitation coverage (<10%) [8.2% at baseline]
- Implementing partner expects normal scale up
- Village has own primary school (to minimize misclassification due to migration)
- Stable and reasonably acceptable water supply [85.7% handpumps at baseline]
- No other WASH interventions planned or anticipated in next 30 months
- Reasonable year-round access by bicycle to permit household visits by surveillance staff

Baseline Survey

- Following enrolment, a household survey was conducted using PDAs to collect information on demographics, socio-economic characteristics, water and sanitation practices, etc.
- Mothers of children under 4 years asked to verify the date of birth for each such child.
- Village-wide sanitary survey to document baseline level of latrine coverage, obtain GPS coordinates of each households and the type and GPS location of each primary water collection points and OD sites for mapping the study area spatial analysis.

Process Evaluation

- Agree process with implementing partners
- Initial meetings with all implementing partners to obtain and review implementation plan
- Trained enumerators making monthly visits to intervention villages during 6-month intervention period
- Review of village-level implementation registers, maps and records; meeting with VWSC; on-site inspections/photos; checklist of each phase of planned implementation

Diarrhoeal Disease Surveillance

- Visit all participating households 9 times over 21 months.
- At each visit, the primary care giver will be asked to provide information on common health conditions, including diarrhoea, to minimize courtesy bias
- WHO case definition of 3 or more loose stools in 24 hrs.
- Results in an estimate of the longitudinal prevalence of diarrhoea

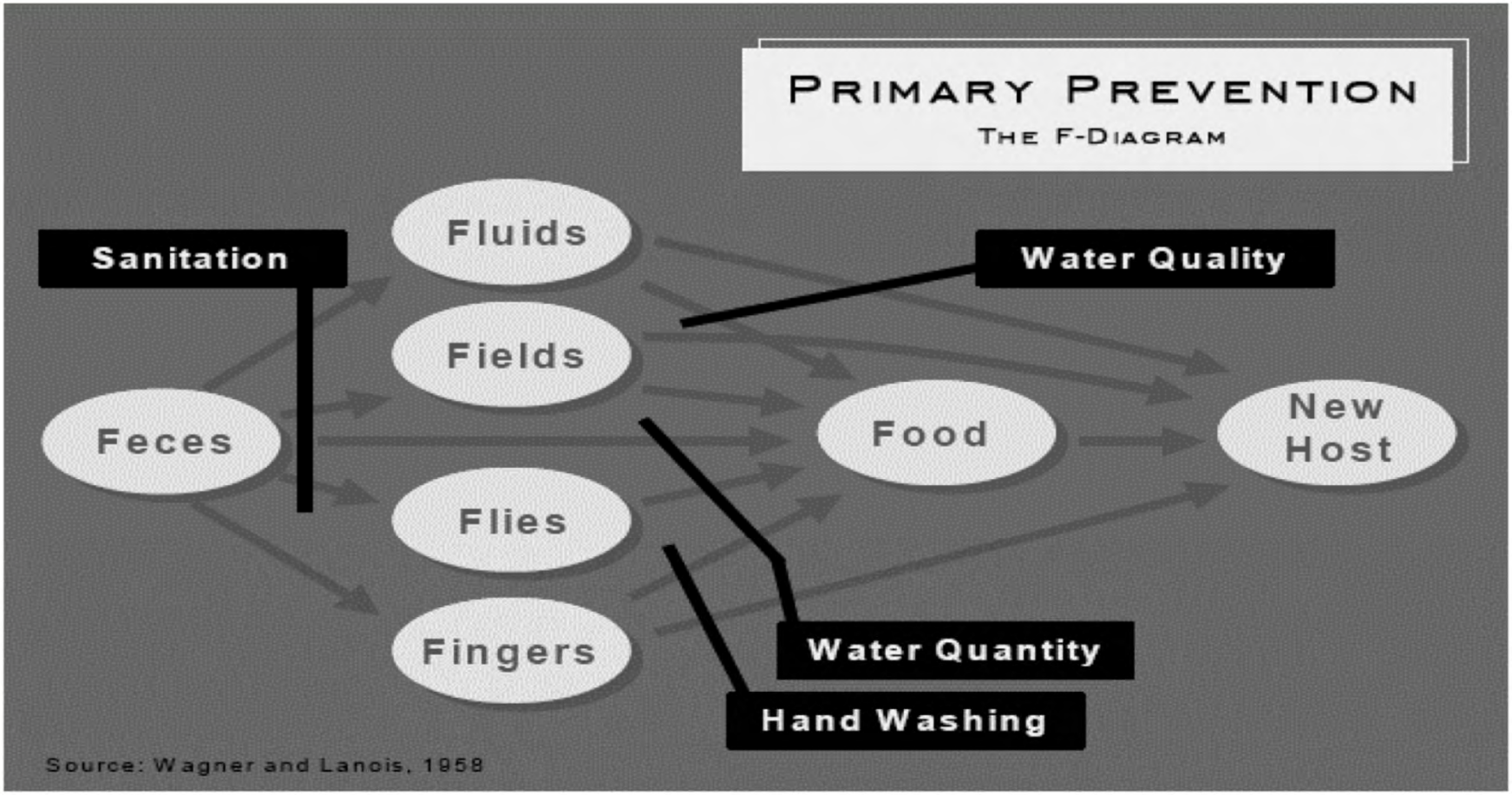
WAZ Score

- Some evidence in <5s of an association between weight for age z score (WAZ) and diarrhoea over the last 2 weeks, suggesting that WAZ may be a good (and objective) proxy for recent diarrhoea (Schmidt 2009).
- During each household visit, weight will be recorded for each child less than 5 years

Helminth Infection

- Following a pilot study, stools will be collected from a random sample of 3000 participants (600 households) and assayed for STH ova (*Ascaris*, *Trichuris*, Hookworm) and protozoan cysts (*Giardia*).
- Participants who provided a stool sample will be given a broad-spectrum anthelmenthic drug (Albendazole) recommended by the Indian Ministry of Health.
- Survey will be repeated among the same participants 16 months later to determine prevalence and intensity of re-infection.

Comparing Intermediate Outcomes of Improved Sanitation



Comparing Intermediate Outcomes

- Water:
  - 640 samples per quarter of water identified by householders as used for drinking)
  - Assayed for *E. coli (acce*pted indicator for faecal contamination)
- Sanitary/Hygiene Survey
  - Checklist at each household visit
  - Focus on exposure of <5s
  - Possible microbiological assessment following pilot summer 2011

Vector Monitoring--Flies

- Flytraps placed weekly in the food preparation areas of a sample of the study households during dry and rainy seasons throughout the 21-month surveillance period.
- *Musca domestica*, *Musca sorbens*, and key *Chrysomya spp*. collected and identified to species; other flies identified to family.
- Sample flies for *Escherichia coli*, *Vibrio cholerae*, *Shigella* spp., *Salmonella* spp., and *Aeromonas* spp, the primary sources of diarrhea in Orissa (Samal et al., 2008).

Vector Monitoring-Mosquitoes

- Assess the impact of the intervention on breeding of mosquito vectors associated with lymphatic filariasis and malaria.
- Sample mosquitoes tested for presence of *Wuchereria bancrofti*, testing pools of 50 mosquitoes using PCR after Dynalbead purification (Boakye et al., 2007).

School Attendance

- Compare school attendance between school-aged children in intervention and control groups to assess the extent to which the intervention prevents absenteeism.
- As school records are deemed unreliable, we will use roll call at unannounced visits to 8 randomly-selected schools per day (of an estimated 150 schools in the 100 participating villages), providing one data points per school per month.

Cost, Cost-Savings and Cost-Effectiveness

- Collecting information cost of providing the intervention as part of the process evaluation phase
- Collecting data on potential cost savings (reduced expenditures on health-seeking behaviour) if any
- Estimate the cost-effectiveness of the intervention, expressed in cost per disability-adjusted life years (DALYs) averted.

Use

- Investigate associations (determinants, barriers, etc.) with use with covariates from baseline and other data.
- Use will be determined using the methods that the formative research and piloting determines to be most sensitive, specific and practical for large scale monitoring of latrine use
- Further explore our “smart latrine” passive latrine use monitoring system (PLUMS)

Monitoring Sanitation: Current Practices

- Recording availability and access to the facility, including distance/travel time and number of users (JMP)
- Documenting condition and maintenance of the facility, including whether it is operational and the condition and upkeep of pit, slab, floor, door/protected entry, walls and roof
- Using indicators of use, including pit contents (which can be measured and evaluated if there is access), evidence of worn path to the facility, odour, flies, wet slab, and presence of anal cleaning materials (O'Loughlin 2006; Rogers 2007).
- Sanitary surveys to monitor and assess changes in the prevalence of open defecation as a proxy for latrine use (Kar and Chambers 2008).

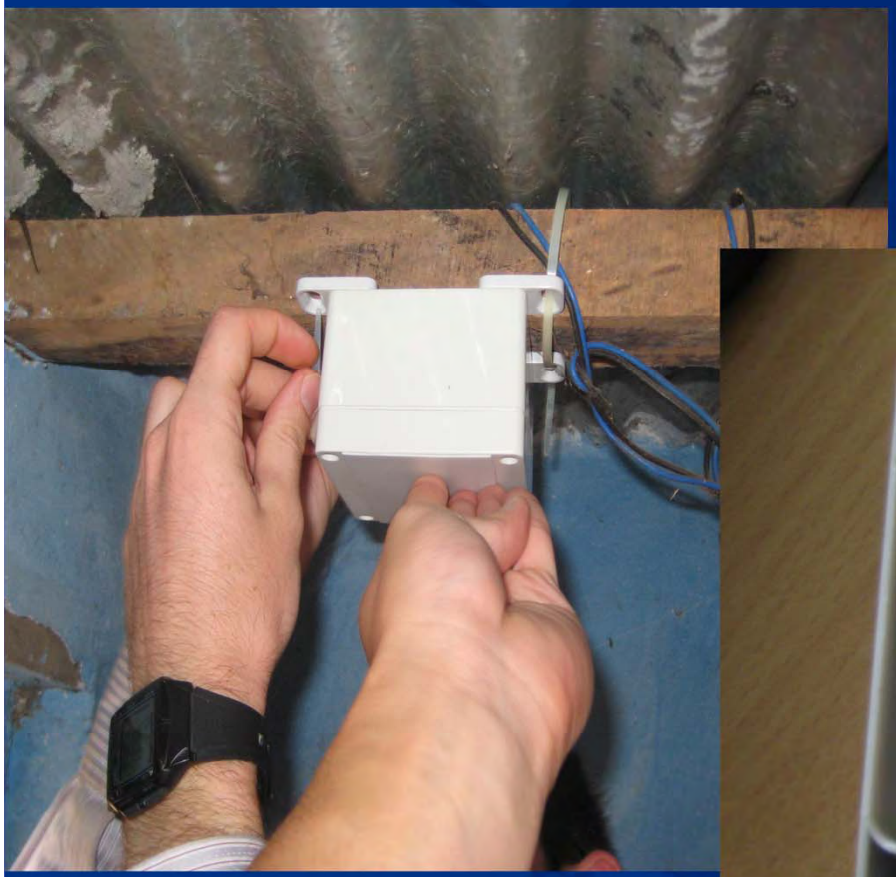
Design Parameters for New Device

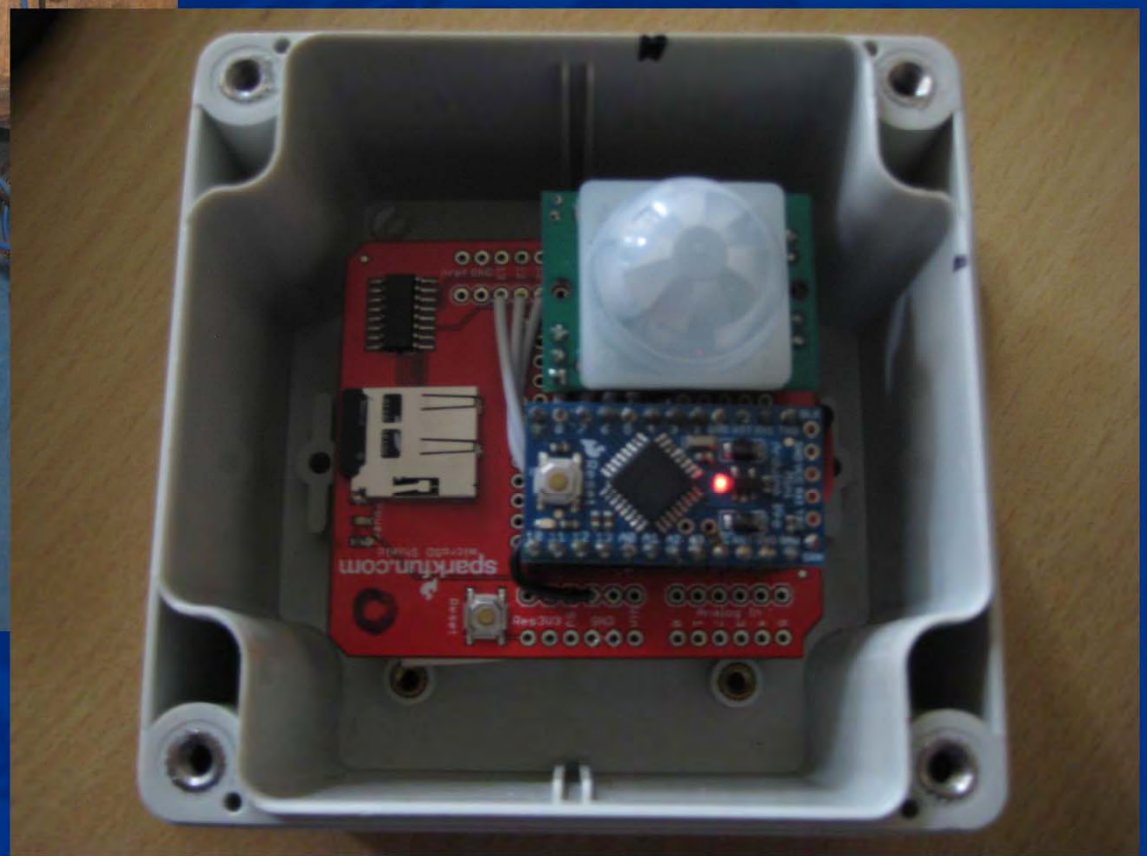
- Discretely detect and accurately record the use of most types of individual household latrines for up to 14 days.
- Weather and tamper resistant, battery powered, easily installed/removed, acceptable to householders, and sufficiently low in cost for use in research and programme assessment.

Options Investigated

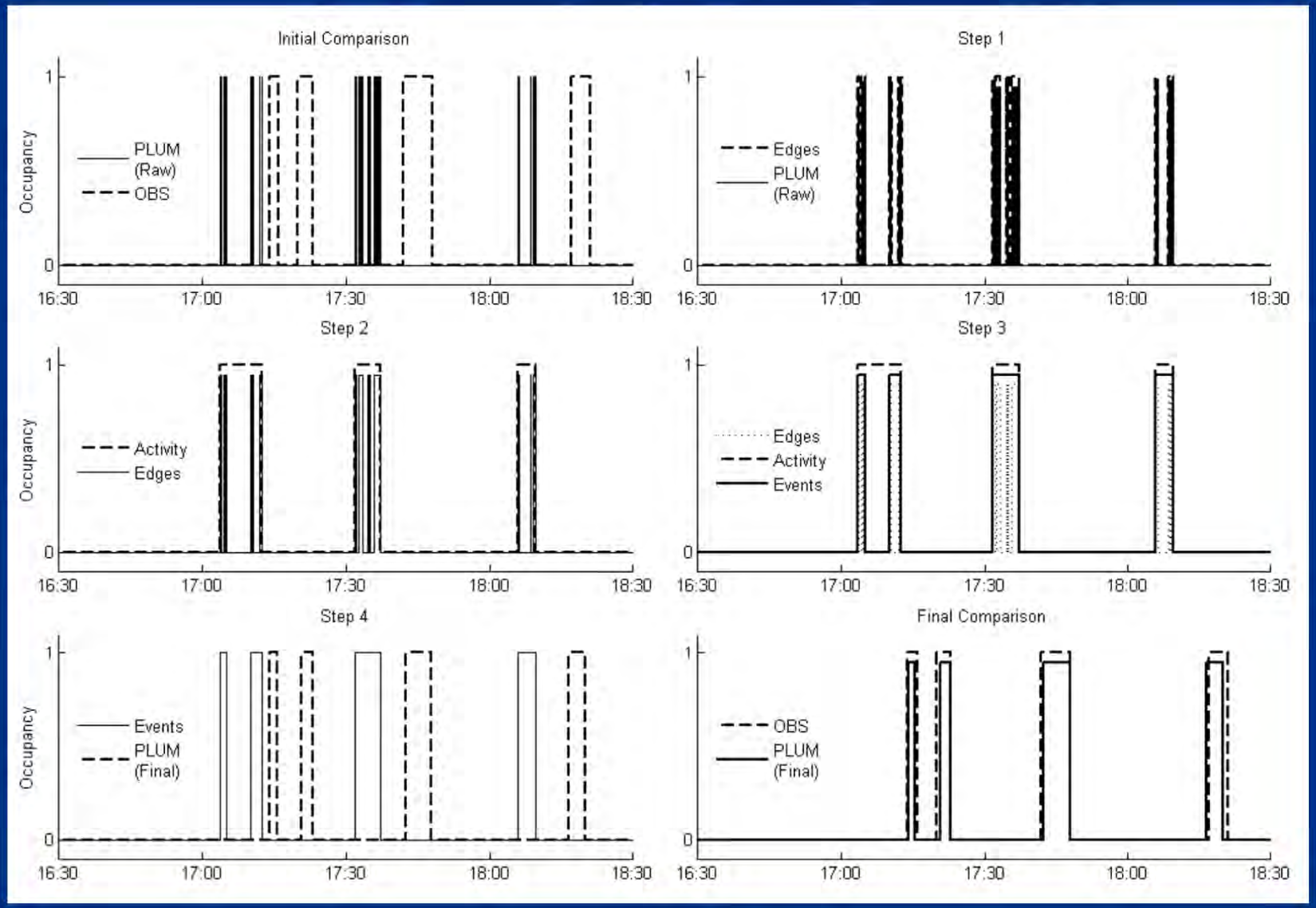
Device	Issue
Door monitors	Multiple door types; no doors
Active infrared	Not robust for conditions
Video cameras	Privacy, cost
Pressure mats	Not robust for conditions
Slab-embedded sensors	Cost, logistics, not suitable for retro-fit
Berkeley TAMS	Cost, compliance

Passive Latrine Use Monitor (PLUM)

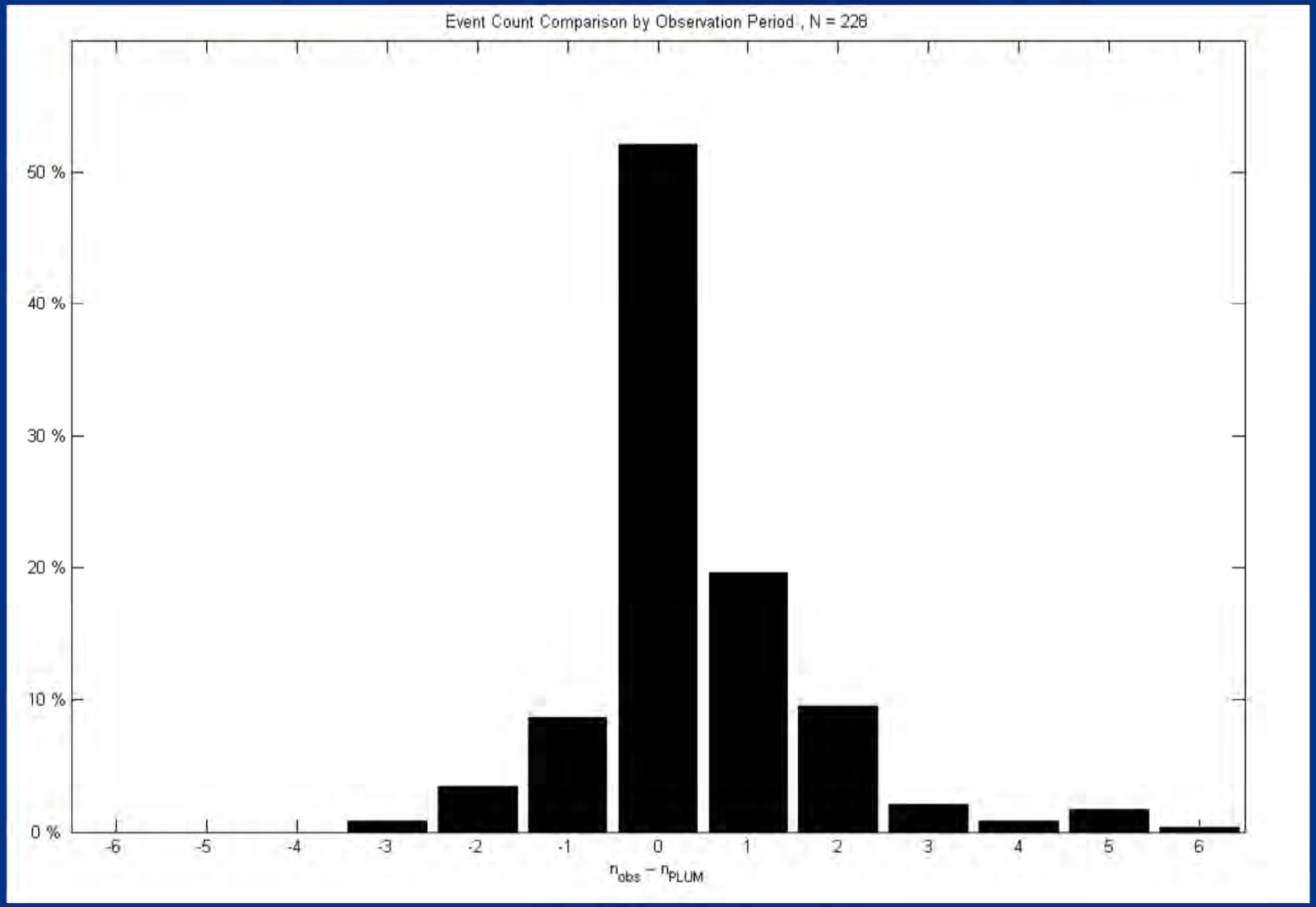




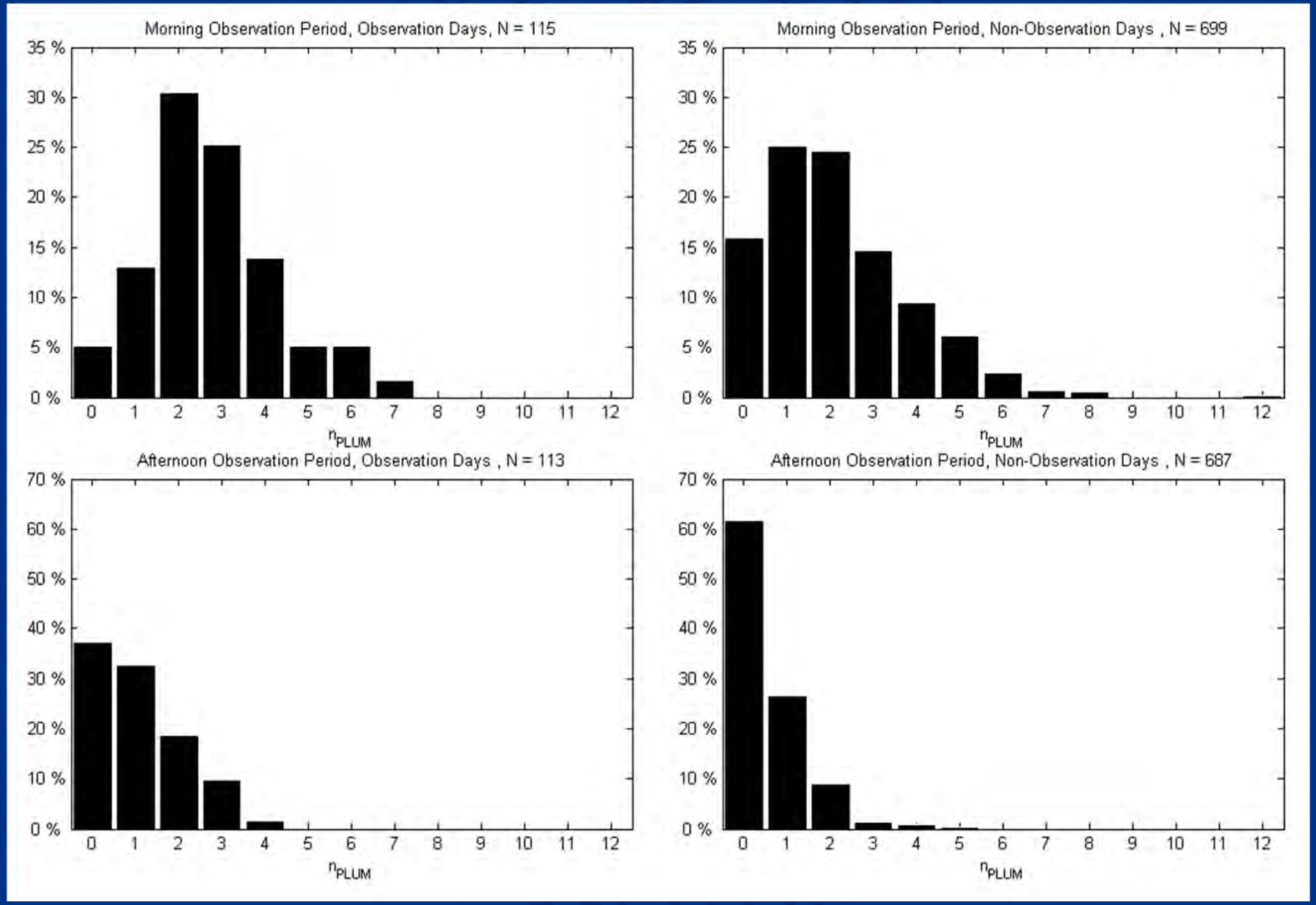
Developing Algorithm for PLUM Data



Comparison of SO and PLUM results



Hawthorne Effect of SO



Summary: Key Aspects of Study

- Effectiveness evaluation of an actual intervention
- Set in high diarrhoeal disease, low sanitation rural India
- Comprehensive process evaluation of actual intervention
- Rigorous RCT study design
- Reasonably large scale (100 villages, 3500 households) and long-term (3 year study with 21 month surveillance)
- Powered to assess diarrhoea in <5s
- Objective outcomes (WAZ and helminth infection) to address lack of blinding

Summary: Key Aspects of Study (2)

- Important non-health outcomes
  - Cost, cost-savings and cost-effectiveness
  - School absenteeism
  - Health-seeking behavior
- Continuous monitoring of intermediate outcomes
  - Drinking water quality
  - Village and household-level environmental exposure
  - Mechanical and biological vectors
- Continuous and innovative monitoring of latrine use
- Spatial analysis to assess spill-over effect

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