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Factors predicting compliance, improved water quality, and lower prevalence of diarrhea: A secondary analysis of a 2008 Aquatab® trial in Orissa, India.

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Epidemiology

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BA Political Science
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Abstract

Factors predicting compliance, improved water quality, and lower prevalence of diarrhea: A secondary analysis of a 2008 Aquatab® trial in Orissa, India.
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Background: Disinfection of drinking water through chlorination and safe storage within a household can reduce microbiological contamination, and reduce the morbidity of and mortality resulting from diarrheal disease in <5 children. Historically, interventions targeted at household water treatment and storage (HWTS) have shown mixed results, and have been plagued by issues with compliance, reduction of microbiological organisms in water, and limited impact on health outcomes of interest. In 2010, Boisson et al. conducted a randomized controlled trial of an HWTS intervention in Orissa, India with the goal of assessing the effect of in-home water chlorination on diarrhea in <5 children. We conducted a secondary analysis of data from the trial to identify factors associated with compliance, improved microbiological quality of drinking water, and reduced diarrhea prevalence in <5 children.
Methods: Multilevel linear and logistic regression techniques were applied to data from the cohort of individuals in the intervention arm of the Orissa trial. Data on household- and individual-level indicators were used to build models predicting compliance, improved microbiological quality of drinking water, and diarrhea in <5 children.
Results: 1080 households and 76,036 data points for <5 children were included in the final analysis, and three separate models were run to determine the significance of household- and individual- level factors in predicting outcomes of interest. Compliance was significantly associated with caregiver education (p=0.001), caste of the household (p=0.001), number of individuals per household (p=0.012) and latrine use compliance (p=0.003). Improved microbial quality of water was also significantly predicted by the number of individuals per household (p=0.001). Only age of child was a significant predictor of diarrhea in <5 children (p<0.001).
Conclusions: In order to work towards better health outcomes reliant upon compliance, improved water quality, and reduced diarrhea, future research should focus on a identifying and measuring behavioral, cultural, and environmental barriers and risk factors.

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1. Introduction

In 2015, the United Nations Children's Fund (UNICEF) estimated that 5.9 million children across the world died before the age of five.[1] Of this, 9.2% of deaths in children under five are attributed to diarrhea (approximately 578 million, overall).[2] Since 2001, India has made large strides in reducing its under-five child mortality.

In 2013, India had reduced its under-five yearly mortality from 2.5 million per year, to just 1.5 million per year.[2] Despite this, the proportion of these deaths caused by diarrhea remained high. Thirteen percent of all under-five deaths in India were attributed to diarrhea (approximately 300,000 children per year), making India first in the world for under-five child mortality due to diarrhea.[3]

However, only 14% of India's rural population and 51% of the urban population had access to an in-residence piped water connection in 2013.[4] For individuals without access to piped water or other sources of clean water, the WHO and UNICEF recommend household treatment and safe storage (HWTS) of drinking water to prevent diarrhea, especially in children.[5] Systematic reviews have shown that treatment of water (include boiling, filtering, and chlorination) and safe storage can remove pre-existing contamination, and prevent contamination in the future.[6-10] However, HWTS interventions have had varied success in the past. Issues with uptake of interventions has contributed considerably to the impact of the interventions to reduce fecal contamination prevalence of diarrhea in <5 children in target populations.[10-13]

In 2010, a trial was conducted in Orissa, India to evaluate the efficacy of Aquatab® (NaDCC) tablets in preventing diarrhea in children <5.[14] In addition to baseline data on demographics and water, sanitation and hygiene practices, the trial collected information on compliance with the intervention, water quality, and diarrhea morbidity. In the intention-to-treat analysis, the researchers reported no effect from the intervention on diarrhea. However, they also reported that use was poor. While reported use 51% in treatment households, only 32% of intervention households had residual free chlorine (RFC)—an objective indicator of use—in their water at site visits.[14] Moreover the intervention did not always ensure that the product water was free of fecal contamination. As a result, the trial was not able to determine that compliance with the intervention (water chlorination) significantly contributed to a reduction in diarrheal morbidity among <5 children.

Compliance presents a challenge for HWTS interventions, in that even small decreases in compliance over the course of a study can significantly impact the benefits of an intervention. According to a model developed by Brown (2012), even a 10% drop in compliance (from 100 to 90%) can reduce health gains by up to 96%.[11] In addition, Engler and Eisenberg (2013) found that lapses in compliance (consuming untreated water for several consecutive days) can completely eliminate annual health benefits of an intervention, and limit the impact of reduction of TTC in drinking water.[13, 15]

This thesis sought to determine what, if any, predictors are significantly associated with compliance, improved water quality, and diarrhea morbidity in <5 children among the intervention arm of the study population. The analysis was supported by comprehensive review of literature to identify factors associated with compliance, improved water quality, and diarrheal disease in order to select candidates for logistic regression variables. Multilevel models with nested random intercepts to control for multiple observations from the same individuals (or households) and clustering at the household and village level were then utilized to explore associations between candidate predictors and outcomes.

2. Background and Literature Review

2.1 Compliance in HWTS Interventions

Compliance represents a major challenge to HWTS interventions. Even occasional exposure to untreated water can vitiate the potential protection that is accorded by the intervention, as shown in studies by Hunter (2009), Brown (2012), and Engler (2013). Hunter found that risk of infection from common enteric pathogens increases drastically when study participants revert to untreated water; when participants continue this behavior several continuous days, almost all annual health benefits are lost entirely.[16]

In 2012, Brown constructed a model predicting gains in health attributable to water quality interventions based on a range of assumptions.[11] The model included estimations for the potential effect of compliance on health outcomes, and concluded that even a 10% decline in compliance (from 100% to 90%) has the potential to reduce beneficial health gains by up to 96%, especially when water quality is poor pre-treatment.[11] According to the study, when pre-treatment water is of moderate to high risk, compliance is more important than treatment effectiveness.[11] Additionally, Engler found that when compliance drops below 80%, additional removal of TTC does not contribute to beneficial health outcomes. If pathogen spikes are considered (as in the case of differential pathogen presence due to seasonality or other event), the effect of TTC removal on health outcomes decreases further.[15]

A systematic review by Arnold and Colford showed NaDCC trial compliance as high as 80%; a NaDCC trial conducted Clasen et al. in Bangladesh reached compliance of over 95%.[7, 17] A HWT trial reached over 90% compliance using solar disinfection (SODIS) methods, and remarked that cultural acceptability of the intervention must be high enough to encourage use.[18] Though compliance did increase over time in both groups in Orissa, compliance in the intervention group was likely affected, at least in part, by a slow rollout of the promotional campaign.[14]

However, lack of compliance with HWTS interventions has not been uncommon, even when extensive promotion is carried out successfully. Another HWTS intervention involving SODIS in Bolivia found only 32.1% compliance with the intervention and no evidence of diarrhea reduction, despite a an "extensive solar disinfection campaign."[19] A 2009 evaluation of an existing water treatment intervention in Guatemala by Arnold et al. found only 3.3% confirmed compliance in the intervention group, despite 3 years of promotion by community health workers.[20] Yet another evaluation on cost and sustainability of a HWTS intervention in Zambia found that only 6.2% of households reported compliance with the intervention.[21] Once again, there was an extensive promotional campaign conducted. Rosa and Clasen (2010) found that African and rural households are less likely to practice HWT or use microbiologically adequate methods in general, increasing the challenge of motivating compliance.[12]

It is difficult to determine what actually drives compliance in HTWS interventions. Clearly, promotional campaigns alone do not guarantee high levels of compliance, and the follow-up periods developed drive compliance are not significantly effective.[14] Rosa et al. (2014), a study conducted in Peru, supports this finding. HWTS practices were consistently reported, drinking water in self-reported users was significantly better than source water, and was also significantly better in the rural setting.[22] Similarly, in a case study in Zambia, Rosa et al (2016) found that 19.6% of urban and 2.4% of rural households had TTC free water at all subsequent site visits, and of those, the majority were self-reported HWTS users.[23]

According to researchers, those with confirmed compliance with interventions have a significantly lower prevalence of diarrhea in children under five than in non-use households.[14] This outcome points to the conclusion that there may be marked differences between users and non-users that make the users of the tablets more apt to adhere to intervention protocols.

Though cultural acceptability of the intervention is an important determinant of compliance, drivers of compliance may be based more in individual characteristics. According to a publication by Figueroa and Kincaid, water treatment behavior is clearly related to many other individual beliefs and values, family relationships, social norms, and ecological factors.[24] It is therefore important to determine what factors in the Orissa study population, if any, are significant predictors of compliance in this study population.

2.2 Assessing water quality

A common indicator used to assess drinking water quality is the presence of thermotolerant coliforms (TTC).[8] TTC are bacteria grow at temperatures of 44°C – 45°C, and are commonly found in the feces of warm-blooded mammals, including humans.[25, 26] TTC concentration acts a proxy for the detection of fecal pathogens in surface water that are often difficult to detect, specifically (*Shigella,* Giardia*, Cryptosporidium, etc*).[27] While many TTC bacteria exist, *Escherichia coli* is most commonly measured, since it is almost exclusively found in feces, and it indicative of recent fecal pollution of a water source.[28]

The presence of TTC in drinking water cannot be ignored, and is in itself an important outcome that warrants reduction. While it does not necessarily correlate to diarrheal outcomes,[8, 29] the level of TTC in drinking water may be associated with proper water and sanitation behaviors. Therefore, it is important to determine what factors, if any, contribute to improved TTC concentration in point-of-use water at the household level.

Clearly, treatment of water in any way impacts TTC contamination. According to Clasen et al., boiling water can reduce the geometric mean TTC count by up to 97% in study households.[30] Straining via filter has also been proven effective, but only if proper technology is used, such as a ceramic drip filter (TTC reductions up to 100% in study households).[31] Chlorination has also been proven effective in reducing TTC (though results vary between potable and TTC free), making water treatment strategies an important predictor of improved TTC concentration.[14, 32]

According to a study by Luby et al. in Karachi, Pakistan, mothers who had knowledge of handwashing behaviors were expected to have 65% less TTC in drinking water than mothers who did not.[33] This is supported by a 2010 study by Pickering et al., which found that levels of fecal contamination on the hands of mothers and their children were positively correlated to levels of TTC in drinking water. Pickering et al. found also that mother's educational attainment, use of an improved toilet, an infant in the household, and dissatisfaction with the quantity of water available for hygiene were all associated with improved concentration of TTC.[34]

Source is often fecally contaminated, even from improved supplies.. Bain et al. conducted a systematic review on drinking water in low and middle income countries, and found that contamination was significantly associated with drinking water source (improved water sources had less contamination).[35] The study also found that protected dug wells were rarely free of contamination, and may be a major predictor of improved TTC. Furthermore, the study found that fecal contamination was commonly present in all water, regardless of source.[35]

Eschol, Mahapatra, and Keshapagu noted that households with contaminated stored water were not significantly distinguished from those households without contamination in terms of demographics, water handling, hygiene, or sanitation practices.[29] Nevertheless, the authors stated that a dramatic increase in contamination after collection indicates household and individual characteristics are still the best place to focus efforts in TTC reduction.[29] Understanding the factors that predict the level of TTC, or the level of reduction of TTC in drinking water, is critical to the design and implementation of future HWTS interventions.

2.3 Diarrheal Disease

Diarrhea is defined as passing three or more loose or liquid stools in a single day, or more frequently than normal for a given individual.[5] Diarrhea is a common symptom of infection by enteric pathogenic organisms, including bacteria, viruses, and protozoans. Approximately 60% of diarrhea cases in children under five are due to infection by *E. coli*, *Shigella*, *Campylobacter,* Cryptosporidium, and *Salmonella*, collectively.[5] However, 40% of all cases of acute diarrhea in children under five can be attributed to a single pathogen, Rotavirus.[36] These pathogens often propagate along similar pathways. Pathogens that cause diarrhea are expelled from the body of an infected individual through their feces, and fecal contamination of food and water is the most common exposure mechanism.[5]

Though diarrhea presents only a moderate risk to healthy adults, children under five are much more vulnerable to the consequences of diarrhea, and are much more likely to be exposed to enteric pathogens. Not only do children under five have a greater proportion of water in their bodies when compared to adults, but they also have higher metabolisms and are less capable of conserving water.[5] Therefore, children under five must consume more water than adults and older children, putting them at a greater risk for adverse health outcomes due to diarrhea. Children who are malnourished or exposed to poor environmental conditions are at an even greater risk for fatal diarrhea.[36]

2.4 Sources of exposure and diarrheal disease

Eisenberg, Scott, and Porco observed that if a single diarrhea transmission pathway alone is sufficient to maintain diarrheal disease, single-pathway interventions will have minimal benefit.[13] If, in fact, point-of-source water quality (TTC count) is not the only pathway through which diarrheal disease was propagated in Orissa, then candidates for more accurate predictors must be investigated so that future interventions can address them in relation to <5 child mortality from diarrhea.

In observational studies, key predictors have been identified as being significantly associated with diarrheal disease in children. Age of the mother, mother's knowledge of diarrhea, age of the child, sources of water, re-use of contaminated water, and absence of hygiene habits including handwashing and safe disposal of feces were all identified as potential predictors of diarrhea in children under five.[34, 37-51] In addition, Hunter (2009) found that HWTS interventions that include a double blinding component are less effective at reducing the relative frequency of diarrhea.[52] However, blinding cannot be assessed as a predictor in this instance, since all participants were exposed to the blinding.

2.5 Aquatabs Trial

The Aquatabs trial had two main components: an intensive promotional campaign on water chlorination, and free distribution Aquatab brand of sodium dichloroisocyanurate (NaDCC) tablets.[14] The investigators sought to blind the trial since open HWTS trials had shown diarrhea prevalence reductions in the realm of 30%–40%.[7, 9, 10, 53] However, blinded HWTS conducted prior to the Orissa intervention had not found HWTS to be protective against diarrhea.[54-56]

Extensive piloting took place prior to intervention to determine optimal tablet dosage to achieve the WHO 0.2mL/L standard of residual free chlorine (RFC) after 24 hours.[57] Participants in each arm of the study received unmarked tablets and were instructed on proper tablet use. Study participants were also encouraged to continue using traditional water disinfection techniques, in addition to use of the tablets provided.[14]

Over the 12-month follow up period, the longitudinal prevalence of diarrhea in children under five among the intervention group was 1.69%, compared to 1.74% among the control group. The resulting longitudinal prevalence ratio (LPR), adjusted for clustering within households, was 0.95 (95% CI 0.79–1.13); among all ages, the LPR was 0.99 (95% CI 0.84–1.15). Analysis of the trial found no evidence that the intervention was effective at preventing diarrhea among under-five children, nor among participants of all ages.[14]

During the trial, reported compliance was moderate among participants (62% in control households, 51% in treatment households). However, only 2% of control households and 32% of intervention households had RFC in their water at site visits.[14] This level of compliance was unanticipated, as a five-week pilot study found greater than 68% of water samples from participating households had residual free chlorine in their water. [14, 58]. The one-year follow-up period was designed to “account for seasonability and reduced compliance over time,”[14] as seen in previous interventions by Arnold and Colford, and Clasen et al.[7, 17]

In addition, analysis of follow up data revealed that households with TTC levels > 1000 per 100ml did not have a greater risk of diarrhea among children when compared to households with TTC levels < 1000 per ml.[14] However, it was noted in the study that a wide range of TTC was observed throughout the cohort, and that water quality was better in the population than initially expected.

The primary outcome measure was longitudinal prevalence of diarrhea among children under five over the total number of observation days. Diarrhea was measured as "daily point prevalence over the previous 3 d (today, yesterday, and the day before yesterday)," which resulted in a potential 36 days of observation for each child

Data was also collected on a large amount of baseline variables, including educational attainment of household heads, household characteristics, including presence and use of handwashing stations, signs of latrine use, animal ownership, seasonal water sources, water treatment behavior and treatment types, as well as data on compliance, TTC, and diarrhea in children <5. Because such a robust amount of data was collected at the household and individual level across the large study cohort (n=1080 households), it presents the opportunity to examine the intervention cohort as a single population, and utilize observed characteristics as potential predictors of health outcomes.

It is important to understand what factors predict compliance with the intervention, reduced TTC in household water, and reduced prevalence of diarrhea in <5 children.[7, 8] This thesis will assess data collected in the Aquatab trial to determine which factors, if any, predict compliance with the intervention, improved water quality in point-of-use drinking water, and reduced prevalence of diarrhea in children <5.

3. Methods

All data analyzed was collected by researchers from the Orissa Aquatab trial. This thesis will focus on data collected from intervention households, and attempt to understand predictors of compliance, water quality, and reduced diarrhea prevalence in <5 children. The dataset contains information on baseline demographics and water, sanitation and hygiene practices; reported and confirmed compliance with the intervention; water quality measured by TTC; and diarrheal prevalence among <5s and all members of the household at 12 monthly points. Baseline characteristics of intervention households can be seen in **Table 1**.

Table 1. Baseline characteristics of intervention arm households (n=1080)

Characteristics	Intervention Arm	
	n	Percent
Demographic and socio-economic		
Number of households	1080	49.9
Urban	338	31.3
Rural	742	68.7
Mean (SD) persons per household	5.7 (2.3)	
Mean (SD) weight for age z-score of <5 child*	-1.58 (1.15)	
Education of household head		
Illiterate	188	17.4
Literate with no formal schooling	90	8.3
Some primary school	160	14.8
Completed primary school	146	13.5
Some secondary school	400	37
Completed +2 years	48	4.4
Completed +3 years (university)	48	4.4
Gender of Household Head		
Male	1016	94.25
Female	62	5.75
Caregiver Education		
Illiterate	136	12.5
Literate with no formal schooling	68	6.3
Some primary school	90	8.33
Completed primary school	103	9.54
Some secondary school	584	54.07

Completed +2 years	68	6.3
Completed +3 years (university)	31	2.87
Caste		
SC	157	14.56
ST	103	9.55
OBC	189	17.53
Minority	2	0.19
Treat child's water	470	43.6
Treatment method		
Boil	331	70.3
Strain	106	22.5
Chlorine	9	1.9
Other	24	3.8
Hand washing station present	658	60.9
Report hand washing after defecation		
No	665	61.57
Yes	415	38.43
Evidence of latrine use		
No	20	4.84
Yes	393	95.16

*n=15,981

3.1 Study Population and Setting

The study was conducted in Orissa, India in 2010 among 11 informal urban settlements of Bhubaneswar, and 20 rural villages in Dhenkanal district. Residents of the informal urban settlements of Bhubaneswar are not provided access to piped water, sewerage, and other hygienic facilities due to their residential "squatter" status. Unprotected boreholes and tap stands provide much of the water used by this population.

The residents of Dhenkanal (located 100km north of Bhubaneswar) work mainly as agricultural laborers and steel plant workers at a nearby facility. They are similar to the residents of Bhubaneswar in that they rely mainly on unprotected water sources (hand dug wells and public taps) in order to procure water for use. In both populations, open defecation is a common and accepted practice.

3.2 Compliance

In the Orissa trial, compliance among the intervention group was measured in two ways, self-report and confirmation via residual free chlorine (RFC) measurements. Once a month, survey enumerators asked heads of household if they had treated their child's drinking water, and if so, which method of treatment was used. RFC concentrations were ascertained using a colorometric method and a color comparator. Households who indicated that they had treated their water with chlorine were recorded as self-reported users; those with detectable RFC were defined as confirmed users, regardless of self-report.

3.2 Water quality

Water quality samples were taken during visits by survey enumerators each month. 20% of all households were randomly selected for TTC testing in children's water. Samples were collected directly from the water storage container from which the child's water was taken (as indicated by household heads), as well as from the household's stored water containers. Samples were processed using membrane filtration techniques, and 10% of samples were processed in duplicate. In this analysis, TTC was treated as a continuous variable.

3.3 Diarrhea prevalence

The primary outcome measure in the Orissa trial was longitudinal prevalence of diarrhea among children <5 as reported by the primary caretaker for the day of the visit and the 2 previous days (today, yesterday, and the day before yesterday), which resulted in a possible 36 days of observation for each child (3 days x 12 visits).

3.4 Variables

Diarrhea varies across seasons.[59-61] Thus, an additional variable for the season (rainy/dry) was also included. The seasonality variable was assigned based on the date at which the observation occurred, as well as data from the Indian government on seasonality in Orissa. Six seasons were identified and collapsed into “dry” (March—June) and “rainy” (July—September) seasons.[62]

In this analysis, it was necessary to redefine the compliance variable into a categorical variable based upon compliance across the study period. Compliance was re-defined by number of times RFC was detected as a proportion of the total number of data points (n=12). The new ordinal variable was defined as high compliance (>80%), compliance (51-79%) and non-compliance (<50%).

Finally, longitudinal data on diarrhea was used to create a dichotomous diarrhea variable. Reported diarrhea in any of the three-day window (up to all three days) was considered confirmed diarrhea.

3.5 Statistical analysis

Analysis was done using multilevel logistic regression models with nested random intercepts to control for multiple observations from the same individuals (or households) and clustering at the household and village level. Seasonality was considered in all initial models.

Three multilevel logistic regression models were fit. Interaction was considered between season and TTC, but no significance was found. Within cluster-analysis were included as a part of the multi-level model, and clustering was accounted for at the village and household level. Models were also adjusted to account for repeated measurements from the same individuals.

The first multilevel model was used to assess predictors of the dichotomous variable, compliance (compliance, non-compliance). This model determined significant predictors of compliance in the intervention groups. Covariates chosen for this model were at the household level. In addition to seasonality, caregiver education, head of household education, gender of head of household, number of individuals per household, evidence of latrine use, presence of handwashing station, and handwashing behavior were chosen as initial covariates. Based on literature, head of household education, caregiver education, caste, number of individuals per household, handwashing station, reported handwashing after defecation, and evidence of latrine use were chosen as final model covariates.[14, 24]

A second multilevel model was fit to determine significant predictors of the dependent continuous variable, TTC. Caregiver education, head of household education, gender of head of household, number of individuals per household, water treatment and treatment type, water source, and handwashing behavior and presence of handwashing station were chosen as initial covariates. Based on literature, seasonality, head of household education, caregiver education, gender of household head, number of individuals per household, handwashing station, reported handwashing after defecation, and evidence of latrine use were chosen as final model covariates.[34]

Finally, a third multilevel model was fit to determine predictors of diarrheal disease in <5 children. Though the parent study concluded no significant association between TTC and diarrheal disease in <5 children, it was included in the initial model to account significance when considered with other variables. In addition to seasonality, age (restricted to ages ≤ 5), sex, caregiver education, household head education, water source, $\log_{10}$TTC, water treatment and treatment type, evidence of latrine use, and handwashing behavior and presence of handwashing station were chosen as covariates. After considering the literature, age, household head education, caregiver education, water treatment (y/n), evidence of latrine use, and handwashing behavior of caregivers were included as covariates.

Multilevel logistic and linear regression models were estimated using STATA 13 in order to account for random effects and clustering.[63] All data cleaning and management was done in SAS 9.5 and models estimations were achieved from STATA 13.

3.6 Regression Interpretations

Multilevel logistic regression models included both continuous and categorical data values. Categorical variables included evidence of latrine use (y=1, n=0), head of household education (0=illiterate, 1=literate with no formal schooling, 2=some primary school, 3=completed primary school, 4=some secondary school, 5=completed 2 year of secondary school, 6=completed 3 years of secondary school or university), reported handwashing after defecation (y=1, n=0), reported treatment of water (y=1, n=0), handwashing stations present (y=1, n=0). Gender of household head used males as the referent category (m=1, f=0) in order to determine if households with a female head had better outcomes.

For categorical variables, the coefficients of the models allow for the determination of the effect of a one-unit change in, for example, education, on dependent variable of interest (i.e. compliance, ttc, or diarrhoea). If two households have the same attributes except education (household with a head who has completed university (6) vs. a household with a head who has completed primary school only (2)), then the model will allow us to determine if education has an impact on compliance *alone.* This method can be used to interpret the impact of a single variable, or several categorical variables taken together. Continuous variable interpretations will occur in the same manner.

3.7 Ethics

The Orissa Aquatab trial was approved by the Ethics Committee of the London School of Hygiene and Tropical Medicine and by local ethics committees in India. The current secondary analysis was within the scope of the original informed consent and done on fully anonymized data, and no further ethics approval was required.

4. Results

4.1 Baseline Characteristics

Overall, 1080 households and 76,036 data points for children <5 were included for analysis. Typically, the educational attainment of heads of household and caregivers was "some secondary school", with 37% of household heads achieving some secondary education, and 54.1% of caregivers achieving secondary education (**Table 1**). The caste of families was also well distributed, with the largest proportion being "general" at 24.7%. Household heads were mainly male.

Households, however, had low rates of handwashing behaviors and water treatment. Only 38.4% of household heads reported regular handwashing after defecation by members of the household, and only 43.6% reported treating children's water**.**

4.2 Compliance

Considering the results of the Aquatab trial (**Table 2**), it is likely that self-reported compliance is exaggerated. Over the course of the trial, compliance in the intervention group was reported at 51% for water treatment; however, confirmation by RFC showed that compliance was closer to 32% in the intervention group. We therefore only used RFC to model compliance.

Table 2. Self-reported (n=11,491) and RFC-confirmed (11,397) compliance

Compliance	Intervention Arm		
	n	Total	Percent
RFC	3,630	11,397	32
Self-report	5,829	11,491	51

Compliance was modeled on covariates as determined from literature. The form of the compliance model can be seen below:

$$log\{odds(compliance)\} = B_0 + B_1HoHEducation + B_2CaregiverEd + B_3Caste + B_4NumberPeopleHH + B_5HandwashingStation + B_6Handwashing + B_7LatrineUse$$

As seen in **Table 3**, caregiver education, caste, the number of individuals per household, and evidence of latrine use were significant predictors of compliance in the intervention group.

Table 3. Household factors associated with compliance with Aquatab intervention

Variable	Beta	95% CI	P Value
Head of Household Education	0.0212	(-0.071, 0.049)	0.413
Caregiver Education	0.1206	(0.041, 0.243)	0.001
Caste	0.0492	(0.009, 0.068)	0.001
Number of people per household	0.0572	(0.011, 0.063)	0.012
Handwashing station present	0.0969	(-0.215, 0.217)	0.523
Reported handwashing after defection	0.0569	(-0.097, 0.111)	0.501
Evidence of Latrine Use	0.2788	(0.068, 0.389)	0.003

As caregiver education increased (illiterate → 3+ years education), the more likely individuals were to comply with the intervention. Those caregivers with higher education were more likely to comply than those who were illiterate ($p=0.001$) when controlling for other covariates. For each one-unit increase in caregiver education, households were 16% more likely to comply with the intervention. Households with caregivers who had completed university, the highest educational attainment, were 2.06 times more likely to comply with the intervention than those with no education (illiterate), holding all other covariates constant.

Similarly, those in a higher caste were also more likely to comply (p=0.001), than those in a minority group. A household not considered a minority us 1.05 times more likely to comply, when compared to those who were considered minorities.

Finally, a higher total number of individuals per household also contributed to a 6.2% increased odds of compliance (p=0.012) when compared to households with less members. A household with 6 members is 1.26 times more likely to comply when compared to a household with 2 members, holding other covariates constant.

Though handwashing behavior (practicing handwashing after defecation, y/n) was a not a significant predictor of compliance (p=0.501), latrine use (y/n) was strongly associated with improved compliance in the intervention group. Those households with evidence of latrine use were 1.32 times more likely to comply than those who did not have evidence of latrine use (p=0.003), when holding other covariates constant.

4.3 TTC

As noted in the Aquatab trial, the study population had lower than expected TTC in drinking water. TTC was modeled on covariates as determined through literature. The form of the TTC model can be seen below.

$$log\{odds(TTC)\} = B_0 + B_1HoHEducation + B_2CaregiverEd + B_3GenderHOH + B_4NumberPeopleHH + B_5LatrineUse + B_6Handwashing + B_7HWStation$$

Results are shown in **Table 4** below. After analysis, only one variable was significant predictors of TTC. Those households with more individuals were more likely to have *increased* TTC concentration in drinking water (p=0.001) when compared to households with lower numbers of residents. For each additional household member, the average TTC per 1000mL increased by 3%, holding other covariates constant. Overall, all of the variables (with the exception of presence of a handwashing station) contributed to *reduced* TTC concentration when considering the regression coefficients alone. However, variability in the data and wide confidence intervals contributed to a lack of significance.

Table 4. Household Factors associated with improved household TTC

Variable	Beta	95% CI	P Value
Head of Household Education	-0.0655	(-0.187, 0.068)	0.275
Caregiver Education	-0.0315	(-0.119, 0.061)	0.172
Gender of Household Head	-0.1675	(-0.456, 0.167)	0.267
Number of individuals per household	-0.1192	(-0.131, -0.013)	0.001
Evidence of latrine use	-0.0458	(-0.377, 0.297)	0.701
Handwashing station present	0.0086	(-0.208, 0.255)	0.950
Reported handwashing after defection	-0.0458	(-0.268, 0.250)	0.842

4.4 Diarrhea

During the Aquatab trial, diarrhea outcomes were not improved in the intervention group compared to control group. However, in the intervention group, there was only one factor that significantly predicted diarrheal outcomes when analyzed in the context of other variables. Diarrhea (y/n) was modeled on covariates as determined from literature. The form of the diarrhea model can be seen below.

$$log\{odds(diarrhea)\} = B_0 + B_1Age + B_2EducationHoH + B_3CaregiverEd + B_4WaterTreat + B_5LatrineUse + B_6Handwashing$$

As shown in **Table 5**, age of the child was a significant predictor of diarrhea ($p<0.001$), with greater age indicating a marked decrease in risk of diarrhea when controlling for other variables. When compared to a child of just 1 year old, a 5 year old child was 2.36 times less likely to experience diarrhea in the previous three days. A single year increase in age increased the probability of not experiencing diarrhea by 29%. Though none of the other factors proved to be significant, it is worth mentioning that all factors showed a protective effect on diarrheal outcomes in under-five children. Caregiver education, treatment of child's water, evidence of latrine use, and handwashing behavior were all associated with decreased odds of diarrhea. However, availability of data on each variable led to considerable issues with precision of confidence intervals.

Table 5. Factors associated with no Diarrhea (during the previous three days) in <5 children

Variable	Beta	95% CI	P Value
Age of child (years)	0.2148	(0.121, 0.270)	<0.001
Head of Household Education	0.0212	(-0.102, 0.079)	0.984
Caregiver Education	0.0253	(-0.027, 0.072)	0.197
Reported treating child's water by any method	0.0607	(-0.102, 0.283)	0.278
Evidence of latrine use	0.0607	(-0.252, 0.502)	0.820
Reported handwashing after defecation	0.1673	(-0.036, 0.398)	0.132

5. Discussion

5.1 Compliance

The results of these analyses support some of what has been found in the literature on HWTS interventions. Compliance with the intervention was significantly associated with caregiver education and evidence of latrine use at the household levels. From the regression coefficients, it can be seen that households who had a household head with a university education would be more likely to comply to the intervention that households where the head was illiterate. This outcome supports the literature where factors involving intervention uptake were analyzed, as well as studies that have previously identified factors that influence compliance.[24, 33, 34] However, compliance with the Orissa trial was low, and therefore data on households that were considered highly compliant and normally compliant was an issue when fitting the model.

Though it cannot be stated for certain, it is likely that the lack of data for this group of households contributed to the non-significance of model variables, as well as the wide confidence intervals surrounding many of the odds ratios. The significance of caregiver education and evidence of latrine use, which was used as a proxy for knowledge of hygiene behaviors, is important; these variables been associated with compliance, improved water quality, and improved health outcomes, and the confirmation of this result by these analyses is encouraging.[33, 34] However, to truly understand the drivers of compliance with HWTS interventions, more directed study is needed. Further research should target individual, household, and cultural factors that contribute to compliance.

5.2 Water Quality

When building a model to identify factors associated with improved water quality (reduced TTC), much of the literature pointed in different directions as to which variables could best explain an improved TTC count. Clearly, treating water is a good predictor of improved water quality. However, as stated by Rosa and Hunter, even households reporting HWTS compliance may consume untreated water regularly, and there may be a marked difference between those who do and do not treat their water.[16, 23] However, as stated by Luby and Pickering, water quality improvements may be associated with knowledge of hygiene behaviors from the mother of the household.[33, 34] Therefore, it was important to include indicators for this knowledge in the model, which necessitated the inclusion of reported handwashing after defecation by family members, as well as evidence of latrine use.

However, though latrine use and reported handwashing after defecation were included in the model, they were not significant predictors of improved water. In fact, the only significant predictor of TTC was the number of individuals in the household. As the number of individuals per household increased, the concentration of TTC in drinking water also increased. Seino et al. found a similar association among families in Vietnam, and concluded that the relationship between fecal contamination and household size could be explained by frequent omission of treating water due to other obligations of the family.[64] However, Peletz et al. found that a larger family size (6 or more members) contributed to increased water quality.[65] Clearly, more research is needed in this area. However, for this analysis, several factors may have contributed to the lack of significance in explanatory variables.

There was large variation across households in the baseline and end line TTC counts, even throughout the intervention group, which may have contributed to variation in the analysis. Additionally, as noted in the Orissa trial, water quality of the participants was much better than initially expected by researchers, which, according to literature, may limit the impact of an HWTS intervention on water quality.[66-68] In any case, future research should take a focus on understanding the behavioral components of a family in a household that contribute to hygiene behaviors. Overcoming these barriers could be key to the success of future HWTS interventions.

5.3 Diarrhea

When building a model to identify factors associated with no diarrhea in <5 children, it was important to consider the pathways by which exposure to fecal contamination may occur in the home. According to Eisenberg, Scott, and Porco, if a single diarrhea transmission pathway alone is sufficient to maintain diarrheal disease, single-pathway interventions will have minimal benefit.[13] Therefore, point-of-source water quality may not be the only pathway through which diarrheal disease was propagated in Orissa, and potential predictors were selected on the basis of literature from potential behavioral predictors. Therefore, mother's knowledge of diarrhea (as well as household head knowledge of diarrhea) was assessed through handwashing behavior and latrine use variables, as well as level of education. Age of the child was also included as a variable, as was self-reported water treatment. As noted by the Orissa trial, as well as other studies, those who report treating water often have better water quality, despite their compliance status.[14, 22, 23] However, the analysis was only able to conclude age of the child as a significant predictor of diarrhea (as age of child increases, chances of diarrhea decreases). It is likely that lack of data contributed to the model outcome. Though prevalence of diarrhea was a longitudinal variable, the predictors chosen were not measured longitudinally, which can contribute to the strength of the model covariates in predicting the outcome variable of interest.[63] It is also a possibility that different transmission pathways were the result of diarrhea in under-five children. Handling of food by unclean hands, proper disposal of child feces, cleanliness of latrines, and even external exposure from the environment while the child is playing could all have contributed to diarrheal outcomes. Therefore, more attention should be given in future research to understanding which behaviors and practices play a more important role in transmission and prevalence of diarrhea to children from caregivers, peers, and the environment.

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