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Evaluating the Role of Sanitation in Improving Child Health and Nutrition: Does it Matter and Can We Make it Count?

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#### Evaluating the Role of Sanitation in Improving Child Health and Nutrition: Does it Matter and Can We Make it Count?

by

Sumeet Rajshekhar Patil

A dissertation submitted in partial satisfaction of the requirements for the degree of Doctor of Philosophy

in

Epidemiology

in the

Graduate Division

of the

University of California, Berkeley

Committee in charge:

Professor John M. Colford, Jr., Chair Professor Paul J. Gertler Professor Alan E. Hubbard

Spring 2016

### Abstract

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Sumeet Rajshekhar Patil

Doctor of Philosophy in Epidemiology

University of California, Berkeley

Professor John M. Colford, Jr., Chair

Poor water, sanitation and hygiene (WASH) infrastructure and behaviors are believed to be the major contributors to the worldwide burden of diarrheal diseases and parasite infections; the second most leading cause of deaths among children under 5 years of age in developing and under-developed countries. India alone accounts for a third of those without improved sanitation (814 million), nearly 60% of those who practice open defecation (626 million), 25% of the world's deaths from diarrheal diseases among children under 5 years of age and approximately one third of the stunted children globally. Compared to this staggering burden of poor WASH in India, research on which WASH interventions are efficacious is limited particularly on sanitation.

This dissertation seeks to bridge some of the gaps in sanitation public health research by answering following three questions.

*Does India's Total Sanitation Campaign (TSC) – one of the largest rural sanitation program in the world – deliver the hypothesized health benefits of improved sanitation to pre-school age children in India?* I use a cluster randomized controlled trial to evaluate the effectiveness of the TSC in terms of prevalence of diarrhea, highly credible gastrointestinal infections, parasitic infections, anemia and child growth in terms of age adjusted height, weight and arm circumference. The sample consists of 5239 children under the age of 5 years from 80 villages in Dhar and Kargone districts of Madhya Pradesh state. I find that while the TSC almost doubled the coverage of private toilets (41% in the intervention group vs. 19% in the control group), the relative reduction in the open defecation rate was small and remained high in absolute magnitude (73% in the intervention group vs. 83% in the control group). Possibly due to inadequate reduction in open defecation levels, the TSC did not improve health of children under the age of 5 years in terms of above health outcome indicators.

*Can the private toilet coverage increase substantially by reducing the price of the toilets through subsidies?* Subsidies are a cornerstone of India's TSC to increase private toilet coverage however little is known whether and to what extend these subsidies can increase the toilet coverage. I estimate the arc price elasticity of demand for private toilets using the data

from the TSC trial in Madhya Pradesh. Taking advantage of variation in the level of subsidies offered by the Government of Madhya Pradesh to build private toilets, I find that the price elasticity of toilet demand is 0.91 so that if the price of a private toilet is reduced from ₹18000 to ₹6000 as per the new sanitation program norms in India, the private toilet coverage in rural India can increase from 30% (as per Census 2011 data) to 80%. However, using data from another experimental efficacy trial in Odisha of a pilot sanitation program that consisted of intensive behavior change, I find that the price elasticity is 0.26 and statistically not different from 0. The findings provide an evidence that the demand for private toilets is inelastic and reducing the price of toilets through subsidies may not be enough to increase the toilet coverage. Whether the built toilets be used regularly resulting in drastic reductions in open defecation levels, and whether this reduction in open defecation will result in improved health outcomes for children still remain unanswered.

What are the importance of risk factors including owning a private toilet in explaining linear growth faltering among children aged 6-24 months? I propose and apply a variable importance analysis method using SuperLearner — a machine learning based ensemble algorithm — to objectively and non-parametrically model the relationship between HAZ and 51 risk factors related to child nutrition, pre- and post-natal care, mothers' health and nutrition, household socioeconomics, and water and sanitation. I also apply a new estimator called Targeted Maximum Likelihood Estimator to estimate the magnitude and standard error of variable importance measures.

I apply the proposed method the nationally representative Demographic and Health Survey data from India as a case study application. Subject to the available data and model limitations, I find that the following are main risk factors for stunting: mother of short stature (< 145 centimeter height); child not fed as per the WHO recommended guidelines; boiling drinking water; and children second or later in the birth order. I find that access to private sanitation explained -0.09 Z loss in HAZ which is a much smaller importance than above variables. However, the importance of sanitation may be underestimated because access to private toilet is an underestimate or poor indicator of reduction in open defecation or the reduction in exposure to enteric pathogens in the community.

I conclude my dissertation by underlying the need for more evidence based advocacy, design and implementation of sanitation programs than what was done over the past 20 years, and flag some of the important consideration in design of future studies based on the insights gained in developing this dissertation.

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## **Chapter 1: Introduction**

#### 1.1 Background

Lack of adequate and safe water supply, sanitation, and hygiene (WASH) is considered as a predominant cause of child mortality and morbidity in both developing and under developed countries. Prüss-Üstün and colleagues [1] identified that 5.48 percent of all deaths and 7.67 percent of the disability adjusted life years (DALYs) lost in developing countries are due to poor WASH related diarrheal diseases and parasite infestations. In children under five years of age, diarrhea alone accounts for approximately 18%, or 1.9 million deaths (including 0.23 million neonatal deaths) [2]; second leading cause of child mortality after pneumonia. The burden of poor WASH and waterborne diseases is nowhere as acute as in India, which alone accounts for a third of those without improved sanitation (814 million), nearly 60% of those who practice open defecation (626 million) [3] and 25% of the world's deaths from diarrheal diseases among children under five years of age. Almost 385,000 children under five years-old die each year from diarrheal diseases [4].

The morbidity due to diarrheal diseases is also staggering in India. A national household survey in 2005-06 found that the two-week period prevalence of diarrhea in children under three years of age was 12% [5]; that is, more than 14 million children suffered diarrhea in a two week period. Frequent diarrhea episodes can result in malnutrition, limited growth of a child, and over long term, can compromise the education and livelihood potential of a child. However, most of the morbidity and mortality due to poor WASH practices is considered preventable [4]. In fact, the World Health organization (WHO) estimated that 94 percent of diarrheal cases are preventable by improving WASH infrastructure and behaviors [6].

Public health and development agencies and the governments have responded to the challenge of poor WASH by committing to, and improving, the WASH infrastructure in developing countries. One of the Millennium Development Goals (MDG) were to reduce the population lacking sustainable access to safe drinking water and basic sanitation in half by 2015 [7]. The targets in the Government of India's Eleventh Five Year Plan (2007-2012) even exceeded MDG targets to envision universal access to potable drinking water in 2009 and ending open defecation by 2012 (which has been now revised to 2019). However, the actual improvements on the ground are grossly lagging behind the targets, especially for the sanitation targets. While 87% of India's households accessed improved drinking sources such as taps, protected springs, covered wells, or hand pumps [8], only 30% of the rural Indian population had access to a private toilet. Between 2001 and 2011, the proportion of households in India without access to any sanitation (toilet) facility fell only from 78.3% to 69.3% [8]; that is, more than half a billion people in India have no access to a basic toilet even today.

#### 1.1.1 Mixed and Poor Quality Evidence on What Works

Although inadequate WASH infrastructure is a concern in spite of billions of dollars of investments over last two decades, the lack of rigorous and high quality research to guide which mechanisms or programs can improve the WASH conditions is equally discomforting. While the available evidence suggests that WASH as a broad concept is effective in preventing over 90% of the waterborne diseases [4], which specific components – either alone or in combination – are

most effective and which programs can deliver these components at scale is less understood. Below, I summarize key insights from five systematic reviews or meta-analyses to suggest that the evidence of effectiveness of different WASH components or interventions is mixed, often based on poorly designed studies, and suffers from publication bias in favor of few interventions.

Fewtrell and colleagues [9] conducted a systematic review and meta-analysis of 62 studies between 1986 and 2003 and estimated the Relative Risk (RR) of different interventions in reducing diarrhea (See Figure 1-1). They found that handwashing and/or hygiene education and point of use water treatment are the most effective interventions, but the authors also found evidence of a publication bias. Piped water supply and source water quality interventions were the least effective in reducing diarrhea, but the meta-analysis could include only two studies of these interventions fit to be included in the analysis. Similarly, only two studies on toilet could be included in the meta-analysis.





\*Number of studies are reported in parenthesis next to intervention categories **Source:** Prepared using results from Fewtrell *et al.*, 2005 [9]

Subsequent systematic reviews and meta-analyses echoed these findings. Arnold and Colford pooled 21 studies to find a strong effect of chlorine disinfection at a household level on child diarrhea risk (pooled relative risk was 0.71) and E. coli contamination of drinking water (pooled relative risk was 0.20) [10]. On the other hand, Schmidt and Cairncross found no health effects across five placebo-controlled trials of water treatment interventions, and concluded that the widespread promotion of household water treatment is premature given the available evidence [11]. Aiello and colleagues reviewed 30 experimental and quasi-experimental trials, reporting

that handwashing reduced gastrointestinal illness (RR of 0.31) and respiratory illness (RR of 0.21), but they also identified evidence of publication bias [12]. Cairncross and colleagues reviewed three systematic reviews to reaffirm that most of the available evidence was of poor quality including inadequate sample size and lack of external validity [13]. A meta-analysis by Waddington and colleagues of 61 impact evaluation studies found strong evidence of publication bias in favor of the water quality interventions, and only a few rigorous evaluations of multiple interventions and sanitation [14]. Additionally, they identified a lack of long term effectiveness trials as well as a lack of trials with strong external validity as key limitations of existing WASH research.

#### 1.1.2 Scarce WASH Research in India

While the global WASH research suffers from several gaps and weaknesses, the WASH research in India is not only of poor quality, it is also severely limited in scope [15]. This contrast is especially stark when we consider the burden of poor WASH in terms high mortality and morbidity from waterborne diseases in India. There are a few peer-reviewed studies evaluating WASH interventions in India, however, these are mainly observational or ecological scale analyses. Most of the existing research is in Africa and Bangladesh but rarely in India, as reported in Table 1-1.

Systematic Review and Meta-Analyses	Total Studies Included	Studies from India
Fewtrell <i>et al.</i> (2005) <b>[9]</b>	62	3
Arnold and Colford (2007) [10]	22	0
Waddington <i>et al.</i> (2009) <b>[16]</b>	61	5
Aiello et al. (2008) [12]	30	0
Clasen <i>et al.</i> (2007) <b>[17]</b>	32	0

 Table 1-1. Number of Studies from India in Systematic Reviews and Meta-Analyses

#### 1.2 Motivation, Research Questions, and Their Importance

The overarching motivation for my research questions is contribute to the thin evidence base on effectiveness of sanitation interventions by answering the following three specific research questions. I answer these questions in the context of one of the largest rural sanitation programs in the World: India's Total Sanitation Campaign (TSC).

#### 1.2.1 How Effective is the TSC in improving health and growth of Pre-School Children?

In spite of billions of dollars in investments every year, there were no randomized control trials (RCT) or even quasi-experimental trials of any large-scale sanitation program in the world. In a first published RCT of a large sanitation program, I evaluate the effectiveness of the Total Sanitation Campaign (TSC) in the state of Madhya Pradesh in terms of child health (diarrhea, highly credible gastrointestinal infections [HCGI], parasitic infections, anemia, and child anthropometry). The findings highlight that while sanitation as a broad concept is an important public health intervention [18], the TSC that delivers private non-networked toilets in rural area may not deliver health benefits. Two competing theories can explain the null effect of the TSC.

First, the TSC may not have increased the private toilet coverage and correspondingly reduced open defecation levels *adequately enough* to deliver the health impacts. Human feces is a source of enteric pathogens so that safe containment and treatment of human feces is expected to reduce the exposure to enteric pathogens and thus improve child health. However, this exposure depends on the efficacy of the toilets constructed under the TSC to contain the feces and the level of reduction in the open defecation levels in the community. Indeed, this rationale was the prime motivation behind the TSC's goal to increase the private toilet overage to 100% and eliminate open defecation was far from universal in the intervention communities, and thus, finding of null effect was probably expected. My second research question is motivated by this theory and seeks to find if and how the toilet construction subsidies under the TSC increase toilet coverage.

Second, community coverage of non-networked private toilet may not be an important "sanitation" pathway to improve child health and growth in the rural Indian population within the short follow up period of less than a year. Other risk factors or pathways such as a mother's nutrition, pre and post-natal care for the mother and child, child nutrition, child care in the house, household's wealth, access to improved (and safe) water sources, access to underground sewerage system for waste water management, sold waste management, access to and use of public toilets connected to safe sewer systems, and more can play a dominant role than access to and use of private non-networked toilets. My third research question is motivated by this theory and seeks to find the importance of several risk factors including the access to private toilets in explaining linear growth of children.

# **1.2.2** Can Sanitation Coverage in Rural India Increase "Enough" by Increasing Subsidies to Private Toilets?

This research question is aligned with my "third" area of specialization– health economics and policy.

Poor households in developing countries often lack the financial ability to improve their WASH infrastructure even if they want to [19] and thus financial support is a mainstay of several development interventions including the TSC. The TSC provided construction subsidies to the Below Poverty Line (BPL) households in terms of materials, payments to masons, and wages for households own labor to poorer households to help them build a private toilet. While the government believed that the subsidies spur the demand for toilets, some behavior change theorist, especially the proponents of Community Led Total Sanitation (CLTS), argue that the private toilet subsidies are counterproductive and may result in lower use of toilet built using subsidies [20]. Unfortunately, there are no published economic studies to analyze the effect of subsidies or toilet price on the demand for private toilets to support or disprove either of the above claims. I seek to provide what may be the only available estimate of the price elasticity of the demand for private toilets using the data from the TSC trial in Madhya Pradesh.

# **1.2.3** What is the Importance of Risk Factors including Owning a Private Toilet in Explaining Height of Children Aged 6-24 months?

Linear growth (height) faltering or stunting is an indicator of chronic malnutrition caused by a vicious cycle of inadequate nutrition and diseases [21]. Some of the recent studies strongly associate lack of sanitation (more accurately, access to private toilets) to stunting among pre-school age children [22–25]. However, there has not been any systematic attempt to compare the relative importance of multiple risk factors that can cause growth faltering such as child feeding and nutrition, ante- and post-natal care, mother's nutrition, child caring during initial years and more including various other aspects of sanitation such as solid waste and waste water disposal. Study of one or a few risk factors without considering others can unknowingly skew the "call for action" in favor of such limited set of risk factors. This can be disastrous if the most efficacious intervention(s) falls behind in the advocacy only because it had no champion to research it.

I argue that the prioritization of research or program design and implementation to reduce chronic malnutrition should be conducted in a more objective, transparent and rigorous manner by giving a fair chance to competing risk factors. I propose and apply a variable importance analysis method using non-parametric machine learning algorithms to model the relationship between the risk factors and the age and sex standardized height-for-age Z scores (HAZ) as well as using a double robust estimator that can estimate a standard error of the variable importance measure to aid statistical inference. I apply this method to 51 risk factors constructed using the publically available Demographic and Health Survey (DHS) data from India. I further critically compare magnitudes and standard errors of the variable importance measures estimated using the proposed method with those estimated using traditional multiple regression analysis with maximum likelihood estimator.

#### 1.3 Ethics

I use publically and freely available datasets with de-identified records for my research, which, by definition, are exempt from Institutional Review Board (IRB) review as per 45 CFR 46.102(f). The TSC trial in Madhya Pradesh was commissioned by the Water and Sanitation Program of the World Bank. The study protocol was approved by the Western Institutional Review Board (IRB) located in Olympia, Washington, USA (Study No 1095420). Additionally, the India study protocol was locally reviewed and approved by the Independent Ethics Committee based in Mumbai, India. While I was involved in the design and implementation of the study, an independent survey firm collected the data, and the Word Bank made the de-identified data available to me for data analysis. Another dataset I use in this dissertation is the DHS data for India for the year 2005-06. The DHS program, funded by USAID, collects nationally representative data from several developing countries. This data is also freely available and de-identified.

I have completed:

- Certification from Collaborative Institutional Training Initiative (CITI) as affiliate of the University of California at Berkeley: Investigator ID # 4112406. Reference No. # 13775060; dated 25 August 2014; and
- 2. National Institute of Health web-based training on "Protecting Human Research Participants". Certificate ID # 1460198; dated 1 May 2014.

#### **1.4 Organization of the Dissertation**

This dissertation is organized as follows:

- 1. Chapter 2 presents the design, implementation and findings from the RCT of the TSC in Madhya Pradesh;
- 2. Chapter 3 presents the method to estimate the arc price elasticity of demand for private toilets using the data from the TSC trial in Madhya Pradesh, and discuss the findings and their policy implications;
- 3. Chapter 4 presents the proposed method to conduct variable importance analysis and presents a case study application using DHS data for India; and
- 4. Chapter 5 concludes by summarizing the findings from above three chapters and discussing key learnings.

## Chapter 2: How Effective is the Total Sanitation Campaign in Reducing Waterborne Diseases and Improving Growth of Pre-School Children?

#### 2.1 Introduction

Observational studies of interventions that prevent human feces from entering the environment have been shown to reduce diarrheal disease [17,26] and enteric parasite infections [27–29]. Most of this research, however, has focused on the provision of sewerage systems in urban centers. However, provision and maintenance of networked sewerage is prohibitively expensive in rural areas. Consequently, most government and donor financing in the rural sanitation sector focuses on the provision of non-networked toilets. Despite the wide scale deployment of such programs, to our knowledge there have been no published randomized trials to measure the effect of rural sanitation programs on diarrheal diseases, intestinal parasite infections, anemia, or growth in young children.

The objective of this study was to measure the effect of India's Total Sanitation Campaign (TSC) in rural Madhya Pradesh on household availability of improved sanitation facilities as defined by WHO/UNICEF Joint Monitoring Program (JMP) for water and sanitation [30], open defecation behaviors of household members, water quality, and child health (diarrheal diseases, highly credible gastrointestinal illness [HCGI], enteric parasite infections, anemia, and growth). The TSC, scaled up to all districts in India and deployed to hundreds of millions of people, is possibly the largest rural sanitation program in the world. As a part of their Total Sanitation and Sanitation Marketing (TSSM) project, the Water and Sanitation Program (WSP; the World Bank) provided capacity building support to ten districts of Madhya Pradesh to strengthen the implementation of the program. In two of these ten districts, we studied the effects of the TSC implemented with support from the WSP under the TSSM project using a cluster-randomized controlled trial in 80 rural villages.

We hypothesized that the program would increase availability of individual household latrines (IHLs) and reduce the practice of open defecation in a community through use of IHLs. On the basis of previous research [17,26,28,29], we further hypothesized that less open defecation would: (i) reduce the quantity of feces in the environment that could contaminate shallow groundwater aquifers, water distribution networks, and soil in the community, and (ii) also reduce enteric pathogen transmission through flies, which are well-established vectors for transmission [31–33]. Conditional on improvements in these intermediate outcomes, we hypothesized that children < 24 months at enrollment in intervention villages would have a lower prevalence of diarrhea, HCGI, enteric parasite infections, and anemia when measured after the intervention. Finally, we hypothesized that the program would improve average weight-for-age and height-for-age in these young children as a result of fewer symptomatic and asymptomatic enteric infections over longer exposure periods to improved sanitation [23,34–37]. The above hypothesized causal chain between the intervention and health outcomes is depicted in Figure 2-1.



Figure 2-1. Logic Model of Total Sanitation Campaign

#### 2.2 Methods

#### 2.2.1 Trial Design

The study design was a cluster randomized controlled trial with randomization at the village level and equal allocation to the two treatment arms. The study population included 80 villages from two neighboring districts in Madhya Pradesh: Dhar and Khargone. The villages randomized to the intervention group received the TSC program and villages in the control group did not receive the TSC until after the study. As a demand driven program, the district administration was duty bound to provide the program to the villages in the control group if they requested it and if the funding was available. The district administration agreed to provide the program to all control villages after the completion of the study. The study measured outcomes, anticipated confounders, and covariates at household and child levels both before and after the intervention in two survey waves. The follow-up survey was administered to the same households who participated in baseline data collection and additional households were included at follow-up (see the section on Sample Size for details).

#### 2.2.2 Study Population

Table 2-1 describes population characteristics for the study region relative to the state and national population on the basis of India's 2011 Census. Overall, Madhya Pradesh is one of the less developed states of India, including its water and sanitation infrastructure. The study districts are more agricultural, with higher proportion of marginalized population groups and lower literacy than the state average, but with better water supply and drainage infrastructure. IHL coverage (percentage of households with access to IHL) in rural areas of study districts (19.2% in Dhar and 13% in Khargone) is comparable to the state average (13.1%) but much worse than the country average (30.7%). The IHLs are predominantly the types included in the JMP definition of improved sanitation [30]. On average the IHL coverage across India increased by approximately 10% between 2001 and the 2011 Census. However, the change in the IHL

coverage between 2001 and 2011 varied widely between states and between districts within each state [38].

Indicators	India	Madhya Pradesh	Dhar District	Khargone District
Population and occupations		Tradesh	District	District
Total population	1.210.569.573	72.626.809	2.185.793	1.873.046
Rural population	833.463.448	52,557,404	1.772.572	1,574,190
Percent rural population	68.80	72.40	81.10	84.00
Percent 0–6 years children (of rural population)	14.60	15.80	16.90	16.60
Percent SCST (of rural population)	29.70	42.90	70.60	55.80
Percent literates (of >6 years rural population)	67.80	63.90	54.10	58.90
Percent of cultivators (of rural workers)	33.00	38.30	42.90	38.30
Percent of agriculture laborers (of rural workers)	39.30	47.30	47.70	52.20
Percent of other occupations (of rural workers)	27.70	14.40	9.40	9.50
Water and sanitation				
Number of rural households (RHHs)	167,826,730	11,122,365	339,844	309,603
Percent RHHs with permanent/good house construction	45.90	33.40	38.90	31.50
Percent RHHs with improved drinking water source <sup>a</sup>	84.30	74.10	79.90	84.20
Percent RHHs with access to tap water (on premise or away)	30.80	9.90	19.70	41.10
Percent RHHs with on premise water source (any type)	35.00	13.00	13.50	24.60
Percent RHHs with bathing rooms	45.00	34.00	38.10	50.40
Percent RHHs with closed drainage	5.70	2.10	3.20	4.20
Percent RHHs with open drainage	31.00	23.10	24.00	43.30
Latrine availability				
Percent RHHs with on-premise latrine <sup>b</sup>	30.73	13.12	19.17	13.00
Flush toilet connected to piped sewer system	2.20	0.80	1.43	1.15
Flush toilet connected to septic tank	14.70	8.32	12.91	9.07
Flush toilet connected to other system	2.53	1.26	1.25	0.70
Pit latrine with slab/ ventilated improved pit	8.19	1.79	2.23	1.50
Pit latrine without slab/open pit	2.34	0.76	1.12	0.41
Toilets disposing waste to open drain	0.22	0.10	0.13	0.07
Serviced toilets where waste is removed by humans	0.35	0.03	0.03	0.02
Serviced toilets where waste is removed by animals	0.19	0.07	0.06	0.08
Percent RHHs with access to public toilets	1.94	0.46	0.68	0.36
Percent RHHs with no toilet / open site (2011)	67.33	86.42	80.15	86.65
Percent RHHs with no toilet / open site (2001)	78.10	91.10	86.40	91.10

Table 2-1. Census statistics for India, Madhya Pradesh, and study districts.

<sup>a</sup>Improved drinking water sources include tap water, covered well, hand pump, and tube well as defined by Census of India, 2011

<sup>b</sup>On premise latrines are also referred to as IHLs. The first four types of toilets—flush toilets connected to sewer system, septic tank or other systems, and pit latrine slab and/or ventilated improved pit—are a subset of latrine types included in the definition of improved sanitation by WHO/UNICEF JMP for water and sanitation [39].

SCST, Schedule Caste or Schedule Tribe (marginalized population group); RHH, rural household.

Study villages were selected in collaboration with the Madhya Pradesh state government. Madhya Pradesh is divided into 50 districts, 313 Blocks, and 23,040 *Gram Panchayats* (referred to as "villages" in this dissertation). A *Gram Panchayat* is the smallest Indian administrative unit and has a local elected body. The 80 study villages were the independent units selected in three steps. First, through a series of meetings and site visits, the state government and the WSP selected two of 50 districts in Madhya Pradesh: Dhar and Khargone. Second, 11 of 13 Blocks from Dhar and eight of nine Blocks from Khargone were selected for the study. The remaining Blocks were excluded from the sample frame because all villages from these Blocks were earmarked for the TSC program, precluding the enrollment of control villages. Third, in each administrative Block the government identified villages where they were amendable to randomizing the TSC program.

In each of the 80 study villages, the field team listed and mapped 200 households and randomly selected 25 households with at least one child < 24 months of age at enrollment. If a village had multiple sub-villages, then to avoid spreading the sample too thin, the survey team selected the most populous two to three sub-villages for the listing purposes. From the numbered list of eligible households, a random starting number was chosen and thereafter every  $n^{\text{th}}$  household number was selected where *n* was determined by dividing eligible number of households by 25. For the follow-up survey we increased the sample size of households per village from 25 to 38 (see section on Sample Size). Additional 100 to 150 households were listed and mapped before the follow-up survey to select additional households. Figure 2 summarizes loss to follow-up in the original cohort and recruitment of new households in the follow-up survey. Because we conducted the follow-up survey 21 months after baseline, the eligibility criteria for newly enrolled households was that they had at least one child between the ages of 21 months and 45 months and were living in the village at the time of the baseline survey to be commensurate with the eligibility criteria for the original cohort. Child caregivers were the main survey respondents, but household heads or other elders occasionally answered questions related to household characteristics.

#### 2.2.3 Intervention Program

India's TSC, initiated in 1999, was an ambitious program with a goal to eliminate the practice of open defecation in India by 2012. In 2012, the government transformed TSC into a new program named *Nirmal Bharat Abhiyaan* (Clean India Campaign). The TSC included subsidies for and promotion of IHLs that can safely confine feces (similar to JMP defined improved sanitation facilities), school sanitation and hygiene education, *Anganwadi* (preschool) toilets, and community sanitation complexes. The TSC also supported rural sanitary marts and production centers to provide good quality but affordable material for toilet construction. Additionally, the TSC included several features such as ongoing social mobilization and behavior change activities at state, district, and village levels, flexible technology options for toilets, and a community award called the *Nirmal Gram Puraskar* (NGP) given to communities that were determined to be "open defecation free"—defined as a community where all households have and use IHLs that can safely confine feces—and meet all of the other "total sanitation" requirements defined by Indian government. The NGP awards ranged from Rs 50,000 (US\$1,000) to Rs 500,000 (US\$10,000) for villages, up to Rs 2,000,000 (US\$40,000) for Blocks, and Rs 5,000,000 (US\$100,000) for districts.

In Madhya Pradesh, the TSC was implemented with a concurrent program named *Nirmal Watika* (Clean House) under the National Rural Employment Guarantee Scheme (NREGS) to provide additional financial and material subsidies to households. TSC and *Nirmal Watika* together provided at least Rs 4,200 (US\$84) to below poverty line (BPL) households in the village. The Indian Ministry of Rural Development classifies households as BPL using characteristics such as land holdings, house type, consumer durables, and literacy [40]. BPL households were identified in this study by their ration card color (a document used to access public food and grain distribution system). While the TSC provided subsidy of Rs 2,200 (US\$44) to BPL households, *Nirmal Watika* provided additional at least Rs 2,000 (US\$40) to BPL and non-BPL households both to support IHL construction. These costs were determined by the government to be adequate to construct an offset two-pit latrine with water sealed squat plate and a brick walled room (which will be a JMP defined improved sanitation facility), and this type of latrine was actively promoted in the study districts.

Beginning in 2006, the WSP India office supported the TSC program under the TSSM project in ten districts in Madhya Pradesh. The WSP worked with local authorities to create an enabling environment for the TSC activities, to develop local implementation capacities at the district level, and to support the use of monitoring systems to assess progress towards the TSC goals. WSP promoted and provided capacity building support to implement community-led total sanitation (CLTS) based behavior change methods [20]. The CLTS methodology involves a series of community "triggering" exercises, led by an external facilitator after building rapport with the community in the pre-triggering phase, which highlight the magnitude of the practice of open defecation, elicit shame and disgust, and mobilize community action to end open defecation [20]. These triggering activities are followed by community follow-up actions that are supported by facilitators. Although the intervention used CLTS based tools for behavior change, it cannot be considered as a classical CLTS intervention. CLTS principles require that no hardware subsidies be provided to individual households and specific latrine models not be prescribed [20], whereas the intervention provided hardware subsidies to individual households to build offset pit latrine designs approved under the Nirmal Watika program. Provision of hardware subsidy as a post-construction incentive was advocated by the WSP, but the mechanisms of the convergence of Nirmal Watika and the TSC essentially meant that the subsidies were released before and during but rarely after IHL construction.

The TSC program in the study areas was implemented by the village government (*Gram Panchayat*) with support from district and block administration personnel or consultants. The study investigators and staff were not involved in program implementation.

#### 2.2.4 Outcome Definition and Measurement

The study measured outcomes using a combination of structured questionnaires and observations, sampling and testing of drinking water, child anthropometry and specimen (stool and blood) testing. GfK Mode Pvt Ltd. was contracted to conduct the fieldwork. The baseline survey was conducted between 25 May and 18 July, 2009, and the follow-up survey was conducted between 23 February and 25 April, 2011. Questionnaires used in the follow-up survey were the same as those used in the baseline survey with some additional questions to measure program exposure and outcomes. The household questionnaire collected information about household socioeconomics, demographics, exposure to the TSC activities, water and sanitation

infrastructure, sanitation- and hygiene-related behaviors, and health/diseases. Interviewers conducted standardized spot-check observations of dwelling sanitation and hygiene facilities. Defecation behavior was reported by adults during private, in-home interviews. Main outcomes were defined as follows.

**Toilets, open defecation, hygienic conditions**. We classified household sanitation facilities using questions and definitions proposed by the JMP [30]. JMP-defined improved sanitation includes flush/pour flush toilet connected to piped sewer, to septic tank or to offset pit, ventilated improved pit latrine, on-pit latrine with slab and composting toilet that can hygienically separate human excreta from human contact. However, it is possible that the households build rudimentary latrines that are not included in the JMP definition of improved sanitation. For example, in addition to no facility or open defecation, the JMP defined unimproved sanitation facilities include flush toilets disposing waste elsewhere, pit latrine without a slab (open hole), bucket latrine, hanging latrine, and shared toilets of any type. We also report availability of all types of IHLs whether improved or unimproved to assess whether the households moved up the sanitation ladder from no facility to some type of latrine even if unimproved. To assess defecation behavior for men, women, and children (<5 years), interviewers asked households separately for each group whether they openly defecate daily/always, occasionally/seasonally, or never. Interviewers also asked about child feces disposal using the standard JMP question [30]; disposal in a toilet, a confined pit, or buried was classified as hygienic. Field staff also observed whether the IHLs (of any type if present) were being used on the basis of worn path, closable door, odor, anal cleaning material, and water to flush. Field staff also recorded any observed human or animal feces in the household living area.

**Caregiver reported illness**. The study's primary outcome was diarrhea and HCGI among children < 5 years old. We defined diarrhea as  $\geq$  3 loose or watery stools in 24 hours, or a single stool with blood/mucus [41] with a 7-day recall period [42] using a previously published instrument [43]. HCGI—a more inclusive measure of enteric infection—was defined as any of the following four conditions: (1) diarrhea; (2) vomiting; (3) soft or watery stool and abdominal cramps occurring together on any day; or (4) nausea and abdominal cramps occurring together on any day; or (4) nausea and abdominal cramps occurring together on any day; or (4) nausea and abdominal cramps occurring together on any day; or (4) nausea and abdominal cramps occurring together on any day [44–47]. We measured respiratory symptoms (constant cough, pulmonary congestion, difficulty breathing, breaths per minute) and defined acute lower respiratory illness (ALRI) as constant cough or difficulty breathing and a raised respiratory rate [48]. We also measured bruising/abrasions and itchy skin/scalp to serve as negative control outcomes [49] to check for differential reporting bias in this unblinded trial [11,50].

**Anthropometry.** We measured children < 24 months at enrollment for height, weight, and midupper arm circumference (MUAC) using a standardized anthropometry protocol [51,52]. Pairs of trained anthropometrists measured child length/height to the nearest 0.1 cm using a portable stadiometer (manufacturer: Seca); children < 24 months were measured in the recumbent (lying) position and older children (at follow-up) were measured standing. Weight was measured to the nearest 0.1 kg using an electronic scale (manufacturer: Tanita); children unable to stand were weighed in their caregiver's arms and the caregiver's weight measured separately. MUAC was measured to the nearest 0.1 cm using a pediatric measuring tape. All measurements were collected in duplicate and we used the average of the two measurements in the analysis. We excluded observations if the two measurements differed by >10% (n = 21 [0.48%] for height, n =85 [1.93%] for weight, n = 23 [0.52%] for MUAC). We converted the anthropometric measurements into Z-scores using the WHO's 2006 growth standards and the WHO publicly available Stata algorithm [53].

**Anemia**. If the caregiver provided informed consent, trained field staff conducted an in-field test for anemia for children between the ages of 6 and 60 months using HemoCue (HemoCue Ltd). We classified children as severely anemic if their hemoglobin concentration was <7.0 g/dl, moderately anemic if their hemoglobin concentration was 7.0-9.9 g/dl, and mildly anemic if their hemoglobin concentration was 10.0-11.9 g/dl [54]. Parents of children who were severely anemic were advised to visit the nearest health facility for medical attention.

**Water quality.** We collected 100 ml stored drinking water samples from a random sample of 404 households in the intervention and 403 households in the control groups, and also collected paired samples from the water source from which the households collected their drinking water (511 source samples). The water samples were collected in sterile containers, labeled, and individually packed in a sterile plastic zip-lock cover provided by the laboratory. The sample collectors were provided with sterile gloves and trained to avoid cross-contamination of water and containers. Water samples were stored and transported in ice boxes and tested for *Escherichia coli* using membrane filtration (100 ml volume filtered) within 36 hours of collection at Envirocare Laboratories Pvt Ltd, Mumbai. The laboratory used HiCrome Agar (M1466) by HiMedia. Each incubation batch included positive and negative control plates. Positive colonies of *E. coli* were further confirmed with Triple Sugar Iron (TSI) agar test and group of Indole, Methyl red, Voges-Proskauer, and Citrate tests (IMViC). Samples below the lower limit of detection were imputed at 0.5 colony forming units (CFU) per 100 ml (half the limit of detection [55]), and samples beyond the upper limit of detection were imputed at the limit of detection (200 CFU/100 ml).

**Child stool parasitology.** At the follow-up survey, we selected a random subsample of 1,150 households from 3,039 households and collected a stool specimen from the oldest child between 21 and <60 months of age. All stool samples were preserved in 10% formalin and analyzed at the National Institute for Cholera and Enteric Diseases in Kolkata. Lab technicians tested the samples for soil transmitted helminthes (*Ascaris lumbricoides, Trichuris trichiura, Ancylostoma duodenale*, and *Necator americanus*) and tapeworm helminthes (*Hymenolepis nana, Taenia sp., Diphyllobothrium latum*) using the Kato-Katz technique [56].

A separate aliquot was analyzed to test for protozoan infections (*Giardia lamblia*, *Cryptosporidium sp., Entamoeba histolytica*) using a commercially available ELISA kit (TechLab) [57,58]. All specimens were tested with a combination of microscopy, ELISA, and PCR to achieve high levels of sensitivity and specificity. If a child tested positive for one of the protozoan infections using either microscopy or ELISA, the result was confirmed using isolated DNA from the ELISA positive samples followed by PCR-restriction fragment length polymorphism (RFLP) methods for genotyping local isolates of giardia ( $\beta$ -giardin), Cryptosporidium (18s rRNA), and *E. histolytica* (SSU rRNA). If a sample tested positive by microscopy or ELISA but was not confirmed by molecular methods then the sample was classified as negative.

#### 2.2.5 Sample Size

The study was originally designed to have 80% power to detect a 4.5 percentage point reduction in diarrhea prevalence among children < 5 years old assuming 15% prevalence in the control group (or a 30% relative reduction) with a two-sided alpha of 5%, and an intra-class correlation of 0.105 [59]. These assumptions led to a design with 40 clusters (villages) per arm and 25 households with children < 24 months per cluster. After the commencement of the study but without knowledge of any study outcomes, we decided to additionally power the trial to detect differences between groups in height-for-age Z-scores on the basis of a hypothesis published on the possible effects of improved hygiene and sanitation on child growth [23]. We reviewed measures of variability and within-cluster correlation of height-for-age Z-scores (SD = 2.09, intra-class correlation = 0.17), and chose to increase the within-cluster sample sizes from 25 to 38 households to ensure the study had 80% power to detect differences of +0.2 Z in height-forage.

#### 2.2.6 Randomization

The village-level randomization was stratified at the administrative Block level because the TSC implementation was coordinated at the Block level and we wanted to ensure that the treatment arms were evenly allocated between districts and geographically stratified within districts. The randomization took place in a public lottery led by study investigators. The Block TSC coordinators or their representatives picked the lottery ticket that assigned villages to treatment groups. Overall, we allocated a total of 20 villages in each district to the intervention and 20 to control (40 villages per arm). The program implementers and researchers were not blinded to the group assignment. Field interviewers were not informed of group assignment, but it was possible for them to identify intervention villages during interviews of Block officers or the village secretary.

#### 2.2.7 Statistical Methods

We checked the baseline balance in the observable characteristics of the randomized groups. Due to highly comparable groups at baseline and the large increase in our within-cluster sample between baseline and follow-up, our analysis focused on group comparisons post-intervention (using follow-up measures only). To evaluate any differential effect of attrition (loss to follow-up) between baseline and follow-up, we compared baseline characteristics of those present at follow-up with those lost to follow-up. We also compared the balance of baseline characteristics across treatment groups for individuals who were present at both baseline and follow-up to determine whether attrition was differential by treatment group.

Our parameter of interest for all outcomes was the mean difference between randomized groups. We conducted the analysis using households and individuals as they were randomized (intention to treat [ITT]). We estimated differences between groups using the following linear regression model:

$$Y_{ijk} = \alpha + \beta T_j + \delta X_{ij} + b_k + \varepsilon_{ijk}$$
<sup>(1)</sup>

Where,  $Y_{ijk}$  is the outcome for individual *i* in village *j* and Block *k*,  $T_j$  is the intervention indicator (1 for intervention, 0 for control);  $X_{ij}$  are individual, household, and village level characteristics used in adjusted analyses;  $b_k$  are indicator variables for Blocks since randomization was stratified

at the Block level; and  $\varepsilon_{ijk}$  is the error term. The parameter  $\beta$  estimates the ITT difference between the randomized groups.

For identifiability of impact at individual level of a community level intervention, we assume that the randomization of 40 villages in each arm balances the community level confounders and those that are remain imbalanced in spite of randomization can be blocked by including individual level covariates in the model. In the adjusted analyses, we included the following covariates to improve precision: whether the household head had attended school; whether the government categorized the household as Scheduled Caste or Tribe; child age; and child sex. Additionally, the adjusted models included three baseline characteristics found to be slightly imbalanced between groups despite randomization. These included: percentage of households in the village that used improved water sources; percentage of households in the village that were observed to have soap and water at the hand-washing place used after defecation; and mean height-for-age Z-score of children in the village. In the above linear model case,  $\beta$  can be interpreted as both an estimate of the conditional (conditional on Xii) and marginal effect (averaged across the *Xij*); because of this, one still derives a consistent estimate of the causal treatment effect even if (1) is miss-specified. To further assess differential impacts of the program by important population subgroups, we re-estimated the effect of the intervention for households with and without IHL (any type) at baseline, and households below the official poverty line and the other households.

Since we would expect behaviors and child health outcomes to be correlated within villages, all estimates used Huber-White robust standard errors for the parameter  $\beta$  clustered at the village level [60] and reported *p*-values for the two sided t-test. Following guidance from Schulz and Grimes [61], we did not adjust *p*-values or confidence intervals for multiple comparisons because many of the outcomes were highly correlated with one another (for example, correlation between primary outcomes diarrhea and HCGI = 0.78); nominal *p*-values should be interpreted with this in mind. All analyses were conducted using Stata v12 (Statacorp), and all primary analyses were independently replicated by two investigators (SRP, BFA) from untouched datasets to final estimates.

#### 2.3 Results

#### 2.3.1 Enrolment, Baseline Balance, and Attrition

Figure 2-2 depicts the study participants flow. The baseline survey enrolled a sample of 3,390 children < 5 years from 1,954 households from 80 villages. In the follow-up survey the sample size was increased to 5,209 children < 5 years from 3,039 households. As reported in Table 2-2, baseline covariates in intervention and control groups were well balanced with four exceptions. First, 89% of the households in the intervention group had access to improved water sources—tap/piped water, tube well and protected dug wells—compared to 80% of households in the control group. In contrast, a larger proportion of control households (54%) were observed to have soap and water at hand-washing locations used after defecation than in intervention households (44%). On average, more children were found to be anemic in the control group (93%) than in the intervention group (88%). Finally, average height-for-age Z-scores were also slightly imbalanced (-1.38 intervention versus -1.81 control).

Attrition was not differential by randomized group on the basis of observable characteristics. Of the 1,954 households enrolled at the baseline, 1,655 were located at the 21-month follow-up survey (15% attrition) without any significant difference between the intervention (16%) and the control (15%) groups. Characteristics remained balanced between intervention and control groups in remaining households.





2) 2600 children under 5 years of age

2) 2609 children under 5 years of age

	Interv	vention (I)	Control (C)		
Characteristics	$\mathbf{N}^{\mathbf{a}}$	Mean or Percent	$\mathbf{N}^{\mathbf{a}}$	Mean or Percent	
Household characteristics		rereent		rereent	
Age in months for children <5 years <sup>b</sup>	1.683	21.89	1.707	22.12	
Age of HH head in years	976	45.34	978	43.18	
Whether HH head went to school	954	49.90%	952	52.73%	
Government category of HH as BPL	976	34.53%	978	38.96%	
Government category of HH as schedule caste/tribe	935	69.73%	905	71.38%	
<i>Pucca</i> (better quality) HH construction	976	57.07%	978	60.43%	
Monthly HH income (Rupees)	976	11,293	978	11,022	
WASH infrastructure and behaviors		,		,	
HH access to improved water source	976	89.24%	978	79.65%	
Reported drinking water treatment at home	976	68.34%	978	66.26%	
Interviewer observed soap and water at hand-washing	0.60	4.4.400/	072	54.2204	
place used post defecation	969	44.48%	972	54.22%	
PCG reports handwashing w/ soap after fecal contact	079	61 760/	095	64 1 60/	
in last 24 hours	978	61.76%	985	64.16%	
Child nutrition					
Child ever breastfed <sup>c</sup>	1,026	99.03%	1,037	98.55%	
Child still breastfeeding <sup>c</sup>	1,013	91.21%	1,021	89.52%	
Iron pills, syrup given <sup>c</sup>	1,019	7.36%	1,033	5.91%	
Drugs for intestinal worms given in past 6 months <sup>c</sup>	1,025	19.12%	1,033	15.97%	
Did receive VitA dose last 6 months <sup>c</sup>	1,013	37.41%	1,032	36.14%	
Sanitation					
Reported main sanitation facility is JMP defined improved sanitation facility	975	13.64%	978	12.37%	
Reported main sanitation facility is any type of IHL/is not open defecation	975	18.36%	978	20.96%	
Reported correct disposal of child feces	976	15.98%	978	13.39%	
Interviewer did not observe feces in living area around HH	973	41.11%	976	38.11%	
Water microbiology					
HH drinking water is contaminated with <i>E. coli</i>	172	95.93%	174	97.70%	
Health status				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Diarrhea 7-day prevalence <sup>b</sup>	1.683	13.19%	1.707	12.13%	
HCGI 7-day prevalence <sup>b</sup>	1.683	15.27%	1.707	15.06%	
ALRI 7-day prevalence <sup>b</sup>	1.683	11.47%	1.707	10.13%	
Weight-for-age Z-score <sup>c</sup>	957	-2.20	943	-2.18	
Length/height-for-age Z-score <sup>c</sup>	932	-1.38	933	-1.81	
Arm circumference-for-age Z-score <sup>c</sup>	921	-1.31	895	-1.33	
Weight-for-height Z-score <sup>c</sup>	895	-1.68	879	-1.43	
Anemic: $Hb < 110 \text{ g/l}^c$	293	88.05%	329	92.71%	

#### Table 2-2. Baseline characteristics by randomized intervention groups, 2009.

<sup>a</sup>N is the base number of observations (the denominator) for the reported percentages or the sample size used to estimate the reported means. N is the number of households except for the variables measured at the child level (as indicated by <sup>b</sup> and <sup>c</sup>) where N is the number of children. N varies across different variables because of measurements in only a subset of the sample by design, non-response/refusal, and the loss due to measurement errors.

<sup>b</sup>For children less than 60 months of age.

<sup>c</sup>For children less than 24 months of age.

HH, household; PCG, primary care giver; VitA, vitamin A; CFU, colony forming units; ALRI, acute lower respiratory illness; Hb, Hemoglobin; WASH, water, sanitation and hygiene.

#### 2.3.1.1 Compliance to Randomization

The study measured intervention implementation in multiple ways because of the complexity of the TSC program. These measures included: reported implementation by Block coordinators, expenditure of funds documented by official program records, and interviews with local village officials. Out of 40 intervention villages, staff collected administrative information on 39 villages from the TSC Block coordinators (government officers). The coordinators reported that 15/39 intervention villages received some CLTS activities, 33/39 villages applied for a NGP award prior to the follow-up survey. According to Block coordinators' records, 25/39 villages had 100% households with IHLs, 11/39 villages had 80%–99% households with IHLs, and three of 39 villages received 100% of the funds allocated under the TSC program, 12/39 villages received between 50% and 99%, and six of 39 villages received <50% of their allocated funds. The latest disbursement of the TSC funds was given to 36/39 intervention villages at least 4 to 5 months before the follow-up survey, which would offer sufficient time for IHLs to be constructed and used for 3 or more months.

The study review meetings with Block coordinators also identified that some control villages were contaminated during the study period: TSC activities were initiated in eight control villages within a few months of baseline survey and possibly in two additional control villages a few months prior to the follow-up survey; official records were not available for control villages to ascertain this information objectively. As per the follow-up survey in these ten contaminated villages, the household level coverage of JMP defined improved sanitation facilities increased from 17.4% at baseline to 41.4% at the follow-up, which is similar to the program effect we observed in the intervention group. The household level coverage of JMP defined improved sanitation facilities in uncontaminated control villages increased from 10.7% to 16.2% in the same period. The study's long follow-up period (21 months) and the highly publicized and politicized nature of the TSC program may have contributed to this contamination.

Information from additional sources (village secretaries, school teachers, *Anganwadi* [preschool] workers in the village, and the rapid assessment from random sample of households) confirmed that TSC activities translated into a higher recollection and knowledge of the TSC program in the intervention villages compared to the control villages. We also found that households in intervention villages were more aware of CLTS activities, had higher knowledge of the TSC, and experienced more personal visits to convince them to build and use IHLs (Table 2-3).

#### 2.3.1.2 IHL Coverage and Sanitation-Related Behaviors

Table 2-3 reports the intervention's effect on IHL availability (JMP defined improved sanitation facilities and any type of IHLs) and open defecation behaviors by household members. The intervention increased the coverage of JMP defined improved sanitation facility by average 19 percentage points (95% CI 12%–26%; *p*-value < 0.001) in intervention villages compared to control villages (41.4% intervention versus 22.6% control). The intervention increased the coverage of any type of IHL facility by 20 percentage points (95% CI 13%–27%; *p*-value < 0.001) in intervention villages compared to control villages (44.1% intervention versus 24.2% control). These results indicate that available IHLs were predominantly JMP defined improved sanitation facilities and very few rudimentary latrines or latrines defined as unimproved by the

JMP were built. These results are consistent with the TSC design that promoted latrine models that can safely contain the feces.

Although on average fewer households in intervention villages were likely to report daily open defecation compared to control villages for adult men (75% intervention versus 84% control; mean difference: 9.5%; *p*-value = 0.001), adult women (73% intervention versus 83% control; mean difference: 10%; *p*-value < 0.001), and children < 5 years (84% intervention versus 89% control; mean difference: 5%; *p*-value = 0.014), these reductions in reported open defecation behaviors were smaller than the gains in IHL availability. Amongst the 630 households in intervention villages that had JMP defined improved sanitation facilities at follow-up, 41% reported that adult men or women still practiced daily open defecation; this same figure was 28% among the 339 control village households at follow-up (not reported in results table). A follow-up debriefing question to households who had IHL identified that the main reasons for daily open defecation in spite of having IHL were culture, habit, or preference for defecating in open followed by inadequate water availability.

#### 2.3.1.3 Drinking Water Quality

In control villages, 82% (331/403) of household drinking water samples tested positive for *E. coli* compared to 77% (310/404) of samples in intervention villages (mean difference: 5.5%; *p*-value = 0.050) (Table 2-3). Of 514 water source samples tested, 74% (210/282) of the sources in control villages and 70% (163/232) in intervention villages tested positive for *E. coli* but the difference was not statistically significant (mean difference: 4%; *p*-value = 0.143).

#### 2.3.1.4 Caregiver Reported Illness

Diarrhea prevalence did not differ between groups (7.4% intervention versus 7.7% control; p-value = 0.687) (Table 2-4). HCGI prevalence also did not differ between groups (11.5% intervention versus 12.0% control; p-value = 0.692). We observed no significant differences between groups in negative control caregiver-reported outcomes including bruising/abrasions (1.4% intervention versus 1.3% control) and itchy skin/scalp (2.5% intervention versus 2.2% control) suggesting that differential outcome reporting bias for diarrhea and HCGI was unlikely.

#### 2.3.1.5 Enteric Parasite Infections

In the subsample of 1,150 children with stool collection, 5.7% (66/1150) had helminth infections and the majority (50/66) were *Ascaris* infections. All remaining infections were tapeworms; no children were infected with *Trichuris trichiura* or hookworm. We observed no difference in helminth prevalence between intervention and control groups. *Giardia* infection was common, and consistent with slightly improved water quality in the intervention group, we found lower *Giardia* prevalence among children in intervention villages (18%) compared to children in control villages (23%) (mean difference: 4.8%; *p*-value = 0.047). We detected no *Cryptosporidium* infections in the study children, and a low prevalence of *E. histolytica* (33 out of 1,150; 2.9%).

Outputs and Outcomes		Control		vention	ITT Unadjusted <sup>b</sup>	ITT Adjusted <sup>c</sup>
		Group <sup>a</sup>		oup <sup>a</sup>		_
	N	Mean	N	Mean	Difference [95% CI] <sup>d</sup>	Difference [95% CI] <sup>d</sup>
Program exposure						
HH received WASH message from mass media	1,511	0.272	1,523	0.295	0.023 [-0.033 to 0.080]	0.000 [-0.048 to 0.048]
HH received WASH message from personal visits	1,472	0.099	1,479	0.240	0.140 [0.097–0.183]***	0.127 [0.081–0.172]***
HH participated or is aware of CLTS activities	1,514	0.157	1,525	0.291	0.135 [0.083–0.186]***	0.140 [0.089–0.191]***
HH knew of TSC/NGP	1,514	0.211	1,525	0.273	0.062 [0.011–0.114]**	0.053 [0.004–0.103]**
Drinking water supply and hand-washing						
Infrastructure						
HH access to improved water source	1,514	0.949	1,525	0.970	0.021 [-0.001 to 0.043]*	0.007 [-0.014 to 0.027]
Interviewer observed soap and water at hand-	1,269	0.436	1,334	0.494	0.056 [-0.006 to 0.118]*	0.052 [-0.002 to 0.105]*
washing place used post defecation						
IHL access and sanitation behaviors						
HH with JMP defined improved sanitation facilities	1,512	0.226	1,522	0.414	0.188 [0.118-0.258]***	0.177 [0.107–0.246]***
HH with any type of IHL	1,514	0.242	1,525	0.441	0.198 [0.126-0.270]***	0.189 [0.116-0.263]***
Interviewer assessed that HH is using IHL (any	1,504	0.167	1,520	0.272	0.104 [0.047–0.161]***	0.093 [0.042–0.144]***
type)						
Reported daily OD by men	1,514	0.841	1,525	0.746	-0.095 [-0.152 to -0.039]***	-0.087 [-0.135 to -0.038]***
Reported daily OD by women	1,514	0.835	1,525	0.732	-0.102 [-0.159 to -0.045]***	-0.091 [-0.141 to -0.041]***
Reported daily OD by children	1,514	0.892	1,525	0.839	-0.053 [-0.095 to -0.011]**	-0.054 [-0.088 to -0.020]***
Reported correct child feces disposal	1,514	0.184	1,525	0.271	0.087 [0.045–0.129]***	0.075 [0.036–0.113]***
Interviewer did not observe human/animal feces in	1,500	0.398	1,512	0.404	0.006 [-0.045 to 0.057]	0.019 [-0.026 to 0.065]
HH living area						
Drinking water quality						
E. coli present in household drinking water	403	0.821	404	0.767	-0.055 [-0.111 to 0.000]*	-0.032 [-0.101 to 0.036]
<i>E. coli</i> present in the source from where household	280	0.743	231	0.701	-0.115 [-0.269, 0.040]	-0.016 [-0.180, 0.149]
collected drinking water						

#### Table 2-3. Effect of the intervention on program outputs, behavioral outcomes, and water quality, 2011.

<sup>a</sup> The number of observations used to estimate means of the intervention and the control groups is the same as the number of observations used in ITT-unadjusted analysis.

<sup>b</sup>Explanatory variables in the unadjusted model include the treatment assignment and indicator variables for Blocks. Therefore, the ITT effects for outcomes may not be exactly the difference between the listed mean in intervention and control groups in previous columns.

<sup>e</sup>Because of missing adjustment variables data, the observations used in adjusted analysis are fewer than those used in unadjusted analysis. The number of observations used is seven to 113 less than that in unadjusted analysis.

<sup>d</sup>Following the commonplace norms, statistical significance is indicated as: \*\*\*significant at  $\alpha = 0.01$ ; \*\*significant at  $\alpha = 0.05$ ; \*significant at  $\alpha = 0.10$ . Please note that *p*-values are not adjusted for multiple comparisons following guidance from Schulz and Grimes [61].

CFU, colony forming units; HH, household; OD, open defecation; TSC/NGP, Total Sanitation Campaign/Nirmal Gram Puraskar; WASH, water, sanitation and hygiene.

Health Outcomes		Control Group <sup>a</sup>		tion Group <sup>a</sup>	ITT Unadjusted <sup>b</sup>	ITT Adjusted <sup>c</sup>
		Mean	N	Mean	Difference [95% CI] <sup>d</sup>	Difference [95% CI] <sup>d</sup>
Caregiver reported illness in the last 7 days <sup>e</sup>						
Diarrhea	2,609	0.077	2,600	0.074	-0.003 [-0.019 to 0.013]	-0.002 [-0.019 to 0.015]
HCGI	2,609	0.120	2,600	0.115	-0.004 [-0.026 to 0.017]	-0.002 [-0.024 to 0.020]
Acute lower respiratory illness	2,609	0.128	2,600	0.163	0.038 [0.003–0.073]**	0.049 [0.009–0.089]**
Enteric parasite infections <sup>f</sup>						
Any protozoan present	569	0.257	581	0.217	-0.040 [-0.089 to 0.008]	-0.027 [-0.082 to 0.029]
Entamoeba histolytica present	569	0.025	581	0.033	0.008 [-0.009 to 0.024]	0.009 [-0.009 to 0.028]
Giardia lamblia present	569	0.232	581	0.184	-0.048 [-0.096 to -0.001]**	-0.036 [-0.088 to 0.015]
Any helminth present	569	0.056	581	0.059	0.001 [-0.021 to 0.023]	-0.005 [-0.028 to 0.018]
Ascaris lumbricoides present	569	0.044	581	0.043	-0.002 [-0.021 to 0.017]	-0.011 [-0.031 to 0.010]
Any enteric parasite present	569	0.309	581	0.270	-0.040 [-0.087 to 0.006]*	-0.032 [-0.083 to 0.020]
Anemia and anthropometry <sup>e</sup>						
Anemic: $Hb < 110 g/l$	1,922	0.508	1,919	0.562	0.050 [-0.011 to 0.110]	0.033 [-0.030 to 0.096]
Child weight (to 0.1 kg)	2,161	10.277	2,154	10.069	-0.229 [-0.492 to 0.033]*	-0.130 [-0.345 to 0.085]
Child height (to 0.1 cm)	2,185	82.312	2,175	81.682	-0.678 [-1.362 to 0.006]*	-0.242 [-0.789 to 0.304]
Child arm circumference (to 0.1 cm)	2,191	13.805	2,197	13.783	-0.004 [-0.145 to 0.138]	-0.022 [-0.167 to 0.123]
Weight-for-age Z-score	2,161	-1.833	2,154	-1.921	-0.095 [-0.253 to 0.063]	-0.094 [-0.246 to 0.058]
Length/height-for-age Z-score	2,185	-2.155	2,175	-2.189	-0.034 [-0.195 to 0.127]	-0.040 [-0.223 to 0.144]
MUAC-for-age Z-score	2,191	-1.337	2,197	-1.337	0.020 [-0.115 to 0.155]	-0.022 [-0.151 to 0.108]
Weight-for-height Z-score	2,054	-0.834	2,054	-0.847	-0.018 [-0.195 to 0.160]	0.029 [-0.142 to 0.199]
BMI Z-score	2,052	-0.604	2,052	-0.664	-0.062 [-0.241 to 0.117]	-0.019 [-0.191 to 0.153]

Table 2-4. Effe	ct of the inter	vention on hea	Ith outcomes, 2011.
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<sup>a</sup>The number of observations used to estimate means of the intervention and the control groups is the same as the number of observations used in ITT-unadjusted analysis.

<sup>b</sup>Explanatory variables in the unadjusted model include the treatment assignment and indicator variables for Blocks. Therefore, the ITT effects for outcomes may not be exactly the difference between the listed mean in intervention and control groups in previous columns.

<sup>e</sup>Because of missing adjustment variables data, the observations used in adjusted analysis are fewer than those used in unadjusted analysis.

<sup>d</sup>Following the commonplace norms, statistical significance is indicated as: \*\*\*significant at  $\alpha = 0.01$ ; \*\*significant at  $\alpha = 0.05$ ; \*significant at  $\alpha = 0.10$ . Please note that *p*-values are not adjusted for multiple comparisons following guidance from Schulz and Grimes [61].

<sup>e</sup>For children less than 60 months of age

<sup>f</sup>For children less than 60 months of age. The eldest child less than 60 months of age selected from a household.

BMI, body mass index; Hb, hemoglobin; OD, open defecation; HH, household.

#### 2.3.1.6 Anemia and Anthropometry

Anemia was prevalent in the study children (54%) and children were small according to international growth standards (Table 2-4). However, we found no differences between the randomized groups in anemia prevalence or growth outcomes.

#### 2.3.2 Subgroup Results

Table 2-5 presents the results of subgroup analyses of the effect of the intervention on households with or without any type of IHL at baseline and BPL or non-BPL households. As expected, the program had the largest improvements on JMP defined improved sanitation facilities, IHL use as assessed by enumerators, and reduced reported open defecation by household members in households that did not have IHL (any type) at baseline and in BPL households. This finding is consistent with the TSC design that targeted households without IHLs and offered larger IHL construction subsidies for BPL households. Among BPL households, the intervention increased JMP defined improved sanitation facilities coverage by 30 percentage points (48% intervention versus 18% control; *p*-value < 0.001) and it reduced open defecation among women by 17 percentage points (73% intervention versus 90% control; *p*-value < 0.001). Despite larger improvements in these intermediate outcomes among BPL households or households without IHL at baseline, we did not observe consistent improvement in health outcomes in these subgroups (Table 2-5).

#### 2.4 Discussion

The TSC program, implemented with support of the WSP in Dhar and Khargone districts, increased household level coverage of JMP-defined improved sanitation facilities by a modest 19 percentage points in intervention villages compared to control (41% intervention versus 22% control; *p*-value < 0.001). However, the reductions in reported open defecation by adults were even more modest: falling 9 to 10 percentage points (among men: 75% intervention versus 84% control; *p*-value = 0.001; among women: 73% intervention versus 83% control; *p*-value < 0.001), while reports of correct child feces disposal increased because of intervention by 9 percentage points (27% intervention versus 18% control; *p*-value < 0.001). The availability of IHL and the reductions in open defecation were higher in the BPL household or households without any IHL at the time of baseline but we did not find consistent improvements in the multiple health outcomes in these subgroups. The less than universal or very high levels of IHL coverage in the intervention villages combined with relatively small behavior changes are consistent with our finding of no improvements in child health outcomes including: diarrhea, enteric parasite infection, growth, and anemia.

The study's findings should be viewed as a measure of effectiveness for this specific implementation of India's TSC program in rural Madhya Pradesh. By the end of the study in the intervention group, coverage of JMP defined improved sanitation facilities in a village ranged between 5% and 79% households and percentage of households in a village reporting daily open defecation by adult men ranged between 32% and 97% and that by adult women ranged between 34% and 97%. It is unknown whether enteric pathogen risk is linearly or non-linearly related to the level of improved sanitation in a community, and the intervention did not achieve the goal of universal availability of IHLs or universal elimination of open defecation during the study period. Therefore, our findings cannot speculate the child health outcomes for universal or higher

levels of IHL availability or larger open defecation reductions that may be feasible under different contexts, program designs, or implementation efficacy. Additional, forthcoming cluster randomized sanitation intervention trials [62,63] may generate such evidence if they can achieve adequately high latrine coverage and proportional reductions in open defecation.

This study presents a cautionary tale of how difficult it can be to achieve universal IHL coverage or elimination of open defecation for scaled up rural sanitation programs. The study documented clear evidence of more social mobilization, exposure to behavior change activities, and IHL construction in intervention villages compared to control villages. However, these intermediate outputs of the TSC could not translate into high enough levels of IHL availability and reductions in open defecation practice to deliver the health impacts. This evaluation was a part of a broader six-country effort to also study large-scale sanitation promotion programs in rural Indonesia and Tanzania, as well as large-scale hand-washing promotion programs in Peru, Vietnam, and Senegal. While the Tanzania results are forthcoming, the Indonesia study found even smaller increases in availability of JMP defined improved sanitation facilities and reductions in open defecation following a large-scale sanitation campaign [64] that was similar in design to the classical CLTS approach [20]. A recent cross-sectional survey in Orissa found more optimistic results—72% IHL availability following the TSC [65]—but implementation was heterogeneous. Much less than universal levels of IHL coverage and use were reported in past evaluations of pilot programs and early implementations of India's TSC [66,67].

Within the broader water-sanitation-hygiene sector, the difficulty of scaling up interventions that are efficacious when widely adopted and properly used across a community is not unique to rural sanitation. Evaluations of large-scale hand-washing promotion campaigns in Peru and Vietnam—part of the broader research effort that included the present trial—found almost no improvements in hand-washing behavior and thus no downstream impacts on child health [68,69]. Furthermore, the interim evaluation of the national-level Sanitation Hygiene Education and Water supply in Bangladesh program found very small improvements in hygiene and sanitation outcomes, with no impacts on child health [70].

The present evidence from the sector suggests that with few exceptions [71] scaled up sanitation and hygiene programs in rural settings have had difficulty in delivering the health benefits measured in small efficacy studies. Typically, the well-controlled efficacy trials can result in high enough levels of sanitation and hygiene infrastructure and behaviors necessary to deliver the health benefits, but the same levels of infrastructure or behavior change are not guaranteed to accrue to large-scale programs. From a public health perspective, these findings call into question the likelihood of the TSC in its current form to improve child health. Still, the program may be valuable from the policy and development perspective for reasons beyond public health, such as the social benefits of sanitation (dignity, privacy, safety, and reduced burden of coping especially for women) accrued to households that have and use IHLs, and the obligation of the government to provide access to sanitation as a recently recognized human right by the United Nations General Assembly (Resolution number 64/292). As the next iteration of the TSC program—named Nirmal Bharat Abhiyaan (Clean India Campaign)—continues, research efforts that focus on how to significantly increase the access to and use of IHLs would be particularly valuable to guide future program refinement. High levels of IHL coverage and use should be demonstrated in pilot programs before these program refinements are taken to national scale.

Characteristics	Control	Group <sup>a</sup>	Intervent	ion Group <sup>a</sup>	ITT Unadjusted <sup>b</sup>	ITT Adjusted <sup>c</sup>
	N	Mean	N	Mean	Difference [95% CI] <sup>d</sup>	Difference [95% CI] <sup>d</sup>
HH with JMP defined improved sanitation						
facilities						
All HH	1,512	0.224	1,522	0.414	0.189 [0.119–0.259]***	0.178 [0.108–0.247]***
HH with IHL (any type) at baseline	190	0.979	212	0.967	-0.018 [-0.056 to 0.020]	0.001 [-0.027 to 0.029]
HH with no IHL (any type) at baseline	1,319	0.114	1,297	0.318	0.202 [0.139–0.264]***	0.209 [0.142–0.277]***
BPL HH	551	0.181	452	0.476	0.307 [0.227–0.388]***	0.320 [0.234–0.406]***
Non-BPL HH	961	0.249	1,070	0.388	0.135 [0.059–0.210]***	0.108 [0.027–0.189]***
Reported daily OD by women						
All HH	1,514	0.835	1,525	0.732	-0.102 [-0.159 to -0.045]***	-0.091 [-0.141 to -0.041]***
HH with IHL (any type) at baseline	191	0.105	214	0.103	0.000 [-0.078 to 0.077]	0.005 [-0.070 to 0.080]
HH with no IHL (any type) at baseline	1,320	0.941	1,297	0.837	-0.101 [-0.140 to -0.062]***	-0.097 [-0.140 to -0.054]***
BPL HH	551	0.902	453	0.733	-0.178 [-0.241 to -0.115]***	-0.169 [-0.233 to -0.105]***
Non-BPL HH	963	0.796	1,072	0.732	-0.061 [-0.129 to 0.006]*	-0.029 [-0.097 to 0.040]
E. coli present in household drinking water						
All HH	403	0.821	404	0.767	-0.055 [-0.111 to 0.000]*	-0.032 [-0.101 to 0.036]
HH with IHL (any type) at baseline	54	0.796	60	0.817	0.004 [-0.183 to 0.192]	-0.003 [-0.137 to 0.131]
HH with no IHL (any type) at baseline	347	0.827	340	0.765	-0.064 [-0.121 to -0.006]**	-0.055 [-0.135 to 0.026]
BPL HH	147	0.803	111	0.739	-0.069 [-0.169 to 0.031]	-0.076 [-0.198 to 0.047]
Non-BPL HH	256	0.832	293	0.778	-0.054 [-0.125 to 0.017]	-0.042 [-0.128 to 0.043]
Diarrhea in the past 7 days <sup>e</sup>						
All HH	2,609	0.077	2,600	0.074	-0.003 [-0.019 to 0.013]	-0.002 [-0.019 to 0.015]
HH with IHL (any type) at baseline	302	0.063	343	0.035	-0.034 [-0.072 to 0.003]*	-0.037 [-0.083 to 0.010]
HH with no IHL (any type) at baseline	2,302	0.079	2,231	0.080	0.001 [-0.016 to 0.018]	0.003 [-0.015 to 0.021]
BPL HH	949	0.085	783	0.078	-0.005 [-0.031 to 0.021]	0.004 [-0.022 to 0.029]
Non-BPL HH	1,660	0.072	1,817	0.073	0.000 [-0.019 to 0.019]	-0.001 [-0.023 to 0.021]
Ascaris lumbricoides infection <sup>f</sup>						
All HH	569	0.044	581	0.043	-0.002 [-0.021 to 0.017]	-0.011 [-0.031 to 0.010]
HH with IHL (any type) at baseline	82	0.037	92	0.043	-0.004 [-0.051 to 0.043]	-0.005 [-0.087 to 0.078]
HH with no IHL (any type) at baseline	487	0.045	482	0.041	-0.004 [-0.025 to 0.017]	-0.013 [-0.033 to 0.006]
BPL HH	221	0.045	160	0.044	0.008 [-0.030 to 0.046]	0.023 [-0.026 to 0.072]
Non-BPL HH	348	0.043	421	0.043	-0.001 [-0.027 to 0.026]	-0.022 [-0.046 to 0.001]*
Giardia lamblia infection <sup>f</sup>						
All HH	569	0.232	581	0.184	-0.048 [-0.096 to -0.001]**	-0.036 [-0.088 to 0.015]
HH with IHL (any type) at baseline	82	0.232	92	0.185	-0.115 [-0.221 to -0.008]**	-0.060 [-0.206 to 0.086]

 Table 2-5. Differential effect of the intervention by population subgroups, 2011.

HH with no IHL (any type) at baseline	487	0.232	482	0.185	-0.041 [-0.094 to 0.011]	-0.036 [-0.094 to 0.023]
BPL HH	221	0.226	160	0.144	-0.073 [-0.141 to -0.005]**	-0.059 [-0.139 to 0.020]
Non-BPL HH	348	0.236	421	0.200	-0.041 [-0.098 to 0.016]	-0.027 [-0.088 to 0.035]

<sup>a</sup>The number of observations used to estimate means of the intervention and the control groups is the same as the number of observations used in ITT-unadjusted analysis.

<sup>b</sup>Explanatory variables in the unadjusted model include the treatment assignment and indicator variables for Blocks. Therefore, the ITT effects for outcomes may not be exactly the difference between the listed mean in intervention and control groups in previous columns.

<sup>e</sup>Because of missing adjustment variables data, the observations used in adjusted analysis are fewer than those used in unadjusted analysis.

<sup>d</sup>Following the commonplace norms, statistical significance is indicated as: \*\*\*significant at  $\alpha = 0.01$ ; \*\*significant at  $\alpha = 0.05$ ; \*significant at  $\alpha = 0.10$ . Please note that *p*-values are not adjusted for multiple comparisons following guidance from Schulz and Grimes [61].

<sup>e</sup>For children less than 60 months of age.

<sup>f</sup>For children less than 60 months of age. The eldest child less than 60 months of age selected from a household.

BPL, based on verification of household's food ration card; non-BPL, households who do not have/show BPL ration card; HH, household; OD, open defecation.
#### 2.4.1 Limitations

Like other effectiveness studies that measure the impact of large-scale government programs, we faced the challenges typically not encountered in well-controlled efficacy trials such as imperfect compliance with treatment assignment and poor fidelity of intervention implementation. We found that by 21 months of follow-up, none of the intervention villages achieved the program goal of 100% households having and using IHLs that can safely confine feces; the average household level coverage of JMP defined improved sanitation facilities was 40% (range: 5%–79%). The reasons for the gap between the official monitoring records of the TSC and the actual status are discussed elsewhere [72]. The Block coordinators also identified that at least eight and possibly ten control villages received the TSC program. ITT estimates of program impacts with imperfect compliance will underestimate the effect possible under perfect compliance.

Another challenge in trials where study investigators have limited control over the program implementation, is significant deviations in the actual implementation timeline compared to the timeline on which the evaluation study is based. While the planned follow-up period from the baseline was 18 months in this study, the actual follow-up measurement at 21 months was the latest possible point we could measure outcomes under the possibility of program expansion into control villages and contractual constraints with the evaluation funding. Although it was possible that impacts on diarrheal disease could begin relatively soon after intervention, as documented in short-duration efficacy trials [14], we would expect impacts on enteric parasite infection, anemia, and growth to potentially accrue more slowly.

The limited length of follow-up could have also influenced our estimates of the program's effect on IHL availability and use. Longer follow-up could have led to potentially higher levels of IHL coverage or, conversely, lower levels of use (if IHLs are not maintained). Despite this limitation, our estimates of IHL coverage and reported use are broadly consistent with other independent measures following rural sanitation programs in India [65–67]. For example, Barnard and colleagues [65] found that 4 to 6 years after TSC implementation in Orissa that 53% of households with an IHL reported some individuals still practiced open defecation. In the present study, 41% of men and 38% of women from the intervention group who have JMP defined improved sanitation facilities reported practicing daily open defecation.

Self-reported outcomes can be subject to differential, biased reporting in unblinded trials [11,50]. Therefore, in addition to self-reported illnesses, we included several objective child health measurements in this study (parasite infections, anemia, anthropometry). However, we did not include objective measures of sanitation behaviors (disposal of child feces, IHL use, and open defecation). To the extent that our measurements of reported outcomes were subject to courtesy bias, we may have over-estimated IHL use or under-estimated open defecation prevalence in the study population. Furthermore, if the bias was differential by treatment group, then we would expect the study to have over-estimated the improvements due to intervention because we would expect the intervention households to be more sensitized to the stigma of open defecation. Measures of IHL use could be improved in future sanitation studies through the use of passive sensors mounted in the latrine [73,74].

### 2.4.2 Generalizability

There is wide variation in TSC implementation within India, and it remains possible that the TSC program was more or less successful in other states [38]. We note, however, that very few Indian states had large growth in IHL availability between 2001 and 2011 when the TSC program was active across India. In Madhya Pradesh, the TSC program was combined with *Nirmal Watika* that served to increase the IHL construction subsidies available to all eligible households. Additionally, the districts enrolled in this study received support from the WSP's TSSM project to build capacity for creating enabling environment, record keeping and monitoring, and implementing CLTS-based behavior change approaches. Therefore, the behavior change approaches in the study districts were arguably more intensive than those in the rest of Madhya Pradesh. However, this study should be not viewed as an evaluation of the CLTS approach as advocated by its practitioners [20] because the intervention only used CLTS behavior change tools and did not follow the key principles of CLTS such as not providing hardware subsidy and not prescribing latrine models.

## 2.4.3 Conclusions

This 80 village study in rural Madhya Pradesh represents the first published large-scale, randomized evaluation of India's TSC to measure and report outcomes at all stages of the causal chain (Figure 1). While the TSC program in rural Madhya Pradesh implemented with support from the WSP increased the household level availability of JMP defined sanitation facilities (+19%) and to a lesser extent reduced open defecation (-10%), these improvements were insufficient to improve child health outcomes (diarrhea, parasite infections, anemia, growth). Despite the limitations of the present study, including short follow-up and evidence for contamination in the control group, the results underscore the challenge of achieving adequately large levels of improvements in sanitation to deliver the expected health benefits within the scaled-up rural sanitation programs.

# Chapter 3: Can Sanitation Coverage in Rural India Increase "Enough" by Increasing Subsidies to Private Toilets?

# 3.1 Introduction

Throughout the decade of 2000, the Indian government sought to improve the coverage of individual household latrines (IHL or private toilets) in rural villages through a flagship program named the Total Sanitation Campaign (TSC). The main mechanism to increase the coverage of IHLs was behavior change communication combined with material and labor cost subsidies. These subsidies, provided only to the Below Power Line (BPL) houses, were considered adequate to almost entirely offset the engineering cost of building a single or double offset pit latrine with a basic room, roof and door. Later, in a new variant of the TSC called *Nirmal Bharat Abhiyan* (NBA), the subsidies were extended to eligible non-BPL households so that almost all rural households without private toilets were eligible for the subsidies.

In spite of the provision of a large amount of subsidies throughout India, hard evidence on whether and how prices drive the demand or uptake of private toilets is lacking. This question is important to address, even in the broader global debate, on the role prices or financial incentives in improving sanitation vis-à-vis only behavior change communication [24,66,75,76]. From the Indian perspective, this question is important to assess the potential for high coverage of private toilets under the newer version of TSC/NBA called *Swachha Bharat* (clean India) Mission (SBM) that substantially increased the subsidies or financial incentives to rural households to build a private toilet.

In this paper, we estimate the price elasticity of demand for private toilets and predict the effect of proposed subsidies under the SBM on toilet coverage in India. We use data from a Randomized Control Trial (RCT) of the TSC in Madhya Pradesh (MP)<sup>1</sup> between 2009 and 2011 to estimate the price elasticity of private toilets [77]. The TSC in MP offered different levels of subsidies to the BPL and non-BPL households, and the subsidies also differed across regions. We take advantage of the randomized intervention assignment and the variation in subsidies to estimate the price elasticity using a difference-in-difference estimator. Later, we also estimate the price elasticity by using data from a published efficacy trial in Odisha, which had an intensive focus on behavior change and provided smaller amount of subsidies [66].

# 3.1.1 Background and Policy Context

Meaningful investment in sanitation programs in India started with the Central Rural Sanitation Program in 1986, but the major impetus to the effort was given in 1999 under the TSC, which adopted a demand driven approach of combining information, education, and communication (IEC) or behavior change communication (BCC) strategies, capacity building at various levels, and subsidies for toilet construction to the BPL households. Substantial portion of the TSC

<sup>&</sup>lt;sup>1</sup> The TSC implementation can differ by states, mainly in terms of amount of subsidies (to a minor extent), how subsidies are provided or the financial mechanism, and when subsidies are provided – before, during, or after the toilet construction.

budget (85%-90%) was earmarked for the infrastructure or "hardware", and the rest for the IEC/BCC or "software" activities.

Initially, the subsidies in the form of materials and labor were provided to only the BPL households. As per the TSC program costing, these subsidies were expected to cover 80-85% of the cost of a pit latrine (different designs could be promoted by different states), and the rest could be borne by the households in terms of self-labor or minor investments in materials. However, the cost estimates used in the program design were arguably an underestimate of the true market prices [78]. As a result, the subsidy support under the TSC increased rapidly over the years. Starting with ₹500 subsidies (additional beneficiary share of ₹125) in 1999, the allocated subsidy amount was increased to ₹1,200 (additional beneficiary share of ₹300) in 2005-06, to ₹2,200 (additional beneficiary share of ₹300) in 2010-11<sup>2</sup>. These subsidies were ostensibly offered only to the BPL households whereas the non-BPL households were expected to build the toilets on their own.

In 2012, the TSC was replaced by the NBA that offered material and labor cost subsidies to both the BPL and eligible non-BPL households<sup>3</sup>, and increased the subsidies significantly to ₹9,900 by converging funds under the TSC and another program named National Rural Employment Guarantee Scheme (NREGS)<sup>4</sup>. The subsidy was considered adequate to build a two pit offset latrine with necessary plumbing, room, roof, and door as per the engineering costing done by the government.

In 2014, the newly elected government renamed the NBA as the SBM with a deadline to make India ODF by 2<sup>nd</sup> October 2019. Under SBM, the allotted subsidies were further increased to ₹12,000 [79]. SBM also strongly recommended direct subsidy transfer in beneficiaries' bank accounts to check pilferage of funds and also advocated provision of the subsidy as an incentive "after" the household builds and demonstrates the use of toilet<sup>5</sup>. The SBM also got sanitation center stage in policy discourses and media as one of the pet projects of the new Prime Minister.

Although subsidies have been provided and even increased substantially since 2001, less than 30% of the rural households had a private toilet as per the 2011 Census [8]. During 2001-11, when the TSC was active across India, the proportion of rural households without access to any sanitation facility fell from 78.3% to 69.3%. There are four possible reasons why high subsidies could not result in higher toilet coverage.

First, the price of a toilet was prohibitive in spite of subsidies. Indeed, income was reported as the main constraint to building private toilets in the recent evaluation studies [75,77,80]. The

<sup>&</sup>lt;sup>2</sup> The amount of subsidies may differ slightly by states.

<sup>&</sup>lt;sup>3</sup> Eligible non-BPL households included all schedule caste and tribes, small and marginal farmers, landless farmer, physically handicapped, and women headed households.

<sup>&</sup>lt;sup>4</sup> NREGS guarantees 100 days of unskilled labor work to those who want work. The villages can decide the type of development/infrastructure works they want to undertake from a menu of choices (including private toilets) and NREGS pays approx. 40% of the material cost in addition to daily wages of workers. To build their private toilets, households were given money for their own labor in addition to money to masons and materials. The TSC paid for mainly the materials.

<sup>&</sup>lt;sup>5</sup> The newly elected government has linked millions of rural households with a bank account and accelerated provision of *Adhaar* card (a unique identification scheme) so that direct cash transfer is now at least technically feasible and being tested at a pilot scale.

subsidies covered 80-90% of the engineering cost estimates, but these cost estimates were possibly an underestimate of the market price. For example, a qualitative study in Bihar found that the estimated cost of the household latrine promoted under the TSC was ₹2,500 in 2009-10 whereas the focus group discussions identified that the market price of similar toilet would be ₹5,000 so that the subsidy of ₹2,200 covered only 44% of the market price [78].

Second, a large proportion of poor households were ineligible for subsidies because they did not have the official BPL status and thus could not afford to build toilets. The non-BPL households are not necessarily less poor than BPL households. It has been well documented that BPL cards are distributed without strict adherence to the poverty criteria [81,82]. Later, the NBA and the SBM indeed extended subsidies to the eligible non-BPL households, which validates the concern that most non-BPL households also faced budget constraints to build toilets. As per the baseline data for the NBA in 2012, out of 111.2 million households without a toilet, 42% are BPL households, 48% are subsidy eligible non-BPL households, and only 9% are ineligible non-BPL households [83].

Third, the inefficiency and leakage in utilization of the subsidies further increased the price faced by the households on average. While subsidies were budgeted at a household level, the distribution and utilization was done by the village level administration (Gram Panchayats). With support from the block and district administration, the Gram Panchayats played a significant role in procurement and disbursement of the materials and paying masons. Without a reliable monitoring and audit system, the possibility of fund leakage cannot be denied. For example, the monitoring data for the TSC reported that the coverage of private toilets increased from 18% in 2000 to 74% in 2011 (this data is not available online any more), but the 2011 Census identified that approximately only 30% households had access to any type of sanitation facility. One can argue that the toilets were built of poor quality and were dilapidated by the time of census. However, a cross sectional survey conducted one year after the census in a representative sample of 110 villages in Madhya Pradesh found that only 2% of toilets were dilapidated, 9% were under construction, and 14% were fully constructed, as compared to the census data of 13% households with toilets [84]. Therefore, it seems unlikely that the dilapidated toilets can explain the huge gap between the TSC monitoring reports and the census, so the leakage/inefficient fund utilization theory has merit.

Fourth, the toilet could be perceived a "bad" thing due to constraints other than money. Lack of space, unavailability of water for washing and flushing, and habit or culture related factors are reported constraints to building and using private toilets [85]. Perhaps households considered the promoted toilet designs unsafe and did not want the fecal matter near the house environs. Perhaps subsidies resulted in the entitlement expectations and the households held off building a toilet in expectation of a higher subsidy. Therefore, it is possible that even with subsidies and being aware of toilet benefits/harms, the consumers "chose" against building toilets.

# 3.1.2 Evidence on Effectiveness of Subsidies

The body of evidence on the drivers of toilet uptake and the role of prices in driving the demand is thin. However, recent research provides some evidence of the role prices may play. Gertler and colleagues [24] investigated the mechanisms of changing open defecation behavior through investment (toilet construction) and behavior change (nudging) pathways by pooling data from RCTs in four countries. They found that the largest reduction in open defecation is through

construction of private household latrines rather than the use of shared or public facilities, and that subsidy is a dominant pathway to get households to build a private toilet. However, they find that only one of the four countries (Mali) could achieve large reductions in open defecation due to intensive behavior change interventions. A recent RCT in Bangladesh found that subsidies combined with CLTS-based behavior change interventions increased the toilet uptake and their use, but only the CLTS-based behavior change did not [75]. This study also found that the reductions in open defecation were modest (-14%) and possibly not large enough to deliver health benefits. Pattanayak and colleagues [66] found that more than one third of the functional (in-use) private toilet construction was attributed to subsidies and almost two thirds to the intensive BCC campaign delivered under strict adherence to the protocol.

We are also aware of two unpublished studies that have investigated the effect of subsidies on the demand for toilets. Stopnitzky [86] uses the BPL status as a proxy for access to subsidies, and in a cross sectional regression analysis, finds that the BPL status is associated with a negligible 0.4 and 0.6 percentage point increase from the mean level of 19.2% toilet coverage. While the estimated effects are negligible, they are likely a gross underestimate because the BPL households only have access to the subsidies in the villages where the TSC was implemented, and not uniformly across India. Another cross sectional survey of 188 villages in MP found that subsidies in the form of materials, labor, or cash are associated with 50%-60% probability of owning a private toilet [84].

Collectively, availability of toilet infrastructure seems to be an important precursor to behavior change (use of toilets), and the construction of toilets is apparently driven by price of the toilets. However, intensive behavior change is also important to drive the demand for toilets and ensure that their usage is high.

Although evidence on the effectiveness of different behavior change strategies and subsidies to improve sanitation is being built, the evidence from the larger WASH and public health sectors suggests that the subsidies (and thus prices) play a strong role in driving the demand and use of the health goods. Ahuja and colleagues reviewed evidence from several experimental studies to assess the effectiveness of water access and water quality interventions and make a case for subsidies on the basis of this review [87]. They found that the households don't invest in water quality interventions even when they are highly effective in reducing disease burden and argue that the subsidies are necessary considering the positive health externality of reducing the infectious disease prevalence. In addition to price, they also identified other drivers of demand such as easier and more convenient water treatment options and promotion of regular use.

Comprehensive research on the effect of subsidies on the demand for insecticide treated bed nets (ITNs) is conducted by Dupas and colleagues, and can provide insights into the role of subsidies in driving the demand for health goods. In economic sense, the ITNs and Malaria are somewhat similar to toilets and diarrhea. For example, using ITNs or toilets is a private household decision, but the lack of use of ITNs can impose negative health externalities for the entire community, and the subsidies and behavior change both can be used to promote the use of ITNs and toilets. We specifically review three studies by Dupas and colleagues.

Cohen and Dupas found that charging a positive price for the ITNs reduced their demand by 60% and the cost-sharing didn't result in high use compared to the use of freely distributed [88]. The

authors argue that the households who could not buy ITNs were credit and income constrained, charging positive price (however small) reduced the public health benefits, and that the free distribution of ITNs may be a more cost-effective strategy.

In a 2013 working paper, Dupas describes an experiment to assess if long term adoption of the ITNs was affected by the short term subsidies due to an *anchoring effect* – people unwilling to pay higher price in future and expecting subsidies to use the product in future [89]. She found that the "learning effect" was dominant, so that people were willing to pay a higher price for ITNs one year after because the subsidies enabled them to experience the benefits of the ITNs, and there was no evidence of anchoring effect. The author argues that a similar effect can be expected in health goods whose benefits are well known, which last long enough for users to learn the benefits during the learning period. These conditions should largely be met by a private toilet, but the use of the toilet can also impose costs such as higher time and money investments in their upkeep, higher water collection requirement, and in case of poorly constructed toilet, even adverse health effects.

In the *Perspective* in *Science*, Dupas [90] argues that high subsidies are essential to ensure public health effectiveness for certain types of preventive health goods. She reviews studies that show that demand for deworming, water filters, and ITNs falls significantly with positive price and high subsidies, which yield much higher demand. However, providing health information about these products did not reduce price sensitivity. She also found that contrary to the sunk cost effect, the use of such goods was high, even when they were given free and people valued these products even when they didn't pay for them. However, she warns that implementation issues such as corruption, poor service, and poor product quality can undermine the effectiveness of subsidy programs. She also cautions that the demand for certain health products may remain low in spite of heavy subsidies, but mechanisms such as conditional cash transfers can help bolster the demand.

# 3.2 Research Question

This paper estimates the arc price elasticity of the demand for private toilets, and then predicts the expected toilet coverage in rural India with the higher subsidies amount under the SBM.

An important caveat is that we estimate the price elasticity of uptake or construction of private toilets, but not their use. Past research has shown that the reduction in open defecation does not exactly correspond to the increase in the IHL coverage. For example, in the two RCTs in India, the reduction of the open defecation rate was approximately half the increase in the availability of IHL, which suggests that about half of the toilets built were not used regularly or never used [77,80].

# 3.3 Identification Strategy

We estimate the price elasticity using the following model as,

$$S_{ij} = \beta_0 + \beta_1 \cdot TSC_j + \beta_2 \cdot bpl_{ij} + \beta_3 \cdot bpl_{ij} \cdot TSC_j + b_k + \varepsilon_{ij}$$
(3-1)

where,  $S_{ij}$  is an indicator variable for a newly constructed private toilet in household *i* in village *j*;  $\beta_I$  is the change in private toilet ownership among the non-BPL households between the villages that got the TSC intervention and those who didn't;  $\beta_2$  is change in private toilet ownership between the non-BPL and BPL households in the villages that didn't receive the TSC intervention;  $\beta_3$  is the change between the villages that received and didn't receive the TSC in the difference in the private toilet ownership between the non-BPL and BPL households (double difference);  $b_k$  are block level fixed effects; and  $\varepsilon_{ij}$  collects unobservable and unmeasured error terms.

The variable  $bpl_{ij}$  controls for differences between the BPL and non-BPL households other than the price (or subsidies) of toilets. The variable  $TSC_j$  controls for any non-subsidy related program effect such as intensity of IEC or BCC interventions. The coefficient  $\beta_3$ , thus, captures the effect of only the price difference on the private toilet ownership. All standard errors are clustered at the village level [60].

# **3.4 Estimation and Results**

# 3.4.1 Data

We estimate the above model using the data from the RCT of the TSC in MP state presented in Chapter 2.

## 3.4.2 Estimation of and Variation in Toilet Price

Although the TSC provided subsidies for toilet construction to only BPL households, the intervention evaluated in MP provided subsidies to even non-BPL household because of state level programmatic decisions. The BPL and non-BPL households were provided additional subsidies under a state program called *Nirmal Watika* (Clean House) under the NREGS<sup>6</sup>.

*Nirmal Watika* provided funds to the *Gram Panchayats* for materials and labor (masons as well as household's own labor) to build two-pit offset latrines and plant five fruit trees [92]. The funds under *Nirmal Watika* varied by different blocks and villages depending upon the local (block) administration's cost estimation for the specified toilet construction on the basis of difficulty in travelling to the villages, prevailing mason's rate, hard or rocky soil substrata which required special efforts, unavailability of material in local markets, and other such considerations. From the NREGS funds disbursement records [93], we identified the funds sanctioned for *Nirmal Watika* by abstracting out the entries that included the words "toilet", "TSC", or "*Nirmal Watika*" in their description of fund purpose. These records also include the number of households for whom the funds were sanctioned. We estimated the per household subsidy entitlement under *Nirmal Watika* as an average and sometimes mode of the perhousehold. Under the TSC, the sanctioned BPL household subsidy was ₹2,200 during the study period.

<sup>&</sup>lt;sup>6</sup> The NBA program is inspired by the intervention in MP. Thus, the intervention evaluated in MP is similar to the NBA which provides subsidies to both BPL and eligible non-BPL households by converging funds from the TSC and the NREGS, except that in MP the amount of subsidies varied by different administrative blocks and regions, and the subsidy amounts were lar lower than those under the NBA.

Therefore, for a BPL household, the total subsidy entitlement is the sum of sanctioned amounts under the TSC and *Nirmal Watika*, and varied from  $(2,000 + 2,200 =) \notin 4,200$  to  $(5,200 + 2,200 =) \notin 7,400$ . For a non-BPL household, the subsidy entitlement varied from  $\notin 2,000$  to  $\notin 5,200$ . We could not access any reliable data on the actual receipts and spending of above entitlements by the *Gram Panchayat*. It is possible that the actual subsidy amount spent on building toilets is lower than these estimates, but personal communication with the State monitoring and evaluation officer confirmed that the entitled subsidy amounts were at least released to the *Gram Panchayats* by the district administration [94].

We obtain the cost of a two pit offset latrines from the engineering cost estimates as per the NBA guidelines [95]. Although the cost estimates under the NBA are based on realistic price analysis by the government departments, in reality, the actual toilet price faced by the individual households can be higher if they cannot obtain the rates a government agency can from the market. The unit cost of a toilet, as per the NBA guidelines, was estimated as ₹9,900 as of April 2012. We used a ratio of building construction cost inflation indices in Delhi in April 2012 and January-March 2010 to estimate the cost of a toilet during the intervention period as ₹9,030 [96].

The potential price of the toilet is estimated by subtracting per-household subsidy entitlement from the cost of toilet (₹9,030). The average price of a toilet for the BPL households was ₹3,452 (range: ₹1,630 to ₹4,330), and for the non-BPL households was ₹5,599 (range: ₹3,830 to ₹6,530). Figure 3-1 presents the distribution of average toilet price of the BPL and non-BPL households from both the treatment and control groups.



Figure 3-1. Distribution of Price Faced by Households by their BPL Status

#### 3.4.3 Balance between the BPL and non-BPL Households at the Baseline

We test the balance between the BPL and non-BPL households at the baseline in terms of the variables listed in Table 3-1. We restrict the analysis to only those households that didn't have a toilet at the time of the baseline. On average, fewer BPL household heads attended school, more BPL households belonged to the schedule-castes-and-tribes category (also a variable correlated with poverty), fewer BPL households had a pucca (permanent/robust) house construction, and BPL households were also poorer on average. However, the proportion of households that used an improved drinking water source and had a functioning handwashing station at home - the other two important WASH infrastructure items - were similar between the BPL and non-BPL households. Figure 3-2 compares the monthly household income distribution of the BPL and non-BPL households. These distributions overlap to a great extent except at the tail ends. The Two-sample Kolmogorov-Smirnov test statistic for equality of these two distributions was 0.0875, so that the null hypothesis of equality is rejected (p-value = 0.003). Overall, socioeconomic differences between BPL and non-BPL households who didn't own a toilet at the baseline exist even though access to WASH infrastructure was not differential between these two groups. Our analysis controls for the differences between the BPL and non-BPL through an indicator variable.

	Non-E	Non-BPL Households			L Househo	Households		D 1
	N	Mean	SE	N	Mean	SE	Z	P-value
Number of members in a household (HH)	949	6.97	0.10	751	6.51	0.09	3.32	0.001
Age of HH head	949	45	0.72	751	41	0.66	3.26	0.001
Whether HH head attended school?	921	0.50	0.03	733	0.41	0.03	2.58	0.010
Whether HH belongs to Schedule caste/tribe category	899	0.70	0.03	703	0.84	0.02	-3.69	0.000
Whether HH construction is pucca type	949	0.60	0.03	751	0.46	0.03	3.46	0.001
Number of rooms in HH	940	2.17	0.06	741	1.82	0.05	4.34	0.000
Whether HH uses JMP defined improved water source	949	0.83	0.03	751	0.82	0.03	0.27	0.787
Whether soap and water present at handwashing station	945	0.43	0.04	742	0.42	0.04	0.17	0.869
Log (e) of Monthly HH income	947	8.82	0.04	751	8.70	0.03	2.27	0.023
Principal component based HH wealth index	938	-0.48	0.11	737	-0.98	0.07	3.92	0.000

 Table 3-1. Balance Between BPL and non-BPL at Baseline for Households who don't have a toilet

# 3.4.4 Relationship between Price and Toilet Ownership

Next, we compare the relationship between toilet prices and ownership of the toilet using the data from the 2011 endline survey in Figure 3-4. The sample includes households from 40 intervention villages and 10 control villages, where the funds under the TSC and *Nirmal Watika* were provided. We find that the slope or the sensitivity of toilet coverage to the toilet price is similar between the BPL and non-BPL households. However, this similarity in the relationship

can be influenced by non-price factors such as the behavior change interventions. Therefore, we control for the non-price effect of the intervention by including an indicator variable for program assignment in our analysis.





(Kolmogorov-Smirnov test statistic p-value =0.003)

# 3.4.5 Estimation of Arc Price elasticity

We estimate the arc price elasticity as discussed in Section 3.3. We estimate Equation (3-1) for all households without a toilet at the baseline, with the original treatment assignment as an indicator variable, and by specifying fixed effects at the administrative block levels because the TSC implementation can be influenced by the block level considerations and the randomization was done within the blocks. The results are presented in Table 3-2.

The average toilet coverage was 21.5 percentage points so that the percentage change in toilet coverage due to the price change is (0.097 / 21.5 =) 0.45. The difference in the toilet price between the BPL and non-BPL households is ₹2,200; equal to the subsidy provision under the TSC. The average toilet price for the BPL and non-BPL households is ₹4,526, so the percentage change in price is (2,200/4,526 =) 0.49. Dividing above two percentage changes, we estimate the arc price elasticity of the demand for private toilets as (0.45 / 0.49 =) 0.92.

Figure 3-3. Relationship between toilet price and new toilet coverage in the TSC village by BPL status of households (Lowess with moving mean average smoothing; band width 0.8)



 Table 3-2. Difference in Difference Estimate of Price Sensitivity of Demand for Private

 Toilet

Outcome: Availability of JMP defined improved sanitation facility	Coefficient	SE	Z	P-value
<b>Treat</b> $(\beta_l)$	0.154	0.035	4.36	0
<b>Bpl</b> $(\beta_2)$	-0.049	0.023	-2.14	0.035
<b>bpl*treat</b> ( $\beta_3$ )	0.097	0.039	2.45	0.016
N = 2616				
F = 5.27 (P-value < 0.001)				

#### 3.4.6 Potential Increase in Toilet Coverage due to Increased Subsidies under the SBM

The potential price faced by households under the new SBM guidelines are estimated based on an engineering cost estimate of a two pit offset latrines with water tank, brick room with a proper door and roof, and the available subsidy. Using the online e-catalogue for toilet costing, the engineering cost estimate of a household toilet is ₹18,000 (see Figure 3-6). As per the SBM guidelines, financial incentive (subsidies) of ₹12,000 is provided to a household for toilet construction [79]. Therefore, the price faced by a rural household will be (18000-12000 =) ₹6,000. Under the new SBM norms, the toilet price would change by (12,000 divided by an

average of 18,000 and 6,000 =) 100%. With the estimated price elasticity of 0.92, this price reduction can also increase the toilet coverage by 92% (relative). That is, the current toilet coverage of 30% as per 2011 Census can increase to 80% under the SBM.



Figure 3-4. Engineering costing of a two pit offset latrines with water tank.

Source: Downloaded windows app from http://sbm.gov.in/sbm\_new/

An important caveat is that the price elasticity is based on data from Madhya Pradesh and thus not externally valid to entire of India. The demand for private toilets may be more or less elastic elsewhere in India.

# 3.5 Conclusion

Using the experimental data from the TSC trial in Madhya Pradesh, we find that the arc price elasticity of the demand for private toilets is 0.92, and thus, somewhat inelastic. Because of inelastic demand, we expect that the private toilet coverage in India can increase to 80% from the current level of 30% as per the 2011 Census if the price of the toilet is reduced from 18,000 to  $\gtrless6,000$  under the SBM. However, consider four important limitations of this analysis in interpreting these finding.

First, the price elasticity can change in either direction of unity  $(\pm 1)$  if the ratio of actual subsidy utilization to subsidy entitlement is differential between the BPL and non-BPL households. In our analysis the toilet price is estimated by subtracting the "entitled" subsidies from the toilet cost. A natural concern is that the actual price is a function of actual subsidy and not only entitlements because of leakages and inefficient utilization of the subsidies. However, if the ratio of actual subsidy utilization to subsidy entitlement is the same for the BPL and non-BPL households, then the estimated price elasticity would remain unchanged because percentage change in price will remain unchanged. In the case the leakage or subsidy utilization is differential between the BPL and non-BPL households then even the percentage change in toilet

price would be differential in these two groups and the estimated price elasticity will not be a reliable estimate.

Second, the actual percentage change in price may be much lower than what we used in our analysis. We assumed that the price will reduce from Rs 18000 to Rs 6000 with a subsidy of Rs 12000, but in reality the price reduction could be much smaller due to leakages and inefficient subsidy utilization or much higher cost of toilet than we assumed. For example, if we assume, say, 50% loss of subsidy (effective subsidy of Rs 6000 instead of Rs 12000) to leakages, the percentage change in price will be (6000/15000 =) 40% so that the corresponding percentage change in the toilet coverage will be  $(0.92 \times 40 =) 37\%$  or in absolute terms increase of toilet coverage from 30% to 44%. We are aware that direct cash transfer is being considered under the SBM to reduce the potential for leakage of funds.

Third, the potential toilet coverage in a community is dependent on the current current level of toilet coverage. For example, the potential toilet coverage in villages with current toilet coverage of 20% will be 54% with increased subsidies under the SBM, and in the villages with current toilet coverage of 10%, the potential toilet coverage will be only 27%. Therefore, the objective of Open Defecation Free village may not be met if the current toilet coverage is significantly lower.

Fourth, increase in toilet coverage by itself will not ensure corresponding reduction in open defecation. For example, pooling data from four RCTs, Gertler and colleagues found that the open defecation levels fell by only about 30% when the toilet coverage increases by 80% [24]. The TSC trial in Madhya Pradesh also found that 40% of those who had built a private toilet in the intervention group continued to defecate in open [77]. Another RCT of the scaled up TSC in Odisha also found that while the TSC increased toilet coverage by 51% the functional (in-use) toilets increased by only 28% compared to the control group levels [17]. Therefore, even universal coverage of private toilets through subsidies may not eliminate open defecation. However, infrastructure built through subsidies is an important pathway for reducing open defecation along with intensive behavior change campaigns [24,75].

The future research should investigate the role subsidies can play to spur the demand for private toilets and their use. The currently SBM mechanism uses subsidies to reduce the price but the subsidies can be also restructured to incentivize not only construction of private toilets but also reducing open defecation levels in the entire community. For example, the subsidies or direct cash transfers can be made conditional on both the private toilet construction as well as the group/community level toilet coverage to create social pressures. Guiteras and colleagues [75] find that social networks and group level subsidies are effective designs based on their RCT in Bangladesh. The financial incentives can also be conditional on demonstrated use over several months or a few years instead of a one-time payment. The existing group level award such as *Nirmal Gram Puraskar* (NGP) can be designed to create social pressures for consistent and sustained use. Even social business models can be promoted through market driven mechanisms. Overall, several options for "economic incentives through subsidies" are possible but remain untested in the field.

On the other hand, the role for traditional (non-economic) behavior change interventions is also important to address the non-economic constraints such as habits or social norms and the "intensity" of such interventions matter [24,75,77]. However, only behavior change interventions would not be sufficient to significantly increase the toilet coverage and use [75]. Therefore, a strong "nudge" to create demand should continue to be a part of the SBM guidelines and actual implementation both, and ideally, integrated with economic incentives. Rigorous data driven and experimental research is lacking on which behavior change interventions can be effective and this presents another major research gap in sanitation sector.

# Chapter 4: Is Sanitation the (only) Noah's Arc? Importance of Other Risk Factors for Linear Growth Faltering

# 4.1 Introduction

The impact evaluation of the Total Sanitation Campaign (TSC) in Madhya Pradesh found that the coverage of improved sanitation facilities (private toilets) increased modestly, but the much smaller reduction in the open defecation levels was arguably inadequate to result in health benefits in terms of reduced enteric diseases and increased child growth [77]. Another impact evaluation of the TSC in Odisha found much larger impact on the availability of functional toilets than those found in Madhya Pradesh but almost half of them were not used regularly. This impact evaluation also did not find any effect of the TSC on various health outcomes. On the other hand, a RCT of Community Led Total Sanitation (CLTS) intervention [20] in Mali that consisted of intensive behavior change communication without any subsidies for toilet construction found that the diarrhea prevalence did not decrease but the children younger than two years grew taller (height-for-age increased by of 0.2 Z) [97]. An observational ecological scale analysis from India also associated open defecation or lack of toilets with stunting or lower height-for-age for pre-school age children [25]. A pooled cross sectional analysis of data from four different RCTs of sanitation interventions also linked sanitation with stunting [24]. Overall, whether sanitation programs are effective or not can depend on the regional or local contexts and the mechanisms used to promote sanitation, and the height-for-age Z score for younger children is emerging as a sensitive indicator to evaluate health effects of sanitation interventions.

In this chapter, I explore what are the important risk factors, including ownership of improved sanitation facilities (private toilets), for impairing linear growth — height-for-age Z [HAZ] — of children aged 6-24 months using a nationally representative Demographic and Household Survey (DHS) data from India. Objective assessment of importance of several risk factors for growth impairment during the initial life years can help the public health sector prioritize research and action in a more objective and evidence based manner especially in resource constrained settings within developing countries. I propose a variable importance analysis method based on machine learning based non-parametric prediction using SuperLearner [98,99] and statistical inference using a double robust estimator called Targeted Maximum Likelihood Estimator (TMLE) [100,101].

# 4.1.1 Growth Faltering and the Risk Factors

Stunting — defined as HAZ below -2 Z (2 standard deviations) from the median of the WHO Child Growth Standards — is a strong indicator of chronic malnutrition and health status during the initial years of life [102]. Child malnutrition is strongly associated with shorter adult height, less schooling, reduced economic productivity, and lower birthweight of the offspring [103]. Berkman and colleagues found that severe stunting in the second year of age is associated significantly with lower cognitive function in the ninth year of age [104]. Adair and colleagues confirmed these findings and further associated lower birthweight and linear growth to a few adult-life chronic diseases [105].

The burden of stunted or malnourished children is high in developing countries, especially India. A Lancet series from 2013 highlighted that while the proportion of stunted children under five years of age decreased over the past two decades, 167 million children globally were stunted and 3.1 million perished due to aggregate undernutrition related factors in 2011; 45% of all child deaths [106]. Close to 99.5 million or 58% of the stunted children were from the Asia region as of 2010; India accounted for approximately one third of the stunted children globally [107]. A nationally representative survey in 2014 found that the prevalence of stunted children under five years of age was 38.8% (48.7 million) in 2013-14 [108,109]. As per the ongoing and partially published (15 states) DHS data (2015-16), the proportion of stunted pre-school children ranged from 21% to 50% in rural areas and 17%-40% in urban areas [110] suggesting that the burden of impaired growth is still substantial in India.

There is growing evidence on which risk factors need to be targeted to help reduce the burden of chronic malnutrition or linear growth faltering in the initial years of life. Nutritional interventions are often considered more efficacious than others. For example, Bhutta and colleagues reviewed the programs and interventions that can help reduce stunting and found that education about complementary feeding and breastfeeding in populations with sufficient food, and provision of food supplements (with or without education) in populations without sufficient food are effective [111]. Other interventions delivering micronutrient and iron folate supplements for pregnant women, vitamin A, zinc and iron supplements for children, and iodized salt were also effective. A review of four intervention trials also suggested that the adverse effects of certain infections (*e.g.*, diarrhea caused by poor water and sanitation) on growth can be reduced by improving nutrition [112].

Mother's nutrition and intergenerational effects through the mother are also known risk factors for impaired growth of children. For example, mother's body mass index (BMI) and height are strong predictors of a child's stunting [106,111]. Low birthweight, stunting, delivery complications, and increased child mortality are also associated with the mother's height [113]. The intergenerational effects via mother who was malnourished as a child can be overcome through improvements in health, nutrition, and the environment through the life of the potential mother before she conceives.

Poor water, sanitation and hygiene are also emerging as risk factors for stunting. Humphrey and colleagues argued that *environmental enteropathy* results in retarded growth and a decrease in the efficacy of nutritional interventions [23]. Environmental enteropathy causes nutrient malabsorption by changing the structure and function of the small intestine, even without any outward symptoms. Environmental enteropathy is unlikely to reverse without improved sanitation and hygiene practices, which can reduce the risk of re-infections by waterborne pathogens. For example, the risk of stunting was lowest and the likelihood of reversing stunting was highest in the group that came from homes that had both water and sanitation, compared to children from homes without these facilities [114]. Lin and colleagues found poor household environment is associated with environmental enteropathy and impaired growth [22]. Deworming has potential to improve nutritional status and growth, but recovering the nutritional deficits would require extra energy, protein, and micronutrients supplements [115]. Recent observational and ecological scale analyses also strongly associated open defecation with stunting [24,25].

Several socio-economic and social factors are also known to be associated with stunting. For example, factors such as poverty, education, burden of diseases, and women's empowerment were recommended as effective interventions to reduce stunting [111]. The mother's post-partum depression is also found to be associated with the child's stunting possibly due to inadequate care during the child's growth period [113]. Wealth is also a strongly associated with stunting suggesting that the underlying socio-economic factors can play a role [116,117].

While several risk factors and interventions to manage these risk factors are studied, which risk factors are more important to be addressed or which interventions will be efficacious in a local context is unclear. Even the strongest reported nutritional intervention (+0.7 standard deviation on WHO growth standards) accounts for only about a third of the average HAZ deficit among Asian and African children (-2.0 Z) [23]. The effectiveness of different interventions will also be moderated through underlying factors such as education, poverty, women's empowerment, and adolescent health of the future mother [111]. Therefore, several interventions are potential candidates to reduce stunting and include mothers' education, mothers' health and nutrition before conception and during pregnancy, both pre and post-natal child and mother care, vitamins and micronutrient supplements for the mother and child, breast feeding, complimentary feeding, child care during growth stages, deworming, water-sanitation-hygiene improvements, and more.

The existing evidence also cannot help but prioritize the risk factors for further research or action because most existing studies include one or a few risk factors to investigate ignoring others that may also matter. The modeling assumptions and methods used to estimate the association or importance of risk factors for growth faltering also differ across different analyses and studies so the level of importance reported cannot be easily compared across the studies. The importance of a risk factor can also be moderated by the prevailing population, as well as geographical and temporal factors. For example, in a population where adequate breast feeding and complimentary feeding practices have high coverage, interventions targeting these risk factors will likely prove less important than those targeting, say, water and sanitation infrastructure. Therefore, what may be an important risk factor in, say, Africa need not be so in India.

Overall, there is a need for an objective, standardized and transparent method to estimate importance of several known and measured risk factors for growth faltering in initial years of life — to the extent feasible with available data — so that further prioritization of research and action can be driven by evidence.

#### 4.1.2 Research Objectives

The research objectives of this paper is two folds:

1. *Demonstrate a non-parametric machine learning-based method* to estimate the magnitude and statistical significance of the variable importance measures (VIM) of the risk factors for linear growth (HAZ) faltering. We used an ensemble machine learning algorithm SuperLearner for prediction of the relationship between HAZ, risk factors, and covariates and a double robust estimator TMLE to estimate the marginal effect of a risk factor on HAZ along with its standard error.

To evaluate the improvement in inference by using TMLE estimator instead of the traditional maximum likelihood estimator, we compare the magnitude and standard errors

of the marginal effects estimated using a Generalized Linear Model with identity link (GLM; a linear regression model with only main effects) with both the TMLE and maximum likelihood estimation.

To assess the advantage of using TMLE estimator with non-parametric machine learning algorithms instead of parametric GLM models, we compare the predictive fit in terms of  $R^2$ , and the magnitudes and standard errors of the marginal effects estimated using SuperLearner prediction with TMLE (SL-TMLE) and GLS prediction with TMLE (GLM-TMLE).

Finally, in addition to the marginal effect of a risk factor on HAZ as a variable importance measure, we also estimate the *population level attributable effect* of the risk factor on HAZ. The marginal effect is the change in HAZ for a unit change in a risk factor whereas the population attributable effect is the change HAZ if the current prevalence of a risk factor in a population is reduced to zero; both these parameters are explained later.

2. Apply the proposed method to the nationally representative DHS data from India [5] to assess the importance of several potential risk factors for linear growth faltering. The DHS datasets are available globally, standardized, and are typically representative at subnational levels. The DHS usually contains rich data on socio-economics, demographics, child and maternal health, and reproductive health, and form an important basis of global public health policies. The sample size of a DHS is also large enough to allow required degrees of freedom for complex non-parametric model specifications. Therefore, I hope that the case study application for India can be replicated for other countries and we can obtain standardized and regionally and locally relevant variable importance measures for several risk factors.

I will estimate the marginal and population attributable effects as variable importance of 51 indicators (or variables) related to child nutrition, a mother's health and nutrition, preand post-natal care, water and sanitation, and various social, demographic and economic risk factors.

It is important to note that the variable importance measures are not causal effects. We mainly argue that non-parametric machine learning based methods with typically available large DHS data can provide a useful and objective decision support tool to prioritize and guide research and action to decrease growth faltering during the initial life years.

#### 4.1.3 Organization of the paper

Section 2 describes the data, statistical methods, and estimation of the variable importance measures. Section 3 presents the results from the case study application using the DHS data from India. Section 4 concludes by summarizing the key findings and their implications.

# 4.2 Methods

## 4.2.1 Proposed Variable Importance Analysis Method

We use a variable importance analysis method proposed by van der Laan [118] and estimate the VIMs that are similar in interpretation to the causal risk parameters commonly encountered in epidemiology and biostatistics such as marginal effect or risk differences and population attributable risk. The proposed method uses a machine learning algorithm called SuperLearner to find the best predictive fit between HAZ, a risk factor under consideration, and other covariates. Then, the marginal effect or population attributable effect as a measure of variable importance is estimated using TMLE estimator.

While the prediction using SuperLearner is proven to be at least as good as one of the ensemble algorithms including any parametric model, the TMLE will perform at least as good as the traditional maximum likelihood estimator, but it will be consistent and more efficient under certain assumptions. Additionally, TMLE estimator is asymptotically linear so that we can estimate standard errors of the variable importance measures even when the prediction is based on machine learning algorithms which don't have any known parametric form to mathematically computer standard errors. These properties of TMLE are proven in simulation studies that compare TMLE performance with other estimators such as the maximum likelihood estimator [119–121] and those that compare machine learning prediction using SuperLearner to the prediction by parametric models [99,122]. The theoretical properties of SuperLearner and TMLE are discussed further in the Methods Section.

### 4.2.2 Data

We use DHS data from India for the years 2005-06 as a secondary data source for our analysis. The DHS, also known as National Family and Health Survey (NFHS) in India, is implemented by the International Institute for Population Sciences under the aegis of the Government of India, and with help of several professional survey agencies in India [5]. The DHS collected data on fertility, mortality, family planning, reproductive health, maternal and child health, nutrition, adolescent health, demographic, and socio economic information at household and individual levels that is representative at state levels or rural and urban populations. The sample size consists of 109,041 households, including 124,385 women aged 15-49 and 74,369 men aged 15-54 from 29 states of India.

The target population for our analysis is rural and urban children between 6-24 months of age (both ends included). The rural sample used in the analysis consists of 7,919 children aged 6-24 months from 7,686 households in 2,045 villages. The urban sample consists of 4,556 children aged 6-24 months from 4,456 households in 1,422 wards. The NFHS collected detailed information on antenatal and postnatal care and child feeding only for the youngest child of a mother in the house so that only the data for the youngest children is used in the analysis. This resulted in a loss of about 5% of the total sample of 6-24 months old children; total sample of children was 8,323 and 4,803 in urban and rural areas, respectively. Additional information is available in the NFHS survey report [5].

We chose the target population of children aged 6-24 months because the DHS data shows that the linear growth faltering happens between 6-24 months of life and thereafter HAZ flattens out

as children age with little variation [5] consistent with global trends [123]. We also chose to model the rural and urban populations separately because environmental risk factors, population densities, access to health care, population composition, and prevalence of risk factors associated with growth faltering can be significantly different between rural and urban populations.

## 4.2.3 Construction of Indicators for Risk Factors

In Table 4-1, we list and describe how we create 51 indicators or variables related to several (potential) risk factors that we use in our analysis. Twenty-five of these 51 indicators are continuous and rest are dichotomous (binary) variables. The proposed variable importance measures discussed in 4.2.4.2 estimate change in HAZ per unit change in each of these 51 variables. However, the "unit change" in the case of binary and continuous variables is a different measurement. In the case of binary variables, the unit change helps us estimate the change in HAZ *with or without* the risk factor or the variable whereas in the case of continuous variable, the unit change help us estimate the change in HAZ if the variable changes by one at that point (instantaneous rate). Therefore, the change in HAZ per unit change in a continuous variable can be different depending upon the starting value of the continuous variable.

In order to ensure that the estimated VIMs are comparable for both binary and continuous variables, we dichotomize the continuous or ordered variables based on a cut-off value of biological or economic significance, or sometimes purely on the basis of an assumption. For example, in the case of a mother's height, we create an indicator variable of whether the mother's height is less than 145 cm; a level at which children are at a higher risk of stunting as per published evidence [106]. In regards to the number of living members in a household, we chose a cut off level of 7 members to dichotomize the variable because we *assumed* that more than 7 members can be considered are large families. Table 4-1 also presents the sample size and mean or percentage for these 51 indicators for the rural and urban populations separately.

# 4.2.4 Statistical Methods

The content of this section is based on the theory and example applications presented by van der Laan [118], Diaz and colleagues [124], and Hubbard and colleagues [125].

#### 4.2.4.1 Data structure

Consider independently and identically distributed (iid) observed data structure  $O = (Y, W^*)$ , where Y is the outcome of interest (HAZ for children 6-24 months of age) and  $W^*$  is a vector of input variables used to predict Y. Let A be a dichotomous variable for which we seek to estimate the effect on Y of A = 1 compared to A = 0, where  $W^* = (A, W)$  such that W is a vector of input variables other than A. Variable A is dichotomized if required as discussed in Section 4.2.3. The observed data is one instance of the true data generating distribution, which we don't observe and the complex relationships between Y and  $W^*$  are unknown. We verify the positivity assumption is not (even nearly) violated, so that 1 > Pr(A = 1 | W) > 0.

 $W^*$  includes 51 variables related to household socio-economics, child and mother demographics, antenatal and postpartum care, child feeding and nutrition, mother and child vaccination and micronutrients, water-sanitation facilities and water treatment, gender attitudes, public health services in the community, prevalence of diarrhea, and acute respiratory infections in the community as summarized in Table 4.1.

#### 4.2.4.2 Target Parameters: Variable Importance Measures

We estimate two parameters for the variable importance measures as follows.

First, drawing from the terminology used by van der Laan [118], we estimate Marginal Variable Importance (Marginal-VIM), which is similar to the causal inference concept of Average Treatment Effect or Risk Difference (see [126–130] for theoretical discussions and reviews) as,

Marginal-VIM = 
$$E_{W}[E(Y|A = 0, W) - E(Y|A = 1, W)]$$
 (4-1)

The Marginal-VIM cannot be interpreted as causal unless three critical assumptions are met: (1) time ordering of observed data structure (Y, A, W); (2) consistency assumption that the observed data is a missing data structure for counterfactual outcomes; and (3) randomization assumption that there is no unmeasured confounding.

Even when these assumptions are not met, Marginal-VIM is a meaningful measure of adjusted association, and can be thought of as a nonparametric generalization to the coefficients on variables of interest in a parametric model. Thus, these measures help prioritize important factors based on "associations" to guide subsequent research to investigate their causal importance [118]. For example, the above assumptions may also not be met even for a parametric model using maximum likelihood estimation. However, if the model for either *A* or *Y* is correctly specified, the TMLE will provide consistent estimates. Because the TMLE is targeted to the parameter of interest instead of all parameters or coefficients of the model, we can gain more efficiency and lower (*not zero*) bias than the traditional maximum likelihood estimation.

Second, we estimate Population-level Variable Importance Measures (Population-VIM), which are similar in construction to the Population Attributable Risk in epidemiology [131] and a new population level estimator based on population intervention models in causal inference literature (See [132,133] for theory and [134,135] for application). The Population-VIM is estimated as,

Population-VIM = 
$$E(Y|A = 0, W) - E(Y|A = a, W)$$
 (4-2)

Where we estimate the difference in the predicted mean Y when entire population is set to A = 0 (no one is exposed to the risk factor) versus the current mean of the distribution of Y in the population. If everyone is the population is currently exposed to the risk factor A, the Marginal-VIM and Population-VIM will both be same and if no one in the population is currently exposed to the risk factor then the Population-VIM will be zero. However, more realistically, Population-VIM is always lower than the corresponding Marginal-VIM.

Finally, for the sake of comparison of the proposed method with traditional parametric regression based methods, we specify a linear regression model as,

$$E(Y|A, W) = \beta_0 + \beta_1 A + \beta W$$
(4-3)

Where, the coefficient  $\beta_1$  is the change in *Y* as *A* changes from 0 to 1, and thus equivalent to the Marginal-VIM specified above. We also estimate the above model using the TMLE as well as maximum likelihood estimator.

## 4.2.4.3 TMLE Estimator for the Variable Importance Measures

The theoretical construct of the VIMs places no restriction on the distribution of  $O \sim P_0$ . Several non-parametric and semi-parametric estimators are available such as the simple substitution estimator (SSE) based on G-computation [136], Inverse Probability of Treatment Weighted estimator [137–139], and the augmented substitution estimator, Targeted Maximum Likelihood Estimator (TMLE) [100,101,140]. We estimate the variable importance measures using TMLE, but also compare the results with those estimated using the SSE.

The TMLE is theoretically more attractive than the SSE because both there is a Central Limit Theorem for TMLE estimators (which does not exist for general SSE) and because the TMLE is *doubly robust*. Specifically, TMLE is consistent if either E(Y|A, W) or P(A|W) is consistently estimated and is efficient if both are consistently estimated. Finally, the TMLE is also robust to empirical violations of the positivity assumptions (that is when the estimate of Pr(A = 1|W) is close to 0 or 1) [98,141].

A practical attraction of TMLE is obtaining a standard error of the targeted parameter based on an influence curve; a plug-in estimate which works for parametric as well as non-parametric models. Therefore, TMLE estimator can be coupled with SuperLearner based prediction which has no known model or form (non-parametric) whereas maximum likelihood will always require parametric model form to have a predictably normal sampling distribution, and thus no general approach exists for deriving confidence intervals for a SSE.

# 4.2.4.4 SuperLearner Prediction

We impose no parametric assumption on the structural form of the relationship between Y, A, and W. For each continuous A of the 51 variables we analyze ( $A \in W^*$ ), we specify separate predictions models because we need to dichotomize a different A in each model.

SuperLearner finds an optimal combination of the user supplied estimation algorithms (parametric or non-parametric) to find the best possible fit (conditional on supplied list of algorithms) to predict E(Y|A, W) and P(A|W) [98,142]. SuperLearner avoids overfitting by using cross-validated risks to choose the combination of learners, where procedures are fit using, say, nine-tenths of the data and then validated (the risk estimated) using the remaining one tenth of the data. The entire process is repeated for each unique fold (say 10 times) before the best possible fit is selected. The SuperLearner package is available in R [99,143].

SuperLearner is theoretically equivalent to the *Oracle Selector* because it will predict at least as good as the best fit algorithm supplied to it. However, this does not mean that SuperLearner will always have good prediction fit and can perform poorly (but as good or better than any of the user specified estimation algorithms).

To estimate Marginal-VIM, we used the following parametric and non-parametric estimation algorithms in SuperLearner:

- Ordinary Least Square (OLS) and Logistic regression with main terms (GLM)
- GLM with main terms and all possible interactions (GLM.INTERACTION)
- Generalized additive models (GAM)
- Least Absolute Shrinkage and Selection Operator (LASSO) regression (GLMNET)

- Ridge regression (RIDGE); only when predicting continuous *Y*
- K nearest Neighbor regression (KNN); only when predicting binary A
- Earth

To estimate the Population-VIM, we use a R package called *multiPIM* which has the following default algorithms [144,145]:

- For binary A: Polyclass, Penalized.bin, GLM with main terms (logistic)
- For continuous *Y*: Polymars, LARS, GLM with main terms

The R code for estimating Marginal-VIM and Population-VIM is provided in the *Supplemental Material to Chapter 4*. The TMLE is used to estimate the standard error of the marginal-VIM and population-VIM. To adjust for multiple comparisons or testing of independent hypotheses, we apply the Benjamini and Hochberg (BH) correction to control the False Discovery Rate (hereafter, BH FDR Correction) [146].

# 4.3 Results and Discussion

## 4.3.1 Data Description

Table 4-1 summarizes the variables used in the VIM analyses in terms of sample size and means or proportions. Continuous or multi-level variables are dichotomized as described in Section 4.2.3 and Table 4-1.

Over 60% of the households were relatively young with the head of the household aged 45 years or younger. Close to 40% of households in rural India had no access to electricity compared to 7% of households in urban areas. Over 90% of the rural households used unclean cooking fuel such as fire wood or kerosene and 38% of households belong to the marginalized schedule castes or tribes category. The urban households were relatively better off on average, with almost 60% using LPG, biogas, or electricity for cooking, and only 17% having kuccha (a permeable, raw, not permanent or robust) floor. Over 70% of the rural households did not have an improved sanitation facility (a private toilet), and 88% disposed of child feces in open compared to 25% of urban households without a private toilets and 59% that disposed of child feces in open. Overall, the drinking water treatment rate was significantly low in both populations with barely 20% of the households practicing water purification and treatment methods.

A little over 50% of mothers in urban areas and 57% of mothers in rural areas were below the age of 25 years. However, 55% of the mothers from rural areas were adolescents (less than 20 years of age) compared to 38% of mothers from urban areas when they first delivered a child. Seventy-eight percent of mothers from rural areas had less than elementary education (8<sup>th</sup> grade or lower) compared to 49% of mothers from urban areas. Out of seven food group categories, rural area mothers consumed on average 3.3 food groups in the past week compared to an average 4.1 food groups consumed by urban mothers. Over 40% mothers from rural areas were severely underweight, with a BMI less than 18.5 compared to 28% of mothers from urban areas.

Variables	Description	R	ural	U	rban
variables	Description	Ν	mean	Ν	Mean
<b>Outcome: Height-for-Age Z Score</b>	HAZ as per WHO Growth Standard (2006)	7919	-1.68	4556	-1.32
<- 7 household Members	Number of living members in the HH	7919	6.90	4556	6.44
<= 7 nousenoiu Members	1 if <= 7	7919	0.67	4556	0.72
Female HH Head	Whether the HH head is a female	7919	0.11	4556	0.10
UU Hood <- 45 Voors	Age of the HH head (Years)	7919	43.73	4556	42.77
nn neau <= 45 Tears	1 if <= 45	7919	0.60	4556	0.62
Outdoors Kitchen	Whether the kitchen is located outdoors	7919	0.16	4556	0.08
Single Deem Dwelling	Number of rooms in the house	7919	1.95	4556	1.91
Single Koom Dwennig	1 if == 1 (Single Room Dwelling)	7919	0.45	4556	0.47
No on < 1 A one of Immigrated I and	Acres of irrigated farm land of the HH	7919	1.11	4556	0.44
No of < 1 Acre of fifigated Land	1 if < 1	7919	0.76	4556	0.92
No Electricity Connection	Whether HH does not have electrical power supply	7919	0.39	4556	0.07
Don't use cleaner cooking fuels	Whether HH do not use LPG, biogas or electricity to cook	7919	0.91	4556	0.41
Below Poverty Line HH	Whether HH has Below Poverty Line status as per Government Records	7919	0.27	4556	0.13
	$\frac{15 \text{ (Poorer HH)}}{1 \text{ if } < 15}$		13.16	4556	18.33
Asset Index < 15 (Poorer HH)	1 if < 15	7919	0.64	4556	0.39
Scheduled Caste/Tribe HH	Whether the HH belongs to Scheduled Castes or Tribes as per Government Classification	7919	0.38	4556	0.26
Floor in House is <i>Kuccha</i>	Whether the floor of the house <i>kuccha</i> or made of material such as mud, wood planks	7919	0.63	4556	0.17
No Bed-net in HH	Whether HH does not own any bed-net(s)	7919	0.55	4556	0.59
Mathania - 25 Vaana	Mothers age (Years)	7919	25.57	4556	25.83
Wother is <= 25 Tears	1 if <= 25	7919	0.57	4556	0.52
Mother's Education <- 8th Std	Years of mother's education	7919	4.16	4556	7.79
Wother's Education <= 8th Stu	1 if $\leq 8$ (Less than secondary education)	7919	0.78	4556	0.49
Mother Not Exposed to Media	Whether mother not exposed to print, radio or television almost daily	7919	0.64	4556	0.27
Mother Adoloscent for First Child	Mothers age at the first child's birth (Years)	7919	19.66	4556	21.19
Wother Adolescent for First Child	1 if < 20 (Adolescent Mother)	tanks7919does not own any bed-net(s)7919(Years)79195579195679196 (Less than secondary education)79196 (Less than secondary education)79196 the first child's birth (Years)7919791979197919791979197919791979197919791979197919791979197919791979197919		4556	0.38
Child Pregnancy was Un-Planned	Whether mother did not want / plan the pregnancy for the child	7919	0.21	4556	0.22
Father did not Attend Antenatal Visits	Whether father was not present during antenatal checks	7919	0.53	4556	0.31
Mother's Gender Attitude Index < 8	Additive index of mother's empowerment and gender based on attitudes (0 to 17): places mother is allowed to visit alone, mother having own money, occasions when mother thinks it's OK for husband	7919	9.06	4556	10.84

 Table 4-1. Variables, Their Dichotomization, Sample Size and Means

Variables	Description			Urban		
variables	Description	Ν	mean	Ν	Mean	
	to hit, Mother involved in decision about healthcare, purchases, family					
	matters					
	1 if < 8	7919	0.33	4556	0.18	
Mother is Currently Pregnant	Whether the mother is currently pregnant	7919	0.09	4556	0.08	
Mother Consumes < 5 Food Croups	Number of food groups the mother consumed at least weekly (Max 7)	7919	3.26	4556	4.08	
Would Consumes < 5 Food Groups	1 if < 5	7919	0.81	4556	0.64	
<b>Tobacco Consumption by Mother</b>	Whether mother smokes or chews tobacco	7919	0.14	4556	0.09	
Mother's Height > 145 cm	er's Height < 145 cm		151.71	4556	152.29	
Wother Sheight < 145 cm			0.11	4556	0.10	
Mothor's RMI < 185	Mother's Body Mass Index	7919	19.47	4556	21.10	
	1 if < 18.5	7919	0.41	4556	0.28	
Child is $> -12$ Months	Child's age in completed months	7919	14.48	4556	14.74	
Cliniu IS >= 12 Wonths	$1 \text{ if } \ge 12$	7919	0.66	4556	0.67	
Male Child	Whether the child is male	7919	0.52	4556	0.52	
	Whether the spacing between two children is $< 36$ months in case of					
Spacing of < 36 Months	second and higher order children. Spacing considered adequate for first	7919	0.41	4556	0.35	
	child					
Not the First Child	Birth order of the child	7919	2.76	4556	2.21	
	1 if != 1 (Not a First Child)	7919	0.71	4556	0.63	
Do Not Use Improved Drinking Water	Whether HH does not use improved drinking water source	7919	0.23	4556	0.09	
Source	when in a des not use miproved dimining water source	()1)	0.25	1550	0.09	
Do not Use Improved Sanitation	Whether HH does not use improved sanitation facility for defecation	7919	0.71	4556	0.24	
Facilities	Whenever the does not use hip oved sumation facinity for detection	,,,,,,	0.71	1000	0.21	
Unsafe Child Feces Disposal	Whether youngest child feces not disposed safely in a toilet	7919	0.88	4556	0.59	
Do Not Boil Drinking Water	Whether HH does not regularly boil drinking water	7919	0.82	4556	0.76	
Do Not Sift Drinking Water	Whether HH does not regularly filter drinking water with cloth or	7919	0.88	4556	0.85	
	plastic net or sieve	,,,,,,	0.00		0.00	
Do Not Filter Drinking Water	Whether HH does not regularly filter drinking water with advance	7919	0.96	4556	0.85	
	filters (candle, electrical)					
< 4 Antenatal Checks	Number of antenatal checks/visits	7919	3.18	4556	5.42	
	1 if < 4	7919	0.66	4556	0.34	
	Number or tetanus injections mother received	7919	1.79	4556	2.10	
Inadequate Tetanus Vaccination	1 if mother no tetanus prior to pregnancy and <3 shots during				~ = 1	
<b>1</b>	pregnancy, or $< 2$ shots during pregnancy if tetanus before the	7919	0.79	4556	0.74	
	pregnancy	7010	0.04	4555	0.01	
Mother Not Dewormed	Whether mother was not dewormed during pregnancy	7919	0.96	4556	0.96	
Not an Institutional Delivery	Whether the child was not delivered in an institutional setting	7919	0.66	4556	0.29	

VariablesDescriptionBirth Size Small or AverageWhether the size of the child at birth was av Hours from birth when the child was breastf	Description	R	ural	Uı	rban
variables	Description	Ν	mean	Ν	Mean
Birth Size Small or Average	Whether the size of the child at birth was average or below	7919	0.78	4556	0.75
Not Propertied during the First Hour	Hours from birth when the child was breastfed for the first time	7919	29.23	4556	27.90
Not breastied during the First Hour	1 if > 1	7919	0.57	4556	0.55
	Number of food items other than breastmilk the child was fed during	7010	0.67	1556	0.62
Child Fed Other Foods in First 3 Days	the first 3 days of life	/919	0.07	4330	0.02
	1  if  >= 1	7919	0.50	4556	0.47
Former on Planding in postportum	Whether mother suffered high fever or vaginal bleeding 2 months after	7010	0.22	1556	0.19
rever or bleeding in postpartum	the delivery	/919	0.22	4330	0.18
Child Not Given Vitamin A Dose in 6	Number of Vitamin A doses the child received in past 6 months	7919	0.39	4556	0.47
Months	1 if 0 doses in past 6 months	7919	0.80	4556	0.77
	Number of vaccinations the child received since birth $(0 - 8)$	7919	5.62	4556	6.42
Child Not Fully Immunized	1 if $< 8$ vaccinations for children $>= 9$ months and 1 if $< 7$	7010	0.50	1556	0.42
	vaccinations for children 6-9 months	/919	0.39	4330	0.45
Inadequate Iodine in House Salt	Whether the HH salt has $< 15$ PPM iodine	7919	0.53	4556	0.26
Child Commontly Not Broogtfod	Number of times the child is breastfed in 24 hours	7919	9.25	4556	7.61
Clinia Currentity Not Breastied	1 if child not currently breastfed	7919	0.12	4556	0.24
	Principal Component based index of number of food groups and	7010	0.37	1556	0.63
Child Not Fed as per IYCF Guidelines	number of times the child ate	/919	0.37	4330	0.05
	1 if child fed as per WHO IYCF guidelines	7919	0.94	4556	0.89
	Principal Component based index of ICDS services received by the	7010	0.25	1556	0.38
Child Not Fed as per IYCF Guidelines       Interpret Component based mean of number of number of number of times the child ate         PCA based ICDS Service Index < 0	child and mother	/919	0.23	4330	-0.38
	1 if < 0	7919	0.68	4556	0.87
Diarrhan Reported in the Community	2-week period prevalence of diarrhea in the PSU (village, ward)	7919	0.10	4556	0.10
Diamica Reported in the Community	1  if  > 0  (diarrhea reported)	7919	0.66	4556	0.59
	2-week period prevalence of acute respiratory infections in the PSU	7010	0.00	1556	0.00
ARI Reported in the Community	(village, ward)	/717	0.09	4550	0.09
	1  if > 0  (ARI reported)	7919	0.60	4556	0.53

Acronyms and Abbreviations: Height-for-Age Z Score (HAZ); Liquid Petroleum Gas (LPG); Infant and Young Child Feeding (IYCF); Household (HH), Primary Sampling Unit (PSU), Acute Respiratory Infections (ARI); Principal Component Analysis (PCA); and Integrated Child Development Scheme (ICDS)

Blue colored font: Dichotomization rule applied to continuous variables.

The percentage of rural mothers who did not receive the recommended level of four antenatal health check-up visits was 66% compared to 34% mothers from urban areas. Almost 75% or more mothers did not receive the recommended tetanus doses and almost no one was dewormed during the pregnancy. Almost two-thirds of deliveries in rural areas were not in an institutional setting (66%) compared to 29% of non-institutional deliveries in urban areas. More than 55% mothers reported that the child was not breastfed within the first hour of birth, and more than 50% children were even fed something other than breast milk in the first three days of life.

Almost 80% of the children did not receive even one vitamin-A dose in the past 6 months and approximately 60% of the children in rural India and 43% in urban India were not fully immunized as per the national health mission norms. About 90% of the children were not fed as per the WHO recommended infant and young children feeding (IYCF) practices<sup>7</sup>.

The average HAZ of children 6-24 months old is -1.7 Z below the global median in rural India and -1.3 Z in urban India. This corresponds to 44% children as stunted (HAZ < -2 Z) and 21% children as severely stunted (HAZ < -3 Z) in the rural areas, and 34% children as stunted (HAZ < -2 Z) and 14% children as severely stunted (HAZ < -3 Z) in the urban areas.

## 4.3.2 Prediction Fit

The SuperLearner prediction fit is evaluated in terms of *Cross Validated Risks* of the individual ensemble estimation algorithms and the SuperLearner [98,99]. Smaller the cross validated risk better is the prediction. Figure 4-1 presents the plot of cross validated risks for predicting HAZ by different algorithms listed in Section 4.2.4.4. The cross validated risk is lowest for the SuperLearner (although not discernible in the plot), but even other individual algorithms except the GLM model with main and all interaction terms (SL.GLM.Interaction.All) did "practically" equally good in terms of the cross validated risk. SL.GLM.Interaction.All model has the largest cross validated risk and thus the poorest fit.

Different learning algorithms contributed to the SuperLearner prediction in different proportions and thus each help explain a part of data generation distribution better than other algorithms. Appendix Table A-1 presents the SuperLearner prediction fit and contribution of the individual learning algorithms — including the GLM with main effects — to the SuperLearner prediction for the rural sample; Table A-2 presents these fit results for the urban sample.

Although SuperLearner prediction is better than any single algorithm, the overall prediction fit in terms of  $R^2$  is poor and negligibly superior to  $R^2$  of the traditional GLM with main effects model. For example, Figure 4-2 is a scatter plot of observed HAZ and predicted HAZ for the rural population by SuperLearner. The  $R^2$  for this prediction is 0.2 for the SuperLearner and 0.19 for the GLM with identity link function. This was expected because the Cross Validated risks of the GLM model and SuperLearner Prediction were practically the same. The important lesson is that SuperLearner or any machine learning algorithm is not guaranteed to model (possibly) non-linear and complex relationships between HAZ and  $W^*$  and can be restricted in prediction by missing or miss-specified variables similar to traditional GLM models.

<sup>&</sup>lt;sup>7</sup> We used "Summary infant and young child feeding indicator" recommended by WHO based on minimum required food diversity and frequency of meals depending upon the age and breastfeeding status of a child [147,148].

I further discuss the reasons for and implication of poor prediction using SuperLearner for the estimated variable importance measures in the conclusion Section.



#### Figure 4-1. Cross Validated Risk of Ensemble Algorithms and SuperLearner

Figure 4-2. Scatter Plot of Observed HAZ and HAZ Predicted using SuperLearner



#### 4.3.3 Comparison of SuperLearner plus TMLE with Traditional GLM Models

As discussed previously, TMLE is theoretically expected to less biased and more efficient than maximum likelihood [100,118]. We assess whether this theoretical advantage results in meaningful differences in the magnitude and standard error of the variable importance measures compared to the marginal effect (or the coefficient of regression) estimated using GLM with maximum likelihood with an actual large scale survey data. Next, TMLE is expected to be consistent if either *Y* or *A* is modelled consistently and efficient if both are modelled consistently. Since SuperLearner is better, even if only slightly, at predicting relationships, we also expect that combination of SuperLearner with TMLE can provide less biased and more efficient estimates of the variable importance than GML with TMLE. We assess whether there are indeed meaningful insights in terms of magnitude and standard error of the variable importance measures using SuperLearner with TMLE, our proposed method, compared to GLM with maximum likelihood or with TMLE.

In Table 4-2, we present the Marginal-VIM estimated using GLM with a maximum likelihood estimator (results with the column heading "GLM") and GLM with the TMLE estimator (results with the column heading "TMLE-GLM") for the rural population. In the last three columns, heading "TMLE-SL" presents the Marginal-VIM estimated using SuperLearner with the TMLE estimator. Table 4-3 presents these results for the urban population. In both tables, we present the Marginal-VIMs, their standard errors, and unadjusted *p*-values. We do not correct the *p*-values for multiple comparisons because our objective is not inference but performance assessment of the estimators in terms of magnitude and standard error of the variable importance measures.

Most of the Marginal-VIMs, estimated with GLM or with TMLE-GLM are statistically not significant at conventional levels but among those which are statistically significant the standard errors are lower in the case of TMLE-GLM than GLM. Because of lower standard error the following indicators were statistically significant using TMLE-GLM but not GLM: having an outdoor kitchen, tobacco consumption by mother, ICDS service utilization. The magnitude of the marginal-MVIs that are significant with both GLM and TMLE-GLM estimation are highly similar, at least in the practical sense. However, the TMLE-GLM estimation substantially increased the magnitude of two indicators: mother's education level and boiling drinking water. Overall, we can confirm that TMLE is more efficient than maximum likelihood with a non-simulated actual survey data and by theory the estimated magnitude of the effect should be less biased if the relationship of *A* or *Y* is modelled consistently.

However, we also find evidence that TMLE with GLM may be biased because the GLM model may not have modelled *A* or *Y* more consistently compared to SuperLearner. For example, the following four variables were identified as statistically significant and of similar magnitude with GLM and TMLE-SL estimation but not with TMLE-GLM: age of the household head; spacing between two children; birth order of the child; and whether child received vitamin-A doses. The following variables were identified as statistically significant only with TMLE-GLM estimation but not with GLM or TMLE-SL: unsafe child feces disposal and inadequate tetanus vaccination of mother. These findings suggest that TMLE is more useful in practical sense when coupled with SuperLearner than can increase our confidence that *A* or *Y* is consistently estimated.

The TMLE-SL combination worked at identifying as important several variables that the other two methods did not find statistically significant:

- 1) Household does not use cleaner cooking fuels (Marginal-VIM = -0.122 Z);
- 2) Asset index < 15 (Poorer HH) (Marginal-VIM = -0.086 Z);
- 3) Mother is  $\leq 25$  Years (Marginal-VIM = -0.147 Z);
- 4) Father did not attend antenatal visits (Marginal-VIM = -0.07 Z);
- 5) Household does not have private toilets (Marginal-VIM = -0.091 Z);
- 6) Mother was an adolescent when first child was borne (Marginal-VIM = 0.314 Z); and
- 7) Household does not sift drinking water (Marginal-VIM = 0.078 Z).

The direction of the effect on HAZ for the last two variables is counter-intuitive, but other results have important policy implications. For example, the lack of improved sanitation (private sanitation) was not previously identified as a risk factor, but using TMLE-SL, we were able to identify it as such. Although the magnitude of the Marginal-VIM is barely -0.1 Z, this result is consistent with recent literature that suggests a association between sanitation and HAZ [23–25]. For the following variables, TMLE-SL estimation resulted in larger and statistically more significant Marginal-VIMs than the other two methods:

- 1) Household kitchen is outdoors (Marginal-VIM = -0.187);
- 2) Mother's education  $\leq 8$ th Std (Marginal-VIM = -0.179);
- 3) Household does not boil drinking water (Marginal-VIM = -0.348);
- 4) Child is not fed as per IYCF guidelines (Marginal-VIM = -0.568);
- 5) PCA based ICDS Service Index < 0 (Marginal-VIM = 0.084); and
- 6) Inadequate tetanus vaccination of mother (Marginal-VIM = -0.044).

In the case of "boiling drinking water", the Marginal-VIM estimated using TMLE-GLM was - 0.2 Z, but that estimated using TMLE-SL is -0.4 Z, almost doubling the importance of this variable. Similarly, for the variable "Child not fed as per IYCF guidelines", the Marginal-VIM estimated using TMLE-SL is -0.57 Z as compared to -0.25 Z estimated using TMLE-GLM and - 0.18 Z estimated using MLE-GLM methods, making appropriate child feeding a much important variable than previously suggested and magnitude is also consistent with existing literature [149–151].

In the case of urban population, TMLE-SL estimation found the following variable as important while the other two methods could not:

- 1) Household head is a female (Marginal-VIM = -0.096);
- 2) Household owns 0 or < 1 acres of irrigated farm land (Marginal-VIM = -0.104);
- 3) Household is Below Poverty Line (Marginal-VIM = 0.175);
- 4) Mother is  $\leq 25$  Years (Marginal-VIM = -0.224);
- 5) Mother was an adolescent when the first child was borne (Marginal-VIM = -0.153); and
- 6) Child was reportedly small or average in size at birth (Marginal-VIM = -0.089).

Also in the case of urban population, the variable "Child is not the first borne" has marginal-VIM of -0.55 Z using TMLE-SL estimation compared to -0.31 Z estimated using TMLE-GLM and this variable was not significant in the case of GLM estimation.

 Table 4-2. Comparison of Marginal-VIM Estimated using GLM with TMLE and Maximum Likelihood Estimators, and

 SuperLearner with TMLE estimator – Rural Sample of Children Aged 6-24 Months

Mariahlar		<u>GLM</u>		]	MLE-GL	M	TMLE-SL		
variables	VIM	SE	p-value	VIM	SE	p-value	VIM	SE	p-value
<= 7 household Members	0.021	0.046	0.648	-0.006	0.059	0.924	-0.032	0.051	0.539
Female HH Head	0.029	0.058	0.615	0.007	0.067	0.916	0.036	0.049	0.456
HH Head <= 45 Years	-0.077	0.043	0.077	-0.056	0.067	0.404	-0.102	0.043	0.017
Outdoors Kitchen	-0.063	0.050	0.206	-0.127	0.047	0.006	-0.187	0.037	0.000
Single Room Dwelling	-0.080	0.044	0.066	-0.060	0.059	0.305	-0.096	0.043	0.027
No or < 1 Acre of Irrigated Land	0.031	0.046	0.494	0.070	0.050	0.161	0.047	0.041	0.258
No Electricity Connection	-0.026	0.045	0.567	-0.011	0.056	0.845	0.001	0.041	0.986
Don't use cleaner cooking fuels	-0.033	0.074	0.653	-0.082	0.058	0.157	-0.122	0.041	0.003
Below Poverty Line HH	-0.060	0.041	0.148	-0.067	0.042	0.111	-0.060	0.038	0.112
Asset Index < 15 (Poorer HH)	-0.031	0.049	0.528	-0.036	0.059	0.543	-0.086	0.045	0.054
Scheduled Caste/Tribe HH	-0.041	0.040	0.295	-0.036	0.044	0.407	-0.056	0.037	0.138
Floor in House is Kuccha (Permeable, not permanent)	-0.034	0.044	0.440	-0.046	0.052	0.368	-0.024	0.039	0.540
No Bed nets in HH	-0.173	0.039	0.000	-0.189	0.043	0.000	-0.151	0.037	0.000
Mother is <= 25 Years	-0.007	0.055	0.894	-0.032	0.059	0.587	-0.147	0.040	0.000
Mother's Education <= 8th Std	-0.120	0.055	0.028	-0.219	0.066	0.001	-0.179	0.052	0.001
Mother Not Exposed to Media Daily	0.009	0.045	0.835	0.021	0.054	0.701	0.037	0.046	0.417
Mother Adolescent when First Child	0.079	0.048	0.103	0.098	0.093	0.289	0.314	0.047	0.000
Child Pregnancy was Un-Planned	-0.010	0.045	0.832	0.005	0.049	0.912	0.005	0.043	0.899
Father did not Attended Antenatal Visits	-0.015	0.041	0.709	-0.005	0.049	0.912	-0.062	0.035	0.075
Mother's Gender Attitude Index < 8	0.003	0.039	0.939	0.024	0.044	0.591	0.016	0.038	0.678
Mother is Currently Pregnant	-0.360	0.067	0.000	-0.407	0.081	0.000	-0.371	0.076	0.000
Mother Consumes < 5 Food Groups Weekly	-0.067	0.048	0.160	-0.039	0.053	0.458	-0.022	0.043	0.605
Tobacco Consumption by Mother	0.051	0.054	0.348	0.128	0.061	0.035	0.143	0.046	0.002
Mother's Height < 145 cm	-0.638	0.057	0.000	-0.648	0.057	0.000	-0.640	0.051	0.000
Mother's BMI < 18.5	-0.207	0.038	0.000	-0.199	0.040	0.000	-0.191	0.037	0.000
Child is $>= 12$ Months	-0.967	0.044	0.000	-0.955	0.063	0.000	-0.996	0.054	0.000

X7 • 11		<u>GLM</u>		7	MLE-GL	M	TMLE-SL		
Variables	VIM	SE	p-value	VIM	SE	p-value	VIM	SE	p-value
Male Child	-0.184	0.036	0.000	-0.184	0.035	0.000	-0.185	0.034	0.000
Spacing of < 36 Months	-0.073	0.041	0.078	-0.081	0.076	0.288	-0.109	0.053	0.040
Not the First Child	0.138	0.061	0.025	0.008	0.030	0.775	0.056	0.030	0.059
Do Not Use Improved Drinking Water Source	0.135	0.044	0.002	0.136	0.051	0.007	0.103	0.043	0.016
Do not Use Improved Sanitation Facilities	-0.071	0.050	0.155	-0.092	0.062	0.139	-0.091	0.050	0.073
Unsafe Child Feces Disposal	-0.054	0.063	0.387	-0.140	0.083	0.093	-0.117	0.077	0.129
Do Not Boil Drinking Water	-0.116	0.054	0.033	-0.198	0.064	0.002	-0.348	0.041	0.000
Do Not Sift Drinking Water	0.083	0.057	0.149	0.080	0.060	0.183	0.078	0.047	0.098
Do Not Filter Drinking Water	-0.049	0.094	0.598	0.003	0.073	0.966	0.049	0.055	0.376
< 4 Antenatal Checks	-0.038	0.048	0.420	0.029	0.052	0.573	0.017	0.042	0.693
Inadequate Tetanus Vaccination	-0.061	0.045	0.173	-0.078	0.047	0.096	-0.044	0.042	0.297
Mother Not Dewormed	-0.054	0.097	0.577	-0.035	0.079	0.659	-0.016	0.074	0.832
Not an Institutional Delivery	-0.062	0.047	0.184	-0.083	0.069	0.227	-0.090	0.055	0.103
Birth Size Small or Average	-0.154	0.043	0.000	-0.161	0.044	0.000	-0.157	0.041	0.000
Not Breastfed during the First Hour	0.005	0.042	0.908	-0.031	0.056	0.588	-0.020	0.040	0.611
Child Fed Other Foods in First 3 Days	-0.023	0.040	0.557	0.012	0.065	0.857	0.031	0.041	0.442
Fever or Bleeding in postpartum	0.066	0.044	0.129	0.047	0.046	0.308	0.042	0.040	0.296
Child Not Given Vitamin A Dose in 6 Months	0.095	0.047	0.042	0.030	0.066	0.647	0.048	0.049	0.328
Child Not Fully Immunized	-0.035	0.041	0.391	-0.033	0.047	0.485	-0.041	0.041	0.317
Inadequate Iodine in House Salt	-0.125	0.038	0.001	-0.113	0.038	0.003	-0.110	0.035	0.002
Child Currently Not Breastfed	0.354	0.063	0.000	0.357	0.089	0.000	0.281	0.064	0.000
Child Not Fed as per IYCF Guidelines	-0.176	0.081	0.030	-0.252	0.077	0.001	-0.568	0.040	0.000
PCA based ICDS Service Index < 0	0.052	0.041	0.205	0.082	0.048	0.089	0.084	0.041	0.041
Diarrhea Reported in the Community	-0.030	0.039	0.437	-0.009	0.042	0.834	0.016	0.037	0.663
ARI Reported in the Community	0.028	0.038	0.471	0.027	0.040	0.507	-0.041	0.037	0.271

Acronyms and Abbreviations: Generalized Linear Model (GLM), SuperLearner (SL), Targeted Maximum Likelihood Estimation (TMLE) Liquid Petroleum Gas (LPG); Body Mass Index (BMI) Infant and Young Child Feeding (IYCF); Household (HH), Acute Respiratory Infections (ARI); Principal Component Analysis (PCA); and Integrated Child Development Scheme (ICDS).

Table 4-3. Comparison of Marginal-VIM Estimated using GLM with TMLE and Maximum Likelihood Estimators, andSuperLearner with TMLE estimator – Urban Sample of Children Aged 6-24 Months

Mariahlar	MLE-GLM			Γ	MLE-GL	M	TMLE-SL		
Variables	VIM	SE	p-value	VIM	SE	p-value	VIM	SE	p-value
<= 7 household Members	0.078	0.063	0.214	0.136	0.073	0.060	0.077	0.059	0.193
Female HH Head	-0.096	0.076	0.203	-0.116	0.089	0.190	-0.195	0.065	0.003
HH Head <= 45 Years	-0.051	0.059	0.385	-0.092	0.094	0.327	-0.039	0.054	0.464
Outdoors Kitchen	-0.130	0.089	0.142	0.079	0.071	0.270	0.098	0.042	0.020
Single Room Dwelling	-0.073	0.059	0.214	-0.056	0.078	0.473	-0.035	0.052	0.496
No or < 1 Acre of Irrigated Land	-0.116	0.082	0.159	-0.089	0.094	0.344	-0.104	0.059	0.077
No Electricity Connection	-0.110	0.103	0.285	-0.136	0.069	0.047	-0.148	0.054	0.006
Don't use cleaner cooking fuels	-0.128	0.063	0.042	-0.200	0.076	0.009	-0.212	0.061	0.000
Below Poverty Line HH	0.098	0.070	0.163	0.134	0.090	0.138	0.175	0.066	0.009
Asset Index < 15 (Poorer HH)	-0.038	0.062	0.537	-0.130	0.068	0.055	-0.131	0.050	0.008
Scheduled Caste/Tribe HH	-0.060	0.054	0.268	-0.037	0.053	0.486	-0.072	0.044	0.102
Floor in House is Kuccha (Permeable, not permanent)	0.010	0.075	0.896	-0.023	0.070	0.740	-0.016	0.047	0.733
No Bed nets in HH	-0.148	0.050	0.003	-0.116	0.056	0.038	-0.091	0.045	0.043
Mother is <= 25 Years	0.023	0.067	0.727	-0.105	0.094	0.267	-0.224	0.043	0.000
Mother's Education <= 8th Std	-0.015	0.060	0.803	-0.041	0.074	0.575	-0.006	0.059	0.925
Mother Not Exposed to Media Daily	-0.035	0.059	0.557	-0.035	0.071	0.624	0.010	0.051	0.839
Mother Adolescent when First Child	-0.016	0.063	0.797	0.060	0.106	0.573	-0.153	0.070	0.029
Child Pregnancy was Un-Planned	0.043	0.057	0.448	0.050	0.058	0.388	0.068	0.049	0.170
Father did not Attended Antenatal Visits	0.015	0.054	0.779	0.005	0.066	0.938	0.021	0.050	0.680
Mother's Gender Attitude Index < 8	0.042	0.061	0.492	0.040	0.065	0.540	0.033	0.053	0.529
Mother is Currently Pregnant	-0.176	0.087	0.043	-0.126	0.075	0.094	-0.134	0.042	0.002
Mother Consumes < 5 Food Groups Weekly	-0.204	0.049	0.000	-0.211	0.052	0.000	-0.214	0.047	0.000
Tobacco Consumption by Mother	0.111	0.084	0.186	-0.012	0.096	0.899	0.060	0.056	0.284
Mother's Height < 145 cm	-0.662	0.078	0.000	-0.726	0.081	0.000	-0.720	0.070	0.000
Mother's BMI < 18.5	-0.139	0.053	0.008	-0.109	0.057	0.055	-0.095	0.053	0.071
Child is >= 12 Months	-0.929	0.055	0.000	-0.896	0.076	0.000	-0.897	0.056	0.000

X7 • 11		MLE-GLN	1	<u>r</u>	MLE-GL	M	TMLE-SL		
v artables	VIM	SE	p-value	VIM	SE	p-value	VIM	SE	p-value
Male Child	-0.118	0.045	0.009	-0.119	0.045	0.009	-0.120	0.044	0.006
Spacing of < 36 Months	-0.139	0.056	0.014	-0.240	0.122	0.048	-0.193	0.055	0.001
Not the First Child	-0.041	0.079	0.602	-0.313	0.027	0.000	-0.548	0.031	0.000
Do Not Use Improved Drinking Water Source	0.142	0.082	0.081	0.166	0.093	0.073	0.147	0.057	0.010
Do not Use Improved Sanitation Facilities	-0.025	0.061	0.681	0.015	0.099	0.882	0.018	0.064	0.782
Unsafe Child Feces Disposal	-0.090	0.051	0.078	-0.041	0.058	0.479	-0.052	0.053	0.327
Do Not Boil Drinking Water	-0.073	0.057	0.203	-0.142	0.081	0.079	-0.122	0.053	0.022
Do Not Sift Drinking Water	0.106	0.065	0.107	0.167	0.084	0.046	0.185	0.054	0.001
Do Not Filter Drinking Water	-0.037	0.069	0.595	-0.057	0.082	0.485	-0.043	0.069	0.535
< 4 Antenatal Checks	-0.103	0.060	0.086	-0.101	0.073	0.169	-0.100	0.063	0.109
Inadequate Tetanus Vaccination	-0.037	0.052	0.476	-0.032	0.052	0.543	-0.028	0.048	0.557
Mother Not Dewormed	-0.240	0.112	0.032	-0.174	0.090	0.055	-0.256	0.071	0.000
Not an Institutional Delivery	-0.176	0.062	0.005	-0.140	0.069	0.043	-0.163	0.052	0.002
Birth Size Small or Average	-0.085	0.053	0.105	-0.080	0.051	0.118	-0.089	0.045	0.048
Not Breastfed during the First Hour	-0.027	0.052	0.604	-0.061	0.082	0.454	-0.025	0.050	0.617
Child Fed Other Foods in First 3 Days	0.110	0.049	0.025	0.195	0.071	0.006	0.205	0.053	0.000
Fever or Bleeding in postpartum	0.013	0.059	0.822	0.022	0.063	0.722	0.024	0.055	0.659
Child Not Given Vitamin A Dose in 6 Months	0.044	0.056	0.433	0.042	0.071	0.558	0.058	0.055	0.288
Child Not Fully Immunized	-0.023	0.050	0.651	-0.045	0.052	0.379	-0.060	0.049	0.222
Inadequate Iodine in House Salt	-0.134	0.055	0.016	-0.088	0.062	0.159	-0.080	0.050	0.107
Child Currently Not Breastfed	0.133	0.060	0.027	0.043	0.085	0.612	0.000	0.059	0.999
Child Not Fed as per IYCF Guidelines	0.026	0.077	0.735	0.165	0.080	0.039	0.131	0.058	0.024
PCA based ICDS Service Index < 0	-0.001	0.070	0.992	0.027	0.078	0.724	0.056	0.056	0.314
Diarrhea Reported in the Community	-0.035	0.048	0.470	-0.036	0.049	0.464	0.015	0.044	0.730
ARI Reported in the Community	0.011	0.047	0.819	0.019	0.046	0.688	-0.025	0.042	0.562
ARI Reported in the Community	0.028	0.038	0.471	0.027	0.040	0.507	-0.041	0.037	0.271

Acronyms and Abbreviations: Generalized Linear Model (GLM), SuperLearner (SL), Targeted Maximum Likelihood Estimation (TMLE) Liquid Petroleum Gas (LPG); Body Mass Index (BMI) Infant and Young Child Feeding (IYCF); Household (HH), Acute Respiratory Infections (ARI); Principal Component Analysis (PCA); and Integrated Child Development Scheme (ICDS).

#### 4.3.4 Marginal and Population VIM Estimates

Figure 4-3 presents the Marginal-VIM and Population-VIM of variables estimated using SuperLearner with TMLE method for rural population of children aged 6-24 months. The detailed results are provided in Appendix Table A3. The blue bar is the Marginal-VIM and the light brown bar represents the Population-VIM. The error bars represent 95% confidence interval estimated using the Influence Curve based standard errors. The BH FDR corrected statistical significance for the Marginal-VIM is indicated as by a \* next to the variable names as: \*\*\* at  $\alpha = 0.01$ ; \*\* at  $\alpha = 0.05$ ; and \* at  $\alpha = 0.1$ . We do not indicate the BH FDR corrected significance level for the Population-VIM in the figure but refer the reader to Appendix Table A1 instead. Figure 4-3 includes only those variables whose Marginal-VIM are statistically significant at  $\alpha =$ 0.1 after the BH FDR correction. We have also ordered the variables by the magnitude of the Marginal-VIM.

We find that the Marginal-VIM of the variable "child is older than 12 months" is the most important variable that explains almost -1 Z loss in HAZ. This represents growth faltering progression by age consistent with global trends [123]. Mothers with height under 145 cm and children not fed as per ICYF guidelines each explain approximately -0.6 Z loss in HAZ. A mother being currently pregnant and not boiling drinking water is associated with almost -0.4 Z loss in HAZ. Other variables such as a mother's BMI, small birth size, not having bed nets in the house, not having adequate spacing between the children, and others explain less than -0.1 Z. Contrary to our expectation, a mother being an adolescent when conceiving for the first time and a child currently not being breastfed appear protective. Tobacco consumption by the mother and not using improved drinking water are protective as well. This serves to remind us that the prediction, however sophisticated the machinery, is critically dependent on how well the variables are measured (without bias), preponderance of missing or unmeasured variables, and the relationship between the variables being modeled and the measured or unmeasured confounders.

The Population-VIM indicates the population level effect if the exposure is entirely removed from the population and are expected to be smaller in magnitude than the Marginal-VIM. Age of child remains the most important variable for HAZ, again describing that growth falters as child ages. Other variables with a higher Population-VIM include children not fed as per IYCF guidelines, not boiling drinking water, smaller birth size, and no bed nets in the house. Most of these Population-VIMs explain a loss of less than -0.1 Z only and are not statistically significant.

Figure 4-4 presents the statistically significant marginal and population VIMs for the urban sample of children aged 6-24 months; Appendix Table A4 provides detailed results. The importance of the child's age and the mother being under 145 cm are qualitatively similar to those in the rural population. However, not being the first borne child explains the -0.6 Z of HAZ and identified as one of the important variables in urban population. Other variables such as the mother being younger than 25 years, the mother not consuming at least five food groups weekly, and the use of unclean cooking fuels are also more important than in the rural population (in terms of magnitude). In the case of the population-VIMs, a mother not dewormed during pregnancy and a mother not consuming five food groups both explain the less than 0.1 Z loss to HAZ. However, the magnitude of the Population-VIM for other variables is quite small given the current low prevalence of these risk factors in the population.


#### Figure 4-3. The Marginal-VIM and Population-VIM of Variables on Y in Rural Children aged 6-14 Months

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#### Figure 4-4. The Marginal-VIM and Population-VIM of Variables on Y in Rural Children aged 6-14 Months

## 4.4 Conclusion

We presented a machine learning based method that used a theoretically more consistent and targeted TMLE estimator to estimate the marginal and population level importance of variables (or indicators for risk factors) in explaining the reduction in HAZ among children aged 6-24 months. We also compared the Marginal-VIMs estimated using the proposed method with the typical GLM model with main effects as well as compared the performance of the usual maximum likelihood estimator with that of the TMLE. We applied the proposed method as a case study to the DHS data from India for children aged 6 to 24 months from rural and urban areas. Below we summarize the key findings and insights.

### 4.4.1 Comparison of Prediction of SuperLearner with Parametric Models

We find that the cross validated risk of SuperLearner was highly similar to that of individual learning algorithms supplied to it including the GLM model. Therefore, it is not a surprise that both the SuperLearner and the GLM model both have similar and low  $R^2$  (< 0.20) in predicting HAZ as a function of 51 variables. The inability of machine learning algorithms to find a better fit can indicate one or more of the following:

- Important risk factors that could explain HAZ were excluded from the analysis. However, our analysis included almost all risk factors the existing literature has linked with stunting and more. There could be additional risk factors that are not yet been identified so that we included a wide range of indicators associated with health, demographics, and socio-economics in our analysis even when the existing literature have not specifically identified these as risk factors.
- The "indicators used" could be erroneous and not highly correlated with the risk factor they intended to measure. For example, whether or not a child is fed as per the IYCF guidelines is an indicator of appropriate level of nutrition through food. A better indicator may be the amount of calories and nutrients consumed based on a year-long food intake diary maintained by the child's caregivers. It is possible that the count of the number of food groups or number of times a child ate in the past 24 hours is not a good indicator for the child's nutrition intake. Most of the indicators are also based self-reported answers to structured questions and not objective measures so that there can be enumerator and respondent specific biases in the measurements. Even when an indicator is measured objectively, the measurement may be too general and not highly correlated with the risk factor. For example, enumerators assessed whether a household owns a private toilet or not, but for actual use of the toilet or reduction in open defecation we must measure actual behaviours.
- Use of binary variables instead of continuous variables may have limited the ability of SuperLearner algorithms to model the nonlinear relationships well. DHS was not designed to measure all the risk factors associated with HAZ objectively and robustly, but to help present descriptive statistics of the national health and demographics. Therefore, most questions could result in binary indicators and fewer resulted in continuous indicators. The risk factor per say could potentially be measured on a continuous scale but the survey exigency dictated that only simplistic binary indicators would suffice. For

example, again consider the case of child nutrition intake which could potentially be measured in terms of calorific intake through an entire year but that would need a very different (and expensive) survey design than the DHS so that, instead, the indicators in terms of number of food groups the child consumed and number of times the child ate in past 24 hours are used.

• None of the algorithms included in SuperLearner prediction could explain most parts of the data generating process. We included a mix of linear, nonlinear, parametric and non-parametric models in the SuperLearner algorithm library for this case study application. Therefore, we do not anticipate that the predictive fit will be substantially improved by including more algorithms in the SuperLearner library.

# 4.4.2 Advantages of TMLE combined with machine learning algorithms over estimating the VIMs using parametric models

Theoretical simulations have shown that the TMLE can estimate the effects consistently if either relationship between the outcome and the covariates or the relationship between the exposure or risk factor of interest and the covariates is correctly specified, and efficient if both are correctly specified [100,101,138,140]. In this regard, SuperLearner prediction is theoretically more attractive than the linear parametric models [98,99,122]. Using machine learning is no guarantee of accurate or unbiased prediction and thus unbiased VIM estimation as discussed above. However, with machine learning the statistical bias could theoretically go to zero with increase in sample size but the SSE does not have a predictable sampling distribution and thus no rigorous inference is possible with the SSE. Further, machine learning combined with TMLE can not only reduce the statistical bias to 0 but TMLE also has asymptotically normal distribution that enables rigorous statistical inference.

Due to the combination of better prediction with SuperLearner and *targeted* estimation of the Marginal-VIM using TMLE, we could identify a few variables as important and a few variables as significantly more important than what we could infer using only the GLM model with TMLE or the maximum likelihood estimation. For example, whether a household has fewer than 15 durable assets was not statistically significant using the SSE, but SuperLearner with TMLE could identify the Marginal-VIM as -0.086 Z. By using SuperLearner with TMLE, the Marginal-VIM of whether a household does not boil drinking water increased to -0.35 Z from -0.2 Z estimated using GLM with TMLE. The Marginal-VIM for whether or not a child is fed appropriately as per the IYCF guidelines by WHO is -0.5 Z for TMLE-GLM estimation but -0.57 Z for TMLE-SL estimation. Overall, even modest gains in modeling of the risk factors using SuperLearner yielded different values for the Marginal-VIM when combined with TMLE. Some of the variables were identified as important only in the SuperLearner-TMLE based estimation but not in other methods. Also, a higher number of variables were statistically significant by using SuperLearner with TMLE.

### 4.4.3 What explains most of the Growth Faltering in India and what can be done?

Four risk factors explain significant amount of loss in HAZ among the children aged 6-24 months as per the Marginal-VIM.

First, children aged 12 moths or older have on average -1.0 Z lower HAZ than the children under 12 months of age in the rural population and -0.9 Z among the urban children. Aging itself will not cause growth faltering and this finding is only describing a worrisome progression that at children age beyond 12 months the growth faltering is more severe. This finding suggests that something that changes as the child ages or the chronic exposure to something is affecting his/her growth even after controlling for the effect of other risk factors and covariates in terms of their indicators used in the analysis. For example, existing evidence suggests that as children are weaned off from breastfeeding the supplemental nutrition especially providing animal-source food along with maternal education on supplemental nutrition is critical [112]. We controlled for child supplemental feeding in terms of indicators: the number of food groups and the number of times a child ate in past 24 hours. However, it is possible the chronic poor nutrition is captured at *least partly* by the age but not by the feeding indicator based on what the child ate over the past 24 hours. Additionally, or instead, the age variable can be capturing the effect of a risk factor we could not measure. For example, we do not have a good measure of environmental exposure to enteric pathogens in the DHS data. A cross sectional study in Brazil found association between Giardia lamblia, Trichuris Trichuria, Ascaris lumbricoides, or hookworm infections and standardized anthropometric parameters for children aged 6-84 months [152]. Another observational study in Malaysia found that Giardia lamblia infections were a strong predictor of wasting in this study population in children aged 2-15 years [153]. It is possible that the chronic exposure to these and many more pathogens over time is "indicated" by the age. Similar arguments can be extended to many other risk factors.

The importance of child's age highlights a need to better specification and measurement of known risk factors that are confounded by time. The existing large scale and descriptive-purpose surveys such as DHS may not provide the specific and accurate measurements of all the risk factors although these measure child anthropometry (outcomes) well. Therefore, chronic malnutrition specific surveillance and surveys that measure both child anthropometry and chronic risk factors rigorously will be a necessary requirement for future research.

Second, HAZ for children born to mothers with height < 145 centimeters is almost -0.7 Z less than that for children born to taller mothers consistent with existing literature [106,111,113]. A study based on the same DHS data from India also found that probability of stunting among children < 60 months was 2.35 times higher for the children born to mothers <145 centimeters height compared to the mothers > 160 centimeters height [154]. Therefore, as advocated by Martorrell and colleagues, the intergenerational effects on the child through the mother are a strong risk factor for stunting and stunting among children can be reduced to the extent health, nutrition and growth of future mothers can be improved [113]. However, the proportion of mothers with <145 centimeter height is barely 10% among rural and urban populations so that removing this risk factor entirely from the population would still improve HAZ by much less than 0.1 Z as per the Population-VIM estimates. This suggests how an influential risk factor may still have modest or small effect on HAZ because most of the population does not face that risk. However, this inference is conditional on the cut off value used to dichotomize mothers' heights.

When we used a cut off value of 150 centimeters instead of the current value of 145 centimeters, the Marginal-VIM estimate was -0.55 Z, and the Population-VIM was -0.2 Z because 38% of the mothers in our sample have height < 150 centimeters compared to 10% mothers with height < 145 centimeters. Therefore, we believe that interventions targeting growth faltering of the (future) mother growing up (indicated by her stature) will have important intergenerational public health benefits.

Also, above is an illustration of how cut off values can change the Population-VIM measure of a risk factor and thus inference about its importance. Because the way an indicator is constructed can affect the inference, sensitivity analysis of different ways the indicator for a risk factor can be defined can provide a more balanced inference of importance of a risk factor.

Third, HAZ of children not fed as per IYCF guidelines is on average -0.57 Z less than that for the children fed as per IYCF guidelines in the rural population. However, the Population-VIM is barely 0.07 Z and statistically not significant. As in the case of mother's height, how we dichotomize the child feeding variable can affect both the Marginal-VIM and Population-VIM. Interestingly, the Marginal-VIM for feeding as per the IYCF guidelines is positive for urban children suggesting that providing proper nutrition in last 24 hours is actually a risk factor. Clearly, there is a logical fallacy in this interpretation which is can be a result *reverse causation*. However, we cannot convincingly identify a reason for this finding given the cross sectional nature of the data without time ordering.

Therefore, even if experimental methods may not be possible or even recommended to answer all research questions, at least time ordering related questions may help future analyses. For example, DHS surveys could include follow -up questions for the children who are stunted so assess how the household members coped with the challenge if they are aware of it. Also, when so many variables (51 in our case) are included in a model, it is possible that non-linearities between the variables result in illogical Marginal-VIM. The TMLE estimator is actually more attractive in such a situation than the maximum likelihood because it is targeted to the parameter of interest. Obviously, even this is a tall order in practical applications with missing and inaccurate measurements.

Fourth, Mother being currently pregnant is also a risk factor as per the Marginal-VIM estimates (-0.37 Z) in the rural population but the Marginal-VIM in urban population is small (-0.13 Z). This probably indicates the lack of care for the child when the mother is pregnant with another child. We controlled for the gap between two children in our analysis so this variable likely does not capture the effect of inadequate spacing.

Fifth, the Marginal-VIM for boiling water is also high in rural population (-0.35 Z) but the Marginal-VIM is small in the urban population (-0.12 Z) which suggests that exposure to environmental pathogens through drinking water is a major risk factor but more so in the rural population. Although, the Population-VIM for boiling water is statistically not significant, in magnitude and direction of the effect, it suggests that improved water quality can be an effective intervention.

Sixth we find strong evidence of birth order on HAZ in the urban areas. HAZ of the children borne second or later is on average -0.56 Z lower than HAZ of the firstborn children. A study in West Bengal state of India [155] and a country wide study in India [156] both also find that as the birth order increases the risk of stunting also increases and the firstborn are most protected against stunting. This could be capturing the effect of additional care and nurturing – time, food and money – the first borne receives whereas with more children the resources have to be divided.

### 4.4.4 Cautions in interpreting the variable importance measures

Throughout the discussion of the results and the conclusion, we have presented how the magnitude and significance of VIMs can be affected by issues related to missing variables, measurement biases, inadequate modeling of the complex relationship between the covariates, time ordering of indicators, and the effect of confounders. Below we highlight few of the most important caveats in interpreting the VIMs.

First, a variable may have high importance because of the importance of underlying and unmeasured confounding variables or factors. For example, strong contribution of the mother's height to the HAZ of the child indicates an inter-generational effect of chronic malnutrition of the mother during her growing years and how that affects her child's HAZ possibly as a pure height effect or epi-genetic effects. Similarly, the importance of child's age suggests that there are unmeasured or poorly measured risk factors confounded by time that are more important in predicting HAZ.

Second, additional research is needed to assess why a variable is important and the VIM's main purpose is to prioritize future research and action. For example, being the first or only child is protective but additional research is needed to understand why. Similarly, surveys that enable better construction or measurement of risk factors such as child nutrition, exposure to enteric pathogens and their sources, child caring and nurturing, water-sanitation, and more will be required to understand what really causes growth faltering.

Third, a lack of importance can be an artifact of measurement errors or unmeasured variables. We can only coarsely (and poorly) measure indicators for several known risk factors such as exposure to enteric pathogens, child nutrition, access and use of sanitation facilities, and others. The dichotomization of variables itself introduces a source of bias and could have affected the estimated VIMs. Therefore, the lack of importance can be only due to poor measurement of the risk factor.

The above cautions or limitations are certainly not unique to the methods we proposed, but the proposed method has three unique advantages that make it attractive in spite of these limitations.

First, the variable importance parameters are based on well-known epidemiological risk measures such as risk difference and population attributable risk. Therefore, they can be understood by larger public health audience and even interpreted causally to the extent the assumptions related to time ordering and randomness (no confounding) are adhered to.

Second, the proposed method does not assume a structural statistical relationship, and thus, free from at least one source of bias – the modeling choice by the researchers which may not always be objective. Therefore, all the risk factors — limited only by the available data — are treated equally.

Finally, we demonstrated that the proposed methods can be applied to standardized DHS datasets and generate valuable insights to guide future research. The DHS datasets are available for many developing countries and are a cornerstone of country and global public health policy making. Therefore, standardized VIM estimation and their comparison across different regions and context remains possible, and potentially, the proposed method can aid more evidence based and objective policy, as well as research and action in the public health sector.

# **Chapter 5: Conclusion**

The timeline of my dissertation coincides with a period of contrasting research findings, passionate advocacy, and unprecedented public attention on sanitation in India. Cross sectional and observational studies find that sanitation is a serious risk factor associated with diarrheal diseases and growth faltering in early years of life [22–25], but the experimental evidence is mixed with two trials finding null effect [77,80] and one trial finding modest effect of an intensive sanitation program on HAZ [97].

The sanitation advocacy got the impetus in the UN's Millennium Development Goals which included a target to halve by half population without access to *basic sanitation* arguably because of its link with child mortality, women empowerment and environmental sustainability goals [7]. The targets set under the Joint Monitoring Program [30] went beyond the definition of basic sanitation and tracked "improved" sanitation facilities – toilet designs that would (hopefully) contain the feces from mixing with the environment, but also only those facilities that were private. That is, even the well-constructed maintained community toilet would not be considered an improved sanitation facility. With these targets and definition, what was supposed to be "sanitation" got linked with "private toilets". Unsurprisingly, the Indian government responded to meet the MDG target by financing private toilet construction through subsidies.

At the same time, buoyed by the success in Bangladesh, a strong advocacy in the favor of intensive behavior change intervention without any subsidy emerged. The proponents of the Community Led Total Sanitation (CLTS) advocated that ending open defecation was the first step even if it meant that the toilets built were rudimentary and not "improved" [20]. They argued that the household can then climb the "ladder of sanitation" [39] once their behavior is changed and the community sees value in ending open defecation.

In between these two spectrums of thoughts a few other models emerged which combined subsidies and behavior change in different measures. The program I evaluated in Madhya Pradesh is one such program where CLTS based behavior change tools were combined with the government subsidies called the Total Sanitation Campaign (TSC).

### 5.1 Summary of Key Findings

The first research question sought to evaluate the effectiveness of the TSC in improving child health on multiple dimensions. I found that the TSC did not improve child health in terms of diarrhea, HCGI prevalence, anemia, Ascaris lumbricoides infection, anemia, and height-for-age. I postulated that there were possibly two reasons for the lack of health effects of sanitation.

First, the reduction in open defecation rate was not enough to reduce the exposure to fecal pathogens in the environment, and thus, the child health did not improve. The toilet coverage doubled from the control group level of 22% to 41% in the intervention group, but the reduction in open defecation was only 10%. For example, 83% of the women in the control group reported daily open defecation compared to 73% of them in the intervention group. Since 73% of the women still continued to defecate in open, it is not too hard to imagine how little the environmental exposure to enteric pathogens may have reduced in the intervention group.

Indeed, even the program design hypothesized that unless the community is open defecation free, there would not be health impacts and the TSC was designed with an objective to make villages open defecation free.

The second research question I answered was linked with this line of reasoning. I assessed how price sensitive the demand for private toilet is and what can be the potential toilet coverage under substantially increased subsidies. I find that the demand for private toilets is *price inelastic* (elasticity = 0.91). I used this price elasticity estimate to predict that the private toilet in rural India could potentially increase to 80% from the current levels of 30% as per Census 2011. While this is an encouraging finding, two caveats are important. One, the increased toilet coverage does not necessarily mean correspondingly large reduction in open defecation. For example, in Chapter 2, I have reported that of the households that had a private toilet in the intervention group, about 40% were not used regularly. Second, using data from an efficacy trial of a sanitation pilot Odisha, I found that the demand for private toilet was price inelastic (price elasticity  $\rightarrow$  0). Third, the potential coverage with increased subsidies critically depends on the current level of private toilet coverage and loss of subsidies to leakages.

In addressing my third research objective I entertained an arguably unlikely reasoning for the lack of impacts of the TSC. I hypothesized that a lack of sanitation may not be the most important risk factor compared to others or the effectiveness of sanitation may depend on the prevalence of other risk factors in the population. Effectiveness of sanitation is thus far studied and proved only in urban contexts with networked toilets. However, the toilets built in rural India are non-networked offset pit latrines whose safety performance is not yet well understood. For example, an engineering field experiments in India found fecal coliform at up to 10-meter distance from the pit latrine [157]. Another engineering study in India also found that ground water was contaminated near the pit latrines but the hydrology and soil strata of the region played a key role [158]. Therefore, it is possible that the toilets built in rural India were less protective against exposure to fecal pathogens. It is also possible that any gains in child health from improved sanitation were negated by exposure to fecal pathogens through other pathways such as drinking water or handwashing or other risk factors such as inadequate nutrition were dominant risk factors compared to sanitation. Therefore, it remains unclear whether sanitation as a single intervention could have been effective in the study sample given the prevalence of other risk factors in the population.

In Chapter 4, I importance of 51 risk factors that are potentially associated with the linear growth faltering within the first 6-24 months of life. I proposed a method that combined non-parametric machine learning algorithm called SuperLearner to model the relationship between HAZ and the risk factors, and a new class of double robust estimator called Targeted Maximum Likelihood Estimator (TMLE). This method proved advantageous compared to GLM model with only main terms and maximum likelihood estimation and identified a few risk factors as important. I found that five risk factors explained significant reduction in HAZ: (1) mothers with height < 145 centimeters; (2) children not fed as per IYCF guidelines; (3) boiling drinking water; and (4) mother being currently pregnant. However, considering the current prevalence if these risk factors in the Indian population, removing exposure to these risk factors entirely would result in much smaller gains in the HAZ. Lack of availability of an improved sanitation facility at home explained reduction of 0.09 Z in HAZ compared to households with improved sanitation facility at home the smaller than the other risk factors listed above and

statistically not significant once we correct the p-values for multiple testing. The findings overall suggest that while sanitation is a risk factor for reduced HAZ, other risk factors have a more dominant effect.

## 5.2 Final Reflections

While conducting research with above specific research aims, I developed following insights into other reasons for underestimating the impacts of sanitation, possible gaps in research that failed to guide the government and implementation agencies on effective sanitation interventions, and what can be done to give sanitation a chance it deserves to improve public health.

### 5.2.1 Case of underestimation – What to measure and how long to wait

British Medical Journal readers voted sanitation as the most important medical advance of the last century [18] not without a reason. Improved health and development in the western countries if often credited to concurrent improvements in water, sanitation and environment. Therefore, health was and is the prime outcome expected from sanitation programs and majority research focused on evaluating health effects of sanitation.

Which is the right indicator for health impact evaluations? Diarrheal diseases in younger children has been the health outcome indicator of interest for past few decades for water-sanitation and hygiene (WASH) related interventions because waterborne diseases are most directly linked with WASH. Diarrhea is a prevalent symptom in younger children, relatively easy to measure based on care giver recall, and can budge within few months of improving WASH. However, like most diseases, this indicator is binary – either the child has diarrhea or not. Further, this indicator is highly cyclical with weather and known to peak during high rains and high summer. Because it is based on recall and self-report, diarrhea prevalence measures also suffer from responder recall bias and other measurement biases.

On the other hand, stunting or height-for-age (HAZ) is fast emerging as a good indicator of chronic exposure to enteric pathogens and poor nutrition. Humphrey argued that a condition of environmental enteropathy will undermine the nutritional outcome of the child without any outward disease symptom (like diarrhea) and cannot be reversed without improving WASH conditions. Subsequently, a few papers associated HAZ with poor access to toilets but not water supply. Therefore, stunting or HAZ are now strong contender for primary health outcome from improved sanitation especially in the early life years. However, increased HAZ is a more distal outcome than reduced diarrhea. The upcoming evidence suggests that 2-3 years of exposure to improved sanitation at the beginning periods of life will be most sensitive waiting period for sanitation effects to be observed.

Future trials and studies may have to consider this waiting period in their designs if stunting is to be the main health indicator.

*If there are no health benefits, then are there no impacts?* The argument in favor of sanitation are certainly not restricted to the health benefits. In fact, the TSC positioned sanitation as a matter or dignity, privacy and women empowerment in addition to the health effects. The UN has also passed a resolution to recognize water and sanitation as a basic human right. Therefore, impact evaluation that focuses on health as the primary outcome can ignore other non-health benefits by design.

For example, health impact evaluation may include as target population only young children where diarrhea and growth is sensitive and thus observed. However, such a focus can ignore other target groups such as elderly, adolescents, and women. The elderly is also a vulnerable population group and can be affected by enteric pathogens besides the risk of fall and inconvenience in accessing open areas instead of a private toilet for defecation. Older children can suffer in terms of missed school days because of illness but also missing schools because the school does not have toilet or, in the case of adolescent girls, menstrual hygiene management facilities. The variable importance analysis I conducted also found strong effect of mothers height on child's HAZ, but mothers height itself can be a result of poor sanitation conditions she faces growing up. Therefore, sanitation can have intergenerational effect too.

However, all these different impacts will have different waiting or follow up periods. The savings of time in walking to open defecation site will be almost immediate once a person starts using a primate toilet but the intergenerational health effects of improved toilets will need a generational study spanning a few decades!

### 5.2.2 20-200 Hindsight: Case for implementation science or operations research

One of the painful realizations I had during my research was sheer lack of rigorous and evidence based guidance for design and implementation of sanitation programs. The first RCT of a scaled up sanitation program in the World was conducted in Madhya Pradesh almost 12 years after the World committed to the Millennium Development Goals and India launched the TSC. Chapter 3 is an example of an operational research question that tried to find out whether and how the toilet demand will be affected by subsidies. Unfortunately, I also find myself wondering why such a key operations question was not asked and answered before India spent billions of dollars on sanitation promotion strategy, I could not find a single evaluation of this approach until a few months ago when Pickering and colleagues published a RCT of a CLTS program in Mali. Only last year was a trial published that compared CLTS with CLTS+Subsidies in Bangladesh where CLTS was conceived and implemented at scale.

While there has been some focus on private toilets in recent research, I find virtually no mentionable public health research on waste water management, solid waste management, environmental sanitation which are also components of sanitation. I also find no research on evaluating different technologies for providing sanitation. For example, one of the most curious questions I find myself asking is what evidence was used to decide that shared toilets are unimproved sanitation. I cannot convince myself after working in this sector for several years that a basic private pit latrine will accord more protection and health benefits than a sewer connected community toilet. The argument that community toilets are not used and maintained but private toilets are is valid but I found no evidence to support this claim. I found virtually no intervention in rural areas of developing countries that evaluated networked/sewer connected

private toilets from engineering, economics or public health perspectives whereas the initial evidence in favor of sanitation has always been in the favor of networked toilets. Again, I could only find arguments suggesting that networked toilets are expensive and there are maintenance issues but without any data based research to support such an argument.

Overall, I believe that the sanitation sector has been guided by rhetoric, beliefs, passions, and advocacy but little robust evidence. There have been numerous studies that looked at different operations research aspect but these studies are only descriptive and often qualitative in nature making claims not substantiated by the data or the analysis. Therefore, high quality operations or implementation research is a high priority for the sector. Without such a research it is unlikely that high levels of sanitation coverage required to deliver health impacts can be achieved.

Thankfully, recently a few organizations have set collaborations and projects to address pressing operations research questions. For example, Bill and Malinda Gates foundation have invested significantly in innovating toilet technologies. Water and Sanitation Program of the World Bank, UNICEF, Sanitation and Hygiene Applied Research for Equity and other organizations are conducting action research and developing innovative models based on public private partnerships and market driven mechanisms.

Much still needs to be done both on research and implementation from in India and we have miles to go before India can realize the full public health potential of improved sanitation that goes beyond just toilets.

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# **Annexure: Supplemental Material for Chapter 4**

*R* code for estimating variable importance measures

```
library(SuperLearner)
library(rpart)
library(tmle)
library(parallel)
SL.libraryQ = c("SL.glm", "SL.glm.interaction", "SL.gam", "SL.glmnet",
"SL.earth", "SL.ridge")
SL.libraryG = c("SL.glm", "SL.glm.interaction", "SL.gam", "SL.glmnet",
"SL.earth", "SL.knn")
set.seed(110276)
print("packages loaded")
#**read data into R
AData = read.csv("C:/stata/PhDPaper/VIM/nfhs-indiaA.csv")
WData = read.csv("C:/stata/PhDPaper/VIM/nfhs-indiaW.csv")
#** Data frame with only rural data
AS = subset(AData, AData$rural == 1 & complete.cases(AData), select = -
c(state, rural, haz, sevstunting, chronicstunting))
WS = subset(WData, WData$rural == 1 & complete.cases(WData), select = -
c(state, rural, haz, sevstunting, chronicstunting ))
HAZ = subset(WData, WData$rural == 1 & complete.cases(WData), select =
c(haz))
varlist = names(AS)
test = mclapply(varlist,
             function(x) {
               print(x)
               #create datafram of continuous W and Binary A
               AW = WS
               AW[,x] = AS[,x]
               # Dataframe with continuous W but no A
               W = WS
               W[,x] = NULL
               #Create Dataframe with A= 1, A= 0, and A as current
               AOW = A1W = AW
               n = nrow(AW)
               AOW[,x] = 0
               A1W[,x] = 1
               allAdata = rbind(AW,AOW,A1W)
```

```
#** Simple Substitution **
                print("SL Qinit started")
                print(date())
                Qinit = SuperLearner(Y=HAZ$haz, X=AW, SL.library=SL.libraryQ,
family="gaussian", cvControl=list(V=10))
                print("SL Qinit ENDED")
                print(date())
                #Smple Subsitution is marginal effect for binary A. Predicts
Y for A=0 and A=1 while W remain unchanged
                Yhat.SS = predict(Qinit, allAdata, X=AW)$pred
                QbarAW = Yhat.SS[1:n]
                Qbar0W = Yhat.SS[(n+1):(2*n)]
                Obar1W = Yhat.SS[(2*n+1):(3*n)]
                #R-sq for the prediction fit of SS
                R2Y = var(ObarAW)/var(HAZ$haz)
                PsiHat.SS = mean(Obar1W - Obar0W)
                #PsiHat.SS.se = sqrt(var(Qbar1W - Qbar0W)/(length(Qbar1W -
Qbar0W)-2))
                #PsiHat.SS.p = 2* pnorm( abs(PsiHat.SS / PsiHat.SS.se ),
lower.tail=F )
                #population Attri Effect / PIM... remove the exposure to
"risk factor"
                PsiHat.SS.PIM = mean(Qbar0W - QbarAW)
                #** IPTW-Stabilized ***
                #Predict A in step 1
                qHatSL = SuperLearner(Y=AW[,x], X=W, SL.library=SL.libraryG,
family="binomial", cvControl=list(V=10))
                gHat1W = gHatSL$SL.predict
                gHat0W = 1 - gHat1W
                #R-sq for predicting A
                R2A = var(gHat1W)/var(AS[,x])
                qHatAW = rep(NA, n)
                gHatAW[AW[,x]==1] = gHat1W[AW[,x]==1]
                gHatAW[AW[,x]==0] = gHatOW[AW[,x]==0]
                PsiHat.IPTWS = mean(as.numeric(AW[,x]==1)*HAZ$haz/gHatAW) /
mean(as.numeric(AW[,x]==1)/gHatAW) -
mean(as.numeric(AW[,x]==0)*HAZ$haz/gHatAW) /
mean(as.numeric(AW[,x]==0)/gHatAW)
                #PIM effects... remove exposure so A = 0
                PsiHat.IPTWS.PIM = mean(as.numeric(AW[,x]==0)*HAZ$haz/qHatAW)
/ mean(as.numeric(AW[,x]==0)/qHatAW) - mean(as.numeric(AW[,x]==0
AW[,x]==1)*HAZ$haz/gHatAW) / mean(as.numeric(AW[,x]==0 | AW[,x]==1)/gHatAW)
```

#\*\* TMLE \*\*\* Yhat.TMLE = tmle(Y=HAZ\$haz, A=AS[,x], W=W, Q=cbind(Qbar0W, Qbar1W), g1W=gHat1W, family="gaussian") #tmle.out = tmle(Y=HAZ\$haz, A=AS[,x], W=W, Q.SL.library=SL.libraryQ, cvQinit=TRUE, q.SL.library=SL.libraryG, family="gaussian") PsiHat.TMLE = Yhat.TMLE\$estimates\$ATE\$psi PsiHat.TMLE.se = sqrt(Yhat.TMLE\$estimates\$ATE\$var.psi) PsiHat.TMLE.p = Yhat.TMLE\$estimates\$ATE\$pvalue GLMMVI = glm(HAZ\$haz ~ hhsize7 + headfemale + headage45 + odkitchen + numrooms1 + acreirri1 + noelectricity + nocleancook + bpl + assetindex15 + scst + nopuccaf1 + nobednet + mthage25 + mthnosechi + nomediaexp + mthfirstcldage20 + notwantcld + fthnotante + genderno + currpreg + mthfoodpoor + mthtobacco + mthuht + mthuwt + cldmth12 + cldmale + cldgap36 + cldnofirst + nodwimpr + nosanimpr + cldfeces + noboil + noclothfilter + nofilter + antecare4 + notetanus + antenoworms + noinstdel + birthsmall + nobflhr + food3daysany + vagbleedfever2mth + nocldvita6 + noimm + noiodine + nocurrbf + iycfno + icdspoor + villdiar14d0 + villari14d0, family = gaussian, data = AW) GLMMVI.coef = coefficients(summary(GLMMVI))[row.names(coef(summary(GLMMVI))) %in% x,1] GLMMVI.se = coefficients(summary(GLMMVI))[row.names(coef(summary(GLMMVI))) %in% x,2] GLMMVI.p =coefficients(summary(GLMMVI))[row.names(coef(summary(GLMMVI))) %in% x,4] R2OLS = 1-(GLMMVI\$deviance/GLMMVI\$null.deviance) print(date()) #Coef are the weights given by SL to individual library algorithms for Y and Acoefs are for A list(varname=x, ss=PsiHat.SS, iptwst=PsiHat.IPTWS, tmle=PsiHat.TMLE, tmle se=PsiHat.TMLE.se, tmle p=PsiHat.TMLE.p, R2Y=R2Y, coef1=Qinit\$coef[1], coef2=Qinit\$coef[2], coef3=Qinit\$coef[3], coef4=Qinit\$coef[4], coef5=Qinit\$coef[5], coef6=Qinit\$coef[6], R2A=R2A, Acoef1=gHatSL\$coef[1], Acoef2=gHatSL\$coef[2], Acoef3=gHatSL\$coef[3], Acoef4=gHatSL\$coef[4], Acoef5=gHatSL\$coef[5], Acoef6=gHatSL\$coef[6], glm=GLMMVI.coef, glm\_se=GLMMVI.se, glm\_p=GLMMVI.p, glm\_R2 = R2OLS ) }, mc.preschedule = TRUE, mc.set.seed = TRUE, mc.cores = 1) write.csv(test, "C:/stata/PhDPaper/VIM/results\_rural\_8feb2016.csv", row.names=FALSE) #\*\* Data frame with only rural data AS = subset(AData, AData\$rural == 0 & complete.cases(AData), select = c(state, rural, haz, sevstunting, chronicstunting)) WS = subset(WData, WData\$rural == 0 & complete.cases(WData), select = -

c(state, rural, haz, sevestunting, chronicstunting))

```
HAZ = subset(WData, WData$rural == 0 & complete.cases(WData), select =
c(haz))
varlist = names(AS)
#varlist = "sanimpr"
test = mclapply(varlist,
              function(x) {
                print(x)
                #create datafram of continuous W and Binary A
                AW = WS
                AW[,x] = AS[,x]
                # Dataframe with continuous W but no A
                W = WS
                W[,x] = NULL
                #Create Dataframe with A= 1, A= 0, and A as current
                AOW = A1W = AW
                n = nrow(AW)
                AOW[,x] = 0
                A1W[,x] = 1
                allAdata = rbind(AW,A0W,A1W)
                #** Simple Substitution **
                print("SL Qinit started")
                print(date())
                Qinit = SuperLearner(Y=HAZ$haz, X=AW, SL.library=SL.libraryQ,
family="gaussian", cvControl=list(V=10))
                print("SL Qinit ENDED")
                print(date())
                #Smple Subsitution is marginal effect for binary A. Predicts
Y for A=0 and A=1 while W remain unchanged
                Yhat.SS = predict(Qinit, allAdata, X=AW)$pred
                QbarAW = Yhat.SS[1:n]
                Obar0W = Yhat.SS[(n+1):(2*n)]
                Qbar1W = Yhat.SS[(2*n+1):(3*n)]
                #R-sq for the prediction fit of SS
                R2Y = var(QbarAW)/var(HAZ$haz)
                PsiHat.SS = mean(Qbar1W - Qbar0W)
                #PsiHat.SS.se = sqrt(var(Qbar1W - Qbar0W)/(length(Qbar1W -
Qbar0W)-2))
                #PsiHat.SS.p = 2* pnorm( abs(PsiHat.SS / PsiHat.SS.se ),
lower.tail=F )
                #population Attri Effect / PIM
                PsiHat.SS.PIM = mean(Qbar0W - QbarAW)
```

```
#** IPTW-Stabilized ***
                #Predict A in step 1
                gHatSL = SuperLearner(Y=AW[,x], X=W, SL.library=SL.libraryG,
family="binomial", cvControl=list(V=10))
                gHat1W = gHatSL$SL.predict
                gHat0W = 1 - gHat1W
                #R-sq for predicting A
                R2A = var(gHat1W)/var(AS[,x])
                gHatAW = rep(NA, n)
                gHatAW[AW[,x]==1] = gHat1W[AW[,x]==1]
                gHatAW[AW[,x]==0] = gHatOW[AW[,x]==0]
                PsiHat.IPTWS = mean(as.numeric(AW[,x]==1)*HAZ$haz/gHatAW) /
mean(as.numeric(AW[,x]==1)/gHatAW) -
mean(as.numeric(AW[,x]==0)*HAZ$haz/gHatAW) /
mean(as.numeric(AW[,x]==0)/gHatAW)
                #PIM effects
                PsiHat.IPTWS.PIM = mean(as.numeric(AW[,x]==0)*HAZ$haz/gHatAW)
/ mean(as.numeric(AW[,x]==0)/gHatAW) - mean(as.numeric(AW[,x]==0
AW[,x]==1)*HAZ$haz/gHatAW) / mean(as.numeric(AW[,x]==0 | AW[,x]==1)/gHatAW)
                #** TMLE ***
                Yhat.TMLE = tmle(Y=HAZ$haz, A=AS[,x], W=W, Q=cbind(Qbar0W,
Qbar1W), g1W=gHat1W, family="gaussian")
                #tmle.out = tmle(Y=HAZ$haz, A=AS[,x], W=W,
Q.SL.library=SL.library, cvQinit=TRUE, g.SL.library=SL.library,
family="gaussian")
                PsiHat.TMLE = Yhat.TMLE$estimates$ATE$psi
                PsiHat.TMLE.se = sqrt(Yhat.TMLE$estimates$ATE$var.psi)
                PsiHat.TMLE.p = Yhat.TMLE$estimates$ATE$pvalue
                GLMMVI = glm(HAZ$haz ~ hhsize7 + headfemale + headage45 +
odkitchen + numrooms1 + acreirri1 + noelectricity + nocleancook + bpl +
assetindex15 + scst + nopuccaf1 + nobednet + mthage25 + mthnosechi +
nomediaexp + mthfirstcldage20 + notwantcld + fthnotante + genderno + currpreg
+ mthfoodpoor + mthtobacco + mthuht + mthuwt + cldmth12 + cldmale + cldgap36
+ cldnofirst + nodwimpr + nosanimpr + cldfeces + noboil + noclothfilter +
nofilter + antecare4 + notetanus + antenoworms + noinstdel + birthsmall +
nobflhr + food3daysany + vagbleedfever2mth + nocldvita6 + noimm + noiodine +
nocurrbf + iycfno + icdspoor + villdiar14d0 + villari14d0, family = gaussian,
data = AW)
                GLMMVI.coef =
coefficients(summary(GLMMVI))[row.names(coef(summary(GLMMVI))) %in% x,1]
                GLMMVI.se =
coefficients(summary(GLMMVI))[row.names(coef(summary(GLMMVI))) %in% x,2]
                GLMMVI.p =
coefficients(summary(GLMMVI))[row.names(coef(summary(GLMMVI))) %in% x,4]
                R2OLS = 1-(GLMMVI$deviance/GLMMVI$null.deviance)
                print(date())
```

}, mc.preschedule = TRUE, mc.set.seed = TRUE, mc.cores = 1)

write.csv(test, "C:/stata/PhDPaper/VIM/results\_urban\_8feb2016.csv", row.names=FALSE)

			Predic	tion of '	Y			Prediction of A								
Dichotomized A Variables		C	Contribution (	of Learr	ning Alş	gorithms	,		(	Contribution	of Lear	ning Al	gorithm	3		
	<b>R</b> <sup>2</sup>	GLM	GLM- Interaction	GAM	GLM- NET	EART H	Ridg e	$\mathbb{R}^2$	GLM	GLM- Interaction	GAM	GLM- NET	EART H	KNN		
<= 7 household Members	0.19	7%	3%	30%	34%	26%	0%	0.37	0%	6%	32%	0%	56%	6%		
Female HH Head	0.19	6%	3%	35%	34%	21%	0%	0.12	12%	2%	0%	0%	69%	17%		
HH Head <= 45 Years	0.19	0%	3%	71%	3%	17%	6%	0.39	0%	4%	27%	0%	68%	0%		
Outdoors Kitchen	0.19	0%	4%	37%	34%	26%	0%	0.10	0%	6%	66%	8%	10%	9%		
Single Room Dwelling	0.19	0%	2%	25%	0%	30%	43%	0.38	0%	8%	55%	0%	35%	2%		
No or < 1 Acre of Irrigated Land	0.19	0%	5%	76%	0%	19%	0%	0.18	0%	10%	51%	0%	31%	9%		
No Electricity Connection	0.19	0%	4%	26%	0%	27%	43%	0.38	0%	7%	67%	0%	24%	3%		
Don't use cleaner cooking fuels (LPG, Biogas, Electricity)	0.19	19%	3%	31%	15%	32%	0%	0.37	0%	2%	40%	39%	12%	6%		
Below Poverty Line HH	0.19	0%	4%	24%	3%	32%	37%	0.08	0%	9%	45%	0%	39%	7%		
Asset Index < 15 (Poorer HH)	0.19	0%	4%	31%	34%	31%	0%	0.46	43%	8%	0%	0%	46%	2%		
Scheduled Caste/Tribe HH	0.19	0%	4%	31%	35%	30%	0%	0.17	0%	14%	25%	0%	55%	6%		
Floor in House is Kuccha (Permeable, not permanent)	0.19	0%	3%	35%	38%	23%	0%	0.32	0%	21%	34%	0%	41%	4%		
No Bed nets in HH	0.19	0%	2%	49%	23%	26%	0%	0.20	0%	22%	36%	0%	39%	4%		
Mother is <= 25 Years	0.18	0%	3%	22%	42%	33%	0%	0.78	0%	0%	28%	0%	72%	1%		
Mother's Education <= 8th Std	0.19	0%	4%	25%	0%	32%	39%	0.43	0%	8%	64%	0%	25%	3%		
Mother Not Exposed to Media Daily	0.19	6%	2%	24%	0%	34%	34%	0.34	15%	3%	60%	1%	15%	6%		
Mother Adolescent when First Child	0.19	0%	1%	34%	16%	31%	18%	0.66	0%	1%	14%	0%	85%	0%		
Child Pregnancy was Un-Planned	0.19	31%	2%	24%	5%	36%	0%	0.09	0%	8%	62%	6%	21%	3%		
Father did not Attended Antenatal Visits	0.19	0%	3%	38%	39%	20%	0%	0.32	0%	4%	22%	0%	73%	1%		
Mother's Gender Attitude Index < 8	0.19	0%	1%	26%	0%	41%	32%	0.08	0%	8%	35%	24%	21%	12%		
Mother is Currently Pregnant	0.19	30%	5%	27%	10%	28%	0%	0.24	0%	0%	77%	0%	23%	0%		
Mother Consumes < 5 Food Groups Weekly	0.19	0%	3%	33%	0%	31%	33%	0.14	0%	12%	58%	0%	29%	1%		
Tobacco Consumption by Mother	0.19	2%	3%	25%	0%	34%	36%	0.12	0%	11%	60%	0%	26%	3%		

 Table A1. Prediction Performance of SuperLearner and Contribution of Individual Learning Algorithms – Rural Sample

			Predict	tion of Y	Y		Prediction of A								
Dichotomized A Variables		C	Contribution	of Learn	ing Alg	orithms			Contribution of Learning Algorithms						
	$\mathbb{R}^2$	GLM	GLM- Interaction	GAM	GLM- NET	EART H	Ridg e	$\mathbf{R}^2$	GLM	GLM- Interaction	GAM	GLM- NET	EART H	KNN	
Mother's Height < 145 cm	0.17	3%	3%	26%	46%	23%	0%	0.01	0%	0%	0%	90%	3%	7%	
Mother's BMI < 18.5	0.19	24%	2%	24%	18%	32%	0%	0.08	35%	6%	2%	19%	34%	5%	
Child is >= 12 Months	0.16	11%	3%	0%	72%	15%	0%	0.35	0%	5%	17%	0%	77%	0%	
Male Child	0.19	19%	3%	30%	16%	32%	0%	0.00	0%	3%	0%	74%	17%	7%	
Spacing of < 36 Months	0.19	0%	4%	20%	3%	35%	37%	0.56	0%	0%	7%	0%	93%	0%	
Not the First Child	0.19	0%	4%	24%	39%	33%	0%	0.99	0%	0%	0%	60%	40%	0%	
Do Not Use Improved Drinking Water Source	0.19	0%	4%	35%	42%	19%	0%	0.09	0%	11%	22%	22%	42%	3%	
Do not Use Improved Sanitation Facilities	0.19	4%	5%	31%	36%	23%	0%	0.40	12%	9%	61%	0%	16%	3%	
Unsafe Child Feces Disposal	0.19	0%	4%	31%	0%	32%	34%	0.25	0%	1%	29%	65%	4%	1%	
Do Not Boil Drinking Water	0.19	1%	5%	34%	36%	24%	0%	0.33	0%	14%	55%	0%	26%	4%	
Do Not Sift Drinking Water	0.19	10%	3%	22%	36%	30%	0%	0.09	0%	9%	56%	0%	26%	9%	
Do Not Filter Drinking Water	0.19	18%	1%	28%	19%	25%	8%	0.11	5%	2%	44%	48%	1%	0%	
< 4 Antenatal Checks	0.19	0%	1%	26%	0%	41%	33%	0.39	0%	9%	81%	0%	5%	5%	
Inadequate Tetanus Vaccination	0.19	0%	2%	30%	0%	35%	33%	0.09	0%	7%	22%	0%	64%	7%	
Mother Not Dewormed	0.19	18%	5%	33%	16%	29%	0%	0.03	39%	0%	0%	49%	12%	0%	
Not an Institutional Delivery	0.19	0%	2%	48%	27%	23%	0%	0.38	17%	6%	56%	0%	19%	1%	
Birth Size Small or Average	0.19	0%	2%	25%	40%	33%	0%	0.02	0%	9%	7%	82%	2%	0%	
Not Breastfed during the First Hour	0.19	19%	7%	35%	8%	31%	0%	0.30	0%	11%	57%	0%	30%	1%	
Child Fed Other Foods in First 3 Days	0.19	8%	4%	26%	34%	29%	0%	0.40	13%	17%	0%	0%	62%	7%	
Fever or Bleeding in postpartum	0.19	2%	5%	36%	34%	23%	0%	0.04	0%	10%	42%	23%	22%	4%	
Child Not Given Vitamin A Dose in 6 Months	0.19	0%	5%	23%	0%	29%	42%	0.13	0%	7%	43%	0%	48%	3%	
Child Not Fully Immunized	0.19	0%	4%	29%	32%	35%	1%	0.24	0%	5%	29%	0%	62%	4%	
Inadequate Iodine in House Salt	0.19	0%	4%	34%	35%	27%	0%	0.14	0%	10%	48%	0%	37%	5%	
Child Currently Not Breastfed	0.19	0%	1%	53%	27%	19%	0%	0.24	0%	3%	26%	31%	34%	6%	
Child Not Fed as per IYCF Guidelines	0.19	0%	3%	18%	2%	33%	44%	0.16	0%	3%	54%	2%	26%	15%	

Dichotomized A Variables			Predict	tion of Y	Y		Prediction of A								
		Contribution of Learning Algorithms							Contribution of Learning Algorithms						
	$\mathbf{R}^2$	GLM GLM- Interaction GA	GAM	GLM-	EART	Ridg	$\mathbf{R}^2$	GLM	GLM-	GAM	GLM-	EART	Γ KNN		
			Interaction	ction	NET	Н	e		GEM	Interaction	UAN	NET	Н	IXININ	
PCA based ICDS Service Index < 0	0.19	0%	3%	66%	0%	17%	13%	0.16	0%	13%	46%	0%	38%	3%	
Diarrhea Reported in the Community	0.19	0%	4%	34%	16%	23%	24%	0.09	0%	10%	36%	0%	49%	5%	
ARI Reported in the Community	0.19	0%	2%	31%	45%	22%	0%	0.12	0%	10%	49%	0%	40%	0%	

			Predict	tion of `	Y		Prediction of A								
Dichotomize A Variables		C	Contribution (	of Learr	ning Alg	orithms			(	Contribution	of Learı	ning Alş	gorithms	\$	
	R <sup>2</sup>	GLM	GLM- Interaction	GAM	GLM- NET	EART H	Ridg e	$\mathbb{R}^2$	GLM	GLM- Interaction	GAM	GLM- NET	EART H	KNN	
<= 7 household Members	0.19	0%	3%	56%	29%	12%	0%	0.39	0%	0%	51%	0%	41%	8%	
Female HH Head	0.19	0%	3%	58%	27%	11%	0%	0.13	0%	0%	18%	7%	63%	13%	
HH Head <= 45 Years	0.19	0%	4%	57%	32%	7%	0%	0.49	0%	2%	31%	0%	67%	0%	
Outdoors Kitchen	0.19	0%	4%	56%	19%	21%	0%	0.18	31%	4%	0%	54%	11%	0%	
Single Room Dwelling	0.20	0%	3%	71%	4%	22%	0%	0.47	0%	3%	46%	0%	43%	8%	
No or $< 1$ Acre of Irrigated Land	0.19	0%	2%	55%	18%	25%	0%	0.03	0%	1%	4%	52%	27%	16%	
No Electricity Connection	0.19	0%	5%	57%	21%	17%	0%	0.36	0%	1%	39%	38%	16%	6%	
Don't use cleaner cooking fuels (LPG, Biogas, Electricity)	0.19	0%	3%	63%	24%	10%	0%	0.51	0%	6%	40%	38%	15%	2%	
Below Poverty Line HH	0.20	0%	2%	63%	17%	18%	0%	0.08	0%	2%	29%	38%	19%	12%	
Asset Index < 15 (Poorer HH)	0.19	0%	2%	60%	21%	17%	0%	0.47	0%	2%	56%	16%	22%	4%	
Scheduled Caste/Tribe HH	0.19	0%	3%	59%	18%	20%	0%	0.12	0%	8%	59%	0%	25%	8%	
Floor in House is Kuccha (Permeable, not permanent)	0.20	0%	3%	58%	18%	20%	0%	0.37	0%	2%	30%	41%	24%	3%	
No Bed-nets in HH	0.19	0%	3%	62%	22%	13%	0%	0.18	0%	10%	57%	0%	30%	3%	
Mother is <= 25 Years	0.19	0%	1%	65%	19%	15%	0%	0.74	0%	0%	23%	0%	75%	3%	
Mother's Education <= 8th Std	0.19	0%	3%	53%	21%	22%	0%	0.47	3%	2%	46%	0%	43%	6%	
Mother Not Exposed to Media Daily	0.19	0%	3%	63%	17%	16%	0%	0.27	0%	2%	19%	44%	25%	10%	
Mother Adolescent when First Child	0.20	0%	2%	71%	18%	9%	0%	0.71	0%	0%	17%	0%	83%	0%	
Child Pregnancy was Un-Planned	0.20	0%	3%	62%	25%	10%	0%	0.08	0%	5%	34%	52%	2%	7%	
Father did not Attended Antenatal Visits	0.20	0%	2%	68%	11%	19%	0%	0.23	0%	0%	38%	0%	58%	4%	
Mother's Gender Attitude Index < 8	0.20	0%	3%	68%	18%	11%	0%	0.07	0%	2%	17%	63%	11%	7%	
Mother is Currently Pregnant	0.19	0%	3%	46%	33%	17%	0%	0.19	0%	3%	65%	0%	23%	9%	
Mother Consumes < 5 Food Groups Weekly	0.20	0%	1%	72%	20%	6%	0%	0.11	16%	5%	47%	18%	9%	5%	
Tobacco Consumption by Mother	0.20	0%	4%	73%	16%	7%	0%	0.16	0%	2%	41%	47%	1%	9%	
Mother's Height < 145 cm	0.17	0%	5%	60%	21%	14%	0%	0.03	0%	0%	47%	44%	5%	4%	

 Table A2. Prediction Performance of SuperLearner and Contribution of Individual Learning Algorithms – Urban Sample

			Predict	tion of Y	Y			Prediction of A							
Dichotomize A Variables		Contribution of Learning Algorithms							Contribution of Learning Algorithms						
	R <sup>2</sup>	GLM	GLM- Interaction	GAM	GLM- NET	EART H	Ridg e	R <sup>2</sup>	GLM	GLM- Interaction	GAM	GLM- NET	EART H	KNN	
Mother's BMI < 18.5	0.19	0%	5%	48%	38%	9%	0%	0.09	14%	0%	21%	44%	13%	8%	
Child is >= 12 Months	0.18	0%	2%	32%	65%	1%	0%	0.29	0%	5%	41%	0%	54%	0%	
Male Child	0.19	0%	1%	55%	18%	26%	0%	0.00	0%	0%	16%	78%	6%	0%	
Spacing of < 36 Months	0.19	0%	4%	55%	21%	20%	0%	0.63	0%	2%	12%	0%	87%	0%	
Not the First Child	0.19	0%	2%	61%	22%	15%	0%	0.98	0%	0%	0%	79%	21%	0%	
Do Not Use Improved Drinking Water Source	0.19	0%	1%	67%	21%	12%	0%	0.10	24%	2%	32%	26%	8%	7%	
Do not Use Improved Sanitation Facilities	0.20	0%	4%	63%	29%	5%	0%	0.24	2%	4%	0%	56%	35%	2%	
Unsafe Child Feces Disposal	0.19	0%	2%	61%	22%	14%	0%	0.20	1%	2%	61%	12%	24%	1%	
Do Not Boil Drinking Water	0.20	0%	3%	76%	12%	8%	0%	0.19	0%	7%	63%	0%	26%	4%	
Do Not Sift Drinking Water	0.20	0%	3%	75%	19%	4%	0%	0.10	0%	6%	64%	4%	17%	10%	
Do Not Filter Drinking Water	0.20	0%	4%	67%	20%	10%	0%	0.17	0%	0%	43%	40%	10%	7%	
< 4 Antenatal Checks	0.20	0%	4%	66%	20%	10%	0%	0.38	0%	2%	42%	44%	11%	1%	
Inadequate Tetanus Vaccination	0.20	0%	4%	58%	18%	19%	0%	0.05	0%	0%	48%	7%	37%	9%	
Mother Not Dewormed	0.20	0%	3%	63%	15%	19%	0%	0.02	0%	0%	20%	63%	3%	13%	
Not an Institutional Delivery	0.19	0%	3%	47%	29%	21%	0%	0.38	0%	2%	46%	28%	17%	7%	
Birth Size Small or Average	0.20	0%	3%	66%	26%	5%	0%	0.02	0%	7%	18%	56%	13%	6%	
Not Breastfed during the First Hour	0.19	0%	2%	62%	16%	20%	0%	0.26	0%	1%	52%	7%	37%	3%	
Child Fed Other Foods in First 3 Days	0.20	0%	3%	68%	15%	14%	0%	0.36	32%	2%	1%	0%	52%	14%	
Fever Or Bleeding in postpartum	0.20	0%	5%	65%	11%	18%	0%	0.01	9%	1%	4%	75%	12%	0%	
Child Not Given Vitamin A Dose in 6 Months	0.20	0%	3%	65%	20%	12%	0%	0.12	0%	1%	33%	12%	54%	0%	
Child Not Fully Immunized	0.19	0%	2%	58%	25%	15%	0%	0.23	0%	0%	13%	11%	73%	4%	
Inadequate Iodine in House Salt	0.19	0%	3%	58%	21%	19%	0%	0.15	6%	5%	0%	60%	23%	5%	
Child Currently Not Breastfed	0.19	0%	4%	54%	21%	22%	0%	0.23	0%	4%	28%	35%	25%	7%	
Child Not Fed as per IYCF Guidelines	0.19	0%	4%	53%	19%	23%	0%	0.18	0%	1%	37%	10%	33%	19%	
PCA based ICDS Service Index < 0	0.19	0%	2%	60%	23%	15%	0%	0.09	0%	2%	19%	51%	14%	13%	
Dichotomize A Variables			Predict	tion of Y	Y			Prediction of A							
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		Contribution of Learning Algorithms							(	Contribution	of Leari	ning Alg	orithms	\$	
	R <sup>2</sup>	GLM	GLM- Interaction	GAM	GLM- NET	EART H	Ridg e	$\mathbb{R}^2$	GLM	GLM- Interaction	GAM	GLM- NET	EART H	KNN	
Diarrhea Reported in the Community	0.20	0%	1%	76%	13%	10%	0%	0.13	0%	8%	36%	0%	56%	0%	
ARI Reported in the Community	0.19	0%	2%	57%	17%	23%	0%	0.13	0%	10%	28%	4%	57%	1%	

 Table A3. The Marginal-VIM and Population-VIM for Dichotomized Exposure Variables – Rural Sample

	SS		TMLE	Marginal-VI	М	TMLE Population-VIM					
Variables	Marginal- VIM	Marginal -VIM	SE	Unadjusted p-value	BH Significance	Populatio n-VIM	SE	Unadjusted p-value	BH Significance		
<= 7 household Members	0.015	-0.032	0.051	0.539		0.012	0.063	0.855			
Female HH Head	0.022	0.036	0.049	0.456		0.002	0.009	0.804			
HH Head <= 45 Years	-0.062	-0.102	0.043	0.017	**	0.057	0.380	0.882			
Outdoors Kitchen	-0.050	-0.187	0.037	0.000	***	0.009	0.008	0.249			
Single Room Dwelling	-0.056	-0.096	0.043	0.027	*	0.024	0.027	0.366			
No or < 1 Acre of Irrigated Land	0.026	0.047	0.041	0.258		-0.064	0.042	0.131			
No Electricity Connection	-0.018	0.001	0.041	0.986		0.027	0.029	0.363			
Don't use cleaner cooking fuels (LPG, Biogas, Electricity)	-0.023	-0.122	0.041	0.003	***	0.101	0.868	0.907			
Below Poverty Line HH	-0.039	-0.060	0.038	0.112		0.019	0.011	0.104			
Asset Index < 15 (Poorer HH)	-0.024	-0.086	0.045	0.054		0.032	0.046	0.481			
Scheduled Caste/Tribe HH	-0.029	-0.056	0.037	0.138		0.025	0.021	0.239			
Floor in House is Kuccha (Permeable, not permanent)	-0.021	-0.024	0.039	0.540		0.045	0.038	0.244			
No Bed-nets in HH	-0.181	-0.151	0.037	0.000	***	0.109	0.028	0.000	***		
Mother is <= 25 Years	0.005	-0.147	0.040	0.000	***	-0.089	0.046	0.051			
Mother's Education <= 8th Std	-0.126	-0.179	0.052	0.001	***	0.098	0.079	0.214			
Mother Not Exposed to Media Daily	0.008	0.037	0.046	0.417		-0.016	0.043	0.712			
Mother Adolescent when First Child	0.052	0.314	0.047	0.000	***	0.005	606.108	1.000			

	SS		TMLF	Marginal-VI	М	TMLE Population-VIM					
Variables	Marginal-	Marginal	SE	Unadjusted	BH	Populatio	SE	Unadjusted	BH		
	VIM	-VIM	SL	p-value	Significance	n-VIM	55	p-value	Significance		
Child Pregnancy was Un-Planned	-0.005	0.005	0.043	0.899		0.003	0.010	0.766			
Father did not Attended Antenatal Visits	-0.011	-0.062	0.035	0.075		0.026	0.016	0.104			
Mother's Gender Attitude Index < 8	0.003	0.016	0.038	0.678		0.000	0.014	0.982			
Mother is Currently Pregnant	-0.389	-0.371	0.076	0.000	***	0.040	0.008	0.000	***		
Mother Consumes < 5 Food Groups Weekly	-0.044	-0.022	0.043	0.605		0.008	0.045	0.856			
Tobacco Consumption by Mother	0.032	0.143	0.046	0.002	***	-0.002	0.008	0.802			
Mother's Height < 145 cm	-0.632	-0.640	0.051	0.000	***	0.073	0.007	0.000	***		
Mother's BMI < 18.5	-0.199	-0.191	0.037	0.000	***	0.077	0.016	0.000	***		
Child is >= 12 Months	-0.927	-0.996	0.054	0.000	***	0.627	0.056	0.000	***		
Male Child	-0.182	-0.185	0.034	0.000	***	0.096	0.018	0.000	***		
Spacing of < 36 Months	-0.102	-0.109	0.053	0.040	*	0.023	0.758	0.976			
Not the First Child	0.064	0.056	0.030	0.059		-0.076	0.015	0.000	***		
Do Not Use Improved Drinking Water Source	0.104	0.103	0.043	0.016	**	-0.032	0.011	0.003	**		
Do not Use Improved Sanitation Facilities	-0.081	-0.091	0.050	0.073		0.072	0.048	0.130			
Unsafe Child Feces Disposal	-0.036	-0.117	0.077	0.129		0.085	0.115	0.459			
Do Not Boil Drinking Water	-0.098	-0.348	0.041	0.000	***	0.124	0.103	0.228			
Do Not Sift Drinking Water	0.049	0.078	0.047	0.098		-0.100	0.084	0.234			
Do Not Filter Drinking Water	-0.027	0.049	0.055	0.376		0.062	0.369	0.867			
< 4 Antenatal Checks	-0.020	0.017	0.042	0.693		-0.030	0.053	0.567			
Inadequate Tetanus Vaccination	-0.039	-0.044	0.042	0.297		0.036	0.044	0.403			
Mother Not Dewormed	-0.032	-0.016	0.074	0.832		0.029	0.111	0.794			
Not an Institutional Delivery	-0.046	-0.090	0.055	0.103		0.065	0.062	0.298			
Birth Size Small or Average	-0.160	-0.157	0.041	0.000	***	0.124	0.035	0.000	***		
Not Breastfed during the First Hour	0.004	-0.020	0.040	0.611		0.002	0.165	0.992			
Child Fed Other Foods in First 3 Days	-0.007	0.031	0.041	0.442		0.009	0.035	0.793			
Fever or Bleeding in postpartum	0.046	0.042	0.040	0.296		-0.016	0.010	0.101			

	SS		TMLE	Marginal-VI	М		TMLE Po	opulation-VIN	ſ
Variables	Marginal- VIM	Marginal -VIM	SE	Unadjusted p-value	BH Significance	Populatio n-VIM	SE	Unadjusted p-value	BH Significance
Child Not Given Vitamin A Dose in 6 Months	0.062	0.048	0.049	0.328		0.006	0.065	0.921	
Child Not Fully Immunized	-0.024	-0.041	0.041	0.317		0.064	0.030	0.033	
Inadequate Iodine in House Salt	-0.128	-0.110	0.035	0.002	***	0.059	0.021	0.005	**
Child Currently Not Breastfed	0.321	0.281	0.064	0.000	***	-0.033	26.659	0.999	
Child Not Fed as per IYCF Guidelines	-0.118	-0.568	0.040	0.000	***	0.117	0.150	0.434	
PCA based ICDS Service Index < 0	0.048	0.084	0.041	0.041	*	-0.067	0.039	0.085	
Diarrhea Reported in the Community	0.022	0.016	0.037	0.663		-0.021	0.014	0.118	
ARI Reported in the Community	-0.021	-0.041	0.037	0.271		0.001	0.016	0.951	

 Table A4. The Marginal-VIM and Population-VIM for Dichotomized Exposure Variables – Urban Sample.

	22		TMLE N	larginal-VIM		]	TMLE Po	pulation-VIN	1
Variables	Marginal- VIM	Marginal- VIM	SE	Unadjusted p-value	BH Significance	Population -VIM	SE	Unadjusted p-value	BH Significanc e
<= 7 household Members	0.057	0.077	0.059	0.193		-0.048	0.101	0.631	
Female HH Head	-0.067	-0.195	0.065	0.003	**	0.007	0.009	0.422	
HH Head <= 45 Years	-0.023	-0.039	0.054	0.464		0.037	0.321	0.908	
Outdoors Kitchen	-0.133	0.098	0.042	0.020	*	0.006	0.007	0.412	
Single Room Dwelling	-0.055	-0.035	0.052	0.496		0.051	0.069	0.463	
No or < 1 Acre of Irrigated Land	-0.082	-0.104	0.059	0.077		0.073	0.086	0.398	
No Electricity Connection	-0.058	-0.148	0.054	0.006	**	0.004	0.008	0.648	
Don't use cleaner cooking fuels	-0.107	-0.212	0.061	0.000	***	0.071	0.045	0.117	
Below Poverty Line HH	0.078	0.175	0.066	0.009	**	-0.011	0.010	0.240	
Asset Index < 15 (Poorer HH)	-0.019	-0.131	0.050	0.008	**	0.012	0.057	0.835	
Scheduled Caste/Tribe HH	-0.052	-0.072	0.044	0.102		0.016	0.015	0.291	
Floor in House is Kuccha (Permeable, not permanent)	0.013	-0.016	0.047	0.733		-0.002	0.020	0.927	

	SS		TMLE N	larginal-VIM		TMLE Population-VIM					
Variables	Marginal- VIM	Marginal- VIM	SE	Unadjusted p-value	BH Significance	Population -VIM	SE	Unadjusted p-value	BH Significanc e		
No Bed-nets in HH	-0.117	-0.091	0.045	0.043	*	0.046	0.034	0.170			
Mother is <= 25 Years	0.031	-0.224	0.043	0.000	***	0.020	0.035	0.566			
Mother's Education <= 8th Std	-0.010	-0.006	0.059	0.925		0.042	0.073	0.564			
Mother Not Exposed to Media Daily	-0.016	0.010	0.051	0.839		0.007	0.020	0.711			
Mother Adolescent when First Child	-0.002	-0.153	0.070	0.029	*	0.006	3.747	0.999			
Child Pregnancy was Un-Planned	0.035	0.068	0.049	0.170		-0.010	0.013	0.435			
Father did not Attended Antenatal Visits	0.010	0.021	0.050	0.680		-0.004	0.015	0.810			
Mother's Gender Attitude Index < 8	0.035	0.033	0.053	0.529		-0.006	0.011	0.571			
Mother is Currently Pregnant	-0.137	-0.134	0.042	0.002	***	0.016	0.007	0.025			
Mother Consumes < 5 Food Groups Weekly	-0.204	-0.214	0.047	0.000	***	0.137	0.037	0.000	***		
Tobacco Consumption by Mother	0.093	0.060	0.056	0.284		-0.006	0.009	0.535			
Mother's Height < 145 cm	-0.648	-0.720	0.070	0.000	***	0.064	0.008	0.000	***		
Mother's BMI < 18.5	-0.119	-0.095	0.053	0.071		0.042	0.015	0.006	*		
Child is >= 12 Months	-0.893	-0.897	0.056	0.000	***	0.559	0.078	0.000	***		
Male Child	-0.086	-0.120	0.044	0.006	**	0.061	0.023	0.009	*		
Spacing of < 36 Months	-0.150	-0.193	0.055	0.001	***	0.049	0.531	0.927			
Not the First Child	-0.040	-0.548	0.031	0.000	***	0.025	0.018	0.167			
Do Not Use Improved Drinking Water Source	0.107	0.147	0.057	0.010	**	-0.008	0.008	0.281			
Do not Use Improved Sanitation Facilities	-0.025	0.018	0.064	0.782		0.012	0.016	0.468			
Unsafe Child Feces Disposal	-0.089	-0.052	0.053	0.327		0.019	0.042	0.662			
Do Not Boil Drinking Water	-0.058	-0.122	0.053	0.022	*	0.076	0.091	0.401			
Do Not Sift Drinking Water	0.100	0.185	0.054	0.001	***	-0.131	0.115	0.254			
Do Not Filter Drinking Water	-0.033	-0.043	0.069	0.535		0.024	0.181	0.895			
< 4 Antenatal Checks	-0.082	-0.100	0.063	0.109		0.021	0.035	0.540			
Inadequate Tetanus Vaccination	-0.024	-0.028	0.048	0.557		0.020	0.041	0.623			
Mother Not Dewormed	-0.183	-0.256	0.071	0.000	***	0.163	0.108	0.129			

	55		TMLE N	/arginal-VIM		TMLE Population-VIM				
Variables	Marginal- VIM	Marginal- VIM	SE	Unadjusted p-value	BH Significance	Population -VIM	SE	Unadjusted p-value	BH Significanc e	
Not an Institutional Delivery	-0.164	-0.163	0.052	0.002	***	0.057	0.029	0.048		
Birth Size Small or Average	-0.080	-0.089	0.045	0.048		0.059	0.039	0.130		
Not Breastfed during the First Hour	-0.017	-0.025	0.050	0.617		0.002	0.169	0.989		
Child Fed Other Foods in First 3 Days	0.092	0.205	0.053	0.000	***	-0.052	1.000	1.000		
Fever or Bleeding in postpartum	0.011	0.024	0.055	0.659		-0.002	0.010	0.837		
Child Not Given Vitamin A Dose in 6 Months	0.020	0.058	0.055	0.288		-0.017	0.050	0.737		
Child Not Fully Immunized	-0.022	-0.060	0.049	0.222		0.022	0.026	0.394		
Inadequate Iodine in House Salt	-0.124	-0.080	0.050	0.107		0.038	0.017	0.022		
Child Currently Not Breastfed	0.044	0.000	0.059	0.999		-0.025	1.000	0.998		
Child Not Fed as per IYCF Guidelines	0.016	0.131	0.058	0.024	*	-0.029	0.118	0.808		
PCA based ICDS Service Index < 0	-0.006	0.056	0.056	0.314		-0.020	0.071	0.780		
Diarrhea Reported in the Community	0.027	0.015	0.044	0.730		-0.015	0.021	0.461		
ARI Reported in the Community	-0.008	-0.025	0.042	0.562		0.009	0.022	0.684		