CONCEPT NOTE

WASHPaLS #2 SBC Research:
Improving Hygienic Environments for Infants and Young Children in Ethiopia

Version: 21 August 2023

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WASHPaLS #2, in collaboration with World Vision, proposes to conduct a realist randomized controlled trial (RCT) (see Box 1, and Annexes 1 and 2 for a fuller description) to address research questions related to hygienic environment interventions that can plausibly reduce fecal contamination in the household environment and infant and young children's exposure to soil and fecal pathogens.

> ***Box 1. Realist RCT Definition*** Realist RCTs combine the experimental design of traditional RCTs with realist evaluation methods that unpack the causal drivers of complex interventions. Realist evaluation methods articulate and test a theory of change, comprised of *a priori* hypotheses on the relationship between interventions, mediating factors (causal drivers) and study outcomes. Realist RCTs maintain the strong internal validity of experimental research designs, while also accounting for social, economic and political context that may influence the observed effect of the intervention on study outcomes. In doing so, translation of study findings to other contexts is possible, enhancing the broader generalizability; and researchers can disentangle the effects of intervention components in studies with complex interventions, such as the one proposed here (Bonell et al., 2012; Bonell et al., 2018; Jamal et al., 2015; Moore et al., 2015; Warren, Torres and Bonell, 2022).

BACKGROUND

Traditional WASH interventions designed to interrupt the transmission of (adult human) fecal contamination have largely focused on water treatment, household sanitation, and handwashing (Cairncross et al., 2010; Luby et al., 2018; Null et al., 2018); but in settings heavily contaminated with feces, these interventions may not be sufficient in reducing diarrhea, particularly for infants and young children (IYC) (Cummings et al., 2019; Pickering et al., 2019; Clasen et al., 2012; Null et al., 2018; Kwong et al., 2021). Critical areas of further exploration include interventions that interrupt contamination and transmission pathways that specifically threaten IYC health and growth, focusing on child and animal feces, including but not limited to poultry and other animal husbandry, safe disposal of IYC feces, infant playpens/playmats, food hygiene, and improved indoor/outdoor flooring (USAID, 2022).[1] Recent research on these various interventions indicates that no one intervention alone is *biologically plausible* at sufficiently reducing IYC exposure. Given the limited potential impact of any one intervention studied, and evidence that infant health can be influenced by the health of other household members, it is most likely that a combination of interventions is the way to cleaner and safer environments for IYC.

The proposed study will explore the impact of a Whole Hygiene Household (WHH) intervention that engages household members to address multiple pathways simultaneously through use of simple hardware which facilitates improved practices. We refer to this as a 'transformative WASH intervention,' because of its potential to improve household hygiene sufficiently to improve IYC health and growth.

The proposed realist RCT will generate evidence on the impact of a transformative WASH intervention, while also developing a theory of change to articulate the causal mechanisms through which the intervention and the respective components work. We note that calls for transformative WASH are growing. For example, during the May 2023 Strengthen PSNP5 (Productive Safety Net Program)

[1] The extent of the impact of these various sources and pathways of contamination are more thoroughly discussed in the WASHPaLS 1 hygienic environments desk review (USAID, 2018) and final summary report (USAID, 2022).

Institutions and Resilience II (SPIR II) Learning Event held in Addis Ababa, Ethiopia, Dr. Sisay Sinamo, Chair of the Seqota Declaration, challenged the donor audience to put forward adequate funding to achieve needed transformation in desired WASH and nutrition outcomes. As discussed in the next section, this challenge echoes similar calls in the literature. However, evidence of how to achieve transformative WASH is scant.

The purpose of this document is to present:

- Rationale for the research
- Research questions
- Implementation context for the proposed research setting
- Proposed research design and methods
- Anticipated contributions from the research, and
- Roles and responsibilities for research partners.

RATIONALE

The proposed study will seek to disrupt many of the locally relevant fecal contamination pathways and risky behaviors identified in recent observational studies conducted in Ethiopia, and similar settings. To date no study has sought to intervene on all major fecal contamination pathways during pregnancy and lactation by dramatically improving both indoor and outdoor household environments. Thus, this study will fill a key gap in the evidence base, summarized in the following sections, to determine whether a comprehensive package is acceptable, effective, and scalable among Productive Safety Net Program Temporary Direct Support (TDS) households.

Evidence on Interventions to Improve Hygienic Environments

Poultry Cooping/Animal Penning. Chicken and other animal feces in the environment pose a threat to IYC health. Research on the nutritional benefits of poultry rearing in rural households indicates that chickens kept inside the home may have a net negative effect on IYC health (Headey & Hirvonen, 2016). Additional studies have found that even households that have dedicated spaces for poultry (including chicken houses and fenced-in spaces) still have high rates of poultry feces in household compounds due to the free-range rearing of chickens (USAID, 2021a; USAID 2021b). Similarly, animal penning, especially for small ruminants such as sheep and goats, may be necessary to further keep animal feces separate from areas where household members spend their time (USAID, 2022). Penning and cooping concentrates feces for the time the animals are penned, potentially facilitating collection and safe management and disposal of the feces and providing a barrier between IYC and the pathogens in the feces.

IYC Feces Management. Research on IYC feces management indicates that the combination of group and household strategies focusing on influential determinants of behavior (identified through formative research), together with increased access to "enabling technologies," (products which facilitate improved practices such as potties or modifications to latrines) may be effective at changing IYC feces management and latrine training behaviors (USAID, 2022). Studies also reinforce the need for technologies that are tailored to the local context and specific to the age cohort of users, particularly accounting for the child's developmental stage, independence and mobility levels (USAID, 2022).

Safe Play Spaces. In multiple countries including Ethiopia, playmats and playpens are generally considered feasible and acceptable and provide multiple perceived benefits to caregivers[2] (Alonge et al., 2020; Rosenbaum et al., 2021; Budge et al., 2021b; Budge et al., 2021a; Reid et al., 2018; Fundira, 2019). The evidence suggests that playmats and playpens, while not effective as a standalone intervention to eliminate all fecal exposure pathways, may be considered as an intervention that can be combined with other strategies (such as IYC and animal feces management and improved flooring) to improve the hygienic environment. Furthermore, playmats and playpens are likely to be more effective when used in the context of clean (and cleanable) surroundings, such as indoor and outdoor improved flooring/surfaces.

Improved Flooring. Research suggests that improved floors are a motivating and biologically plausible technology to improve hygienic environments for IYC (USAID, 2022). This intervention uses "choice architecture" to modify the physical environment and guide behavioral improvements without intensive social behavioral change communications required to trigger or sustain the practice, so is of particular interest to explore. Research has highlighted benefits such as, changes in hygiene-related behaviors in households with improved floors and lower loads of (fecally contaminated) dust on improved floors (USAID, 2022). However, economic barriers must be addressed to facilitate wide-spread adoption in resource poor environments. In addition, IYC and other family members spend limited daylight time inside, so the overall impact on protecting IYC from pathogen exposure is limited to the time they are inside. This invites exploration of additionally ensuring outside porch and/or courtyard surface improvements, portable play/feeding mats, or other to be identified innovations.

Evidence on Combined WASH Interventions to Improve Hygienic Environments

Researchers posit that comprehensive, area-wide packages of WASH interventions tailored to address the local exposure landscape and enteric disease burden—transformative WASH or WASH++— are needed (Cumming et al., 2019; Pickering et al., 2019; Vila-Guilera et al., 2021). Transformative WASH interventions seek to create enabling environments that provide access to basic WASH services and infrastructure and, importantly, change overall WASH norms (Palomares, 2018). Yet, there remains a considerable evidence gap on the effectiveness of layered or multi-component WASH interventions that address IYC hygienic environments (USAID, 2022). Research designs that test layered or multi-component interventions need to take into account the influence of contextual factors and work to ensure external validity and generalizability of findings (Cumming et al., 2019). Notably, researchers have pointed to additional research methodologies that extend beyond RCTs as critical for building the evidence base on the impacts of transformative WASH, to address the mechanisms of change within contexts and across social systems (Burton et al., 2021; Vila-Guilera et al., 2021). These recommendations inform our proposed study design and methods, as presented below.

Concerns about the sustainability and scalability of intensive behavior change communication (BCC) for hygiene, as well a myriad of other health areas, feeds interest in documenting less intensive, more scalable approaches to improving hygiene practice. These include behavior change approaches that address the physical environment to elicit behavioral improvements without intensive interpersonal BCC, such as nudging behavior with enabling technology. Under WASHPaLS 1, research documented the essential role of enabling technologies as *one* component of improving hygiene behaviors within households, expanding the standard approach to hygiene behavioral change initiatives which center

[2] References provide detailed elaboration of perceived and measured health and non-health benefits. Caregivers perceived playpens to protect their infants from contact with animals, dirt and feces; prevented IYC from eating dirt; and generally protected them from harm. Some mothers specifically mentioned babies appeared less dirty and their clothes needed laundering less frequently. Formative work conducted as part of the proposed study will explore ways to ensure playmats and playpens are optimally used in both indoor and outdoor environments.

around communication activities (USAID, 2022). Additional research is needed to learn about required intensity and thresholds of BCC vis-à-vis approaches such as choice architecture or nudging, to advance hygiene improvement best practice that is both sustainable and scalable.

OUTCOMES OF INTEREST

We have identified the following primary outcomes of interest for our study:

The current primary outcome will be the percent of children with 7-day caregiver reported diarrhea measured through household surveys with primary caregivers of children aged 0-6 months. We note here that this measure is used throughout the literature on hygienic environments and is currently included in data on Disability Adjusted Life Years (WHO, 2020) and useful for cost effectiveness analyses. We are also seeking funds to include a biologic primary outcome, measuring pathogen carriage at 6 months of age. Specifically, the SPIR II WHH RCT will seek to measure infection of the target child, measured at 6 months of age, with any one of the following: *Campylobacter spp*., *Giardia, Cryptosporidium*, *Shigella*, E. coli pathotypes EAEC, STEC, EPEC, ETEC, or any soil-transmitted helminth (*Ascaris lumbricoides*, *Trichuris trichuria*, *Necator americana*, *Ancylostoma spp*.). Resources allowing, the SPIR II WHH RCT will seek to measure biological primary outcomes in infants at 12 months of age as well. Note, the pathogen panel will be dependent on availability and funding, preference is for Taqman array card (TAC) panel utilized by CHAMPS study. Additional secondary outcomes are summarized in Annexes 1 and 2.

RESEARCH QUESTIONS

In response to the above challenges and based on our literature review, WASHPaLS #2 proposes to address the following research questions (RQ):

RQ 3.1a: What is the impact of a Whole Hygiene Household intervention in reducing the transmission of fecal pathogens in infants, as measured by 7-day caregiver reported prevalence of diarrheal disease among infants 0-6 months of age?[3,4]

RQ 3.1b: What are the effects (direct and indirect) of behavioral, contextual, demographic, and socio-cultural factors that mediate the impact of intervention components on environmental contamination and pathogen carriage among IYC?

RQ 3.1c: What are the effects of social and behavior change interventions (including enabling hardware) in driving the uptake of hygienic environment behaviors at the household level and community level?

IMPLEMENTATION CONTEXT

WASHPaLS #2 proposes to undertake implementation research to address the above RQs in Ethiopia, in partnership with World Vision and local partners, Haramaya University.

Over the past decade, Ethiopia has made great strides to improve the health and wellbeing of its citizens, yet a continued lack of safe water, sanitation, and hygiene remains a major threat to health and development gains across the country. Almost one half of all Ethiopians obtain their daily water supply from unclean water sources, and only 18 percent have access to improved toilet facilities of which

[3] Resources allowing, we will shift the primary outcome of interest to the biologic measure discussed above.
[4] The rationale for this age cohort is two-fold: 1) The study team aims to start at birth when pathogen carriage is zero; and 2) The study team can only follow them through 6 months of age given project timelines. Annex 1 explains further.

almost nine percent are shared (JMP, 2020). Sixty-five percent of households use an unimproved latrine, and 17 percent still practice open defecation (JMP, 2020).

The Demographics and Health Survey, published by the Central Statistical Agency in 2017 found that while under-5 mortality rates have decreased since 2000, the latest mortality rates show that one in 15 Ethiopian children dies before their fifth birthday. Stunting rates for the country are around 37 percent, with wide variations between geographies from a prevalence of stunting of 14 percent in Addis Ababa to 49 percent in Tigray region (Amaha, 2020). The survey also found that more than one in 10 children under five years of age had diarrhea in the two weeks prior to the survey. For children under five with diarrhea, 46 percent received oral rehydration therapy (ORT), while 38 percent of children under five received no treatment.

Implementing Partner Description

WASHPaLS #2 is in advanced conversations with World Vision regarding establishment of an implementation research partnership with the Strengthen Productive Safety Net Program (PSNP5)[5] Institutions and Resilience II (SPIR II) Resilience Food Security Activity (RFSA) social protection project in Ethiopia.

SPIR II works in collaboration with more than 500,000 PNSP5 clients in 17 of the most vulnerable woredas (districts) in Amhara and Oromia regions of Ethiopia. PSNP5 households are generally considered to comprise the poorest 10 percent of the population. SPIR II's planned activities include the rollout of the Livelihoods for Resilience Activity (LRA) that provides financial support and social behavioral education and training to 97,900 participants from PSNP5. Under this LRA, members of PSNP5 households participate in informal village economic and social associations (VESAs, similar to nurturing care groups [NCG] often used by nutrition programs and a common platform used by World Vision) that provide communal spaces to increase individual capacities to lead resilient lives, collaborate, and learn. Trainings are delivered by members of the LRA team that facilitate community discussions around activities such as animal penning, animal and IYC feces management, and child feeding. Specific hygienic environment objectives can be targeted through the rollout of these trainings and community networks.

The WASHPaLS #2 study with SPIR II is planned to take place in Oromia Region, in the woreda of Daro Lebu or a similar woreda pending review of security conditions. In this region, there has been a new wave of safety net program clients, (including about 40,000 households in Daro Lebu), thus allowing this collaboration to target new PSNP5 clients who have not yet benefited from SPIR II programming and who have not been a part of another research study. WASHPaLS #2 will work closely with World Vision Ethiopia to co-design the research to complement SPIR II's implementation approach and to ensure that research findings are of value to the Government of Ethiopia (GoE). Two important selection criteria for the proposed realist RCT study that the SPIR II woredas would need to meet are:

[5] For over 30 years, responses to food insecurity in Ethiopia were dominated by emergency food aid. While this saved lives, it often failed to protect livelihoods, and this became a growing concern. In response, the Ethiopian government revised its emergency food aid system in 2005 and launched the Productive Safety Net Program (PSNP), a more productive approach to providing a safety net to vulnerable populations. Furthermore, between 2010 and 2014, the Ethiopian government stepped up its efforts to address both relief and development, with harmonized donor support. Through this enhanced developmental approach, the PSNP provides a safety net for households that are both chronically food insecure and poor, and often affected by shocks. With an objective to assure food consumption, and simultaneously to protect and develop assets along with services, PSNP operates across widespread geographies and rural communities to determine eligibility to receive payments based on specific criteria. Such payments are made to households that can contribute to public works (labor); or, if labor is limited or impossible, unconditional support is provided. Through this infrastructure, PSNP contributes to a local enabling environment for community development. Source: https://essp.ifpri.info/productive-safety-net-program-psnp/.

(1) an intervention area where at least basic water and sanitation are assured at community level, yet (2) diarrheal morbidity and mortality for children under five years of age remains high.

Proposed Program Intervention for Evaluation

The planned Whole Hygiene Household intervention will be implemented only in the selected study areas in Daro Lebu; however, the intervention design builds on existing GoE and SPIR II programming, and will include all or most of the following components (depending on formative research findings): indoor flooring, outdoor patio flooring, animal pens/coops (likely chicken coops), playpen, child play/feeding mat, child potty or potty mat (or other enabling technology), latrine slab, food hygiene storage accessories, handwashing device with soap, water treatment, and lite-touch SBC through 3-4 household-level promoter visits. An initial formative study phase will help shape the household-level intervention, focusing on identifying feasible and appealing hardware to facilitate improved hygiene practices (what handwashing device, poultry coop, etc.) as well as identifying psychosocial motivators to influence improved practices.

While households will be given all hardware as part of their PSNP5 inputs, with an eye to sustainability and scale, we will aim to identify products that are available in local markets and potentially affordable to rural, resource-poor households. In addition, World Vision is considering the selection of enabling products in the context of their growing WASH Business Centers (WBCs, as well as existing PSI WASH Centers); looking ahead by laying groundwork for future marketing of the line of WASH products, which are currently unknown and unavailable. World Vision plans to utilize WBC agents in the delivery of intervention components and use intervention activities to bolster product demand, supporting investment higher up in the value chain as community interest and demand grows in study communities.

Current BCC promotion to households in the SPIR II catchment area includes "periodic" household visits from government staff and volunteers: Health Extension Workers, Women's Development Army (WDA), and Nutrition Champions. SPIR II further enhances the work of government outreach to PSNP5 clients through the placement of Programmatic Community Health Facilitators, WASH officers, and other SPIR II staff at the community/kebele level.

An underlying concept critical to the design of this study is that hygiene messaging already is part of the World Vision (and to some extent the GoE) programming, but PSNP5 client households receiving temporary direct support have limited, and more often no, access to the enabling products due to affordability. If available, these products could facilitate the practices currently being promoted. This study will assume (and document) on-going household visits already taking place involving BCC, and supplement with limited SBC related to the uniting WHH themes (to be identified in the formative research). This SBC will use limited but proven SBC techniques including engaging influential community members like traditional healers, village leaders, imams or other religious leaders (this area is 100 percent Muslim), and neighbors.[6] SBC also will leverage public commitments and celebration of milestones.

This study will recruit pregnant women, ideally by second semester and certainly by early in the third trimester, to ensure protective hygienic measures are in place at birth. This is in response to recent research findings indicating extensive pathogen carriage in infants under 12 months of age (specifically various genera of *campylobacter* measured through qPCR (Deblais, Ojeda et al.). SPIR II is also

[6] SBC best-practice involves programming for target and influencing audiences. These will be minimal add-ons that will be vetted prior to inclusion in the intervention but are also included as a strategy to counter jealousy/ ill-will in the community around intervention households receiving a broad range of hand-outs. Involvement of influentials (e.g., neighbors – see Table 1) will therewith support uptake of behaviors by the target households and generate buy-in and support rather than resistance from key community members.

prioritizing pregnant women as they are recipients of Temporary Direct Support within PSNP, and pregnancy and the birth of a child are recognized as key moments which can facilitate dramatic behavior and lifestyle changes such as smoking cessation (Greenland et al. 2013, McBride 2003). The adoption of multiple WASH-related behaviors during pregnancy and infancy was demonstrated in a recently published large-scale trial in India which found substantial improvements in birthweight and reduced stunting and included an extensive intervention package that included SBC and provision of WASH hardware such as water filters, play mats, soap, and plastic potties (Taneja et al. 2022). Table 1 presents a summary of the WHH intervention that World Vision plans to implement under SPIR II.

TABLE 1: WHOLE HYGIENE HOUSEHOLD INTERVENTION – LIFE CYCLE PHASES[7]

VISIT	ENABLING TECHNOLOGIES	SUPPORTING BCC[8]

1st Pregnancy Visit	• Handwashing stations (2) with stand/table
	  ○ Stand – height appropriate for household members 3yrs+
	  ○ One by latrine or nearest secure location
	  ○ One by cooking or family's preferred location
	• Hand soap (bar/liquid) + dish/clothes soap (e.g., Ajax)
	  ○ At each of four already existing Community Health Volunteer visits conducted by GoE/SPIR II
	  ○ Can consider distribution of soap at antenatal/postnatal visits using a punch card
	• Household water filter with built-in safe storage, effective against viruses, bacteria, and protozoa (LifeStraw 2.0)
		• Comprehensive SBC/orientation session - "triggering"
		• Family pledge
		• Neighbor Pledge

2nd Pregnancy Visit	• Food hygiene
	  ○ Food cover
	  ○ Dish rack
	  ○ ~3 metal spoons
	• Cleanable infant baby mat (or 1wk after birth)
	• Potty for older sibling if applicable
	
	Other products under consideration:
	• Safe baby bed or playpen for day and/or night[9]
	• Baby box, basinet, or portable crib
	• Cleanable pad
	• Safe swaddle
		Application of relevant SPIR II Nurturing Care Group modules relevant to provided hardware and key behaviors
		
		Neighbor (renewed) commitment

[7] The intervention design will be finalized based on initial findings from formative analysis and exploration currently being conducted by SPIR II and the University of California Berkeley, and in consultation with WASHPaLS #2.

[8] The SBC components will be integrated into the study in coordination with routine and ongoing BCC activities already underway with PSNP households via GoE and SPIR II.

[9] These enabling technologies do extend beyond typical WASH and hygiene interventions but are being considered as part of the transformative WASH package in an attempt to reduce all possible sources of pathogen exposure, including infant sleeping zones which can become contaminated due to contaminated bedding, co-sleeping with other household members, and proximity to animals due to lack of elevated beds. Final selection of all enabling hardware will depend on formative analysis and local context, including social norms on co-sleeping and nighttime breastfeeding practices.

During pregnancy – Household upgrades	• Hired masons/Contractors/WASH Business Center agent • Outdoor cement porch – located where family would prefer, possibly with shade (to protect flooring) • Indoor cement floor: sleeping room (determine affordability of additional rooms) • Outdoor animal pen • Indoor animal retrofit away from sleeping area: additional door and/or wall/barrier • Latrine Slab and Sato Pan • Other latrine construction/upgrades if needed	Application of relevant SPIR II Nurturing Care Group modules relevant to provided hardware and key behaviors[10] Other (limited) BCC TBD
1 week after birth	• Playpen/crib for daytime/outside use • Hardware tweaks/modifications	Reinforcement visit SBC - Community Nutrition Champions using NCG new improved "BabyWASH" materials developed for NCGs (NCGs not part of *this* intervention but a different SPIR II RCT) Neighbor pledge/WBC Agent linkage
6 months after birth	• Dedicated cup/bowl/spoon for target child • Hardware tweaks/modifications to existing products introduced including coops, flooring, latrines, etc.	Reinforcement visit SBC – Community Nutrition Champions using NCG new improved "BabyWASH" materials developed for NCGs (NCGs not part of *this* intervention but a different SPIR II RCT)

METHODS

Figure 1 presents an operational logic model for the proposed study, including the respective research components making up the realist RCT [intention to treat (ITT) analysis and realist evaluation[11]], along with research partner roles and responsibilities, and a projected timeline (both addressed in more detail in later sections). Realist approaches are ideal for evaluating complex interventions and are particularly useful for evaluating interventions with mixed outcomes where we do not understand how and why those differing outcomes occur (Mercer and Lacey, 2021; Nielsen et al., 2022). We note that our study will build on existing work conducted by local partners to effectively account for the impacts of context as part of our realist evaluation, namely work conducted by Haramaya University in collaboration with the University of Florida on the CAGED and EXCAM studies (Deblais, Ojeda et al. 2023; Bardosh, Hussein et al. 2020; Yimer, Gebreyes et al. 2020; Havelaar, Brhane et al. 2022; Magalhães, Ojeda et al. 2022). See next section for a discussion of partner contributions and roles.

The study partners plan to implement a two-arm realist RCT (see Annex 1 for a description of the planned RCT and Annex 2 for further explanation of realist RCTs). Realist RCTs enable researchers to determine if a specific intervention (from one of several) has an impact on specified outcomes, while also examining the impacts of key causal drivers, including mediating and contextual factors. This way

[10] NCGs not part of this intervention but part of the RCT in other SPIR II operational areas evaluating some of the impacts of the SPIR II project.

[11] Realist evaluations examine how, for whom and under what conditions interventions have an impact by identifying underlying generative mechanisms that drive social and behavioral changes and reasoning and that mediate the impacts of an intervention on the outcome of interest. Realist evaluations also take into consideration the effect contextual factors may have on an intervention and associated outcomes, connecting context to generative mechanisms and outcomes. Realist evaluations may also be used to test and refine programmatic theories of change (Pawson and Tilley, 1997).

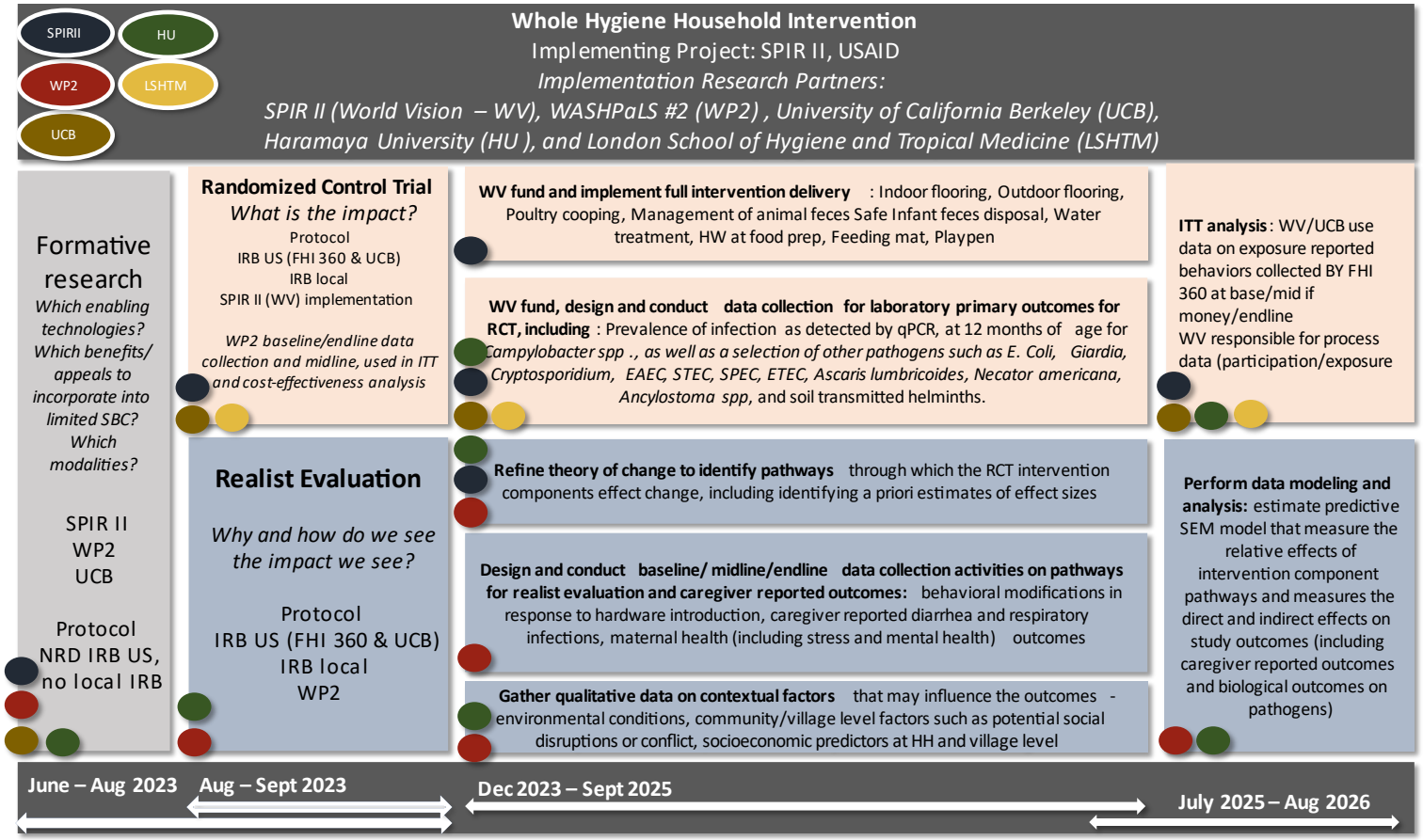
realist RCTs generate evidence on the effectiveness of an intervention while also testing and refining theories that explain how interventions work, including the contributions of components of complex interventions.

WASHPaLS #2 will complement the World Vision-led RCT with a realist evaluation of the study's intervention components using mixed methods analyses, following a convergent parallel design, to identify how the intervention components impact IYC health outcomes. Through the realist evaluation design, WASHPaLS #2 will use structural equation modeling (SEM), using Bayesian estimation techniques, to analyze the pathways through which each intervention component leads to social and behavioral change and the extent to which these changes subsequently reduce IYC exposure to fecal pathogens. Through this quantitative analysis, we will test the direct and indirect effects of the intervention components alone and combined with SBC. Qualitative data will be collected through key informant interviews (KII) and by gathering existing secondary data sources. The team will conduct a thematic analysis of KII data and content analysis of secondary data to account for the impacts of critical contextual factors that may influence the effects detected in the quantitative data; following the socio-ecological model, these factors may include, environmental factors, implementation fidelity, and social norms (Bronfenbrenner, 1979). Annex 4 presents a set of critical questions and answers regarding the implementation and study design.

The RCT, currently planned with a sample size of 620 households, 310 to intervention arm and 310 to control arm, will test the effects of the WHH intervention on IYC exposure to fecal pathogens and caregiver reported incidence of diarrhea. SPIR II will report by September 2023 if funds are available to support enrollment of all 620 households (HH); if not, *currently allocated* SPRI II funds will allow for a sample size of 300. While 300 HHs is a large enough sample to support the planned quantitative analyses (ITT and Bayesian SEM) (Aberson, 2019), the study team recognizes that there would be additional benefit to expanding this sample size and following households over a longer time-period and are thus seeking additional World Vision program and research funds to allow for this. Confirmation in September of the total additional funds for SPIR II also will determine whether there is scope to increase the SPIR II contribution to the research budget to support biological testing for outcome measures (detailed in Annex 1).

Figure 1. Research Operational Logic Model[12]

Colored ovals denote which institutions will have a significant role in the various research activities



[12] Haramaya University's and LSHTM's role in the research is currently being determined, based on local research capabilities, procurement requirements, and study site. Once clarified their respective roles throughout the research phases will be outlined in a detailed scope of work. NRD stands for non-research determination and SEM stands for structural equation modeling.

DATA COLLECTION AND ANALYSIS

The study team will collect data through community HH surveys, observations, and environmental and fecal pathogen testing. The RCT ITT analysis (see Annex 1) will utilize data collected through fecal pathogen testing; meanwhile the RE analysis will use data obtained from HH surveys, structured observations, environmental sampling for *E. coli* (e.g. water, soil, hands), and infant stool sampling for enteric pathogens. These data will be utilized for quantitative modeling, as explained below. The team will contract with Haramaya University for data collection and laboratory analyses. Haramaya University has extensive experience conducting the aforementioned CAGED and EXCAM studies.

Data Analysis

The study team will develop a full Data Analysis Plan (DAP) for the study, following the approval of the Inception Report and Study Protocol. The DAP will outline how both qualitative and quantitative data will be analyzed to answer the research questions. We provide a brief explanation of both for illustrative purposes in understanding the research that is proposed.

Qualitative data collected as part of formative research to inform the study design, as well as qualitative data collected on contextual factors will be analyzed for structural and emergent themes using Nvivo. We note here that a formative assessment has been conducted by University of California Berkeley. Based on the findings of these consumer and market assessments, the study team has determined additional formative research is necessary to inform the intervention design, including SBC components. SPIR II is managing the data collection and analysis of this formative research with support from WASHPaLS #2 and PRO-WASH teams.

Quantitative data (on reported and/or observed usage of intervention components, *E. coli* measures in the household environment, and infant pathogen carriage as primary outcome) will be analyzed using a form of SEM to test the program's theory of change and identify direct and indirect causal drivers (Bollen, 2011; Byrne, 2016). SEM is a statistical technique used to model complex relationships among variables (Bollen, 2011; Byrne, 2016). We note that heterogeneity in our independent and dependent variables (primary and secondary outcomes) will be a strength for this type of analysis within a realist evaluation framework. Given real-world programmatic and implementation context, there will almost certainly be variation in both fidelity of how the intervention is delivered and adherence among household members, as well as varying seasonal impacts and local community-level factors (e.g. ODF prevalence, access to utilities) that will provide the variability in our data for analysis using SEM. In the context of intervention research, SEM can be used to estimate the effects of various interventions on one or more outcomes through one or more mediator variables. A mediator variable is a variable that explains how or why two other variables are related.

For example, we intend to examine the effect of chicken cooping (one of the intervention components) on caregiver reported IYC diarrheal incidence (one of the outcome variables). We might hypothesize that this component works reducing the amount of chicken feces inside the home (the mediator variable), which then leads to fewer diarrheal incidents. To test this hypothesis using SEM, we would create a model that includes three variables: the intervention component, the mediator variable, and the outcome variable. We specify the relationships between these variables based on our theoretical model. Specifically, we specify a path from the intervention (chicken coops) to the mediator variable (reduced chicken feces in the home), a path from the mediator variable to the outcome variable (caregiver reported IYC diarrheal incidence), and a path from the intervention to the outcome variable (which represents the direct effect of the intervention on the outcome). We can then estimate the strength and

significance of each path using standard regression techniques, controlling for other possible determinants of caregiver reported IYC diarrheal incidence and chicken feces management. Data from the study baseline, household observations and endline will enable us to measure change across independent and dependent variables included in our analyses. The path from the intervention to the mediator variable represents the direct effect of the intervention on the mediator variable, while the path from the mediator variable to the outcome variable represents the direct effect of the mediator variable on the outcome. Finally, the total effect of the intervention on the outcome can be decomposed into the direct effect of the intervention on the outcome (which does not pass through the mediator) and the indirect effect of the intervention on the outcome (which passes through the mediator). By estimating these effects, we can determine whether the intervention component has an effect on the mediator variable, and whether the mediator variable in turn affects the outcome variable. These hypotheses configurations are also depicted in the expanded discussion of realist RCTs in Annex 2.

We will specify a SEM to test the theoretical models by including all the intervention components, the behaviors that are targeted by those components, and the key outcome variables. (These theoretical models are depicted in Annex 3.) If we find effects of the mediator variables, we would then be able to conclude that they play a role in explaining how the different intervention components affect the outcomes. Identifying significant pathways between intervention, mediator, and outcome variables across all intervention components, and when taken into account simultaneously, will generate a refined theory of change capable of informing WASH programming at the community and household level that may be extended across multiple contexts.

RESEARCH TEAM ROLES AND RESPONSIBILITIES

The table below lists the contributions of research partners. As previously explained, WASHPaLS #2 will primarily collaborate with SPIR II, led by World Vision. WASHPaLS #2 and SPIR II have finalized research partnership with Haramaya University (HU), which has extensive experience with related research in Oromia with the University of Florida and has extensive laboratory testing capabilities and facilities. We also note that HU's involvement in the research will be critical to unpacking, understanding and analyzing context as part of our realist evaluation. Working with a local research partner is a priority for WASHPaLS #2. It is also expected that the University of California-Berkeley (UCB) will serve as a research partner for the RCT portion of the study (particularly formative research and RCT data analysis).

	WASHPaLS #2	SPIR II
Roles	• Realist Evaluation Research Lead, Co-Principal Investigator • Baby WASH/SBC Technical Consult • Collaborate with SPIR II team • Fund data collection and collaborate with local research partners, Haramaya University	• Implementation and ITT Research Lead, Co-Principal Investigators – including World Vision HQ WASH Research lead, World Vision SPIR II WASH lead and UC Berkely Co-investigator • WASH and Maternal/Child Health technical and operational staff • Fund intervention implementation
Activities	• Collaborate with SPIR II project team to refine theory of change and SBC interventions (including specific hardware and sequencing) • Fully fund, design, implement, manage and disseminate research activities and results for the realist RCT (with the exception of funding fecal pathogen testing for infants), including research design, sampling frame for the RE component, data collection instrument development, data collection training and field implementation, data quality monitoring and assurance, quantitative modeling and analysis, report/manuscript writing and research results dissemination	• Collaborate with WASHPaLS #2 to finalize behavioral interventions and refine theory of change as it pertains to the research questions • Oversee formative assessment conducted by UCB interns, facilitate transparent communications across study team with UCB, and integrate results into project design and implementation • Fully fund, implement, manage and monitor program interventions and activities: Implementation design (with inputs from WP2), program theory of change, intervention implementation including behavior change activities and hardware provided, RCT sampling frame in collaboration with UCB, data collection and analysis (as part of project M&E plan), perform ITT analysis and dissemination, contribute to report/manuscript writing and research results dissemination • Fully fund, or seek additional funding for, the collection and processing of primary outcomes (see Annex 1, fecal pathogen carriage among children at 6 months of age) to inform the ITT analysis
Resources	• Principal investigator, research associate, BabyWASH/SBC technical consultant, quantitative and qualitative analyst • Funding to support international and Ethiopia IRB review and approval, field Research Manager and Data Collectors from HU, research participation incentives, and reporting and dissemination activities	• Principal investigator (WVUS), Co-Investigators from SPIR II Project Team (including PhD candidate Alazar Negash) • Field implementation team, VESAs SBC module, HH visits, HE enabling technologies and interventions, and SBC communications materials, potentially including documents, posters, stickers, calendars • Laboratory analyses TBD

The research collaboration process will develop a cohesive theory of change to inform the realist evaluation and to inform the SPIR II research and learning agenda. We also will work together to define expectations for the partnership and outcomes, including respective roles for collaborators and resources required. We will seek to formalize the partnership during the third quarter of CY2023, including establishing an MOU or partnering agreement, as well as establishing data sharing and communications norms and procedures.

Budgetary Considerations

The proposed study will be funded by multiple partners, including:

- WASHPaLS #2: $200,000- $250,000
    - These funds are in addition to the contributions of the WASHPaLS #2 Social and Behavior Change Research Lead (Dr. Gretchen Thompson), Senior Technical Advisor (Julia Rosenbaum), Statistician (Andres Martinez), and Research Associate (Ashwini Deshpande).
- World Vision: $56,000 confirmed, $185,000 pending.
    - Pending funds will be confirmed through budgeting process (called PREP for SPIR II) in July/August 2023; if approved as expected an additional $185,000 funds will be available to support intervention implementation costs ($110,000) and lab analyses ($75,000). These funds are in addition to the contributions of the World Vision WASH Technical Lead, Alazar Negash, who is conducting his PhD work (at Addis Ababa University) as part of this study, and Dr. Miles Kirby, a Sr. Research Specialist at WV-US who will be contributing 10-20 percent of his time in-kind.
- LSHTM: $30,000
    - Assistant Professor Dr. Ian Ross, has verbally communicated to World Vision his intent to support direct observation data collection for SPIR II's ITT research, and will be conducting cost-effectiveness and cost-benefit analyses as a Reckitt Global Hygiene Institute Fellow. This collaboration is currently unfolding, and more details will be shared as they are received.
- UCB: funding amount unknown
    - Assistant Professor Dr. Layla Kwong has supported 2 interns for 10 weeks to conduct formative research (primarily focusing on human-centered design [HCD] issues around choice and use of enabling products). WASHPaLS #2 will have input into the implementation design and interpretation of results, alongside other collaborators. Dr. Kwong has also applied for a fellowship through the Reckitt Global Hygiene Institute, along with HU. Funding awards will be announced in mid-October.

STUDY TIMELINE

The study team is currently designing the research and following up on learnings gathered during the research scoping visit conducted in May 2023 and feasibility work in June-July 2023. We aim to develop a research protocol for global and local IRB submission and review by October 2023, with the intention to launch the study by January 2023. The study will last for 17 months (until June 2025), with analyses and dissemination activities planned for Q3 and Q4 of FY2025 and Q1 of FY2026. See table below for an estimated timeline of activities.

Study Activity	Jun-Sept 2023	Oct-Dec 2023	Jan-Mar 2024	April-Jun 2024	July-Sept 2024	Oct-Dec 2024	Jan-Mar 2025	April-Jun 2025	Jul-Sept 2025	Oct-Dec 2025	FY 2026
Formative	X	X	X								
Enrollment/baseline			X	X	X						
Intervention delivery			X	X	X	X	X	X			
Birth				X	X	X					
6 mos						X	X	X			
Analysis								X	X	X	
Dissemination											X

ANTICIPATED CONTRIBUTIONS FROM THE RESEARCH

The study aims to contribute a data-driven theory of change for the combination of interventions included in the Whole Hygiene Household intervention, to improve hygienic environments for IYC. We will also generate evidence on the effects of SBC interventions and enabling technologies on IYC exposure to fecal pathogens and reported health outcomes listed in Annex 1. The RCT will tell us *whether* the intervention package has any impact on the IYC health outcomes, the realist evaluation further aims to explain *how* and to *what extent* intervention components impact IYC health outcomes. Results from the proposed study will contribute to SPIR II and broader World Vision and USAID programming in Ethiopia and could be leveraged for other USAID projects, such as Ethiopia Healthy Behaviors SBC project, to improve hygienic environments and behaviors. The designed hygienic environments package will advance the understanding of hardware-based interventions likely to support and sustain HE behaviors at the individual and community level, and provide evidence on ability to improve a range of health outcomes including pathogen carriage, child diarrhea, and health outcomes listed in Annex 1. Lastly, the research will contribute to a broader evidence base informing the make-up of transformative WASH programming in rural settings that reduces IYC exposure to pathogens and contributes to improved health, growth, and development.

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ANNEX 1: World Vision/SPIR II RFSA - Daro Lebu Whole Hygiene Household WASH RCT

Research Overview

SPIR II envisages conducting a realist randomized controlled trial (RCT) on hardware and social and behavior change (SBC) interventions relevant to creating a comprehensively clean household environment to improve the health and well-being of infants and young children. The study aims to examine the microbial efficacy and health impacts (reduced enteric pathogen infections) of hardware and minimal messaging relevant to water, sanitation, hand and food hygiene, and animal feces management, delivered to households within the context of PSNP's Temporary Direct Support (TDS) program during pregnancy and lactation.

This study in rural Ethiopia will evaluate the impact of a Whole Hygiene Household intervention on pathogen carriage among children <6 mos old. The intervention will consist of providing enabling hardware to address each pathway of fecal-oral pathogen transmission and limited behavior change communication emphasizing the value of using the hardware and instructions on how to use the hardware properly.

SPIR II's study will seek to disrupt many of the locally relevant fecal contamination pathways and risky behaviors identified in recent observational studies conducted in Ethiopia, and similar settings. To date no study has sought to intervene on all major fecal contamination pathways during pregnancy and lactation by dramatically improving both indoor and outdoor household environments. Thus, this study will fill a key gap in the evidence base to determine whether a comprehensive package is acceptable, effective and scalable among PSNP households.

Target Population

The target population is pregnant women (12-32 weeks' gestation) in rural Ethiopia enrolled within the government's Productive Safety Net Programme (PSNP), their newborns, and other household members.

Sample frame and sampling method

Eligibility: The study will enroll pregnant women who primarily reside within a government-identified PSNP household (according to official woreda list) within Daru Lebu woreda (TBC) and who are identified for Temporary Direct Support (TDS).

Pregnant women who primarily reside in PSNP houses will be identified at health facilities during antenatal care visits, and additionally identified through the Health Extension Program, including health extension workers (HEW) and women's development army (WDA). Each week, a list of identified pregnancies [pre-screening] will be compiled for the entire woreda and provided to study staff [World Vision and learning partners].

Study staff will determine and confirm eligibility by visiting listed mothers at their households [screening/enrollment]. The list will be randomly ordered to avoid selection bias and increase woreda representativeness. Pregnant women in PSNP will be eligible if they are in the second or early third trimester (<32 weeks) according to reported last menstrual period (LMP), and have a confirmed pregnancy test. Ideally this will be done at a health facility, but it may need to occur at home, especially if combined with consent/baseline/randomization in a household setting.

Exclusion criteria: high risk pregnancy, history of twins, plans to move away from Daru Lebu woreda within the next 2 years.

Upon meeting eligibility criteria, study staff will explain the study, administer informed consent, conduct a baseline survey, and then randomize into intervention or control arms (e.g. using envelope approach).

Intervention

The intervention will consist of multiple physical components and multiple behavioral components that address each pathway.

Formative research will determine timing and sequence of delivery of each component, but it is expected that the majority of hardware components will be delivered during pregnancy so that the child is born into a safe household environment. Since the intervention will be delivered within the context of the existing PSNP TDS program, the intervention will leverage existing contact points such as antenatal care visits, well-child checkups, and as well as TDS-specific meetings such as VESAs.

World Vision will support 3-5 community health facilitators (CHFs) who will support the delivery and fidelity of the intervention in the woreda. These CHFs will help facilitate the identification of study participants and delivery of intervention hardware to households randomized to receive the intervention, and will also help deliver SBC materials.

SBC will be provided at antenatal care visits within a local health facility (kebele health post), and will be layered into existing government SBC programmatic materials typically provided to TDS participants. It is anticipated that a CHF will make four household-level visits during the study: one visit at baseline/enrollment, a second visit during pregnancy (after baseline), one visit at 1 month of age, and one visit at 6 months of age. These household visits will serve as hardware delivery moments, as well as instructions on usage and maintenance, and other SBC materials that emphasize the importance of using the hardware consistently. Additional programmatic household-level visits will be considered, but it is anticipated that these three household-level visits will be complemented by participant visits to health posts (antenatal care and post-birth visits).

The control arm will receive the TDS program as normally delivered. Because the household-level visit by a CHF may have its own effect independent of the intervention hardware and SBC, CHF will also make 3 household-level visits to the control households and deliver standard TDS messaging regarding health and nutrition.

Further intervention details by category are described below – households will receive *at least* one component from each category:

Category	Intervention components (precise selection and sequence in each category to be determined during formative activities)
Hand hygiene	• Two handwashing stations (at latrine and home) consisting of a SATO tap (and potentially stand) • Monthly provision of soap • BCC for adult handwashing, particularly prior to food preparation and breastfeeding • BCC for child handwashing
Food hygiene and drinking water	• Water treatment (likely Lifestraw 2.0 filter with built-in safe storage) • Food storage covers • BCC for water treatment and safe storage • BCC for safe food preparation and storage
Breastfeeding hygiene	• BCC for breastfeeding hygiene
Animal feces management	• Animal pens (for poultry/goats/sheep/cows as needed)

	• Deep pit with cover for feces disposal OR raised, covered storage (basket/bucket) • Animal feces scoop/hoe • BCC for animal cooping • BCC for animal feces management
Child and adult feces management	• feces scoop/hoe • Child defecation mat • Child potty (if older sibling 1-4yrs of age) • Latrine slab with SATO pan • BCC for child "safe" defecation
Indoor improved flooring	• Cement flooring (may also consider EarthEnable/Linoleum)
Outdoor safe play spaces	• Portable play mat • Portable play pen • Outdoor courtyard (front porch) of cement covered by a shade

Analysis

We will conduct an intention to treat (ITT) analysis to determine overall intervention effectiveness. Binary and continuous outcomes will be analyzed using appropriate methods to derive risk ratios and mean difference. Pre-specified subgroup and sensitivity analyses, as well as per-protocol analyses, will be conducted, and detailed in a statistical analysis plan prior to study enrollment.

Sample size

We assume a 50% prevalence of any soil-transmitted helminths (STH), *Campylobacter spp. Giardia spp, Cryptosporidium spp.,* Shigella, ETEC, STEC, EPEC, at 6 months of age, detected by qPCR. This prevalence estimate is based on several studies conducted in Ethiopia (noting that for STH, qPCR is more sensitive than wet-mount/Kato-Katz methods).

We will aim to enroll 620 households, 310 randomly allocated to intervention and 310 to control. Assuming a 15% loss to follow-up, 80% power, significance of p=0.05, and two-sided hypothesis, we will be powered to detect a 25% relative difference in prevalence of enteropathogen carriage (any pathogen detected on qPCR panel), or difference in prevalence of 12% (e.g. 50% in control, 38% in intervention arm).

Outcomes

Primary outcome

1. The primary outcome is infection of the target child, measured at 6 months of age, with any one of the following: *Campylobacter spp.*, *Giardia*, *Cryptosporidium*, *Shigella*, *E. coli* pathotypes EAEC, STEC, EPEC, ETEC, or any soil-transmitted helminth (*Ascaris lumbricoides*, *Trichuris trichuria*, *Necator americana*, *Ancylostoma spp.*). Note pathogen panel will be dependent on availability and funding, preference is for Taqman array card (TAC) panel utilized by CHAMPS study.

Secondary outcomes

1. Prevalence of infection with individual *Campylobacter spp. (jejuni, coli, etc.)* as detected by qPCR, at 6 months of age.

2. Prevalence of infection with *Giardia* as detected by qPCR, at 6 months of age.
3. Prevalence of infection with *Cryptosporidium* as detected by qPCR, at 6 months of age.
4. Prevalence of infection with *Shigella* as detected by qPCR at 6 months of age.
5. Prevalence of infection with EAEC as detected by qPCR, at 6 months of age.
6. Prevalence of infection with STEC as detected by qPCR at 6 months of age.
7. Prevalence of infection with EPEC as detected by qPCR, at 6 months of age.
8. Prevalence of infection with ETEC as detected by qPCR, at 6 months of age.
9. Prevalence of infection with *Ascaris lumbricoides* as detected by qPCR at 6 months of age.
10. Prevalence of infection with *Necator americana* as detected by qPCR, at 6 months of age.
11. Prevalence of infection with *Ancylostoma spp.* as detected by qPCR, at 6 months of age.
12. Prevalence of infection with any soil-transmitted helminths (*Ascaris lumbricoides*, *Trichuris trichuria*, *Necator americana*, *Ancylostoma spp.*), as detected by qPCR, at 6 months of age.
13. Prevalence of any viral pathogens, as detected by qPCR, at 6 months of age.
14. Prevalence of any bacterial pathogens (*Campylobacter*, pathogenic *E. coli*, *Shigella*), as detected by qPCR, at 6 months of age.
15. Prevalence of any protozoal pathogens (*Giardia*, *Cryptosporidium*), as detected by qPCR, at 6 months of age.
16. Number of unique pathogen species, as detected by qPCR, at 6 months of age.
17. Prevalence of child diarrhea in the previous 7 days, as reported by the child's caregiver
18. Prevalence of child acute respiratory infection in the previous 7 days, as reported by the child's caregiver
19. *E. coli* in drinking water child would drink
20. *E. coli* from hand rinse of child
21. *E. coli* measured in food infant would eat
22. Maternal depression, as measured by the PHQ9
23. Maternal perceived stress, as measured by the PSS10

Other outcomes: Intervention usage and behaviors of target child, primary and secondary caregivers, and other household members will also be documented through multi-hour observations and structured survey tools, pending funding.

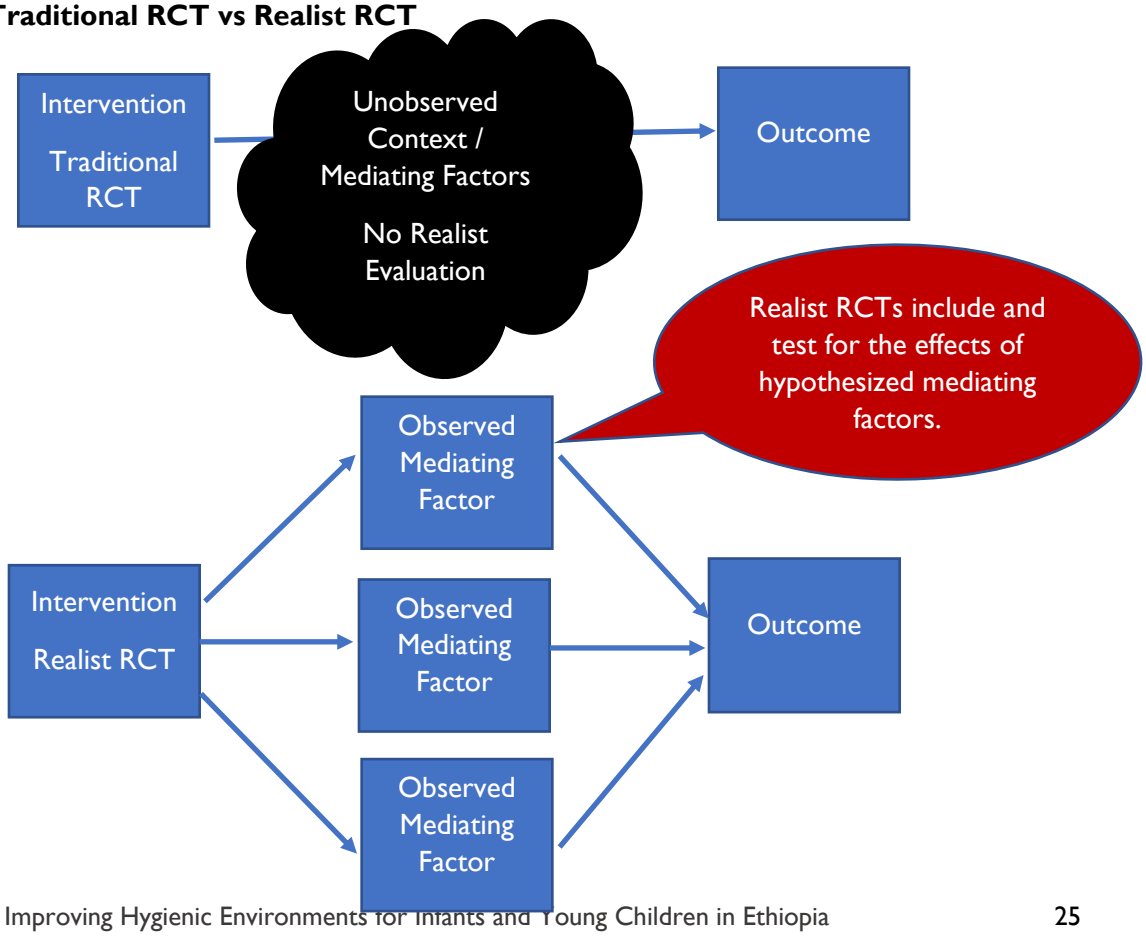
ANNEX 2: Realist RCT

Realist Evaluation and RCTs

Realist RCTs aim to assess the effectiveness of an intervention (explained in Annex 1) while also teasing out the causal mechanisms through which it works. In doing so, realist RCTs enable researchers to improve the external validity of RCTs because the design explicitly accounts for and estimates the effects of contextual factors that may confound the impact detected through the RCT analysis. This way realist RCTs simultaneously generate evidence on the effectiveness of an intervention while also building out mid-range theories that explain the pathways through which those interventions work. In short, realist RCTs account for, measure the effects of, and explain the inter-relatedness of context through the inclusion, measurement and estimation of the effects of mediating factors that attenuate the impacts an intervention may have on study outcomes (see Figure 2.1). Mediating and contextual factors are included in the behavioral pathways shown in Annex 3.

Guidance from the Medical Research Council on incorporating process evaluations into clinical research recognizes the value of realist RCTs in accounting for and addressing the frailties of RCTs, which do not identify and analyze causal mechanisms which would support the application of findings across varying contexts thereby improving the external validity of studies. Understanding the mechanisms that lead to change in complex interventions, such as the intervention proposed in the Whole Hygiene Household realist RCT, is critical to identifying the effects of specific intervention components and how these effects might be replicated in similar future interventions. Additionally, realist RCTs may use both quantitative and qualitative data to generate evidence on the effects of hypothesized causal pathways and to identify unexpected mechanisms. Recent examples of realist RCTs have been published in the *Lancet* (Charles et al., 2015), *Social Science and Medicine* (Bonell et al., 2012), and *Trials* (Warren et al., 2020), amongst others.

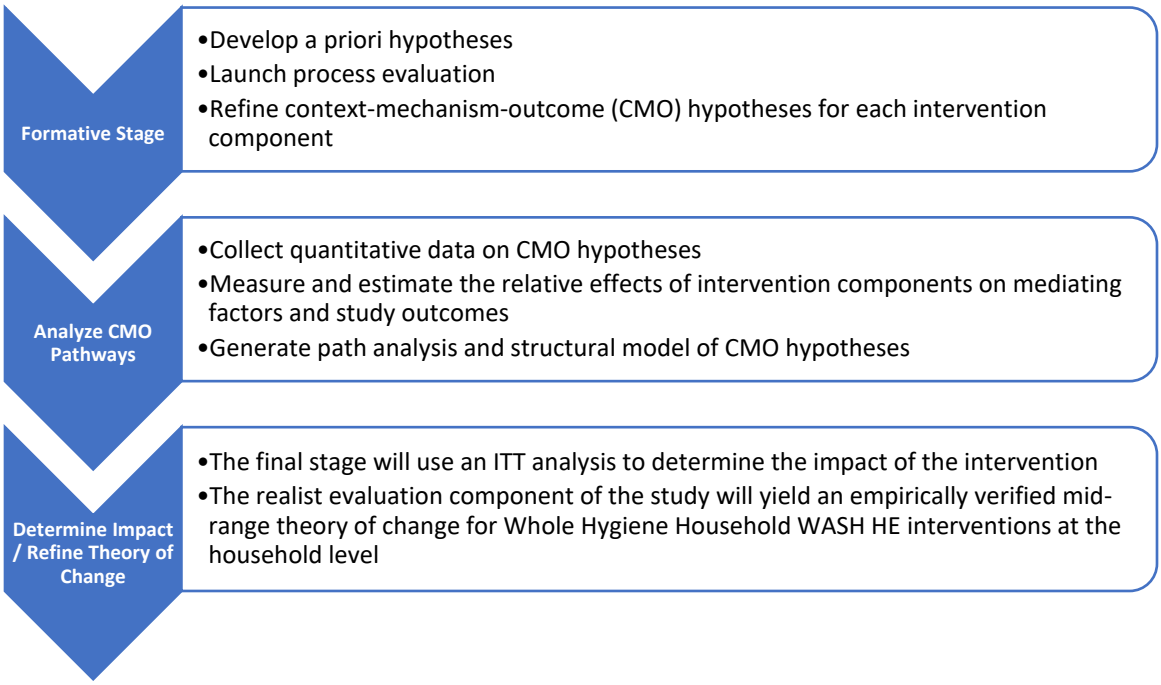
Figure 2.1. Traditional RCT vs Realist RCT



Stages of Developing Realist RCT

For our study, we will be following a staged process similar to that in Figure 2.2. We will begin with a formative stage to build out our initial theory of change and develop *a priori* context-mechanism-outcome (CMO) hypotheses that we will quantitatively test using structural equation modeling (SEM) (for a study using SEM as part of a realist evaluation, see: Ford et al., 2018). During this stage, we will incorporate into the RCT a process evaluation to capture data on the fidelity of implementation, and we will gather qualitative data through exploration at the study site and an in-depth review of the literature to refine the CMO hypotheses, depicted through the pathways in Annex 3. Next, our team will collect quantitative data on mediating factors (depicted in our behavioral pathways diagrams) to test the CMO hypotheses and measure the relative effects of intervention components on mediating factors and study outcomes. This stage will also generate a path analysis and structural model (using SEM) to test the full configuration of CMO hypotheses. Finally, the realist RCT will use an "intention to treat" (ITT) analysis to measure effectiveness and will yield an empirically verified mid-range[13] theory of change specific to behaviors linked to improving hygienic environments and interrupting infant-specific exposure pathways (see Annex 3 for hypothesized CMO pathways on behavioral changes and pathogen exposure).

Figure 2.2. Stages of the Realist RCT (adapted from Jamal et al., 2015)



[13] "…***theories of the middle range*** [*emphasis added*]: theories that lie between the minor but necessary working hypotheses that evolve in abundance during day-to-day research and the all-inclusive systematic efforts to develop a unified theory that will explain all the observed uniformities of social behavior, social organization, and social change. Middle-range theory is principally used in sociology to guide empirical inquiry. It is intermediate to general theories of social systems which are too remote from particular classes of social behavior, organization, and change to account for what is observed and to those detailed orderly descriptions of particulars that are not generalized at all. Middle-range theory involves abstractions, of course, but they are close enough to observed data to be incorporated in propositions that permit empirical testing (Merton, 1949)."

ANNEX 3: Behavioral Pathways

Figure A. Behavioral Pathway – Animal and IYC Safe Feces Management and Disposal

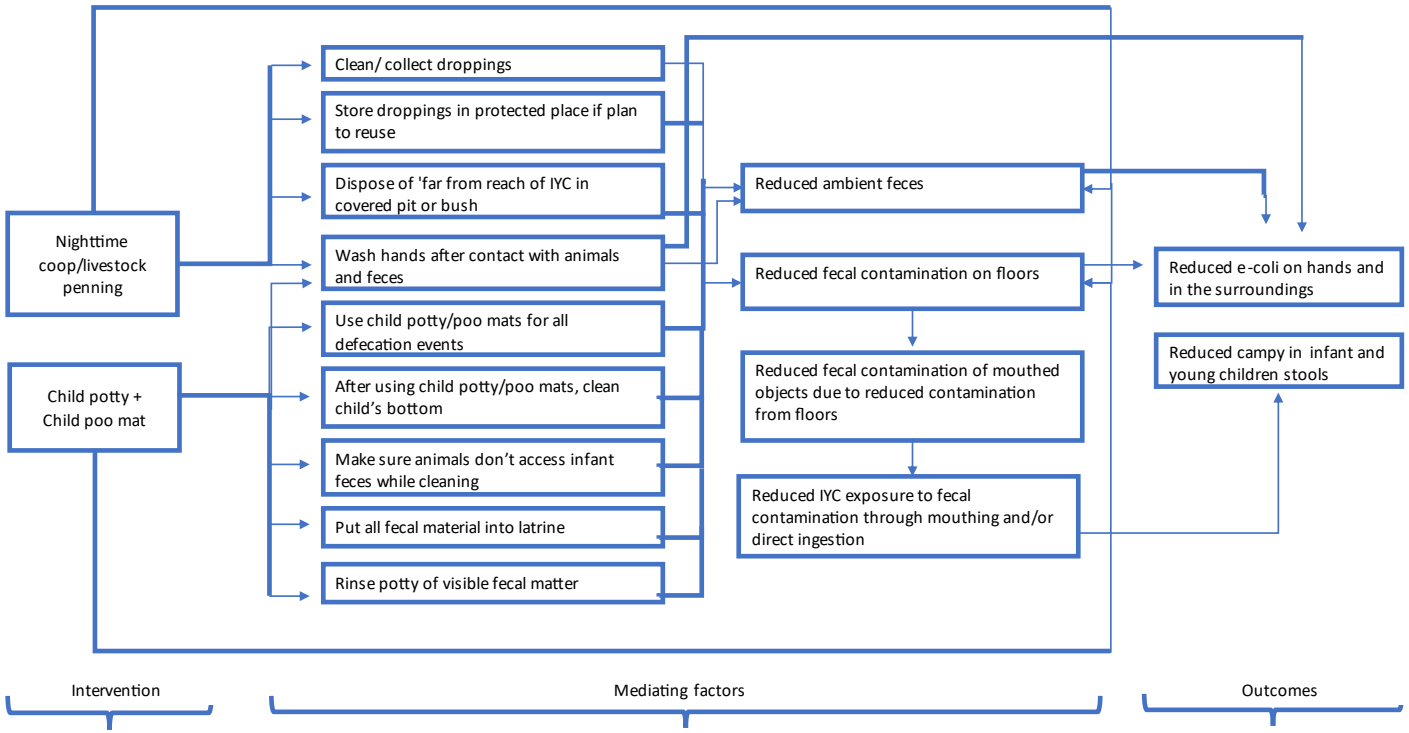


Figure B. Behavioral Pathway – Improved Indoor and Outdoor Flooring

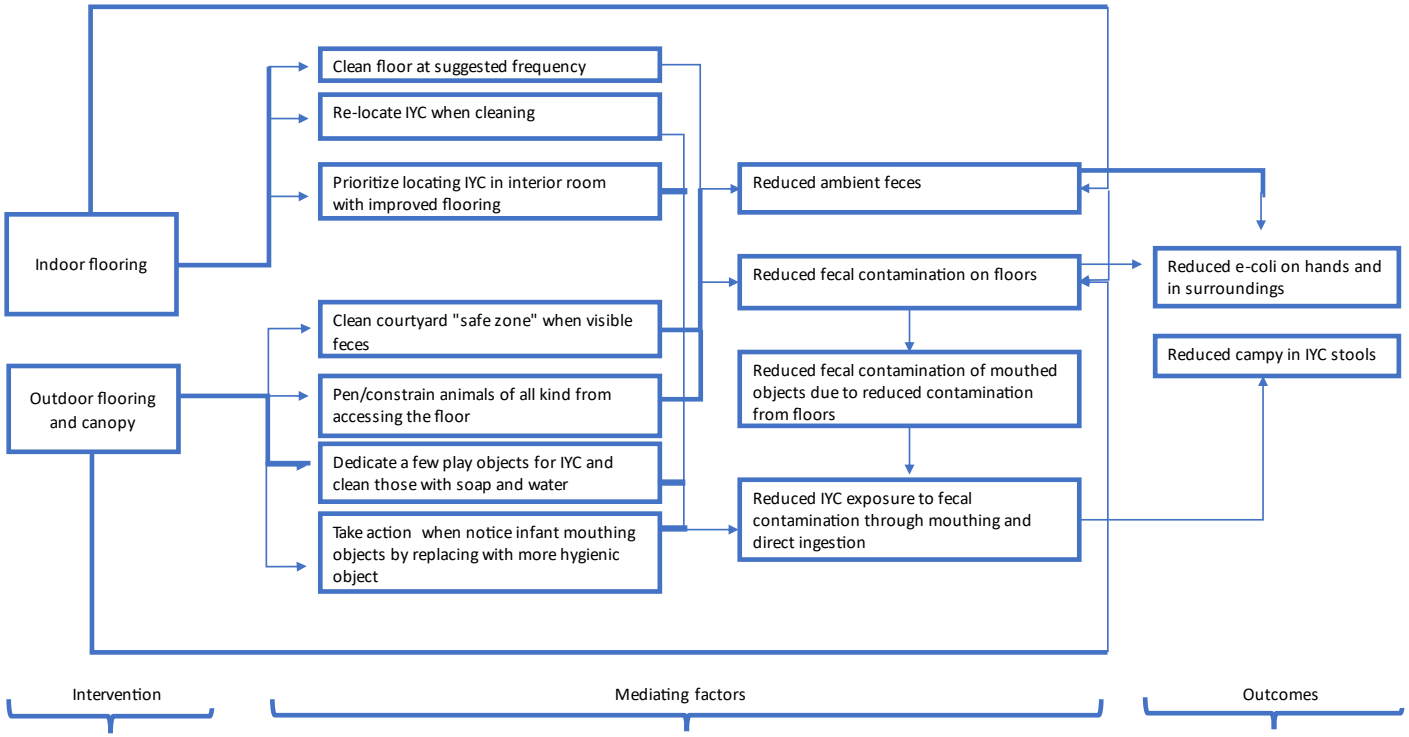


Figure C. Behavioral Pathway – Hygienic Play Spaces

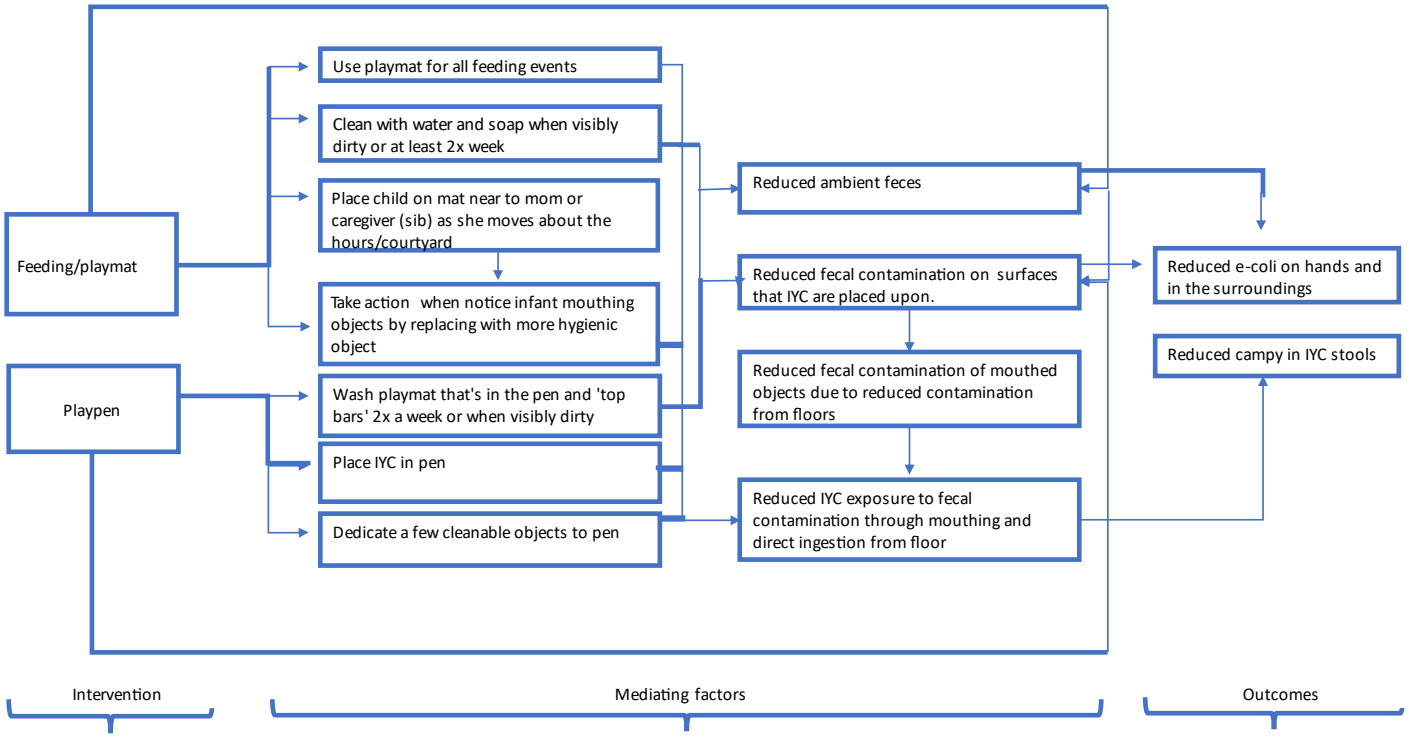
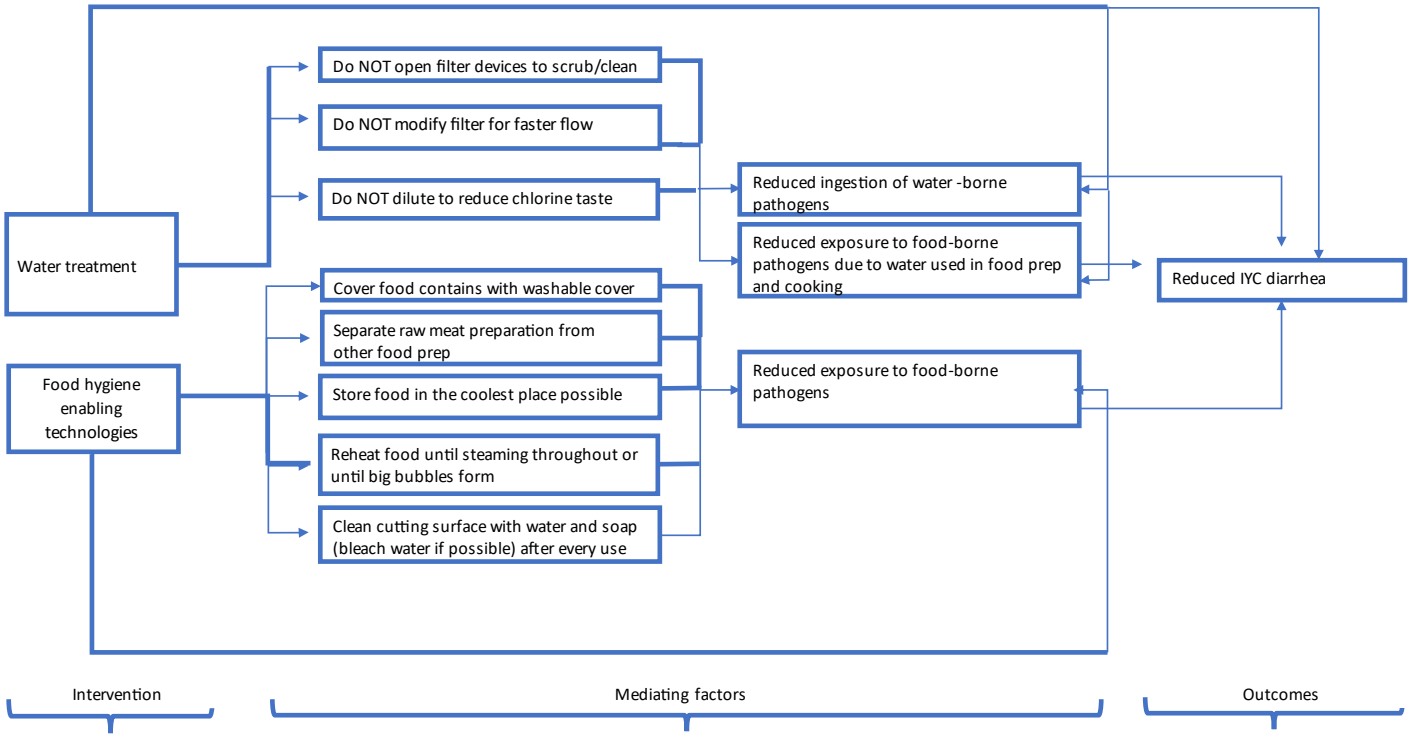


Figure D. Behavioral Pathway – Water and Food Hygiene



ANNEX 4: Critical questions and answers

Issue	Response/ Context
Delivery of 'hardware and minimal messaging relevant to water, sanitation, hand and food hygiene, and animal feces management.'	• An underlying concept critical to the design of this study is that hygiene *messaging* is already part of the World Vision (and to some extent the Government of Ethiopia) programming, but people have limited, and more often *no access,* to the enabling products to **facilitate** the practices currently being promoted. This is especially true among PSNP clients who are among the poorest 10% of the population.
Conceptual	
• Given that such a high cost 'hand out' approach to programming is neither scalable nor advisable (doesn't take into account the market, doesn't allow people free will/choice, is too expensive, would only target limited recipients, etc.), how can we justify even testing this Whole Hygiene Household intervention, **given WASHPaLS #2 mandate to conduct *implementation* research**? • What will we learn that can concretely inform programming going forward? Both from the RCT and from the realist evaluation?	• **Handout approach not scalable:** BHA and the Health Office employ vastly different approaches to their programming; under BHA "handouts" are in fact the *modus operandi*, both direct unconditional and conditional cash transfers, agricultural inputs, livestock transfers, etc. (The evidence of the impact of these cash and in-kind transfers is mixed, but none-the-less this is how most BHA programming is designed.) At the SPIR II learning event, researchers shared that transfers help to build assets but do not [significantly] increase consumption but speculated this was because transfers were not large enough.[14] Dr. Sisay, Chair of the Seqota Declaration clearly stated: "*What is scalable is up to us. It's all a matter of will power,"* implying investment thresholds on household and community levels to achieve impact, and possibility of scalability, are relative and subjective. • **Does not take into account the market:** While the products are not offered through a market-based approach, World Vision is conceptualizing the selection of enabling products in the context of their growing WASH Business Centers (WBCs) (as well as existing PSI WASH Center). World Vision plans to use intervention activities to bolster demand among immediate neighbors and the wider community, supporting investment higher up in the value chain as community interest and demand grows in study communities. In addition, some of the products like buckets with taps for handwashing and plastic sheeting for feeding mats are already available in the 'general' marketplace, though still financially out of reach for the vast majority of PSNP houses. • **Does not allow people free will/ choice:** Formative research is being designed to explore a range of enabling products. The plan is to offer choice when several options test well in formative (e.g. different choices of handwashing stations, soap, feeding mats or kitchen utensils, etc.)

[14] Gilligan et al present quantitative evidence from Ethiopia's SNNP region **combining cash transfers with an integrated package of multisectoral nutrition services**. On the benefits side, the program (i) increased the probability of attending ante and postnatal care sessions; (ii) children vaccinations, treatment of malnutrition, and school attendance soared; (iii) multisectoral collaboration among social workers, health extension workers, and school officials was enhanced; and (iv) PSNP-linked behavioral change sessions held at public works sites were successful. What challenges arose? (i) social and health workers were understaffed and overburdened with reporting requirements; (ii) patchy access to implementation manuals; (iii) hiccups with the new management information system; and (iv) the transition from public works to unconditional transfers for caregivers of malnourished children often failed.

UNICEF recently released a **rapid review of gender-sensitivity of "cash plus" programs in Tanzania, Nepal, Turkey, Nigeria, and Ethiopia** (see box 1, p.13-14 for a nice summary of each, and p.32 for a comparative overview of design). Penned by Holmes et al, the report documents a range of positive effects, but also underscores that "… there is insufficient evidence currently available (…) on which types or combinations of "plus" interventions work best [for gender outcomes]."

Can so many different types of hardware, each with their own *set* of behaviors, be delivered in such a short space of time, and will pregnant women/ young moms (and the rest of the family) be able to carry out all these new behaviors in parallel, especially given the 'disruption' that comes from having a new baby/the extra pressure this is put on their broader use of time/ responsibilities?	• New mothers are certainly stressed, but it has also been shown to be a key milestone for change, as seen in the smoking and obesity prevention literature. • There are clear mental health benefits of giving caregivers/families a way to do what they have been told to do, and what they aspire to deliver to their new infant. • Products will be delivered in "life cycle phases" – pregnancy (2x), 1 week, and 0-6 months. It ***is*** quite a lot of behaviors. As 'behavioralists,' we share these concerns. However, most of these behaviors (and more) are already being promoted in existing government and USAID-funded programming, without financial or physical access to the enabling products to carry them out. • The intervention will be phased during pregnancy and 2-3 visits after birth, spread out over 9 months *(could add this as a fourth data collection visit – we are pushing to add 5 touch points that are sequenced and clustered logically)* • Formative research will look to further 'cluster' behaviors in ways that facilitate their practice by all caregivers and household members (all from householder point of view).
• What will be the impact of having been given all these new hardware and tools, including vis-à-vis the broader community? Will this affect how the recipients perform the behaviors?	• Our response leads with *yes, it's a lot of stuff!* Above we note it will be a phased introduction and not offered all at once. • PSNP households are already identified within communities. They already 'get' things from government that other community members do not, so for better or worse, this is the norm in the communities. • World Vision/WASHPaLS will engage a Community Advisory Board (evidence-based best practice for Good Participatory Practices in clinical research), building on existing advisory board structures for SPIRIl and recently-completed studies by Haramaya University, to sensitize communities and garner buy in for poorest study households receiving inputs; and in addition, there is an existing food security task force at the Woreda level and kebele/gott level WASHCOs. • We plan to work with the UFlorida/Haramaya U CAGE team to assist with community integration and can share lessons learnt. • We learned that in our intervention area, many families are related, which reduces animosity although certainly does not eliminate jealousy. • We plan to *engage* neighbors (who may be relatives), to support the target household's success and health of the index newborn/infant, to have them sign a pledge of support in a community ceremony at a community sensitization session at first entry/deliver post enrollment.
• What happens if not all behaviors are practiced as intended/behavioral fidelity is low? What does that mean for the study results – both RCT and realist evaluation? If we are depending primarily on self-reports, will we even *know* accurately the levels of fidelity?	• Fidelity and adherence will be captured through observations and surveys conducted by the research team as well as at 'routine' HEW/CHA visits and programmatic monitoring and evaluation data. • Could undermine the ITT analysis, but will be counteracted/complemented by the realist evaluation which will pick up such fidelity and adherence issues and their impact. • With heterogeneity in how interventions/behaviors are implemented/adopted, we have the ability to model the impacts across components, also meaning that we can control for the impacts of other intervention components (e.g. water filter, handwashing) when looking at the contributions of HE specific interventions (e.g. IYC safe feces management (SFM), animal SFM, improved flooring, safe play spaces) on our outcome measures.

	• Calls for transformative WASH are high but evidence of how to do this is scant, particularly rural settings where utility-level water and sanitation provision is scare, so *a null finding is a finding*. If one pathway is sufficiently addressed (or not addressed) with evidence to back it up, the study will still be a contribution. Objective biological measures of environmental and stool contamination will be really important but put a significant strain on the budget. The study partners will confirm in July what is possible and whether there is scope to increase the World Vision contribution to the research budget to help cover these measures.
• On top of all these interventions (and considering the cost of the entire package), should a higher service level water supply not be included? i.e. running water on premises?	• We would love to find a programming context where this could be an offering (and better yet if an additional arm added to study the impact); but World Vision does not currently have such a project site, and this would likely require a cluster-randomized design which would increase intervention costs. The aim is therefore to select intervention and control groups with at least basic access to water supply (and basic sanitation).
Data collection	
• Recall likelihood of so many different behaviors? Reliability of recall data?	• We are doing observations of behaviors and rapid observations with behavioral proxies (soap and water at handwashing station, visible dirt on cooking utensils) in addition to surveys and *E. coli* and *campy.* microbiology which we can triangulate with reported practices.
• Keeping a diary or similar approach may be too time-consuming/complex/not reliable given the long list of behaviors and the time-constraints of new moms?	• Agree. Looking for proxy measures/observations at touch points. *See above* • Review and incorporate from Matt Freeman's spot checks with fewer longer observations • Also depending on microbiology
• Security concerns?	• Security is certainly an issue, with ongoing violent events along the road to/from the proposed study site. As a back-up measure, the study partners are exploring a move to Kurfa chelle and Grawa woredas East Hararghe where CARE is implementing SPIR II activities and there are fewer security issues. The current SPIR II partnering arrangement between WV and CARE is relatively seamless (the project deputy is CARE staff) and CARE was already involved in many aspects of the scoping trip. Our MoU would still be with WV, but all communication would include CARE leadership within SPIR II. • The IFPRI IMPEL RCT study (comparing impact of NCGs and NCGs plus monthly $20 cash transfers on various practices and outcomes) is active in East Hararghe but there are several kebeles within SPIR II's operational area not part of the sample that could provide an adequate sample size for the Whole Hygiene Household RCT (new name to be determined). • Though unlikely, if we overlapped with the IMPEL study area, we could compare light touch with heavy touch BCC; NCGs will be present. • Comparative case study analysis – looking at *E. coli* levels and key hygienic behaviors in comparable IMPEL areas with more intensive care group programming compared to the light-touch SBC plus enabling hardware in 'our' communities.

	• Another cross-consideration is to assure adequate levels of sanitation coverage in these 'non-IMPEL' woredas, though we note the interventions are intended to reduce fecal contamination risks in a household environment even in areas of poor community sanitation coverage.
Focus on pregnant women	
• We understand the proposed reason for limiting ourselves to this cohort, but is it fully realistic to think that expectant mothers would be able to maintain this 'fully clean' household (and all the behaviors that come with it) as the baby comes, with everything else they will have on their minds?	• New mothers are certainly stressed, but it has also been shown to be a key milestone for change. • We are incorporating a neighbor pledge, as we understand social support will be critical to ensuring new mothers are able to implement all the behaviors identified. Also, the realist evaluation can be conducted with a large amount of heterogeneity in how these behaviors are adopted, and is in fact, improved by this increase in heterogeneity. The ITT analysis may suffer. • See above re*sponse to 'so much hardware at once' for more discussion.*
• Does this reduce feasibility/available sample size?	• Yes, enrolling pregnant women does limit the available sample size. But consulting PSNP/Health Center records we believe we can certainly recruit the needed sample size for study, as explained in the body of the report and Annex 1.
Others	
• What portion of total costs of research activity are being covered by WASHPaLS #2?	• WP2- 250,000 • We will know more in July/August if the SPIR II budget (called PREP) is approved, additional $185,000 towards implementation costs ($110,000) and data collection ($75,000), plus time/costs of Alazar Negash PhD work • LSHTM- 30,000 (Ian Ross, specified to support direct observations.) • UCB- funding 2 interns for 10 weeks to conduct formative research (primarily focusing on HCD issues around choice and use of enabling products) • WP2 *will* have *input* into the implementation design, but there are several voices
• What risks in implementation (e.g., data collection), funding and outcomes (e.g., no lab work) will affect the RE? What is the 'minimum' that we would need to be able to conduct a meaningful RE? Do we currently have adequate funding for that 'minimum'?	• RE can be conducted with behavioral outcomes only and a caregiver reported outcome, such as diarrhea incidence. Regarding using a diarrhea incidence indicator as our primary outcome, we note that disability adjusted life years measures still rely upon this measure, and several other notable studies also use it. Meaning that our findings will be relevant both to previous research using this outcome and to current standard public health measures. While not optimal (and the preference still is to include biological measures), the RE remains viable and informative in the event that we do not have lab work.
• Please provide an illustrative finding, worded as it would come from the RE, and an illustrative recommendation stemming from the study?	• Homes with improved flooring who also *had no visible signs* of animal or child feces on their floors were 15% less likely to have children who were colonized with *Campylobacter* in their stools at 12 months, compared to homes with no flooring (control) and when controlling for confounding factors. Homes with improved flooring *who had visible signs* of animal or child feces on their floors showed no significant difference in the outcome measure compared to those homes without flooring and when controlling for confounding factors.

	• Homes in the higher quintile of wealth (according to our measures) had a correlation of XX for higher levels of practicing animal penning, which indirectly led to a XX reduction in the levels of *E. coli* present in soil samples among study households.
• As extensive as it is, Whole Hygiene Household still will not address every possible contamination pathway (e.g., not all FH pathways will be addressed). What implications for findings and recommendations?	• True indeed. But we revert to the original 'rationale': 1. *An underlying concept critical to the design of this study is that most extensive hygiene messaging is already part of the World Vision (and to some extent the Government of Ethiopia) programming, but people have limited and more often no access to the enabling products to facilitate the practices currently being promoted. 2. Also, by using a realist RCT framework, the success of the study does not entirely rest on the ability to detect a significant difference between intervention and control households, where failure to detect would leave people wondering why.* Rather, because we are integrating a realist evaluation component to understand the why and how the intervention works, even if the ITT does not yield results indicating a significant impact, we can test and determine the effects of multiple causal pathways to generate an applicable theory of change useful for WASH programming. • We believe we are most vulnerable to the issue of *not* providing greater access to running water. But we are working to ensure access to at least basic water and sanitation, to address this concern.