Sanitation Hygiene Infant Nutrition Efficacy (SHINE) Trial in Zimbabwe:

Rationale, Design, Methods, Intervention Uptake

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SHINE

Finding ways to help children shine!

Donors

- Bill and Melinda Gates Foundation
- Department for International Development, UK (DFID)
- Wellcome Trust

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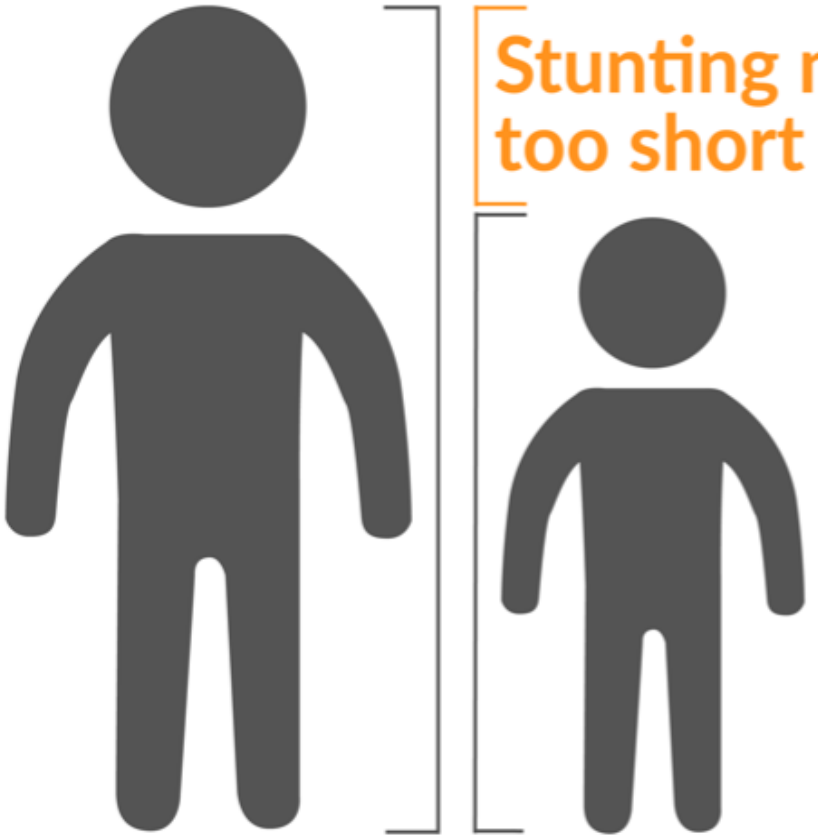
Childhood Stunting



Stunting means you're too short for your age

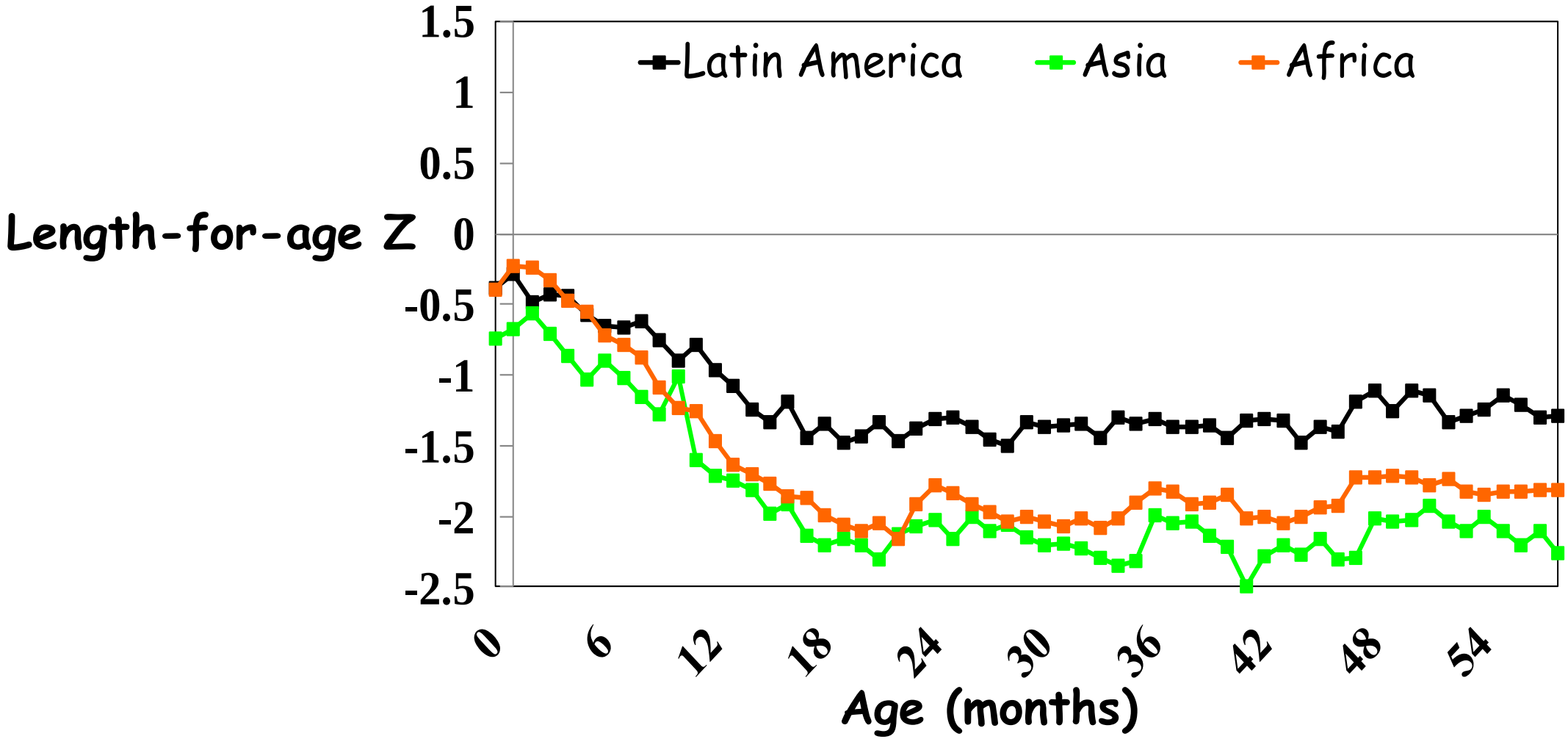
are more likely to:

stay in school longe
earn higher wages
escape poverty

https//www.one.org July 14, 2015

Stunting develops between conception and 2 years of life

Victora, et. al. Pediatrics 2010;125;e473



Child Stunting affects all life stages:

<u>Preschool</u>: Mortality

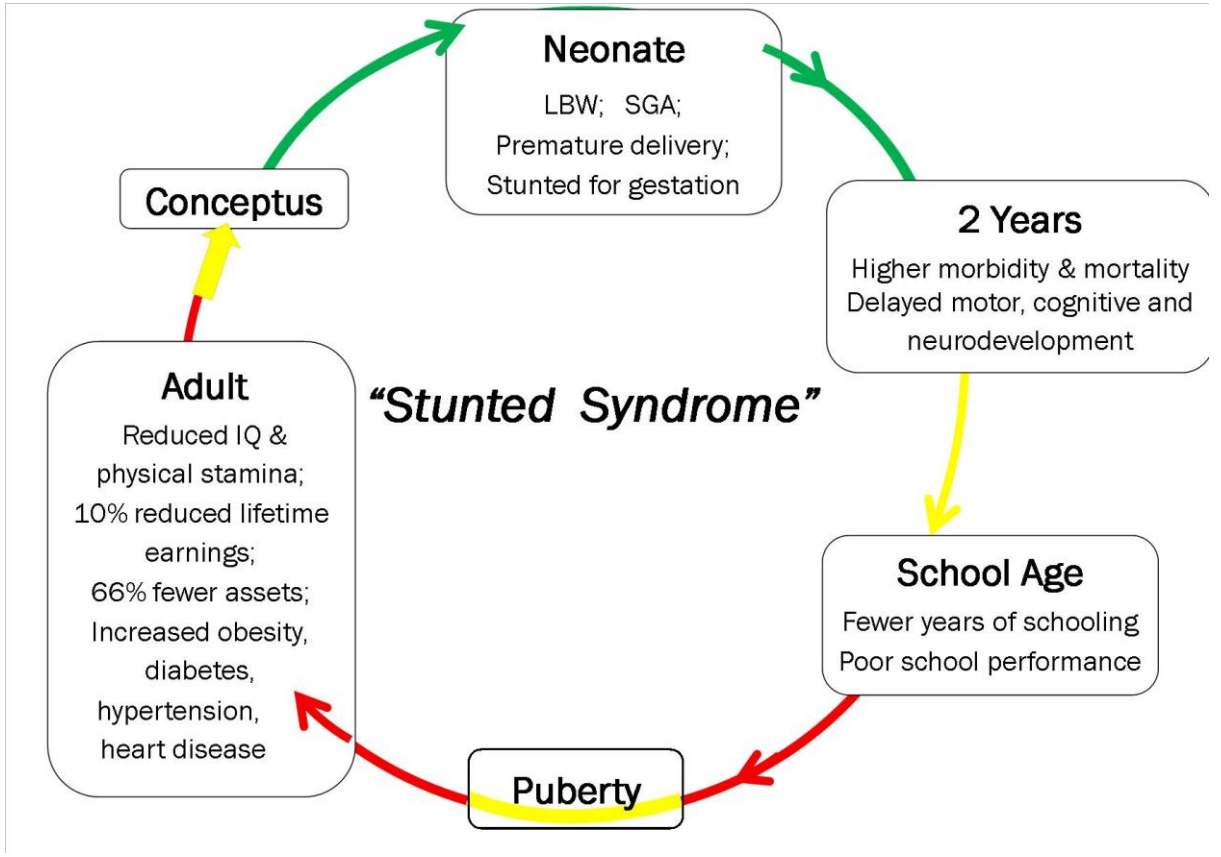
14% - 17% of all under-5-y deaths

<u>School-age</u>: Educational Attainment

- Attend less school
- Perform more poorly while there

<u>Adulthood</u>: Economic Productivity

- 66% lower economic productivity
- More likely to have stunted children



Prendergast and Humphrey: Paediatrics and International Child Health, 2014

Stunted Children

155 million (23%)

<5 y-olds are **stunted**

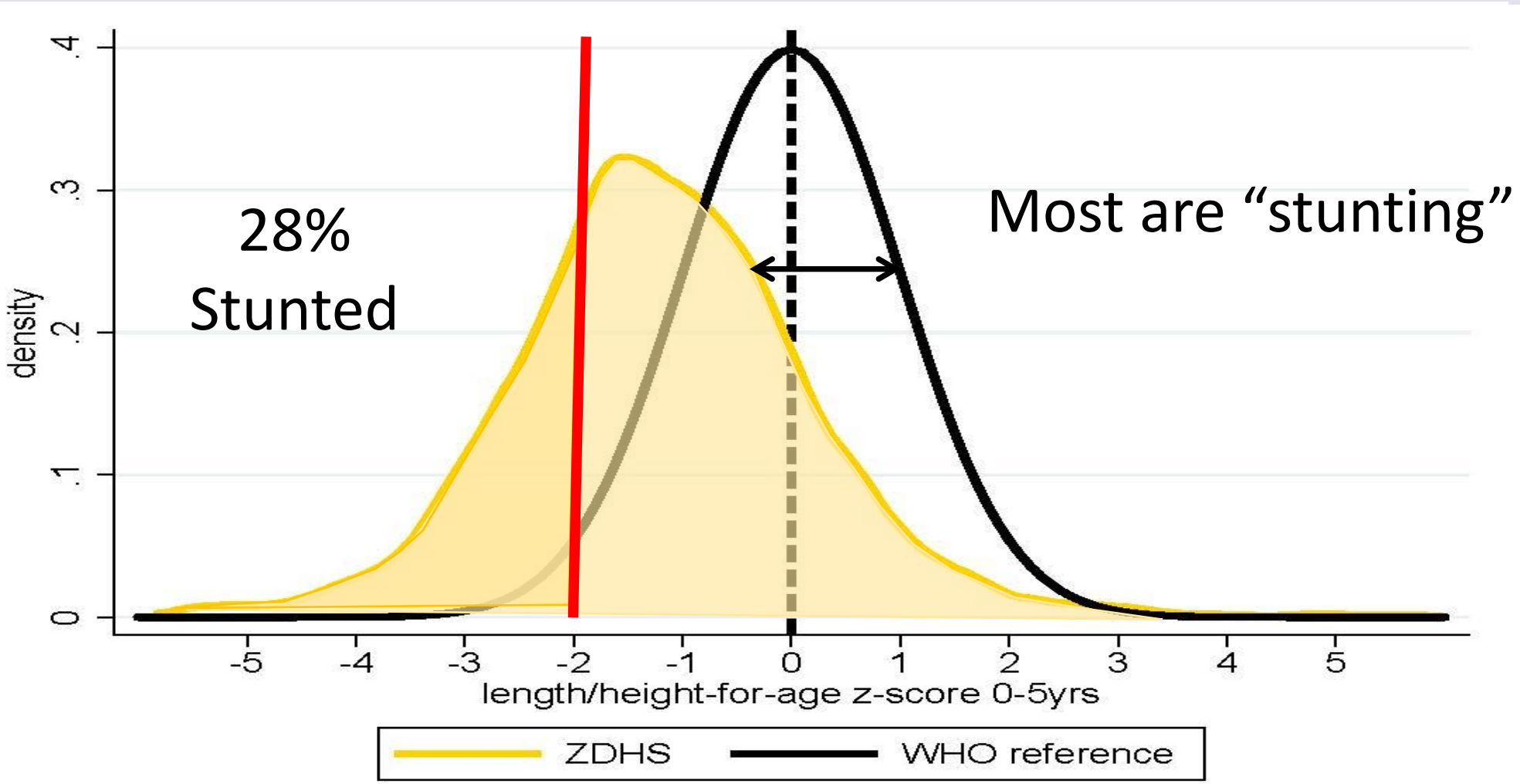
Length-for-age Z

(LAZ) < -2

However, many more

are **stunting**

LAZ distribution among <5 year olds
Zimbabwe 2015 DHS vs. WHO reference



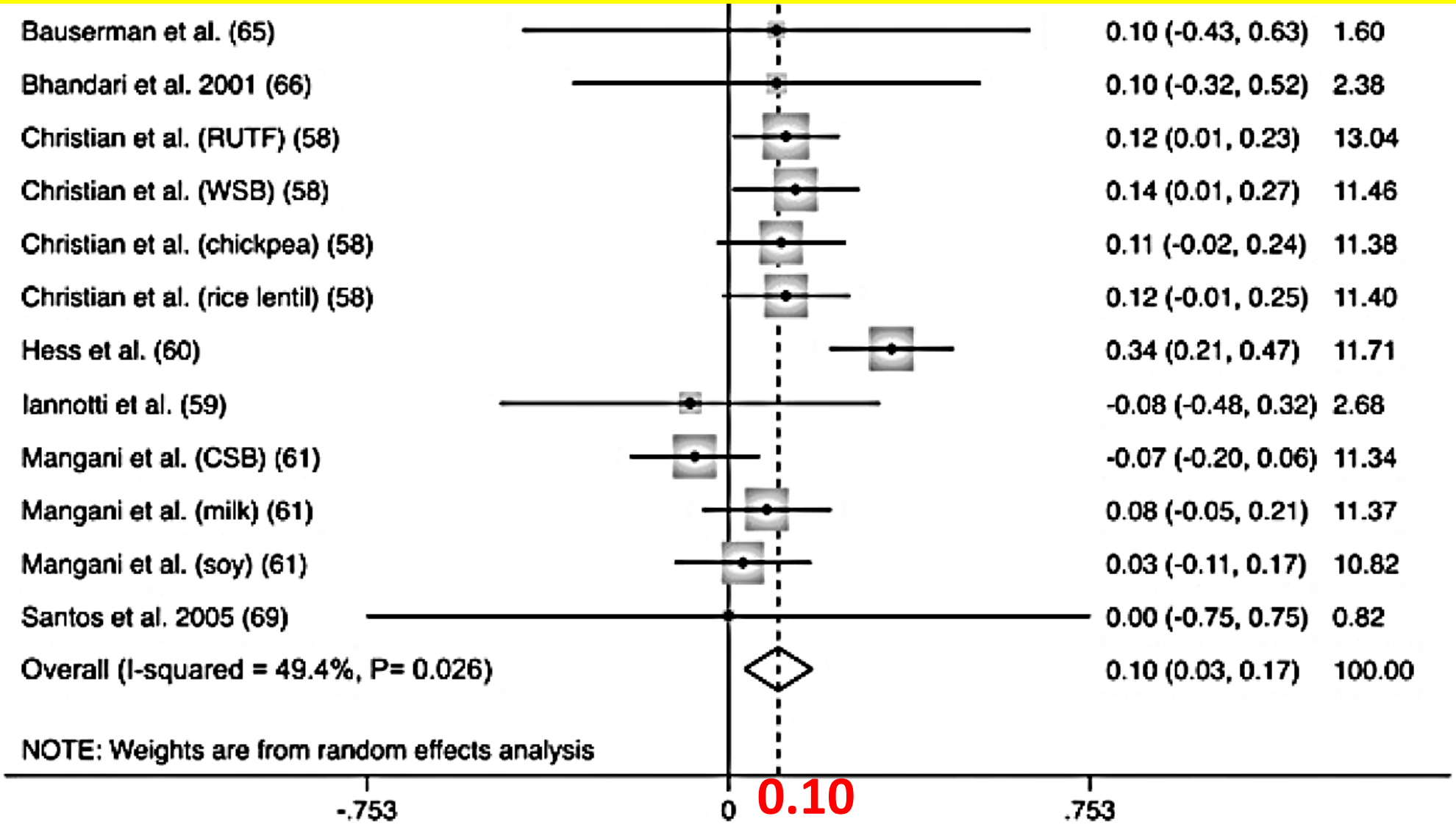
Causes of stunting remarkably poorly understood

Diet?
Diarrhea?

Effect of provision of food supplement on LAZ

Panjwani A and Heidkamp R: J Nutr September 2017

Unadjusted Mean Difference = **0.10** (0.03, 0.17) Z-score

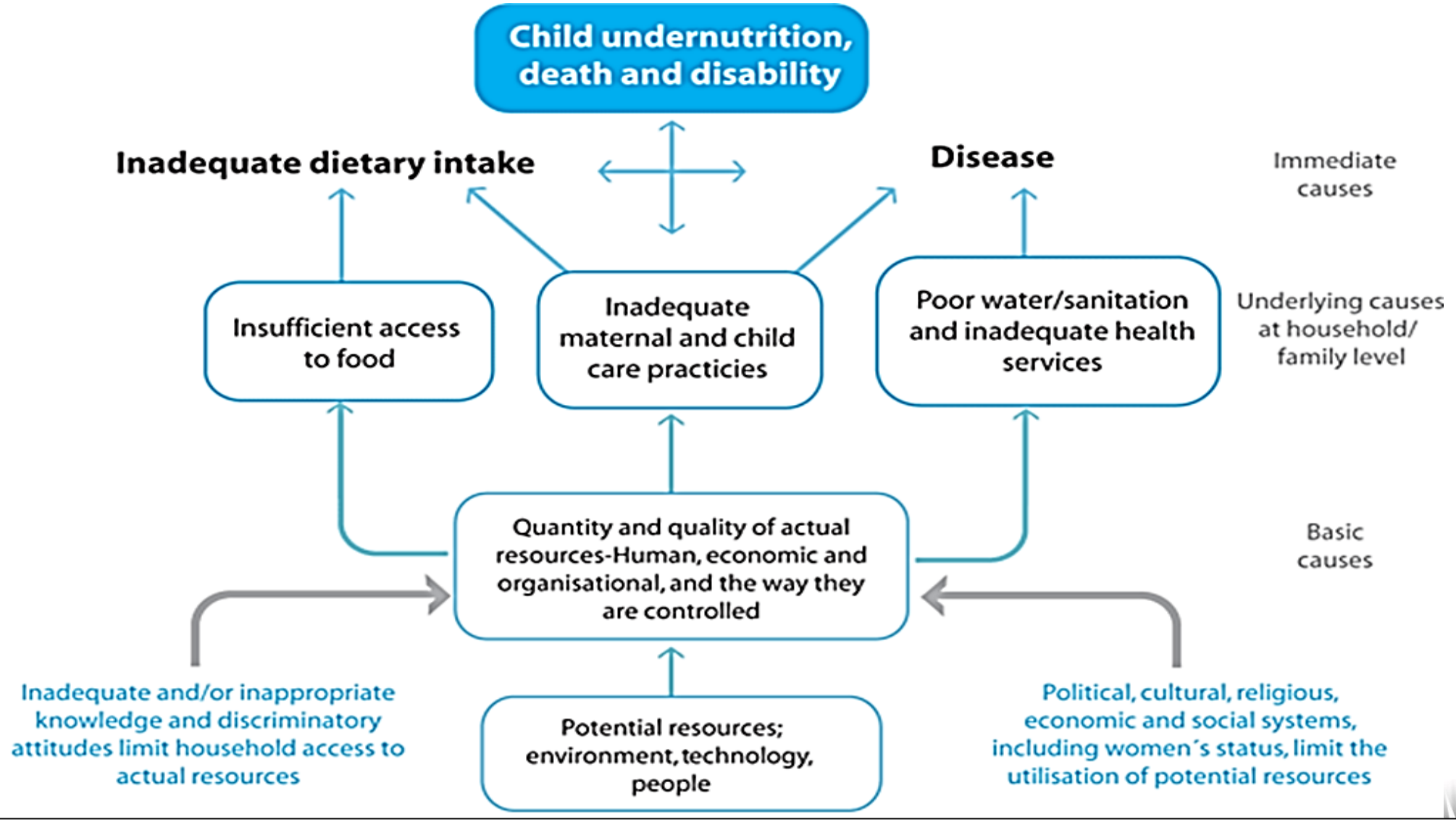


Diarrhea

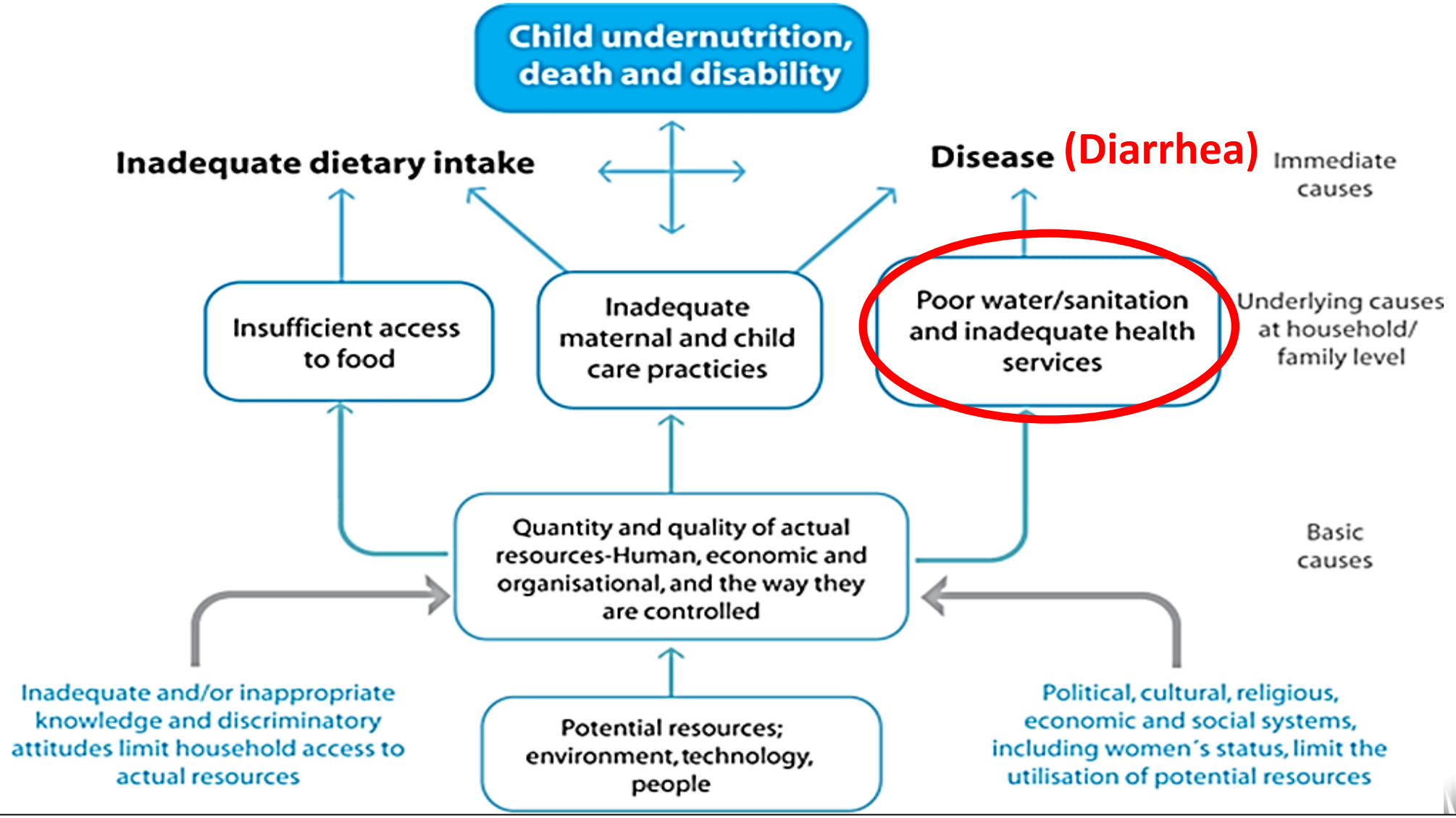
Analysis of 7 Studies of < 2 y children

Checkley, et al, *Am J Epi 2013*

- Average diarrhea burden = 23 days per year
- At 2 years a child who had had average diarrhea was 0.38 cm shorter compared to a child who had had no diarrhea.
- 0.38 cm at 2 years = 0.13 LAZ score



Source: **UNICEF**, Strategy for Improved Nutrition of Children and Women in Developing Countries, UNICEF, New York, **1990**



Source: **UNICEF**, Strategy for Improved Nutrition of Children and Women in Developing Countries, UNICEF, New York, **1990**

Determinants of stunting

65 papers published 2016-2017

Survey data from 137 LMIC countries

- In all but 2 reports at least one WASH factor was retained as an independent determinant of linear growth:
  - Sanitation: OD, any latrine, improved latrine, community sanitation coverage, exposure to open sewers
  - Hygiene: Caregiver or child handwashing, presence of soap
  - Water: improved source, on plot, fetching time, filtration, storage, treatment,
  - Baby WASH: Geophagia and infant feces disposal
  - Combination of WASH inputs

Hypothesis:

Adverse effects of poor WASH on linear growth are partially mediated through diarrhea but primarily through EED

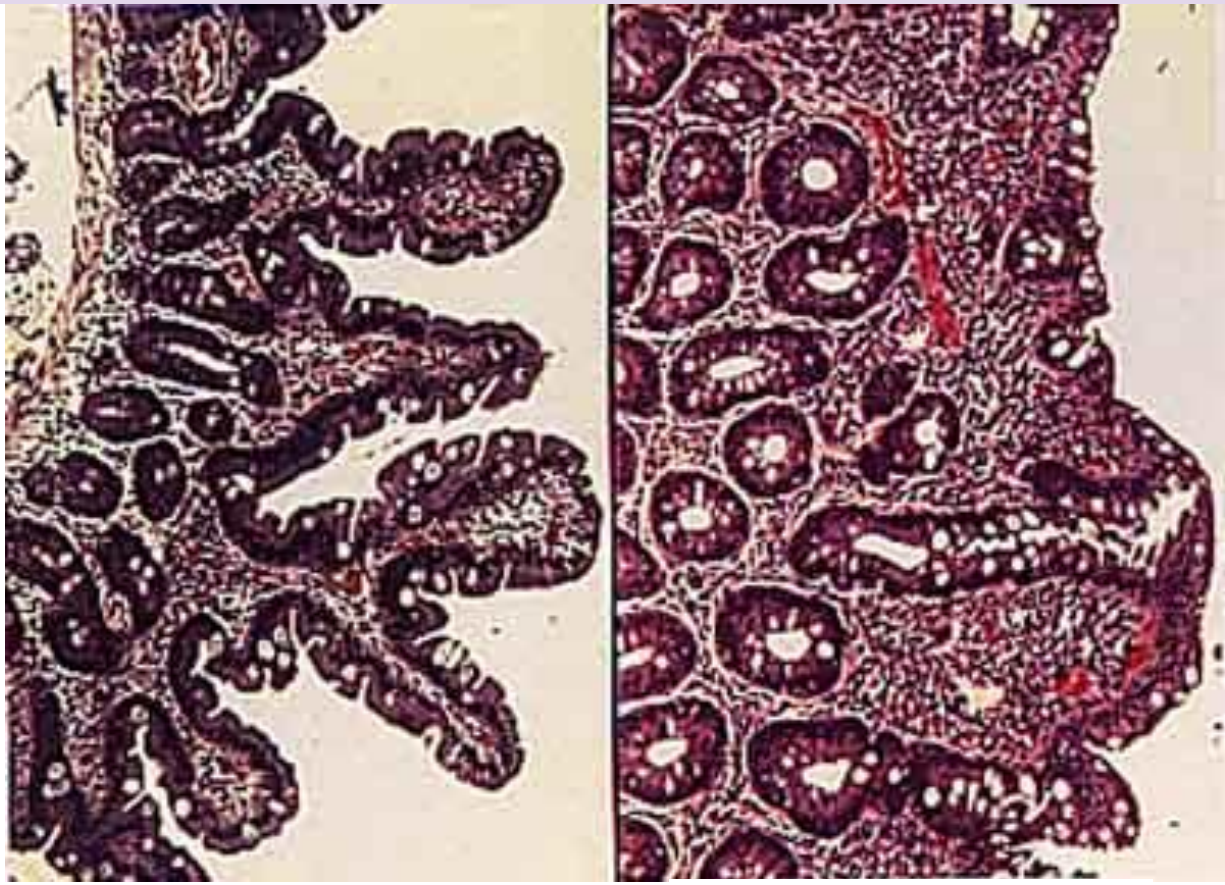
Humphrey Lancet 2009; 374:1032

Environmental Enteric Dysfunction (EED)

- Asymptomatic
- Gut is
  - Flat
  - Inflamed
  - Permeable
- Reduced absorption

  Increased microbial translocation

  Increased immune activation
- Virtually ubiquitous among people in impoverished living conditions



Normal EED

Hypothesis

- Adverse effects of poor WASH on linear growth are partially mediated through diarrhea but primarily through EED
- EED can be reduced by WASH interventions that protect children from ingesting feces and are delivered at the household level
- EED also suppresses iron mobilization an erythropoiesis resulting in anemia
- The effects of adequate diet on stunting will be ADDITIVE to those of protection from feces ingestion.

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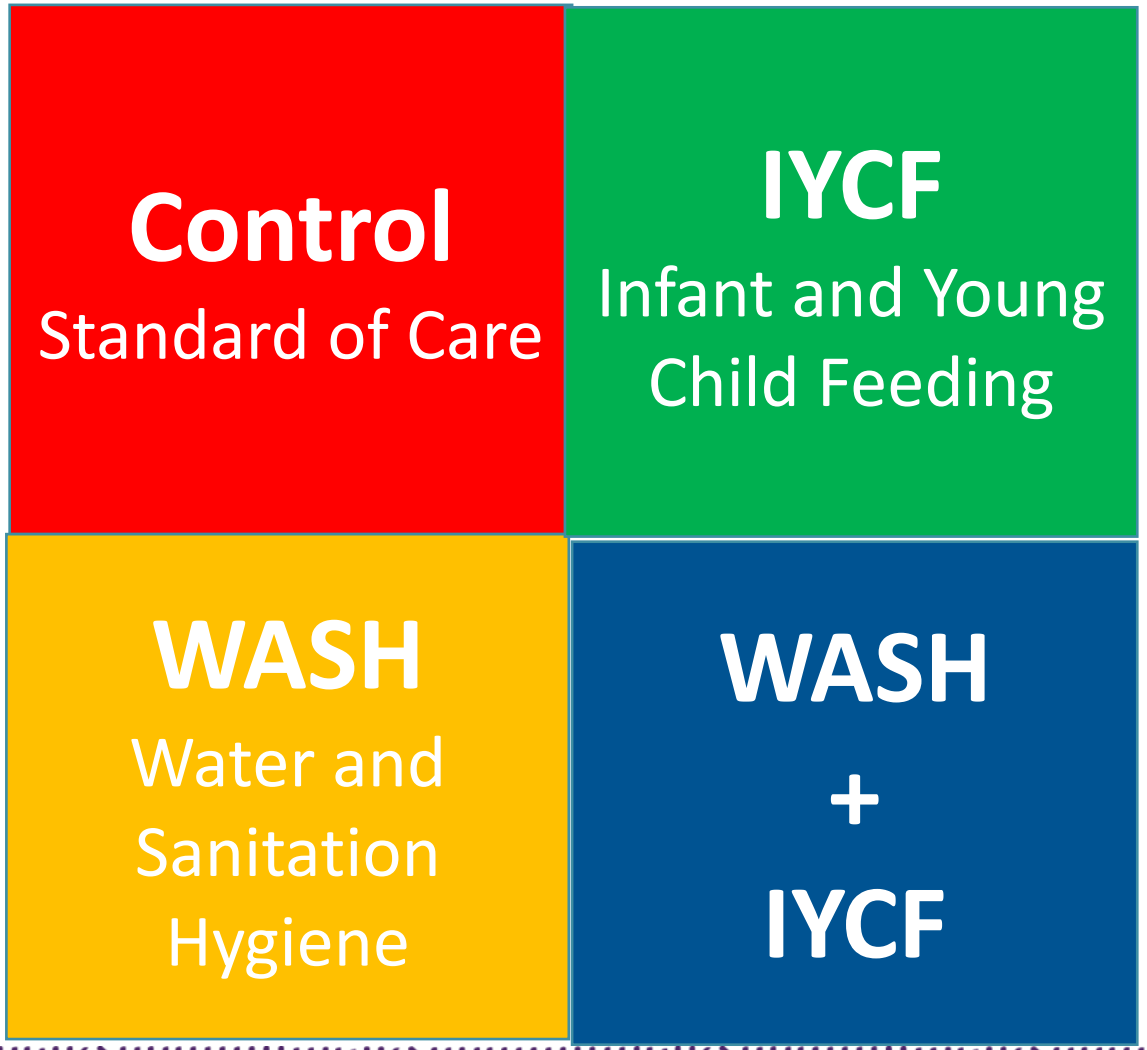
Design and Methods

2 x 2 factorial design: **independent** and **combined** effects



Study population:

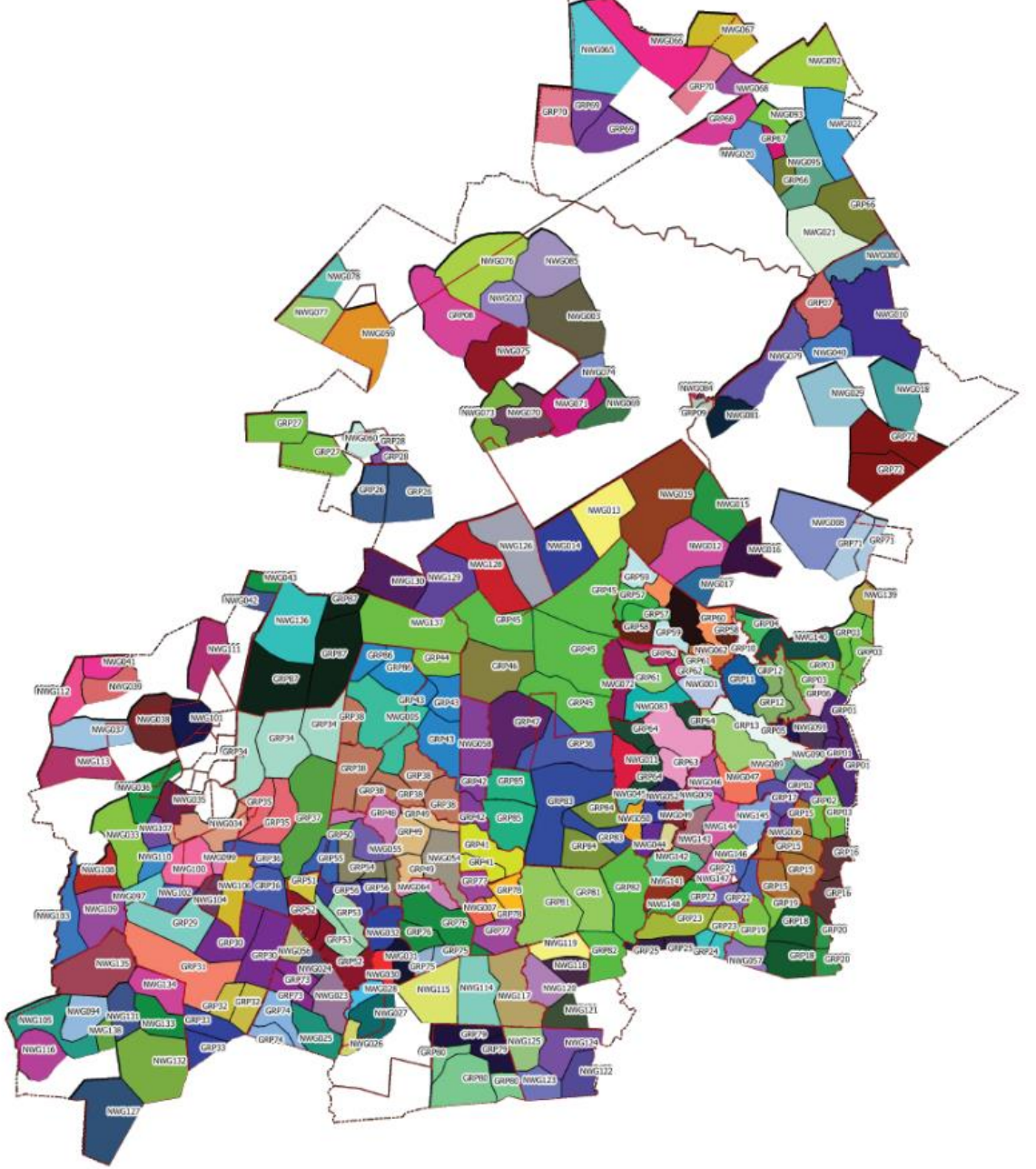
Women in Chirumanzi and Shurugwi districts who became pregnant between November 2012 - March 2015

400 Village Health Workers (VHWs)
employed by
Zimbabwe Ministry of Health and Child Care (MoHCC)

- Conducted prospective pregnancy surveillance
- Referred to SHINE
- 5280 women recruited
- Median (IQR) age at enrolment:
  12.5 (9,16) wk gestation

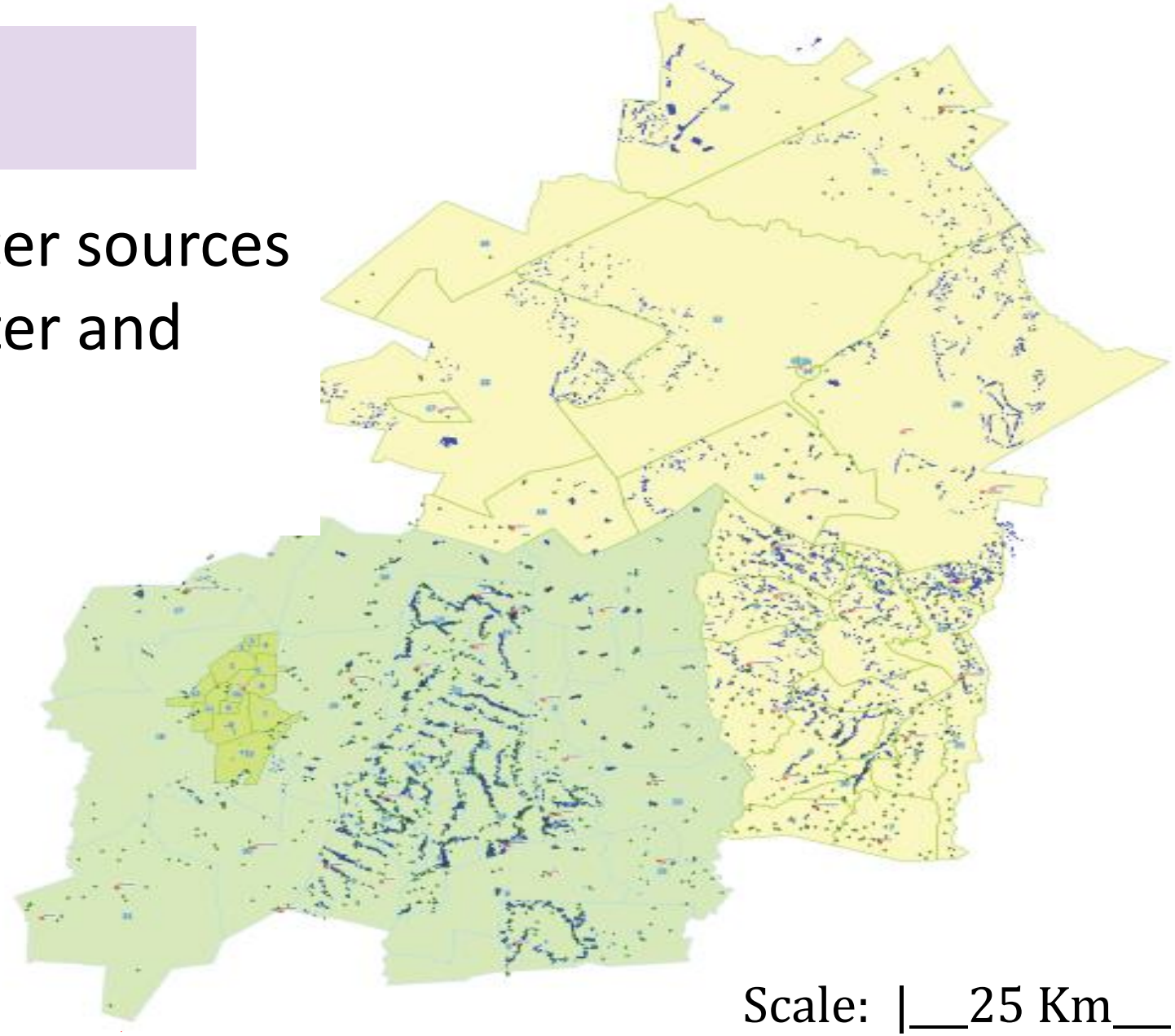
Cluster randomized

- 212 Clusters
- Defined as catchment area of 1 -4 VHW's

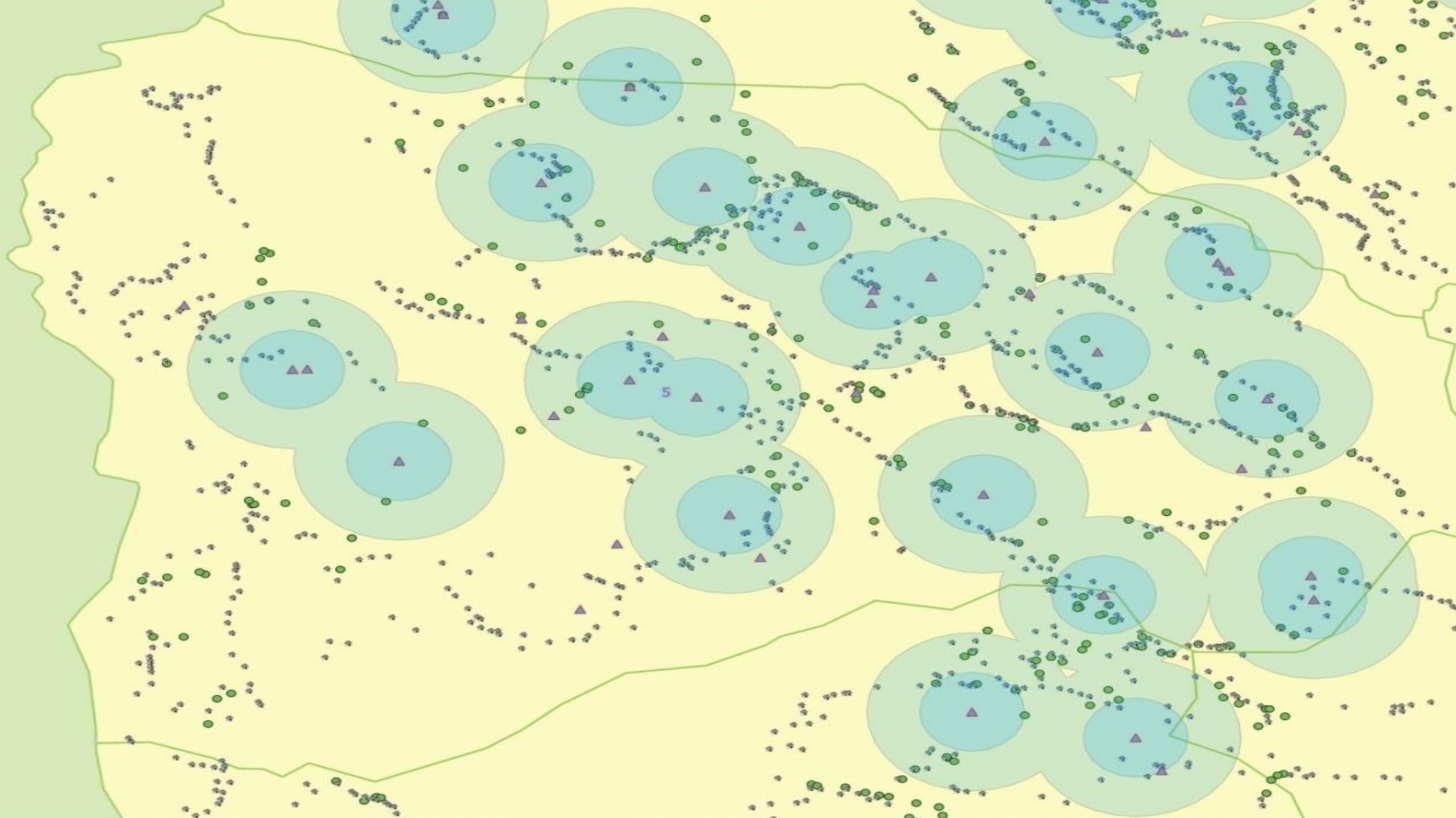


Water survey

- Inspected all 6108 water sources
- GIS coordinates of water and homesteads

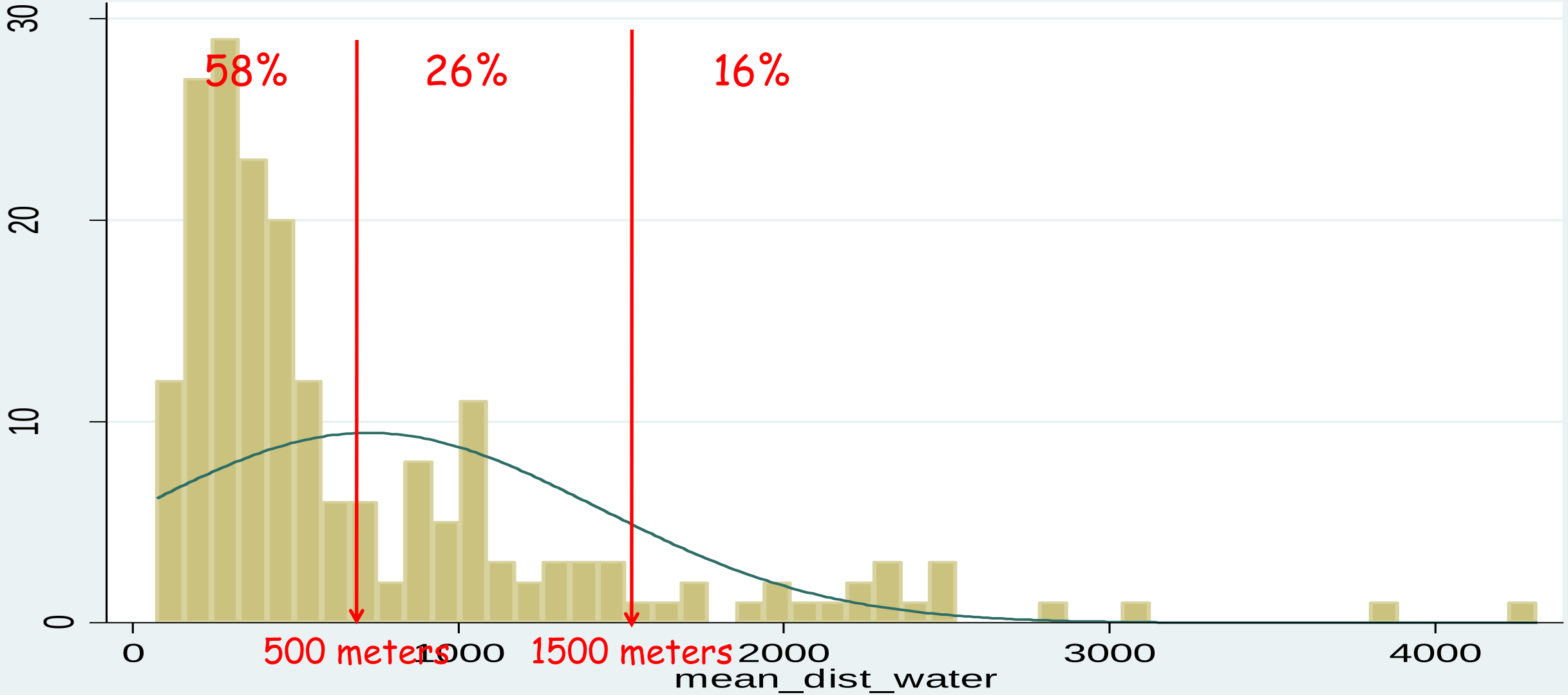


Scale: |___25 Km___|


5

Calculated:

% households <500 meters and >1500 meters in each cluster



4 field offices established

- Data Management
- Laboratory: specimen processing and -80^{o}C storage
- Located so that all homes within a 2 hour motorcycle ride of an office

Interventions

400 VHWs

Delivered treatment-arm-specific behavior-change interventions at 15 infant age-specific visits

Outcome assessment

43 Research nurses:

Assessed outcomes at:
14, 32 wk gest & 1, 3, 6, 12, 18 mo

Assessed intervention uptake at 12 mo

Outcomes assessed at 18 months infant age

Primary

- LAZ
- Hemoglobin

Secondary

- Stunted
- Anemic
- Diarrhea at 12 and 18 months
- Mortality

Early Child Development Substudy

Primary inferences from HIV-unexposed infants

(results from HIV-exposed infants will be reported separately)

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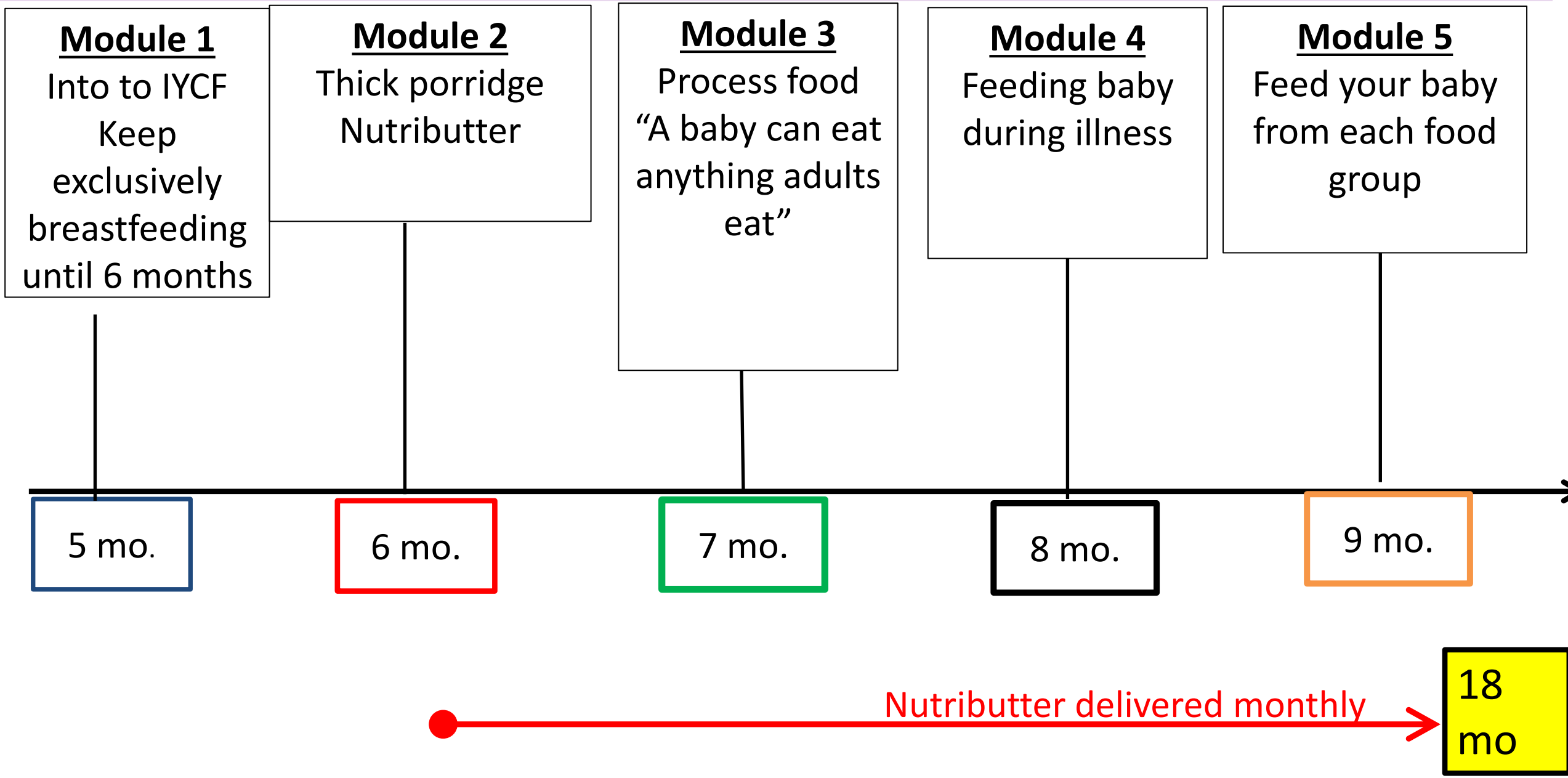
Interventions

All children received the Standard of Care (Control) interventions

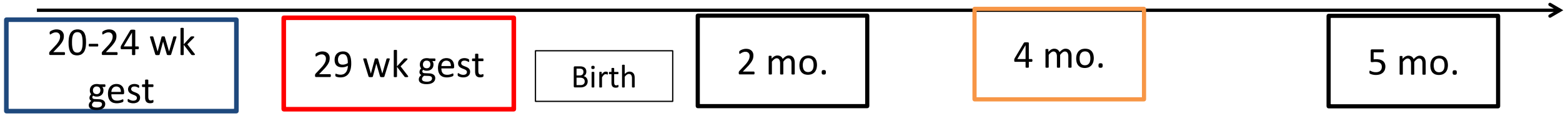
- Exclusive breastfeeding intervention
- Promoted uptake:
  - ANC
  - PMTCT
  - Immunization
  - Family Planning

The IYCF Intervention



The WASH Intervention

5 Core Modules



The WASH Intervention

Module 1
Put all feces in latrine.
Latrine constructed

20-24 wk gest

Use latrine

18 mo

Centralized brick and slab moulding

Community builders

MoHCC supervised

2500 WASH latrines at enrolment

2500 Non-Wash latrines after trial

The WASH Intervention

Module 1
Put all feces in latrine.
Latrine constructed
Tippy Taps installed

Module 2
Handwashing with soap at key times
Soap delivered

20-24 wk gest

29 wk gest

Use latrine

Soap delivered monthly

18 mo

The WASH Intervention

Module 1
Put all feces in latrine.
Latrine constructed Tippy Taps installed

Module 2
Handwashing with soap at key times
Soap delivery

Module 3
Protect child from feces and soil ingestion
Play space and mat delivered

20-24 wk gest

29 wk gest

Birth

2 mo.

Use latrine

Soap delivered monthly

18 mo

The WASH Intervention

Module 1
Put all feces in latrine.
Latrine constructed Tippy Taps installed

Module 2
Handwashing with soap at key times
Soap delivery

Module 3
Protect child from feces and soil ingestion
Play space and mat delivered

Module 4
Treat drinking water especially for infant after EBF
Water Guard delivery

20-24 wk gest

29 wk gest

Birth

2 mo.

4 mo.

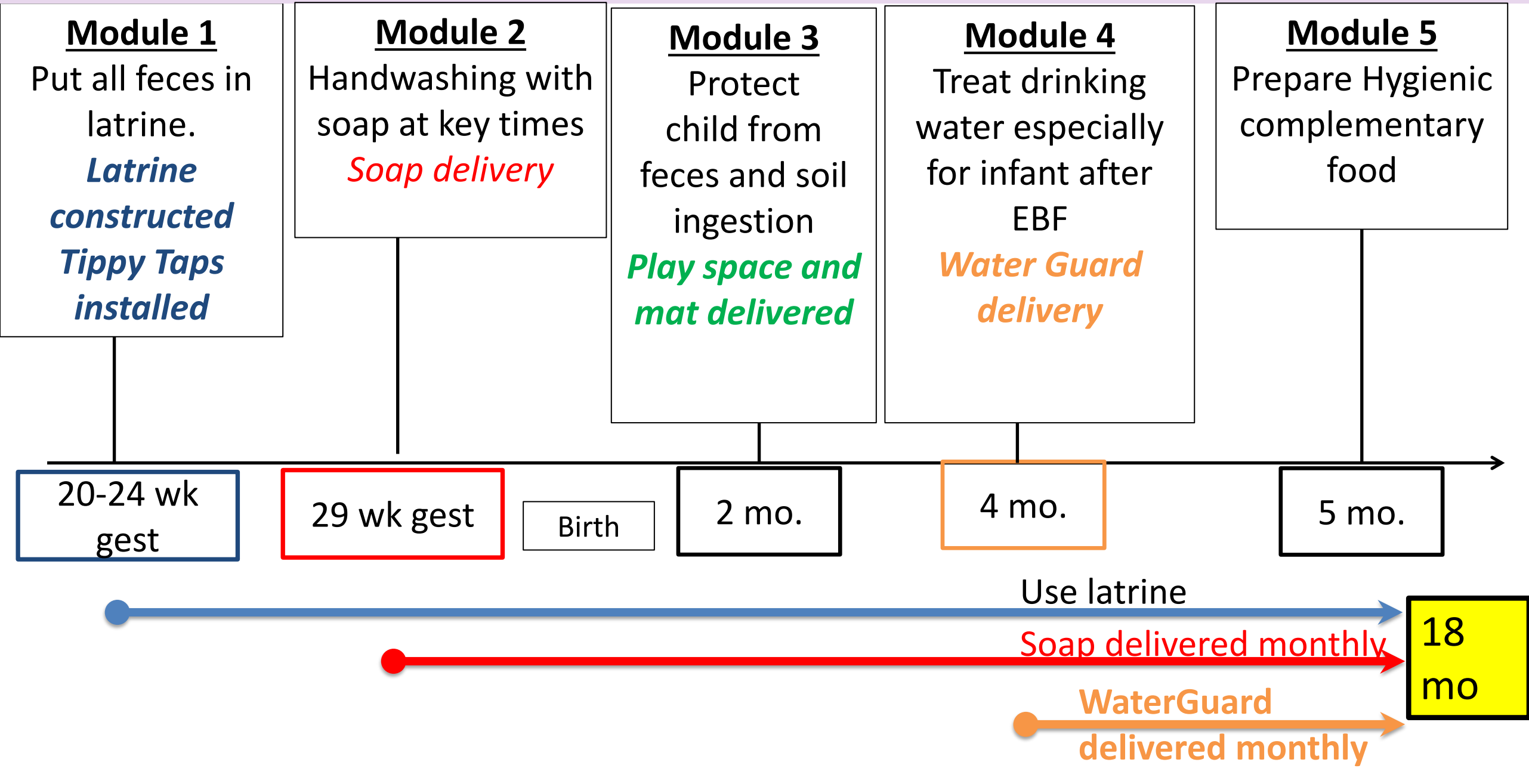
Use latrine

Soap delivered monthly

WaterGuard delivered monthly

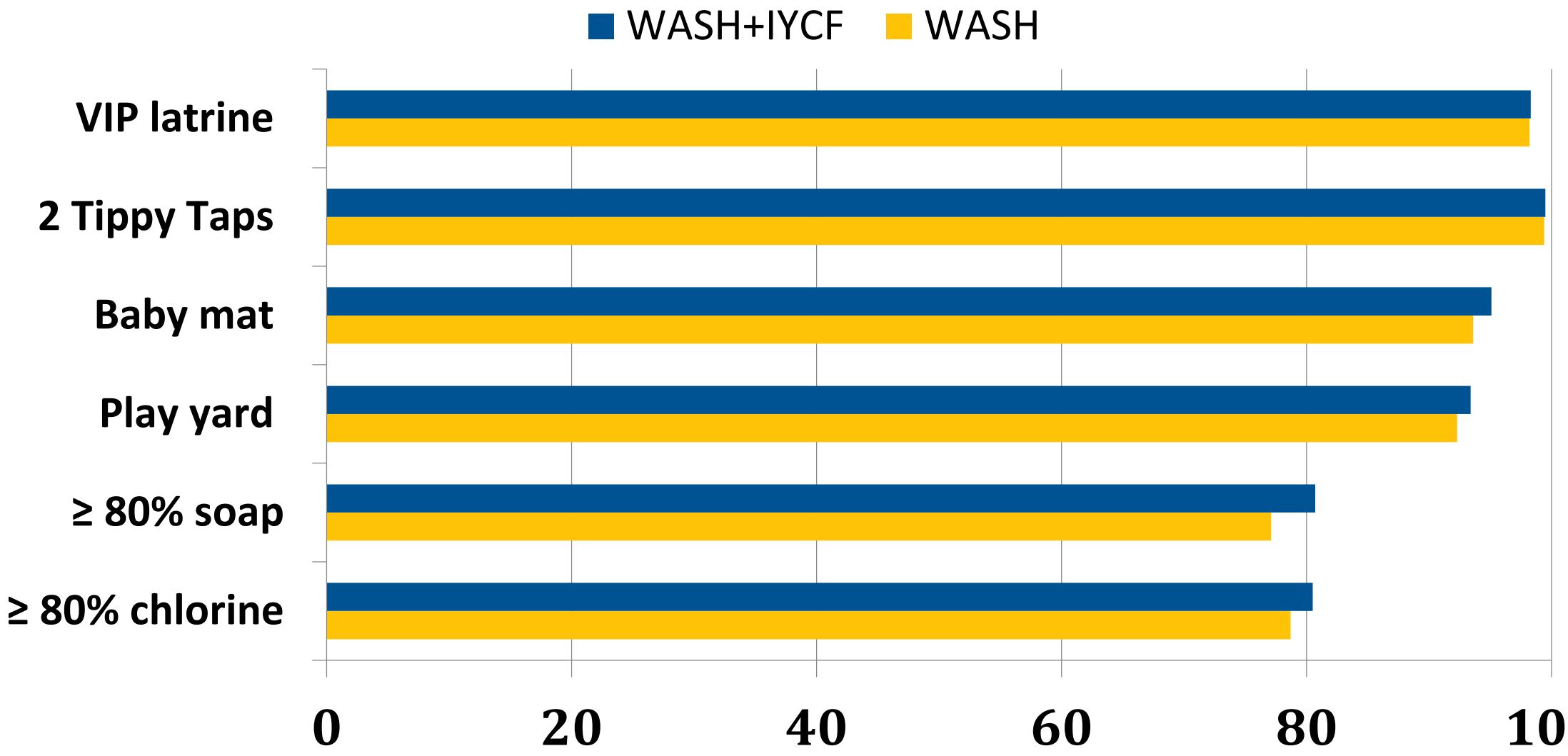
18 mo

The WASH Intervention

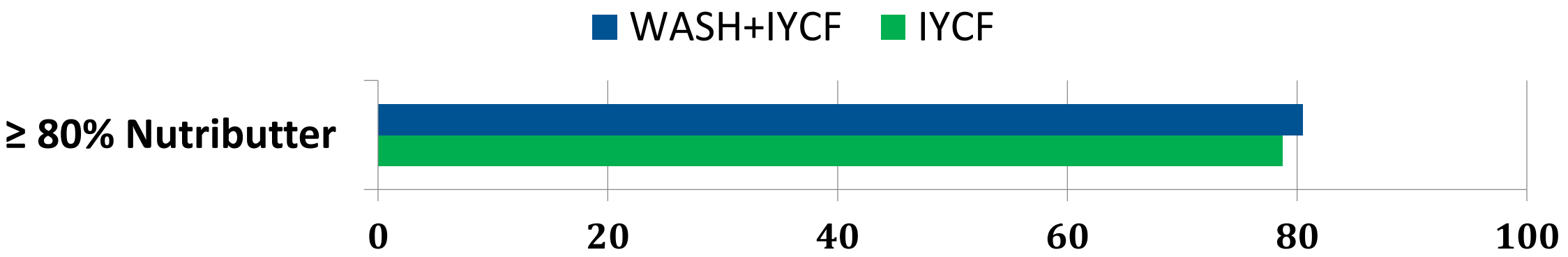


Fidelity of Intervention Delivery

% WASH Households receiving commodities

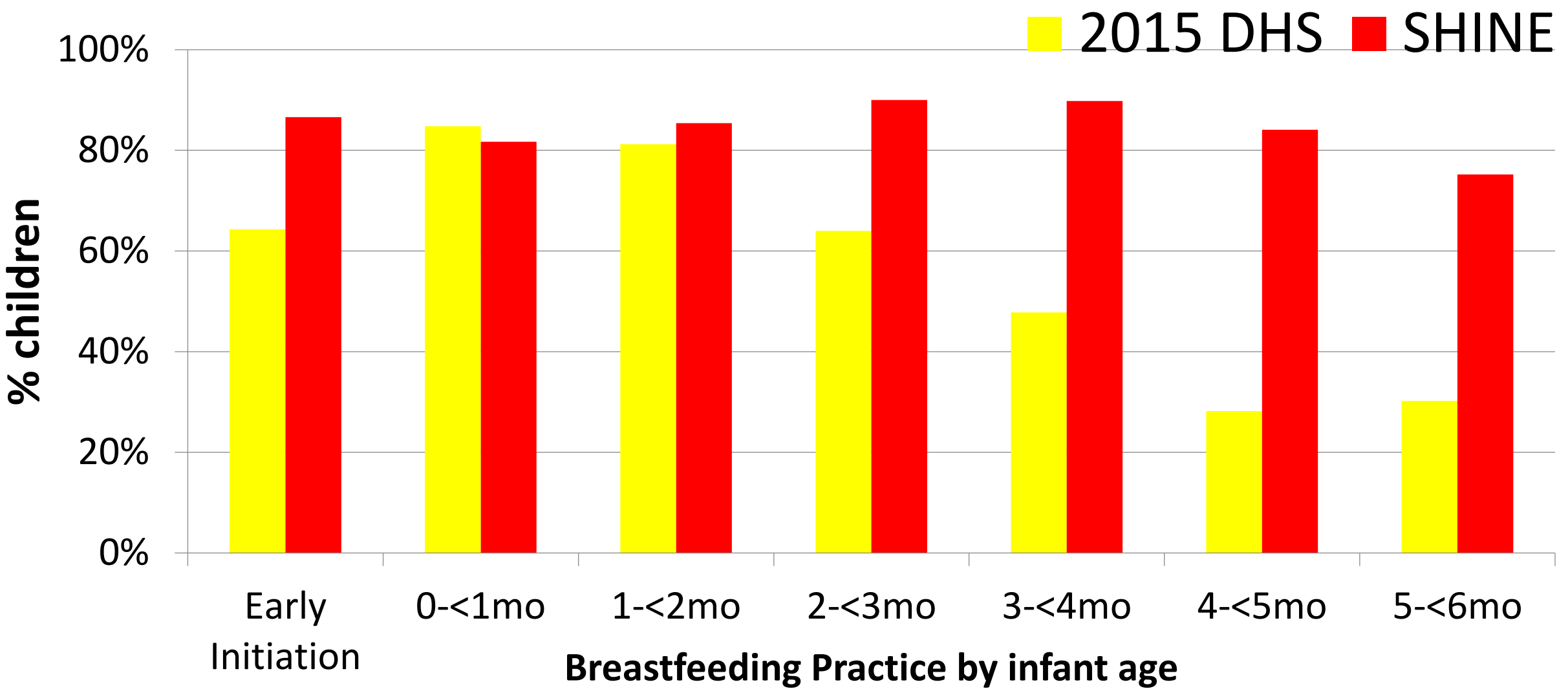


% IYCF household receiving commodities

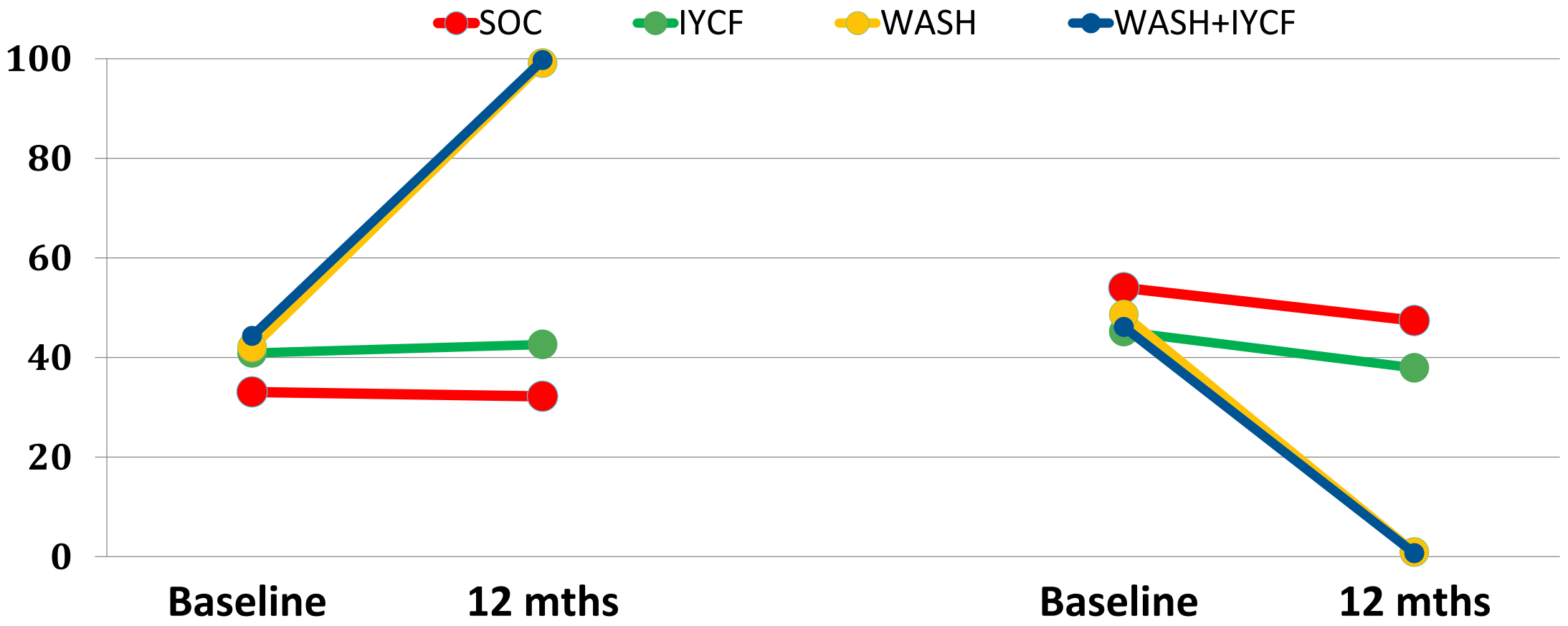


Intervention uptake

SOC Uptake: **Early Initiation and Exclusivity of Breastfeeding:** SHINE compared to rural 2015 DHS



WASH uptake: **Any Latrine** & **Open Defecation**



Any latrine at household

% Household members openly defecating

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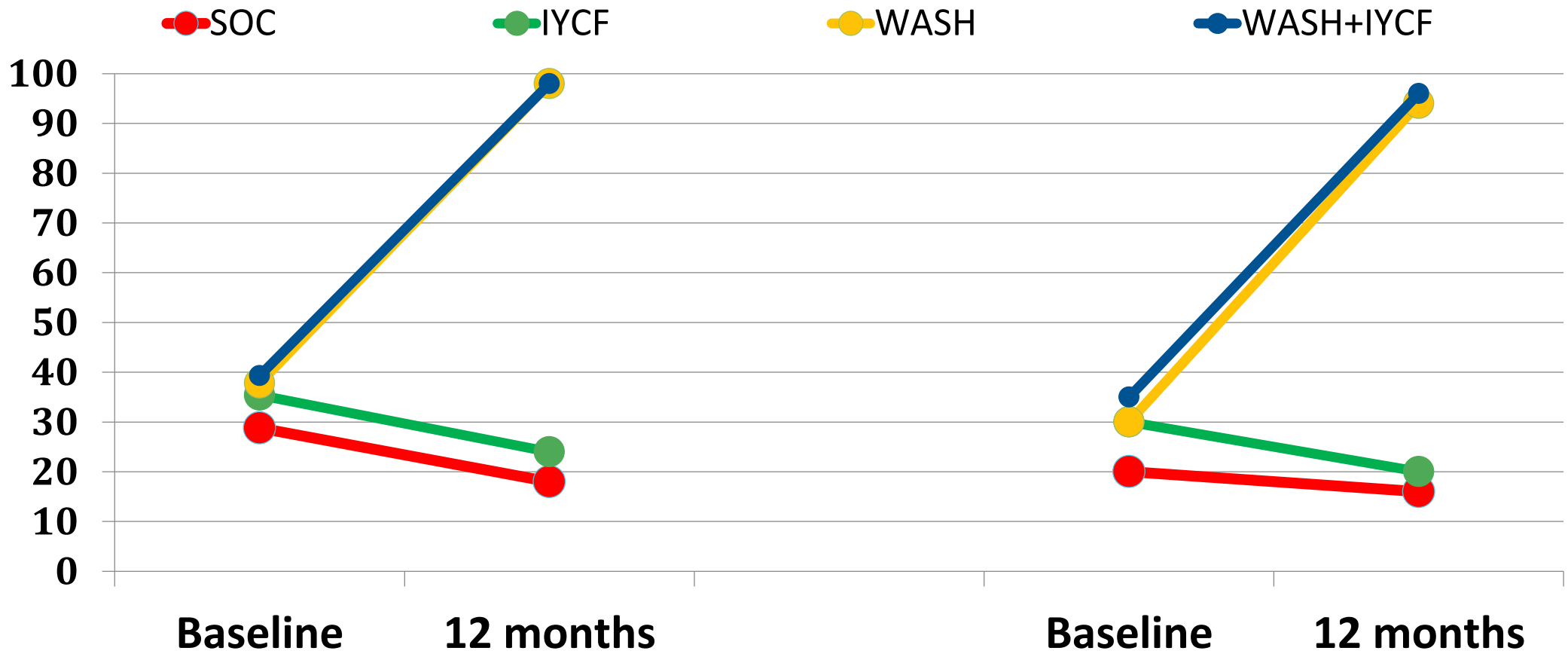
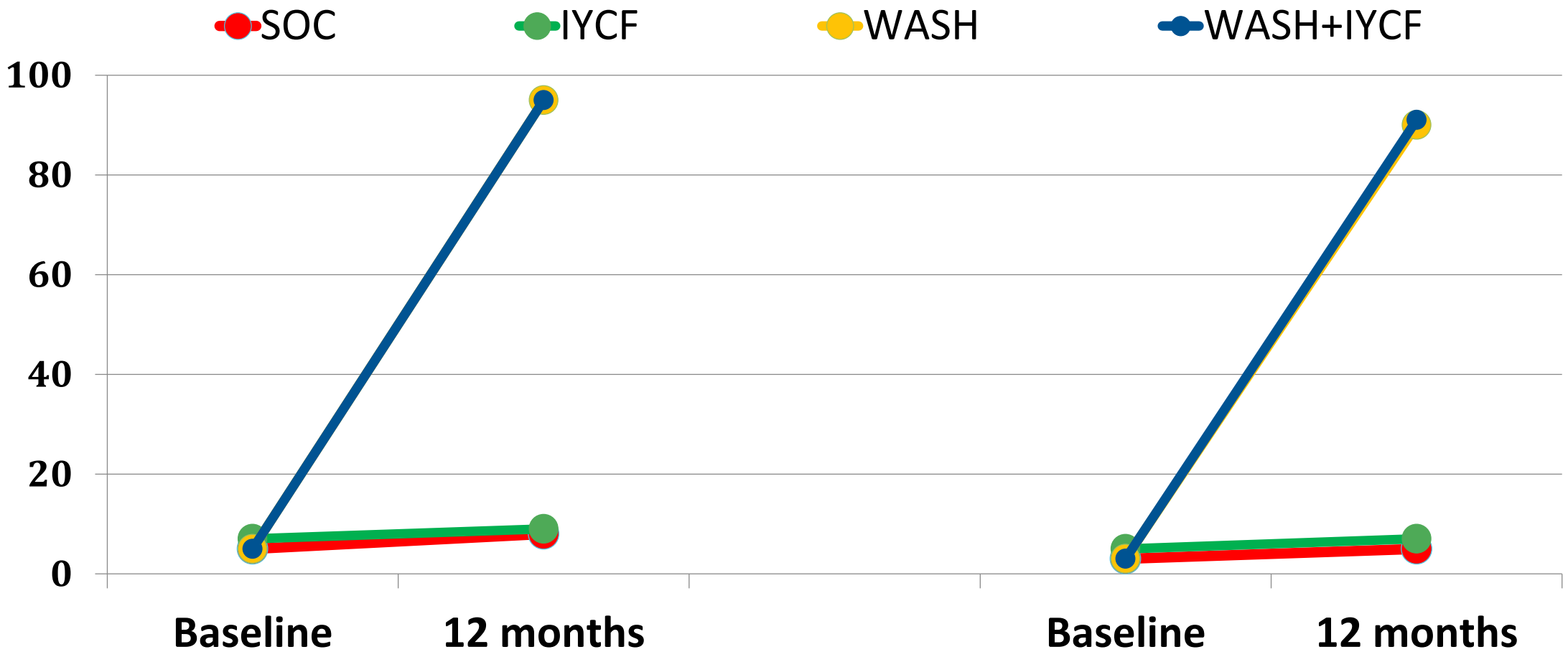
WASH uptake: Improved Latrine



Improved latrine

Improved latrine
+ Well-trodden path
+ Not shared
+Not used for storage

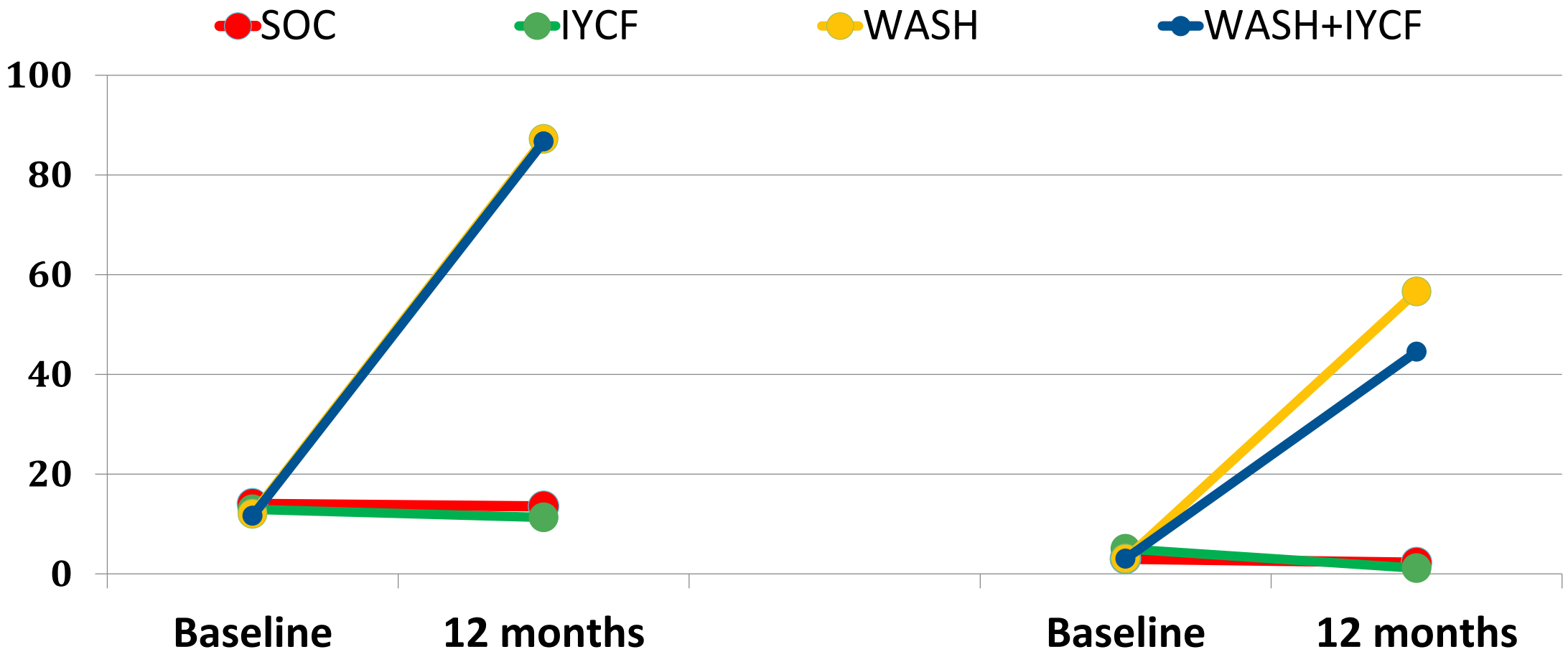
WASH uptake: Hand-washing station



Any hand-washing station

Hand-washing station
+ Water
+ Soap/Rubbing Agent

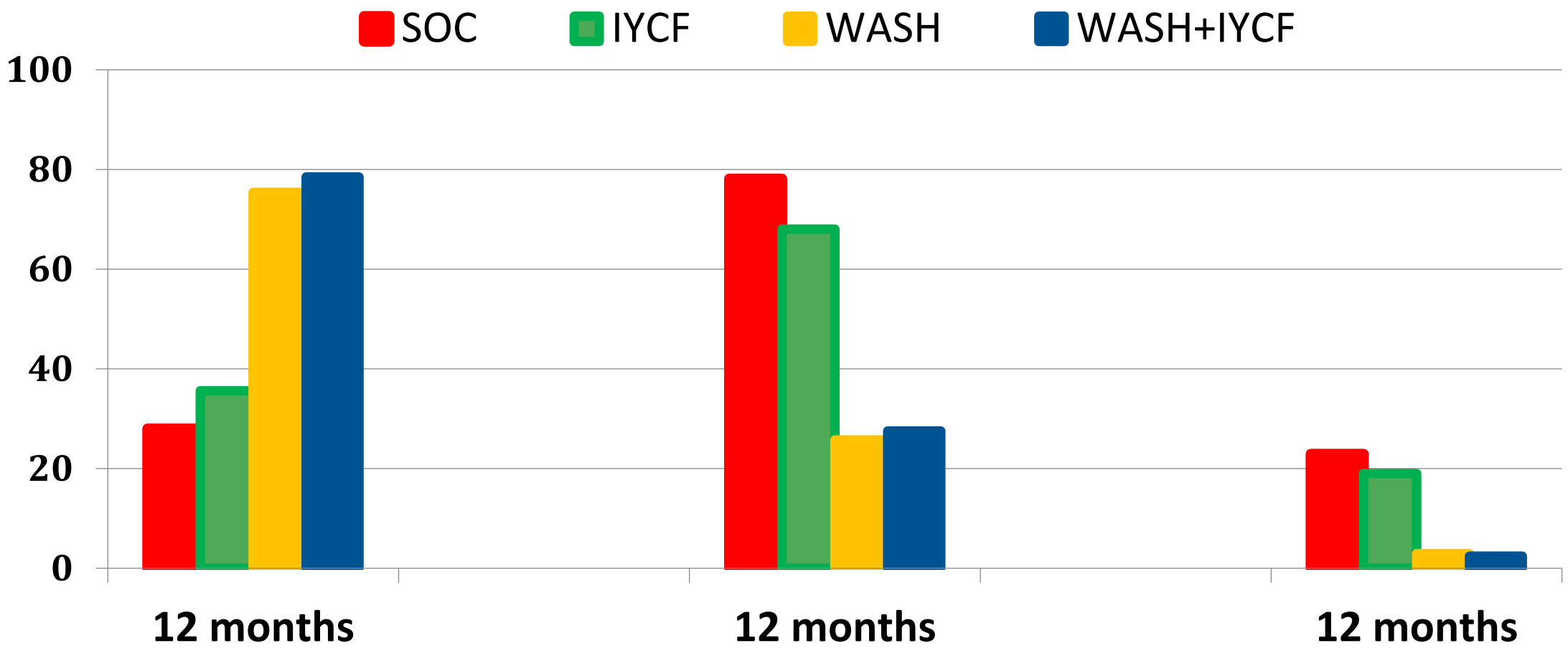
WASH uptake: Water Treatment



Usually treats drinking water

Treated drinking water
+ in past 7 days
+ with chlorine
+ Free Chlorine >0.1 ppm

WASH uptake: Infant feces disposal and geophagia

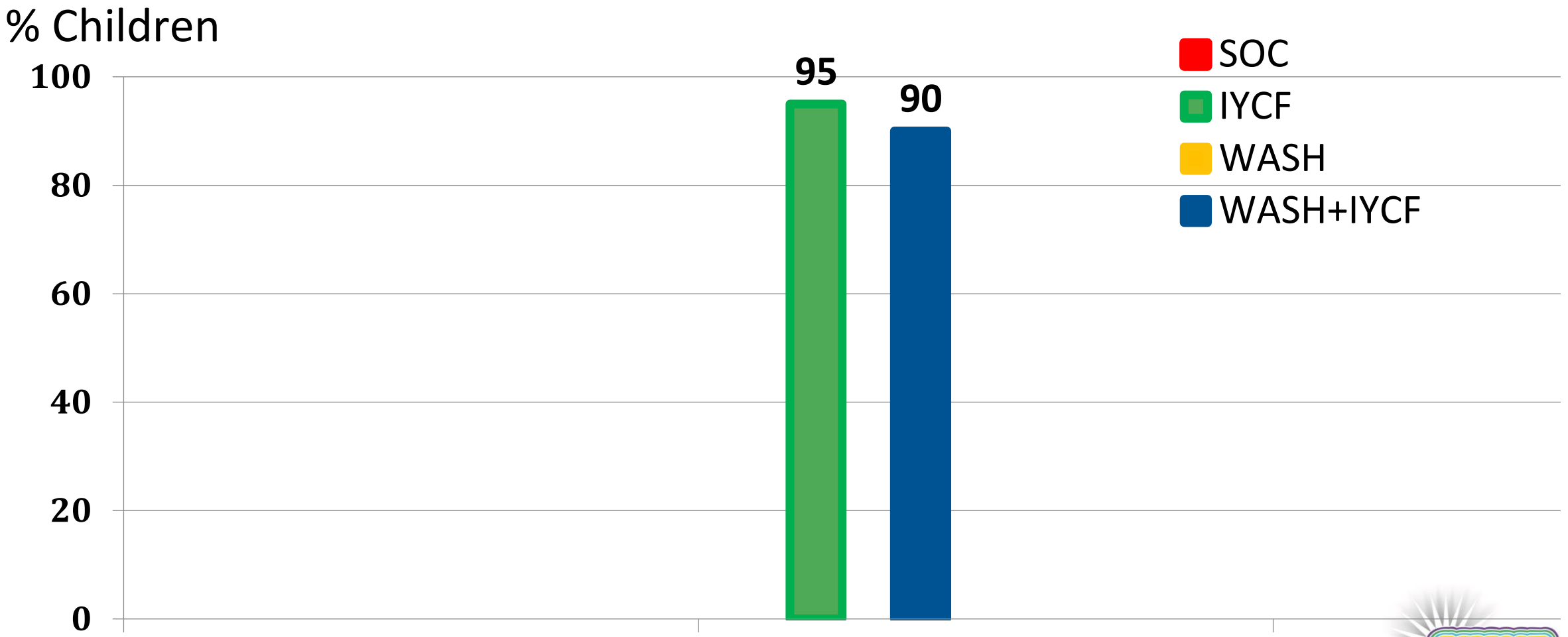


Disposes nappy water in latrine

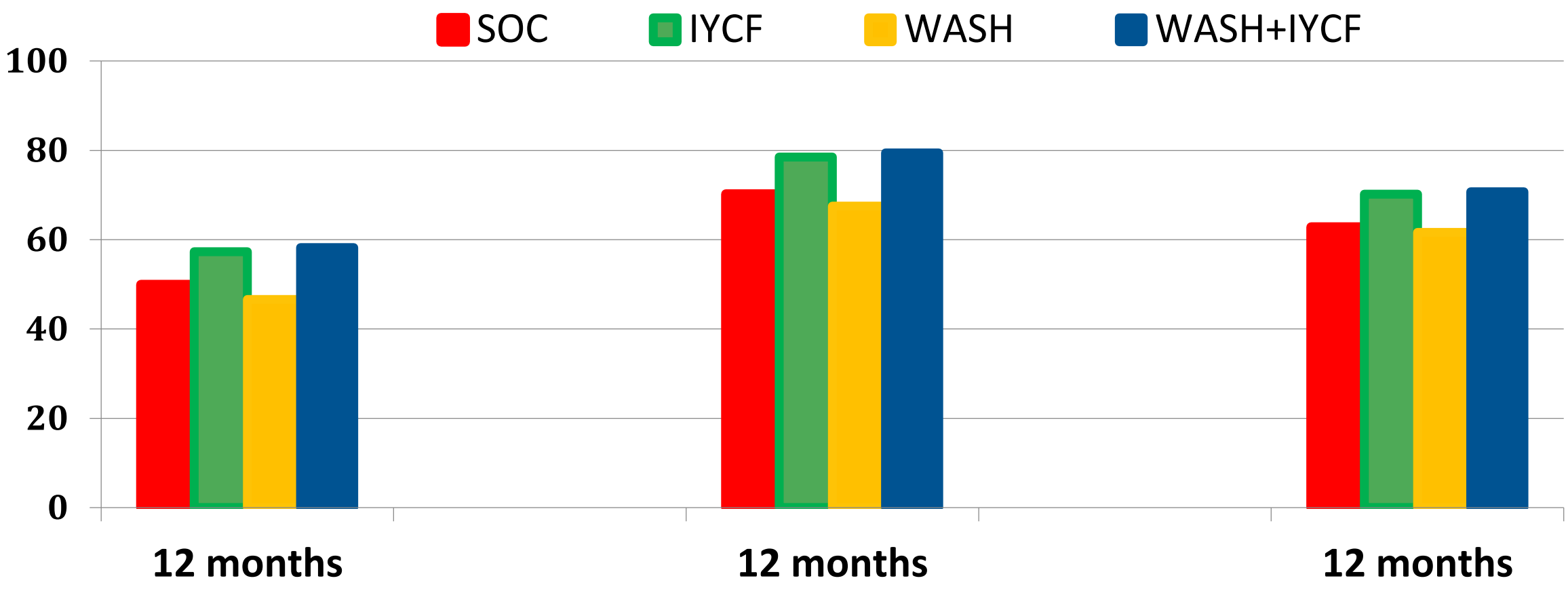
Child ever observed to eat soil

Child ever observed to eat chicken feces

IYCF uptake: Consumed Nutributter past 24 hours



IYCF uptake: Child diet quality (without Nutributter)



Iron-rich food consumed

Vitamin A-rich food consumed

Animal-source food consumed

Measurement of Outcomes

Baseline

Household Characteristics, including:

- Sanitation, Water, Hygiene
- Food security
- Asset index

Maternal Characteristics, including:

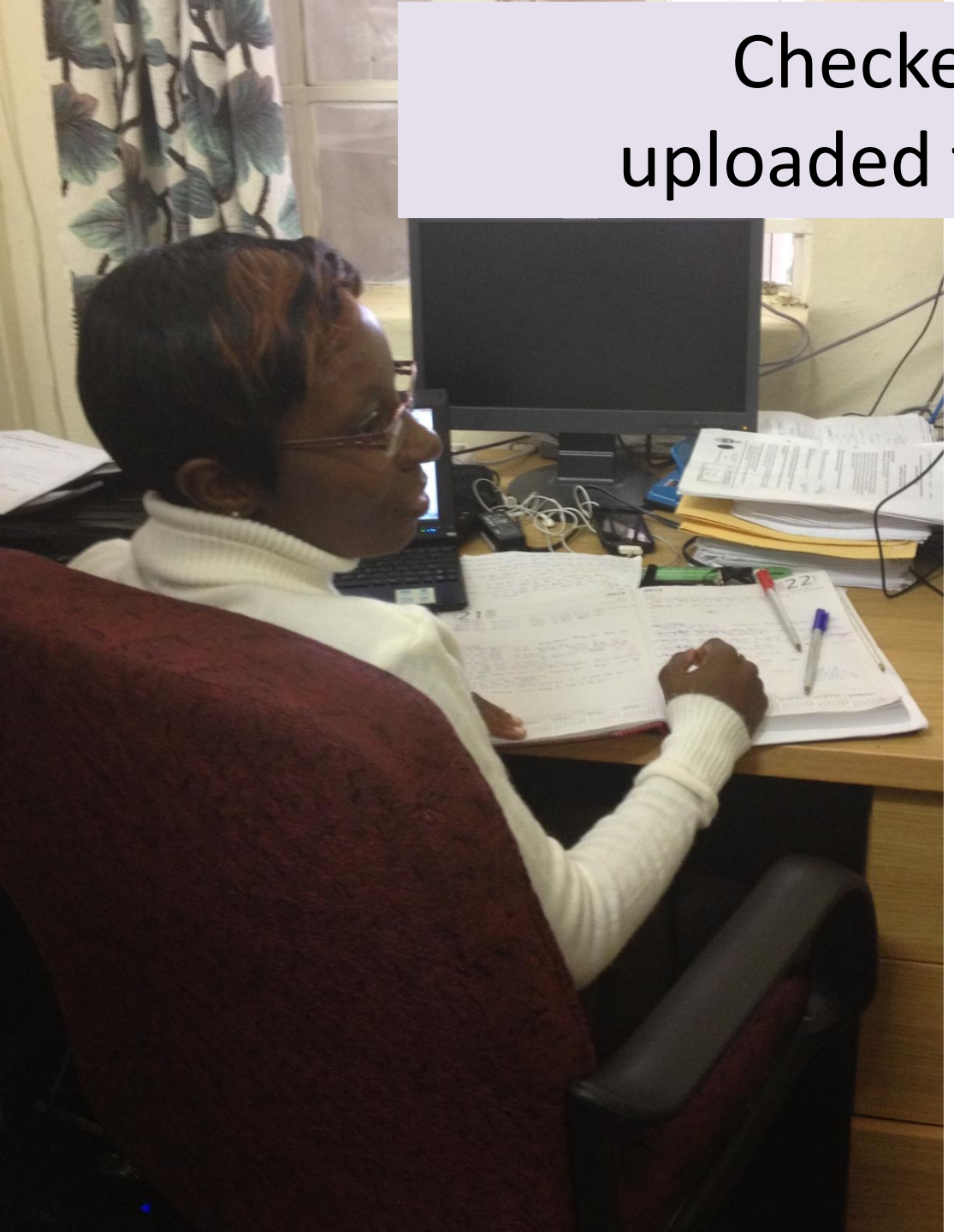
- Height
- Education
- HIV status

Birth date and weight transcribed from health records

Infants assessed by research nurses during home visits at 1, 3, 6, 12, and 18 mo

Questionnaire data entered on netbooks

Checked at field office, uploaded to Harare overnight



Data Analysis: Modified Intent to Treat

Modified: Randomized clusters,
Enrolled pregnant women

Intent to treat: All babies assessed at 18 months are included in primary analyses regardless of how much intervention they received.

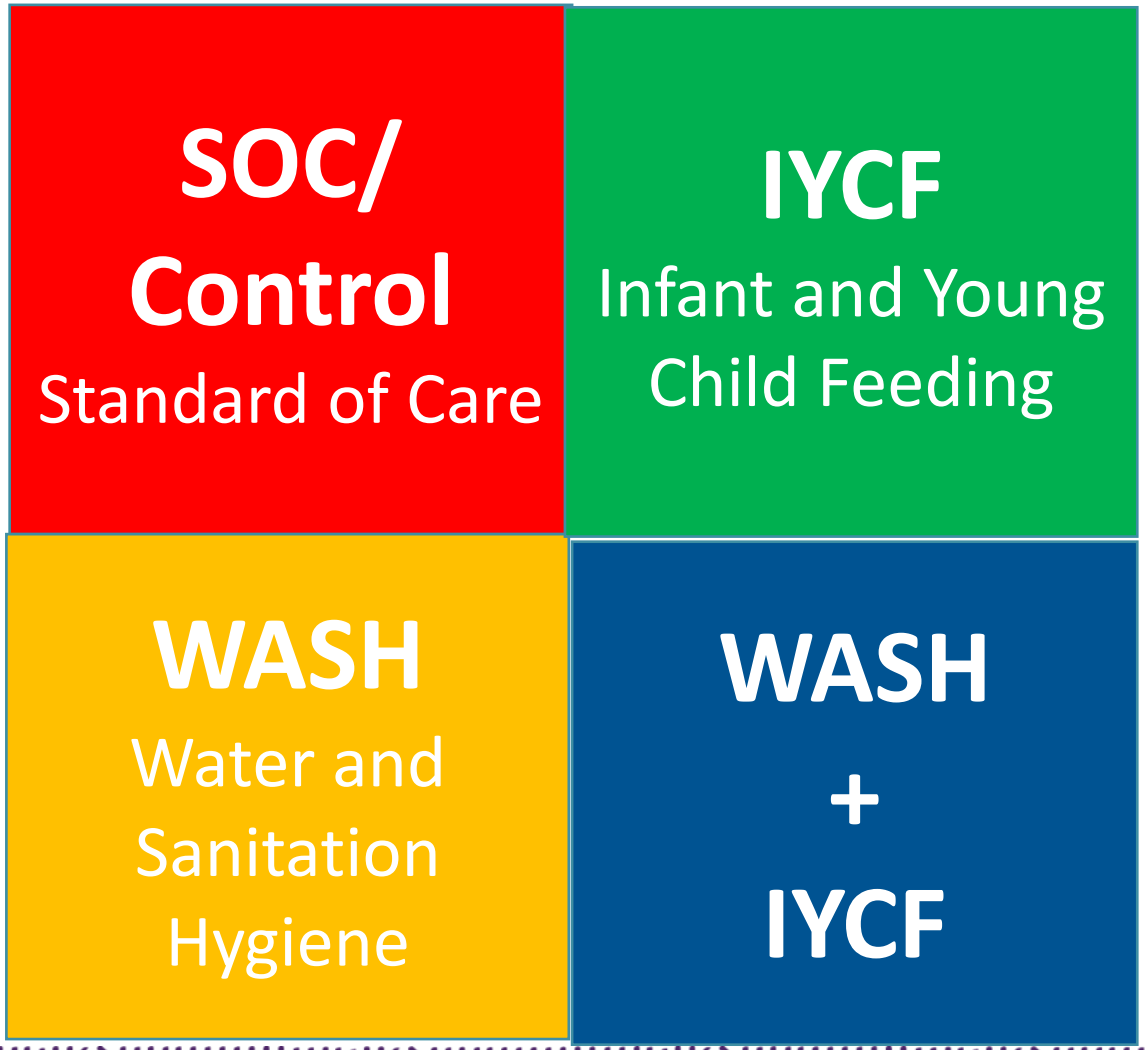
Data Analysis

Unadjusted Analyses: GEE regression models adjusted only for within-cluster correlations

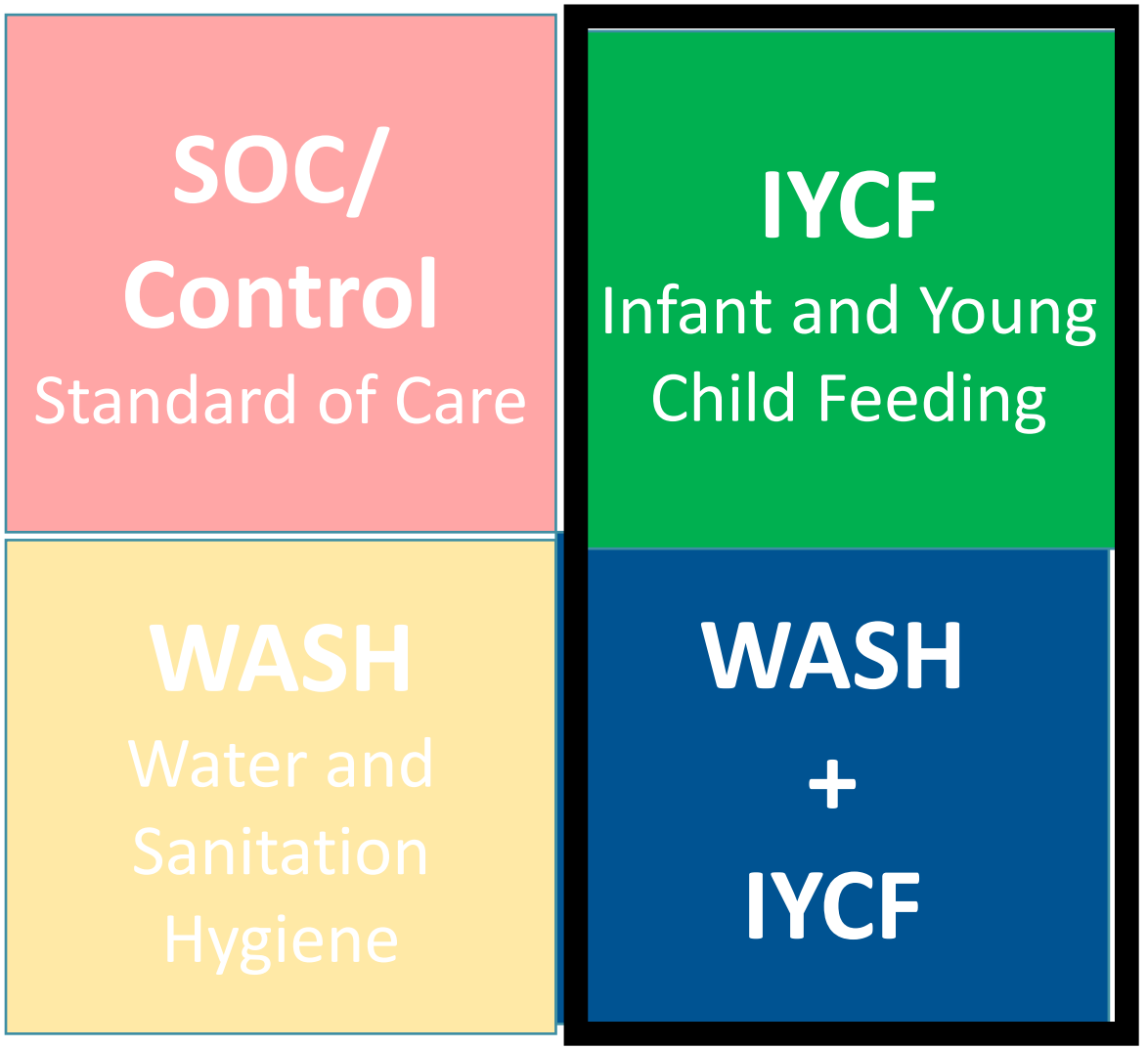
Adjusted Analyses: GEE regression adjusted for cluster and other baseline covariates

- Covariates considered were pre-specified.
- Initially assessed in bivariate analyses to identify those with an important association with outcome
- Offered to GEE model, backward step-wise elimination, retaining those with $p<0.2$.

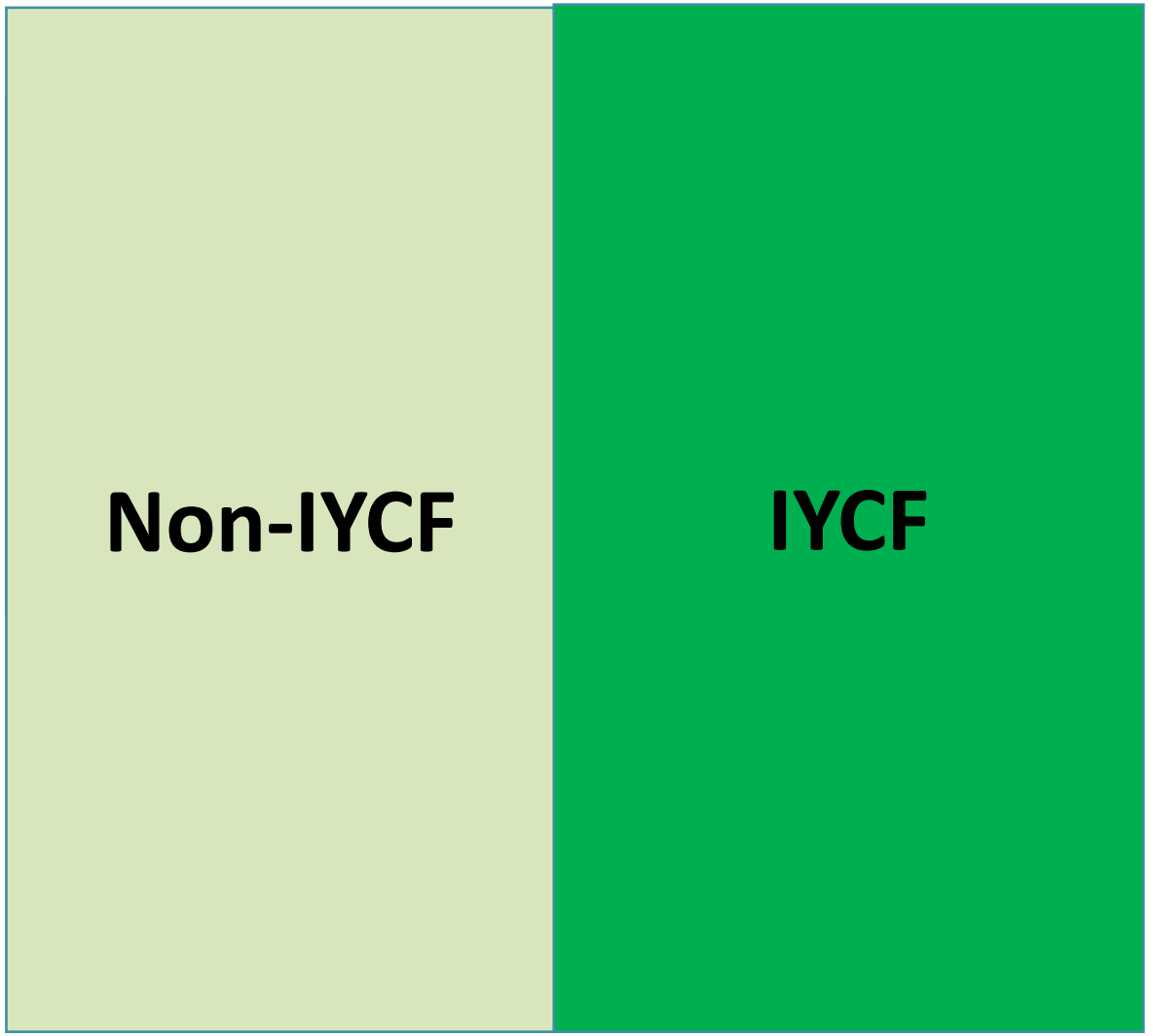
2 x 2 factorial design: **independent** and **combined** effects



IYCF arms


SOC/
Control
Standard of Care
IYCF
Infant and Young
Child Feeding
WASH
Water and
Sanitation
Hygiene
WASH
+
IYCF

IYCF arms



WASH arms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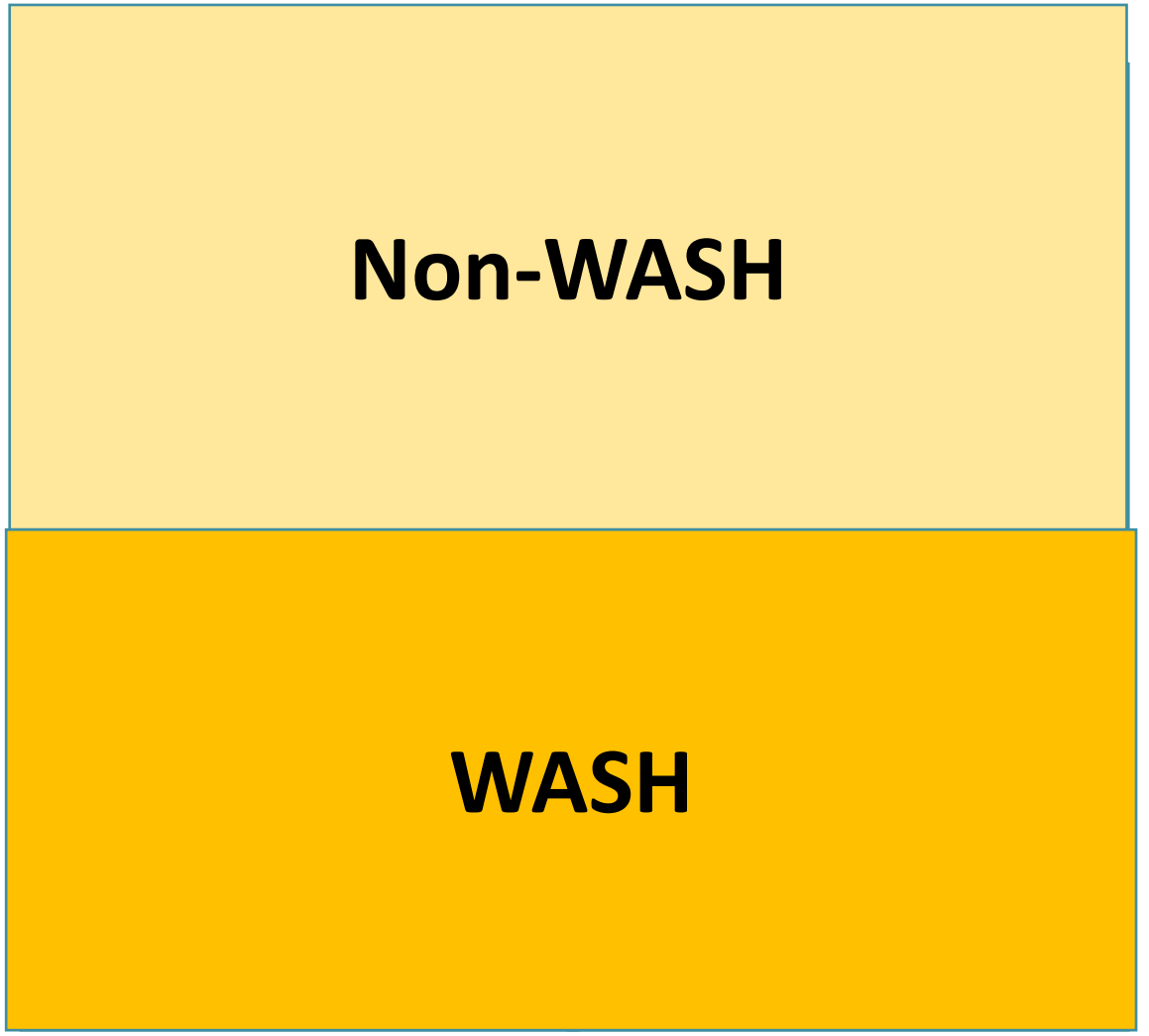

Primary and Secondary Outcomes

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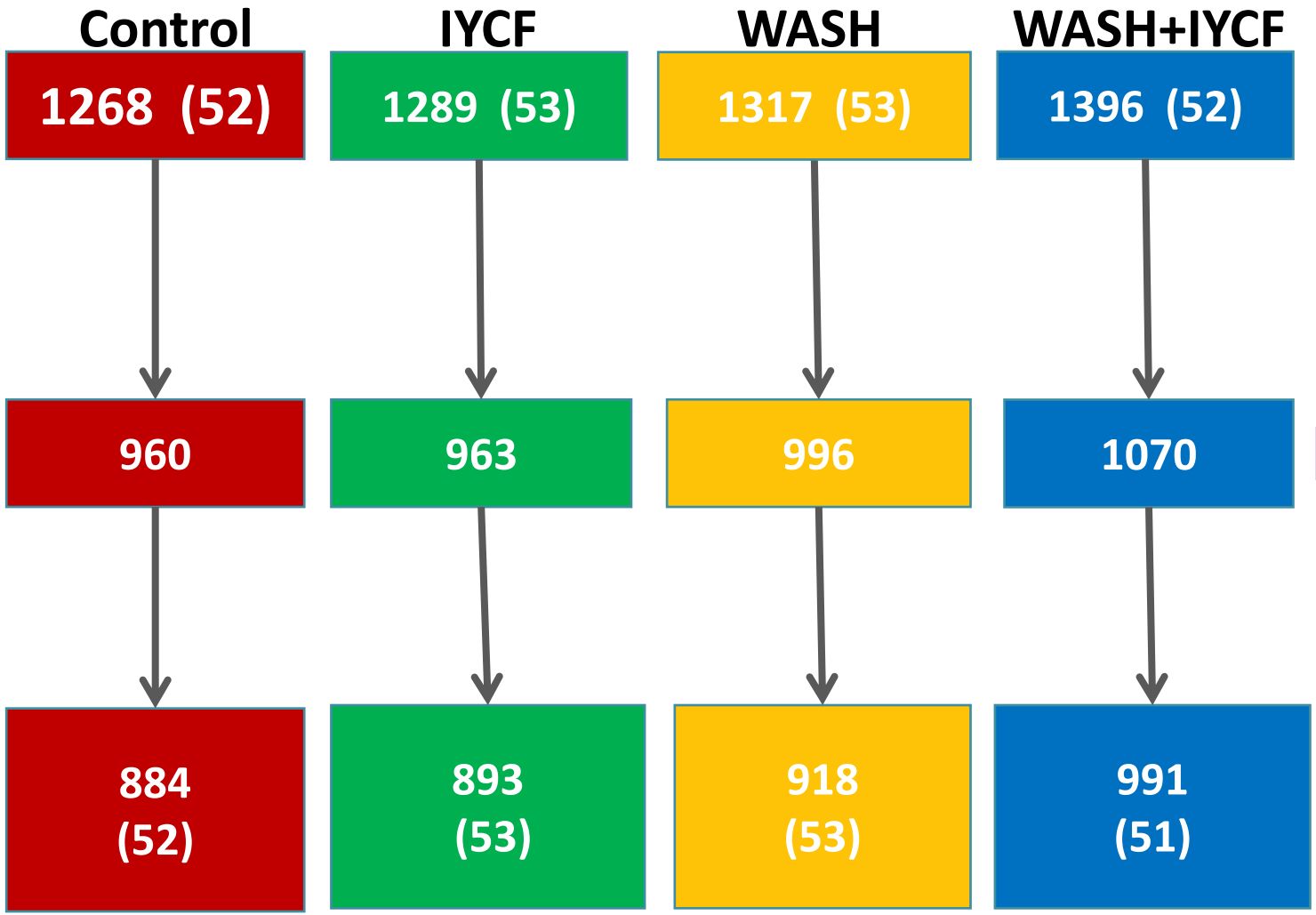
5280 women (210 clusters)



Losses between enrollment and delivery

138 (2.6%) Mothers exit/lost

363 (6.9%) fetal deaths, 4 mothers died

+81 (6.9%) fetuses from twin/triplets

726 (13.8%) HIV+ mothers

114 (2.2%) HIV unknown mothers

3989 live-born HIV unexposed infants

Losses between delivery and 18 months

191 (4.8%) infant deaths

= 3798 live born infants surviving to 18 mths

100 (2.5%) lost to follow-up, 5 exits

3686 infants assessed at 18 months
(97% live births surviving to 18 months)

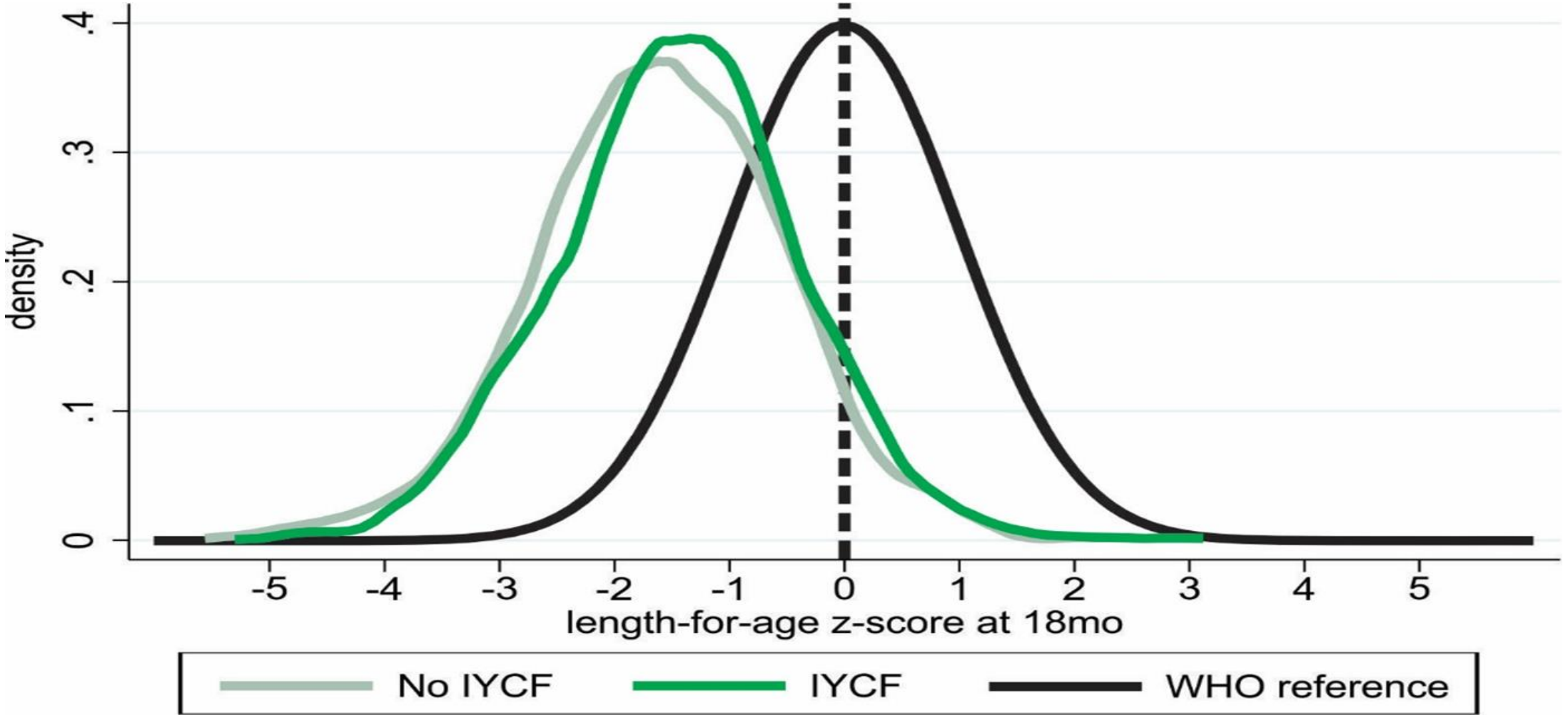
Baseline Characteristics	Control	IYCF	WASH	WASH+IYCF
Any latrine, %	33	41	42	44
Open defecation, % HH members	54	47	49	46
Primary water source is unimproved, %	38	35	39	36
One way walk time >15 minutes, %	30	25	30	29
Volume collected mean (SD) L/PC/d	9.4 (10.1)	9.6 (8.4)	9.8 (16.3)	9.5 (9.9)
Handwashing station, %	5	3	15	15
Electricity, %	3	4	3	2
Wealth index, centered at 0, mean (SD)	-0.06(1.88)	0.27(1.76)	0.03(1.80)	0.12(1.76)
Coping Strategies Index, Median (IQR)	1 (0,7)	0 (0,6)	1 (0,7)	1 (0,7)
Maternal schooling, y, mean (SD)	9.6 (2.2)	9.7 (2.8)	9.5 (2.0)	9.6 (2.5)
Infant birth weight, Kg mean (SD)	3.1 (0.6)	3.1 (0.5)	3.1 (0.5)	3.1 (0.5)
Institutional delivery, % infants	88	88	89	90

Impact of Infant and Young Child Feeding (IYCF) Intervention

Effect of IYCF on LAZ at 18 months of age

	N	Mean (SD)	Difference due to IYCF	
			Unadjusted (95%CI)	Adjusted (95%CI)
No IYCF	1792	**-1.59** (1.08)	**+0.16** (0.08, 0.23) p<0.001	**+0.13** (0.06, 0.20) p<0.001
IYCF	1879	**-1.44** (1.06)		

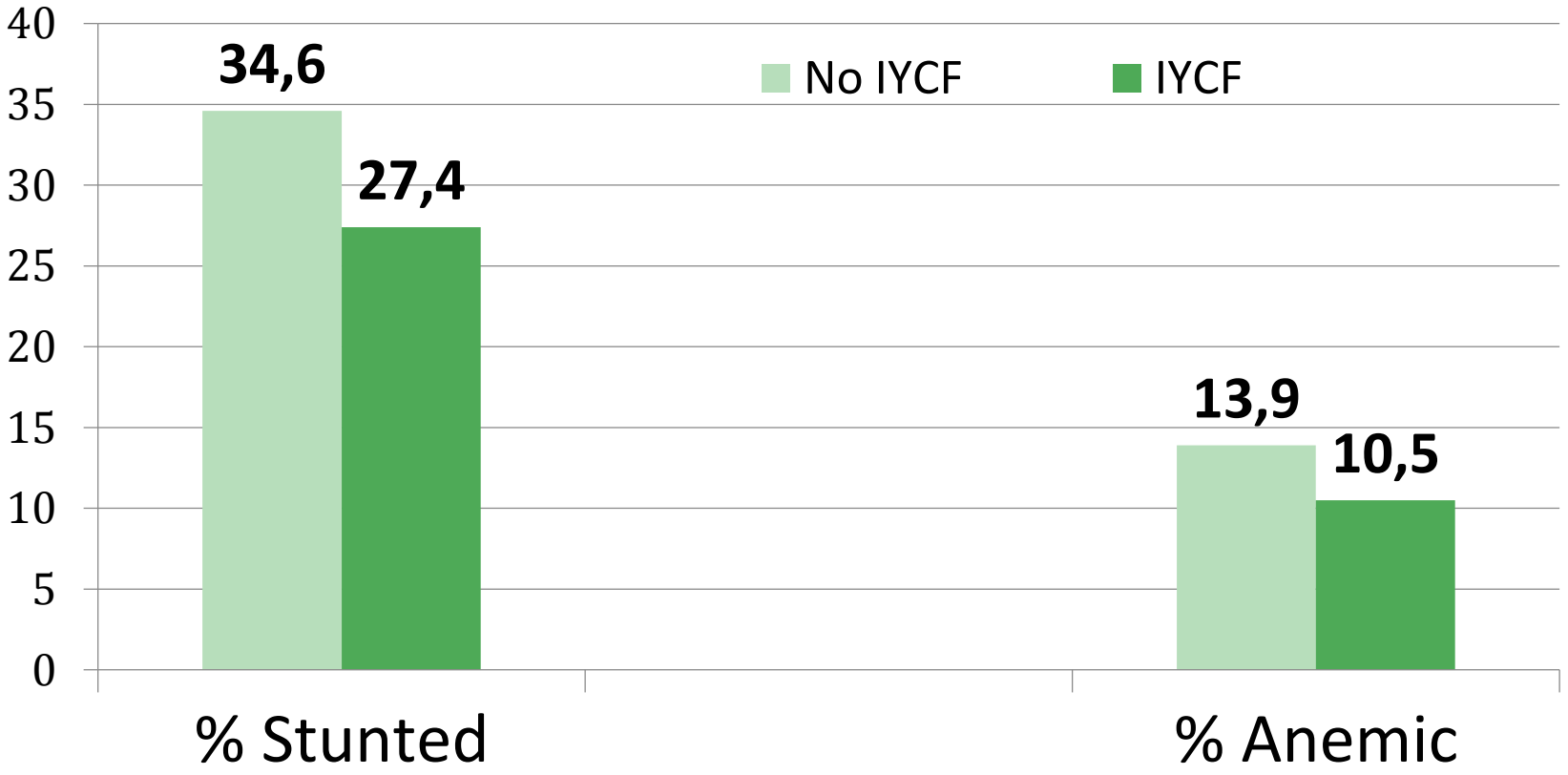
Effect of IYCF on LAZ distribution compared to WHO reference



Effect of IYCF on Hemoglobin (g/dL) at 18 mth of age

	N	Mean (SD)	Difference due to IYCF	
			Unadjusted (95%CI)	Adjusted (95%CI)
No IYCF	1759	**11.63** (1.18)	**+0.20** (0.13, 0.28) p<0.001	**+0.19** (0.12, 0.27) P<0.001
IYCF	1845	**11.83** (1.15)		

Effect of IYCF on Stunting and Anemia



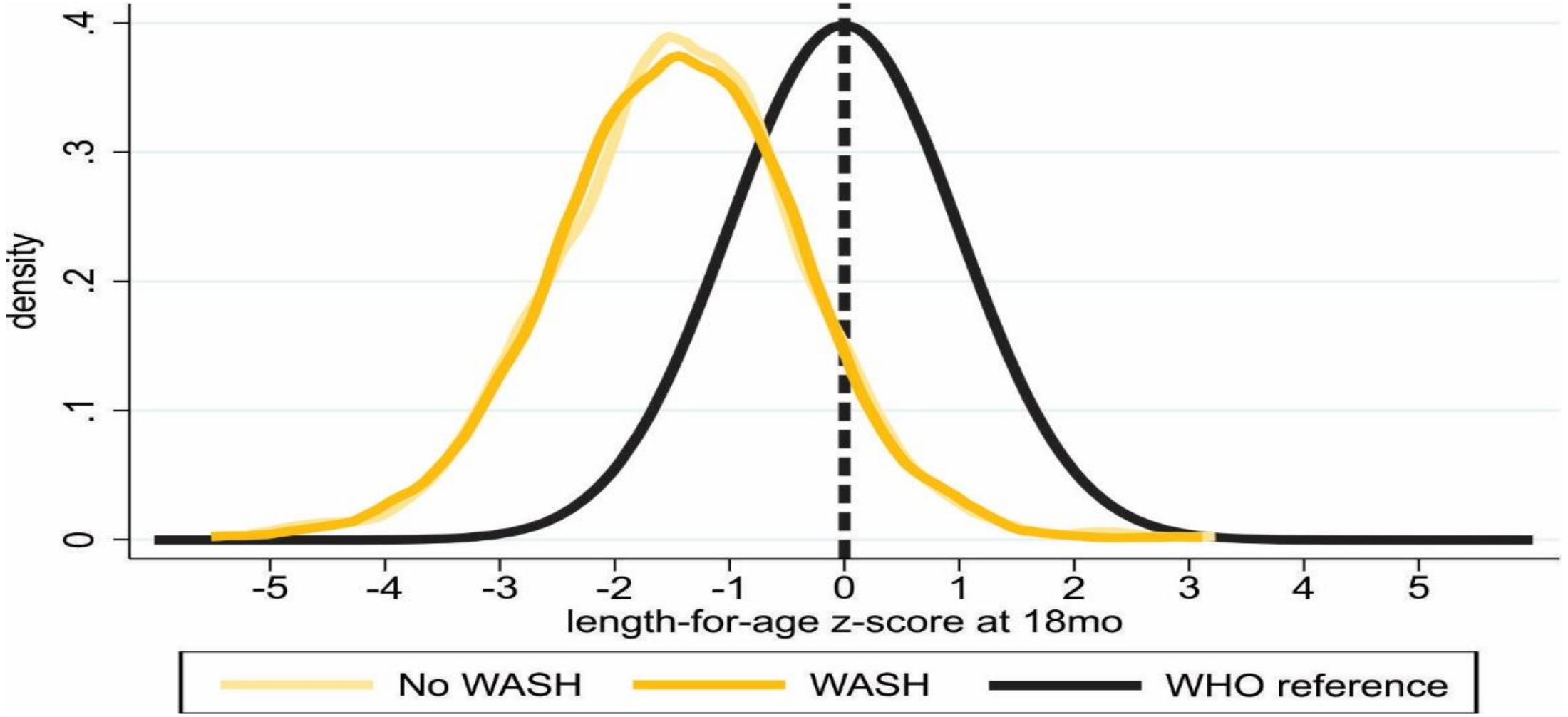
	% Stunted	% Anemic
	RR (95%CI)	RR (95%CI)
Unadjusted	**0.79** (0.72, 0.87)	**0.75** (0.62, 0.90)
Adjusted	**0.81** (0.74, 0.88)	**0.76** (0.63, 0.92)

Impact of WASH intervention

Effect of WASH on LAZ at 18 months of age

	N	Mean (SD)	Difference due to WASH: Unadjusted (95%CI)	Difference due to WASH: Adjusted (95%CI)
No WASH	1769	**-1.52** (1.07)	**+0.02** (-0.06, 0.09) p=0.70	**+0.05** (-0.02, 0.12) p=0.13
WASH	1902	**-1.50** (1.07)		

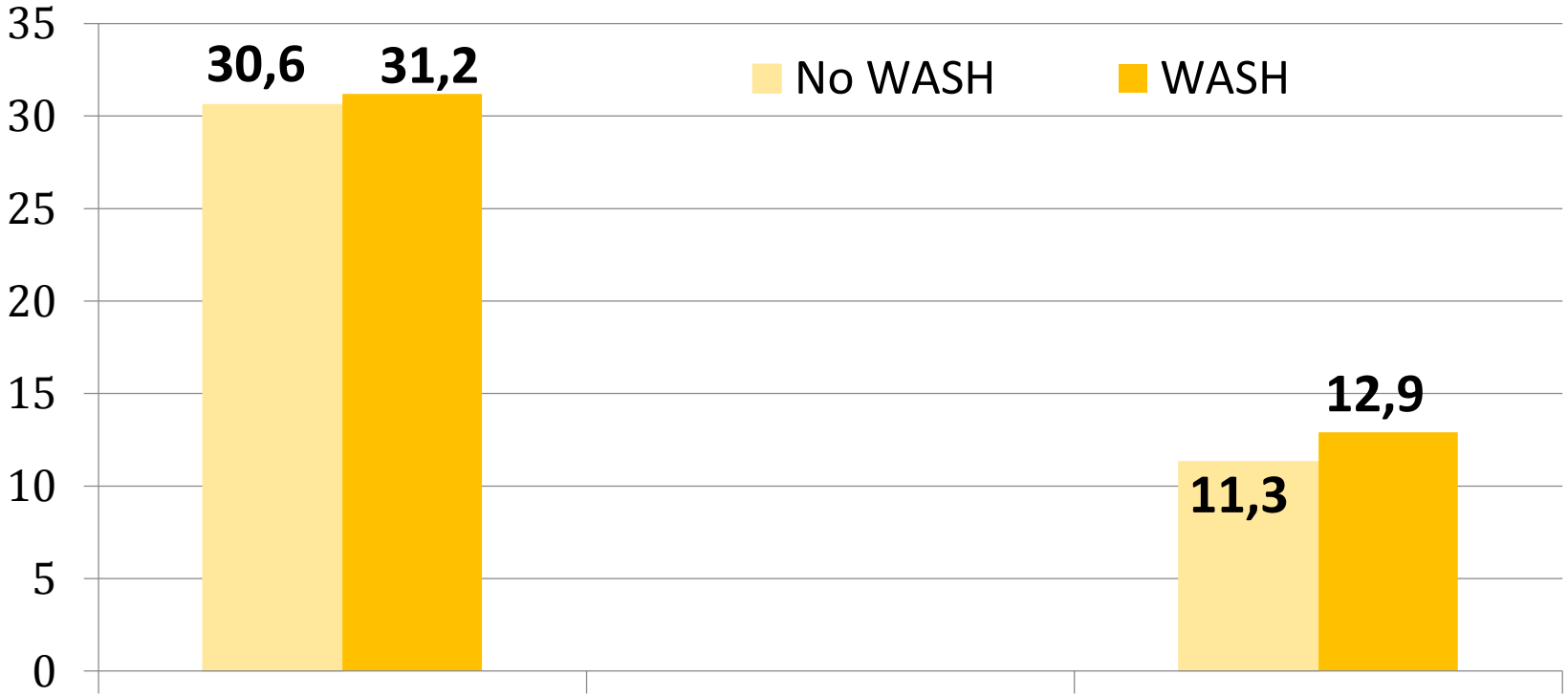
Effect of WASH on LAZ distribution compared to WHO reference



Effect of WASH on Hemoglobin (g/dL) at 18 months of age

	N	Mean (SD)	Difference due to WASH	
			Unadjusted (95%CI)	Adjusted (95%CI)
No WASH	1748	**11.75** (1.13)	**-0.03** (-0.10, 0.05) p=0.47	**-0.06** (-0.14, 0.02) p=0.13
WASH	1856	**11.72** (1.21)		

Effect of WASH on Stunting and Anemia



	% Stunted	% Anemic
	RR (95%CI)	RR (95%CI)
Unadjusted	**1.03** (0.93, 1.13)	**1.14** (0.95, 1.36)
Adjusted	**1.00** (0.91, 1.10)	**1.13** (0.92, 1.37)

Other secondary outcomes

7-day diarrhea prevalence at 12 months

Group	Prevalence (%)	Diff vs SOC (95%CI)	p	Adjusted Diff vs SOC (95%CI)	p
SOC/ Control	9.1	1.0 (Ref)		1.0 (Ref)	
IYCF	12.5	**1.37** (1.04,1.80)	0.03	**1.32** (1.00,1.75)	0.05
WASH	11.6	**1.26** (0.92,1.71)	0.15	**1.18** (0.87, 1.61)	0.29
WASH +IYCF	10.3	**1.13** (0.84,1.52)	0.14	**1.05** (0.79, 1.40)	0.72

7 day diarrhea prevalence at 18 months

Main Effects	Prevalence (%)	Difference (95%CI)	p	Adjusted (95%CI)	p
NO IYCF	9.9	1.0 (Ref)		1.0 (Ref)	
IYCF	9.4	**0.94** (0.77,1.16)	0.82	**0.97** (0.80, 1.20)	0.82
NO WASH	8.4	Ref		Ref	
WASH	10.7	**1.28** (1.04,1.57)	0.02	**1.15** (0.93, 1.41)	0.19

Cumulative mortality

Group	Percent	(95%CI)	p
SOC/Control	5.2	(3.9, 6.8)	
IYCF	4.2	(3.0, 5.6)	0.35
WASH	4.9	(3.7, 6.5)	0.91
WASH+IYCF	4.9	(3.7, 6.4)	0.70
Total	***4.8***	***(4.2, 5.6)***	
IYCF	4.6	(3.7, 5.6)	0.46
Non-IYCF	5.1	(4.1, 6.1)	
WASH	4.9	(4.0, 5.9)	0.77
Non-WASH	4.7	(3.8, 5.7)	

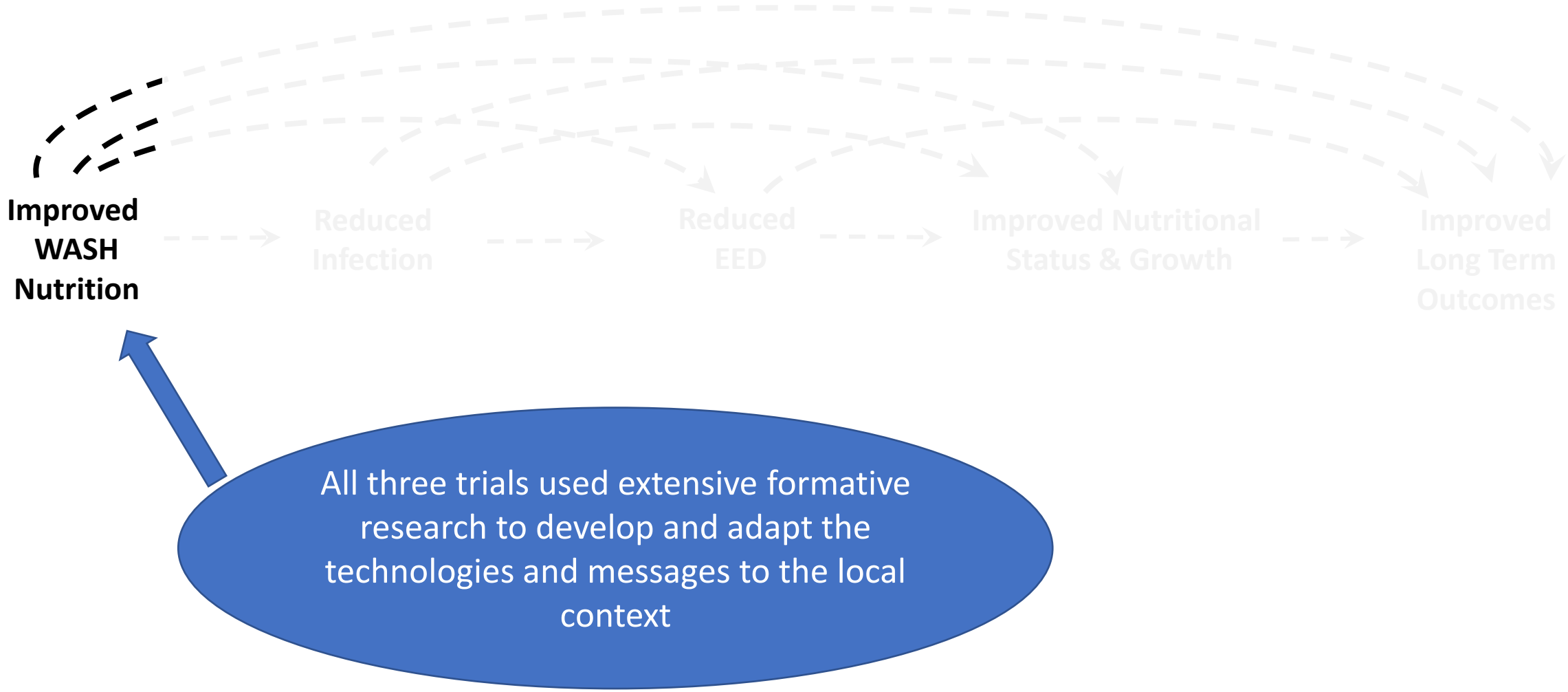
Summary

- SHINE was an efficacy trial: interventions were delivered with high fidelity and substantial behavior change was achieved;
- The WASH intervention had no benefit on any child health outcome assessed;
- The IYCF intervention had a significant but modest improvement; this is consistent with decades of studies on complementary feeding

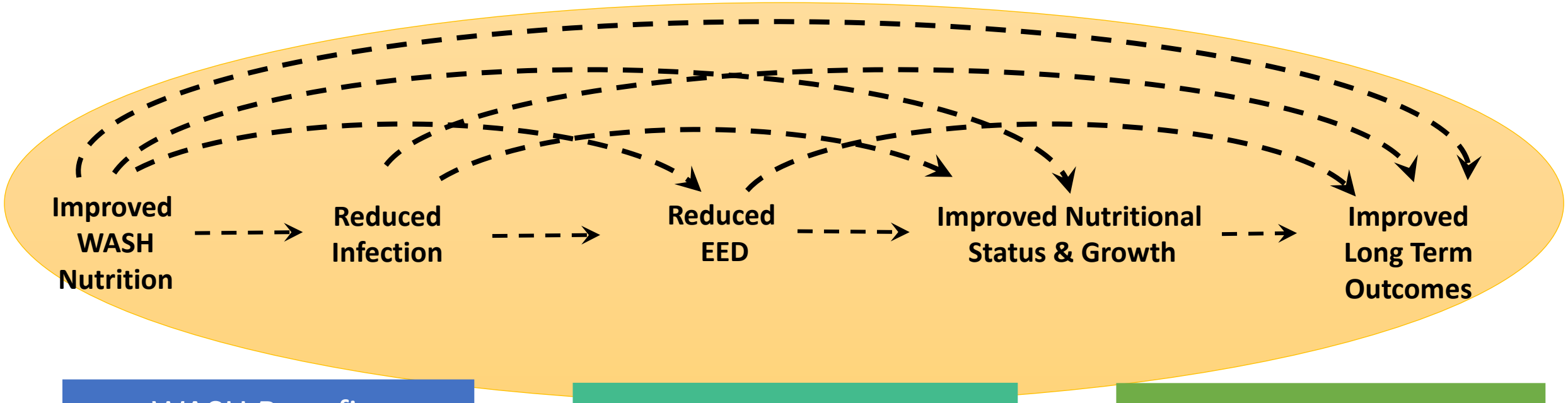
Three similarly designed trials conducted concurrently:

- WASH Benefits –Bangladesh
- WASH Benefits – Kenya
- SHINE - Zimbabwe

Design element differences and similarities



Contexts vary



WASH Benefits Bangladesh	WASH Benefits Kenya	SHINE Zimbabwe
• Low prev. diarrhea • Low prev. anemia • Low prev. HIV • High pop. density	• High prev. diarrhea • High prev. anemia • Moderate prev. HIV • Lower pop. density	• Mod prev. diarrhea • Mod prev. anemia • High prev. HIV • Lower pop. density

Results to date

WASH Benefits Bangladesh: 7 arms: C, S, H, W, N, WSH, WSHN

- **IYCF** Increased length by 0.25 LAZ, reduced anemia, reduced diarrhea
- **WASH**: NO EFFECT on length, NO EFFECT on anemia, reduced diarrhea
- Reduced hookworm in water containing arms

WASH Benefits Kenya 8 arms: Cpassive, C active, S, H, W, N, WSH, WSHN

- **IYCF:** Increased length by 0.13 LAZ, reduced anemia,
- **WASH:** NO EFFECT on length, NO EFFECT on anemia, NO EFFECT on diarrhea
- Reduced ascaris in water containing arms

SHINE Zimbabwe: 4 arms: WASH, Nutrition, WASH+Nutrition, active C

- IYCF: Increased length by 0.16, reduced anemia
- WASH: No EFFECT on Length, NO EFFECT on anemia, NO EFFECT on diarrhea

What's Next?

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WASH Benefits and SHINE summary

		Bangladesh	Kenya	SHINE
Stunting	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Anemia	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Diarrhea	IYCF	YES	NO	NO
	WASH	YES	NO	NO

WASH Benefits and SHINE summary

		Bangladesh	Kenya	SHINE
Stunting	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Anemia	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Diarrhea	IYCF	YES	NO	NO
	WASH	YES	NO	NO

WASH Benefits and SHINE summary

		Bangladesh	Kenya	SHINE
Stunting	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Anemia	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Diarrhea	IYCF	YES	NO	NO
	WASH	YES	NO	NO

WASH Benefits and SHINE summary

		Bangladesh	Kenya	SHINE
Stunting	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Anemia	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Diarrhea	IYCF	YES	NO	NO
	WASH	YES	NO	NO

WASH Benefits and SHINE summary

		Bangladesh	Kenya	SHINE
Stunting	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Anemia	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Diarrhea	IYCF	YES	NO	NO
	WASH	YES	NO	NO

WASH Benefits and SHINE summary

		Bangladesh	Kenya	SHINE
Stunting	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Anemia	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Diarrhea	IYCF	YES	NO	NO
	WASH	YES	NO	NO

WASH Benefits and SHINE summary

		Bangladesh	Kenya	SHINE
Stunting	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Anemia	IYCF	YES	YES	YES
	WASH	NO	NO	NO
Diarrhea	IYCF	YES	NO	NO
	WASH	YES	NO	NO

Stunting

- All 3 trials found a small but consistent effect of IYCF
  - Improvement of 0.13 - 0.26 LAZ
- Consistent with many years of nutrition literature
- All 3 trials were proof of concept studies designed to test the independent and combined effects of WASH interventions
- NONE found any effect of WASH on stunting

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Reason 1 – Hypothesis incorrect

Poor WASH ➡ EED ➡ STUNTING

Reason 1 – Hypothesis incorrect

Poor WASH → EED ✗ STUNTING

Reason 1 – Hypothesis incorrect

Poor WASH ✗ EED → **STUNTING**

Reason 1 – Hypothesis incorrect

Poor WASH ✗ EED ✗ **STUNTING**

Reason 1 – Hypothesis incorrect

Poor WASH ✗ **EED** ✗ **STUNTING**

- EED remains poorly understood
- Appears to be almost universal but no case definition
- Need to understand the drivers and reversibility of EED
- Ongoing lab work from all 3 studies will help to address this

Reason 2 – WASH interventions ineffective

- All 3 trials did extensive formative WASH research
- Designed interventions that we believed would protect young infants from ingesting feces and met JMP basic standards for latrines and hand-washing:
  - Chlorination of drinking water
  - Hand-washing with soap
  - Disposal of feces in latrines (kipupu scoops/potties, WASH B)
  - Cleaning yards of animal feces (protective play space, SHINE)
- **Maybe these are insufficient to clean up highly contaminated environments enough to affect linear growth**

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Reason 2 – WASH interventions ineffective

Is this what it will take?

What about all the observational data?

- In all but 2 of 65 recent papers at least one WASH factor was an independent determinant of linear growth:
  - Sanitation: OD, any latrine, improved latrine, community sanitation coverage, exposure to open sewers
  - Hygiene: Caregiver or child handwashing, presence of soap
  - Water: improved source, on plot, fetching time, filtration, storage, treatment,
  - Baby WASH: Geophagia and infant feces disposal
  - Combination of WASH inputs

This is why we do trials…

Baseline Factor	Coefficient	95% CI	P value
Birth weight	+ 0.62	0.45, 0.78	<0.001
Female	+ 0.43	0.30, 0.56	<0.001
Maternal Height	+ 0.42	0.29, 0.54	<0.001
Maternal Depression	- 0.22	-0.37, - 0.08	0.003
Improved Latrine	**+ 0.20**	**0.08, 0.31**	**0.001**

GEE Model, adjusted for within-cluster correlation. Factors included in model that were not significant: maternal education, household food security, gestational age at birth.

Reason 3 – Intervention duration/coverage

- Enrolled women in pregnancy
  - Aimed for families to change WASH behaviors before the baby was born
  - Maybe it takes much longer to clean up heavily contaminated environments and improve child health outcomes

- All 3 trials tested household-level interventions
  - Community latrine coverage may be an important factor
  - Improved LAZ seen in studies from India and Mali

Reese H, #170 ASTMH 2017; Pickering AJ, Lancet Glob Health 2015

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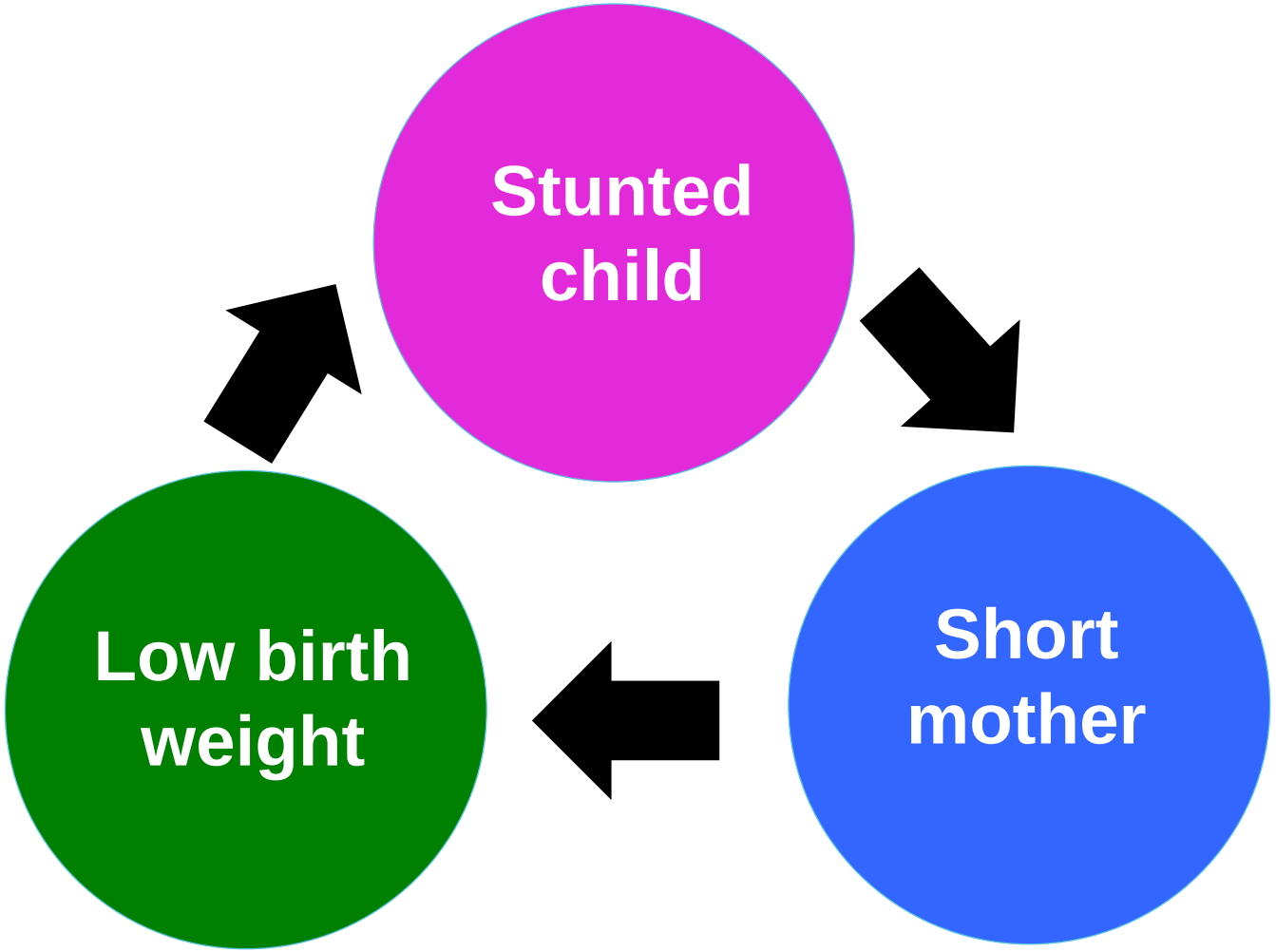
Reason 4 – Intergenerational factors



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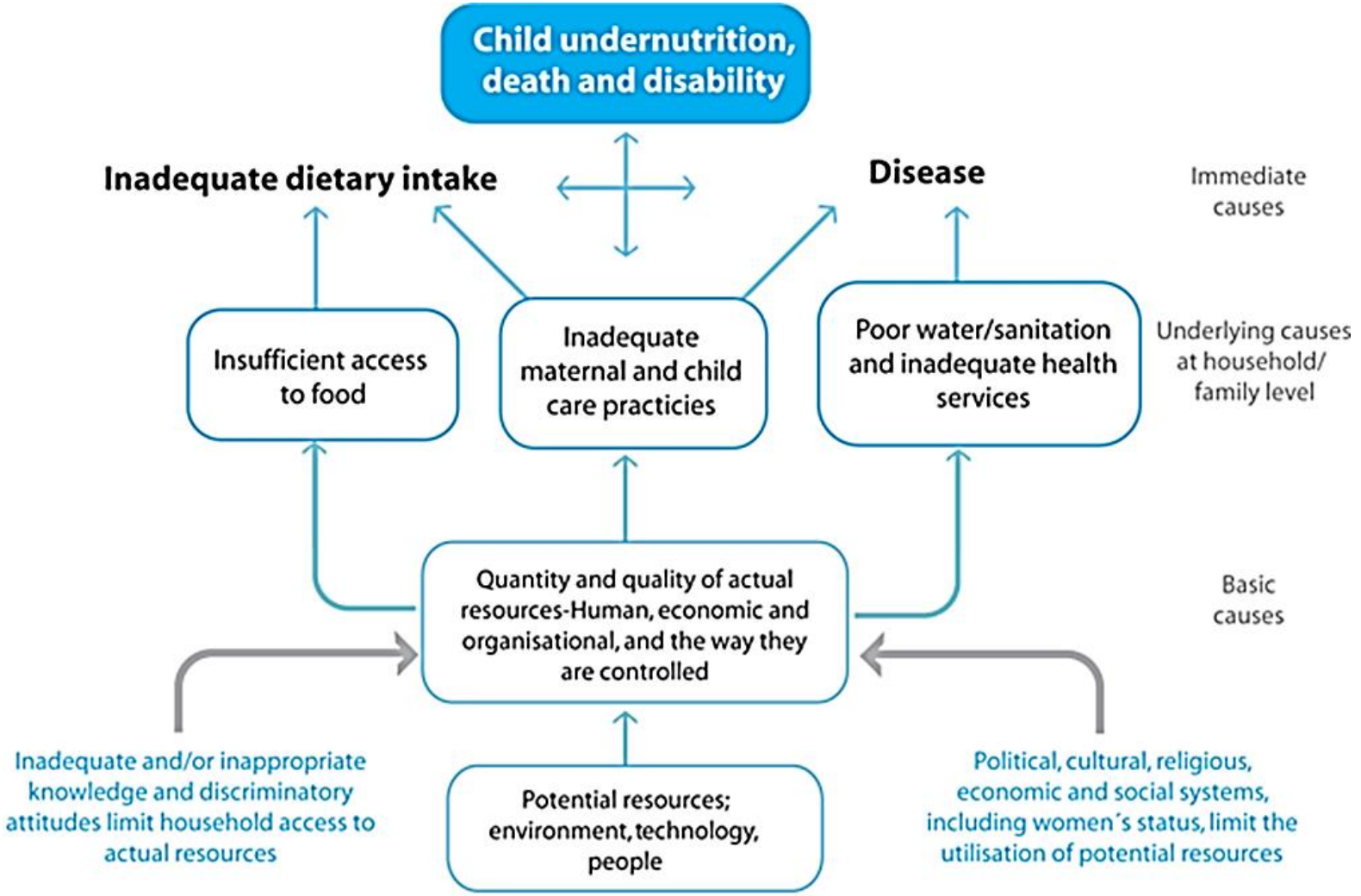
Reason 5 – Necessary but not sufficient



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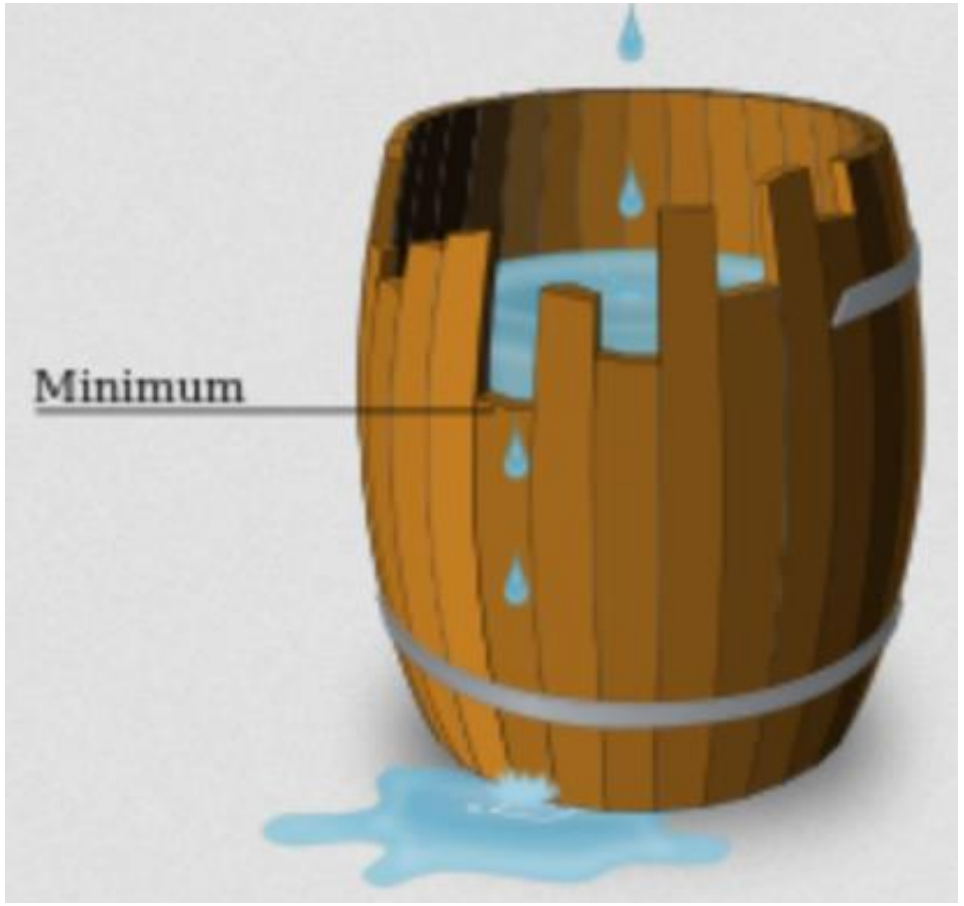
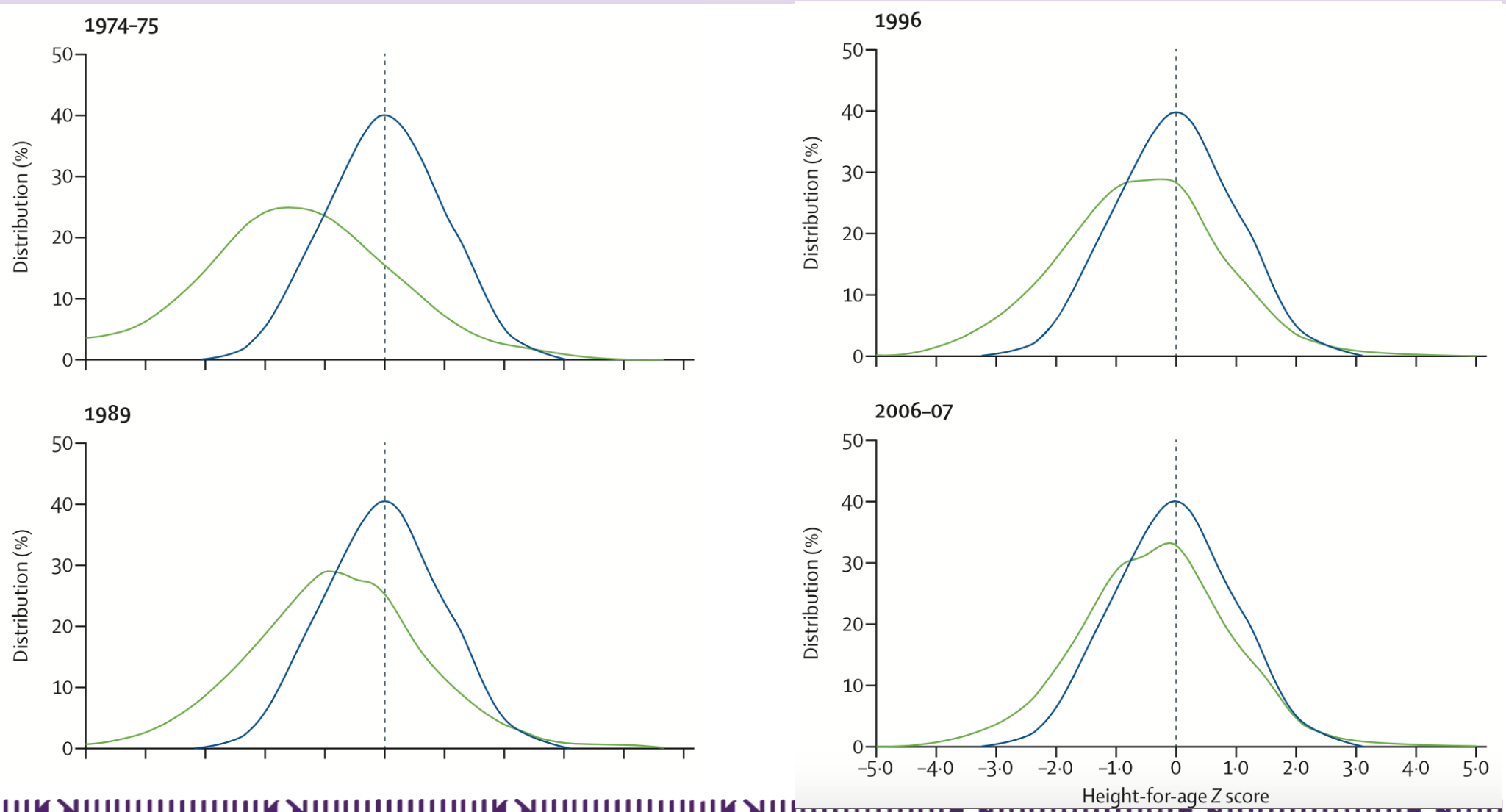
Reason 5 – Necessary but not sufficient

Liebig's "law of the minimum"



Multisectoral interventions reduce stunting



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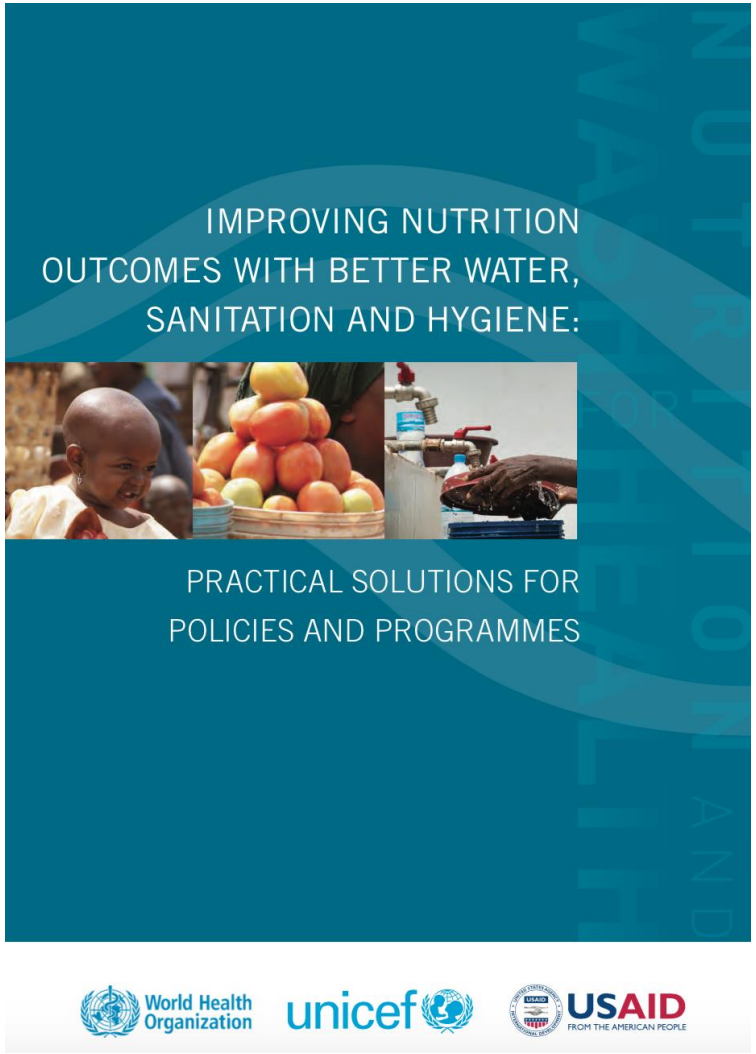
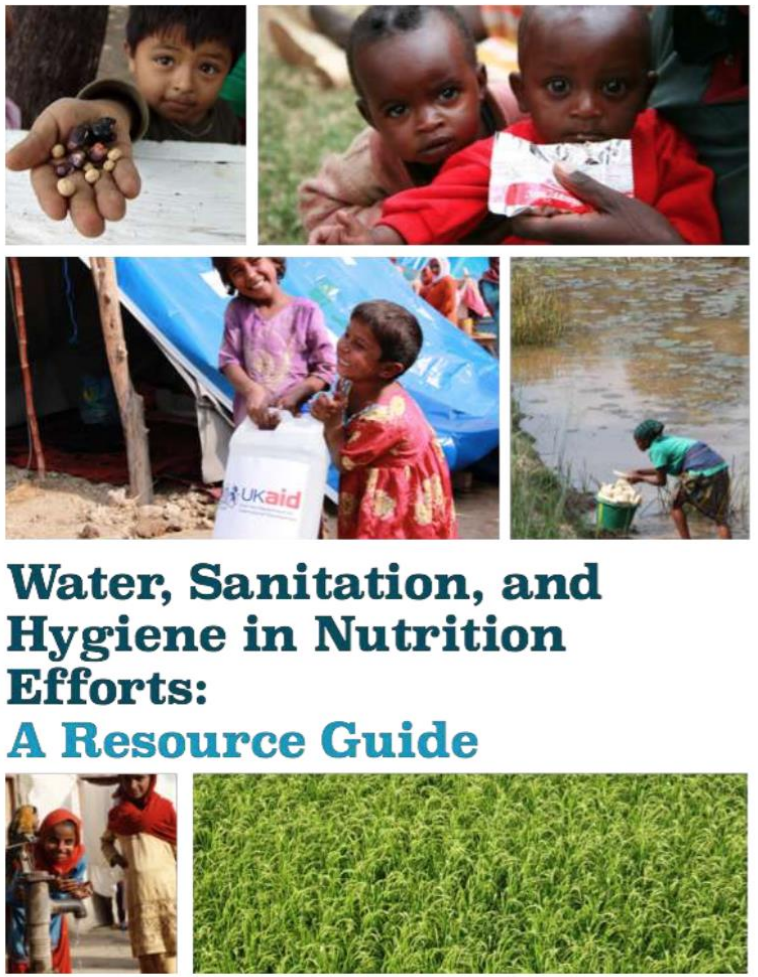
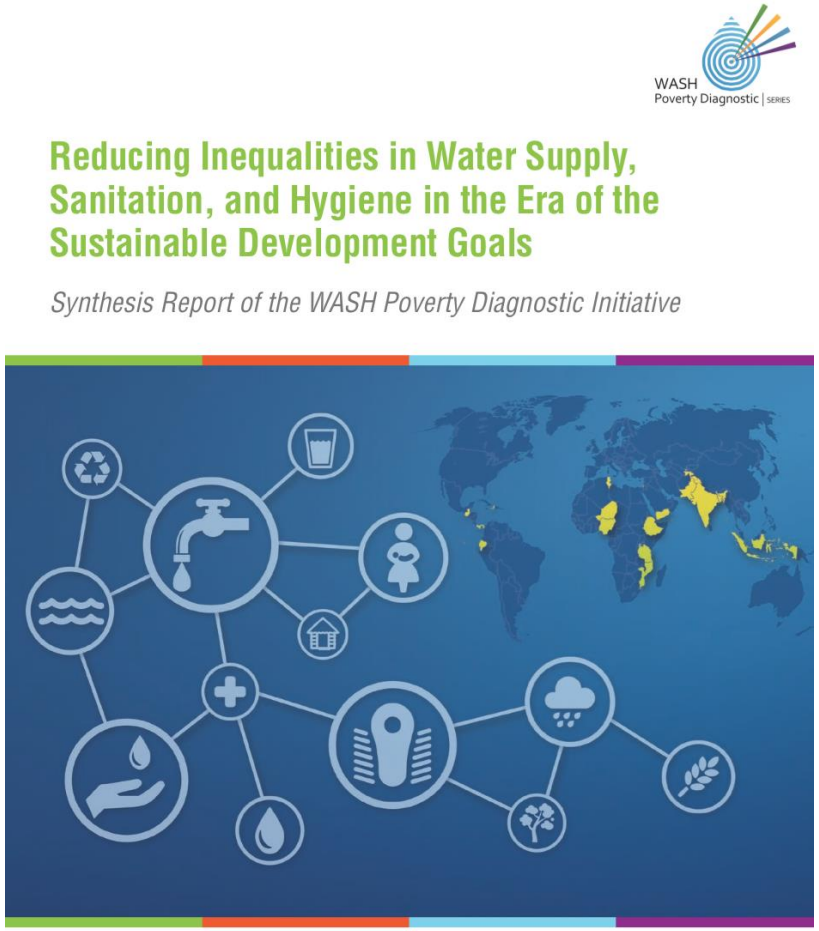
Huge push to scale up WASH for stunting







Implications for policy and programmes

- High-level evidence from 3 randomized trials across varied settings:
  - Implementing WASH alone with current tools (pit latrines, water chlorination, hand washing with soap) will not reduce stunting.
  - Implementing WASH with current tools plus IYCF will not reduce stunting more than IYCF alone.
  - Implementing WASH with current tools will reduce diarrhea in some settings but not others.

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So what is next?

WASH Sector:

- History suggests there is no doubt that effectively interupting fecal-oral tranmission improves growth. How can current tools be technicall improved to be more effective and rely less on behavior change and time intensive labor?

Biomedical Sector

- What exactly it the pathophysiology of stunting
  - What is the final common pathway to linear growth failure?
  - How can we restore healthy growth?

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Ongoing work in SHINE

- Impact of the interventions in HIV-exposed infants
- Rotavirus vaccine immunogenicity
- EED biomarkers
- Metabolomics, TAC analyses, FUT2
- Microbiota
- Mycotoxin exposure
- 24h dietary recalls
- Schistosomiasis exposure (low STH in Zimbabwe)
- Case-control studies of birth outcomes (maternal EED)


Discussion