WATER, SANITATION, AND HYGIENE PARTNERSHIPS AND LEARNING FOR SUSTAINABILITY (WASHPaLS)

Toward a Hygienic Environment for Infants and Young Children: A Review of the Literature

FHI 360

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TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS II
EXECUTIVE SUMMARY III
1.0 BACKGROUND 7
1.1 WASH and Child Undernutrition 7
1.2 IYC Exposure to Excreta in Home Environments 8
1.3 Objectives and Organization of the Review 9
2.0 SOURCES OF HOUSEHOLD FECAL CONTAMINATION AND HEALTH RISKS 11
2.1 Adult Feces 11
2.2 Child Feces 11
2.3 Animal Feces 12
3.0 PATHWAYS OF FECAL PATHOGEN TRANSMISSION 15
3.1 IYC Soil and Feces Ingestion 15
3.2 Contaminated Water 16
3.3 Hand Hygiene 17
3.4 Complementary Food Hygiene 17
4.0 INTERVENTIONS TO BREAK PATHWAYS FOR FECAL PATHOGEN INGESTION 19
4.1 WASH Interventions 19
4.1.1 Water 19
4.1.2 Sanitation 20
4.1.3 Infant and Young Child Feces Management 22
4.1.4 Handwashing 23
4.1.5 Improved Complementary Food Hygiene 24
4.1.6 Combined WASH Interventions 25
4.2 Other Interventions to Improve Environmental Hygiene 26
4.2.1 Animal Husbandry Practices 27
4.2.2 Clean Play Space Interventions 28
4.2.3 Improved Household Flooring 29
4.2.4 Interventions to Address Social Determinants 30
5.0 DISCUSSION AND NEXT STEPS 31
ANNEX A. RECENT OR CURRENT PROJECTS WITH BABYWASH FOCUS 33
ANNEX B. OVERVIEW OF CURRENT RESEARCH TRIALS AND TOOLS 40
ANNEX C. REFERENCES 43

ACRONYMS AND ABBREVIATIONS

CF	Complementary Food
CFU	Colony-Forming Units
CLTS	Community-Led Total Sanitation
DHS	Demographic Health Surveys
EED	Environmental Enteric Dysfunction
FIB	Fecal Indicator Bacteria
FSM	Fecal Sludge Management
GEMS	Global Enteric Multicenter Study
HACCP	Hazard Analysis Critical Control Points
HAZ	Height-for-Age Z-score
IE	Impact Evaluation
IYC	Infants and Young Children
IYCF	Infant and Young Child Feeding
LMIC	Low and Middle-Income Country
MST	Microbial Source Tracking
OD	Open Defecation
OR	Odds Ratio
RCT	Randomized Controlled Trial
RR	Relative Risk
SBCC	Social and Behavior Change Communication
SD	Standard Deviations
SDW	Stored Drinking Water
SHINE	Sanitation Hygiene Infant Nutrition Efficacy
STH	Soil-Transmitted Helminths
TSC	Total Sanitation Campaign
UN	United Nations
UNICEF	United Nations International Children's Emergency Fund
US	United States
USAID	United States Agency for International Development
WASH	Water, Sanitation, and Hygiene
WASHPaLS	Water, Sanitation, and Hygiene Partnerships and Learning for Sustainability
WAZ	Weight-for-Age Z-score
WHO	World Health Organization
WHZ	Weight-for-Height Z-score
WSP	Water and Sanitation Program of the World Bank

EXECUTIVE SUMMARY

INTRODUCTION

As of 2014, 24 percent of children under age five globally were stunted, with the vast majority living in low- and middle-income countries (LMIC) (UNICEF et al., 2015). Undernutrition and stunting are related to poor overall health, increased susceptibility to infections, lower economic productivity, cognitive deficits and learning disabilities, and increased mortality. Concurrent exposures of inadequate diet and poor water, sanitation, and hygiene (WASH) conditions predispose infants and young children (IYC) to a debilitating cycle of infections and undernutrition in early life.

Additionally, over the past decade, environmental enteric dysfunction (EED), a condition characterized by inflammation of the small intestinal lining that inhibits permeability and nutrient absorption, has been identified as a potential major mediating pathway linking poor WASH conditions and chronic undernutrition. Though the etiology of EED is not fully understood, it has been linked with ingestion by IYC of high loads of human and animal fecal microbes. The EED hypothesis proposes chronic exposure to fecal microbes, independent of the effects of diarrhea, as a significant underlying cause of child growth faltering. EED is thought to explain why even the most rigorous dietary interventions have only a modest effect on reducing child stunting.

For nearly six decades, routes of pathogen transmission have been identified and summarized in a seminal "F-diagram" via fluids, fingers, flies, fields (floors, earth, dirt), fomites (surfaces), and food (Wagner & Lanoix, 1958). The traditional F-diagram focuses exclusively on human excreta, tracing the transmission of pathogens through different exposure routes into water and food and onto hands that are then ingested by a host. Based on existing evidence, we suggest that two refinements be made to the F-diagram: (1) inclusion of domestic animal excreta as a distinct and potentially important source of risk, and (2) in the case of IYC, framing ingestion of pathogens via eating dirt (geophagy) and/or human and animal excreta and through mouthing behaviors as an additional *direct* transmission pathway not disrupted by the traditional suite of WASH measures targeted at adults and older children.

WASH interventions to disrupt transmission pathways in the F-diagram have traditionally focused on increasing access to an improved water supply, improving drinking water quality, and refining hand hygiene and sanitation measures (through the reduction of open defecation (OD) and the adoption of improved toilets). These strategies have paid less attention to behaviors and technologies separating IYC from human and animal feces through interventions such as clean play spaces, IYC mouthing behaviors, and safe disposal of IYC feces.

The USAID Water, Sanitation, and Hygiene Partnerships and Learning for Sustainability (WASHPaLS) project conducted a review of the scientific and grey literature, complemented by dozens of key informant interviews with researchers and field implementers, to synthesize the latest understanding of key pathways of fecal microbe ingestion by IYC and their links to diarrhea, EED, and poor nutrition and development outcomes. Specifically, the review sought to:

- consider both human and animal sources of fecal contamination and the pathways presenting major exposure risks to IYC, including sources and pathways previously underemphasized (and to the extent possible, seek to understand the relative potential importance of the various pathways in terms of magnitude of pathogen transmission);
- examine technological and behavioral interventions to disrupt the transmission pathways (including established WASH measures) as well as interventions that address the underemphasized pathways,

such as clean play spaces, animal husbandry, IYC feeding practices, and IYC-focused WASH behaviors; and,

- identify areas of priority for implementation research to address the issue of clean play spaces for infants and young children.

The findings of the literature review will inform the design of research to measure the additive effects of specific measures to reduce IYC exposure to fecal pathogens and other fecal microbes in their home environments when coupled with independent or integrated WASH and nutrition interventions.

PRINCIPAL FINDINGS

The review begins by documenting the traditional transmission pathways outlined in the F-diagram and the effectiveness of traditional rural WASH interventions to disrupt them. Key findings are as follows:

- The evidence of WASH interventions reducing the risk of diarrhea among under five-year old children is mixed, and is stronger for particular categories of WASH interventions, such as water supply and point-of-use water treatment, than for others.
- An emerging body of evidence from high-quality (experimental) studies also shows mixed effects of improved sanitation on health outcomes such as diarrhea, EED, soil-transmitted helminths (STH), and child growth outcomes. However, a recent community-led total sanitation (CLTS) trial provides evidence suggesting that promoting intensive behavior changes over a 12-month period can improve child linear growth (Pickering et al., 2015).
- Evidence also suggests that, unless threshold levels of community sanitation coverage are reached to achieve herd effects, household sanitation improvements may be insufficient to mitigate fecal-oral pathogen exposure and achieve desired health benefits.
- Substantial evidence has been found on the effectiveness of handwashing with soap in preventing diarrhea and STH infections. However, the magnitude of the effect differs between studies and across contexts.
- The additive or synergistic effects of different WASH interventions on child health are complex and not well understood, and evidence on the effect of focused and combined WASH interventions on child health outcomes, such as diarrhea and growth, is far from definitive.
- Food hygiene is largely a neglected aspect of WASH and the few existing intervention studies are weak in quality and not easily generalized.

While evidence of the impact of traditional WASH interventions on improving health outcomes is mixed, the review suggests other underemphasized sources and pathways for fecal pathogens that may force some re-evaluation of the types of interventions needed to limit pathogen exposure in IYC.

A NEGLECTED CONTAMINANT SOURCE: ANIMAL EXCRETA IN THE DOMESTIC ENVIRONMENT

Risks from human excreta have been well-documented, but uncontained animal feces also are abundant in rural areas in developing countries, constituting an important reservoir of zoonotic pathogens and non-commensal fecal microbes to the domestic environment and water supply sources. As an example, at a study site in rural India, over half of household-stored water samples, 90 percent of mothers' and children's hands, and 74 percent of public ponds were contaminated with animal feces (mainly ruminants) across 24 villages (Schriewer et al., 2015). Several other studies documented significant sources of animal fecal contamination in the domestic environment, including ruminants in urban Bangladesh and both ruminants and avian species in rural Bangladesh (Harris et al., 2016); poultry and livestock in rural Ethiopia (Headey et al., 2016); and poultry in Zimbabwe (Ngure et al., 2013), Zambia (Brie et al., 2017), and peri-urban Peru (Marquis et al., 1990). Overnight corralling of poultry and/or livestock within the same room as IYC also is associated with elevated markers of EED (George et al., 2015a) and stunting (George et al., 2015a; Headey & Hirvonen, 2016). While the relative magnitudes of pathogen exposure from these sources remain largely unknown, substantial data exist to demonstrate that animal feces contribute significant contamination to the home environment.

AN UNDEREMPHASIZED PATHWAY: DIRECT INGESTION OF FECES AND SOIL

Direct ingestion of fecally contaminated soil and/or animal feces is a critical pathway for exposure of fecal pathogens by IYC. IYC ingest dirt and feces through mouthing soiled fingers, play objects, and household items (Marquis et al., 1990; Ngure et al., 2013; Brie et al., 2017); as well as through exploratory ingestion of contaminated soil and/or poultry feces. Contamination by ingestion is common in low-income environments (Kwong et al., 2016; Brie et al., 2017; George et al., 2015b; Marquis et al., 1990; Ngure et al., 2013; Shivoga & Moturi, 2009). Soil ingestion among IYC is associated with increased risk of diarrhea (Shivoga & Moturi, 2009), elevated markers of EED, and stunting (George et al., 2015b).

PROTECTING IYC: NEW INTERVENTIONS TO ADDRESS UN-DISRUPTED PATHWAYS

Barriers: In addition to the interventions intended to disrupt the pathways of the traditional F-diagram (e.g., increasing use of improved latrines, improving access to safe water, handwashing with soap at critical junctures and, to a lesser extent, emphasizing food hygiene), efforts have been made to construct barriers that prevent fecal contamination of the domestic environment and associated ingestion of soil and animal feces by IYC. These barriers include finished flooring; improved animal husbandry practices, such as corralling and other means to separate IYC and animals; playmats for immobile infants; and a playmat/playpen combination for crawling and mobile infants.

While the introduction of barriers is gaining attention in IYC and nutrition communities of practice, to date there have been no published studies finding that protective play spaces[1] prevent fecal ingestion or improve child health. Likewise, a few implementing organizations have conducted formative research and executed interventions to address poultry feces through modified animal husbandry practices; however, data are not generally available on the effectiveness of these approaches. Moreover, poultry corralling interventions have not largely been successful due to individual household preference for free-range poultry and eggs, and various cultural, structural and economic barriers (Harvey et al., 2003). Similarly, there is some initial evidence of the potential protective effect of improved flooring, with a study suggesting that replacing dirt flooring with washable cement may reduce exposure to contaminants: in an observational study of a Mexican government program that replaced dirt floors with cement floors found that in households with the new floors, child diarrhea and parasitic infestations were reduced significantly (Cattaneo et al., 2009).

Animal Feces Management: Reducing or eliminating animal feces in household compounds is challenging. Both ruminant and fowl feces are used productively as fuel, farm fertilizer, and in building materials. Because of its utility, households are reluctant to get rid of what they consider to be a valuable resource. Storage and handling of fresh animal feces for such purposes exposes household members including children to contamination, suggesting that a focus on safer management of animal

[1] A protective play space refers to the combination of a playmat and an enclosure or playpen for use by IYC to prevent direct contact with soil and feces (Humphrey et al. (2015)).

feces and handwashing after handling may be more successful than focusing on eliminating animal feces from household compounds altogether.

Management of child excreta: Researchers have measured the impact of uncontained feces on the health and growth of the IYC cohort, but until recently, little attention has been focused on feces management *of* the IYC cohort. This review highlights findings from recent analyses indicating that IYC feces disposal is sub-optimal in many LMICs. Field practitioners have responded to these findings with interventions that promote the safe disposal of IYC feces out of the belief that promoting age-cohort specific behaviors (supported by enabling technologies such as potties, diaper cloths, and use of hoes) facilitate improved IYC feces disposal practices. Data supporting this recommendation, however, have come from program evaluations with low rigor. In some deployments, CLTS has begun to include a focus on safe disposal of IYC feces as part of triggering, follow-up, and verification of open defecation-free status. Nutrition programs also have begun to include safe disposal of IYC feces and handwashing after handling child feces (often not regarded as "dirty" by their caregivers) as part of comprehensive IYC growth initiatives.

DISCUSSION

The relative magnitudes of transmission pathways of enteric microbes in IYC are not well-defined and may be highly context-specific, making it difficult to conclude which pathways represent the highest risk. A number of ongoing studies (among them WASH Benefits, GEMS, SHINE, and NOURISH; see Annex B) may offer important insights into pathways when findings are published. Still, the growing attention to risks from direct and indirect consumption of animal waste and direct consumption of contaminated soil point to the potential benefits of separating IYC from fecal pathogen sources in the home environment.

Playmat and play space interventions may be promising, but assessing their true potential requires a better understanding of the biological plausibility of their protective effects against fecal contaminant risk; extended periods of protection on a mat or within a play yard may not be sufficient to prevent risk posed by even short periods of IYC time spent in areas of increased hazard (e.g. on bare soil with excreta present, or eating contaminated food from contaminated hands). A number of studies of water treatment interventions argue that there is an exposure threshold above which infection becomes probable (Engell et al., 2013; Brown & Clasen, 2012; Hunter et al., 2009); however, the exposure-response relationship for ingestion of animal excreta or contaminated soil remains a source of considerable uncertainty. Due to the heterogeneous nature of the formative and observational studies of fecal microbe transmission pathways, developing findings on the relative magnitudes of fecal microbe exposures across different pathways was not possible in this review; further research is needed to make better and more informed programmatic decisions.

Analysis of the available literature, as well as feedback from key informant interviews, underscores how little is understood about the etiology of EED. Given that EED may facilitate linear growth failure *independently of diarrhea,* the historic research focus on diarrhea as the primary outcome variable may have missed key relationships among various WASH interventions, EED and child growth. Measuring EED, however, is far more complex and expensive than measuring diarrhea (including specific diarrhea-causing pathogens). There is a need to develop less costly proxy measures predictive of EED and child stunting.

This review underscores a significant evidence gap on various technologies and social behavior change interventions promoted through current programmatic efforts. Additional research is needed to investigate the effectiveness, adoption, constraints, and scale potential of measures to reduce IYC exposure to fecal pathogens, including safe play spaces, improved animal husbandry practices, and flooring, among others. This research should explore the additive benefits of these interventions when coupled with traditional WASH measures such as expanded water supply, improved water quality, utilization of improved toilets, handwashing with soap, and promotion of other hygienic behaviors.

1.0 BACKGROUND

1.1 WASH and Child Undernutrition

Infants and young children (IYC) in low- and middle-income countries (LMICs) are exposed to the combined risks of inadequate diet and recurrent infections during the critical first 1,000 days of life (from conception to 24 months of age), when gut health, immune competence, growth, and development trajectories are established. Poor conditions of water, sanitation, and hygiene (WASH), inadequate caregiving[2] and food insecurity underlie these immediate causes of child growth faltering. The Global Burden of Disease study estimates diarrheal disease to be the ninth leading cause of death globally, at about 1.3 million deaths per year, but the fourth leading cause of death in children under five years of age, with roughly 499,000 deaths annually (Wang et al., 2016). Using earlier data, it was estimated that inadequate WASH was responsible for over half the global diarrheal disease burden, amounting to 842,000 deaths in 2012 (and over 5 percent of the global mortality of infants and children under age five) (Prüss-Ustün et al., 2014). In 2014, it was estimated that globally, 22.9 percent of children under five years old were stunted (UNICEF et al., 2015), with more than half living in Asia and more than one-third in Africa (Black et al., 2013). In 2011, 43 percent of 6- to 59-month-old children were anemic (WHO, 2011). Africa and Asia account for the highest prevalence of childhood anemia, at 60 percent and 42 percent, respectively. Stunting and anemia can negatively affect child development, adult intellectual capacity, and future economic productivity (Black et al., 2013; Walker et al., 2011). Together with other social and environmental factors, the effects of poor diet and infectious diseases occur both concurrently and cumulatively during early life, preventing millions of children from achieving their full development potential (Walker et al., 2007; Black et al., 2016).

Poor water, sanitation, and hygiene conditions contribute to undernutrition and, in turn, growth stunting and impaired development in children. Of the approximately 660 million people lacking access to improved drinking water sources in 2015, nearly half live in sub-Saharan Africa, and another fifth live in South Asia (WHO/UNICEF, 2015). Meanwhile, about 950 million people practice open defecation (OD). Southern Asia accounts for two-thirds of the world's OD, occurring nearly three times as much as in sub-Saharan Africa. At the same time, the number of people practicing OD in Southern Asia is reported to have decreased by roughly one-fifth between 1990 and 2015 (from roughly 770 million [65 percent] to roughly 610 million [34 percent]), while the absolute number increased in sub-Saharan Africa, as the region's population nearly doubled over this period (WHO/UNICEF, 2015). The increase in access to sanitation has not kept pace with population growth in sub-Saharan Africa, with only 36 percent of the additional population gaining access (WHO/UNICEF, 2015).

Moreover, global efforts to expand non-sewered sanitation, combined with population growth, make attention to the full sanitation value chain all the more vital. Proper sanitation entails not only the elimination of OD and the delivery of an improved toilet; it also requires timely emptying of pits and storing of sub-surface excreta, as well as safe handling, transport, treatment, and disposal or reuse. In an analysis relying on Demographic Health Survey (DHS) data, it was reported that 63 percent of the populations in 58 LMICs (constituting approximately 1.8 billion people) use facilities that lack proper fecal sludge management (FSM) (Berendes et al., 2017).

Inadequate WASH represents the dominant cause of diarrheal diseases globally (Prüss-Ustün et al., 2014), and diarrhea, in turn, increases susceptibility to acute respiratory infections (Ashraf et al., 2013; Schlaudecker et al., 2011; Schmidt et al., 2009). The vicious cycle between recurrent childhood

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[2] Caregiving refers to adequate child-care practices such as stimulation, protection, infant feeding, hygiene, and health seeking. Caregiving behaviors include care for pregnant/lactating women, feeding/breastfeeding, psychosocial and cognitive stimulation, hygiene behaviors, health seeking, food preparation, and storage (Engle, Menon, & Haddad, 1999).

infections and undernutrition is well recognized (Petri et al., 2008). Evidence on the magnitude of the relative contribution of diarrhea to chronic child undernutrition, as reflected by stunting, is mixed. In 2004, evidence was found consistent with the hypothesis that a higher cumulative burden of diarrhea increases the stunting risk (Checkley et al., 2004), whereas Briend (1990) referred to earlier studies that questioned whether diarrhea-induced growth faltering was short term or sustained. Reduction of diarrheal morbidity and employment of rigorous dietary interventions have proven to be only modestly successful at reducing the child height deficit among the poor in sub-Saharan Africa and South Asia (Bhutta et al., 2008; Dewey & Adu-afarwuah, 2008; Humphrey, 2009).

In light of these uncertainties, a growing body of evidence has hypothesized environmental enteric dysfunction (EED), an energy-intensive subclinical condition characterized by chronic inflammation of the gut and subsequent immune stimulation, as the primary pathway linking inadequate WASH to child stunting and anemia (Humphrey, 2009; Humphrey et al., 2015; Prendergast et al., 2014 and 2015). EED appears to be linked to chronic enteric pathogen and non-commensal fecal bacteria[3] overload of the small intestine, and is common in resource-poor contexts with inadequate sanitation (Humphrey, 2009).

1.2 IYC Exposure to Excreta in Home Environments

The major transmission pathways for infectious disease (as well as their barriers) were originally summarized in the iconic F-diagram (Wagner & Lanoix, 1958). Introducing barriers to transmissions are the basis for such WASH interventions as drinking water treatment, expanded water supply, improved sanitation, handwashing, and food hygiene. However, it does not appear that the current suite of evidence-based WASH measures alone is sufficient to protect IYC in low-income countries from ingesting large quantities of disease-causing fecal microbes (Ngure et al., 2013 and 2014). IYC are frequently at a high risk of infection by fecal pathogens and soil-transmitted helminthes (STH) as a result of crawling on contaminated areas and mouthing behaviors that are common in early child development (Ngure et al., 2014). Even when children have no detectable infections, the microbe-laden environment may provide low-level chronic immune stimulation plausibly linked to anemia, inflammation, and catabolic processes that result in impaired growth (Humphrey, 2009).

As noted in Mills & Cumming (2016), "a greater understanding is needed of the impact of non-traditional/new WASH interventions, such as safe disposal of child feces, complementary feeding hygiene, hygienic play areas, and others." Increased focus is needed on how best to interrupt underemphasized fecal-oral transmission pathways among under two-year-old IYC by paying increased attention to animal feces as a pathogen reservoir and direct ingestion of feces and contaminated dirt as transmission pathways (Ngure et al., 2014). The additional reservoir and pathways are reflected in a modified F-diagram (Figure 1). We highlight the pathways of greatest interest to this review: direct exposure to infants and young children through direct ingestion of animal feces, geophagy and mouthing play objects and household items.

To address these pathways, a combination of behavioral and technological inputs was suggested to support a more hygienic environment in which IYC can thrive and play (Ngure et al., 2014). They argue that exposures, possibly leading to EED, can be minimized by frequent baby handwashing at critical times, as well as by creating a hygienic and protective play[4] environment to complement hygienic infant feeding, providing safe drinking water, promoting handwashing by caregivers before food preparation and feeding, and implementing improved sanitation measures.

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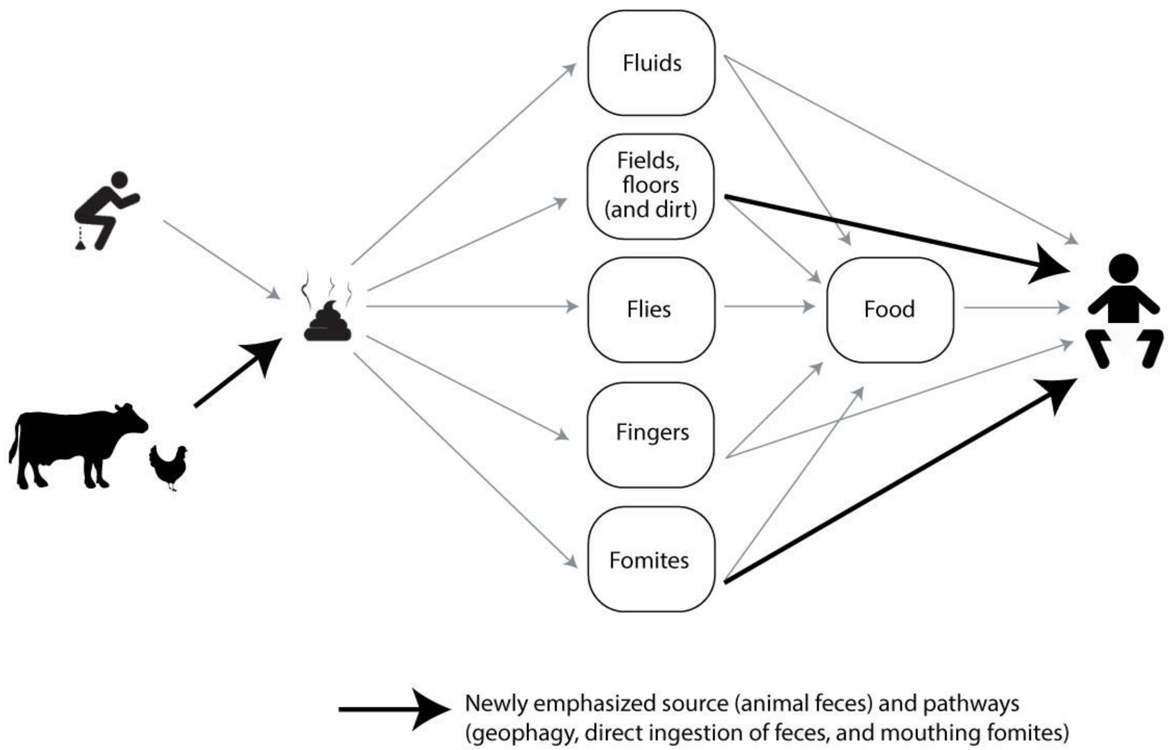
3 We note that the etiology of EED is not currently well understood. In this review we focus on the transmission of fecal/ enteric pathogens to also represent pathways for other general, non-commensal fecal bacteria that might have a role in exacerbating diet-induced changes in gut microbiota (Brown et al., 2015), and induce inflammation of the small intestine mucosal lining (Humphrey, 2009).

4 The term "play" refers to any time the infant or child is not in a "protected" position (sleeping or on the caretaker's back, lap or hands), or left un-attended either sitting on the ground, crawling, using toys or exploring its environment.

Figure 1: Modified F-Diagram that highlights geophagy and direct feces ingestion by IYC.



Undeniably, poor WASH conditions are concentrated in the most disadvantaged households (Mason & Mosello, 2017). Households with low socioeconomic status experience conditions of inadequate water supply, poor water quality, inferior sanitation infrastructure, and lack of access to sanitation services and goods. Poor households also are more likely to be crowded, have dirt floors, cohabitate with animals, and lack refrigeration for foods (Keusch et al., 2006). Within these households, women, who are principally responsible for procuring water and maintaining household hygiene, experience significant time poverty due to their involvement in market-based work and non-market work (Kes & Swaminathan, 2006). Time poverty also constrains the ability of women, who are the primary caregivers, to provide comprehensive child care including practices that prevent diarrheal disease. It is thus unsurprising that the highest prevalence of diarrheal disease is among poor populations. Further, poor children who experience diarrhea are also less likely to receive treatment than children from more well-off households (Barros et al., 2010). Lack of resources leading to late diagnosis and treatment of diarrheal disease as well as limited access to and affordability of health services are key causes of the higher mortality associated with diarrheal disease among poor children (Keusch et al., 2006). In turn, the greater burden of diarrheal disease further compound the disadvantage experienced by poor individuals by leading to conditions such as undernutrition and poor child development with long-run sequelae on health and well-being.

1.3 Objectives and Organization of the Review

This review synthesizes the latest understanding of key pathways of fecal microbes and, in particular, enteric pathogens and STH, ingestion by IYC and the link to diarrhea, EED, and poor nutrition and development outcomes. The review is based on a thorough search of the scientific and grey literature on WASH, child undernutrition, and health, including snowball sampling (chain sampling) from citations within articles. The electronic searches and review of the literature were complemented by key informant interviews with researchers and field implementers to examine sources and pathways of fecal microbe transmission as well as the interventions to disrupt them.

This report seeks to:

- consider both human and animal sources of fecal contamination and the pathways presenting major exposure risks to IYC, including sources and pathways previously underemphasized (and to the extent possible, seek to understand the relative potential importance of the different pathways in terms of magnitude of pathogen transmission);
- examine the exposure pathways to which children in the first two years of life may be most susceptible to enteric pathogens and their potential importance; and,
- identify interventions to break these pathways, including established WASH measures as well as underemphasized risk factors such as animal husbandry, IYC feeding practices and IYC-focused WASH behaviors.

Findings of the literature review will be used to design field research activities to study the additive effects of specific measures to reduce IYC exposure to fecal pathogens and other fecal microbes in their home environments when coupled with independent or integrated WASH and nutrition interventions.

Following the background section, Section 2.0 reviews key evidence on sources of fecal contamination and Section 3.0 provides the transmission pathways of fecal pathogens and intestinal parasites. This is followed in Section 4.0 by a presentation and discussion of the evidence on the effectiveness of various interventions to disrupt the transmission pathways. Section 5.0 provides a discussion of major findings and recommendations for further areas of research.

2.0 SOURCES OF HOUSEHOLD FECAL CONTAMINATION AND HEALTH RISKS

Human and animal fecal contamination of household environments is pervasive in LMICs where OD, poor environmental hygiene, and close animal husbandry practices are common. Inadequate human and animal excreta disposal, poor wastewater conveyance, and use of animal feces for fuel and housing material are each sources of fecal pathogens and STH. Inadequate IYC feces disposal and OD by older children are common in many LMIC contexts. Where fecal contamination is abundant, both humans and animals may spread it throughout the living environment (Curtis et al., 2000).

2.1 Adult Feces

Environmental contamination by human feces due to OD and poor FSM represents a key risk factor for diarrhea, acting as a reservoir for specific bacterial pathogens (*Campylobacter jejuni*, enteropathogenic strains of *E. coli*, and *Salmonella* species) (Byers et al., 2001; Curtis et al., 2000; Marquis et al., 1990) as well as protozoan parasites, viruses, and other infectious disease agents (Curtis et al., 2000; Pickering and Davis, 2012). It has been asserted that human feces is the definitive source of diarrheal disease, because even feces from healthy people likely contain more human pathogens than that of animals, and should therefore be targeted as the first priority unless there is evidence to the contrary (Curtis et al., 2000). Potential pathogens were identified in 83 percent of children with diarrhea and 72 percent of controls in the large prospective multicenter case-control study, the Global Enteric Multicenter Study (GEMS) (Kotloff et al., 2013). Similarly, one or more pathogens were commonly detected in children without diarrhea from early infancy (64.9 percent versus 76.9 percent of non-diarrhea compared to diarrhea specimens) in a multi-site birth cohort study, MAL-ED[5] (Platts-Mills et al., 2015). These data highlight the frequency of enteric pathogen carriage even in asymptomatic individuals.

OD presents negative effects within communities and could be especially harmful where population density is much higher (Spears, 2013), although the evidence on population density effects is mixed (Jarquin et al., 2016). It has been asserted that OD predicts stunting in India, with between 35 percent and 55 percent of the average difference in stunting between Indian districts attributable to differences in OD (Spear, 2013). In the context of the MAL-ED study, OD was associated with elevated risks of enteric infection among all age groups (less than 5, 5–12 years, and adults) in Vellore, India; similarly, the presence of a private toilet was associated with decreased risks of enteric infection (Berendes et al., 2016).

The same study points to inadequate FSM representing a growing challenge as access to on-site dry and pour-flush latrines accelerates in both rural and urban households. Direct discharges of lower-water content fecal biosolids into the immediate environment (particularly through flood events) elevate the risks of enteric infection among children in a drain-flooding area in Vellore; meanwhile, even as toilets within the household were associated with reduced enteric infection, toilets emptying to drains were *not* effective at reducing risks of enteric disease during the rainiest season in that area (Berendes et al., 2016).

2.2 Child Feces

Unsafe management of child excreta is common in many countries (Rand et al., 2015; Freeman et al., 2016; George et al., 2016; Gil et al., 2004; Majorin et al., 2014; Miller-Petrie et al., 2016; Mara et al.,

[5] The Etiology, Risk Factors, and Interactions of Enteric Infections and Malnutrition and the Consequences for Child Health Study

2010). Unsafe disposal is defined as feces that is not deposited into any kind of improved or unimproved toilet or latrine. Safe disposal of child feces includes helping a child use a toilet or latrine or, for very young children, placing or rinsing their feces into an improved or unimproved toilet or latrine (Rand et al., 2015). In an analysis of Multiple Indicator Cluster Surveys and DHS data, more than 50 percent of households in 15 out of 25 LMICs practiced unsafe disposal of feces of children under the age of three (Rand et al., 2015). The highest levels of unsafe child feces disposal were reported among poor, rural households, among the youngest children, and where other household members were practicing OD. Children less than three years old were more likely to practice OD across all 25 countries, independent of household defecation practices. All countries reported some unsafe child feces disposal practices even in households with improved sanitation. In India, for example, 56 percent of households with improved sanitation practiced unsafe child feces disposal, with 23 percent of these households leaving child feces in the open (Rand et al., 2015).

Older children are increasingly more likely to use toilets/latrines by themselves, unlike younger ones for whom primary responsibility for feces disposal and training is with the caregiver. In Haiti, for example, 59 percent of households with children less 12 months old reported safe disposal, as compared to 72 percent of those with children older than four (Rand et al., 2015). The transition toward safe disposal of child feces increasing with child age is happening in many countries, although OD of the older child cohorts remains high. Income is also a predicting factor, with safe disposal of child feces for under three-year-olds more likely among the 40 percent of the wealthiest households than among the least wealthy 60 percent (Rand et al., 2015).

Inadequate infant feces disposal was associated with a 23 percent increase in the risk of diarrhea among children in Peru (Lanata et al., 1998) and an 11 percent increase among children in India (Bawankule et al., 2017). In a prospective cohort study of children less than 30 months old in rural Bangladesh (George et al., 2016a), unsafe disposal of infant feces was associated with elevated markers of EED, lower weight-for-height z-score (WHZ,) and lower weight-for-age z-score (WAZ). Unsafe child feces disposal also was associated with five times greater odds of detecting diarrheagenic *E. coli* in areas where children were observed playing (George et al., 2015a). In households where soil samples were collected in children's outdoor play areas, 97 percent had at least one sample with detectable *E. coli*, and 14 percent had at least one sample with detectable diarrheagenic *E. coli,* attributable to human and/or animal feces.

2.3 Animal Feces

Increasingly, animal feces are being investigated as an additional source of disease risk from zoonotic pathogens. Penakalapati et al. (2017) provide a systematic review of literature addressing (a) human exposure to poorly managed animal feces; (b) negative human health outcomes from exposure to animal feces (e.g., diarrhea, gastroenteritis, EED, trachoma, STH infections, child growth (anthropometric) outcomes, and infection by zoonotic pathogens); and (c) animal feces contamination of the environment (e.g., water or fields), identifying 62 articles meeting the inclusion criteria. Among their findings of the consequences of animal feces exposure are the following:

- Observed effects of feces on human diarrheal illness are heterogeneous;
- Child growth may be impaired, although these effects do not consistently appear in the literature;
- Trachoma (*Chlamydia trachomatis* infection) risk may increase by potentially providing breeding sites for flies that propagate the infection; and,
- Evidence suggests that particularly cats and dog excreta can lead to an increased risk of Soil-transmitted helminths (STH) infections.

Animal feces are important sources of zoonotic bacteria (enteropathogenic *E. coli*, *Campylobacter* and *Salmonella*) and protozoa (*Cryptosporidium* and *Giardia*) (Kotloff et al., 2013). Animal feces are more widespread in contexts where free-range animal husbandry is practiced and animals are corralled within environments where children sleep and play. For instance, validated microbial source tracking (MST) markers of animal fecal contamination were widely detected in households (as well as water sources) in rural India, indicating widespread risks of exposure to animal feces and zoonotic pathogens; nearly every fecal-oral pathway explored was contaminated with animal feces in both the public and household domains (Schriewer et al., 2015). Over 50 percent of household-stored water samples, 90 percent of mothers' and children's hands, and 74 percent of public ponds were contaminated with animal feces (Schriewer et al., 2015). Meanwhile, in a dense, urban low-income setting in Dhaka, Bangladesh, ruminant fecal contamination of surfaces and hands were also common (Harris et al., 2016). Widespread ruminant and avian fecal contamination was also found in rural settings in Bangladesh, where animal fecal contamination increased with animal ownership (Boehm et al., 2016). In a multi-country study, presence of animal feces in the domestic environment was negatively associated with hand cleanliness in mothers and children (Headey et al., 2016).

Free-scavenging poultry are especially common in rural and peri-urban settings (Marquis et al., 1990; Ngure et al., 2013; and Harvey et al., 2013). Several studies have isolated pathogenic bacteria (Simango 2006; Marquis et al., 1990) and other fecal bacteria from soil and chicken feces sampled from the domestic environment (Pickering et al., 2012 Ngure et al., 2013). In rural India, levels of both human and animal (mainly ruminant) fecal contamination in households showed significant associations with subsequent child diarrhea, suggesting that exposure to animal (in addition to human) fecal contamination may increase the risk of child diarrhea in this setting (Odagiri et al., 2016). *Cryptosporidium* and *Giardia* were detected in 12 percent of clinic-admitted diarrhea patients in areas where animal loading estimates suggested cattle were the greatest contributor of *Cryptosporidium* oocysts and *Giardia* cysts to the environment in the region (Daniels et al., 2015). In a recent systematic review, 69 percent of the studies reported an association between exposure to domestic food-producing animals (such as poultry and livestock) and diarrheal illness (Zambrano et al., 2014). Exposure to domestic poultry more than doubled the risk of human campylobacteriosis, and failure to identify the microbial cause of disease might have actually underestimated the effect (Zambrano et al., 2014)[6]. Elevated prevalence of *Giardia duodenalis* among Ethiopian children was associated with cattle and manure contact (Wegayehu et al., 2013).

There is evidence of the direct child health hazards of household animal husbandry. In a prospective cohort study in Western Kenya, children from households with animals with digestive disorders experienced slower growth than children in households with healthy animals (Mosites et al., 2016). Explanations offered for this association include the possibility that sick animals were an indicator of household poverty, food shortage, or overall poor household health (Thumbi et al., 2015; Zambrano et al., 2014). Another hypothesis is that sick animals are a source of zoonotic pathogens leading to infectious diarrhea and subsequent growth failure (Checkley et al., 2008; Schlaudecker et al., 2011). Within the same cohort, livestock disease reports were associated with simultaneous human disease reports (Thumbi et al., 2015). While controlling for household size, the odds of human gastrointestinal, febrile and respiratory illness increased by 31 percent for every 10 cases of animal illness or death observed within the household. Similarly, a 6 and 10 percent increase in the probability of human gastrointestinal and respiratory illness, respectively, was associated with each additional case of the respective illness observed in animals in the same household during the same visit.

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6 Molecular studies also provide compelling evidence that identical protozoal strains of *Cryptosporidium* and *Giardia* exist in domestic animals and humans (Zambrano et al., 2014).

In Bangladesh, having an animal corral within a child's sleeping room was associated with elevated EED scores and doubled the odds of stunting (George et al., 2015). The most common animals corralled in children's sleeping rooms were chickens and cows, both important sources of common zoonotic diseases *Campylobacter*, diarrheagenic *E. coli* and *Cryptosporidium* (Bender, 2004). Presence of animal feces in the household environment was negatively associated with child height-for-age z-score (HAZ) among 6- to 24-month-olds in Ethiopia and Bangladesh, but not in Vietnam (Headey et al., 2016). Poultry ownership was strongly associated with observed animal feces in the three countries.

It is important to note, however, that these costs may co-occur with potential nutritional benefits offered by increased food access from domestic animal husbandry (Kaur et al., 2017). Mosites et al. (2016) report a modest child growth benefit of owning household livestock, with a ten-fold increase of livestock ownership associated with lower stunting prevalence in Ethiopia and Uganda (though not in Kenya). The authors adjusted their analysis for such confounding factors as child age at baseline, child sex, number of household members, household baseline wealth, and baseline household livestock ownership count, concluding that "ownership of healthy livestock may improve child baseline health and decrease the impact of infectious diseases that would otherwise lead to stunting" but that the "pathway has not been well-evaluated and further research is needed."

A recent cross-sectional analysis of a large agricultural survey in rural Ethiopia suggests that while poultry ownership may be beneficial to child growth, overnight corralling of poultry within the household dwelling may present a concurrent risk for undernutrition via increased risk of infectious diseases (Headey & Hirvonen, 2016). With their distinctly mixed findings within a cross-sectional meta-analysis of DHS survey data from 30 sub-Saharan African countries, Kaur et al. (2017) reinforce the hypothesis that domestic animal husbandry is, at the same time, "protective against stunting, an indicator of chronic malnutrition, and a risk factor for all-cause mortality in children." They identify 13 countries for which domestic livestock ownership is a risk factor for elevated child diarrhea, but in another 10, found a protective association (Kaur et al., 2017). The authors acknowledge that their results reveal considerable heterogeneity among countries for which further data would be needed to infer the relative costs and benefits of the practices within a particular geography.

3.0 PATHWAYS OF FECAL PATHOGEN TRANSMISSION

The transmission pathways for human and animal-sourced zoonotic pathogens are multiple; however, the relative contribution of these various pathways is not well documented. Similarly, the context-specific environmental, behavioral, technological, and infrastructure factors that affect these pathways and their relative predominance across time and space also are not well understood. What is clear is that contamination of the household environment permeates all other pathways of fecal pathogen transmission including soil, hand cleanliness, food, and water at source and during storage.

The general household physical environment in low-income settings is frequently contaminated with child, adult, and animal feces. The sources of contamination provide a microbial-laden environment where IYC frequently eat, crawl, and play. Maintenance of personal and household hygiene, as well as inculcating healthy hygiene habits in young children, falls primarily to women who are already constrained by many other demands on their time. The same social and cultural norms that hold women responsible for household hygiene consequently stigmatize caregivers for household contamination and sick children.

Poor hygiene of the domestic environment has been linked to EED and growth faltering. In an observational follow-up study of 10- to 48-month-old children in Bangladesh, young children living in a more hygienic household environment had lower levels of parasitic infection, improved gut function, and improved growth compared to their peers living in a contaminated environment (Lin et al., 2013). Children living in cleaner household environments had 0.54 higher HAZ, 22 percent lower stunting and 0.32 standard deviation (SD) lower lactulose: mannitol ratio[7] than children living in dirtier households. A clean environment was defined as a household with good water quality (median *E. coli* < 10 CFU/100mL in quarterly drinking water samples collected over 24 months), improved sanitation (flush/septic/piped sewerage or a pit latrine with a slab and a water seal), and hygienic handwashing conditions (a dedicated handwashing location stocked with soap and water). In contrast, a contaminated environment was defined as a household with poor water quality (median *E. coli* ≥10 CFU/100mL), inadequate sanitation (OD, open pit latrines, slabs with broken water seals, toilets that flush to somewhere else, or hanging toilets), and unhygienic handwashing conditions (a dedicated handwashing location that lacked either water or soap, or the absence of such a dedicated location). In a cross-sectional study in Ethiopia, a hygiene index representing personal and household cleanliness was associated with child growth or stunting among children aged two to five years, independent of water quality, the presence of sanitation facilities, infant feeding practices, recent morbidity, household food security, and socio-economic status (Ngure, 2012). The hygiene index was an additive score of eight attributes, including mother's hands cleanliness, child's hands cleanliness, compound appearance relative to hygiene, general appearance inside the house, whether the area around house needed to be swept, garbage around the house/compound, whether the floor inside the house needed to be swept, and a pile of dirty clothes.

3.1 IYC Soil and Feces Ingestion

Exploratory mouthing of hands and objects occurs often and is theoretically desired in early stages of child development. However, IYC frequently explore, crawl, sleep, and feed in contaminated environments, concurrently exposing them to risk as well as opportunity, spending much of their time on these contaminated surfaces (Teunis et al., 2016). Ingestion of dirt and feces by IYC through mouthing soiled fingers, play objects, and household items, as well as exploratory ingestion of

[7] Lactulose:mannitol ratio is a measure of intestinal permeability, which is an indicator of EED.

contaminated soil and/or poultry feces, is common in low-income environments (Marquis et al., 1990; Ngure et al., 2013; Brie et al., 2017). Hand and object mouthing is frequent and common among 3- to 18-month old children in rural Bangladesh (Kwong et al., 2016). An in-depth observation study of 23 households in rural Zimbabwe, lasting over six hours, found infants ingested nearly a dozen handfuls of soil and two direct ingestions of chicken feces (Ngure et al., 2013). Although based on a small non-random sample (with wide variance around the centers of spread), exploratory soil and chicken feces ingestion were identified as potentially significant pathways for fecal matter among 3- to 18-month-old children due both to a high indicator bacterial load in chicken feces and the frequency of ingestion. On average, 69 and 10 million CFU of *E. coli* per of soil and chicken feces, respectively, were detected in laundry areas. In a similar study in rural Zambia, 93 percent of mothers surveyed reported observing their children eating soil and 17 percent reported observing their child eating chicken feces (Brie et al., 2017). Ingestion of soil was also reported in 18 percent of 7- to 30-month-old children in rural Bangladesh (George et al., 2015b), a context in which 97 percent and 14 percent of the households exhibited detectable *E. coli* and pathogenic *E. coli* in the soil, respectively. In a longitudinal study of 175 households in two rural locations in Njoro, Kenya, 37 percent of the children between one and four years old, being observed, occasionally ingested less than a handful of soil, while 12 percent ingested a handful or more (Shivoga & Moturi, 2009). Ingestion of chicken feces by young children also was reported in an in-depth observation study in a peri-urban setting in Lima, Peru (Marquis et al., 1990). In the Peruvian study, *Campylobacter jejuni*, a pathogenic bacterium that causes dysenteric diarrhea, was isolated in chicken feces up to 48 hours after deposition.

A Monte Carlo Simulation using fecal indicator bacteria (FIB) data from hand rinses and stored drinking water estimated that Tanzanian children ingested more feces each day from hand-to-mouth contacts than from drinking water (Mattioli et al., 2015). Hand-to-mouth contact also far outweighed contaminated water as the dominant source of FIB for children less than six months old. (Many infants rely on breastfeeding and thus drink the least amount of water.) A recent cross-sectional study in urban slums in Nairobi, Kenya, found diarrhea to be associated with caregiver-reported soil ingestion by IYC between three months and five years old (Bauza et al., 2017). *E. coli* and human associated *Bacteroides* fecal marker (HF183), enumerated with locally validated methods, were detected in 100 percent and 93 percent of soil samples, respectively, collected near each of the 54 households in the study sample. Diarrhea in children was also associated with soil ingestion in rural Kenya (Shivoga & Moturi, 2009).

3.2 Contaminated Water

Fecal contamination of drinking water sources, including piped water sources, is widespread and affects an estimated 1.8 billion people globally (Bain et al., 2014). In general, drinking water in rural areas is more likely to be contaminated with feces than water in urban areas, although the relative safety of rural water versus urban water is dependent upon the mix of local sources and the operational success of individual water service providers.

An inverse relationship between the distance of a water supply from a latrine and the level of fecal contamination of such a water supply has been reported (Sclar et al., 2016). Although groundwater contamination often occurs downgradient from latrines, pollutant transport distances, recommendations based on empirical studies, and latrine siting guidelines are not well aligned (Graham & Polizzotto, 2013).

By using more traditional fecal indicator tests as well as novel MST markers, a compelling picture was shown of the extent and mix of human and animal fecal contamination of water (among other fecal-oral pathogens transmission pathways) (Odagiri et al., 2016). In their cross-sectional study of 60 villages in Odisha, India, they found 74 percent of household-stored drinking water (SDW) tested positive for thermotolerant coliforms (TTC), while 53 percent of SDW samples tested positive for the *Bacteroidales* (Odagiri et al., 2016). The authors highlight that there was significant animal fecal contamination (33 percent of samples) and human fecal contamination (19 percent of samples) of SDW. These findings further support the notion that the domestic environment is important for transmission of animal-sourced zoonotic pathogens in addition to human pathogens (Schriewer et al., 2015).

More than 50 percent of tubewells sampled contained detectable fecal contamination (measured by the total *Bacteroidales* fecal marker), with such specific pathogens as rotavirus, *Cryptosporidium* and *Giardia* detected in 8 to 15 percent of protected groundwater sources (Odagiri et al., 2016). Tubewells have long been considered among the safest of the groundwater sources because they are less susceptible to contamination than open wells, protected springs, or such unimproved surface water sources as streams, rivers, and ponds. It was also noted that increased village prevalence of child diarrhea, in the six weeks following sampling conducted at each additional tubewell, was detected with a tested diarrheal pathogen (Odagiri et al., 2016). More than half the ponds in the study area exhibited domestic animal feces contamination, with this pattern persisting throughout the monsoon season (Daniels et al., 2016). The study population was characterized by low sanitation coverage (10 percent of households) and high domestic animal ownership (59 percent), mostly cattle. Critically, the use of open ponds for non-drinking purposes such as anal cleansing after defecation, brushing teeth and domestic hygiene activities was common in more than 50 percent of the households (Odagiri et al., 2016).

3.3 Hand Hygiene

Unhygienic hands are important vectors of fecal pathogen transmission. In Bagamoyo, Tanzania, enteric viruses were frequently detected on hands, suggesting hands are vectors of viral illness transmission (Mattioli et al., 2013). *E. coli* virulence genes (ECVG) were detected with roughly equal frequency in stored water and on hands, suggesting that both hands and water were important pathways for bacterial pathogens transmission. Similarly, enteric pathogen markers in SDW were more likely to be found in households where these markers were detected on hands, as well as households with unimproved water supply and sanitation infrastructure (Mattioli et al., 2013). These findings are consistent with the idea that contaminated hands can affect the quality of SDW, as suggested by studies testing FIB (Pickering et al., 2010) as well as those using human and animal MST fecal markers in rural India (Shriewer et al., 2015). In places where hand feeding is common, high dosages of fecal pathogens may be directly ingested by IYC through a caregiver's hands.

Visible soiling of caregiver hands was associated with elevated levels of fecal calprotectin (a fecal marker of EED) in a cross-sectional study of 216 children under the age of 30 months in rural Bangladesh (George et al., 2015). In a low-income urban setting in Dar es Salaam, Tanzania, an increase in FIB contamination of caregivers' hands was found after toilet use, cleaning up child feces, sweeping, cleaning dishes, preparing food, and bathing (Pickering et al., 2011). Fecal contamination of mothers' and children's hands appeared to drive post-collection contamination of household SDW (Mattioli et al., 2014; Schriewer et al., 2015). Separately, lower-than-recommended volumes of water used for daily hand washing and hand-water or hand-food contacts were associated with elevated enteric pathogen markers on mothers' hands in Bagamoyo, Tanzania (Mattioli et al., 2014). These findings underscore the role of hands as an important vector in contamination of the home and in disease transmission and emphasize the difficulty of maintaining good personal hygiene in resource-poor settings that lack access to high-quality water supplies and improved sanitation.

3.4 Complementary Food Hygiene

Consumption of contaminated food, compounded by its preparation with contaminated water, is a significant vehicle for bacteria, virus, and parasite transmission to IYC, particularly when foods and liquids are added to the diet of previously exclusively breastfed children (Islam et al., 2012; Saha et al., 2009). Food is among the most important factors in transmitting pathogens that cause diarrheal illness (Motarjemi et al., 2012). While a wide range of pathogens can cause foodborne diseases, viruses, bacteria, and parasites pose the greatest share of preventable foodborne threats (Lee et al., 2014; Fischer-Walker et al., 2013). Food serves as a vehicle for virus and parasite transmission to a new host; however, for many bacteria, food offers an opportunity to grow exponentially to infectious levels. Some bacteria, such as *Staphylococcus aureus* and *Bacillus cereus*, will produce toxins while growing in food, resulting in foodborne intoxications, or food poisoning. More than 120 important viral, bacterial, and parasitic agents transmitted by food have been identified. Thirty-two of these are significant public health problems and more than half of these cause diarrhea, either alone or in combination with other adverse symptoms (Motarjemi et al., 2014).

Water also is a critical component of food hygiene, playing a significant role at multiple points in food preparation, including washing ingredients, rinsing utensils, cooking, and handwashing (or not). At the point of consumption, it is challenging to attribute the extent to which food in isolation contributes to disease transmission, exclusive of water. Therefore, many research studies that evaluate household food hygiene include water as a component of food (Woldt & Moy, 2015). Up to an estimated 70 percent of diarrheal episodes among young children could be due to pathogens transmitted through food (Motarjemi et al., 1993; Esrey & Feachem, 1989).

Fecal contamination of complementary foods (CF)[8] is important in the transmission of bacteria and pathogens to IYC, although the burden of diarrhea attributable to CF contamination is still not yet well documented. Contamination of CF is determined by several factors, including poor quality of water, water scarcity, contaminated hands of food preparers and child-feeder, contaminated preparation surfaces (fomites), contaminated cooking utensils, cross-contamination by raw food and flies, improper cooking and storage, and exceeded food storage time. Child feeding practices, such as bottle-feeding, use of unclean hands by caregivers, and self-feeding, all may increase the risk of fecal pathogen ingestion.

In rural and urban Bangladesh, 18 percent of tested complementary food samples for children were contaminated with high levels of fecal coliforms (≥ 100 CFU/g of food) and 29 percent were positive for *E. coli*, (Islam et al., 2012). Freshly prepared foods had lower FIB counts compared to leftover foods meant for multiple feeding, and microbial counts increased with the duration of storage at room temperature for the leftover food. As in many other LMIC, most of the decline in HAZ among rural Bangladeshi IYC occurs during the complementary feeding age (Saha et al., 2009). In a Tanzania study, FIB counts increased significantly for complementary foods stored longer than four hours, compared to freshly prepared food (Kung'u et al., 2009). In the Tanzania study, no drinking water source samples met the WHO guideline for drinking water safety, and thus may have served as a source of contamination in the preparation of commercially fortified and instant porridge flours.

A number of pathogenic *E. coli* strains, including enterotoxigenic, enteropathogenic and Shiga-toxin *E. coli*, also were detected in complementary food samples in Bangladesh (Islam et al., 2012). The report also indicated that elevated aerobic plate counts were associated with the presence of *E. coli* in CF as well as with the frequency of feeding the same food for multiple meals over time.

[8] Complementary foods are foods introduced to complement breastfeeding, ideally only after the first 6 months of exclusive breastfeeding. In many contexts, complementary liquids are given in early infancy and complementary feeding can start as early as 3-4 months.

4.0 INTERVENTIONS TO BREAK PATHWAYS FOR FECAL PATHOGEN INGESTION

The interventions discussed below are approaches to disrupt major pathogen transmission pathways discussed in the previous section. Diarrheal disease reduction strategies have generally focused on increasing water supply, improving drinking water quality, facilitating better hand hygiene, and improving sanitation, both through the reduction of OD and the installation and use of latrines. However, interventions to disrupt pathogen transmission pathways typically have not been designed to address animal feces as a source of pathogens nor the underemphasized pathways; and thus have not typically incorporated animal husbandry practices, proper disposal of animal wastes, or direct ingestion of feces by IYC.

As discussed in some detail below, there is considerable variance in observed effects across interventions, which is not surprising given the differences in baseline conditions of water and sanitation access and hygiene behaviors, as well as in geography and context. Most of the high-quality intervention studies reviewed in this section or included in previous systematic reviews are randomized controlled trials (RCTs) conducted under near ideal and rigorous experimental conditions and have limited scaling potential because of the intensity to replicate at scale. There is a dearth of implementation and process evaluation data (such as fidelity of intervention delivery and household uptake of promoted behaviors and practices) from RCTs, observational, programmatic, and grey literature to inform future programming and scaling efforts. The few studies available are included in this review. Additional such data are expected from the SHINE research trial (Humphrey et al., 2015).

4.1 WASH Interventions

4.1.1 WATER

Published studies of water and diarrhea have considered a wide variety of interventions (e.g., water supply improvements, community-level water quality improvements, and household-level water quality improvements) and baseline conditions (e.g., reliance on unimproved sources, reliance on improved supply community sources, reliance on basic piped delivery to premises with continuous supply, etc.). There is substantial and strong evidence on the effects of improved water supply and point of use water treatment in reducing the risk of diarrhea among children under five years old. The magnitude of risk reduction varies with the type of intervention and study context. Such evidence is mixed for water supply interventions alone. There is limited and suggestive evidence on the effects of (1) access to improved water supply on child stunting and wasting, and (2) water treatment on weight-for-age body measurement for underweight children.

In a systematic review updating reviews conducted by Fewtrell et al. (2005), Waddington et al. (2009), and Cairncross et al. (2010), Wolf et al. (2014) provided a comprehensive schematic depiction of the myriad combinations of baseline conditions and interventions addressed in the literature and concluded that there are large *potential* reductions in diarrheal disease risk through water interventions. At the same time, the authors caution that results must be considered carefully because of inconsistencies among baseline condition/intervention combinations. Combining random effects meta-analysis and Bayesian meta-regression (as well as statistical tools to adjust for both bias and discrepancies between blinded and non-blinded studies), it was estimated that the largest water-related diarrhea risk reductions occurred when households lacking improved water supply were provided with continuous, high-quality piped water (Wolf et al., 2014).

Evidence of the effects of improved water supply on diarrhea (without accompanying water treatment interventions) are mixed. The seminal meta-analysis yielded a pooled estimate of a 27 percent diarrhea reduction attributable to water supply interventions (Esrey et al., 1991). By contrast, it was reported that the water supply interventions included in their meta-analysis average "a negligible and insignificant impact on diarrhea morbidity compared to controls" (Waddington et al., 2009).

It was estimated that water quality (point of use water treatment using chlorine) interventions reduced diarrhea morbidity by 17 percent compared to contaminated water (Esrey et al., 1991). Such interventions had an average effect, reducing diarrhea morbidity by 42 percent relative to controls (Waddington et al., 2009). Household filters generally outperformed household chlorination, and in each case, safe storage provided significant additional protection (on the order of an additional 12 to 15 percent risk reduction) (Wolf et al., 2014).

With respect to water-related interventions specifically and child growth, we are aware of three published attempts to disaggregate child growth impacts of water from those attributable to more general WASH interventions. These are (1) an analysis of the Young Lives Younger Cohort data from Ethiopia, India, Peru, and Vietnam (Dearden et al., 2017), where access to improved water was associated with a reduction in stunting and wasting/thinness at one and five years of age among children in Ethiopia; (2) an analysis of DHS data that yielded an 8 percent reduction in odds of mild to severe stunting from improved water supply access (Fink et al., 2011); and (3) a study of the benefits of household solar disinfection, which detected significant increases in WAZ scores among children under five years old attributable to the intervention (Du Preez et al., 2011). Articles forthcoming from the WASH Benefits study trial[9] should provide additional insights on water-related interventions and child growth; although the study is limited to water treatment (as opposed to water supply) interventions (Arnold et al., 2013).

4.1.2 SANITATION

Based on evidence drawn largely from observation (non-experimental) studies, improved sanitation is associated with a lower risk of diarrhea and STH infections. An emerging body of evidence from high-quality experimental studies shows mixed effects of improved sanitation on health outcomes such as diarrhea, EED, STHs and child growth.

Improved sanitation is one of the primary barriers to fecal-oral transmission of pathogens. Sanitation improvements can take a variety of forms (from pit latrines with slabs to pour-flush latrines with septic tanks to piped conveyance of sewerage, among others). However, "improvements" do not necessarily equate to "safety." It was estimated that diarrhea was reduced about 16 percent after a transition from unimproved to improved (but *non*-sewered) sanitation, but much larger benefits were found with progression up the sanitation ladder, with risk reductions in the order of 60 to 70 percent from the introduction of piped sewerage (the number of studies considered was quite small) (Wolf et al., 2014). More generally, current literature emphasizes diarrhea reductions ranging from 22 percent to 36 percent attributable to improved sanitation (Fewtrell et al., 2005; Waddington et al., 2009; Cairncross et al., 2010; Engell & Lim, 2013; Wolf et al., 2014). A Cochrane review of interventions to improve disposal of human feces found the interventions to be protective against diarrhea in 11 out of 13 studies (Clasen et al., 2010), but the poor quality and heterogeneous nature of the studies limited an estimation of effect

[9] WASH Benefits Study trial in Kenya and Bangladesh. The WASH Benefits Study will provide rigorous evidence on the health and developmental benefits of water quality, sanitation, handwashing, and nutritional interventions during the first years of life. The study includes two, cluster-randomized controlled trials to measure the impact of intervention among newborn infants in rural Bangladesh and Kenya. The studies are large in scope (> 5,000 newborns per country) and will measure primary outcomes after two years of intervention.

size. Evidence from a recent systematic review shows no effect of sanitation interventions on water quality (source or household), hands or sentinel toys, food, household and latrine surfaces, or soil fecal contamination (Sclar et al., 2016). Household toilets were associated with reduced risk for bacteria and parasites (although statistically insignificant for parasites), but no association for viruses was observed in a low-income urban setting in Vellore, India. Meanwhile, toilets emptying to conveyances from the households were protective against enteric infection only in the dry season but were ineffective during the rainiest season in India (Berendes et al., 2016).

The combined effects of increased availability and use of sanitation facilities appear to reduce the odds of STH infection for *Ascaris lumbricoides*, *Trichuris trichiura*, and hookworm combined (Ziegelbauer et al., 2012) and for any STH (Strunz et al., 2014). However, evidence from more recent higher-quality studies on the impact of sanitation interventions on diarrhea, STH infections, and child growth is mixed. Two randomized controlled evaluations of the Indian government's Total Sanitation Campaign (TSC) showed no impact on diarrhea, gastrointestinal illness, helminth infection, growth, and anemia in rural Madhya Pradesh (Patil et al., 2015) or on fecal contamination of the household, diarrhea, STHs and child HAZ in Odisha (Clasen et al., 2014). The absence of an observable health effect in both Indian cases was likely due to low utilization of sanitation facilities. Qualitative research in India determined that toilet use did not increase in sites where toilet access rapidly increased because many of the government latrines were poorly constructed and, in many cases, lacked a nearby water supply source for anal cleansing (Routray et al., 2015). People are more likely to use latrines when they are functional, well maintained, accessible, clean, private, and provide amenities for practicing hygienic behaviors such as anal cleansing and menstrual management (Garn et al., 2017).

In addition to latrine coverage as a response parameter in their systematic review of sanitation interventions, an estimated 13 percent increase was observed in latrine usage likely resulting from CLTS, CLTS combined with other programming (such as sanitation marketing), education, and total sanitation campaigns (Garn et al., 2017). It must be noted, however, that only 10 studies are included in this analysis (as opposed to other analyses on latrine coverage drawing from 27 countries), and the overall pooled estimate is driven largely by three outliers: a 34 percent increase in latrine utilization observed in Mali (Pickering et al., 2015), a 39 percent increase resulting from the introduction of community health clubs in Zimbabwe (Waterkeyn & Cairncross, 2005), and a 27 percent increase in households with any observable latrine use under India's TSC in Odisha (Clasen et al., 2014). Studies also determined latrine usage to be highly sub-optimal in Odisha, which could explain why the apparent high usage did not lead to health gains (Jenkins et al., 2014). Latrine use was frequently non-exclusive and limited to one or two household members and OD persisted at high rates even with latrine ownership (as is common in rural India). In addition, threshold levels of coverage to achieve herd effects may not have been reached, and household sanitation improvements may be simply insufficient to mitigate fecal-oral pathogen exposure (Clasen et al., 2014).

Two recent randomized controlled evaluations of CLTS interventions are also worth noting. The first, a national-scale CLTS rollout in Indonesia achieved a significant (44 percent) reduction in roundworm infestation, but discerned no other impact on diarrhea (perhaps unsurprisingly, since it resulted in only a 3.3 percent increase in toilet construction) (Cameron & Shah, 2017). The second evaluation took place in the Koulikoro district of Mali, which also found no impact on diarrhea despite a 33 percent reduction in OD between treatment and control arms (Pickering et al., 2015). Diarrhea was only measured at one time during the dry season. There are several possible explanations for the lack of impact on diarrhea in these studies. Some were underpowered because of small sample size to detect meaningful reduction in diarrhea and other health outcomes (Arnold et al., 2010; Clasen et al., 2014); others achieved insufficient latrine coverage and/or use to bring about measurable impact (Arnold et al., 2010; Clasen et al., 2014; Hammer & Spears, 2013; Patil et al., 2015).

It is important to note that the CLTS intervention tested in Mali involved intensive behavior change interventions over a 12-month period, which resulted in greater adoption of toilets and of handwashing with soap than observed in other trials (Pickering et al., 2015). Children in the CLTS communities were significantly taller (0.18 increase in HAZ) and less likely to be stunted (6 percent reduction in prevalence) at the end line compared to those from the control communities, with effects largely driven by gains in children under two years of age at enrollment (0.24 HAZ) (Pickering et al., 2015). This study suggests that CLTS may have prevented growth faltering through pathways other than diarrhea, and mostly likely through reduction in EED.

A sub-group analysis within a recent systematic review of 29 studies, most of which were observational studies and low in quality, suggested an 80 percent coverage threshold beyond which sanitation interventions are more effective at reducing levels of observed feces (Sclar et al., 2016). Studies from India, Indonesia, Mali, and Tanzania, identified a fairly linear relationship between OD and a measure of child growth, in which conversion of a community from full OD to ODF status corresponded to a 0.44 standard deviation increase in child height (Gertler et al., 2015). The slope of the curve suggests that small-to-modest OD reductions are unlikely to result in measurable child height changes.

4.1.3 INFANT AND YOUNG CHILD FECES MANAGEMENT

Most of the previously discussed sanitation interventions do not emphasize or are not explicit on strategies to address child feces disposal. TSC and CLTS interventions do not explicitly focus on adequate child feces disposal (Freeman et al., 2016). More recently, some CLTS programs have begun to incorporate a focus on IYC feces disposal (Rand et al., 2015).

Evidence from observation studies suggest that the use of enabling technology, such as child potties, sani-scoop and diapers, facilitate adequate disposal of child feces. In a survey of 130 households in 21 villages across two provinces in Cambodia, hygienic disposal of children's feces was associated with child age, years of latrine ownership, caregiver's age, consistency of adult latrine use, and presence of child feces management tools in the latrine (Miller-Petrie et al., 2016). Notably, the youngest caretakers with the newest latrines and the youngest children were the least likely to manage IYC excreta hygienically, and thus represent a key target for behavior change (Miller-Petrie et al., 2016). Child potties and diapers were helpful in facilitating hygienic disposal of child feces in this context, but locally available potties were designed for generic household use and not specifically for ease, safety and convenience of use by IYC, making them less convenient for caregivers. Reusable diapers with easy-to-use covers, child friendly potties, and child-safe latrine seats were attractive "enabling products" for caretakers that offered a time and cost savings, easy disposal, and cleaning. Disposable diapers were less likely to be disposed of hygienically than reusable diapers and therefore may not have been an ideal product (Miller-Petrie et al., 2016), and presented a solid waste disposal challenge. The use of potties or chamber pots have been culturally accepted and used in improving hygienic disposal of child feces in Nigeria and Peru (Jinadu et al., 2007; Yeager et al., 1999).

In the context of the formative research preceding the WASH Benefits Study trial in Kenya and Bangladesh, an observation study of 20 households in rural Bangladesh suggested that a light and easy-to-use mini-hoe, redesigned from a heavy-duty farming hoe, was well accepted for removal of child feces from the household courtyards into a proper latrine (Sultana et al., 2013). In this context, most children under the age of three defecated in the open within the household courtyard. Caretaker preference for a particular method of feces disposal was driven by disgust, convenience, availability and affordability of materials/tools. This mini-hoe was later adapted for use as an enabling product (a locally developed sani-scoop) for child and animal feces management in the full trial (Arnold et al., 2013). While providing enabling technologies for disposal of child feces, the WASH Benefits Study trial did not factor in willingness-to-pay into the design, a limitation to adoption and scaling up of technologies, which is common with such trials, including SHINE. In a study in Cambodia, the adoption of scoops and shovels for transporting feces to latrines was rare due to consumer fears about filling pits with dirt, even as these same tools were used widely for burying feces (Miller-Petrie et al., 2016). Although scoops were useful for burying child feces, this practice was deemed "unhygienic" by a consultation group of sanitation experts because natural disturbances may uncover the feces (Bain & Luyendijk, 2015).

A USAID project in Bangladesh conducted qualitative research to develop and program age-cohort-specific IYC feces disposal options. One outcome was documentation of age cohorts recognized by mothers and families, and age-specific options for disposing feces that were effective at separating feces from the environment and considered feasible from the point of view of the mother and household. Cohorts included the lap child, crawling baby, toddler, and young child, with feces disposal recommendations for each. In Bangladesh, the WASHplus activity saw a 13 percent increase in safe disposal of child feces (for all age cohorts) through technological and behavioral inputs, and a 14 percent drop in feces being disposed of indiscriminately (USAID/WASHplus, 2016a). The study methodology, however, was conducted pre-program and post-program, at random project focal areas without a control group.

Also under WASHplus, an integrated WASH-nutrition project in Mali included a focus on child handwashing and safe disposal of IYC feces, and documented a 33 percent increase in the practice of safe disposal of infant feces. A similar intervention in Kenya documented a 25 percent increase, both through intensive interpersonal communication and promotion of enabling technologies such as potties (no products were actually distributed to households) (USAID/WASHplus, 2016b and 2016c)

Access to water within households was associated with hygienic disposal of child feces. In Burkina Faso, mothers with access to tap water in the yard reported hygienic disposal of infant feces three times more often than those who relied on wells outside the compound, and twice as often as mothers who used public standpipes or wells within the yard (Curtis et al., 1995). The authors concluded that improved water service provisions encouraged safe disposal of child feces by reducing the time spent collecting water and allowing more consistent hygienic excreta disposal.

Identifying age-cohort-specific actions and technologies for the improved disposal of IYC feces were critical to improving practices, with interventions specifying safer disposal options for each developmental stage. Low perception of risk of IYC feces influences proper disposal, as does lack of enabling technologies, feasible behaviors, and water supply to facilitate proper disposal. Modifications of household latrines to make them more "child-friendly" may lead to increased use by young, mobile children, as in Bangladesh, Mali and Kenya, where household were encouraged to make latrines less "scary" and more stable, and were associated with increases in safe feces disposal (WASHplus, 2016a, 2016b, and 2016c).

4.1.4 HANDWASHING

Substantial evidence exists on the effectiveness of handwashing in preventing diarrhea and STH infections. This ranges from weak evidence from observational studies to high quality evidence from RCTs. However, the magnitude of effect size ranges between studies and contexts.

A recent Cochrane review concluded that handwashing promotion in LMIC communities (as opposed to school settings specifically) can prevent about 28 percent of diarrhea episodes, based on eight trials with a total of roughly 14,000 participants (Ejemot-Nwadiaro et al., 2015). Notably, however, six of the eight trials are from Asia, with one study each for South America and Africa having evidence categorized as "moderate quality" (according to the GRADE Working Group, "moderate quality" means that further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate). Among the best known studies is a cluster randomized trial in Karachi, Pakistan, in which intervention households receiving both soap and a program of household-level handwashing promotion reported 53 percent less diarrhea than did those in control households (Luby, 2006). Handwashing with soap is associated with reducing diarrhea risks by up to 48 percent in several systematic reviews (Cairncross et al., 2010; Curtis & Cairncross, 2003; Fewtrell et al., 2005; Waddington et al., 2009), some of which included studies of much lower quality that were likely to be subject to reporting bias. Handwashing before food preparation and/or child feeding is a frequently missed opportunity for habituating hygienic behaviors (Halder et al., 2010; Winch et al., 2013) and reducing childhood diarrhea. Handwashing with water before food preparation was associated with reduced risk of diarrhea among Bangladeshi children (Luby et al., 2011). A much higher risk reduction was associated with handwashing with soap. A large-scale IYC feeding program in Bangladesh, Ethiopia, and Vietnam conducted by Alive & Thrive demonstrated large and rapid increases in handwashing behaviors before food preparation and child feeding. The initiative's comprehensive program consisted of advocacy, interpersonal communication, community mobilization, mass communication, and strategic use of data (Saghvi et al., 2013).

Evidence from a meta-analysis of cross-sectional studies and five RCTs suggested a protective effect of handwashing on STH infection (Strunz et al., 2014). Handwashing before eating and after defecating was associated with lower risks of *A. Lumbricoides* infection. Availability and use of soap was also associated with lower infection with any STH, as was handwashing after defecation. Two school-based studies also found an additive effect of hygiene education when coupled with the administration of deworming medication, significantly reduced rates of reinfection (Bieri et al., 2013; Gyorkos et al., 2013).

4.1.5 IMPROVED COMPLEMENTARY FOOD HYGIENE

Evidence drawn from a few recent studies suggests that interventions promoting key complementary food hygiene behaviors are effective in reducing FIB. However, this evidence comes from observation studies of short duration, and it is unclear if these behaviors are sustained in the long term.

Most food hygiene interventions promote improved food hygiene practices by focusing on health and safety benefits. A food hygiene intervention that followed hazard analysis critical control points (HACCP) quality control and quality assurance[10] conducted to identify CF contamination points in Bangladesh significantly reduced fecal coliforms by 1.74 and fecal streptococci by 1.83 log10 CFU/g of CF (Islam et al., 2013). The food hygiene behaviors encouraged in the study were sustained three months after the intervention. After training and observation, recommendations were made for (1) washing hands with safe water (defined as "water free from harmful microorganisms and substances") and soap before starting meal preparation or feeding a child, after cleaning a child's bottom, and after using the toilet; (2) using safe water to wash utensils and prepare food; (3) cooking and reheating foods until boiling; and (4) covering food with a lid during storage. A similar study in peri-urban Mali demonstrated substantial reduction in the number of fresh, stored, and reheated CF samples contaminated with fecal coliforms (at >10 CFU/g) after a food hygiene intervention based on a modest resource HACCP approach (Touré et al., 2013), with better results three months after the intervention. A complementary food hygiene intervention promoting five key behaviors, following the HACCP approach, in rural Nepal reduced the mean coliform count by 100 and *E. coli* by 10 fold CFU/g after adjusting for baseline counts (Gautam, 2015). In the Nepalese context, contamination of water at baseline was low compared to food, and did not improve after the intervention.

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[10] For more information on HACCP, see http://www.fsis.usda.gov/Oa/background/keyhaccp.htm. Seven principles of HACCP in the food industry include: 1) hazard analysis, 2) critical control point identification, 3) establishment of critical limits, 4) monitoring procedures, 5) corrective actions, 6) record keeping, and 7) verification procedures (U.S. Department of Agriculture 1998).

4.1.6 COMBINED WASH INTERVENTIONS

The evidence on the effect of combined WASH interventions on child health outcomes, such as diarrhea and growth, is far from definitive. Some evidence obtained from observation studies suggests improved water and sanitation conditions are associated with improved linear growth and weight gain in under five-year-old children. Similarly, evidence from a few experimental studies of low quality suggests a modest effect of WASH interventions on HAZ scores in children under five years old.

The additive or synergistic effects of different WASH interventions on child health are complex and not well understood. A synergistic effect of water and sanitation on child growth among infants in Lesotho was documented in a prospective study (Esrey et al., 1992), but not in Sudan (Merchant et al., 2003); however, the lack of an effect in Sudan was potentially due to modification of hygienic conditions of the external environment or hygiene practices. Using a non-randomized but robust matched cohort design, no health impacts were found of a combined sanitation promotion, water supply, and hygiene intervention on diarrhea and HAZ among infants and children under the age of five in rural southern India, although the absence of a detected benefit in that study may be explained by the low prevalence of endemic diarrhea in the area (and consequent under-powering of the study) (Ejemot-Nwadiaro et al., 2015). In a simulation that modeled different fecal-oral transmission pathways for enteric pathogens, the benefits of a household water quality intervention depended on existing sanitation and hygiene conditions, with water quality improvements having minimal effects in contexts with poor sanitation conditions (Eisenberg et al., 2007). This study supported an integrated WASH approach to address the interdependent and complex pathways of fecal pathogens transmission (Eisenberg et al., 2007). Evidence from observation studies (VanDerslice & Briscoe, 1995), analysis of DHS data (Esrey, 1996) and water quality intervention trials (Gundry et al., 2004) supported the assertion that the interaction of different levels of water and sanitation service improvements may impact child health.

Other evidence from published RCTs questioned the synergy among WASH interventions specifically with respect to diarrhea. Clasen et al. (2015) noted that "the effectiveness of [household water treatment] interventions in settings without improved sanitation contradicts earlier findings that interventions to improve water quality are effective only where sanitation has already been addressed". It was also found that, while household water treatment and handwashing with soap reduced child diarrhea by 51 percent and 64 percent, respectively, there was no additional reduction in diarrhea among children in Pakistan who were exposed to both interventions (55 percent) (Luby et al., 2006). An earlier meta-analysis of 46 studies on interventions to improve WASH found that combined interventions were no more effective in reducing diarrhea than those with a single focus (Fewtrell et al., 2005). The need for high-quality evidence on the independent and combined effects of WASH motivated the design of the WASH Benefits Study trials in Kenya and Bangladesh (Arnold et al., 2013), results from which are forthcoming.

Evidence from a sub-study of a multi-armed randomized trial (from the WASH Benefits Study) found limited reduction in overall fecal contamination in the household environment from a sanitation intervention in rural Bangladesh (Boehm et al., 2016). The limited effect was attributed to widespread ruminant and avian fecal contamination. The sanitation intervention included provision of a hygienic dual-pit latrine, child potty, metal scoop for removal of child and animal feces from the environment, and behavior change promotion on the use of latrines and accompanying hardware inputs. Despite limited overall reductions in fecal contamination in the household, the interventions did, however, reduce ruminant fecal contamination in drinking water and general fecal contamination of the soil, likely due to the use of the sanitary scoop to reduce the amount of ruminant feces in the environment and ultimately in water sources.

Integrated WASH measures related to child growth are exceedingly complex. A Cochrane Review of evidence on WASH interventions and child nutritional status identified no evidence of an effect of

WASH interventions on WAZ or WHZ, but did identify a borderline statistically significant effect on HAZ, with findings supported by data from more than 5,300 children from five cluster-randomized controlled trials (Dangour et al., 2013). However, the reported modest effect on HAZ was specifically for solar water disinfection, provision of soap, and improvement of water quality for intervention studies of relatively short duration, none of which was of high methodological quality. Other studies that detected beneficial effects on caregiver-reported diarrhea among IYC did not detect improvements in linear growth (Bowen et al., 2012; Arnold et al., 2010; Langford et al., 2011; Luby et al., 2006; Stanton et al., 1988).

At the same time, there are a number of studies that observed improved linear growth resulting from sanitation and water supply improvements (Esrey et al., 1992; Esrey, 1996; Cousens et al., 1990). A prospective cohort pilot study from rural Bangladesh enrolled in a pilot for the WASH Benefits Study trial found lower parasite infection, improved biomarkers for EED, and better growth among children raised in "cleaner" households (those with improved sanitation, hygiene, and water quality conditions) than those in "dirtier" ones (Lin et al., 2013). A similar study from Peru found children in the cleanest households to be, on average, one cm taller at 24 months of age than those from the most contaminated households (Checkley et al., 2004).

4.2 Other Interventions to Improve Environmental Hygiene

While the WASH interventions discussed in Section 4.1 directly improved environmental hygiene by addressing containment of human feces, such interventions are not designed to address contamination from animal feces. There are several non-WASH interventions that do so by focusing on technologies and behavior change (BC) to encourage corralling animals, improving hygiene of animal corrals and animal feeding practices; improving household flooring; and creating clean protective play spaces. Below we highlight some of the available evidence and on-going and recently concluded research projects focusing on these interventions. We provide a summary of ongoing programmatic efforts that include age-focused WASH and environmental hygiene improvement interventions (herein referred to as BabyWASH[11] efforts) through management of animals and animal feces, playpens, mats and protective spaces, and flooring.

A growing number of development projects, as well as private-sector organizations, are beginning to address the neglected pathways through programs focusing on the BabyWASH suite of interventions to prevent fecal contamination of the domestic environment and associated ingestion of soil and feces by IYC. Many of these interventions draw on the available evidence base, and conduct qualitative research to develop feasible practices with promise of improving environmental hygiene and creating barriers between IYC and both human and animal feces. Some have best practice pre- and post- evaluation designs to document changes in household practice. However, none are rigorous research designs with random assignment or controls to establish causality, and therefore primarily document association.

These are included in this literature review because they elucidate the panorama of interventions that come closest to meeting our literature review objective:

- *Examine interventions to break these pathways, including established WASH measures as well as underemphasized risk factors such as animal husbandry, IYC feeding practices and IYC-focused WASH behaviors; and*

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[11] The use of the term BabyWASH was first coined by Ngure et al., 2014 and thoroughly defined in the cited paper. It is worth noting our use of Baby WASH does *not* refer to the name of the BabyWASH Coalition that integrates WASH, Nutrition, Early Childhood Development and Health programming for improved nutrition, health and development outcomes.

- *Help inform a WASHPaLS field research design to study the additive effects of specific measures to reduce IYC exposure to fecal pathogens and other fecal microbes in their home environments.*

Annex A provides a summary of several recent or current interventions, their BabyWASH focus, intervention modality, the use of formative research (or not) to design the intervention, and notes on any rigorous research and learning agenda associated with the intervention. As illustrated in the matrix provided therein, the interventions cover a range of BabyWASH focal areas, including: caregiver handwashing; baby hygiene (hands, mouth, face, body); safe disposal of baby feces; food hygiene, particularly focused on complementary feeding during the first 6 to 24 months; clean/safe water; feeding practices; use of playmat/playpen; and animal husbandry practices, including corralling during day and/or night, modified husbandry practices, safe management of productive feces, and regularly cleaning yard of stray feces.

4.2.1 ANIMAL HUSBANDRY PRACTICES

Promoting improved housing, feeding and health care of poultry and livestock has great potential to reduce the transmission of zoonotic diseases via animal feces (Gelli et al., 2017). However, there is scarce evidence on the effectiveness of interventions to reduce human health risks from poor animal husbandry practices. Over the years, programs have focused on promoting frequent sweeping of feces from courtyards; suggesting disposal in latrines and/or garbage pits. Other interventions have generally promoted separating children's sleeping area from domestic animals, and corralling of animals in daytime. However, no rigorous evaluation of these programs is available in the literature.

Low-income households face various barriers and constraints in corralling and improving livestock housing and hygiene. Some of the knowledge barriers include a low perception of the risk of close proximity of livestock and poultry to child health. There is also a widespread belief that free-range chicken has better tasting eggs and meat. Other constraints include the fear of theft or loss of animals to predators when animals are kept outside, the cost of animal feed, vaccinations, and materials for constructing corrals and time spent on feeding corralled animals.

An additional challenge to reducing or eliminating animal feces in household compounds is its productive use as fuel, farm manure, and building materials. Because of its utility, residents are reluctant to rid the households of what they consider to be a valuable resource. Storage and handling of fresh animal feces for such purposes exposes household members and children to contamination, suggesting that a focus on safer management of feces and handwashing after handling may be more successful than a focus on eliminating animal feces from household compounds altogether.

The Women's Poultry Program to Improve Income and Nutrition (SE LEVER) project in Burkina Faso is using an integrated approach combining revenue generation, women's empowerment, and nutritional behavior change interventions to improve child nutrition and health (details in Annex A). The project has several interventions, including improving access to poultry value chain services (such as vaccinations), financing, and training on flock management (including housing). A formative research phase of the project is underway to (1) assess WASH and animal husbandry risks related to diarrhea, chest infections, EED and child stunting, and (2) inform the design of an impact evaluation (IE) of the project. The proposed IE will employ an RCT design to measure whether incorporating comprehensive WASH and improved hygiene of poultry housing to a package of agricultural and nutrition interventions results in additive benefits on children's nutrition status and morbidity.

Separately, USAID's Empowering the New Generation to Improve Nutrition and Economic opportunities (ENGINE) project in Ethiopia (2011–2016) integrated agricultural systems to strengthen livelihood interventions focused on improving agricultural productivity through provision of sheep, goats, and dual-purpose breeds of poultry for meat and eggs. Farmers were first required to construct poultry corrals before receiving chicks and feed. A total of 41 percent of the households did not follow

ENGINE's guidelines on preparing enough food for the flocks, even when provided with a start-up supply of poultry feed by the project, indicating the persistence of free scavenging and only intermittent poultry corralling throughout the intervention (Save the Children, 2017). No health outcomes associated with husbandry practices were measured.

In a two-month trial performed within a larger observation study in peri-urban Peru on the use of corrals in 12 households, the majority of participants were willing to corral poultry after extensive orientation and technical assistance (Harvey et al., 2003). However, birds were corralled intermittently due to time and financial costs associated with corralling. Corralling poultry requires household members to provide adequate feed, as well as water, in addition to the time costs of bird care and maintaining corral hygiene. In rural Zimbabwe, households were resistant to corralling poultry during the day due to feed constraints (Mbuya et al., 2015; Ngure et al., 2013). Such challenges are common in other rural contexts where small-scale production is characterized by low-input scavenging systems with minimal investment in housing, feeding, and health care, and consequently weak biosecurity, with high disease and mortality rates (Dessie et al., 2013). Fear of theft and predation also serves as an impediment to building poultry corrals further away from sleeping and food preparation areas (Headey & Hirvonen, 2016; Save-the-Children/Ethiopia and The Manoff Group, 2014)

Although most participants in the Peruvian study viewed bird feces in the house and yard as dirty, few saw its connection with illness (Harvey et al., 2003). In this context, free-range birds were perceived as healthier, happier, and able to produce better quality meat and eggs. Similar observations were made in formative research in Ethiopian villages in the aforementioned ENGINE Project (Save the Children/Ethiopia and The Manoff Group, 2014).

These findings suggest that while behavior change strategies may address key knowledge and attitudinal barriers on the importance and practical approaches to hygienic livestock management, more comprehensive behavior change approaches are required to address the myriad financial, logistical, and structural constraints to adoption of a broader set of improved livestock practices, including management of feed and water; cleaning; and construction of improved poultry housing.

4.2.2 CLEAN PLAY SPACE INTERVENTIONS

In contexts where domestic poultry and livestock farming is common and where households do not corral animals, protecting IYC from soil and animal feces ingestion is critical. There are numerous programmatic and research efforts promoting the use of playmats and/or playpens to protect IYC from soil and feces ingestion, among other BabyWASH interventions. However, there is limited evidence on the uptake, uses and effectiveness of these interventions in reducing soil and feces exposure and ingestion by IYC, and ultimately on health outcomes such as reducing diarrhea, EED, STHs and improved child growth outcomes. The SHINE project trials hypothesized that a prescribed and hygienic space would protect IYC from key pathways of enteric pathogens and bacterial ingestion (Humphrey & Jones, 2015), especially direct ingestion of soil and feces (Ngure et al., 2013 and 2014). The concept of a safe play space is designed to protect, stimulate, and promote learning for IYC. The SHINE protective space is a playmat for immobile infants and a combination of both a playmat and playpen for older and mobile IYC (Mbuya & Humphrey, 2016). The SHINE trial used commercially available sturdy and brightly colored plastic playpens. In the context of a research activity, it was important to use a product that had been tested for strength and physical stability to support a child while practicing how to stand up. The behavior change elements of the SHINE BabyWASH framework (Mbuya & Humphrey, 2016) were designed to elicit motivating emotions for hygiene (e.g., disgust or nurture) and to encourage a full range of BabyWASH practices.

In the SHINE trial, soil and feces ingestion by IYC was reduced by about 50 percent between the WASH intervention and non-WASH households[12] in an in-depth observation of 180 households. These initial data suggest that the behavior change messages and use of a playpen were effective in raising perception of risk and changing exploratory behavior to reduce soil and animal feces ingestion. Even with minimal use of playpens for children above 12 months of age, as children became more mobile, the SHINE researchers speculate that the children who previously used playpens during the crawling stage would be less likely to ingest soil as they grew older (Personal communication, Dadirai Fundira, SHINE Trial); however, this has not been confirmed through tests.

In Zambia, an innovative play yard intervention was developed and designed locally, with local materials, intended for caregivers of IYC. Under 24-hour recall, caregivers reported placing their children in the play yard for extended periods of time (more than 1.5 hours in a single use) in eight of the 10 households observed (Brie et al., 2016). Although drawn from a small pilot study and based on self-reporting, these data suggest that such an intervention may have potential to limit time IYC spend on bare contaminated household soil.

Through a community-based approach, the ENGINE project provided WASH products through micro-enterprises and local women's saving groups in 46 kebeles (neighborhoods) within 10 woredas (sub-districts) in Ethiopia. The products offered included concrete latrine slabs, subsidized PVC playmats, subsidized water filters, and tippy taps. The goal of this approach was to improve WASH, nutrition and health in households with children under the age of two years. Ninety-six percent (n=4,286) of targeted households bought the PVC playmats at 42 percent of the market price based on a previous willingness-to-pay study by the same group and in the same context. According to a small follow-up consumer satisfaction survey, playmats were well received and reported to be regularly used for intended purposes (77 percent reported using them always and another 9 percent occasionally); all 22 households that participated in the survey were satisfied with their purchase and cited cleanliness and health as the major reasons for buying the playmats (Save the Children, 2017). Four out of the five saving groups sold out of the mats in the fourth year of the ENGINE project and two groups planned to purchase more in the near future; however, in the end, none of the groups purchased more mats to sell in the fifth year. This was attributed to the subsidized pricing that could not be sustained after the project ended. Lack of established supply chains to provide these the playmats at market value made these efforts unsustainable (Personal communication, Daniel Abbott, USAID/ Save the Children ENGINE Project).

4.2.3 IMPROVED HOUSEHOLD FLOORING

Children in rural and low-income peri-urban settings are exposed to fecal microbes and STH through bare and loose courtyard soil. Indoor dirt floors also provide primary breeding grounds for microbial pathogens due to pockets of high moisture content from spilled water and food. Though such floors are commonly swept, they are hard to clean and sanitize. Improving indoor and courtyard flooring by providing a hard and impermeable surface will potentially reduce microbial exposure to IYC. Such surfaces are easier to clean with soap and water and dry off in case of spills. Importantly, these interventions assume a household has access to sufficient quantities of water to clean the floors;

[12] A WASH household received a household ventilated pit latrine, tippy taps, monthly liquid soap, water treatment solution, and protective play space, and accompanying interpersonal communication interventions promoting feces disposal in a latrine, handwashing with soap, drinking water treatment, hygienic weaning, food preparation, and preventing babies from putting dirt and animal feces in their mouths. Non-WASH households were either drawn from the control arm which only received standard of care or the nutrition arm which received nutrition interventions, including 20 g/d nutri-butter from 6–18 months, interpersonal communication interventions promoting optimal use of locally available foods for complementary feeding after 6 months old, continued breastfeeding, and feeding during illness. All the households in the trial received standard care interventions which included promotion of exclusive breastfeeding promotion for all infants, birth to 6 months, strengthened PMTCT services and village health worker system.

otherwise, the increase in the household's (usually, women's and girls') water collection duties can reduce the positive benefits of the intervention.

In an impact evaluation of a large-scale Mexican program called Piso Firme, replacement of dirt floors with cement flooring was associated with a nearly 20 percent reduction in incidence of parasitic infestations, approximately 13 percent reduction in prevalence of diarrhea, and 20 percent reduction in prevalence of anemia compared to the control group. The program also was associated with improvements in child cognitive development (Cattaneo et al., 2009). No significant differences were observed in HAZ and WAZ, but the program was associated with significant improvements in adult welfare, as indicated by increased satisfaction with housing and quality of life and lower depression and perceived stress scores. These benefits were realized at an average cost of $150 per household. The authors do caution, however, that these results are not necessarily able to be generalized in rural contexts, where the share of total area under cement floor might be significantly less than in the Piso Firme urban context. Households in this urban context also had water and sanitation facilities which might not generally be the case in rural contexts.

Given the high cost of cement floors, market-based efforts are developing and promoting inexpensive floors that can be washed, cleaned, and used to support a healthier home environment for poor consumers. The EarthEnable commercial enterprise in Rwanda is marketing improved floors made of a multi-layer surface that allows for drainage yet seals the surface to make it waterproof, washable, durable, and appealing to customers. As of January 2017, EarthEnable had installed earthen-finished flooring to replace dirt in roughly 1,400 households, at costs significantly lower than that of cement. No health data is yet available; however, the enterprise will be examining reduced IYC exposure of contaminated soil and feces as well as positive health outcomes such as reducing the risk of diarrhea, EED, and STHs, and improved child growth.

4.2.4 INTERVENTIONS TO ADDRESS SOCIAL DETERMINANTS

Other types of interventions, such as policies and programs that address the underlying social determinants of diarrheal disease can serve as critical, complementary strategies to directly focus on barriers to contamination pathways. In Brazil, economic growth coupled with reduced income disparities between the rich and the poor and increased educational attainment for women, as well as water and sanitation infrastructure improvements and increased provision of oral rehydration salts led to decreased infant mortality (92% from 1990 to 2007) from to diarrheal disease (Victora et al., 2011). In a dated study from Bangladesh, higher maternal education and household wealth was associated with lower risk of diarrheal disease among children – seven more years of maternal education was associated with more than a halving of diarrheal disease prevalence, and those in the wealthiest quintile had a 41 percent lower risk of diarrhea compared to those in the lowest quintile (Mahalanabis et al., 1996). In Ghana, children of illiterate mothers were found to experience greater risk of diarrhea in conditions of poor water supply and lack of toilets (Gyimah, 2003). These studies lend evidence that interventions acting on the upstream, social determinants have important implications for lowering diarrheal disease prevalence. There are opportunities for integrating these interventions with those focusing on the proximal determinants, with the potential for synergistic effects (Casanovas et al., 2013).

5.0 DISCUSSION AND NEXT STEPS

This review of the recent literature identified several important findings and gaps in the evidence with implications for future research and programming. The findings highlight a clear path for WASHPaLS research towards a hygienic environment for infants and young children.

Practitioners and researchers have underestimated potentially key pathways of disease transmission in Wagner & Lanoix's 1958 "F-Diagram"

The growing attention to risks from direct and indirect consumption of animal and human waste and direct consumption of contaminated soil point to the need for separating IYC from fecal pathogen reservoirs in the home environment.

Animal feces contamination may be extensive and could be more abundant than human feces in low-income rural, peri-urban, and urban contexts where free-scavenging poultry and livestock husbandry practices are common. Animal feces are a primary source of zoonotic organisms and contamination of public and private water sources. Presence of animal feces in the immediate household environment increases the risk of contamination of hands, and consequently, of water and food. Overnight corralling of poultry and/or livestock within the same room as IYC has been linked to EED (George et al., 2015a) and stunting (George et al., 2015a; Headey & Hirvonen, 2016). However, the role of animal density with respect to diarrhea, EED and child stunting is not well-understood (Headley and Hirvonen, 2016).

Exploratory mouthing behaviors of children using contaminated household objects, as well as direct consumption of fecally contaminated soil, serve as an additional pathway of transmission for IYC. Additionally, until recently many of the current WASH interventions overlook infant and child feces disposal, which is sub-optimal in many LMICs and contributes to diarrhea, EED, and other health consequences. In general, CLTS and other sanitation approaches have not addressed child feces disposal, or at least with any emphasis. Recently, however, some CLTS programs have begun to explicitly incorporate a focus on IYC feces disposal (Rand et al., 2015).

The relative importance of different disease transmission pathways is not well-documented

The relative magnitude of transmission pathways of enteric microbes faced by IYC are not well defined and may be highly context-specific, making it difficult to conclude which pathways may represent the highest risks. The disease transmission pathways may vary greatly as infants progress through development levels, with increasing levels of mobility. We expect that a number of research studies (e.g., WASH Benefits, GEMS, SHINE, and NOURISH), will offer important insights when findings are published.

EED as a mediator of child growth faltering is not yet well-understood

Analyzing the available literature as well as key informant interviews also underscores how little is understood about the etiology of EED, specifically issues of intermittent exposure to contagion, thresholds, and dose-response relationships that are critical to develop effective interventions.

Despite some important gains in interventions reducing diarrheal morbidity, achieving widespread reductions in child stunting in LMICs remains elusive. This has been increasingly attributed to the pervasive EED (Humphrey, 2009), hypothesized to be caused primarily by fecal microbes and pathogens ingested from contaminated soil and feces, among other vectors. Given that EED may facilitate linear growth failure *independent of diarrhea,* research focusing on diarrhea as the primary outcome variable may have missed key relationships between various WASH interventions, EED and child growth, in both positive and negative directions. Measuring EED, however, is far more complicated and expensive in terms of research methods and biomarkers than measuring diarrhea outcomes, particularly studies relying on *reported* rates of diarrhea. There is a need to develop inexpensive proxy measures that are predictive of EED and child stunting.

Implementers are increasing their focus on preventing IYC from exposure to fecal pathogens through previously neglected pathways, but there is little evidence to support the effectiveness of such interventions.

At least 17 distinct medium-to-large-scale service delivery programs employ measures that fall within the scope of "BabyWASH," including the distribution of mats and playpens, and promotion of behavior change interventions directed at keeping play spaces clean and corralling animals away from IYC.

Despite recent interest in rolling out the playmat/play space interventions through various programmatic efforts, there is no empirical evidence on the efficacy or effectiveness of these interventions in reducing the risk of soil, human, and animal feces ingestion and improving child growth and health.

Playmat and play space interventions are interesting, but assessing their true potential requires a better understanding of the biological plausibility of their protective effects against fecal contaminant risk. More specifically, intermittent exposures to microbial pathogens may still result in risk: extended periods of protection on a mat or within a play yard may not be sufficient to prevent risk posed by even short periods of IYC time spent in areas of increased hazard (on bare soil with excreta present) or eating contaminated food from contaminated hands. A number of studies of water treatment interventions argue that there is an exposure threshold above which infection becomes probable (Enger et al., 2013; Brown & Clasen, 2012; Hunter et al., 2009), and that exposure-response relationship for ingestion of animal excreta or contaminated soil remains a source of considerable uncertainty.

Data from the sub-study of the SHINE trial and other less rigorous play space studies discussed above raise additional research questions about the relative importance of reducing soil and chicken feces ingestion for children 3 to 12 months old and the persistence of changes in caretaker and IYC behavior after 12 months. Is the risk perception by caregivers sustained post-playmat use, and how does the risk perception translate into changes in caregiver behavior over time? Do changes in infant practices at earlier ages continue as they age and increase mobility, even in the absence of restraints?

Evidence on the impact of improved flooring on child nutrition and health is limited to a single study in urban Mexico, where most of the households had cement floors (Cattaneo et al., 2009). Notably, open courtyards with bare loose soil are common in rural areas, where households are less likely to have cement floors. Human and animal density and flow of livestock in such contexts may influence the effectiveness of such improved floors on child health outcomes. The positive impact of cement floors on adult psycho-social well-being prompts further research questions on whether finished flooring is likely to improve WASH behaviors like cleaning the floor and keeping poultry and animals away, and more generally impact child health and growth in rural areas as well as the Mexican urban context.

This review underscores a significant evidence gap on various technologies and social behavior change interventions promoted through current programmatic efforts. Additional research is needed to investigate the effectiveness, adoption, constraints, and scale potential of measures to reduce IYC exposure to fecal pathogens, including safe play spaces, improved animal husbandry practices, and flooring, among others. This research should allow exploration of the additive benefits of these interventions when coupled with traditional WASH measures such as expanded water supply, improved water quality, delivery and utilization of improved toilets, and handwashing with soap and promotion of other hygienic behaviors.

ANNEX A. RECENT OR CURRENT PROJECTS WITH BABYWASH FOCUS

ORGANIZATION PROJECT DATES COUNTRIES	SPECIFIC BABYWASH FOCUS AND TYPE OF INTERVENTION	FORMATIVE RESEARCH TO DEVELOP INTERVENTION OR TEST CONCEPTS – FORMAL OR INFORMAL	RIGOROUS DESIGN TO DOCUMENT IMPACT OF BABYWASH ON BEHAVIORS, EED, OR GROWTH
SPRING Project 2011-2016 with extension year through 2017 Guinea, India, Ghana, Niger, Bangladesh, Sierra Leone, Burkina Faso, Nigeria	Interventions vary across 8 countries, focusing on some combination of: • Safe disposal of child feces • Playpens and playmats • Managing animals and feces (sweeping and modified chicken coops) • Handwashing of child and caretaker • Treated water for 6-24 month olds Interventions vary across countries, but most include Community-Infant and young child feeding (IYCF) Counselling Package including training of outreach cadre (some volunteer, some paid) and counselling cards to support consistent and behavior-focused messaging; and in some countries, community videos; enhanced CLTS (WASH 1000, focusing on the First 1000 Days), Improved chicken husbandry, encouraging caging/ corralling of chickens when feasible; playmats. https://www.spring-nutrition.org/about-us/news/springghana-presents-wash-1000-39th-annual-water-engineering-and-development-centre https://www.spring-nutrition.org/stories/spring-promotes-nutrition-sensitive-agriculture https://www.spring-nutrition.org/publications/posters/developing-effective-messages-better-nutrition-and-hygiene-tonkolili-tips	Trial of improved practices (TIPS)[13] in Sierra Leone. Other formative research in Guinea, Ghana, Bangladesh. Illustrative highlights of findings include: Sierra Leone: Main objections to playpens seemed to be motivated by lack of familiarity with the practice, and low perception of risk. Parents generally preferred sweeping to playpens. Ghana: Currently, most households have a chicken coop that opens into the enclosed courtyard. Research identified families were willing to create a clean play space by turning the chicken coops to open outside of the courtyard, reducing the time chickens are in a courtyard and thus reducing child contact with chicken feces.	No rigorous learning agenda. Project pre- post- evaluations to be conducted, but not particularly focused on BabyWASH elements. Monitoring data showed Bangladesh participants much more likely to wash hands after defecation (75%) than non-participants (6%).

[13] Trials of Improved Practices, or TIPS, is a research methodology that involves target actors to develop and test feasible and effective solutions to a range of health and development areas. Various behavior and/or behavior-technology dyads are developed, verified for efficacy or biological plausibility, and then tested over time for effectiveness, feasibility and popularity. Most often, the outcome is a menu of feasible and effective options to integrate into programs. TIPS can be more or less rigorous in their application. Unlike other methods, subjects are actively engaged as consultants, and modifications often made throughout the course of the study.

ORGANIZATION PROJECT DATES COUNTRIES	SPECIFIC BABYWASH FOCUS AND TYPE OF INTERVENTION	FORMATIVE RESEARCH TO DEVELOP INTERVENTION OR TEST CONCEPTS – FORMAL OR INFORMAL	RIGOROUS DESIGN TO DOCUMENT IMPACT OF BABYWASH ON BEHAVIORS, EED, OR GROWTH
Food for the Hungry (FH) DRC On-going	• Geophagy • Playmats/playpens Study with Johns Hopkins University (Christine Marie George) investigating EED and Stunting; and effective methods for decreasing EED and reducing stunting.		A prospective cohort study will investigate the relationship between exposure to enteric pathogens through geophagy, EED and stunting. The study will include a RCT to determine which activities (e.g., playmats or playpens) are the most effective strategy in preventing geophagy and decreasing EED. The findings will be incorporated into a Baby WASH lesson plan in the "Essential Hygiene Actions" Care Group module in FH programming in DRC.
Food for the Hungry Ethiopia On-going	• Hygienic Play Spaces • Handwashing, including children, emphasizing BabyWASH times • Managing animal feces • Latrines, including child-friendly to increase use Promotion of Essential Hygiene Actions through Care Groups (column 4 above), to encourage improved behaviors through support, increased perception of risk, skills and changing norms.	Conducting a formative "Barrier Analysis" to assess determinants of practicing Essential Hygiene Actions, including Baby WASH related practices.	No rigorous evaluation design following evidence-based program development.
Save the Children and The Manoff Group USAID ENGINE 2011-2016 Ethiopia	• Playmats • Poultry corrals Subsidized WASH products (latrine concrete slabs, PVC playmats and water filters) were marketed through micro-enterprises and local women's saving groups. The added products were a late addition in 10 districts (out of 116) to reduce fecal bacteria and parasite ingestion. Sensitization was done by the women saving groups, with mothers in the groups as the first target group. https://ethiopia.savethechildren.net/ENGINE	Willingness-to-pay study	Standard best-practice program monitoring and evaluation design used (not high rigor). ENGINE monitoring showed about 5,000 households bought these PVC playmats, and qualitative follow-up showed most used as intended. A significant majority of the households (77%) reported always using the playmat for the intended purpose and another 9% reported using the mat occasionally Poultry corrals were mandatory (with subsidized materials and feed provided) in order to receive ruminants and poultry as part of ag systems strengthening efforts. Most program participants complied to some extent, however, intermittent poultry corralling and free-scavenging local poultry were still practiced. No data explain why, but anecdotal information suggests householders still supplemented 'costly' food by letting animals graze.

ORGANIZATION PROJECT DATES COUNTRIES	SPECIFIC BABYWASH FOCUS AND TYPE OF INTERVENTION	FORMATIVE RESEARCH TO DEVELOP INTERVENTION OR TEST CONCEPTS – FORMAL OR INFORMAL	RIGOROUS DESIGN TO DOCUMENT IMPACT OF BABYWASH ON BEHAVIORS, EED, OR GROWTH
			There was no measure of the WASH intervention's impact on child health outcomes. WASH was introduced as a relative small scale/ pilot study. Qualitative case studies and further conversation with program managers suggest Lack of messages or sensitization at community level on the use of play-mats contributed to low demand at population level. In addition, Lack of established supply chains to provide these the playmats at market value made these efforts unsustainable; as well as weak linkages between suppliers and the saving groups.
Save the Children and The Manoff Group Growth through Nutrition (2016-2021) Ethiopia	• Playmats ENGINE follow-on Growth through Nutrition Project will research practices / outcomes related to the playmats sold under ENGINE.		Under new Growth Through Nutrition activity, project beginning to research household practices / outcomes related to the playmats sold under ENGINE.
CARE NUTRITION AT THE CENTER Project (2012-2017) Bangladesh, Ethiopia, Benin, Zambia	• Playpens, playmats • Poultry feces Aimed at decreasing child stunting and women and child anemia; promoting animal corralling, especially in men's groups and VSLA. Explicit EED module, focused on building caretaker 'awareness'/ perception of risk of EED-related behaviors CARE *Collaborates with SHINE Project in Zambia* https://nutritionatthecenter.wordpress.com/	Some formative research in Zambia, learning that women perceive positive consequences of geophagy, more than negative. Formative research on community-built (mud-brick) playpens and plastic playpens (following SHINE trial play yard intervention); semi-structured interviews suggests that both are equally acceptable (~30 HH).	Observation results under review at AJTMH; intervention results currently being written up. Presently testing the impact of 24 small-scale, community-operated egg production facilities on the egg consumption and growth of children in the Luangwa Valley, Zambia. These facilities and roosting structures help restrict poultry feces to a contained area.
Feed the Children On-going from 2015 (private funds) Kibera (Kenya)	• Playmats • Sanitize toys • Separate IYC from livestock in pens or cages Focused Care Group module for groups of 10-12 women, every two weeks for approximately three months.	Formative research conducted to develop intervention, identifying behavioral determinants and addressing barriers through solutions generated or tested by householders to assure feasibility. (see detail in column 2)	No data to be collected from activity.

ORGANIZATION PROJECT DATES COUNTRIES	SPECIFIC BABYWASH FOCUS AND TYPE OF INTERVENTION	FORMATIVE RESEARCH TO DEVELOP INTERVENTION OR TEST CONCEPTS – FORMAL OR INFORMAL	RIGOROUS DESIGN TO DOCUMENT IMPACT OF BABYWASH ON BEHAVIORS, EED, OR GROWTH
	Caregivers encouraged to provide a "clean" playmat, asked to sanitize the playmat once a week and whenever it is soiled with food or dirt. Also encouraged to clean and sanitize toys and other items that babies frequently stick in their mouths at least two or three times per week; when the baby is recovering from an illness; and when other children have put the items in their mouth. Specifically asked parents to request that caretakers at day care center to use clean mats and to clean and sanitize mats and toys regularly.		
Project Concern International (PCI) Tanzania's USDA-funded Food for Education III Project 2016-2021	• Playmats and clean toys • Handwashing of child and before food preparation • Food hygiene Integrates Early Childhood Development/ Education ECD/ECE with health/ nutrition/ WASH (handwashing, food hygiene), playmats and cleaning toys. Uses Education Cascade Groups, weekly sessions led by a trained outreach worker, with home follow-up. Trains grandparents or primary caretaker in a range of skills. Each household gets a kit ($6) that includes easy DIY stim toys, and a playmat. PCI pilot of the approach in 2017, scaling-up to 5,376 HHS (10%) in 2018, then to 27,000 and 54,000 HHs by 2020.	Modeled after Hawaii ECD initiative with extensive formative research. Concepts tested and modified for Tanzania.	Longitudinal study starting in 2018.
World Vision with The Manoff Group Uganda, Kenya, Somalia July -Dec 2017	• Clean play spaces Interventions not yet developed– aims to determine what are culturally acceptable and practical play space options in both development and emergency contexts	TIPs research on 'Clean Play Spaces' just getting underway. Findings will guide a menu of viable options for clean play spaces to incorporate into WV BabyWASH programming, "test" in-country and share with the global community. Somalia is specifically to look at an emergency context to see if similar behaviors may be utilized. Research to be carried out in June and July – results published in September 2017	No rigorous design (yet).

ORGANIZATION PROJECT DATES COUNTRIES	SPECIFIC BABYWASH FOCUS AND TYPE OF INTERVENTION	FORMATIVE RESEARCH TO DEVELOP INTERVENTION OR TEST CONCEPTS – FORMAL OR INFORMAL	RIGOROUS DESIGN TO DOCUMENT IMPACT OF BABYWASH ON BEHAVIORS, EED, OR GROWTH
World Vision Osiligi Integrated BabyWASH Program Kenya June 2017 - 2019	• Full BabyWASH Program including play space, though pilot. The program will focus on one community bringing together health, WASH and ECD in both community and facility settings. The facility will be rehabilitated and communities will be encouraged through a modified CLTS to become ODF (including focus on under 2s) and will have parenting programs to keep children away from harmful environments.	Operational research underway to define culturally-acceptable 'clean play spaces'	The WV Kenya team is working with Jomo Kenyatta University, exploring if a coordinated BabyWASH approach is more effective than individual interventions carried out without coordination. Research questions and methods are still being developed.
Johns Hopkins Center for CCP, Health Communication Capacity Collaborative (HC3) Western Highland Integrated Program (WHIP) 2014- Sept 2017 Guatemala	• Caregiver handwashing • Baby hygiene (hands, mouth, face, body) • Safe disposal of baby feces • Food hygiene • Active feeding/ engaging child for better eating and ECD • Use of playmat • Corralling domestic animals Comprehensive program to reduce chronic malnutrition and address maternal health, family planning, crops diversification, home gardens and gender equity. https://healthcommcapacity.org/where-we-work/guatemala/	Literature Review (generalized findings similar to Nepal-specific findings below) and original formative research "Opening our Minds": on Aspirations and Family Dynamics in Relation to Hygiene and Nutrition. Findings included an openness to protecting children from being in contact with feces; and a more comprehensive understanding of mother/baby/child well-being (health, nutrition, hygiene, caring and love, etc.) Comparison of Household Observations of Positive Deviants and Non-Positive Deviants (in progress) Study completed and the publication will be ready in July 2017	No evaluation data forth-coming.
Suaahara/ **Nepal** 2011-2016, USAID funded Save the Children with host of other CAs and national partners	• Wash hands with soap and water before feeding the baby. • Create physical barriers between children and floor, particularly separate from animals (including chickens), dirt and all feces. Integrated nutrition, WASH and Agriculture Program. Modeled improved BabyWASH behaviors through all communication activities, mass media including radio entertainment education, radio spots, community activities and one-on-one, including home visits. Developed specific video to demonstrate how to manage improved chicken coops, especially when a family has a	Formative survey found: No regular handwashing by adults, baby handwashing not practiced Use of latrines not consistent Baby feces are considered "normal" and don't contain germs. Domestic animals around children considered normal and little perceived risk associated. Putting animals in pens perceived to increase costs and amount of work for parents.	No rigorous research design, but based on LQAS monitoring and a process evaluation to document campaign effects. People exposed to the campaign were significantly more likely to have a handwashing station with soap or ash and know that they should wash their hands before feeding children, to have a clean toilet, use water treatment or use covered water. 121 villages declared Open Defecation-Free. 2015 earthquake interrupted plan for endline survey.

ORGANIZATION PROJECT DATES COUNTRIES	SPECIFIC BABYWASH FOCUS AND TYPE OF INTERVENTION	FORMATIVE RESEARCH TO DEVELOP INTERVENTION OR TEST CONCEPTS – FORMAL OR INFORMAL	RIGOROUS DESIGN TO DOCUMENT IMPACT OF BABYWASH ON BEHAVIORS, EED, OR GROWTH
	small child. https://www.youtube.com/watch?v=HINVLiul0mA Program also had an Open Defecation Free community mobilization element https://www.usaid.gov/nepal/fact-sheets/suaahara-project-good-nutrition		
Save the Children USAID Nurture Project, 2016-2018 Laos	• Child feces disposal • IYC handwashing No intervention yet, research underway https://www.usaid.gov/asia-regional/fact-sheets/usaid-nurture	Informal research ("mini-TIPS") to identify feasible actions to safely dispose of child feces; and learn from families how IYC's hands can be washed with soap before feeding/eating	Forthcoming
CARE Bangladesh Shouhardo III (CARE's Title II /USAID's FFP Program) September 2015-2020	• Separating children from animal feces through cleaning the area where child plays. Incorporate preventive measures to reduce risk of EED in Community Health Volunteers' (CHV) *Health, Hygiene and Nutrition* module, in the Farmer Field and Business School (FFBS) Module, and School Based Teen Brigade Module. By adding to three above modules, BabyWASH now part of courtyard sessions and CHV household visits. http://carebangladesh.org/shouhardoIII/	Intervention based on extensive formative analysis findings and developing a comprehensive SBCC strategy. Formative research guided focus on cleaning/ sweeping the compound and safely disposing of animal feces in compost pits.	Expect project evaluation data at close of project in 2020.
WaterSHED "Child Potties: Sanitation for the Most at Risk" April 2017 – 2018 Cambodia	• Safe Disposal of IYC Feces Initiative to test if IYC sanitation products (i.e. 'potties') can be marketed sustainably and used consistently in rural areas to improve safe disposal of IYC feces, reducing exposure to diarrheal disease pathogens.	Formative research documented evidence of the efficacy of potties in hygienically managing child feces, and information on consumer demand and consumer preferences through product testing. Link to formative research paper: http://www.watershedasia.org/cambodia-iycs-study/	No rigorous design to document behaviors or impact. Results from sales records and HH surveys anticipated end of Q1 2018.
CRS THRIVE	• Clean toys regularly • Keeping the compound clean of feces	Working with Emory University using TIPs for SBC activities focusing on	Quasi-experimental design looking at development milestones, uptake of IYCF and

ORGANIZATION PROJECT DATES COUNTRIES	SPECIFIC BABYWASH FOCUS AND TYPE OF INTERVENTION	FORMATIVE RESEARCH TO DEVELOP INTERVENTION OR TEST CONCEPTS – FORMAL OR INFORMAL	RIGOROUS DESIGN TO DOCUMENT IMPACT OF BABYWASH ON BEHAVIORS, EED, OR GROWTH
(Conrad Hilton Foundation) 2012-2015 2016-2018 Kenya, Malawi, Tanzania	• Food hygiene THRIVE Project is an ECD initiative providing 15,000 children <5 affected by HIV with a "sustainable culture of care and support". Intervention includes direct provision of services (training to parents, caretakers, and community health workers; home visits; child-friendly spaces; Child Health Days). Case managers and Care Group Volunteers lead sessions at neighbor mother groups, plus home visits to support mothers practicing behaviors and provide booster sessions. https://www.usaid.gov/asia-regional/fact-sheets/usaid-nurture	different three thematically-designed packages. 1. Food preparation and storage 2. Mealtime 3. Clean compound, Clean family TIPS planned to run through March 2018 with report available by June 2018.	WASH behaviors, health seeking behaviors, maternal well-being.

ANNEX B. OVERVIEW OF CURRENT RESEARCH TRIALS AND TOOLS

- **WASH Benefits Study (2012-2016):** This study is motivated by the need to generate quality evidence on the effects of individual (water quality, sanitation, handwashing, and nutrition) and combined interventions on diarrhea and growth when delivered to IYC. WASH Benefits include two cluster-randomized trials to assess improvements in water quality, sanitation, handwashing and child nutrition - alone and in combination - to rural households with pregnant women in Kenya and Bangladesh. Geographically matched clusters (groups of household compounds) were randomized to one of six intervention arms or control. The studies aimed to enroll newborn children (N=5,760 in Bangladesh and N=8000 in Kenya) and measure outcomes at 12 and 24 months after intervention delivery. Primary outcomes include child length-for-age Z-scores and caregiver-reported diarrhea. Secondary outcomes include stunting prevalence, markers of environmental enteropathy and child development scores (verbal, motor and personal/ social) (Arnold et al., 2013).
- **SHINE Trial (2012-2017):** The Sanitation Hygiene Infant Nutrition Efficacy (SHINE) trial is motivated by the premise that EED is a major underlying cause of both stunting and anemia, that chronic inflammation is the central characteristic of EED mediating these adverse effects, and that EED is primarily caused by high fecal ingestion from living in poor WASH conditions. SHINE is a proof-of-concept, 2x2 factorial, cluster-randomized, community-based trial in two rural districts of Zimbabwe that will test the independent and combined effects of protecting babies from fecal ingestion (Factor 1, operationalized through a WASH intervention) and optimizing nutritional adequacy of infant diet (Factor 2, operationalized through an infant and young child feeding [IYCF] intervention) on length and hemoglobin at 18 months of age. Within SHINE 2, causal pathways will be measured. The program impact pathway will evaluate processes and behaviors linking implementation of the interventions with the two child health primary outcomes. This pathway will be modeled using measures of fidelity of intervention delivery and household uptake of promoted behaviors and practices. This pathway will also measure a range of household and individual characteristics, social interactions, and maternal capabilities for childcare to explain heterogeneity along these pathways. The biomedical pathway comprises the infant biologic responses to the WASH and IYCF interventions that ultimately result in attained stature and hemoglobin concentration at 18 months of age. This pathway will be elucidated by (1) measuring biomarkers of intestinal structure and function (inflammation, regeneration, absorption, and permeability); (2) microbial translocation; (3) systemic inflammation; and (4) hormonal determinants of growth and anemia among a subgroup of infants enrolled in an EED sub-study (Humphrey et al., 2015).
- **NOURISH Impact Evaluation (2014-2019):** The impact evaluation (IE) of the USAID-funded Cambodia Integrated Nutrition, Hygiene and Sanitation Project that will use a cluster randomized control trial design with four arms, which are (1) Nutrition only, (2) WASH only, (3) Nutrition+WASH, and (4) Control (MSI 2016). The project interventions are focused on four key strategies: (1) improving community delivery platforms to support improved nutrition through the Baby-Friendly Community Initiative (BFCI), (2) creating demand for health and WASH practices, services, and products through the use of conditional cash transfers (CCTs), community-led total sanitation (CLTS), vouchers, and SBCC, (3) using the private sector to advance supply of WASH and nutrition products, and (4) building the capacity of government and civil society in nutrition. The IE will evaluate the effectiveness of co-delivery of WASH and nutrition interventions, and the separate effect of each, in a field setting (scalable conditions), a step further than the current efficacy studies (WASH benefits and SHINE trial) integrating WASH and nutrition. Primary outcomes include HAZ,

WAZ and WHZ. Secondary outcomes are prevalence of enteric infections and measures of EED, whereas tertiary outcomes are self-reported diarrheal disease and all-cause infant mortality.

- **GEMS**: The Global Enteric Multicenter Study (GEMS) was motivated by the need for a well-designed study to obtain information on the etiology and burden of more severe forms of diarrheal disease to guide global investment and implementation decisions. The study was designed to overcome limitations from earlier studies, and determine the etiology and population-based burden of pediatric diarrheal disease. GEMS included one of the largest case/control studies of an infectious disease syndrome ever undertaken (target approximately 12 600 analyzable cases and 12 600 controls). The study was rolled out in four sites in sub-Saharan Africa (Gambia, Kenya, Mali, and Mozambique) and in three sites in South Asia (Bangladesh, India, and Pakistan). Each site is linked to a population under demographic surveillance (total approximately 467 000 child years of observation among children <five years of age). GEMS data will guide investment and help prioritize strategies to mitigate the morbidity and mortality of pediatric diarrheal disease (Levine et al., 2012).

- **MAL-ED Study**: The Etiology, Risk Factors, and Interactions of Enteric Infections and Malnutrition and the Consequences for Child Health (MAL-ED) Study, led by the Fogarty International Center of the National Institutes of Health and the Foundation for the National Institutes of Health, has been established at sites in eight countries with historically high incidences of diarrheal disease and undernutrition. Central to the study is the hypothesis that enteropathogen infection contributes to undernutrition by causing intestinal inflammation and/or by altering intestinal barrier and absorptive function. It is further postulated that this leads to growth faltering and deficits in cognitive development. The effects of repeated enteric infection and undernutrition on the immune response to childhood vaccines is also being examined in the study. MAL-ED uses a prospective longitudinal design that offers a unique opportunity to directly address a complex system of exposures and health outcomes in the community- rather than the relatively rarer circumstances that lead to hospitalization-during the critical period of development of the first two years of life. Among the factors being evaluated are enteric infections (with or without diarrhea) and other illness indicators, micronutrient levels, diet, socioeconomic status, gut function, and the environment. MAL-ED aims to describe these factors, their interrelationships, and their overall impact on health outcomes in unprecedented detail, and to make individual, site-specific, and generalized recommendations regarding the nature and timing of possible interventions aimed at improving child health and development in these resource-poor settings.

- **MAPSAN (2015-2018):** A control before-and- after trial to estimate the health impacts of an urban sanitation intervention in informal settlements in Maputo, Mozambique, with assessment of localized population density as an effect modifier (Brown et al., 2015). The intervention consists of private pour-flush latrines (to septic tank) shared by multiple households in a compound or household clusters. Outcomes will be measured in approximately 1,000 children (500 children accessing interventions and 500 controls using existing shared private latrines in poor sanitary conditions) at two points: immediately before the interventions and at follow-up after 12 months. The primary outcome will be combined prevalence of enteric infections among under five year old children. Secondary outcome measures include STH re-infection in children following baseline deworming and prevalence of reported gastrointestinal illness. The study will make use of exposure assessment, fecal source tracking and microbial transmission modeling to examine whether and how routes of exposure for diarrhea pathogens and STHs vary and the impact of effective sanitation on transmission of pathogens.

- **SAFE START (2016-2018):** A cluster randomized control trial to evaluate the impact of child hygiene interventions (targeting food preparation and infant feeding practices) on prevalence of enteric infections (primary outcome), height and weight adjusted for age (secondary outcomes) and infant mortality (tertiary outcome) (Mumma & Esteves-mills 2016). Other intermediate objectives include the effect of the interventions on observed and reported household behaviors, fecal contamination of child environment (food, water and fomites) and presence of flies. The study will be conducted in two informal settlements in the city of Kisumu- a context found to have high fecal contamination even in households with improved water and sanitation, in a previous cross sectional study by the same partners (http://www.shareresearch.org/project/urban-wash-disparities). Children will be enrolled at 3 months and will be followed until 18 months. Contact jnmumma@gmail.com

- **SaniPath Tool:** The SaniPath Exposure Assessment Tool aims to increase the evidence base available to sanitation policy makers and implementers in low-income urban communities (http://sanipath.org). It is designed to assess risk related to poor sanitation and to help prioritize sanitation investments based on the exposures that have the greatest public health impact. Data from simple environmental microbiology methods and behavioral surveys are combined to assess the relative exposure to fecal contamination. Relevant exposure pathways include open drains, drinking water, surface waters, public latrines, soils, wastewater-irrigated produce, and floodwater. The tool automatically generates risk profiles for each pathway using data entered by the user. The risk profiles show users which pathways contribute the greatest risk and where interventions may have the greatest impact on reducing exposure to fecal contamination.

- **SE LEVER Impact Evaluation:** Soutenir l'Exploitation Familiale pour Lancer l'Élevage des Volailles et Valoriser l'Économie Rurale (SE LEVER) or Women's Poultry Program to Improve Income and Nutrition project is a five-year project implemented by Agribusiness Systems International (ASI) in partnership with local NGOs, private institutions, and governmental services. It is a poultry value chain program that leverages agriculture development strategies and nutrition to increase poultry production and improve the nutritional status of women and children in the Centre Ouest and Boucle de Mouhoun regions of Burkina Faso. The project uses an integrated approach combining revenue generation, women's empowerment, and nutritional BC interventions, including:

  – Improved access to value chain services. This component includes vaccinations, financing and training on poultry flock management (including housing).

  – Behavior change communication (BCC) on nutrition and health provided through women's groups, poultry producer groups and local community leaders. The content of BCC includes the promotion of improved diets at key stages of the lifecycle, and additional content focusing on nutrition during the first 1000 days, including IYC feeding practices and basic hygiene practices.

  – Community-level sensitization on women's economic empowerment and gender equity, including strengthening of women's groups.

  In addition to these activities, SE LEVER is undertaking formative research on the need for a more intensive WASH/health component to improve health and hygiene in the context of poultry flock management that could be integrated into an enhanced SE LEVER package.

  An IE, using a cluster randomized control trial design, will be overlaid on the SE LEVER project. The IE will include two groups: 1) SE LEVER intervention group; and 2) Control group with no intervention. An additional intensive WASH/health component designed to improve child health and nutrition in the context of poultry flock management will be added if the results of the formative research suggest the need for such an intervention. A sub-study would be undertaken within the SE LEVER intervention, and the SE LEVER clusters would be randomly allocated to either: 1a) SE LEVER only; or 2) SE LEVER + with an intensive WASH/health component. The primary outcomes of the study include the mean probability of adequacy of diets for women and children (two to five years), infant and young child feeding practices for caregivers of children aged zero to two years, and household poultry output and sales.

ANNEX C. REFERENCES

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