Enterics for Global Health: *Shigella* surveillance study (EFGH) statistical analysis plan and case report forms

EFGH

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Enterics for Global Health (EFGH)
Statistical Analysis Plan
Version 2.0

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SECTION 1. ADMINISTRATIVE INFORMATION

Title: Statistical Analysis Plan (SAP) for the Enterics for Global Health (EFGH) study

SAP Version: 2.0 (17 June 2024)

Protocol Version: 5.0 (09 June 2023)

SAP Revision History:

SAP version (date)	Justification for Revision	Timing of SAP in relation to interim analysis
2.0 (17 June 2024)	Adding complete secondary aim sections and revised SAP per consortium review	N/A

SAP Working Group

Name	EFGH Role
Faisal Ahmmed	Co-Investigator, icddr,b
Hannah Atlas	Co-Investigator, University of Washington (UW)
John Clemens	Co-Principal Investigator-Bangladesh, International Vaccine Institute (IVI)
Erika Feutz	Data Manager & Analyst, UW
Sean Galagan	Senior Data Manager & Analyst, UW
Jahangir Hossain	Co-Principal Investigator-the Gambia, The Medical Research Council Unit - The Gambia (MRCG)
Muhammed Jawwad	Co-Investigator, The Aga Khan University (AKU)
Karen Kotloff	Co-Principal Investigator-Mali, Kenya, the Gambia, The University of Maryland, Baltimore (UMB)
Donnie Mategula	Co-Investigator, Malawi-Liverpool-Wellcome Trust (MLW)
Christine McGrath	Co-Investigator, UW
Billy Ogwel	Co-Investigator, Kenya Medical Research Institute (KEMRI)
Dr. Patricia Pavlinac	Co-Principal Investigator-Coordination, UW
James Platts-Mills	Co-Investigator, The University of Virginia (UVA)
Elizabeth Rogawski-McQuade	Co-Investigator, Emory University
Francesca Schiaffino	Co-Investigator, UVA
Mili Tapia	Co-Investigator, UMB
Tahir Yousufzai	Co-investigator, AKU

Also Contributed to SAP Content

Name	EFGH Role
Chloe Morozoff	Implementation Science Analyst, UW
Arianna Rubin Means	Co-Investigator, University of Washington (UW)
Olivia Schultes	Data Manager & Analyst, UW

Abbreviations

∆LAZ/HAZ	Linear growth
AIC	Akaike information criterion
AKU	The Aga Khan University
CI	95% confidence interval
CLSI	Clinical and Laboratory Standards Institute
CT	Cycle threshold
DCS	Diarrhea case surveillance
EFGH	Enterics for Global Health
ETEC	Enterotoxigenic *E. coli*
GEMS	Global Enteric Multicenter Study
GLM	Generalized Linear Models
HAZ	Height for age Z-score
HUS	Healthcare Utilization Survey
ICD-11	International Classification of Diseases 11th Revision
IMCI	Integrated Management of Childhood Illness
IR	Incidence rate
IRB	Institutional Review Board
IQR	Interquartile range
IVI	International Vaccine Institute
JMP	WHO/UNICEF Joint Monitoring Programme for Water Supply, Sanitation and Hygiene
KEMRI	Kenya Medical Research Institute
LAZ	Length for age Z-score
LRTI	Lower respiratory tract infection
LSD	Less-severe diarrhea
LTFU	Lost to follow-up
MAD	Medically-attended diarrhea
MAL-ED	Malnutrition and Enteric Disease Study
mBGS	Modified buffered glycerol saline
MDR	Multidrug-resistant
MLW	Malawi-Liverpool-Wellcome Trust
MRCG	The Medical Research Council Unit - The Gambia
MSD	Moderate-to-severe diarrhea
MUAC	Mid-upper arm circumference
MVS	Modified Vesikari score
NPV	Negative predictive value
PPV	Positive predictive value
PR	Prevalence ratio
ROC	Receiver operating characteristics
RR	Relative risk
SAP	Statistical analysis plan
SD	Standard deviation
SES	Socioeconomic status
TAC	TaqMan Array Card
UMB	The University of Maryland, Baltimore
USD	United states dollars
UVA	The University of Virginia
UW	University of Washington
WAZ	Weight for age Z-score
WHO	World Health Organization
WLZ	Weight for length Z-score
XDR	Extensively drug-resistant

SECTION 2. INTRODUCTION

Background and Rationale

In low- and middle-income countries, nearly one third of children experience at least one episode of *Shigella*-attributable diarrhea during their first two years of life.[1] In addition to being a leading cause of diarrhea, this enteric bacterium is also associated with linear growth faltering, a precursor to stunting.[2,3] Stunting is a marker of vulnerability to childhood infection, decreased vaccine efficacy and lifelong morbidity. Currently, several promising *Shigella* vaccines are in development. Eventual Phase 2b/3 *Shigella* vaccine trials will require a consortium of potential vaccine trial sites in settings with a high incidence of *Shigella*-attributed medically-attended diarrhea (MAD)*,* high participant retention, and the laboratory capacity to confirm *Shigella* infection. The Enterics for Global Health (EFGH) *Shigella* surveillance study will employ cross-sectional and longitudinal study designs to establish updated incidence rates and document consequences of *Shigella* diarrhea within seven country sites in Africa, Asia, and Latin America. Specifically, we aim to:

Aims

1. **Primary Aim**: Determine the incidence of *Shigella*-attributed MAD in children 6 to 35 months of age in each of the EFGH country sites.
2. **Secondary Aim 1:** Determine the incidence of *Shigella* MAD by serotype, severity definition, laboratory method (culture vs. qPCR), age, and by season.
3. **Secondary Aim 2:** Describe the prevalence of resistance to commonly used antibiotics in *Shigella* isolates in each EFGH country site.
4. **Secondary Aim 3:** Determine the risk of death, hospitalization, persistent diarrhea, experiencing a subsequent diarrhea episode, and linear growth faltering in the three months following an episode of *Shigella* MAD.
5. **Secondary Aim 4:** Compare various severity definitions in their ability to predict risk of death or hospitalization among cases of MAD and *Shigella*-attributable medically attended diarrhea, respectively.
6. **Secondary Aim 5:** Quantify the cost incurred by families and health care systems due to *Shigella* morbidity and mortality.
7. **Secondary Aim 6:** Identify optimal laboratory methods for *Shigella* culture by:
    a. Comparing the isolation rate of *Shigella* between two transport media for rectal swabs (Cary-Blair and modified Buffered Glycerol Saline [mBGS]).
    b. Comparing the isolation rate of *Shigella* between two fecal sample types (rectal swabs and whole stool) among the subset of children who produced whole stool in The Gambia and Bangladesh country sites.

SECTION 3. STUDY METHODS

Study Design

The EFGH study will employ cross-sectional and longitudinal study designs to establish incidence and consequences of *Shigella* diarrhea. Children aged 6-35 months of age presenting with diarrhea at selected study health facilities will be recruited over a 24-month period and followed for three months. Randomly selected households will be visited within each EFGH site catchment area over the 24-month recruitment period to estimate the population of children aged 6-35 months in the catchment area. A healthcare utilization survey (HUS) will be conducted among households in the catchment area with one or more children in the 6-35-month age range to determine the proportion of diarrhea cases that present to EFGH study health facilities. The number of cases divided by the estimated number of children 6-35 months of age residing in the catchment area and time of surveillance will estimate the crude incidence rate of *Shigella* diarrhea in 6-35 months of age. This incidence rate will be adjusted by the proportion of eligible children

enrolled and the proportion of eligible children with diarrhea who sought care at an EFGH recruiting facility.

Sample Size

The minimum number of confirmed *Shigella* cases (numerator) and minimum size of the source population within health facility catchment area (denominator) required to estimate *Shigella* incidences and 95% confidence intervals with specified precision (half-widths of 0.25 cases per 100 child-years) within children aged 6-35 months were estimated. To ensure appropriate precision in estimates of serotype and antibiotic susceptibility of *Shigella* isolates, we aim recruit at least 65 children with culture-confirmed *Shigella* diarrhea at each EFGH site. We assumed that 4.8% of diarrhea cases will be *Shigella* culture-positive in the EFGH study, requiring that we enroll 1400 children presenting to health facilities with diarrhea over the 24-month period (~58 per month). The size of the catchment area population (>97,000) was determined assuming an unadjusted *Shigella* incidence rate of 0.63 per 100 child-years (unadjusted for health care seeking behavior) and 95% confidence interval precision of 0.25 (half-width).

Framework

Not applicable.

Interim Statistical Analysis and Stopping Guidance

Interim "Data Readouts" presenting preliminary study results will be generated on a biannual basis and shared with study investigators and the BMGF. As this study is not a randomized trial and there is no intervention, there is no stopping guidance.

Timing of Final Analysis

The primary study publication will be prepared for the primary aim when every enrolled child has completed their three-month follow-up visit or is deemed lost to follow-up and all data for the primary aim has been cleaned (anticipated publication submission in May of 2025).

Figure A. Timeline of study activities

Key Activity	2022				2023				2024				2025	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Diarrhea case surveillance (24 months recruitment + 3 months final follow-up)		▓	▓	▓	▓	▓	▓	▓	▓	▓	▓	▓		
Population enumeration activities		▓	▓	▓	▓	▓	▓	▓	▓	▓				
Healthcare utilization survey		▓	▓	▓	▓	▓	▓	▓	▓	▓				
Data cleaning			▓	▓	▓	▓	▓	▓	▓	▓	▓	▓	▓	
Data analysis				▓	▓	▓	▓	▓	▓	▓	▓	▓	▓	
Publication preparations												▓	▓	▓
Dissemination of results													▓	▓

Longitudinal follow-up

The schedule of study procedures is outlined in Figure A. Regularly scheduled clinical visits include those at enrollment and at follow-up (week four and month three) and are defined as a 14-day period in which visits are considered completed (24-37 days post-enrollment for the week four visit and 84-97 days post-enrollment for the month three visit). Additionally, visits are allowed for up to 30 days past the visit window (38-67 days post-enrollment for the week 4 visit and 98-127 days post-enrollment for the month 3 visit) though may be excluded from analyses (**Table B**).

Table B. Allowable windows for longitudinal follow-up		
Visit	**Visit Window**	**Allowable visits**
Week four follow-up visit	24-37 days post-enrollment.	38-67 days post-enrollment.
Month three follow-up visit	84-97 days post-enrollment.	98-127 days post-enrollment.

SECTION 4. STATISTICAL PRINCIPLES

Confidence Intervals and P-values
Level of Statistical Significance
All statistical tests will be two-sided using a 5% significance level (alpha of 0.05).

Type I Errors
We will not adjust the alpha for multiple testing in the primary or secondary aims. For secondary aims that involve multiple hypothesis tests, we will frame the results as exploratory and acknowledge type-I error in the limitations sections.

Confidence Intervals to be Reported
Two-sided 95% confidence intervals will be used. The specific calculation of confidence intervals is described under each specific aim.

Protocol Deviations
Definition of protocol deviations
The following are pre-defined major protocol deviations with a direct bearing on the primary outcome:
- Errors in applying inclusion/exclusion criteria that are discovered after enrollment, including lack of informed consent.

The following are pre-defined minor protocol deviations:
- Missed sample collection (stool/rectal swab, blood spot) due to participant refusal or other barrier to sample collection (such as visit occurring over phone).
- Missed anthropometry assessment due to follow-up visit occurring over the phone

Description of which protocol deviations will be summarized
Protocol deviations will be classified as major and minor. The number (and percentage) of participants with major and minor protocol deviations will be summarized by study site in relevant analyses with details of the deviation provided. No statistical tests will be performed.

Analysis Populations
All children with non-missing outcome data (for each relevant aim) will be included in primary and secondary analyses.

Missing data for symptom duration variables will be assumed as absence of a given symptom in primary analyses and in secondary analyses assumed to be presence of the given symptom.

SECTION 5. STUDY POPULATIONS

Diarrhea Case Surveillance Screening
The total number pre-screened, screened, and enrolled in Diarrhea Case Surveillance (DCS) will be reported along with summary of reasons for exclusion into the study.

DCS Eligibility
Children aged 6 to 35 months old presenting at an EFGH facility with diarrhea (three or more abnormally loose or watery stools per 24 hours) (Table C).

> **Table C.** Description of study population and criteria for the inclusion and exclusion of DCS enrollment.

Study Population	Children aged 6 to 35 months old presenting at an EFGH facility with diarrhea (three or more abnormally loose or watery stools in the previous 24 hours).

Inclusion Criteria	• Primary caregiver and child plan to remain at their current residence for at least the next four months
	• Primary caregiver is able to provide informed consent (legal age or emancipated minor) and provides consent within a common language for which translations are available
	• Child resides within the pre-defined study area
	• Fewer than four hours have passed since the child presented to a health facility
	• Diarrhea episode is:
	   o Acute (onset within seven days of study enrollment) and
	   o Represents a new episode (onset after at least two diarrhea-free days)
	• Caregiver is willing to have child participate in follow-up visits at week four and month three
	• Willingness to have samples collected from the child (rectal swabs at enrollment)
	• Site enrollment cap has not been met
	• Child is not being referred to a non-EFGH facility at the time of screening

Exclusion Criteria	• Children younger than six months or 36 months or older • Diarrhea does not meet the study definition (three or more abnormally loose or watery stools in the previous 24 hours) • Primary caregiver unable to provide informed consent or refuses to provide consent • Primary caregiver refuses verbal consent to screening procedures • Child does not reside in the study catchment area • four or more hours have passed since child presented to the study facility • Diarrhea episode is not acute (>7 days) or does not represent a new episode (<2 diarrhea free days) • Caregiver unwilling to have child participate in follow-up at four weeks and three months • Caregiver unwilling to have samples collected at enrolment (rectal swabs) • Site enrolment cap has been met • Child is being referred to a non-study facility

Population Enumeration and HUS Eligibility

All households residing in the study catchment area and where an adult household member provides verbal consent will be eligible to participate in population enumeration activities. Children who are (1) 6-35 months of age, (2) had diarrhea (three or more unusually loose or watery stools during a 24-hour period) in the past 14 days, and (3) whose primary caretakers provides written or verbal informed consent (per site procedures and institutional review board [IRB] requirements) will complete the HUS.

Recruitment

Children will be passively recruited from study outpatient facilities for DCS enrollment. Prior to the screening process, potential participants will be pre-screened for eligibility by the study staff.

Per CONSORT guidelines, we will report the number of individuals who (**Figure 1**):
1. Underwent pre-screening
2. Underwent screening

3. Did not undergo screening (and reasons)
4. Met inclusion criteria
5. Did not meet inclusion criteria (and reasons)
6. Enrolled in the study
7. Not enrolled in study (and reasons)
8. Completed week four and month three follow-up visits

Withdrawal/Follow-Up
Withdrawal
Withdrawal of consent will be tabulated by country site using the following categories: withdrawal but allow prior collected data/ samples to be used and withdrawal and disallow already collected data/samples to be utilize.

Missed Visits/Loss to follow-up
Week four visits (defined as study visits 24 to 67 days after enrollment) and month three visits (defined as study visits 84 to 127 days after enrollment) that were missed will be tabulated in categories of completely missed, visit occurred but outside of window, visit occurred over phone by country site. Lost to follow-up (LTFU) will be defined as missing both the week four and month three visit.

SECTION 6. ANALYSIS

Definitions

1. **Diarrhea** defined as three or more abnormally loose or watery stools in a 24-hour period**.**

2. **Diarrhea episode** will be defined as the period of days in which the above definition is met followed by two diarrhea-free days.

3. **Culture-confirmed *Shigella* diarrhea case** will be defined as a case of acute diarrhea presenting to an EFGH facility in which *Shigella* was isolated from either of the cultured fecal sample collected by rectal swab and transported in mBGS or Cary-Blair media.

4. **qPCR-confirmed *Shigella* diarrhea case** will be defined as a case of acute diarrhea presenting to an EFGH facility in which *Shigella* DNA was identified in the fecal sample by qPCR (cycle threshold [CT] <31.1 for rectal swab or CT<29.8 for whole stool) by the TaqMan Array Card (TAC) assay.

5. ***Shigella* – attributed diarrhea case** will be defined as a case of acute diarrhea presenting to an EFGH facility in which *Shigella* was confirmed by either culture or qPCR (as outlined in #3 and #4 above).

6. **Dysentery** will be defined for DCS as a caregiver report of blood in the stool during the index diarrhea episode or a clinician diagnosis during the enrollment procedures and for the HUS as caregiver report of blood in the stool.

7. **Watery diarrhea** will be defined for DCS as the lack of caregiver report of blood in the stool during screening, enrollment and during the diarrhea episode, and no dysentery diagnosis by the clinician among enrolled participants in the DCS, and for the HUS as the lack of caregiver report of blood in the stool for children whose caregiver reported diarrhea in the previous 14 days.

8. **Severity of diarrhea** will be defined according to multiple definitions (dysentery/watery diarrhea, hospitalized diarrhea, modified Vesikari score [MVS], moderate or severe diarrhea by MVS or dysentery, the Global Enteric Multicenter Study [GEMS] moderate-to-severe diarrhea [MSD] or less-severe diarrhea [LSD], GEMS-*Shigella,* Clark or the Malnutrition and Enteric Disease Study [MAL-ED] for incidence rate and consequence comparisons.

9. **Deaths** occurring within the three-month follow-up period will be assessed by caregiver report at each scheduled visit or during upcoming visit phone reminders. Date and cause of death will be obtained from caregiver history, hospital records or death certificate, when available. The death certificate will be considered the gold standard for date of death. If a child died in the three-month period, but this information was not known until up to five months (two months beyond scheduled three-month visit), this will be included as death. Deaths occurring outside of the three-month window will not be included. Causes of death will be determined by a panel of International Classification of Diseases 11th revision (ICD-11) trained clinicians using information from the child's death certificate (if available), caregiver interview (if available), and case notes from the child's care team.

10. **Hospitalization** will be assessed at the week four and month three visits by caregiver recall and hospital records (gold standard) when available. Date and time of admission, length of hospital stay, presenting signs/symptoms, and treatment received will be obtained. Hospitalizations that are a continuation of management from a previous hospitalization (such as referrals) will be excluded from the analysis. For the purpose of standardization across sites, hospitalization will be defined as an overnight stay (child was on the ward from at least 12am to 6am or self-discharged prior to that timeframe).

11. **Loss to follow-up (LTFU)** will be defined as not having attended both the week four and month three follow-up visits after two months of actively tracing the child.

12. **Linear growth** will be defined as the change in mean length/height-for-age Z-score (ΔLAZ/ΔHAZ) from enrollment to three months. The 2006 World Health Organization (WHO) reference population will be used to calculate HAZ from the average of two repeated length/height (cm) measures per child per time point.

13. **Duration of diarrhea/dysentery/vomiting/fever** will be determined as the number of days a child has the symptoms within an episode of diarrhea. Because an episode is defined by two diarrhea-free days, the duration of each symptom may differ from the duration of the diarrhea episode (for example if there is one diarrhea free day within an episode). Notably this is distinct from the duration of the episode.

14. **Duration of diarrhea episode** will be defined as the number of days between when the caregiver reported the child's diarrhea starting and the last day of diarrhea prior to the two consecutive diarrhea-free days concluding the episode.

15. **Prolonged diarrhea** will be defined as seven or more days of diarrhea within the index diarrhea episode beginning from diarrhea onset.

16. **Persistent diarrhea** will be defined as 14 or more days of diarrhea within the index diarrhea episode beginning from diarrhea onset.

17. **Chronic diarrhea** will be defined as 30 or more days of diarrhea within the index diarrhea episode beginning from diarrhea onset.

18. **Extended case fatality** will be calculated as the proportion of enrolled participants that experience a mortality event from any cause during the three months of EFGH follow-up.

19. **Stunting** will be defined as a length-for-age Z-score (LAZ, children <24 months of age) or height-for-age Z-score (HAZ, children ≥24 months of age) <-2.

20. **A subsequent diarrhea/dysentery episode** will be defined as new diarrhea/dysentery episodes (>48 hours after a diarrhea-free period).

21. **Cost per episode treated** will be calculated using the direct and indirect costs of *Shigella*-associated MAD per outpatient and inpatient episode, from the household, health system, and societal perspectives.

22. **Antibiotic resistance** will be based on zone size (from disc diffusion) values for each tested antibiotic and categorized as susceptible, intermediate, or resistant according to the most recent Clinical and Laboratory Standards Institute (CLSI) interpretive standards at the time of data analysis. Resistant and intermediate categories will be collapsed into a non-susceptible category to create a dichotomous variable. Multidrug-resistant (MDR) will be defined as resistance to at least three of the following medications: Ampicillin, Azithromycin, Ceftriaxone, Ciprofloxacin, Nalidixic Acid, Pivemicellinam, and Trimethroprim-Sulfamethoxazole. Extensively drug-resistant (XDR) will be defined as resistance to Ampicillin, Azithromycin, Ciprofloxacin, Ceftriaxone and Trimethoprim-Sulfamethoxazole. Resistance to all WHO recommended treatments will be defined as resistance to Azithromycin, Ciprofloxacin and Ceftriaxone.

Analysis Methods

Statistical Analysis

1. **Primary Aim.** *To determine the incidence of* Shigella-*attributed diarrhea in children 6 to 35 months of age in each of the EFGH country sites.*
   a. *Statistical Analysis:* The adjusted incidence of *Shigella* will be calculated as the sum of total confirmed *Shigella* diarrhea cases divided by the child-years at risk of children 6-35 months of age in the defined catchment area, adjusting for healthcare-seeking behavior and children who were eligible but not enrolled (w_n). Crude incidence rates as well as incidence rates adjusted for enrollment but not care-seeking will also be presented. Analyses will be conducted separately using both culture-confirmed *Shigella* and attributable *Shigella* by molecular methods (TAC). All incidence rates will first be calculated using the number of *Shigella* cases and defined population size at the facility level, adjusted for the facility-specific enrollment adjustment, summed to determine the total enrollment-adjusted incidence rate, and then adjusted for care-seeking to determine the final adjusted incidence (**Table 3**).

   Child-years at risk to *Shigella* is determined by the defined population size and the facility-specific period of follow-up ($days_j/365.25$; approximately two years). The first is the estimated number of children 6-35 months of age in the catchment area which will be determined by totaling the number of children in this age range enumerated during population enumeration activities and extrapolating this estimate to study clusters not visited and households that were not reached (w_d).

   Among children 6-35 months of age who had diarrhea in the past 14 days and whose caregiver consented the HUS, the healthcare seeking adjustment, w_{HC} is defined as the proportion of children with a similar syndrome who sought care for diarrhea at an EFGH-facility. The healthcare seeking adjustment will be estimated for each enrolled case using the estimated coefficients from a 'propensity to seek care' weighting model fit to data from children reporting diarrhea in the previous two weeks in the HUS. At a minimum, w_{HC} will be computed separately for dysentery and watery diarrhea (i.e., the weighting model will include dysentery as a covariate as ascertained by the caregiver answering the HUS). The weighting model may also include other characteristics of diarrhea severity, socioeconomic status (SES), age and other variables of importance depending on the numbers of comparable cases observed in the HUS. The propensity to seek care model in the HUS will use any care-seeking at a primary healthcare facility and will then be adjusted for the site-specific difference in overall care-seeking and care-seeking to EFGH facilities ($w_{HC\ at\ EFGH}$).

In sensitivity analyses, we will restrict the weighting model to cases of diarrhea from the HUS within the past seven days instead of 14 days as seven-day recall is likely less biased than 14-day recall (although will inevitably be less precise because of fewer episodes included). Because children who have more severe diarrhea are more likely to seek care, we expect to upweight diarrhea cases enrolled with less severe diarrhea more heavily than diarrhea cases enrolled with more severe diarrhea.

Cases with *Shigella* who enrolled in EFGH

Cases with *Shigella* who sought care at EFGH facility

All cases with *Shigella*

$w_{enroll} = 1/\%\ enrolled$

$w_{screen} = 1/\%\ screened$

$w_{HC\ at\ EFGH} = 1/\dfrac{\%\ sought}{care\ at\ EFGH}$

$w_{HC} = 1/\dfrac{propensity\ score}{for\ healthcare\ seeking}$

$$w_{ni} = w_{enroll,i} \times w_{screen,i} \times w_{HC\ at\ EFGH,i} \times w_{HC,i}$$

$$w_{di} = w_{HH\ enum,i} \times w_{area\ enum,i}$$

$$cases_j = \sum_{i=1}^{n_{cases}} w_{ni} \qquad children\ at\ risk = \sum_{i=1}^{n_{enumerated}} w_{di}$$

$$\textbf{Adjusted incidence} = \frac{1}{\textbf{children at risk}} \times \sum_{j=i}^{n_{facilities}} \frac{\textbf{cases}_j}{\textbf{days}_j / 365.25}$$

$w_{HH\ enum}$ = weight to adjust for the proportion of households enumerated in selected clusters

$w_{area\ enum}$ = weight to adjust for the proportion of geographic area (clusters) enumerated

The enrollment adjustment will be episode and facility-specific based on DCS enrollment procedures. Specifically, it will be computed separately for dysentery and watery diarrhea and for each facility. The enrollment adjustment is defined as the percentage of children who were enrolled among the estimated number of children six to 35 months of age living in the catchment area who met the study definition of diarrhea and therefore would have been eligible for study participation but screened out due to lack of consent, no longer being at the facility, or other administrative reasons (i.e. presented overnight or during a weekend when EFGH screening did not occur). This adjustment is split into two parts: *prescreening* (w_{screen}) and *screening* (w_{enroll}). The *screening* adjustment determines the percentage enrolled of those who were theoretically eligible (6-35 months, living in catchment area, and met diarrhea definition) to account for children who were not enrolled due to caregiver refusal or withdrawal of consent, limited staff of clinic capacity, the respondent not planning to remain in the study area four months, the child being enrolled in another interventional study, more than four hours having passed since the child began screening procedures, the child being referred to a non-EFGH facility or the child not being enrolled due to the enrollment cap. The *prescreening* adjustment determines the percentage of children 6-35 months of age whose caregiver or clinical records indicated they presented with diarrhea, dysentery or gastroenteritis and who were not already enrolled in EFGH who were screened to account for children who did not get screened due to verbal refusal by the caregiver or the child not being present in the facility. Because it is unknowable whether or not these children would have been eligible had they undergone full screening, we will apply the observed eligibility proportion from screening to those pre-screened. The final enrollment adjustment is taken by multiplying the screening and prescreening adjustments. Summaries of the calculation of denominators and adjustments will be presented in supplementary tables.

Confidence intervals around the primary aim of adjusted incidence of *Shigella* (as well as secondary aims presenting stratified *Shigella* incidence by age, serogroup, serotype, disease severity and seasonality) will be generated using M-estimation. Specifically, estimating equations will be constructed for each component of the incidence estimate (the number of confirmed *Shigella* cases, screening adjustment [w_{screen} and w_{enroll}], healthcare seeking adjustment [w_{HC} and $w_{HC\ at\ EFGH}$], defined population size [w_d], and incidence [w_n]) and solved in a single step using the *geex* package in R. The sandwich variance estimator will be used to calculate standard error and generate Wald-based confidence intervals (estimate +/- 1.96*standard error).

b. Sensitivity analyses:
   i. We will restrict the care seeking adjustment to cases of diarrhea within the past seven days instead of 14 days as seven-day recall is likely less biased than 14-day recall (although will inevitably be less precise because of fewer episodes included).
   ii. As the enrollment adjustment does not consider, as potentially eligible, children who are currently enrolled in EFGH and in the three-month follow-up period, we will estimate the potential impact of this exclusion on the diarrhea incidence by estimating, through follow-up visit and unscheduled visit questionnaires, the proportion of enrolled cases who presented to EFGH facilities with diarrhea who would otherwise meet the EFGH eligibility criteria. We will estimate incidence rates that include these subsequent diarrhea episodes to estimate the upper bound of incidence rates (such as might be observed in a prospective cohort study).

iii. Attributable *Shigella* by TAC will be defined as a rectal swab ipaH CT<31.1, however a sensitivity analysis using a cutoff of CT<30.0 will be conducted.

Statistical Analysis of Secondary Aims

1. ***Secondary Aim #1:*** Determine the incidence of *Shigella* by serotype, severity definition, laboratory method (culture vs. qPCR), age, and by season.
   a. *Statistical Analysis:* Enrollment- and healthcare seeking-adjusted *Shigella* incidence following the protocol incidence calculation as measured by culture and qPCR will be stratified by the following factors:
      i. **Serogroup and Serotype (Table 1.1, Figure 1.1)**:
         1. *Shigella* species (*S. boydii*, S. *dysenteriae, S. flexneri, S. sonnei* or undetermined), *S. flexneri* serotype (1a, 1b, 1d, 2a, 2b, 3a, 3b, 4a, 4b, 5a, 5b, 6, 7a, X, Y, non-typable and other) and combined bivalent and quadrivalent vaccine target indicators (defined as *Shigella* positive for *S. flexneri* 2a or *S. sonnei, and S. flexneri* 2a, 3a or 6 or *S. sonnei*, respectively).
         2. The denominator for this sub-analysis will be the overall denominator for the primary endpoint.
         3. Serotype distribution will be visualized graphically either as pie charts or as a map with country-level pie-charts (**Figure 1**, not shown).
      ii. **Age (Table 1.2)**:
         1. Stratified by age at enrollment visit (6-8 months, 9-11 months, 12-17 months, 18-23 months or 24-35 months).
         2. The denominator for this sub-analysis will be the estimated child-years at risk in the catchment area for each age stratification.
      iii. **Diarrhea severity definition:** *Shigella* incidence will be stratified by the following diarrhea severity definitions (**Table 1.2**):
         1. **Dysentery vs. watery diarrhea** will be defined according to whether or not dysentery was present during the diarrheal episode.
         2. **Hospitalized diarrhea** defined as the child being admitted to hospital (overnight stay) during the diarrheal episode.
         3. **Modified Vesikari Score** (MVS) defined as in PATH Vesikari Clinical Severity Scoring System Manual[8]: Duration of diarrhea: 1-4 days (1 point), 5 days (2 points) ≥6 days (3 points); Max # of stool in 24 hour period: 1-3 (1 point), 4-5 (2 points), ≥6 (3 points); Duration of vomiting: 1 day (1 point), 2 days (2 points), ≥3 days (3 points); max # of vomiting episodes in 24 hour period: 1 (1 point), 2-4 (2 points), ≥5 (3 points); Axillary temperature 36.6-37.9°C (1 point), 38.0-38.4°C (2 points), ≥38.5°C (3 points); dehydration defined using WHO dehydration categories of some and severe as per Integrated Management of Childhood Illness (IMCI) guidelines, some dehydration (2 points), severe dehydration (3 points); treatment: rehydration (1 point), hospitalization (2 points). The scores will be summed and categorized as severe illness (11+ points), moderate illness (7-10 points), mild illness (0-6 points). If pre- or post-rehydration weights are not known to calculate % dehydration, WHO dehydration categories of some and severe as per IMCI guidelines will be used.
         4. **Moderate or severe diarrhea by MVS or dysentery** will be defined as a MVS of 9+ points or presence of visible blood in stool (Pavlinac,

Vaccines, 2022)[9]. Secondary analyses will use a more stringent cut-off of 11 points and a less stringent cut-off of 7 points.

5. **GEMS MSD and LSD** will be defined as in Kotloff, Lancet GH, 2019.[6] Moderate-to-severe diarrhea (MSD) defined as presenting to a health facility with diarrhea and severe or some dehydration (by WHO criteria), visible blood in stool, or inpatient admission. Less-severe-diarrhea (LSD) defined as presenting to a health facility without MSD.

6. **GEMS-*Shigella*** will be defined as in Pavlinac, CID, 2021.[7] Duration of diarrhea 1-3 days (0 points), 4-5 days (2 points), ≥6 days (3 points); WHO-defined dehydration categories: severe (8 points), some (4 points), none (0 points); inpatient admission (5 points). The scores will be summed and categorized as mild (<6 points), moderate (6-8 points), and severe (9+ points).

7. **Clark score** will be defined as in Clark, JID, 1988[10]. Duration of diarrhea: 1-4 days (1 point), 5-7 days (2 points), >7 days (3 points); Max # of stool in 24 hour period: 2-4 (1 point), 5-7 (2 points), >7 (3 points); Duration of vomiting: 2 days (1 point), 3-5 days (2 points), >5 days (3 points); max # of vomiting episodes in 24 hour period: 1-3 (1 point), 4-6 (2 points), >6 (3 points); Duration of reported fever: 1-2 days (1 point), 3-4 days (2 points), ≥5 days (3 points); Rectal temperature 38-38.2°C (1 point), 38.3-38.7°C (2 points), ≥38.8°C (3 points); behavioral signs: Irritable/less playful (1 point), Lethargic/listless (2 points), Seizures (3 points). The scores will be summed and categorized as mild (2-8 points), moderate to severe (9+ points).

8. **MAL-ED score** will be defined as in Lee, J Pediatr Gastroenterol Nutr., 2016[11]: Duration of diarrhea: 2-4 days (1 point), 5-7 days (2 points), ≥8 days (3 points); Max # of stool in 24 hour period: <5 loose stools/24 hours (1 point), 5-7 loose stools/24 hours (2 points), ≥8 stools/24 hours (3 points); Duration of vomiting: 1 day (1 point), 2 days (2 points), ≥3 days (3 points); duration of reported fever: 1+ days (1 point); Confirmed temperature: ≥37.5°C (confirmed by field worker) (2 points); Dehydration: Some (2 points), severe (3 points). The scores will be summed and categorized as non-severe (<6 points) or severe (6+ points)

9. The denominator for each subgroup of this sub-analysis will be the overall child-years at risk of *Shigella* in the catchment area (same as the primary analysis). Participants who are missing one or more component of scores will be presented as "Unknown".

   iv. **Diarrhea season**:
   1. Seasonality will be presented graphically (**Figure 1.2** [not shown]) as monthly or quarterly incidence.
   2. The denominator for this sub-analysis will be the estimated child-years at risk in the catchment area for each study month or quarter.

b. The adjusted incidence rate and 95% confidence interval will be reported for each stratification both overall and by country.

c. To describe the prevalence *Shigella* and other important enteric pathogens (see below) among participants enrolled in EFGH, the proportion of participant samples testing positive for each pathogen will be calculated among participants who had a stool sample tested by TAC:

   i. Pathogens tested and attributable CT thresholds:
   1. *Shigella* (CT<31.1)
   2. Adenovirus 40/41 (CT<25.5)

3. *Cryptosporidium* (CT<27.1)
4. Norovirus GII (CT<26.6)
5. Rotavirus (CT<34.2)
6. Heat stable toxin-producing *E. coli* (ST-ETEC, CT<27.9)
7. Typical enteropathogenic *E. coli* (tEPEC, CT<20.7)
8. *Campylobacter jejuni* (CT<20.7)
9. Astrovirus (CT<26.7)
10. Sapovirus (CT<24.4)
11. *Vibrio cholerae* (CT<33.9)
12. *Salmonella* (CT<33.3)
13. *Aeromonas* (CT<23.6)
14. *Cyclospora cayetanensis* (CT<33.9)
15. *Entamoeba histolytica* (CT<32.6)
16. *Cystoisospora belli* (CT<34.4)

ii. Prevalences will be calculated for all participants with MAD and among the following subsets:
1. Among participants presenting with moderate or severe diarrhea (by the Modified Vesikari Score 9+) and/or dysentery.
2. Among participants who tested positive for *Shigella*-attributable MAD (among non-*Shigella* pathogens).
3. Among participants who did not test positive for *Shigella*-attributable MAD (among non-*Shigella* pathogens).

2. ***Secondary Aim #2:*** *Describe the prevalence of resistance to commonly used antibiotics in* Shigella *isolates in each EFGH country site.*

   a. <u>*Statistical Analysis:*</u> The proportion of *Shigella* culture positive stool samples that are resistant to the medications listed below will be calculated by EFGH region and EFGH study site (**Table 2.1, Figure 2.1** [not shown]):
      - Ampicillin
      - Azithromycin
      - Ceftriaxone
      - Ciprofloxacin
      - Nalidixic acid
      - Pivemicellinam
      - Trimethoprim-sulfamethoxazole

   Resistance will be defined as "non-susceptibility", or resistant or intermediate zone size classifications according to the most recent CLSI guidelines at the time of analysis. Resistance will be computed for all of the above antibiotics for all sites, by region (South America [Peru], West Africa [The Gambia and Mali], East Africa [Kenya and Malawi], and Asia [Pakistan and Bangladesh]), and among *S. sonnei* positive samples and *S. flexneri* positive samples. Additionally, we will present the percentage of multi-drug resistant *Shigella* (MDR, resistant to three or more antibiotics), extensively drug resistant *Shigella* (XDR, resistant to all of the following: Azithromycin, Ciprofloxacin, Ceftriaxone, Trimethoprim-sulfamethoxazole, and Ampicillin), and resistance to all WHO recommended treatments (resistant to all of the following: Azithromycin, Ciprofloxacin, and Ceftriaxone).

   b. <u>Confidence intervals</u> around non-susceptibility proportions will be determined assuming a binomial distribution.

3. ***Secondary Aim #3:*** *Determine the risk of all-cause mortality, hospitalization, persistent diarrhea, experiencing a subsequent diarrhea episode, and change in linear growth in the three months following an episode of MAD.*

   a. *Statistical Analysis:*

   Deaths will be described individually in terms of *Shigella* attribution and overall (**Table 3.1**). Extended all-cause case fatality including ICD-11 cause, age, enrollment site, time from enrollment to death, and *Shigella* attribution will be described (**Table 3.2**). A Fisher's exact test will be used to test whether the proportion of children who died differed between those with and without *Shigella* at enrollment. The cumulative incidence of all-cause mortality will be plotted using the Kaplan-Meier survival function, both overall and stratified by *Shigella*-attribution (**Figure 3.1** [not shown]). Participants will be censored at date of death, last known alive date, or latest follow-up date. Models will not be adjusted because of the anticipated small number of outcomes.

   The risk of hospitalization, risk of experiencing subsequent diarrhea episodes, and prevalence of persistent diarrhea will be described by leading attributable cause of the index MAD episode. *Shigella* will either be split into *Shigella* with appropriate antibiotic treatment and *Shigella* without appropriate antibiotic treatment or treated as a mediator and addressed using a formal mediation analysis (**Table 3.3**). The relative risks comparing subsequent diarrhea episodes and hospitalizations among children stratified by the likely etiology of diarrhea at enrollment will be determined using a modified-Poisson model with robust standard errors using a dichotomized outcome (did the outcome occur during follow-up or not) and Wald chi-square tests of the two-way comparison. The proportion of children with persistent diarrhea will be compared overall and by the likely etiology of diarrhea at enrollment, using log-binomial regression (or modified-Poisson regression with robust standard errors if any model does not converge). All multivariate models will adjust for site, age, maternal education, wealth quintile, and breastfeeding. For all outcomes of interest, we will test for effect modification between attribution of any bacterial targets and appropriate antibiotic use, and if no evidence is observed ($p \geq 0.05$) that target will be combined into a single category regardless of antibiotic treatment. In this primary analysis, hospitalizations occurring at any point between enrollment and follow-up will be included.

   Hospitalizations that occur during the index diarrhea episode will be disaggregated from those occurring after the index diarrhea episode has resolved to separately estimate enteric pathogen associations with short- and longer-term severe illnesses (**Table 3.4**). A supplementary analysis will additionally include stratification of risk of subsequent diarrhea by whether or not the subsequent diarrhea episodes were medically-attended. Finally, a supplementary analysis will compare the risk of hospitalization, risk of subsequent diarrhea, and prevalence of persistent diarrhea among children with *Shigella*, by culture-positive *Shigella* vs. culture-negative/TAC-attributable *Shigella*. Multivariate supplementary tables described here will be adjusted for site, age, maternal education, wealth quintile, and breastfeeding.

   The distribution of LAZ/HAZ at enrollment, week four, and month three will be presented as boxplots stratified by likely etiology at enrollment of the top five most prevalent attributable enteric pathogens by qPCR (**Figure 3.2** [not shown]). Supplemental tables will display these values stratified by site.

The mean and standard deviation of LAZ/HAZ from enrollment to week four follow-up and enrollment to month three follow-up will be presented among surviving children by likely etiology at enrollment of the top five most prevalent attributable enteric pathogens by qPCR, including *Shigella* stratified by receiving appropriate antibiotics and untreated. Other bacterial pathogens will be similarly stratified by antibiotic use if there is evidence of effect modification (p<0.05) (**Table 3.5**). Two sets of linear regression models, one modelling enrollment to week four and another from enrollment to month three, will be used to model the association between likely MAD etiology and linear growth (ΔLAZ/HAZ) in the months following the diarrhea episode among surviving children. Models will include adjustment for site, age, sex, maternal education, wealth quintile, breastfeeding, days from enrollment to relevant follow-up visit and baseline LAZ/HAZ. Lowess curves will be generated to show mean ΔLAZ/HAZ between the timepoints (enrollment, week four, and month three) by likely MAD etiology at enrollment (**Figure 3.3** [not shown]). We will report prevalence of stunting (LAZ/HAZ<-2) at enrollment, week four follow up, and month three follow up by likely etiology of MAD at enrollment, including *Shigella* stratified by receiving appropriate antibiotics and untreated. Other bacterial pathogens will be similarly stratified by antibiotic use if there is evidence of effect modification (p<0.05). Prevalence ratios (PR) adjusted for site, age, sex, maternal education, wealth quintile, breastfeeding, and baseline LAZ/HAZ will be generated to describe the association between diarrhea etiology and stunting (**Table 3.6**). An alluvial plot will be generated to show the proportion of stunted and non-stunted at enrollment, week four follow up, and month three follow up and transition of stunting status between study visits (**Figure 3.4** [not shown]**)**. Supplementary tables will report both LAZ/HAZ and stunting analyses stratified by site, by *Shigella* species (*S. flexneri*, *S. sonnei*, *S. boydii*, *dysenteriae*), and by diagnostic method (culture positive vs. culture negative/TAC-attributable). For all analyses utilizing LAZ/HAZ data, individual LAZ/HAZ greater than 6.0 or less than -6.0 will be excluded as implausible values[13]. Also excluded will be any height decrease of greater than 1.5cm or height increase of greater than 6cm between enrollment and month three follow-up[14].

4. ***Secondary Aim #4:*** *Compare various severity definitions in their ability to predict risk of death or hospitalization, or linear growth faltering among cases of medically attended diarrhea and* Shigella-*attributable medically attended diarrhea, respectively.*

Based on signs and symptoms collected from EFGH cases, we will construct diarrhea severity definitions as described above in Secondary Aim 1. Scores will be categorized as originally constructed (i.e. mild, moderate, and severe). We will describe the mean scores and frequencies/percentages of children falling in all severity definition categories both overall, and among children with *Shigella*-attributed diarrhea by site and overall **(Table 4.1)**. In supplementary tables, we will report further stratification by age at enrollment and laboratory method (for *Shigella*-attributable MAD only).

As GEMS and MVS +/- dysentery are severity scores of particular interest for informing *Shigella* vaccine trial clinical endpoints, we will compare the components and symptoms that make up these scores with and without the combination of meeting the GEMS definition of MSD and moderate or severe diarrhea (9+ points) by the MVS +/- dysentery among children with *Shigella*-attributed diarrhea (**Table 4.2**). In supplementary tables, we will present this table further stratified by culture positivity.

To evaluate the scores' associations with poor outcomes, we will dichotomize scores into moderate or severe vs. mild diarrhea (for GEMS-*Shigella*, MVS, Clark and MVS +/- dysentery), severe vs. mild diarrhea (for MAL-ED) or MSD vs. less-severe-diarrhea (LSD) (for GEMS). We will calculate the diagnostic accuracy (sensitivity, specificity, positive predictive value [PPV], and negative predictive value [NPV]) of severe vs. non-severe diarrhea (by each severity score definition) in identifying children who die or were hospitalized during the initial episode (**Table 4.3**). Diagnostic accuracy will be reported overall and stratified by appropriate antibiotic treatment. As part of secondary analysis, we will look at all hospitalizations and deaths occurring throughout the three-month follow-up. We will report the performance of scores for all MAD as well as in the subset of children with *Shigella*-attributed diarrhea. Primary analyses will consider death or hospitalization as a combined outcome, and secondary analyses will report these outcomes separately. As hospitalization is included in many scores, additional secondary analyses will repeat diagnostic accuracy analyses with recalibrated scores which remove hospitalization as a component and adjust the score cut-offs for categories. We will additionally explore varying cut-offs used for score-based severity definitions by conducting Receiver Operating Characteristics (ROC) analyses to identify cut-points that maximally distinguish those children who had experienced a death or hospitalization from those that did not (**Figure 4.1**).

We will also evaluate scores' association with linear growth. We will perform a linear regression of each dichotomized score on the change in length-for-age or height-for-age z-score (ΔLAZ/HAZ), adjusting for baseline LAZ/HAZ, age, site, wealth quintile, maternal education, and breastfeeding (**Table 4.4**). We will report model results among all MAD as well as children with *Shigella*-attributed diarrhea, and results will be further stratified by antibiotic use or with antibiotic use treated as a mediator. We will compare the magnitude of association (beta values) between scores. Secondary analysis will explore a dichotomized endpoint.

Because other EFGH analysis (biomarker sub-study) will evaluate the combination of signs/symptoms and inflammatory biomarkers in their ability to distinguish *Shigella* from non-*Shigella*-attributed diarrhea, we will not address that question in this aim.

5. ***Secondary Aim #5****: Quantify the cost incurred by families and health care systems due to* Shigella *morbidity and mortality.*

For each child enrolled in the study, we will collect data on medical and non-medical resources used to treat the episode of diarrhea, using child medical records and standardized questionnaires administered to caregivers. *Direct medical costs* include medical resources used in the treatment of diarrhea. We will estimate the costs of drugs and diagnostics used in diarrhea management, by applying a standardized country-specific unit cost from National Price Lists to each treatment administered or prescribed in medical records. In situations where data is missing from National Price Lists, we will estimate unit costs using a mean value from local pharmacies and health facilities. We will also estimate service delivery costs: operational costs for medical visits, such as health workers' salaries or maintenance of facility equipment. To estimate these costs, we will apply standardized country-specific unit costs from WHO-CHOICE[14] to each visit based on the level of care (inpatient vs. outpatient) and number of days admitted (inpatient only). Standardized questionnaires include questions regarding whether medical resources were paid for by the caregiver or funded by the public health system. *Direct non-medical costs* include non-medical fees incurred by caregivers, such as costs to travel to the health facility. We will estimate non-medical fees through caregiver direct reports from standardized questionnaires. *Indirect (non-medical) costs* include caregiver time lost from work while caring for their sick child. To estimate indirect costs, we will apply a national average wage rate from the International Labor Organization (https://www.ilo.org) to caregiver-reported time lost from work from standardized questionnaires.

We will estimate the <u>average cost per episode of *Shigella*-attributable MAD</u>, referred to henceforth as the "cost per episode", by averaging costs across *Shigella*-positive cases, including cases of culture-confirmed *Shigella* and/or *Shigella* confirmed by molecular methods (TAC). We will present the mean and standard deviation (SD) of costs per episode, from the household perspective (including out-of-pocket medical and non-medical fees incurred by caregivers), the health system perspective (medical resources funded by the public health system), and the societal perspective (both household and health system costs). We will stratify societal costs by client and visit characteristics, as described in **Table 5.1**. Costs will be presented in 2024 US dollars (USD) to allow for comparability across sites. We will inflate costs incurred in earlier years to 2024 values using GDP price deflators from the World Bank and convert local currencies to equivalent USD values using midyear currency values. Additional sub-analyses will be conducted to determine costs per episode of MAD associated with *Shigella* serotypes, other diarrheal pathogens, and other stratifications as relevant.

To identify the effects of visit characteristics on costs per episode of *Shigella* MAD, we will use multivariate Generalized Linear Models (GLMs). GLMs require explicit specification of the distribution of the dependent variable and the link function describing how independent variables are functionally related to the dependent variable. We will use the modified Park test[15], common to health econometrics, to identify the GLM distribution and link function. Our final model will be determined from the modified Park test results but will be initially tested using a gamma distribution with log link:

$$\ln{(Y_i)} \ = \ \beta_0 + \beta_1 Country_i + \ \beta_2 Severity_i + \ \beta_3 X_i$$

where the cost per episode (*Y*) for a given child, *i,* is a function of the country in which the child was treated (*Country*), the severity of diarrhea *(Severity),* and other client or visit characteristics (*X*). Other client or visit characteristics will be selected based on descriptive results from Table 5.1, with model variables being selected when variability across categories is evident. Models will be run separately per costing perspective. Coefficients, confidence intervals, and p-values will be presented for all independent variables (**Table 5.2**).

We will estimate the <u>annual economic burden of *Shigella* MAD</u> in each EFGH country site (c). The

estimated adjusted incidence of *Shigella* MAD (from the primary aim) and the estimated population sizes of children 6-35 months (converted to person-years) will be used to estimate the number of annual *Shigella* MAD episodes per country site. We will then apply the average cost per episode of *Shigella* MAD to the number of estimated episodes per year. The annual economic burden will be calculated separately per costing perspective (**Table 5.3**). We will produce estimates per site, standardized to 100,000 population size to allow for comparability across catchment areas.

$$\text{Annual } \textit{Shigella} \text{ MAD costs}_c = \frac{\textit{Shigella} \text{ MAD episodes}_c}{100 \text{ person years}} \times \text{ person years}_c \times \text{ cost per episode }_c$$

6. ***Secondary Aim #6***: *To identify optimal laboratory methods for* Shigella *culture by:*

   a. *comparing the isolation rate of* Shigella *between two transport media for rectal swabs (Cary-Blair and mBGS)*

      We will calculate the proportion of rectal swab samples from Cary-Blair and mBGS media from which *Shigella* was isolated overall and per site as well as stratified by serotype (**Table 6.1**). A two-sided 95% confidence interval around each proportion will be calculated assuming a Binomial distribution. Proportions will be compared using a McNemar's test of superiority to determine if one media is superior to the other in terms of *Shigella* isolation rates.

   b. *comparing the isolation rate of* Shigella *between two fecal sample types (rectal swabs and whole stool) among the subset of children who produced whole stool in the Gambia and Bangladesh country sites.*

      We will calculate the proportion of <u>rectal swab</u> samples from which *Shigella* was isolated and the proportion of <u>whole stool</u> samples from which *Shigella* was isolated, matched by media type (Cary-Blair or mBGS), overall and per site and stratified by *Shigella* species (**Table 6.2**). A two-sided 95% confidence interval for the absolute difference in proportions will be calculated using McNemar's test. When assessing non-inferiority, the lower bound of the 95% confidence interval will be compared to the non-inferiority margin of an absolute difference of 0.01.

Statistical Software
All analyses will be conducted using STATA or R and the software used reported in all analysis write-ups.

References
References to be Provided for Non-standard Statistical Methods
All methods being proposed are standard.

Data Management Plan
Procedures relating to data entry, management, and quality assurance and control are outlined in the EFGH Data Management Plan.

Statistical Master File
The Statistical Master File is maintained by the EFGH Central Data Management Team.

Referenced Literature

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Enterics for Global Health (EFGH)
Statistical Analysis Plan – Tables and Figures
Version 2.0

Table of Contents

Primary Aim

**Figure 1: Diarrhea case surveillance participant screening, enrollment and follow-up.**
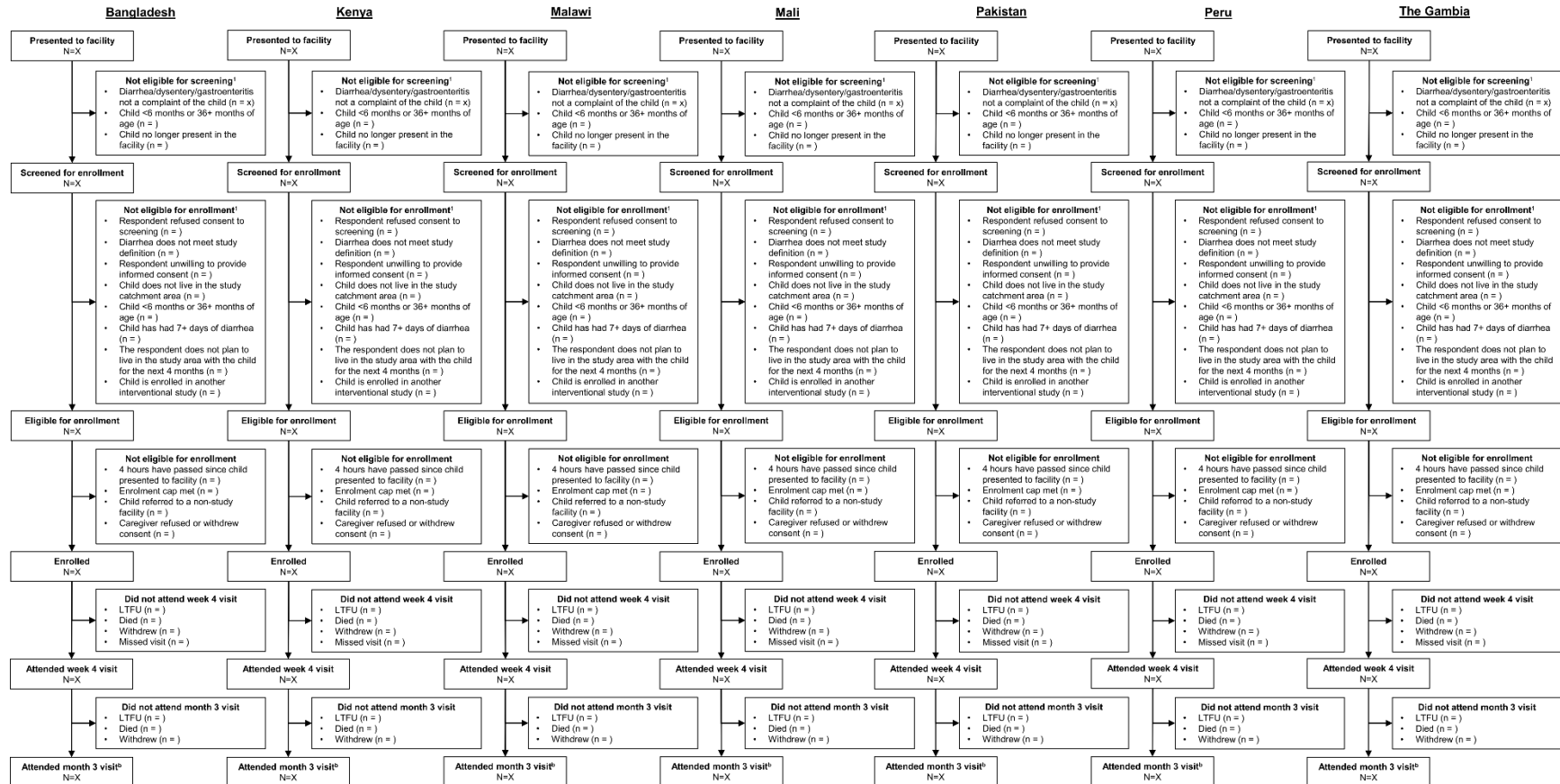
Figure 1. EFGH CONSORT diagram. [a] Reasons participants were not screened or did not meet eligibility do not sum to total as participants could have screened out for multiple reasons. [b] Among enrolled participants who attended the Week Four visit or missed the Week Four visit but not due to death, withdrawal or lost to follow-up (LTFU).

Table 1: Baseline participant characteristics

Table 1. Demographic and clinical characteristics of participants enrolled to Diarrheal Case Surveillance, by study site.

	Bangladesh	Kenya	Malawi	Mali	Pakistan	Peru	The Gambia	Total
Demographics								
Total enrolled: N								
Female sex: n (%)								
Age (months): n (%)								
6 – 8								
9 – 11								
12 – 17								
18 – 23								
24 – 35								
Age in months: median (IQR)								
Highest maternal education achieved: n (%)								
Less than primary school								
Koranic school only								
Primary school or greater								
Unknown or declined								
Accompanying caregiver employment: n (%)								
Not employed								
Employed								
Unknown								
Children <5 years in household: median (IQR)								
Any breastfeeding: n (%)								
Wealth index: median (IQR)								
Water, Sanitation and Hygiene (WASH) characteristics								
Drinking water source[a]: n (%)								
Improved source								
Unimproved source								
Surface water								
Unknown or other source								
Sanitation access[b]: n (%)								
Improved source								
Unimproved source								
Open defecation								
Unknown or other source								
Drinking water treatment: n (%)[c]								
Boil								
Bleach/chlorination								
Solar disinfection								
Let stand and settle								
Strain through a cloth								
Filter (ceramics/sand/composite/LifeStraw)								
Other method								
Clinical characteristics								
Symptoms at enrollment[c]: n (%)								
Dysentery[d]								
Oedema								
Signs of LRTI[e]								
Stiff neck								
Generalized rash								
Convulsions								
Lethargy or unconscious								
Palmar pallor								
Dehydration[f]: n (%)								
None								
Some								
Severe								
Immunization status: n (%)[c]								
Received age-appropriate vaccinations, per country guidelines								
Received rotavirus vaccine								
Care seeking prior to enrollment visit: n (%)[c]								
Community health worker								
Drug seller								
Health outpost								
Inpatient health facility								
Outpatient health facility								
Pharmacist								
Religious or traditional healer								
Other								
Hospitalized: n (%)[g]								
Duration of diarrhea prior to care seeking (days): median (IQR)								
Modified Vesikari score (MVS)[h]: median (IQR), n (%)								
Mild (0-8 points)								
Moderate (9-10 points)								
Severe (11+ points)								
Moderate or severe diarrhea by MVS or dysentery[i]: n (%)								
GEMS[j]: median (IQR), n (%)								
Moderate to severe diarrhea (MSD)								
Less severe diarrhea (LSD)								
GEMS-*Shigella* score[k]: median (IQR), n (%)								
Mild (<6 points)								
Moderate (6-8 points)								
Severe (9+ points)								
Clark score[l]: median (IQR), n (%)								
Mild (2-8 points)								
Moderate to severe (9+ points)								
MAL-ED score[m]: median (IQR), n (%)								

Table 1. Demographic and clinical characteristics of participants enrolled to Diarrheal Case Surveillance, by study site.

	Bangladesh	Kenya	Malawi	Mali	Pakistan	Peru	The Gambia	Total
Non-severe (<6 points)								
Severe (6+ points)								
Anthropometry								
LAZ/HAZ: median (IQR)								
MUAC: median (IQR)								
WAZ: median (IQR)								
WLZ: median (IQR)								
Stunted[n]: n (%)								
Severe								
Moderate								
None								
Wasted[o]: n (%)								
Severe								
Moderate								
None								
Underweight[p]: n (%)								
Severe								
Moderate								
None								

HAZ: height for age Z-score, IQR: interquartile range, JMP: WHO/UNICEF Joint Monitoring Programme for Water Supply, Sanitation and Hygiene, LAZ: length for age Z-score, LRTI; lower respiratory tract infection, LSD: less-sever-diarrhea, MSD: moderate-to-severe diarrhea, MUAC: mid-upper arm circumference, MVS: modified Vesikari score, WAZ: weight for age Z-score, WHO: world health organization, WLZ: weight for length Z-score.

[a] Drinking water source was classified according to the WHO/UNICEF Joint Monitoring Programme for Water Supply, Sanitation and Hygiene (JMP) as surface water (water from a river, dam, lake, pond, stream, canal or irrigation channel), unimproved (unprotected wells or springs), or improved (water piped into the dwelling, yard or plot, public taps or standpipes, tube wells or boreholes, protected dug wells or springs, rainwater collection, water from a tanker-truck, water from a cart with a small tank or drum, filtered or unfiltered water kiosks, bottled water, or sachet water.

[b] Sanitation access was classified according to the JMP as open defecation (no facility, bush or field), unimproved (flush toilets to elsewhere, pit latrines without slab floor, bucket toilets or hanging toilets/latrines), or improved (flush toilets to piped sewer systems, septic tanks or unknown location, ventilated improved pit latrines, pit latrines with slab floors, or composting toilets).

[c] Columns do not sum to 100% as multiple options could be selected.

[d] Blood in the stool as reported by caregiver during the diarrheal episode or by clinical diagnosis

[e] One or more of the following signs indicative of lower respiratory infection: cough, difficulty breathing, chest in-drawing, chest auscultation, central cyanosis, oxygen saturation <90%, or severe respiratory distress.

[f] Based on WHO criteria. Severe dehydration = At least two of the following signs: lethargy, abnormally sunken eyes, drinks poorly, skin pinch >2 seconds. Some dehydration = At least two of the following signs: restless/irritable, abnormally sunken eyes, drinks eagerly, skin pinch 1-2 seconds. [4]

[g] Defined as an overnight stay (child was on the ward from at least 12am to 6am or self-discharged prior to that timeframe.

[h] Defined as in PATH Vesikari Clinical Severity Scoring System Manual: Duration of diarrhea: 1-4 days (1 point), 5 days (2 points) ≥6 days (3 points); Max # of stool in 24 hour period: 1-3 (1 point), 4-5 (2 points), ≥6 (3 points); Duration of vomiting: 1 day (1 point), 2 days (2 points), ≥3 days (3 points); max # of vomiting episodes in 24 hour period: 1 (1 point), 2-4 (2 points), ≥5 (3 points); Axillary temperature 36.6-37.9°C (1 point), 38.0-38.4°C (2 points), ≥38.5°C (3 points); dehydration 1-5% (2 points); ≥6% (3 points); treatment: rehydration (1 point), hospitalization (2 points).

[i] Defined as in Pavlinac, Vaccines, 2022 as a MVS of 9+ or presence of visible blood in stool. N=x could not be assessed due to missing data for diarrhea duration.

[j] Defined as in Kotloff, Lancet GH, 2019. Moderate-to-severe diarrhea (MSD) defined as presenting to a health facility with diarrhea and severe or some dehydration (by WHO criteria), visible blood in stool, or inpatient admission. Less-severe-diarrhea (LSD) defined as presenting to a health facility without MSD.[6]

[k] Defined as in Pavlinac, CID, 2021. Duration of diarrhea through day of presentation: 1-3 days (0 points), 4-5 days (2 points), ≥6 days (3 points); WHO-defined dehydration categories: severe (8 points), some (4 points), none (0 points); inpatient admission (5 points).[7]

[l] Defined as in Clark, JID, 1988. Duration of diarrhea: 1-4 days (1 point), 5-7 days (2 points) >7 days 3 points); Max # of stool in 24 hour period: 2-4 (1 point), 5-7 (2 points), >7 (3 points); Duration of vomiting: 2 days (1 point), 3-5 days (2 points), >5 days (3 points); max # of vomiting episodes in 24 hour period: 1-3 (1 point), 4-6 (2 points), >6 (3 points); Duration of reported fever: 1-2 days (1 point), 3-4 days (2 points), ≥5 days (3 points); behavioral signs: Irritable/less playful (1 point), Lethargic/listless (2 points), Seizures (3 points). N=x could not be assessed due to missing data for diarrhea duration.

[m] Defined as in Lee, BMJ Open, 2014: Duration of diarrhea: 2-4 days (1 point), 5-7 days (2 points), ≥8 days (3 points); Max # of stool in 24 hour period: <5 loose stools/24 hours (1 point), 5-7 loose stools/24 hours (2 points), ≥8 stools/24 hours (3 points); Duration of vomiting: 1 day (1 point), 2 days (2 points), ≥3 days (3 points); duration of reported fever: 1+ days (1 point); Confirmed temperature: ≥37.5°C (confirmed by field worker) (2 points); Dehydration: Some (2 points), severe (3 points). N=x could not be assessed due to missing data for diarrhea duration.

[n] Severe stunting: HAZ/LAZ < -3, Moderate stunting: -3 ≤ HAZ/LAZ < -2.

[o] Severe wasting: WLZ < -3 or MUAC < 11.5, Moderate wasting: -3 ≤ WLZ < -2 or 11.5 ≤ MUAC < 12.5.

[p] Severely underweight: WAZ < -3, Moderately underweight: -3 ≤ WAZ < -2.

Table 2: Baseline characteristics of population enumeration

Table 2. Demographic and Clinical Characteristics of the Population Enumeration and Healthcare Utilization Survey, by study site.

Indicator	Bangladesh	Kenya	Malawi	Mali	Pakistan	Peru	The Gambia	Overall
Population Enumeration								
Total clusters demarcated: n								
Study area: m²								
Clusters enumerated: n (%)								
Cluster enumerated								
No households present in the cluster								
Could not enumerated cluster due to safety or other reasons								
Not enumerated								
Total individuals enumerated: n								
Children 6-35 months of age enumerated: n								
Caregiver reported children 6-35 months of age had diarrhea in the past two weeks: n (%)								
Yes								
No								
Don't know								
Caregiver of child 6-35 months of age with diarrhea consented to HUS: n (%)								
Yes, consented								
No, refused								
No, caregiver not available for consent no successful revisit								
Care-seeking for diarrhea: n (%)ª								
Did not seek care								
Sought care at an EFGH facility								
Sought care at a different outpatient hospital or health center								
Sought care at an inpatient hospital or health center								
Sought care at a health outpost								
Sought care at a drug seller or pharmacist								
Sought care at a traditional or religious healer								
Other								
Days between diarrhea onset and care seeking: median (IQR)								
Demographic indicators of children in the HUS								
Female sex: n (%)								
Age (months): n (%)								
6 – 8								
9 – 11								
12 – 17								
18 – 23								
24 – 35								
Age in months: median (IQR)								
Clinical characteristics								
Symptoms during diarrheal illness: n (%)ª								
Blood in stool								
Irritable								
Very thirsty								
Sunken eyes								
Wrinkled skin								
Drinks eagerly, thirsty								
Unable to drink or drank poorly								
Lethargic, unconscious, or hard to stay awake								

HUS: healthcare utilization survey, IQR: interquartile range.

ª Column does not sum to total as surveyed participants may have sought care from multiple sources or reported multiple clinical symptoms.

Table 3: *Shigella* Incidence by country and method of ascertainment

Table 3. Adjusted incidence of *Shigella* by EFGH country and method of ascertainment.

| EFGH Country | Confirmed *Shigella* cases: n | | | *Shigella* MAD incidence | | |
	Watery diarrhea	Dysentery	Total	Crude IR (CI)	Enrollment-adjusted IR[a] (CI)	Adjusted IR[b] (CI)
Culture-confirmed *Shigella*[c]						
Bangladesh						
Kenya						
Malawi						
Mali						
Pakistan						
Peru						
The Gambia						
Total[d]						
***Shigella* attributable by molecular diagnostics[e]**						
Bangladesh						
Kenya						
Malawi						
Mali						
Pakistan						
Peru						
The Gambia						
Total[d]						

CI: 95% confidence interval, CT: cycle threshold, IR: incidence rate, MAD: medically-attended diarrhea, mBGS: Modified buffered glycerol saline.

[a] The number of confirmed *Shigella* watery diarrhea cases per 100 child-years adjusted for enrollment plus the number of confirmed *Shigella* dysentery cases per 100 child-years at risk adjusted for enrollment.

[b] The number of confirmed *Shigella* watery diarrhea cases per 100 child-years, adjusted for care-seeking and enrollment plus the number of confirmed *Shigella* dysentery cases per 100 child-years at risk, adjusted for care-seeking and enrollment.

[c] Includes isolates from rectal swabs transported in mBGS or Cary-Blair media.

[d] Totals are the sum of country-level estimates weighted to the proportion of child-years contributing to the combined denominator.

[e] Defined as an ipaH cycle threshold (CT) < 31.1.

Secondary Aim 1

Table 1.1: *Shigella* incidence by species and serotype

Table 1.1. Adjusted *Shigella* incidence stratified by *Shigella* species and serotype.

	Serotype	Bangladesh Culture[a]	TAC[b]	Kenya Culture[a]	TAC[b]	Malawi Culture[a]	TAC[b]	Mali Culture[a]	TAC[b]	Pakistan Culture[a]	TAC[b]	Peru Culture[a]	TAC[b]	The Gambia Culture[a]	TAC[b]	Total Culture[a]	TAC[b]
S. flexneri and S. sonnei	*S. flexneri*																
	1a																
	1b																
	1d																
	2a																
	2b																
	3a																
	3b																
	4a																
	4b																
	5a																
	5b																
	6																
	7a	-		-		-		-		-		-		-		-	
	X																
	Y																
	Non-typable																
	S. sonnei																
	Bivalent vaccine targets[c]																
	Quadrivalent vaccine targets[d]																
	Alternate quadrivalent vaccine targets[e]																
Other	*S. boydii*	-		-		-		-		-		-		-		-	
	S. dysentariae	-		-		-		-		-		-		-		-	
	1	-		-		-		-		-		-		-		-	
	Other	-		-		-		-		-		-		-		-	
	Undetermined[f]																

CI: 95% confidence interval, CT: cycle threshold, MAD: medically-attended diarrhea, TAC: TaqMan array card.

[a] *S. flexneri* 7a is not assessed by culture.

[b] Defined as an ipaH cycle threshold (CT) < 31.1. *S. boydii* and *S. dysentariae* are not assessed by TAC.

[c] *S. flexneri* 2a or *S. sonnei*.

[d] *S. flexneri* 2a, 3a, or 6 or *S. sonnei*.

[e] *S. flexneri* 1b, 2a or 3a or *S. sonnei*.

[f] Undetermined by culture means any serotypes/subserotypes not listed in the table. Undetermined by TAC means *Shigella* detected by PCR but molecular criteria to assign species/serotype to *S. sonnei* or *S. flexneri* was not met.

Table 1.2: *Shigella* incidence by age and diarrhea severity

Table 1.2. Adjusted *Shigella* incidence stratified by participant age and diarrhea severity definition.															
	Enrollment- and Healthcare Seeking-Adjusted *Shigella* MAD Incidence Rate (CI)														
	Bangladesh		Kenya		Malawi		Mali		Pakistan		Peru		The Gambia		Total	
Strata	Culture	TAC[a]	Culture	TAC[a]	Culture	TAC[a]	Culture	TAC[a]	Culture	TAC[a]	Culture	TAC[a]	Culture	TAC[a]	Culture	TAC[a]
Age at enrollment (months)															
6 – 8															
9 – 11															
12 – 17															
18 – 23															
24 – 35															
Diarrhea severity classifications															
Dysentery															
Watery diarrhea															
Hospitalized															
Modified Vesikari score (MVS)[b]															
Mild illness (0-8 points)															
Moderate illness (9-10 points)															
Severe illness (11+ points)															
Moderate or severe diarrhea by MVS or dysentery[c]															
GEMS[d]															
Moderate-to-severe diarrhea (MSD)															
Less-severe-diarrhea (LSD)															
GEMS-*Shigella* score[e]															
Mild (<6 points)															
Moderate (6-8 points)															
Severe (9+ points)															
Clark score[f]															
Mild (2-8 points)															
Moderate to severe (9+ points)															
MAL-ED score[g]															
Non-severe (<6 points)															
Severe (6+ points)															

CI: 95% confidence interval, CT: cycle threshold, LSD: less-severe-diarrhea, MAD: medically-attended diarrhea, MSD: moderate-to-severe diarrhea, MVS: modified Vesikari score, TAC: TaqMan array card, WHO: World Health Organization.

[a] Defined as an ipaH cycle threshold (CT) < 31.1. *S. boydii* and *S. dysentariae* are not assessed by TAC.

[b] Defined as in PATH Vesikari Clinical Severity Scoring System Manual: Duration of diarrhea: 1-4 days (1 point), 5 days (2 points) ≥6 days (3 points); Max # of stool in 24 hour period: 1-3 (1 point), 4-5 (2 points), ≥6 (3 points); Duration of vomiting: 1 day (1 point), 2 days (2 points), ≥3 days (3 points); max # of vomiting episodes in 24 hour period: 1 (1 point), 2-4 (2 points), ≥5 (3 points); Axillary temperature 36.6-37.9°C (1 point), 38.0-38.4°C (2 points), ≥38.5°C (3 points); dehydration 1-5% (2 points), ≥6% (3 points); treatment: rehydration (1 point), hospitalization (2 points).

[c] Defined as in Pavlinac, Vaccines, 2022 as a MVS of 9+ or presence of visible blood in stool.

[d] Defined as in Kotloff, Lancet GH, 2019. Moderate-to-severe diarrhea (MSD) defined as presenting to a health facility with diarrhea and severe or some dehydration (by WHO criteria), visible blood in stool, or inpatient admission. Less-severe-diarrhea (LSD) defined as presenting to a health facility without MSD.

[e] Defined as in Pavlinac, CID, 2021. Duration of diarrhea through day of presentation: 1-3 days (0 points), 4-5 days (2 points), ≥6 days (3 points);WHO-defined dehydration categories: severe (8 points), some (4 points), none (0 points); inpatient admission (5 points).

[f] Defined as in Clark, JID, 1988. Duration of diarrhea: 1-4 days (1 point), 5-7 days (2 points) >7 days (3 points); Max # of stool in 24 hour period: 2-4 (1 point), 5-7 (2 points), >7 (3 points); Duration of vomiting: 2 days (1 point), 3-5 days (2 points), >5 days (3 points); max # of vomiting episodes in 24 hour period: 1-3 (1 point), 4-6 (2 points), >6 (3 points); Duration of reported fever: 1-2 days (1 point), 3-4 days (2 points), ≥5 days (3 points); Rectal temperature 38-38.2°C (1 point), 38.3-38.7°C (2 points), ≥38.8°C (3 points); behavioral signs: Irritable/less playful (1 point), Lethargic/listless (2 points), Seizures (3 points).

[g] Defined as in Lee, J Pediatr Gastroenterol Nutr., 2016: Duration of diarrhea: 2-4 days (1 point), 5-7 days (2 points), ≥8 days (3 points); Max # of stool in 24 hour period: <5 loose stools/24 hours (1 point), 5-7 loose stools/24 hours (2 points), ≥8 stools/24 hours (3 points); Duration of vomiting: 1 day (1 point), 2 days (2 points), ≥3 days (3 points); duration of reported fever: 1+ days (1 point); Confirmed temperature: ≥37.5°C (confirmed by field worker) (2 points); Dehydration: Some (2 points), severe (3 points).

Table 1.3: *Shigella* incidence by severity

Table 1.3. Adjusted incidence of relevant vaccine *Shigella* serotypes and species by diarrhea severity.

	Enrollment- and Healthcare Seeking-Adjusted *Shigella* MAD Incidence Rate (CI)															
	Bangladesh		**Kenya**		**Malawi**		**Mali**		**Pakistan**		**Peru**		**The Gambia**		**Total**	
Strata	**Culture**	**TAC[a]**	**Culture**	**TAC[a]**	**Culture**	**TAC[a]**	**Culture**	**TAC[a]**	**Culture**	**TAC[a]**	**Culture**	**TAC[a]**	**Culture**	**TAC[a]**	**Culture**	**TAC[a]**
Bivalent vaccine targets (*S. flexneri* 2a & *S. sonnei*)																
GEMS moderate-to-severe diarrhea (MSD)[b]																
MVS moderate or severe diarrhea or dysentery[c]																
Quadrivalent vaccine targets (*S. flexneri* 2a, 3a & 6 & *S. sonnei*)																
GEMS MSD[b]																
MVS moderate or severe diarrhea or dysentery[c]																
Quadrivalent vaccine targets (*S. flexneri* 1b, 2a & 3a & *S. sonnei*)																
GEMS MSD[b]																
MVS moderate or severe diarrhea or dysentery[c]																

CI: 95% confidence interval, CT: cycle threshold, GEMS: Global Enteric Multicenter Study, MAD: medically-attended diarrhea, MSD: moderate-to-severe-diarrhea, MVS: modified Vesikari score, TAC: TaqMan array card, WHO: World Health Organization.

[a] Defined as an ipaH cycle threshold (CT) < 31.1.

[b] Defined as in Kotloff, Lancet GH, 2019. Moderate-to-severe diarrhea (MSD) defined as presenting to a health facility with diarrhea and severe or some dehydration (by WHO criteria), visible blood in stool, and/or inpatient admission.

[c] Defined as in Pavlinac, Vaccines, 2022 as a MVS of 9+ or presence of visible blood in stool.

Table 1.4: Prevalence of enteric pathogens detected by molecular diagnostics.

Enteric pathogen[a]	Positive below the attributable cycle threshold (CT) cutoff: n/N (%)							
	Bangladesh	Kenya	Malawi	Mali	Pakistan	Peru	The Gambia	Total
All medically-attended diarrhea (MAD)								
Shigella (cycle threshold [CT]<31.1)								
Adenovirus 40/41 (CT<25.5)								
Cryptosporidium (CT<27.1)								
Norovirus GII (CT<26.6)								
Rotavirus (CT<34.2)								
ST-ETEC (CT<27.9)								
tEPEC (CT<20.7)								
Campylobacter jejuni (CT<20.7)								
Astrovirus (CT<26.7)								
Sapovirus (CT<24.4)								
V. cholerae (CT<33.9)								
Salmonella (CT<33.3)								
Aeromonas (CT<23.6)								
Cyclospora cayetanensis (CT<33.9)								
Entamoeba histolytica (CT<32.6)								
Cystoisospora belli (CT<34.4)								
Moderate or severe MAD by the Modified Vesikari Score (9+) +/- dysentery[b]								
Shigella (CT<31.1)								
Adenovirus 40/41 (CT<25.5)								
Cryptosporidium (CT<27.1)								
Norovirus GII (CT<26.6)								
Rotavirus (CT<34.2)								
ST-ETEC (CT<27.9)								
tEPEC (CT<20.7)								
Campylobacter jejuni (CT<20.7)								
Astrovirus (CT<26.7)								
Sapovirus (CT<24.4)								
V. cholerae (CT<33.9)								
Salmonella (CT<33.3)								
Aeromonas (CT<23.6)								
Cyclospora cayetanensis (CT<33.9)								
Entamoeba histolytica (CT<32.6)								
Cystoisospora belli (CT<34.4)								
***Shigella*-attributable MAD (CT<31.1)**								
Adenovirus 40/41 (CT<25.5)								
Cryptosporidium (CT<27.1)								
Norovirus GII (CT<26.6)								
Rotavirus (CT<34.2)								
ST-ETEC (CT<27.9)								
tEPEC (CT<20.7)								
Campylobacter jejuni (CT<20.7)								
Astrovirus (CT<26.7)								
Sapovirus (CT<24.4)								
V. cholerae (CT<33.9)								
Salmonella (CT<33.3)								
Aeromonas (CT<23.6)								
Cyclospora cayetanensis (CT<33.9)								
Entamoeba histolytica (CT<32.6)								
Cystoisospora belli (CT<34.4)								
Non-*Shigella*-attributable MAD (CT≥31.1 or no amplification)								
Adenovirus 40/41 (CT<25.5)								
Cryptosporidium (CT<27.1)								
Norovirus GII (CT<26.6)								
Rotavirus (CT<34.2)								
ST-ETEC (CT<27.9)								
tEPEC (CT<20.7)								
Campylobacter jejuni (CT<20.7)								
Astrovirus (CT<26.7)								
Sapovirus (CT<24.4)								
V. cholerae (CT<33.9)								
Salmonella (CT<33.3)								
Aeromonas (CT<23.6)								
Cyclospora cayetanensis (CT<33.9)								
Entamoeba histolytica (CT<32.6)								
Cystoisospora belli (CT<34.4)								

CT: cycle threshold, tEPEC: typical enteropathogenic E. coli, MAD: medically-attended diarrhea, ST-ETEC: heat stabile toxin-producing E. coli.

[a] The top three most prevalent pathogens by site are highlighted in green.

[b] Defined as in Pavlinac, Vaccines, 2022 as a MVS of 9+ or presence of visible blood in stool.

Secondary Aim 2
Table 2.1: Country and region antibiotic-non-susceptibility

Table 2.1. Country- and region-specific antibiotic non-susceptibility to culture-confirmed *Shigella* isolates

Antibiotic	Kenya	Malawi	East Africa total	Mali	The Gambia	West Africa total	Bangladesh	Pakistan	South Asia total	Peru	Total
						Antibiotic non-susceptibility: % (CI)					
Ampicillin											
All *Shigella* isolates											
S. flexneri											
S. sonnei											
Azithromycin											
All *Shigella* isolates											
S. flexneri											
S. sonnei											
Ceftriaxone											
All *Shigella* isolates											
S. flexneri											
S. sonnei											
Ciprofloxacin											
All *Shigella* isolates											
S. flexneri											
S. sonnei											
Nalidixic acid											
All *Shigella* isolates											
S. flexneri											
S. sonnei											
Pivemicellinam											
All *Shigella* isolates											
S. flexneri											
S. sonnei											
Trimethoprim-sulfamethoxazole											
All *Shigella* isolates											
S. flexneri											
S. sonnei											
Resistance to all WHO recommended treatments[a]											
All *Shigella* isolates											
S. flexneri											
S. sonnei											
Multidrug resistance (MDR)[b]											
All *Shigella* isolates											
S. flexneri											
S. sonnei											
Extensive drug resistance (XDR)[c]											
All *Shigella* isolates											
S. flexneri											
S. sonnei											

CI: 95% confidence interval, MDR: multidrug resistance, XDR: extensive drug resistance, WHO: World Health Organization.
[a] WHO recommended treatments include Azithromycin, Ciprofloxacin, and Ceftriaxone.
[b] Resistant to any three or more antibiotics.
[c] Resistant to all of the following: azithromycin, ciprofloxacin, ceftriaxone, trimethoprim-sulfamethoxazole, and ampicillin.

Secondary Aim 3
Table 3.1: All-cause case fatality

Table 3.1. Extended all-cause case fatality[a] among children enrolled in EFGH with and without *Shigella* attributed MAD.

	All-cause case fatality[a]: n/N (%)							
	Bangladesh	**Kenya**	**Malawi**	**Mali**	**Pakistan**	**Peru**	**The Gambia**	**Overall**
Overall								
Shigella[b]								
No *Shigella*[c]								

MAD: Medically-attended diarrhea, TAC: Taqman array card.
[a] Death occurring within 3 months of EFGH follow-up.
[b] By culture isolation or TAC ipaH <31.1.
[c] By absence of culture isolation or ipaH ≥31.1.

Table 3.2: Causes of death

Table 3.2. ICD-11[a] causes of death[b] for all known mortality events occurring within the EFGH three-month follow-up period

Site	Time since enrollment to death (days)	Age at death (months)	*Shigella* attribution at enrollment[c]	Causes of Death			
				Immediate (1a)	**Distal (1b)**	**Most Distal (1c)**	**Underlying (2)**

ICD-11: International Classification of Diseases 11th Revision.
[a] International Classification of Diseases, Eleventh Revision (ICD-11), World Health Organization (WHO) 2019/2021 https://icd.who.int/browse11. Licensed under Creative Commons Attribution-NoDerivatives 3.0 IGO licence (CC BY-ND 3.0 IGO).
[b] Causes of death are agreed upon by a panel of ICD-11 trained clinicians using information from the child's death certificate (if available), caregiver interview (if available), and case notes from the child's care team.
[c] By culture isolation or TAC ipaH <31.1.

Table 3.3: Hospitalization, subsequent diarrhea episodes, and persistent diarrhea

Table 3.3. Risk of hospitalization, subsequent diarrhea, and diarrhea persistence in the three months following medically attended diarrhea attributed to *Shigella* and other leading attributable causes of the index MAD.

	n/N (%)	RR, PR (CI)	
		Unadjusted	**Adjusted[a]**
Persistent Diarrhea[b]			
Shigella		PR	aPR
Pathogen 1[c]		PR	aPR
Pathogen 2[c]		PR	aPR
Pathogen 3[c]		PR	aPR
Pathogen 4[c]		PR	aPR
Any other attributable pathogen[d]		PR	aPR
Hospitalization[e]			
Shigella		RR	aRR
Pathogen 1[c]		RR	aRR
Pathogen 2[c]		RR	aRR
Pathogen 3[c]		RR	aRR
Pathogen 4[c]		RR	aRR
Any other attributable pathogen[d]		RR	aRR
Subsequent Diarrhea Episodes[f]			
Shigella		RR	aRR
Pathogen 1[c]		RR	aRR
Pathogen 2[c]		RR	aRR
Pathogen 3[c]		RR	aRR
Pathogen 4[c]		RR	aRR
Any other attributable pathogen[d]		RR	aRR

CI: 95% confidence interval, PR: prevalence ratio, RR: Relative risk, MAD: Medically-attended diarrhea.

[a] Adjusted for enrollment site, age, maternal education, breastfeeding history, and wealth quintile.

[b] Persistence is defined by having 14 or more days of diarrhea during the index diarrhea episode.

[c] Pathogens selected based on top five prevalent attributable pathogens by qPCR in the study population.

[d] Includes [list qPCR available attributable pathogens excluding those listed in pathogens 1-4].

[e] Includes any hospitalizations in the month three follow-up period including during the child's index diarrhea episode prior to enrollment, at enrollment, within the child's index episode after enrollment, and after resolution of the index episode.

[f] A subsequent diarrhea episode is defined as one or more days of three or more loose stools following two diarrhea-free days after the index diarrhea episode. Pathogen comparisons refer to the pathogen present at the child's index diarrhea episode and pathogen presence for the subsequent episode is unknown.

Table 3.4: Risk of hospitalization stratified by during index episode and after index episode

Table 3.4. Risk of hospitalization during and following the resolution of a MAD episode stratified by leading attributable causes of the index MAD.

		RR (CI)	
	n/N (%)	**Unadjusted**	**Adjusted[a]**
Hospitalizations during the index diarrhea episode			
Shigella		RR	aRR
Pathogen 1[b]		RR	aRR
Pathogen 2[b]		RR	aRR
Pathogen 3[b]		RR	aRR
Pathogen 4[b]		RR	aRR
Any other attributable pathogen[c]		RR	aRR
Hospitalizations following resolution of index diarrhea episode			
Shigella		RR	aRR
Pathogen 1[b]		RR	aRR
Pathogen 2[b]		RR	aRR
Pathogen 3[b]		RR	aRR
Pathogen 4[b]		RR	aRR
Any other attributable pathogen[c]		RR	aRR

CI: 95% confidence interval, ETEC: Enterotoxigenic *E. coli*, MAD: Medically-attended diarrhea, RR: Relative risk.

[a] Adjusted for enrollment site, age, maternal education, breastfeeding history, and wealth quintile.

[b] Pathogens selected based on top five prevalent attributable pathogens by qPCR in the study population.

[c] Includes [list qPCR available attributable pathogens excluding those listed in pathogens 1-4].

Table 3.5: Mean change in LAZ/HAZ

Table 3.5 Mean change in LAZ/HAZ and difference in LAZ/HAZ from enrollment to week four and enrollment to month three among participants by presence of leading etiologies of the index MAD.

Species	n/N (%)	Mean ΔLAZ/HAZ from enrollment to:		Difference in mean ΔLAZ/HAZ from enrollment to:	
		Week four (SD)	Month three (SD)	Week four (CI)[a]	Month three (CI)[a]
Shigella					
Pathogen 1[b]					
Pathogen 2[b]					
Pathogen 3[b]					
Pathogen 4[b]					
Any other attributable pathogen[c]					
No attributable pathogen					

CI: 95% confidence interval, HAZ: Height-for-age z-score, LAZ: Length-for-age z-score, MAD: Medically-attended diarrhea, SD: standard deviation.

[a] Adjusted for site, age, sex, maternal education, breastfeeding history, wealth quintile, baseline LAZ/HAZ, and days from enrollment to follow-up visit.

[b] Pathogens selected based on top five prevalent attributable pathogens by qPCR in the study population.

[c] Includes [list qPCR available pathogens excluding those listed in pathogens 1-4].

Table 3.6: Prevalence of stunting

Table 3.6. Prevalence of stunting at enrollment, week four follow-up, month three follow-up and association between diarrhea etiology and stunting among children by presence of leading etiologies of the index MAD.

	Enrollment	Week four		Month three	
	n/N (%)	n/N (%)	aPR[a] (CI)	n/N (%)	aPR[a] (CI)
Shigella					
Pathogen 1[b]					
Pathogen 2[b]					
Pathogen 3[b]					
Pathogen 4[b]					
Any other attributable pathogen[c]					
No attributable pathogen					

CI: 95% confidence interval, MAD: medically-attended diarrhea.

[a] Adjusted for site, age, sex, maternal education, breastfeeding history, and wealth quintile. and enrollment LAZ/HAZ (baseline).

[b] Pathogens selected based on top five prevalent attributable pathogens by qPCR in the study population.

[c] Includes [list aPCR available pathogens excluding those listed in pathogens 1-4].

Secondary Aim 4
Table 4.1: Moderate to Severe MAD by site

Table 4.1. Proportion of children with medically-attended diarrhea (MAD) and *Shigella*-attributed MAD by severity score categories by site.

Severity score	Proportion of MAD cases meeting severity definitions: n/N (%)							
	Bangladesh	**Kenya**	**Malawi**	**Mali**	**Pakistan**	**Peru**	**The Gambia**	**Total**
All MAD								
Modified Vesikari score (MVS)[a]: median (IQR), n (%)								
Mild illness (0-8 points)								
Moderate illness (9-10 points)								
Severe illness (11+ points)								
Moderate or severe diarrhea by MVS or dysentery[b]: n (%)								
GEMS[c]: n (%)								
Moderate-to-severe-diarrhea (MSD)								
Less-severe-diarrhea (LSD)								
GEMS-*Shigella* score[d]: n (%)								
Mild (<6 points)								
Moderate (6-8 points)								
Severe (9+ points)								
Clark score[e]: n (%)								
Mild (2-8 points)								
Moderate or severe (9+ points)								
MAL-ED score[f]: n (%)								
Non-severe (<6 points)								
Severe (6+ points)								
***Shigella*-attributed MAD**								
MVS[a]: n (%)								
Mild illness (0-8 points)								
Moderate illness (9-10 points)								
Severe illness (11+ points)								
Moderate or severe diarrhea by MVS or dysentery[b]: n (%)								
GEMS[c]: n (%)								
MSD								
LSD								
GEMS-*Shigella* score[d]: n (%)								
Mild (<6 points)								
Moderate (6-8 points)								
Severe (9+ points)								
Clark score[e]: n (%)								
Mild (2-8 points)								
Moderate or severe (9+ points)								
MAL-ED score[f]: n (%)								
Non-severe (<6 points)								
Severe (6+ points)								

GEMS: Global Enteric Multicenter Study, LSD: less-severe-diarrhea, MAL-ED: Malnutrition and Enteric Disease Study, MSD: moderate-to-severe diarrhea, MVS: modified Vesikari score, WHO: World Health Organization.

[a] Defined as in PATH Vesikari Clinical Severity Scoring System Manual: Duration of diarrhea: 1-4 days (1 point), 5 days (2 points) ≥6 days (3 points); Max # of stool in 24 hour period: 1-3 (1 point), 4-5 (2 points), ≥6 (3 points); Duration of vomiting: 1 day (1 point), 2 days (2 points), ≥3 days (3 points); max # of vomiting episodes in 24 hour period: 1 (1 point), 2-4 (2 points), ≥5 (3 points); Axillary temperature 36.6-37.9°C (1 point), 38.0-38.4°C (2 points), ≥38.5°C (3 points); dehydration 1-5% (2 points), ≥6% (3 points); treatment: rehydration (1 point), hospitalization (2 points).

[b] Defined as in Pavlinac, Vaccines, 2022 as a MVS of 9+ or presence of visible blood in stool.

[c] Defined as in Kotloff, Lancet GH, 2019. Moderate-to-severe diarrhea (MSD) defined as presenting to a health facility with diarrhea and severe or some dehydration (by WHO criteria), visible blood in stool, or inpatient admission. Less-severe-diarrhea (LSD) defined as presenting to a health facility without MSD.

[d] Defined as in Pavlinac, CID, 2021. Duration of diarrhea through day of presentation: 1-3 days (0 points), 4-5 days (2 points), ≥6 days (3 points); WHO-defined dehydration categories: severe (8 points), some (4 points), none (0 points); inpatient admission (5 points).

[e] Defined as in Clark, JID, 1988. Duration of diarrhea: 1-4 days (1 point), 5-7 days (2 points) >7 days (3 points); Max # of stool in 24 hour period: 2-4 (1 point), 5-7 (2 points), >7 (3 points); Duration of vomiting: 2 days (1 point), 3-5 days (2 points), >5 days (3 points); max # of vomiting episodes in 24 hour period: 1-3 (1 point), 4-6 (2 points), >6 (3 points); Duration of reported fever: 1-2 days (1 point), 3-4 days (2 points), ≥5 days (3 points); Rectal temperature 38-38.2°C (1 point), 38.3-38.7°C (2 points), ≥38.8°C (3 points); behavioral signs: Irritable/less playful (1 point), Lethargic/listless (2 points), Seizures (3 points).

[f] Defined as in Lee, J Pediatr Gastroenterol Nutr., 2016: Duration of diarrhea: 2-4 days (1 point), 5-7 days (2 points), ≥8 days (3 points); Max # of stool in 24 hour period: <5 loose stools/24 hours (1 point), 5-7 loose stools/24 hours (2 points), ≥8 stools/24 hours (3 points); Duration of vomiting: 1 day (1 point), 2 days (2 points), ≥3 days (3 points); duration of reported fever: 1+ days (1 point); Confirmed temperature: ≥37.5°C (confirmed by field worker) (2 points); Dehydration: Some (2 points), severe (3 points).

Table 4.2: Clinical characteristics of moderate-to-severe MAD

Table 4.2. Clinical characteristics of children with *Shigella*-attributed diarrhea by GEMS and MVS and/or dysentery.

	MVS moderate or severe diarrhea +/- dysentery[a]			-	
GEMS MSD[b]	+		-	+	-
Symptom / severity score component	+		-	+	-
***Shigella*-attributed MAD (culture or TAC +): N**					
Hospitalized: n (%)					
Dehydration: n (%)					
None					
Some					
Severe					
Dysentery: n (%)					
Diarrhea duration (days): median (IQR)					
Maximum number of stools in a 24-hour period: median (IQR)					
Fever: n (%)					
Number of days with fever: median (IQR)					
Vomiting: n (%)					
Number of days with vomiting: median (IQR)					
Maximum number of vomiting episodes in a 24-hour period: median (IQR)					
ΔLAZ/HAZ from enrollment to 3-month follow-up: median (IQR)					

GEMS: Global Enteric Multicenter Study, HAZ: Height-for-age z-score, LAZ: Length-for-age z-score, MSD: moderate-to-severe diarrhea, LSD: less-severe-diarrhea, MVS: modified Vesikari score, WHO: World Health Organization.
[a] Defined as in Pavlinac, Vaccines, 2022 as a MVS of 9+ or presence of visible blood in stool.
[b] Defined as in Kotloff, Lancet GH, 2019. Moderate-to-severe diarrhea (MSD) defined as presenting to a health facility with diarrhea and severe or some dehydration (by WHO criteria), visible blood in stool, or inpatient admission. Less-severe-diarrhea (LSD) defined as presenting to a health facility without MSD.

Table 4.3: Diagnostic accuracy of severity scores

Table 4.3. Diagnostic accuracy of dichotomized diarrhea severity scores of identifying hospitalization and/or mortality among all medically attended diarrhea (MAD) and *Shigella*-attributed MAD during index diarrhea episode.

Severity score[a]	Sensitivity (CI)	Specificity (CI)	Total Accuracy (CI)	PPV (CI)	NPV (CI)	Sensitivity (CI)	Specificity (CI)	Accuracy (CI)	PPV (CI)	NPV (CI)	Sensitivity (CI)	Specificity (CI)	Accuracy (CI)	PPV (CI)	NPV (CI)
						Appropriate antibiotics prescribed					**No antibiotics prescribed**				
All MAD															
MVS (moderate or severe)[a]															
MVS (moderate or severe) and/or dysentery[b]															
GEMS (MSD)[c]															
GEMS-*Shigella* (moderate or severe)[d]															
Clark score (moderate or severe)[e]															
MAL-ED score (severe)[f]															
***Shigella*-attributed MAD**															
MVS (moderate or severe)[a]															
MVS (moderate or severe) and/or dysentery[b]															
GEMS (MSD)[c]															
GEMS-*Shigella* (moderate or severe)[d]															
Clark score (moderate or severe)[e]															
MAL-ED score (severe)[f]															

CI: 95% confidence interval, GEMS: Global Enteric Multicenter Study, HAZ: Height-for-age z-score, LAZ: Length-for-age z-score, MAL-ED: Malnutrition and Enteric Disease Study, MSD: moderate-to-severe diarrhea, MVS: modified Vesikari score, WHO: World Health Organization.

[a] Defined as in PATH Vesikari Clinical Severity Scoring System Manual as a MVS of 9+.

[b] Defined as in Pavlinac, Vaccines, 2022 as a MVS of 9+ or presence of visible blood in stool.

[c] Defined as in Kotloff, Lancet GH, 2019. Moderate-to-severe diarrhea (MSD) defined as presenting to a health facility with diarrhea and severe or some dehydration (by WHO criteria), visible blood in stool, or inpatient admission.

[d] Defined as in Pavlinac, CID, 2021 as a score of 9+.

[e] Defined as in Clark, JID, 1988 as a score of 9+.

[f] Defined as in Lee, J Pediatr Gastroenterol Nutr., 2016 as a score of 6+.

Table 4.4: Severity scores and relationship to change in LAZ/HAZ

Table 4.4. Linear regression of dichotomized diarrhea severity scores and ΔLAZ/HAZ from enrollment to three-month follow-up among all medically attended diarrhea (MAD) and *Shigella*-attributed MAD during index diarrhea episode. Models stratified by antibiotic use.

Severity score[a]	Total β (CI)	p-value	AIC	Appropriate antibiotics prescribed β (CI)	p-value	AIC	No antibiotics prescribed β (CI)	p-value	AIC
All MAD									
MVS (moderate or severe)[b]									
MVS (moderate or severe) and/or dysentery[c]									
GEMS (moderate-to-severe diarrhea [MSD])[d]									
GEMS-*Shigella* (moderate or severe)[e]									
Clark score (moderate or severe)[f]									
MAL-ED score (severe)[g]									
***Shigella*-attributed MAD**									
MVS (moderate or severe)[b]									
MVS (moderate or severe) and/or dysentery[c]									
GEMS (MSD)[d]									
GEMS-*Shigella* (moderate or severe)[e]									
Clark score (moderate or severe)[f]									
MAL-ED score (severe)[g]									

AIC: Akaike's information Criteria, CI: 95% confidence interval, GEMS: Global Enteric Multicenter Study, MAL-ED: Malnutrition and Enteric Disease Study, MSD: moderate-to-severe diarrhea, MVS: modified Vesikari score, WHO: World Health Organization.
[a] Models adjusted for baseline LAZ/HAZ, age, site, wealth quintile, maternal education, and breastfeeding.
[b] Defined as in PATH Vesikari Clinical Severity Scoring System Manual as a MVS of 9+.
[c] Defined as in Pavlinac, Vaccines, 2022 as a MVS of 9+ or presence of visible blood in stool.
[d] Defined as in Kotloff, Lancet GH, 2019. Moderate-to-severe diarrhea (MSD) defined as presenting to a health facility with diarrhea and severe or some dehydration (by WHO criteria), visible blood in stool, or inpatient admission.
[e] Defined as in Pavlinac, CID, 2021 as a score of 9+.
[f] Defined as in Clark, JID, 1988 as a score of 9+.
[g] Defined as in Lee, J Pediatr Gastroenterol Nutr., 2016 as a score of 6+.

Figure 4.1: ROC curves for severity scores

Figure 4.1 (example output below). ROC curve for the four numeric severity scores (MVS, GEMS-Shigella, Clark score, MAL-ED score) on the outcome of hospitalization and/or mortality.
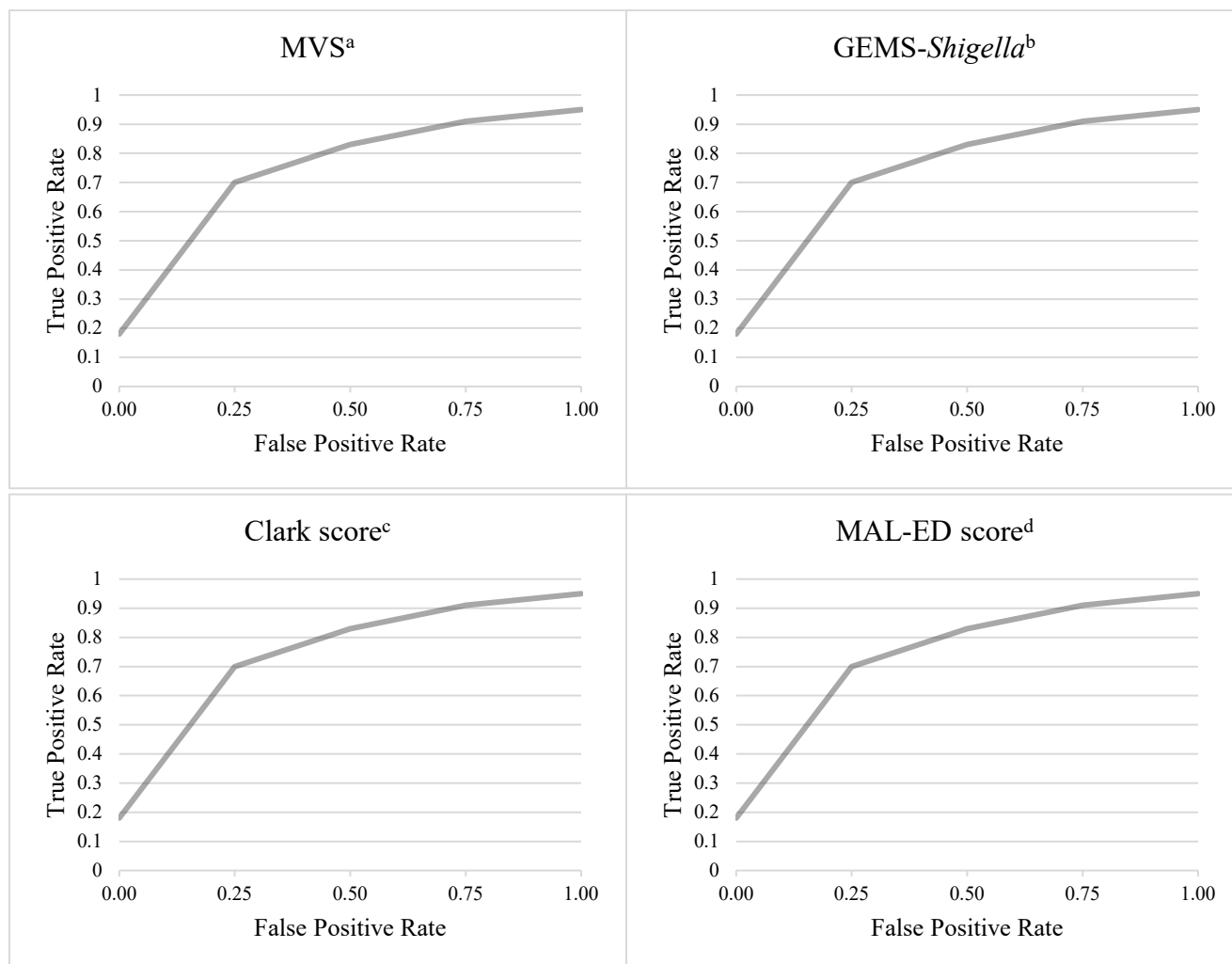
GEMS: Global Enteric Multicenter Study, MAL-ED: Malnutrition and Enteric Disease Study, MVS: modified Vesikari score, ROC; receiver operating characteristic, WHO: World Health Organization.

[a] Defined as in PATH Vesikari Clinical Severity Scoring System Manual: Duration of diarrhea: 1-4 days (1 point), 5 days (2 points) ≥6 days (3 points); Max # of stool in 24 hour period: 1-3 (1 point), 4-5 (2 points), ≥6 (3 points); Duration of vomiting: 1 day (1 point), 2 days (2 points), ≥3 days (3 points); max # of vomiting episodes in 24 hour period: 1 (1 point), 2-4 (2 points), ≥5 (3 points); Axillary temperature 36.6-37.9°C (1 point), 38.0-38.4°C (2 points), ≥38.5°C (3 points); dehydration 1-5% (2 points), ≥6% (3 points); treatment: rehydration (1 point), hospitalization (2 points).

[b] Defined as in Kotloff, Lancet GH, 2019. Moderate-to-severe diarrhea (MSD) defined as presenting to a health facility with diarrhea and severe or some dehydration (by WHO criteria), visible blood in stool, or inpatient admission. Less-severe-diarrhea (LSD) defined as presenting to a health facility without MSD.

[c] Defined as in Clark, JID, 1988. Duration of diarrhea: 1-4 days (1 point), 5-7 days (2 points) >7 days (3 points); Max # of stool in 24 hour period: 2-4 (1 point), 5-7 (2 points), >7 (3 points); Duration of vomiting: 2 days (1 point), 3-5 days (2 points), >5 days (3 points); max # of vomiting episodes in 24 hour period: 1-3 (1 point), 4-6 (2 points), >6 (3 points); Duration of reported fever: 1-2 days (1 point), 3-4 days (2 points), ≥5 days (3 points); Rectal temperature 38-38.2°C (1 point), 38.3-38.7°C (2 points), ≥38.8°C (3 points); behavioral signs: Irritable/less playful (1 point), Lethargic/listless (2 points), Seizures (3 points).

[d] Defined as in Lee, J Pediatr Gastroenterol Nutr., 2016: Duration of diarrhea: 2-4 days (1 point), 5-7 days (2 points), ≥8 days (3 points); Max # of stool in 24 hour period: <5 loose stools/24 hours (1 point), 5-7 loose stools/24 hours (2 points), ≥8 stools/24 hours (3 points); Duration of vomiting: 1 day (1 point), 2 days (2 points), ≥3 days (3 points); duration of reported fever: 1+ days (1 point); Confirmed temperature: ≥37.5°C (confirmed by field worker) (2 points); Dehydration: Some (2 points), severe (3 points).

Secondary Aim 5
Table 5.1: Cost per episode of MAD

Table 5.1. Cost per episode of medically attended *Shigella* diarrhea[a]

	Bangladesh	Kenya	Malawi	Mali	Pakistan	Peru	The Gambia	Total
							Cost per episode, USD 2024: Mean (SD)	
Costing perspective								
Household[b]								
Health system[c]								
Societal[d]								
Visit characteristics[e]								
Visit type								
Inpatient								
Outpatient								
Level of facility presented to								
Primary								
Secondary								
Tertiary								
Client demographics[e]								
Sex								
Female								
Male								
Age at enrollment (months)								
6—8								
9—11								
12—17								
18—23								
24—35								
Diarrhea severity[e]								
Dysentery								
Watery diarrhea								
GEMS[f]								
Less-severe diarrhea (LSD)								
Moderate-to-severe diarrhea (MSD)								
Severity by Modified Vesikari score (MVS)[g]								
Mild (0-8 points)								
Moderate (9-10 points)								
Severe (11+ points)								
MVS moderate or severe diarrhea and/or dysentery[h]								
Anthropometry[e]								
Stunted[i]								
Severe								
Moderate								
None								
Wasted[j]								
Severe								
Moderate								
None								
Underweight[k]								
Severe								
Moderate								
None								

LAZ: Length for age Z-score, LSD: less-severe diarrhea, MSD: Moderate-to-severe diarrhea, MVS: Modified Vesikari score, MUAC: mid-upper arm circumference, SD: standard deviation, TAC: TaqMan Array Card, USD: US dollars, WAZ: Weight for age Z-score, WHO: World Health Organization, WLZ: Weight for length Z-score.

[a] Children who tested positive for *Shigella* by culture and/or molecular (TAC) diagnostics.

[b] Household perspective includes caregiver out-of-pocket costs and indirect costs (caregiver time lost from work).

[c] Health system perspective includes costs of medical treatment funded by the public health system.

[d] Societal costs include all costs presented in the household and health system perspectives.

[e] Costs stratified per visit characteristic, client demographics, diarrhea severity, and anthropometry category are societal costs.

[f] Defined as in Kotloff, Lancet GH, 2019. Moderate-to-severe-diarrhea (MSD) defined as presenting to a health facility with diarrhea and severe or some dehydration (by WHO criteria), visible blood in stool, or inpatient admission. Less-severe-diarrhea (LSD) defined as presenting to a health facility without MSD.

[g] Defined as in PATH Vesikari Clinical Severity Scoring System Manual: duration of diarrhea: 1-4 days (1 point), 5 days (2 points) ≥6 days (3 points); max # of stool in 24 hour period: 1-3 (1 point), 4-5 (2 points), ≥6 (3 points); duration of vomiting: 1 day (1 point), 2 days (2 points), ≥3 days (3 points); max # of vomiting episodes in 24 hour period: 1 (1 point), 2-4 (2 points), ≥5 (3 points); axillary temperature 36.6-37.9°C (1 point), 38.0-38.4°C (2 points), ≥38.5°C (3 points); dehydration 1-5% (2 points), ≥6% (3 points); treatment: rehydration (1 point), hospitalization (2 points).

[h] Defined as in Pavlinac, Vaccines, 2022 as a MVS of 9+ or presence of visible blood in stool.

[i] Severe stunting: LAZ < -3, Moderate stunting: -3 ≤ LAZ < -2.

[j] Severe wasting: WLZ < -3 or MUAC < 11.5, Moderate wasting: -3 ≤ WLZ < -2 or 11.5 ≤ MUAC < 12.5.

[k] Severely underweight: WAZ < -3, Moderately underweight: -3 ≤ WAZ < -2.

Table 5.2: Factors associated with cost

Table 5.2. Factors associated with costs of medically-attended *Shigella* diarrhea.[a]

Parameter	Household perspective[b]			Health system perspective[c]			Societal perspective[d]		
	Coefficient	CI	p-value	Coefficient	CI	p-value	Coefficient	CI	p-value
Intercept									
Country									
Bangladesh	Reference	-	-	Reference	-	-	Reference	-	-
Kenya									
Malawi									
Mali									
Pakistan									
Peru									
The Gambia									
Diarrhea severity									
Mild	Reference	-	-	Reference	-	-	Reference	-	-
Moderate									
Severe									

CI: 95% confidence interval.

[a] Children who tested positive for *Shigella* by culture and/or molecular (TaqMan Array Card) diagnostics.

[b] Household perspective includes caregiver out-of-pocket costs and indirect costs (caregiver time lost from work).

[c] Health system perspective includes costs of medical treatment funded by the public health system.

[d] Societal costs include all costs presented in the household and health system perspectives.

Table 5.3: Annual costs of *Shigella*-associated MAD

Table 5.3. Annual costs of medically-attended *Shigella* diarrhea[a] in country sites.

	Annual costs per site (per 100,000 population), USD 2024						
Strata	**Bangladesh**	**Kenya**	**Malawi**	**Mali**	**Pakistan**	**Peru**	**The Gambia**
Household costs[b]							
Health system costs[c]							
Societal costs[d]							

USD: US dollars.
[a] Children who tested positive for *Shigella* by culture and/or molecular (TaqMan Array Card) diagnostics.
[b] Household costs includes caregiver out-of-pocket costs and indirect costs (caregiver time lost from work).
[c] Health system costs includes costs of medical treatment funded by the public health system.
[d] Societal costs include all costs presented in the household and health system perspectives.

Secondary Aim 6
Table 6.1: Culture Positivity by serotype

Table 6.1. *Shigella* **culture positivity proportion by transport media type and EFGH study site.**

Country	N	*Shigella* culture positivity[a]: % (CI)		p-value[b]
		Cary Blair	mBGS	
All *Shigella* isolates				
Bangladesh				
Kenya				
Malawi				
Mali				
Pakistan				
Peru[c]				
The Gambia				
Overall				
S. flexneri				
Bangladesh				
Kenya				
Malawi				
Mali				
Pakistan				
Peru[c]				
The Gambia				
Overall				
S. sonnei				
Bangladesh				
Kenya				
Malawi				
Mali				
Pakistan				
Peru[c]				
The Gambia				
Overall				
S. boydii				
Bangladesh				
Kenya				
Malawi				
Mali				
Pakistan				
Peru[c]				
The Gambia				
Overall				
S. dysenteriae				
Bangladesh				
Kenya				
Malawi				
Mali				
Pakistan				
Peru[c]				
The Gambia				
Overall				

CI: 95% confidence interval, mBGS: modified buffered glycerol saline.

[a] Culture *Shigella* culture positivity is defined as the percentage of enrolled participants with *Shigella* isolated from culture out of total participants with both rectal swabs cultured using both Cary-Blair and mBGS transport media.

[b] McNemar's test of superiority.

[c] Includes only participants enrolled after January 19, 2023 due to a laboratory error that made previous results incomparable across media types.

Table 6.2: Rectal swab and whole stool comparison

Table 6.2. *Shigella* culture-positivity from rectal swab and whole stool samples, across sites involved in the whole stool/rectal swab comparison sub-study.

Country	N	*Shigella* culture positivity[a]: (CI)		
		Rectal swab	Whole stool[b]	Difference
All *Shigella* isolates				
Cary-Blair				
Bangladesh				
The Gambia				
Overall				
mBGS				
Bangladesh				
The Gambia				
Overall				
S. flexneri				
Cary-Blair				
Bangladesh				
The Gambia				
Overall				
mBGS				
Bangladesh				
The Gambia				
Overall				
S. sonnei				
Cary-Blair				
Bangladesh				
The Gambia				
Overall				
mBGS				
Bangladesh				
The Gambia				
Overall				
S. boydii				
Cary-Blair				
Bangladesh				
The Gambia				
Overall				
mBGS				
Bangladesh				
The Gambia				
Overall				
S. dysenteriae				
Cary-Blair				
Bangladesh				
The Gambia				
Overall				
mBGS				
Bangladesh				
The Gambia				
Overall				

CI: 95% confidence interval, mBGS: modified buffered glycerol saline

[a] *Shigella* culture positivity is defined as the percentage of participants with *Shigella* isolated from culture out of total participants with both rectal swab and whole stool collected for the *Shigella* culture comparison.

[b] Whole stool is collected among children who produce a sample while still at the enrollment facility.

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Enterics for Global Health: *Shigella* Surveillance Study (EFGH)

Diarrhea Case Surveillance Case Report Form Appendix

Table of Contents

CRF Number	CRF Name
01	Pre-Screening
02	Screening
03	Pre-Enrollment
04	Enrollment
04a	Medical Management
04b	Wealth Index - Bangladesh
04b	Wealth Index - The Gambia
04b	Wealth Index - Kenya
04b	Wealth Index - Malawi
04b	Wealth Index - Mali
04b	Wealth Index - Pakistan
04b	Wealth Index - Peru
04c	HIV Information *(Mali, Malawi, Kenya Sites Only)*
04d	Daily record (For Participants with Overnight Stays Only)
04e	Referral
05	Discharge
06	Diarrhea Diary
07	Follow-up
08	Unwell Child
09	Hospital Record Abstraction
10a	Mortality
10b	Mortality Interview
11	Study Close Out
12	Shigella Light Contact
13	Stool Sample Collection
13b	Home Whole Stool Sample Collection
14	Blood Sample Collection
18	Diarrhea Case Surveillance Protocol Violation
19	Adverse Event

Enterics for Global Health – *Shigella* Surveillance Study (EFGH) **Implementing Institution Name (Country Site)** **CRF 01— Pre-Screening Form**		

Purpose: *To assess screening eligibility.*

Instructions: *Please complete this pre-screening for all children appearing less than 5 years with diarrhea/dysentery/gastroenteritis who present to this health facility at any day/time should have this form completed.* Plain text is for prompts for study staff, and *italics* are instructions for study staff.

A.	**VISIT INFORMATION**	
1.	Screening ID	|___|-|___|-|___|___|___|___|-|___|___|___| *(Country ID - Facility ID - Sequential Screening # - Staff ID)*
2.	Date child presented to health facility:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Unknown
3.	Approximate time child presented to health facility:	|___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Unknown
4.	Pre-screening Date:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
5.	Pre-screening Time:	|___|___| : |___|___| *(hh : min, 24:00 hr)*
6.	Based on Q2/Q3 minus Q4/Q5, approximately how many hours have passed since the child presented to the health facility? *(if being completed at the point of presentation please indicate "00" & "00")*	
	|___|___| hours and |___|___| minutes *(if <1 hour/60 minutes*, indicate "00" in hours box)* ☐ Unknown *(if time of presentation to the health facility [Q3] is unknown)*	
7.	EFGH country site:	

☐ Bangladesh	☐ Kenya	☐ Malawi	☐ Mali
☐ Pakistan	☐ Peru	☐ The Gambia	

B.	**PRE-SCREENING QUESTIONS**
8.	Did the child present to the recruitment facility during working hours?
	☐ Yes *(skip to Q10)*
	☐ No
9.	Are the Pre-Screening questions being answered based on facility records or in real-time?
	☐ Real-time
	☐ Facility records *(only applicable for children presenting outside of working hours)*
10.	Please confirm diarrhea/dysentery/gastroenteritis is one of the complaints of the child
	☐ Confirmed
	☐ Not confirmed *(ineligible, skip to Section C)*
11.	Age of the child according to respondent or record: |___|___| months *(if outside age range [6-35 months], ineligible, skip to Section C)* ☐ Missing *(ineligible, skip to Section C)*
12.	Is the child still present in the facility?
	☐ Yes, the child is still present in the facility
	☐ No, the child has already left the facility *(ineligible, proceed to Section C)*
13.	Is the child currently enrolled in EFGH and involved in active follow up?
	☐ Yes *(ineligible because already enrolled, skip to Section C, complete Unwell Child CRF [CRF 08])*
	☐ No

C.	**PRE-SCREENING ELIGIBILITY DETERMINATION**

14.	Based on the responses above, is the child eligible to move on to the screening process?	
	☐ Yes *(complete Section D and continue to Screening CRF [CRF 02])*	
	☐ No *(stop process after completing Section D)*	

D. FORM COMPLETION

15.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
16.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
17.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
18.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

**Enterics for Global Health – *Shigella* Surveillance Study (EFGH)** **Implementing Institution Name (Country Site)** **CRF 02— Screening Form**

Purpose: *To determine study eligibility*

Instructions: *Please complete this screening for all children who are preliminarily eligible based on the Pre-Screening form.* Plain text is for prompts for study staff, and *italics* are instructions for study staff.

A.	VISIT INFORMATION		
1.	Screening ID	|___|-|___|-|___|___|___|___|-|___|___|___| *(Country ID - Facility ID - Sequential Screening # - Staff ID)*	
2.	Screening Date:	|___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)*	
3.	Screening Time:	|___|___| : |___|___| *(hh : min, 24:00 hr)*	
4.	EFGH country site:		
	☐ Bangladesh	☐ Kenya	☐ Malawi	☐ Mali
	☐ Pakistan	☐ Peru	☐ The Gambia	

B.	RESPONDENT INFORMATION & VERBAL SCREENING CONSENT		
5.	Is the child accompanied by a primary caregiver who is able to provide consent?		
	☐ Yes *(conduct verbal screening consent)*		
	☐ No *(thank the respondent and stop screening process, skip to Section G)*		
6.	What is the relationship of the respondent to the child being screened?		
	☐ Biological mother	☐ Biological father	☐ Adopted mother
	☐ Adopted father	☐ Grandmother	☐ Grandfather
	☐ Aunt	☐ Uncle	☐ Older sister
	☐ Older brother	☐ Other, *specify*: _____	
7.	Did the respondent consent to screening?		
	☐ Yes *(skip to Q8)*		
	☐ Not applicable, screening consent is not required at this site *(skip to Q8)*		
	☐ No, respondent did not provide consent to screening		
7a.	*If respondent did not provide consent to screening,* why?		
	☐ Not interested in participating in research *(thank the respondent and stop screening process, skip to Section G)*		
	☐ Not enough time *(thank the respondent and stop screening process, skip to Section G)*		
	☐ Caregiver too busy *(thank the respondent and stop screening process, skip to Section G)*		
	☐ Child too sick *(thank the respondent and stop screening process, skip to Section G)*		
	☐ Other (specify): _____ *(thank the respondent and stop screening process, skip to Section G)*		

8.	What is the *[insert site-specific administrative unit]* that this child lives in? *("lives" defined as having spent 7 or more days of the last 14 days there)*	
	|___|___|___| *OR* ☐ Other *(specify)*: _____ *Please refer to list of smallest administrative units and enter in corresponding code. If list does not contain administrative unit, indicate "Other" and specify.*	
9.	Verification that the child lives in the catchment area *(using site-specific verification process)*	
	☐ Verified child lives in catchment area	
	☐ Verified child does not live in catchment area *(ineligible)*	
	☐ Could not verify that child lives in catchment area *(ineligible)*	

C.	BASIC INFORMATION ABOUT THE CHILD AND THE PRESENT ILLNESS EPISODE			
10.	Child sex			
	☐ Male			
	☐ Female			
11.	What is the child's date of birth?			
	11a.	Day:	|___|___|	☐ Unknown
	11b.	Month:	|___|___|	☐ Unknown
	11c.	Year:	|___|___|___|	☐ Unknown
12.	Age of the child by study team calculation: |___|___| months *(if <10, put "0" before digit)* *(if Day unknown, assume 15th of the month; if outside age range [6-35 months], ineligible)* ☐ Not calculable *(all unknown; day + month unknown; year unknown)*			
13.	Age of the child according to respondent: |___|___| months ☐ Unknown *(if uknown & Q12 not calculable, ineligible)* *(if use caregiver reported age to determine eligibility if month or year are unknown in Q11)*			
14.	How many unusually loose or watery stools has the child had in the past 24 hours?			
	|___|___| *(if <10, put "0" before digit; if < 3, ineligible)*			
15.	When did the diarrhea *(defined as 3 or more abnormally loose/watery stool in a 24 hour period)* start?			
	|___|___| -|___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*			
16.	Including today, how many days has the child had diarrhea *(defined as 3 or more unusually loose or watery stools during a 24 hour period)*? *Review memory aid with caregiver to answer this question.*			
	|___|___| days *(if <10, put "0" before digit; if >7 days, ineligible)*			
17.	Has there been any visible blood in the child's stool since the diarrhea started?			
	☐ Yes			
	☐ No *(skip to Q20)*			
18.	Within the last 24 hours, has there been visible blood in the child's stools?			
	☐ Yes			
	☐ No *(skip to Q20)*			
19.	Including today, how many days has the child had visible blood in their stools?			
	|___|___| days *(if <10, put "0" before digit)*			

	20.	Does the respondent plan to remain in the study area with the child for the next 4 months?
		☐ Yes
		☐ No *(ineligible)*
	21.	Is the child currently enrolled in an interventional study?
		☐ Yes *(ineligible)*
		☐ No
D.	**STUDY ELIGIBILITY DETERMINATION**	
	22.	Diarrhea is one of the complaints of the child *(see Pre-Screening CRF 01, Q10)*
		☐ Yes *(must be "Yes" to be eiligible)*
		☐ No
	23.	Accompanying respondent is able and willing to provide informed consent *(see Q5)*
		☐ Yes *(must be "Yes" to be eiligible)*
		☐ No
	24.	Child is verified to live in catchment area *(see Q9)*
		☐ Yes *(must be "Yes" to be eiligible)*
		☐ No
	25.	The child is between 6-35 months of age *(see Q12 or Q13)*
		☐ Yes *(must be "Yes" to be eiligible)*
		☐No
	26.	Child has had 3 or more unusually loose or watery stools in the past 24 hours *(see Q14)*
		☐ Yes *(must be "Yes" to be eiligible)*
		☐No
	27.	Child has had 7 or fewer days of diarrhea *(see Q16)*
		☐ Yes *(must be "Yes" to be eiligible)*
		☐ No
	28.	The respondent plans to remain in the study area with the child for the next 4 months *(see Q20)*
		☐ Yes *(must be "Yes" to be eiligible)*
		☐ No
	29.	Child is <u>not</u> currently enrolled in an interventional study *(see Q21)*
		☐ Yes *(must be "Yes" to be eiligible)*

		No
E.	**STUDY ELIGIBILITY DETERMINATION**	
	30.	Is the child eligible for enrollment in the EFGH study? *(Responses to Q22-29 must all be "Yes")*
		☐ Yes
		☐ No *(thank the respondent and stop screening process, skip to Section G)*
F.	**OTHER REASONS NOT ENROLLED** *(answered among those who are eligible for enrollment)*	
	31.	Has more than 4 hours passed since the child presented to the health facility and the child started the screening process *(see Pre-Screening CRF 01, Q6)*
		☐ Yes *(thank the respondent and stop screening process, complete Section G)*
		☐ No
	32.	Has the enrollment cap already been met?
		☐ Yes *(thank the respondent and stop screening process, complete Section G)*
		☐ No
	33.	Is the child being referred to another facility?
		☐ Yes, to an EFGH recruiting facility.
		ID EFGH recruiting facility that child is being referred: |___| *(If this child meets eligibility criteria, he/she can continue from the Pre-Enrollment CRF at the referall facility [the screening ID should remain the same]. Thank the respondent and stop the screening process, complete Section G).*
		☐ Yes, to a non-EFGH recruiting facility *(thank the respondent and stop screening process, complete Section G)*
		☐ No *(complete Section G and proceed to the informed consent process)*
G.	**FORM COMPLETION**	
	34.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	35.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	36.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	37.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: *To determine whether or not a potential participant was enrolled in the study (among those who were eligible and ready to be enrolled by the Screening Form)*

Instructions: *Please complete this form after a potential participant is deemed eligibile by Screening Form (CRF 02) and potential participant and caregiver have undergone the informed consent process. If a caregiver does not consent, that will be captured in this form. If a child screened eligible, then was referred to another EFGH recruiting facility, that child can be consented at the referred-to EFGH facility and pre-enrollment form completed using the screening ID assigned at the former facility.* Plain text is for prompts for study staff, and *italics* are instructions for study staff.

A.	PRE-ENROLLMENT INFORMATION	
	1.	Screening ID	|___|-|___|-|___|___|___|___|-|___|___|___| *(Country ID - Facility ID - Sequential Screening # - Staff ID)*
	2.	Was informed consent obtained from the caregiver?
		☐ Yes
		☐ No *(skip to Q2b)*
	2a.	*If yes,* date consented: |___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy) (skip to Q3)*
	2b.	*If no,* why?
		☐ Not interested in participating in research *(thank the respondent and stop screening process, skip to Section B)*
		☐ Not enough time *(thank the respondent and stop screening process, skip to Section B)*
		☐ Caregiver too busy *(thank the respondent and stop screening process, skip to Section B)*
		☐ Child too sick *(thank the respondent and stop screening process, skip to Section B)*
		☐ Other *(specify)*: _____ *(thank the respondent and stop screening process, skip to Section B)*
	3.	Was the child enrolled in the EFGH study?
		☐ Yes *(skip to Q5)*
		☐ No
	4.	Why was the child <u>not</u> enrolled in the EFGH study?
		☐ Caregiver withdrew consent *(skip to Q6)*
		☐ Child was eligible for enrollment but did not continue because of staff/clinic capacity *(skip to Q6)*
		☐ Child was eligible for enrollment but did not continue because of late timing of enrollment *(skip to Q6)*
		☐ Other *(specify)*: _____*(skip to Q6)*
	5.	Please assign the next available PID to the participant: |___|___|___|___|___|___|___|
	6.	Has the child been previously enrolled in EFGH?
		☐ Yes
		☐ No *(skip to Section B)*

		6a.	*If yes*, Previous PID: |___|___|___|___|___|___|___| ☐Unknown
		6b	*If yes*, Date of enrollment: |___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)* ☐Unknown
		6c.	*If yes*, Facility the child recruited from *(refer to facility list and enter facility code)*:
			|___| ☐Unknown
B.	**FORM COMPLETION**		
	7.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
	8.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
	9.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
	10.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*

Please proceed to CRF 04 - Enrollment CRF

Purpose: *To capture information about the enrolled participant at presentation or during the period leading up to presentation to the health facility (subsequent forms will ascertain information about what happens throughout the course of the facility visit).*

Instructions: *Please complete this form after completing the Pre-Enrollment Form and participant been assigned a unique participant identification number (PID).* Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	PARTICIPANT INFORMATION		
	1.	Participant ID	|___|___|___|___|___|___|___|
	2.	Date of Enrollment:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	3.	Time form is started:	|___|___| : |___|___| *(hh : min, 24:00 hr)*
	4.	EFGH country site:	
		☐ Bangladesh	☐ Kenya
		☐ Malawi	☐ Mali
		☐ Pakistan	☐ Peru
		☐ The Gambia	

B.	DIARRHEA EPISODE INFORMATION (PRESENTATION) *(Instructions to staff: Text in **bold** should be read verbatim, plain text is for prompts for study staff, and italics are instructions for study staff. <u>Note</u>: Diarrhea episode is defined as diarrhea (3 or more unusually loose or watery stools in a 24 hour period). Use memory aid to facilitate remembering days.*		
5.	**From the time this diarrhea episode started up until now, has there been any visible blood in the child's stool?**		
	☐ Yes		
	☐ No *(skip to Q6)*		
	☐ Unknown *(skip to Q6)*		
	5a.	*If Yes,* **for how many days has there been blood in the child's stool (including today)?**	|___|___| days
6.	**From the time this diarrhea episode started up until now, what is the maximum number of abnormally loose or watery stools that the child produced in a single 24 hour period?**		
	|___|___|loose stools		
7.	**From the time this diarrhea episode started up until now, has the child vomited?**		
	☐ Yes		
	☐ No *(skip to Q8)*		
	7a.	*If the child has had episodes of vomiting,* **how many days has the child vomited at least once?**	|___|___| days *(if <10, put "0" before digit)*

		7b.	**Thinking about the day when the child had the most vomiting, how many times did s/he vomit in a 24 hour period?**	|___|___| times *(if <10, put "0" before digit)*

	8.	**From the time this diarrhea episode started up until now, has the child felt hot to the touch (fever)?**

☐ Yes

☐ No *(skip to Q9)*

	8a.	If child has had a fever during this diarrhea episode, **how many days did the fever persist**?	|___|___| days *(if <10, put "0" before digit)*

C.	**MEDICAL EXAMINATION: ASSESSMENT OF DEHYDRATION AND THE CHILD'S GENERAL CONDITION**

	9.	What is the child's general condition?	

☐ Well/Alert	☐ Restless/Irritable	☐ Lethargic or Unconscious

	10.	Assess the child's eyes and determine if they are:

☐ Normal *(skip to Q11)*	☐ Abnormally sunken

	10a.	*If child's eyes are determined to be abnormally sunken, please ask the caregiver:* **Is the appearance of your child's eyes abnormal?**

☐ Yes *(abnormal for child)*
☐ No

	11.	Describe the child's ability to drink or breastfeed:

☐ Normal/Not Thirsty	☐ Drinks eagerly/Thirsty	☐ Drinks poorly/Unable to drink

	12.	Using a thumb and forefinger, gently pinch up the child's skin on the abdominal wall and assess the skin's return to normal:

☐ Immediately	☐ 1 to <2 seconds (slowly)	☐ ≥2 seconds (very slowly)

	13.	Dehydration assessment *(to be completed based on data in Q9-Q12 above)*

☐ <u>Severe dehydration</u>	☐ <u>Some dehydration</u>	☐ <u>No dehydration</u>
At least two of the following signs *(check all that apply)*: ☐ Lethargic or Unconscious ☐ Abnormally sunken eyes based on clinician assessment and caregiver confirmation ☐ Drinks poorly/unable to drink ☐ Skin pinch goes back ≥2 seconds (very slowly)	At least two of the following signs *(check all that apply)*: ☐ Restless/irritable ☐ Abnormally sunken eyes based on clinician assessment and caregiver confirmation ☐ Drinks eagerly/Thirsty ☐ Skin pinch goes back 1 to <2 seconds (slowly)	

Please assess the following physical signs:

14.	Vital signs		
	14a.	Temperature *(taken using the Exergen thermometer)*: |___|___|**.**|___|°C	
	14b.	Heart rate: |___|___|___|beats per minute	
	14c.	Respiratory rate: |___|___|breaths per minute	
15.	Tears		☐Normal ☐Decreased ☐Absent
16.	Jaundice/yellow eyes		☐ Yes ☐ No
17.	Cough		☐ Yes ☐ No
18.	Difficulty breathing		☐ Yes ☐ No
19.	Chest in-drawing		☐ Yes ☐ No
20.	Stridor		☐ Yes ☐ No
21.	Stiff neck		☐ Yes ☐ No
22.	Generalized rash		☐ Yes ☐ No
23.	Runny nose		☐ Yes ☐ No
24.	Convulsions		☐ Yes ☐ No
25.	Lethargy or Unconscious		☐ Yes ☐ No
26.	Chest auscultation signs suggestive of pneumonia		☐ Yes ☐ No
27.	Central cyanosis		☐ Yes ☐ No
28.	Oxygen saturation <90% (pulse oximetry)		☐ Yes ☐ No ☐ Not available
29.	Severe respiratory distress		☐ Yes ☐ No
30.	Palmar pallor		☐ Yes ☐ No
31.	Ear pain		☐ Yes ☐ No
32.	Pus drainage from ear canal		☐ Yes ☐ No
33.	Tender swelling behind the ear		☐ Yes ☐ No
34.	Signs of abscess		☐ Yes ☐ No
35.	Signs of oedema		☐ Yes ☐ No
	35a.	*If yes:*	
		☐ Oedema on both feet/ankles *(mild)*	
		☐ Oedema on both feet/ankles, lower legs, hands, or lower arms *(moderate)*	
		☐ Generalized oedema, including both feet, legs, hands, arms, and face *(severe)*	
36.	Tick all diagnoses applicable *(check all that apply)*		
	☐ Diarrhea		☐ Dysentery
	☐Gastroenteritis		☐ Anemia
	☐ Sickle cell		☐ HIV
	☐ Malaria		☐ Urinary Tract Infection
	☐ Suspected sepsis		☐ Tuberculosis
	☐ Upper respiratory tract infection		☐ Fever of unknown origin/Febrile illness
	☐ Other lower respiratory tract infections		☐ Pneumonia
	☐ Acutely unwell, unknown cause		☐ Meningitis

		☐ Asthma	☐ Poisoning/ herbal intoxication
		☐ Moderate acute malnutrition/ moderate wasting	☐ Severe acute malnutrition/ severe wasting
		☐ None	☐ Soft tissue/skin infection
		☐ Other 1 *(specify)*:_____	☐ Other 2 *(specify)*:_____
		REMINDER: Record any therapies initiated in the Medical Management CRF (CRF 04b)	

D1.	**CHILD PRESENTATION ANTHROPOMETRY (<u>PRIOR</u> TO ANY REHYDRATION OR NO REHYDRATION REQUIRED)**		

37.	Will this child be rehydrated in the facility?		
	☐ Yes and pre-rehydration weight and MUAC able to be collected *(complete Sections D1, D2 & D3)*		
	☐ Yes and pre-rehydration weight and MUAC are NOT able to be collected *(complete Section D2 & D3)*		
	☐ No *(complete Section D1 & D2, then skip to Q52)*		
38.	a.	What is the child's mid upper arm circumference (MUAC)? (1st measurement)	|___|___|.|___| (cm)
	b.	Arm from which MUAC is being measured *(please ensure the <u>same</u> arm is used to collect 1st, 2nd, and 3rd measurements)*	☐ Right ☐ Left
	c.	What is the child's MUAC? (2nd measurement)	|___|___|.|___| (cm)
	If measurement 2 differs from measurement 1, subtract the lower measurement from the higher measurement and, if the difference is 0.3cm or greater, obtain a third measurement		
	d.	What is the child's MUAC? (3rd measurement, if applicable)	|___|___|.|___| (cm) ☐ Not applicable *(3rd measurement not indicated)*
	Comments:		
39.	How is the child's weight being recorded?		
	☐ Adult scale, child only *(child is ≥24 months OR able to stand on the scale alone; skip to Q43a)*		
	☐ Adult scale, child and caregiver together *(child is <24 months OR unable to stand on the scale alone)*		
40.	a.	What is the weight of child and caregiver (1st measurement)	|___|___|___|.|___| (kg)
	b.	What is the weight of the caregiver alone (1st measurement)	|___|___|___|.|___| (kg)
	c.	What is the <u>calculated</u> weight of the child *(Q40a minus Q40b)*	|___|___|.|___| (kg)
41.	a.	What is the weight of child and caregiver (2nd measurement)	|___|___|___|.|___| (kg)
	b.	What is the weight of the caregiver alone (2nd measurement)	|___|___|___|.|___| (kg)
	c.	What is the <u>calculated</u> weight of the child *(Q41a minus Q41b)* (2nd measurement)	|___|___|.|___| (kg)
	If measurement 2 (Q41c) differs from measurement 1(Q40c), subtract the lower measurement from the higher measurement and if the difference is 0.2 kg or greater, obtain a third measurement; otherwise skip to Q44		

42.	a.	What is the weight of child and caregiver (3rd measurement)	|___|___|___|.|___| (kg) ☐ Not applicable *(3rd measurement not indicated)*
	b.	What is the weight of the caregiver alone (3rd measurement)	|___|___|___|.|___| (kg) ☐ Not applicable *(3rd measurement not indicated)*
	c.	What is the calculated weight of the child *(Q42a minus Q42b)* (3rd measurement)	|___|___|.|___| (kg) ☐ Not applicable *(3rd measurement not indicated)*
	Comments:		
	If the child is ≥24 months AND able to stand on the scale alone:		
43.	a.	What is the child's weight? (1st measurement)	|___|___|.|___|(kg)
	b.	What is the child's weight? (2nd measurement)	|___|___|.|___|(kg)
	If measurement 2 differs from measurement 1, subtract the lower measurement from the higher measurement and if the difference is 0.2 kg or greater, obtain a third measurement		
	c.	What is the child's weight? (3rd measurement, if applicable)	|___|___|.|___|(kg) ☐ Not applicable *(3rd measurement not indicated)*
	Comments:		

D2. CHILD LENGTH/HEIGHT *(All participants, irrespective of rehydration status)*			
44.	How is the child's length *(if <24 months)* / height *(if ≥24 months)* being recorded?		
	☐ Recumbent length *(if <24 months)*		
	☐ Standing height *(if ≥24 months and able to stand)*		
	a.	What is the length/height of the child? (1st measurement)	|___|___|.|___| (cm)
	b.	What is the length/height of the child? (2nd measurement)	|___|___|.|___| (cm)
	If measurement 2 differs from measurement 1, subtract the lower measurement from the higher measurement and if the difference is 0.5 cm or greater, obtain a third measurement		
	c.	What is the length/height of the child? (3rd measurement, if applicable)	|___|___|.|___| (cm) ☐ Not applicable *(3rd measurement not indicated)*

		Comments:		

D3.		**CHILD POST-REHYDRATION ANTHROPOMETRY** *(complete ONLY if child was rehydrated [partially or fully] in the facility, otherwise skip to Section F)*	
	45.	Was rehydration therapy completed at the facility?	
		☐ Yes, child was fully rehydrated at the facility	
		☐ No, child was not fully rehydrated and is being sent home with rehydration therapy (ORS)	
	46.	a. What is the child's MUAC? (1ˢᵗ measurement)	|___|___|.|___| (cm)
		b. Arm from which MUAC is being measured	☐ Right ☐ Left
		c What is the child's MUAC? (2ⁿᵈ measurement)	|___|___|.|___| (cm)
		If measurement 2 differs from measurement 1, subtract the lower measurement from the higher measurement and, if the difference is 0.3 cm or greater, obtain a third measurement.	
		d. What is the child's MUAC? (3ʳᵈ measurement, if applicable)	|___|___|.|___| (cm) ☐ Not applicable *(3ʳᵈ measurement not indicated)*
		Comments:	
	47.	How is the child's weight being recorded?	
		☐ Adult scale, child only *(child is ≥24 months AND able to stand on the scale alone; skip to Q51a)*	
		☐ Adult scale, child and caregiver together *(child is <24 months OR unable to stand on the scale alone)*	
	48.	a. What is the weight of child and caregiver (1ˢᵗ measurement)	|___|___|___|.|___| (kg)
		b. What is the weight of the caregiver alone (1ˢᵗ measurement)	|___|___|___|.|___| (kg)
		c. What is the underlined calculated weight of the child *(Q48a minus Q48b)*	|___|___|.|___| (kg)
	49.	a. What is the weight of child and caregiver (2ⁿᵈ measurement)	|___|___|___|.|___| (kg)
		b. What is the weight of the caregiver alone (2ⁿᵈ measurement)	|___|___|___|.|___| (kg)
		c. What is the calculated weight of the child *(Q49a minus Q49b)* (2ⁿᵈ measurement)	|___|___|.|___| (kg)
		If measurement 2 (Q49c) differs from measurement 1(Q48c), subtract the lower measurement from the higher measurement and if the difference is 0.2 kg or greater, obtain a third measurement	
	50.	a. What is the weight of child and caregiver (3ʳᵈ measurement)	|___|___|___|.|___| (kg) ☐ Not applicable *(3ʳᵈ measurement not indicated)*

	b.	What is the weight of the caregiver alone (3rd measurement)	|___|___|___|.|___| (kg) ☐ Not applicable *(3rd measurement not indicated)*
	c.	What is the calculated weight of the child *(Q50a minus Q50b)* (3rd measurement)	|___|___|.|___| (kg) ☐ Not applicable *(3rd measurement not indicated)*
	Comments:		
51.	a.	What is the child's weight? (1st measurement)	|___|___|.|___|(kg)
	b.	What is the child's weight? (2nd measurement)	|___|___|.|___|(kg)
	If measurement 2 (Q51b) differs from measurement 1 (Q51a), subtract the lower measurement from the higher measurement and if the difference is 0.2 kg or greater, obtain a third measurement		
	c.	What is the child's weight? (3rd measurement, if applicable)	|___|___|.|___|(kg) ☐ Not applicable *(3rd measurement not indicated)*
	Comments:		

F.	**CHILD HEALTH HISTORY** *(Instructions to staff: Text in* **bold** *should be read verbatim,* plain text *is for prompts for study staff, and italics are instructions for study staff)*	
52.	Is there a known or suspected cholera epidemic in the study area at present?	
	☐ Yes	
	☐ No	
	☐ Unknown	
53.	**Has your child ever been diagnosed with any of the following?** *(check all that apply, check "None" if none apply)*	
	☐ Rheumatic heart disease	☐ Leukemia
	☐ Sickle cell anemia	☐ Tuberculosis
	☐ HIV	☐ Other 1 *(specify)*: _____
	☐ Other 2 *(specify)*: _____	☐ None
	Breastfeeding History	
54.	**Has your child ever breastfed?**	
	☐ Yes	
	☐ No *(skip to Q59)*	

		☐ Unknown *(skip to Q59)*			
55.		**Other than breastmilk, has your child <u>ever</u> consumed any of the following since their birth?**			
		Water *(fluid)*	☐ Yes	☐ No	☐ Unknown
		Formula *(fluid)*	☐ Yes	☐ No	☐ Unknown
		Processed milk *(fluid)*	☐ Yes	☐ No	☐ Unknown
		Cow/goat/camel/donkey milk *(fluid)*	☐ Yes	☐ No	☐ Unknown
		Sweetened water *(fluid)*	☐ Yes	☐ No	☐ Unknown
		Tea *(fluid)*	☐ Yes	☐ No	☐ Unknown
		Fruit juice *(fluid)*	☐ Yes	☐ No	☐ Unknown
		Porridge *(semi-solid food)*	☐ Yes	☐ No	☐ Unknown
		Rice *(solid food)*	☐ Yes	☐ No	☐ Unknown
		Other liquid not listed *(specify)*: _____	☐ Yes	☐ No	☐ Unknown
		Other semi-solid foods not listed *(specify)*: _____	☐ Yes	☐ No	☐ Unknown
		Other solid food not listed *(specify)*: _____	☐ Yes	☐ No	☐ Unknown
		Instructions to staff: If the caregiver answered "Yes" to any rows in Q55, skip to Q57.			
56.		*If the caregiver answered "No" to all questions in Q55:* **According to your answers, your child was exclusively breastfed immediately before (or up until) this diarrheal episode (that is, your child has only ever been given breast milk).** *If caregiver responds that this statement is incorrect, then correct questions in Q55 to show what the child has received other than breastmilk).*			
		☐ Yes, caregiver confirmed that this child was exclusively breastfed up until this illness episode *(skip to Q59)*			
		☐ No, the caregiver stated this child was not exclusively breastfed until this illness episode and the child received 1 or more foods and/or fluids marked in Q55			
57.		*If answered "Yes" to one or more <u>fluids</u> defined in Q55 please ask the caregiver:* **Thinking about the time immediately before (or up until) this illness episode, how old was your child when they first had fluids other than breastmilk (such as water, tea, formula, or milk)?**			
		|___|___| months *(if <10, put "0" before digit)* ☐ Unknown			
58.		*If answered "Yes" to one or more <u>foods</u> defined in Q55 please ask the caregiver:* **Thinking about the time immediately before (or up until) this illness episode, how old was your child when they first had semi-solid or solid foods (such porridge, rice, or other foods)?**			
		|___|___| months *(if <10, put "0" before digit)* ☐ Unknown			
		Immunization History			
59.		Is the child's immunization record available?			
		☐ Yes			

		☐ No *(skip to Q62)*		
		Note: If caregiver has access to the child's immunization record but did not bring the immunization record to the Enrollment Visit, please remind them to bring it to the Week 4 Follow Up Visit and information will be abstracted in Follow Up CRF (CRF 07)		
	60.	Using the immunization record, indicate how many doses of the following vaccines the child has received? *(enter 0 if none, 9 if unknown. If a vaccine was given as part of a composite vaccine but not alone (e.g. measles as part of MMR or MR vaccine, mark "0" to the component (e.g. measles) and "1" to the composite (MMR)*		
		Rotavirus vaccine	|___|	Bacille Calmette-Guerin (BCG)	|___|
		Polio vaccine (OPV or IPV)	|___|	Rubella vaccine	|___|
		Pentavalent vaccine (DPT+HiB+HBV)	|___|	HiB vaccine (Hemophilus influenzae)	|___|
		S. pneumococcus vaccine (PCV)	|___|	Hepatitis A vaccine	|___|
		Measles vaccine	|___|	Hepatitis B vaccine	|___|
		MR vaccine (measles+rubella)	|___|	Typhoid fever vaccine	|___|
		MMR vaccine (measles+mumps+rubella)	|___|	Varicella vaccine	|___|
		Yellow fever vaccine	|___|	Meningococcal A vaccine	|___|
		DPT vaccine (Diphteria+pertussis+tetanus)	|___|	Malaria vaccine (RTS,S)	|___|
	61.	How many doses of Vitamin A has the child received?	|___| *(enter 9 if unknown)*		
		REMINDER TO MALI, MALAWI, AND KENYA SITES ONLY: Please complete the HIV Information CRF (CRF 04c) before proceeding with the enrollment questions		

G.	**CAREGIVER INFORMATION** *(Instructions to staff: Text in **bold** should be read verbatim, plain text is for prompts for study staff, and italics are instructions for study staff)*

	62.	What is the age of the accompanying caregiver?		
		|___|___| years ☐ Unknown		
	63.	What does the accompanying caregiver do for work on a typical day?		
		☐ Not employed	☐ Housewife	☐ Student
		☐ Business (self-employed)	☐ Business (other employer)	☐ Professional (e.g. teacher, lawyer)
		☐ Casual laborer	☐ Farmer	☐ Unknown
		☐ Other *(specify)*:)_____		
	64.	What is the highest level of formal schooling achieved by the child's mother?		
		☐ None	☐ Less than primary school	☐ Declined to answer
		☐ Some secondary school	☐ Secondary school or greater	☐ Unknown
		☐ Koranic school only	☐ Primary school only	
	65.	What is the highest level of formal schooling achieved by the child's father?		
		☐ None	☐ Less than primary school	☐ Declined to answer
		☐ Some secondary school	☐ Secondary school or greater	☐ Unknown

		☐ Koranic school only	☐ Primary school only	

H.	**ADDITIONAL INFORMATION ON THE CHILD'S HOUSEHOLD ENVIRONMENT** *(Instructions to staff: Text in **bold** should be read verbatim, plain text is for prompts for study staff, and italics are instructions for study staff)*

Household, Water, Sanitation, and Hygiene Information

	66.	How many children under 5 years of age are living in the child's household *(including this child)*?
		|__|__| children under 5 years of age *(if <10, put "0" before digit)*
	67.	What is the main source of <u>drinking water</u> for the members of the household *(check one)*

	☐ Piped water into dwelling	☐ Piped into compound/yard/plot	☐ Piped to neighbor
	☐ Public tap/standpipe	☐ Tube well or borehole	☐ Protected well
	☐ Unprotected well	☐ Water from spring (protected)	☐ Water from spring (unprotected)
	☐ Rainwater	☐ Tanker-truck	☐ Cart with small tank/drum
	☐ Water kiosk (filtered)	Water kiosk (un filtered)	☐ Bottled water
	☐ Sachet water	☐ Surface water (river/dam/lake/ pond/canal/irrigation channel)	☐ Other *(specify)*: _____

	68.	Does the household do anything to make the water safer to drink?
		☐ Yes / ☐ No *(skip to Q70)* / ☐ Unknown *(skip to Q70)*
	69.	*If yes,* what does the household usually do to make the water safer to drink? *(Check all that apply)*

	☐ Boil	☐ Add bleach/chlorine	☐ Solar disinfection
	☐ Let it stand and settle	☐ Strain through a cloth	☐ Filter (ceramic/sand/ composite/LifeStraw)

	☐ Other, specify: _____

	70.	What is the source of the water that the household is (currently) using for <u>hygiene</u> (such as hand-washing, showering, or brushing teeth) or cooking? *(Check one)*

	☐ Piped water into dwelling	☐ Piped into compound/yard/plot	☐ Piped to neighbor
	☐ Public tap/standpipe	☐ Tube well or borehole	☐ Protected well
	☐ Unprotected well	☐ Water from spring (protected)	☐ Water from spring (unprotected)
	☐ Rainwater	☐ Tanker-truck	☐ Cart with small tank/drum
	☐ Water kiosk (filtered)	☐ Water kiosk (unfiltered)	☐ Bottled water
	☐ Sachet water	☐ Surface water (river/dam/lake/ pond/canal/irrigation channel)	☐ Other *(specify)*: _____

	71.	Does the household do anything to make the water safer for hygiene and cooking?
		☐ Yes / ☐ No *(skip to Q73)* / ☐ Unknown *(skip to Q73)*
	72.	*If yes,* what does the household usually do to make the water safer for hygiene or cooking? *(Check all that apply)*

	☐ Boil	☐ Add bleach/chlorine	☐ Solar disinfection
	☐ Let it stand and settle	☐ Strain through a cloth	☐ Filter (ceramic/sand/ composite/LifeStraw)

	☐ Other *(specify)*: _____

73.	What kind of toilet facility do members of the household usually use? *(Check one)*	

☐ Flushed or pour flush to piped sewer system	☐ Flushed or pour flush to septic tank	☐ Flushed or pour flush to somewhere else
☐ Flushed or pour flush, don't know where	☐ Ventilated improved pit latrine	☐ Pit latrine with slab floor
☐ Pit latrine without slab floor	☐ Composting toilet	☐ Bucket toilet
☐ Hanging toilet/hanging latrine	☐ Open defecation/bush/field	☐ Other *(specify)*: _____

74.	Does the household share this toilet facility with other households?
	☐ Yes
	☐ No *(skip to Q76)*
75.	How many households use this toilet facility? |___|___| *(if <10, put "0" before digit)* ☐ Unknown
76.	*Please ask the caregiver verbally:* **When do you usually wash your hands?** *(check all that apply)*

☐ Before eating	☐ After handling domestic animals
☐ Before cooking	☐ After cleaning a child who defecated
☐ Before you nurse or prepare baby's food	☐ After you defecate
☐ Never *(skip to Q78)*	☐ Other *(specify)*: _____

77.	**When you wash your hands, what do you usually use?**

☐ Water only	☐ Water and soap
☐ Water and ashes	☐ Water and mud or clay
☐ Other *(specify)*: _____	

REMINDER: Please complete the Household Wealth CRF (CRF 04b-[site specific])
before proceeding with the enrollment questions

I.	**PRIOR CARESEEKING BEHAVIOR** *(Instructions to staff: Text in* **bold** *should be read verbatim,* plain text *is for prompts for study staff, and italics are instructions for study staff)*
78.	**During this episode of diarrhea, did you seek any other medical care for your child before coming to the clinic today?**
	☐ Yes
	☐ No *(skip to Q87)*
79.	*If yes,* **where did you seek other medical treatment and how many times?** *(Not including the current clinic visit. Check all that were visited and report number of times visited. If <10, put "0" as first digit. If times visited unknown put "99")*

☐ Traditional healer	|__|__| times	☐ Religious healer	|__|__| times
☐ Drug seller	|__|__| times	☐ Pharmacist	|__|__| times
☐ Community health worker	|__|__| times	☐ Health outpost	|__|__| times

	☐ Health facility (outpatient care) |_|_| times	☐ Health facility (inpatient care) |_|_| times
	☐ Other *(specify)*: _____ |____| times		
80.	**Did your child receive any tests prior to coming to clinic?**		
	☐ Yes		
	☐ No *(skip to Q83)*		
81.	*If yes,* **Please indicate from the list below which tests your child received when you sought care prior to coming to the health facility today?**		
	☐ Stool culture	☐ Microscopy	
	☐ Rotavirus antigen test	☐ Cryptosporidium/giardia antigen test	
	☐Other *(specify)*:_____		
82.	*If yes,* **Did you pay for any of the tests your child received?**		
	☐ Yes, purchased one or more	☐ No, all were provided for free	☐ Don't know
83.	**Did your child receive any treatment(s) when you sought care prior to coming to clinic?**		
	☐ Yes		
	☐ No *(skip to Q86)*		
84.	*If yes,* **Please indicate from the list below which treatments your child received when you sought care prior to coming to the health facility today?** *(check all that apply)*		
	☐ Oral rehydration solution (ORS)	☐ Zinc	☐ Anti-diarrheal
	☐ RUSF or locally made supplementary food	☐ ReSoMal	☐ Anti-malarial
	☐ Albendazole	☐ Mebendazole	☐ Metronidazole (Flagyl)
	☐ Other 1 *(specify)*: _____	☐ Other 2 *(specify)*: _____	

☐ Antibiotic(s) *(specify below, check all that apply)*			
☐ Amoxicillin	☐ Azithromycin	☐ Ampicillin	☐ Augmentin/ Co-amoxiclav
☐ Ceftriaxone	☐ Ciprofloxacin (Cipro)	☐ Cefuroxime	☐ Cefixime
☐ Clarithromycin	☐ Clindamycin	☐ Chloramphenicol	☐ Cotrimoxazole (Septrin)
☐ Doxycycline	☐ Erythromycin	☐ Gentamicin	☐ Penicillin
☐ Pyrazinamide	☐ Streptomycin	☐ Tetracycline	☐ Unknown
☐ Other 1 *(specify)*: _____	☐ Other 2 *(specify)*: _____	☐ Other 3 *(specify)*: _____	

85.	**Did you purchase any of these treatments?**		
	☐ Yes, purchased them	☐ No, they were provided for free	
	☐ No, received leftover medications from someone else	☐ Do not recall	
86.	**Once you made the decision to seek care outside the household for your child, did you need to seek permission from someone?**		

		☐ Yes	
		☐ No *(skip to Q87)*	
	86a.	If yes, from whom *(check all that apply)*:	
		☐ Head of household	☐ Other household member
		☐ Family member outside of the household	☐ Community leader
		☐ Religious leader	☐ Pharmacist or drug seller
		☐ Other *(specify)*: _____	

J.	**INFORMATION ON COST OF VISIT AND TRANSPORTATION TO THE FACILITY** *(Instructions to staff: Text in **bold** should be read verbatim, plain text is for prompts for study staff, and italics are instructions for study staff)*

	87.	**Approximately how much time did it take you and this child to get to the health facility today?** *(if <10, put "0" before digit)*
		|___|___|days OR |___|___|hours OR |___|___|minutes ☐Don't know
	88.	**What method of transportation did you and your child use to travel to the facility?** *(check all that apply)*

		☐ Walked	☐ Motorbike	☐ Private or shared car
		☐ Personal vehicle	☐ Shared van/bus/taxi	☐ Other *(specify)*: _____

	89.	**Approximately how much did you pay for your transportation to the clinic for this visit?** *(If personal vehicle reported in Q88, include cost of gas; report cost numerically in local currency; if none, put "0")*
		_____ ☐Unknown

K.	**FORM COMPLETION**

	90.	ID of person completing this form: |___|___|___| — Date form completed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
	91.	ID of person reviewing this form: |___|___|___| — Date form reviewed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
	92.	ID of person entering this form: |___|___|___| — Date form entered: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
	93.	ID of person conducting data verification: |___|___|___| — Date of data verification: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*

Purpose: *To ascertain information on clinical management during the enrollment facility visit for all enrolled participants from the point of presentation through the point of being ready to leave the facility/discharge.*

Instructions: *Please complete the following information for all enrolled participants.* Text in **bold** should be read to study participants, plain text are prompts for study staff, and *italics* are instructions for study staff. This form will remain open throughout the entirety of the child's stay during their <u>enrollment visit</u>.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	PARTICIPANT INFORMATION			
	1.	Participant ID	|___|___|___|___|___|___|___|	
	2.	Date of Enrollment:	|___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)*	
	3.	Time form is started:	|___|___| : |___|___| *(hh : min, 24:00 hr)*	
	4.	EFGH country site:		
		☐ Bangladesh	☐ Kenya	☐ Malawi	☐ Mali
		☐ The Gambia	☐ Pakistan	☐ Peru	

B.	ADMISSION INFORMATION
	5.	Was the child admitted to an inpatient ward (i.e. for an overnight stay) during this visit?
		☐ Yes
		Date of admission: |___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of enrollment *(Q2)*
		Time admitted to inpatient ward: |___|___| : |___|___| *(hh : min, 24:00 hr)* ☐Unknown
		(skip to Section C)
		☐ No
	6.	Was the child primarily seen in:
		☐ Outpatient ward
		☐ Emergency room
		☐ Other *(specify):* _____

C.	DIAGNOSTIC TESTS RECEIVED DURING FACILITY VISIT	
	7.	Did the child receive any of the following stool tests during their facility visit? *(check all that apply)*	
		☐ Stool culture *(SEPARATE from culture planned for EFGH)*	☐ Microscopy
		☐ Rotavirus antigen test	☐ Cryptosporidium/giardia antigen test
		☐ Other *(specify):*_____	☐ None

D.	MEDICAL MANGEMENT DURING FACILITY VISIT AND PRESCRIBED FOR DISCHARGE PERIOD
	8.	*To the staff completing this form:* Are you one of the treating clinicians?

		☐ Yes, I am part of this child's clinical team ☐ No, I am abstracting this information from the child's medical record	
9.		Was oral rehydration solution (ORS) or ReSoMal (half strength ORS) administered during the visit?	
		☐ Yes ☐ No, child received other rehydration therapy *(skip to Q10)* ☐ No, not necessary for this child *(skip to Q10)* ☐ No, not available due to stock out *(skip to Q10)* ☐ No, *specify)*_____ *(skip to Q10)*	
	9a.	Type of oral rehydration initiated:	
		☐ Low osmolarity ORS solution (Glucose: 75mmol, Sodium: 75 mmol, Chloride: 65mmol, Potassium: 20mmol)	
		☐ icddr,b ORS solution (Sodium chloride: 1.3 g, Potassium chloride: 0.75 g, Sodium citrate: 1.45 g, Anhydrous Glucose: 6.75 g)	
		☐ ReSoMal/Half-strength ORS (Glucose: 125mmol, Sodium: 45 mmol, Chloride: 70mmol, Potassium: 40mmol)	
		☐ High osmolarity (original formulation) ORS (Glucose: 111mmol, Sodium:90 mmol, Chloride: 80mmol, Potassium: 20mmol)	
		☐ Other *(specify type & composition)*: _____	
	9b.	How was it administered: ☐ Orally ☐ Nasogastrically	
	9c.	Date ORS or ReSoMal initiated: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of enrollment *(Q2)*	
	9d.	Time ORS or ReSoMal initiated: |___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Unknown	
	9e.	Date ORS or ReSoMal completed: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of enrollment *(Q2)* ☐ Continuing ☐ Unknown	
	9f.	Time ORS or ReSoMal completed: |___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Continuing ☐ Unknown	
	9g.	Duration of in-facility ORS/ ReSoMal Treatment |___|___| (hrs) *(Auto-generated from date/time of initiation to date/time of completion. If <10, put 0 before the last digit ie 4 hours would be "04")*	
	9h.	*If answer to 9g is less than 4 hours:* Why?	
		☐ Caregiver did not want to remain in the facility	☐ Not enough space in the facility
		☐ Other *(specify)*: _____	
	9i.	Total number of packets of ORS or ReSoMal offered to the child during visit:	|___|___|. ___| ☐ Unknown ☐ Not applicable (ie packets not used)
	9j.	What volume of water was each packet mixed with:	|___|___|___|___|mL (note standard is 1,000 mL) ☐ Unknown
	9k.	Total volume of ORS or ReSoMal <u>offered</u> to the child during the visit:	|___|___|___|___|mL *(autogenerated as # packets ✕ volume water mixed with packet)*
	9l.	Was there any mixed ORS/ReSoMal remaining that the child did not drink?	☐ Yes ☐ No *(skip to Q9o)*

		9m.	What volume was left over that the child did not drink?	|___|___|___|___|mL ☐ Unknown
		9n.	Total volume of ORS or ReSoMal <u>consumed by</u> the child during the visit:	|___|___|___|___|mL *(autogenerated as volume offered – volume remaining or volume offered if none remained)*
		9o.	Was the ORS administered during the facility visit provided by the health facility (free of charge) or did the caregiver need to buy it either at the health facility or elsewhere?	
			☐ Provided free by facility or national health insurance ☐ Provided by EFGH ☐ Caregiver needed/needs to buy it either at the health facility or elsewhere ☐ Other *(specify)*: _____ ☐ Unknown	
10.			When the child was ready to leave or was discharged, was the child instructed to continue oral rehydration treatment at home?	
			☐ Yes ☐ No *(skip to Q11)*	
			If yes, please provide counseling to the caregiver on how to prepare and deliver the ORS	
		10a.	How many packets of at-home ORS were prescribed?	|___|___|. |___|packets *(half packets can be indicated with ".5")* ☐ Unknown ☐ Not applicable (i.e. packets not used)
		10b.	Was the prescribed ORS/ReSoMal for the discharge period provided by the health facility (free of charge), or does the caregiver need to buy the ORS/ReSoMal at the health facility or elsewhere?	
			☐ Provided free by facility or national health insurance ☐ Provided by EFGH ☐ Caregiver needed/needs to buy it either at the health facility or elsewhere ☐ Other *(specify)*: _____ ☐ Unknown	
11.			Was IV rehydration administered during the visit?	
			☐ Yes ☐ No, contraindication *(skip to Q12)* ☐ No, child received other rehydration therapy *(skip to Q12)* ☐ No, not necessary for this child *(skip to Q12)* ☐ No, not available due to stock out *(skip to Q12)* ☐ No, *specify:*_____ *(skip to Q12)*	
		11a.	Type of IV *(check all administered)*: ☐ Normal saline ☐Dextrose ☐Ringer's lactate solution ☐Cholera saline☐ Other *(specify):* _____	
		11b.	Date IV rehydration initiated: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of enrollment *(Q2)*	
		11c.	Time IV rehydration initiated: |___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Unknown	
		11d.	Date IV rehydration completed:|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of enrollment *(Q2)*	

	11e.	Time IV rehydration completed: |___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Continuing ☐ Unknown
	11f.	Duration of IV rehydration |___|___| (hrs) *(Auto-generated from date/time of initiation to date/time of completion. If <10, put 0 before the last digit ie 4 hours would be "04")*
	11g.	Size of one IV bag*:* |___|___|___|___|mL *(if between 1-999, put "0999")* *If multiple IVs were administered, report volume of the average of all IVs administered.*
	11h.	Total number of IV bags received: |___|. |___| ☐ Unknown *(indicate half bag with ".5")*
	11i.	Total volume administered during visit: |___|___|___|___|mL *(Auto-generated as # bags x volume of each bag but can be edited by staff. If between 1-999, put "0999")* ☐ Unknown
	11j.	Was the IV(s) administered during the facility visit provided by the health facility (free of charge) or did the caregiver need to buy it either at the health facility or elsewhere? *(check all that apply if multiple IVs administered)*
		☐ Provided free by facility or national health insurance ☐ Provided by EFGH ☐ Caregiver needed/needs to buy it either at the health facility or elsewhere ☐ Other *(specify)*: _____ ☐ Unknown
12.		Was zinc supplementation administered during the visit?	☐ Yes ☐ No *(skip to Q13)*
	12a.	Date zinc initiated: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of enrollment *(Q2)*
	12b.	Date zinc completed: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of enrollment *(Q2)* ☐ Continuing ☐ Unknown
	12c.	Amount of zinc administered per day during facility visit: |___|___|mg per day ☐ Unknown *(If child vomited after receiving zinc and another dose was administered consider only the post-vomit dose)*
	12d.	Was the zinc administered during the facility visit provided by the health facility (free of charge) or did the caregiver need to buy it either at the health facility or elsewhere?
		☐ Provided free by facility or national health insurance ☐ Provided by EFGH ☐ Caregiver needed/needs to buy it either at the health facility or elsewhere ☐ Other *(specify)*: _____ ☐ Unknown
13.		When the child was ready to leave or was discharged, was the child instructed to take zinc at home?
		☐ Yes ☐ No, contraindicated *(skip to Q14)* ☐ No, received other nutritional product *(skip to Q14)* ☐ No, not necessary for this child *(skip to Q14)* ☐ No, not available due to stock out *(skip to Q14)* ☐ No, other reason *(specify)*: _____ *(skip to Q14)*
	13a.	What was the prescribed daily dose of at-home zinc supplementation?	|___|___|mg ☐ Unknown
	13b.	What was the prescribed duration of at-home zinc supplementation?	|___|___|days ☐ Unknown

	13c.	Was the prescribed zinc for the discharge period provided by the health facility (free of charge) or does the caregiver need to buy the zinc either at the health facility or elsewhere?
		☐ Provided free by facility or national health insurance ☐ Provided by EFGH ☐ Caregiver needed/needs to buy it either at the health facility or elsewhere ☐ Other *(specify)*: _____ ☐ Unknown
14.		Were supplementary or therapeutic foods administered during the visit?
		☐ Yes *(skip to Q16)* ☐ No *(skip to Q18)* ☐ Unknown
15.		*If Unknown*, why?
		☐ Malnutrition management is handled by a separate unit & records are not available *(skip to Q18)* ☐ Other *(specify)*:_____ *(skip to Q18)*
16.		*Rows below refer to supplementary or therapeutic foods and micronutrients administered during the facility visit*

	Name *(check box if administered)*	Date initiated *(dd-mm-yyyy)*	Daily dose administered during facility visit *(circle unit)*	Date completed *(dd-mm-yyyy)*
	☐F75 *(in-patient cases only)*	|___|___| - |___|___| - | 2 | 0 |___|___|	_____ mL ☐ Unknown	|___|___| - |___|___| - | 2 | 0 |___|___|
	☐F100 *(in-patient cases only)*	|___|___| - |___|___| - | 2 | 0 |___|___|	_____ mL ☐ Unknown	|___|___| - |___|___| - | 2 | 0 |___|___|
	☐RUSF	|___|___| - |___|___| - | 2 | 0 |___|___|	_____ (mg/gram/sachet) ☐ Unknown	|___|___| - |___|___| - | 2 | 0 |___|___| ☐ Continuing
	☐RUTF	|___|___| - |___|___| - | 2 | 0 |___|___|	_____ (mg/gram/sachet) ☐ Unknown	|___|___| - |___|___| - | 2 | 0 |___|___| ☐ Continuing
	☐RUSF (locally made)	|___|___| - |___|___| - | 2 | 0 |___|___|	_____ (mg/gram/sachet) ☐ Unknown	|___|___| - |___|___| - | 2 | 0 |___|___| ☐ Continuing
	☐RUTF (locally made)	|___|___| - |___|___| - | 2 | 0 |___|___|	_____ (mg/gram/sachet) ☐ Unknown	|___|___| - |___|___| - | 2 | 0 |___|___| ☐ Continuing
	☐Multiple micronutrients	|___|___| - |___|___| - | 2 | 0 |___|___|	_____ (mg/gram/sachet) ☐ Unknown	|___|___| - |___|___| - | 2 | 0 |___|___| ☐ Continuing

17.		Were the foods or micronutrients administered during the facility visit provided by the health facility (free of charge) or did the caregiver need to buy it either at the health facility or elsewhere? *(check all that apply if multiple treatments administered)*
		☐ Provided free by facility or national health insurance ☐ Provided by EFGH ☐ Caregiver needed/needs to buy it either at the health facility or elsewhere ☐ Other *(specify)*: _____ ☐ Unknown
18.		When the child was ready to leave or was discharged, was the child instructed to take supplementary or therapeutic foods or micronutrients at home?

	☐ Yes ☐ No *(skip to Q21)*	

19. *Rows below refer to supplementary or therapeutic foods or micronutrients prescribed for the discharge period*

Name *(check box if prescribed)*	Daily dose prescribed for the discharge period *(circle unit)*	Prescribed duration *(if <10, put "0" before digit)*
☐RUSF	_____ (mg/gram/sachet) ☐ Unknown	|___|___| days ☐ Unknown
☐RUTF	_____ (mg/gram/sachet) ☐ Unknown	|___|___| days ☐ Unknown
☐RUSF (locally made)	_____ (mg/gram/sachet) ☐ Unknown	|___|___| days ☐ Unknown
☐RUTF (locally made)	_____ (mg/gram/sachet) ☐ Unknown	|___|___| days ☐ Unknown
☐Multiple micronutrients	_____ (mg/gram/sachet) ☐ Unknown	|___|___| days ☐ Unknown

20. Was/were the prescribed foods/micronutrients for the discharge period provided by the health facility (free of charge) or does the caregiver need to buy the foods either at the health facility or elsewhere? *(check all that apply if multiple treatments prescribed)*

☐ Provided free by facility or national health insurance
☐ Provided by EFGH
☐ Caregiver needed/needs to buy it either at the health facility or elsewhere
☐ Other *(specify)*: _____
☐ Unknown

21. Were antibiotics administered during the visit?   ☐ Yes   ☐ No *(skip to Q24)*

22. *Rows below refer to antibiotics administered <u>during</u> the facility visit*

Name *(check box if administered)*	Route of administration *(check one*	Date initiated *(dd-mm-yyyy)*	mg	Frequency/day *(check one)*	Date completed *(dd-mm-yyyy)*
☐Amoxicillin	☐ IV ☐Oral ☐ IM ☐Other*(specify)*: _____	|___|___| - |___|___| -| 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x *Other:* _____	|___|___| - |___|___| -| 2 | 0 |___|___| ☐ Continuing
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____				
☐Azithromycin	☐ IV ☐Oral ☐ IM ☐Other*(specify)*: _____	|___|___| - |___|___| -| 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x *Other:* _____	|___|___| - |___|___| -| 2 | 0 |___|___| ☐ Continuing
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____				
☐Ampicillin	☐ IV ☐Oral ☐ IM ☐Other*(specify)*: _____	|___|___| - |___|___| -| 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x *Other:* _____	|___|___| - |___|___| -| 2 | 0 |___|___| ☐ Continuing
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____				
☐Augmentin/Co-amoxiclav	☐ IV ☐Oral ☐ IM ☐Other*(specify)*: _____	|___|___| - |___|___| -| 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x *Other:* _____	|___|___| - |___|___| -| 2 | 0 |___|___| ☐ Continuing

Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____

Drug	Route	Start date	Dose	Frequency	End date
☐Cefixime	☐IV ☐Oral ☐IM ☐Other*(specify)*:_____	|__|__| - |__|__| -| 2 | 0 |__|__|	_____ mg ☐Unknown	☐1x ☐2x ☐3x ☐4x *Other:*_____	|__|__| - |__|__| -| 2 | 0 |__|__| ☐Continuing

Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____

| ☐Ceftriaxone | ☐IV ☐Oral ☐IM ☐Other*(specify)*:_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| | _____ mg ☐Unknown | ☐1x ☐2x ☐3x ☐4x *Other:*_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| ☐Continuing |

Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____

| ☐Ciprofloxacin (Cipro) | ☐IV ☐Oral ☐IM ☐Other*(specify)*:_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| | _____ mg ☐Unknown | ☐1x ☐2x ☐3x ☐4x *Other:*_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| ☐Continuing |

Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____

| ☐Cefuroxime | ☐IV ☐Oral ☐IM ☐Other*(specify)*:_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| | _____ mg ☐Unknown | ☐1x ☐2x ☐3x ☐4x *Other:*_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| ☐Continuing |

Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____

| ☐Clarithromycin | ☐IV ☐Oral ☐IM ☐Other*(specify)*:_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| | _____ mg ☐Unknown | ☐1x ☐2x ☐3x ☐4x *Other:*_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| ☐Continuing |
| ☐Clindamycin | ☐IV ☐Oral ☐IM ☐Other*(specify)*:_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| | _____ mg ☐Unknown | ☐1x ☐2x ☐3x ☐4x *Other:*_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| ☐Continuing |

Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____

| ☐Chloramphenicol | ☐IV ☐Oral ☐IM ☐Other*(specify)*:_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| | _____ mg ☐Unknown | ☐1x ☐2x ☐3x ☐4x *Other:*_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| ☐Continuing |

Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____

| ☐Cotrimoxazole/ Septrin/trimethoprim-sulfamethoxazole | ☐IV ☐Oral ☐IM ☐Other*(specify)*:_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| | _____ mg ☐Unknown | ☐1x ☐2x ☐3x ☐4x *Other:*_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| ☐Continuing |

Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____

| ☐Doxycycline | ☐IV ☐Oral ☐IM ☐Other*(specify)*:_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| | _____ mg ☐Unknown | ☐1x ☐2x ☐3x ☐4x *Other:*_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| ☐Continuing |

Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____

| ☐Erythromycin | ☐IV ☐Oral ☐IM ☐Other*(specify)*:_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| | _____ mg ☐Unknown | ☐1x ☐2x ☐3x ☐4x *Other:*_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| ☐Continuing |

Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____

| ☐Gentamicin | ☐IV ☐Oral ☐IM ☐Other*(specify)*:_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| | _____ mg ☐Unknown | ☐1x ☐2x ☐3x ☐4x *Other:*_____ | \|__\|__\| - \|__\|__\| -\| 2 \| 0 \|__\|__\| |

Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition

		☐Other *(specify)*_____			
☐Metronidazole (Flagyl)	☐ IV ☐Oral ☐ IM ☐Other*(specify):* _____	|___|___| - |___|___| -| 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x *Other:* _____	|___|___| - |___|___| -| 2 | 0 |___|___| ☐ Continuing
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____				
☐Penicillin	☐ IV ☐Oral ☐ IM ☐Other*(specify):* _____	|___|___| - |___|___| -| 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x *Other:* _____	|___|___| - |___|___| -| 2 | 0 |___|___| ☐ Continuing
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____				
☐Pyrazinamide	☐ IV ☐Oral ☐ IM ☐Other*(specify):* _____	|___|___| - |___|___| -| 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x *Other:* _____	|___|___| - |___|___| -| 2 | 0 |___|___| ☐ Continuing
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____				
☐Streptomycin	☐ IV ☐Oral ☐ IM ☐Other*(specify):* _____	|___|___| - |___|___| -| 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x *Other:* _____	|___|___| - |___|___| -| 2 | 0 |___|___| ☐ Continuing
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____				
☐Tetracycline	☐ IV ☐Oral ☐ IM ☐Other*(specify):* _____	|___|___| - |___|___| -| 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x *Other:* _____	|___|___| - |___|___| -| 2 | 0 |___|___| ☐ Continuing
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____				
☐Other1 *(specify):* _____	☐ IV ☐Oral ☐ IM ☐Other*(specify):* _____	|___|___| - |___|___| -| 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x *Other:* _____	|___|___| - |___|___| -| 2 | 0 |___|___| ☐ Continuing
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____				
☐Other2 *(specify):* _____	☐ IV ☐Oral ☐ IM ☐Other*(specify):* _____	|___|___| - |___|___| -| 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x *Other:* _____	|___|___| - |___|___| -| 2 | 0 |___|___| ☐ Continuing
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____				
☐Other3 *(specify):* _____	☐ IV ☐Oral ☐ IM ☐Other*(specify):* _____	|___|___| - |___|___| -| 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x *Other:* _____	|___|___| - |___|___| -| 2 | 0 |___|___| ☐ Continuing
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____				

23.	Were the antibiotics administered during the facility visit provided by the health facility (free of charge) or did the caregiver need to buy them either at the health facility or elsewhere?*(check all that apply if multiple antibiotics administered)*	
	☐ Provided free by facility or national health insurance ☐ Provided by EFGH ☐ Caregiver needed/needs to buy it either at the health facility or elsewhere ☐ Other *(specify)*: _____ ☐ Unknown	
24.	When the child was ready to leave or was discharged, was the child instructed to take antibiotics at home?	

		☐ Yes ☐ No *(skip to Q27)*		
25.		*Rows below refer to antibiotics <u>prescribed for</u> the discharge period*		

Name *(check box if prescribed)*	mg	Frequency/day *(check one)*	Prescribed duration *(if <10, put "0" before digit)*
☐Amoxicillin	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
☐Azithromycin	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
☐Ampicillin	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
☐Augmentin/Co-amoxiclav	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
☐Cefixime	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
☐Ceftriaxone	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
☐Ciprofloxacin (Cipro)	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
☐Cefuroxime	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
☐Clarithromycin	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
☐Clindamycin	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
☐Chloramphenicol	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
☐Cotrimoxazole/ Septrin/ trimethoprim-sulfamethoxazole	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
	Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition		

		☐Other *(specify)*_____		
	☐Doxycycline	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
		Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
	☐Erythromycin	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
		Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
	☐Gentamicin	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
		Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
	☐Metronidazole (Flagyl)	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
		Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
	☐Penicillin	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
		Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
	☐Pyrazinamide	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
		Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
	☐Streptomycin	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
		Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
	☐Tetracycline	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
		Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
	☐Other1 *(specify):* _____	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
		Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
	☐Other2 *(specify):* _____	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
		Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
	☐Other3 *(specify):* _____	_____ mg ☐ Unknown	☐ 1x ☐2x ☐3x ☐4x Other *(specify):* _____	|___|___| days ☐ Unknown
		Indication: ☐Diarrhea ☐Dysentery ☐Sepsis. ☐Lower respiratory infection ☐Malnutrition ☐Other *(specify)*_____		
26.	Was/were the prescribed antibiotics for the discharge period provided by the health facility (free of charge) or does the caregiver need to buy the antibiotics either at the health facility or elsewhere? *(check all that apply if multiple antibiotics prescribed)*			
	☐ Provided free by facility or national health insurance ☐ Provided by EFGH ☐ Caregiver needed/needs to buy it either at the health facility or elsewhere ☐ Other *(specify)*: _____			

	☐ Unknown				
27.	Was an anti-helminth initiated during the visit?		☐ Yes ☐ No *(skip to Q30)*		
28.	*Rows below refer to anti-helminth administered during the facility visit*				

	Name *(check box if administered)*	Date initiated *(dd-mm-yyyy)*	mg	Frequency	Date completed *(dd-mm-yyyy)*
	☐ Albendazole	|___|___| - |___|___| - | 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ Hourly ☐Daily ☐Other*(specify):* _____	|___|___| - |___|___| - | 2 | 0 |___|___|
	☐ Mebendazole	|___|___| - |___|___| - | 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ Hourly ☐Daily ☐Other*(specify):* _____	|___|___| - |___|___| - | 2 | 0 |___|___|
	☐ Other *(specify):* _____	|___|___| - |___|___| - | 2 | 0 |___|___|	_____ mg ☐ Unknown	☐ Hourly ☐Daily ☐Other*(specify):* _____	|___|___| - |___|___| - | 2 | 0 |___|___|

29.	Were the anti-helminths administered during the facility visit provided by the health facility (free of charge) or did the caregiver need to buy it either at the health facility or elsewhere? *(check all that apply if multiple anti-helminths administered)*	
	☐ Provided free by facility or national health insurance ☐ Provided by EFGH ☐ Caregiver needed/needs to buy it either at the health facility or elsewhere ☐ Other *(specify)*: _____ ☐ Unknown	
30.	When the child was ready to leave or was discharged, was the child instructed to take anti-helminths at home?	
	☐ Yes ☐ No *(skip to Q33)*	
31.	*Rows below refer to anti-helminths prescribed for the discharge period*	

	Name (check box if prescribed)	Dose prescribed for the discharge period	Prescribed duration (if <10, put "0" before digit)
	☐ Albendazole	_____ mg ☐ Unknown	|___|___| days ☐ Unknown
	☐ Mebendazole	_____ mg ☐ Unknown	|___|___| days ☐ Unknown
	☐ Other(specify): _____	_____ mg ☐ Unknown	|___|___| days ☐ Unknown

32.	Was/were the prescribed anti-helminths for the discharge period provided by the health facility (free of charge) or does the caregiver need to buy the anti-helminths either at the health facility or elsewhere? *(check all that apply if multiple anti-helminths prescribed)*	
	☐ Provided free by facility or national health insurance ☐ Provided by EFGH ☐ Caregiver needed/needs to buy it either at the health facility or elsewhere	

☐ Other *(specify)*: _____	
☐ Unknown	

33.	Were any other treatments given during the facility visit and/or prescribed *(excluding analgesics)*?
	☐ Yes
	☐ No *(skip to Q36)*

34. *Rows below refer to treatments administered during the facility visit and/or prescribed for the discharge period. No need to record analgesics (paracetamol), blood transfusions, probiotics etc).*

Treatment *(check box if administered or prescribed)*	Administered during visit		Prescribed at discharge	
Antimalarial				
☐Artemether lumefantrine	☐ Yes	☐ No	☐ Yes	☐ No
☐Paludrine	☐ Yes	☐ No	☐ Yes	☐ No
☐Artesunate	☐ Yes	☐ No	☐ Yes	☐ No
☐Quinine	☐ Yes	☐ No	☐ Yes	☐ No
☐Proguanil	☐ Yes	☐ No	☐ Yes	☐ No
Other treatments (excluding analgesics, including blood transfusion, probiotics)				
☐Other 1 (specify): _____	☐ Yes	☐ No	☐ Yes	☐ No
☐ Other 2 (specify): _____	☐ Yes	☐ No	☐ Yes	☐ No
☐ Other 3 (specify): _____	☐ Yes	☐ No	☐ Yes	☐ No

35.	Were any of the treatments prescribed for the discharge period provided by the health facility (free of charge) or did the caregiver need to buy it either at the health facility or elsewhere? *(check all that apply if multiple treatments prescribed)*
	☐ Provided free by facility or national health insurance
	☐ Provided by EFGH
	☐ Caregiver needed/needs to buy it either at the health facility or elsewhere
	☐ Other *(specify)*: _____
	☐ Unknown

E. FORM COMPLETION

36.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
37.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
38.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
39.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*

Purpose: To collect household wealth information at the Bangladesh site.

Instructions: Please complete this form for all households that are included in the Healthcare Utilization Survey at the Bangladesh EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):   Participant ID: |___|___|___|___|___|___|___|

A.	WEALTH INDEX

1. **Does your household have a television?** ☐ Yes ☐ No

2. **Does your household have a refrigerator?** ☐ Yes ☐ No

3. **Does your household have an almirah/wardrobe?** ☐ Yes ☐ No

4. **Does your household have an electric fan?** ☐ Yes ☐ No

5. **What is the main material of the floor?** *(select one)*

   ☐ Cement   ☐ Earth/sand

   ☐ Other material

6. **What is the main material of the exterior walls?** *(select one)*

   ☐ Cement   ☐ Other material

7. **What is the main material of the roof?** *(select one)*

   ☐ Cement   ☐ Other material

B.	ADDITIONAL QUESTIONS

8. **Does your household have an oven?** ☐ Yes ☐ No

9. **Does your household have a motor bike?** ☐ Yes ☐ No

10. **Does your household have a car?** ☐ Yes ☐ No

11. **Does your household have an AC?** ☐ Yes ☐ No

12. **Does your household have a sewing machine?** ☐ Yes ☐ No

13. **Does your household have a bi-cycle?** ☐ Yes ☐ No

14. **Does your household have a dining table?** ☐ Yes ☐ No

15. **Does your household have a sofa?** ☐ Yes ☐ No

16. **Does your household have a radio?** ☐ Yes ☐ No

17. **Household ownership?**

    ☐ Own   ☐ Rented

    ☐ Occupied

18. **Source of drinking water**

    ☐ Own tap   ☐ Communal hand pump
    ☐ Own tube well   ☐ Bottled water
    ☐ Own well   ☐ Water vendor
    ☐ Own hand pump   ☐ Stored in reservoir
    ☐ Communal tap   ☐ Pond/canal/river
    ☐ Communal tube well   ☐ Shared tap/tube well/well in HH
    ☐ Others

19. **Shared latrine**   ☐ Yes ☐ No

20. **Latrine type**

    ☐ Sanitary latrine with flush   ☐ Sanitary latrine without flush

    ☐ Non-sanitary/no water seal latrine   ☐ No latrine/use open space

C.	FORM COMPLETION

21. ID of person completing this form: |___|___|___|

    Date form completed:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

22. ID of person reviewing this form: |___|___|___|

    Date form reviewed:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

23. ID of person entering this form: |___|___|___|

    Date form entered:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

24. ID of person conducting data verification: |___|___|___|

    Date of data verification:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To collect household wealth information at The Gambia site.

Instructions: Please complete this form for all households that are included in the Healthcare Utilization Survey at The Gambia EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):   Participant ID: |___|___|___|___|___|___|___|

A.	WEALTH INDEX

DETERMINE IF THE RESPONDENT LIVES IN AN URBAN OR RURAL AREA

☐ Urban   ☐ Rural

1. **Does your household have a sofa?** ☐ Yes ☐ No

2. **Does your household have a wardrobe?** ☐ Yes ☐ No

3. **Does your household have a television?** ☐ Yes ☐ No

4. **Does your household have a refrigerator?** ☐ Yes ☐ No

5. **Does your household have a DVD / VCD player?** ☐ Yes ☐ No

6. **Does your household have a satellite dish?** ☐ Yes ☐ No

7. **Does any member of your household own: a bicycle?** ☐ Yes ☐ No

8. **What is the main source of drinking water for members of your household?** *(select one)*

   ☐ Public tap / Standpipe   ☐ Other water source

   ☐ Piped to yard

9. **What kind of toilet facility do members of your household usually use?**

   ☐ Flush to septic tank   ☐ Other toilet type

   ☐ Pit latrine w/o slab/ Open Pit

10. **What is the main material of the floor in your household?** *(select one)*

    ☐ Ceramic tile   ☐ Other floor material

11. **What is the main material of the exterior walls of your household?** *(select one)*

    ☐ Ceramic tile   ☐ Other wall material

12.	**How many of the following animals does your household own: Cattle?**	☐ None	☐ 1 or more	
13.	**… Milk cows or bulls?**	☐ None	☐ 1 or more	
14.	**… Horses, donkeys, or mules?**	☐ None	☐ 1 or more.	☐ 5 or more
15.	**… Goats?**	☐ None	☐ 1 or more	
16.	**… Sheep?**	☐ None	☐ 1 or more	

B.	**ADDITIONAL QUESTIONS**

17.	**Does your household have a functioning television?**	☐ Yes ☐ No
18.	**Does your household have a functioning radio?**	☐ Yes ☐ No
19.	**Does your household have a functioning refrigerator/fridge?**	☐ Yes ☐ No
20.	**Does any member of your household own: a functioning motorcycle/scooter?**	☐ Yes ☐ No
21.	**Does your household have functioning animal-drawn cart?**	☐ Yes ☐ No

22. **What is the main material of the roof in your household?** *(select one)*

☐ Thatch/Palm leaf   ☐ Metal/Tin/Cement

☐ Other roof material

23.	**Does your household own any chicken, Guinea fowl, ducks, turkeys or geese?**	☐ Yes ☐ No

C.	**FORM COMPLETION**

24.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
25.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
26.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
27.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*

Purpose: To collect household wealth information for participants enrolled at the Kenya site.

Instructions: Please complete this form for all participants enrolled at the Kenya EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):   Participant ID: |___|___|___|___|___|___|___|

A.	WEALTH INDEX

1. **Does your household have electricity?** ☐ Yes ☐ No *(skip Q14)*
2. **Does your household have a television?** ☐ Yes ☐ No *(skip Q15)*
3. **Does your household have a sofa?** ☐ Yes ☐ No
4. **Does your household have a cupboard?** ☐ Yes ☐ No
5. **Does your household have a DVD player?** ☐ Yes ☐ No *(skip Q16)*
6. **Does your household have a radio?** ☐ Yes ☐ No *(skip Q17)*
7. **Does your household have a table?** ☐ Yes ☐ No
8. **Does your household have a clock?** ☐ Yes ☐ No *(skip Q18)*
9. **What is the main material of the floor of your dwelling?** *(select one)*
   - ☐ Cement
   - ☐ Earth/sand
   - ☐ Other
10. **What is the main material of the external walls of your dwelling?** *(select one)*
    - ☐ Dung/mud/soil
    - ☐ Other
11. **What is the main material of the roof of your dwelling?** *(select one)*
    - ☐ Thatch/grass/makuti
    - ☐ Other
12. **What type of fuel does your household mainly use for cooking?** *(select one)*
    - ☐ Wood
    - ☐ LPG/Natural gas
    - ☐ Other
13. **What kind of toilet facility do members of your household usually use?** *(select one)*
    - ☐ No facility/bush/field
    - ☐ Other

B.	ADDITIONAL QUESTIONS

14. **Does your household have a functioning electricity?** ☐ Yes ☐ No
15. **Does your household have a functioning television?** ☐ Yes ☐ No
16. **Does your household have a functioning DVD player?** ☐ Yes ☐ No
17. **Does your household have a functioning radio?** ☐ Yes ☐ No
18. **Does your household have a functioning clock?** ☐ Yes ☐ No

C.	FORM COMPLETION

19. ID of person completing this form: |___|___|___|

Date form completed:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

20. ID of person reviewing this form: |___|___|___|

Date form reviewed:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

21. ID of person entering this form: |___|___|___|

Date form entered:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

22. ID of person conducting data verification:
|___|___|___|

Date of data verification:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

20. ID of person reviewing this form: |___|___|___|

Date form reviewed:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To collect household wealth information at the Malawi site.

Instructions: Please complete this form for all households that are included in the Healthcare Utilization Survey at the Malawi EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):   Participant ID: |___|___|___|___|___|___|___|

A.	WEALTH INDEX

1. **Does your household have electricity?** ☐ Yes ☐ No

2. **Does your household have a radio?** ☐ Yes ☐ No

3. **Does your household have a television?** ☐ Yes ☐ No

4. **Does your household have a bed with a mattress?** ☐ Yes ☐ No

5. **Does your household have a sofaset?** ☐ Yes ☐ No

6. **Does any member of this household own: a mobile phone?** ☐ Yes ☐ No

7. **Does any member of this household have a bank account?** ☐ Yes ☐ No

8. **What is the main material of the floor in your household?** *(select one)*

   ☐ Earth/sand   ☐ Cement

   ☐ Other floor material

9. **What is the main material of the roof in your household?** *(select one)*

   ☐ Thatch/palm leaf   ☐ Metal

   ☐ Other roof material

10. **What type of fuel does your household mainly use for cooking?** *(select one)*

    ☐ Wood   ☐ Other type of fuel

B.	FORM COMPLETION

11. ID of person completing this form: |___|___|___|
    Date form completed:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

12. ID of person reviewing this form: |___|___|___|
    Date form reviewed:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

13. ID of person entering this form: |___|___|___|
    Date form entered:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

14. ID of person conducting data verification: |___|___|___|
    Date of data verification:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To collect household wealth information at the Mali site.

Instructions: Please complete this form for all households that are included in the Healthcare Utilization Survey at the Mali EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):   Participant ID: |___|___|___|___|___|___|___|

A.	WEALTH INDEX

1. **In your house, do you have electricity?** ☐ Yes ☐ No

2. **In your house, do you have a television?** ☐ Yes ☐ No

3. **In your house, do you have a bed?** ☐ Yes ☐ No

4. **In your house, do you have a fan?** ☐ Yes ☐ No

5. **In your house, do you have a cupboard** ☐ Yes ☐ No

6. **In your house, do you have a CD/DVD player?** ☐ Yes ☐ No

7. **In your house, do you have a refrigerator?** ☐ Yes ☐ No

8. **In your house, do you have a chair?** ☐ Yes ☐ No

9. **In your house, do you have a motorcycle or scooter?** ☐ Yes ☐ No

10. **In your house, do you have soap, washing powder, or ash/sand/dirt for washing your hands?** ☐ Yes ☐ No

11. **Does any member of this household have a bank account?** ☐ Yes ☐ No ☐ Don't know

12. **Where is your principal source of drinking water located?** *(select one)*

    ☐ Outside of the plot   ☐ Within the plot

13. **What is the distance to the principal source of drinking water?** *(select one)*

    ☐ Less than 30 minutes round trip   ☐ More than 30 minutes round trip

14. **Main material of exterior walls of the house?** *(select one)*

    ☐ Brick   ☐ Other

15. **Main material of roof of house?** *(select one)*

    ☐ Cement   ☐ Mud with wood

    ☐ Other

16. **Main material of floor of house?** *(select one)*

    ☐ Earth/sand floor   ☐ Ceramic tile floor

    ☐ Other

17. **In your house, what is the main fuel used for cooking?** *(select one)*

    ☐ Charcoal   ☐ Wood   ☐ Other

18. **Does your household own any pigs?**   ☐ Yes ☐ No

19. **Does your household own any camels or dromedaries?**   ☐ Yes ☐ No

20. **Does your household own any Guinea fowl, ducks, turkeys or geese?**   ☐ Yes ☐ No

B.	FORM COMPLETION

21. ID of person completing this form: |___|___|___|
    Date form completed:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

22. ID of person reviewing this form: |___|___|___|
    Date form reviewed:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

23. ID of person entering this form: |___|___|___|
    Date form entered:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

24. ID of person conducting data verification: |___|___|___|
    Date of data verification:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To collect household wealth information at the Pakistan site.

Instructions: Please complete this form for all households that are included in the Healthcare Utilization Survey at the Pakistan EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):   Participant ID: |___|___|___|___|___|___|___|

A.	WEALTH INDEX

1.	**Does your household have a refrigerator?**	☐ Yes ☐ No
2.	**Does your household have a washing machine?**	☐ Yes ☐ No
3.	**Does your household have a sofa?**	☐ Yes ☐ No
4.	**Does your household have a chair?**	☐ Yes ☐ No
5.	**Does your household have an Almirah/cabinet?**	☐ Yes ☐ No
6.	**Does your household have a computer?**	☐ Yes ☐ No
7.	**Does your household have an internet connection?**	☐ Yes ☐ No
8.	**Does your household have a bed?**	☐ Yes ☐ No
9.	**Does any member of this household have a bank account?**	☐ Yes ☐ No

10. **What type of fuel does your household mainly use for cooking?** *(select one)*

☐ Wood   ☐ Other

11. **What is the main material of the roof in your household?** *(select one)*

☐ Cement/RCC   ☐ Other

12. **What is the main material of the walls in your household?** *(select one)*

☐ Cement   ☐ Other

B.	FORM COMPLETION

13.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
14.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
15.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
16.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*

Enterics for Global Health – *Shigella* Surveillance Study (EFGH)
Implementing Institution Name/Country Site
CRF 04b— Wealth Index Form (Peru)

Purpose: To collect household wealth information at the Peru site.

Instructions: Please complete this form for all households that are included in the Healthcare Utilization Survey at the Peru EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):   Participant ID: |___|___|___|___|___|___|___|

A.	WEALTH INDEX

1. **Does your household have a computer?**   ☐ Yes ☐ No

2. **Does your household have a bookshelf?**   ☐ Yes ☐ No

3. **Does your household have windows with curtains or blinds?**   ☐ Yes ☐ No

4. **Does your household have a sofa?**   ☐ Yes ☐ No

5. **What type of toilet does your household use?** *(select one)*

   ☐ Indoor connected to public sewer   ☐ Other

6. **What type of material is the roof made of in your household?** *(select one)*

   ☐ Reinforced concrete   ☐ Other

7. **What type of material are the walls made of in your household?** *(select one)*

   ☐ Brick or cement block   ☐ Other

B.	FORM COMPLETION

8. ID of person completing this form: |___|___|___|
   Date form completed:
   |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

9. ID of person reviewing this form: |___|___|___|
   Date form reviewed:
   |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

10. ID of person entering this form: |___|___|___|
    Date form entered:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

11. ID of person conducting data verification:
    |___|___|___|
    Date of data verification:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: *To ascertain information on HIV information for enrolled participants and biological mother (if present).*

Instructions: *Please complete this form for all enrolled participants at the Malawi, Mali, and Kenya sites ONLY. If the participant underwent HIV testing at the enrollment visit, this form should be initiated at the enrollment visit but completed once results are available (including viral load and/or CD4 results), assuming results are not available at the time of enrollment.* Plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	**PARTICIPANT INFORMATION**		
	1.	Participant ID	|___|___|___|___|___|___|___|
	2	Date of Enrollment:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	3.	Date of Form Completion:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* *Note: Date corresponds to when the entire form is completed (not intiated). If results are pending, this question will not be answered until results are available and this form is complete.*
	4.	EFGH country site:	
		☐ Kenya ☐ Malawi ☐ Mali	
B.	**HIV INFORMATION, BIOLOGICAL MOTHER**		
	5.	Is the accompanying caregiver the child's biological mother?	
		☐ Yes ☐ No *(skip to Q13)*	
	6.	What is the source of information for the mother's most recent HIV status?	
		☐ A rapid test done at the clinic during the enrollment visit (*complete remaining questions when results are available*) ☐ A PCR test done at the clinic during the enrollment visit (*complete remaining questions when results are available*) ☐ Previous laboratory report ☐ Previous hospital record ☐ Maternal health passport, MCH booklet, or other similar document ☐ Mother self-report ☐ Not applicable (results not known and testing not being performed)	
	7.	What is the enrolled child's biological mother's HIV status? *Reminder to offer HIV testing in accordance with guidelines and record result here.*	
		☐ Negative or non-reactive *(skip to Q19, end of form)* ☐ Positive or reactive ☐ Unknown *(skip to Q13)* ☐ Declined to state *(skip to Q13)*	

	8.	Is there a viral load result available for the mother?	
		☐ Yes ☐ No *(skip to Q9)*	
		8a.	*If yes*, number of copies at most recent test: _____ copies/mL. ☐ Undetectable
		8b.	*If yes*, date of most recent viral load test: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Unknown
	9.	Is there a CD4 count or percentage available for the mother?	
		☐ Yes ☐ No *(skip to Q10)*	
		9a.	*If yes*, CD4: |___|___|percent <u>OR</u> |___|___|___|___| count
		9b.	*If yes*, date of CD4 test: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Unknown
	10.	Is the mother currently receiving highly active anti-retroviral therapy (HAART)?	
		☐ Yes ☐ No *(skip to Q12)* ☐ Unknown *(skip to Q12)* ☐ Declined to state *(skip to Q12)*	
		11.	*If yes*, date initated: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Unknown
	12.	Is the mother currently receiving infection prophylaxis with cotrimoxazole (Septrin)?	
		☐ Yes ☐ No *(skip to Q13)*	
		12a.	*If yes*, date initated: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Unknown
C.	**HIV INFORMATION, CHILD** *(To be completed if the child if the biological mother is HIV-infected or HIV status unknown)*		
	13.	What is the source of information on the child's most recent HIV status?	
		☐ A rapid test done at the clinic during the enrollment visit (*complete remaining questions when results are available*) ☐ A PCR test done at the clinic during the enrollment visit (*complete remaining questions when results are available*) ☐ Previous laboratory report ☐ Previous hospital record ☐ Child health passport, MCH booklet, or other similar document ☐ Verbal report from the caregiver ☐ Not applicable (results not known and testing not being performed)	
	14.	What is the child's HIV status? *Reminder to offer HIV testing in accordance with guidelines and record result here.*	
		☐ Negative or non-reactive *(skip to Q17)* ☐ Positive or reactive ☐ Unknown *(skip to 17)*	

	15.	Is there a viral load result available for this child?	
		☐ Yes ☐ No *(skip to Q16)*	
	15a.	*If yes*, number of copies at most recent test: _____ copies/mL. ☐ Undetectable	
	15b.	*If yes*, date of most recent viral load test: |___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of enrollment *(Q2)* ☐ Unknown	
	16.	Is there a CD4 count or percentage available for this child?	
		☐ Yes ☐ No *(skip to Q17)*	
	16a.	*If yes*, most recent CD4 result: |___|___|percent <u>OR</u> |___|___|___|___| count	
	16b.	*If yes*, date of most recent CD4 test: |___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)* ☐ Unknown	
	17.	Is the child currently receiving any of the following:	
		☐ Highly active anti-retroviral therapy (HAART) or anti-retroviral therapy (ART) for treatment *(known HIV-infected children)* ☐ Anti-retroviral (ARV) prophylaxis for prevention of HIV ☐ None *(skip to Q18)* ☐ Unknown *(skip to Q18)*	
	17a.	*If yes*, date initated: |___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)* ☐ Unknown	
	18.	Is the child currently receiving infection prophylaxis with cotrimoxazole (Septrin)?	
		☐ Yes ☐ No *(skip to Section C)* ☐ Unknown *(skip to Section C)*	
	18a.	*If yes*, date initated: |___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)* ☐ Unknown	
D.	**FORM COMPLETION**		
19.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	
20.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	
21.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	
22.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	

Purpose: *To document daily clinical events among participants with overnight stays.*

Instructions: *To be completed at the beginning of each day a child is hospitalized during enrollment. This form does not need to be completed on the same day of enrollment, but is to be completed each day thereafter that the child is in the hospital. If the participant is hospitalized during the weekend/holidays (outside of working hours), the information can be abstracted from the participant's medical record when available.* Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	PARTICIPANT INFORMATION	
1.	Participant ID	|___|___|___|___|___|___|___|
2.	Date of Enrollment	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
3.	EFGH country site:	
	☐ Bangladesh	☐ Kenya
	☐ Malawi	☐ Mali
	☐ Pakistan	☐ Peru
	☐ The Gambia	

B.	CLINICAL EVALUATION INFORMATION
4.	Date seen: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
5.	Time seen: |___|___| : |___|___| *(hh : min, 24:00 hr)*
6.	ID of Study Staff performing clinical evaluation: |___|___|___| ☐ Non-EFGH study staff performed clinical evaluation (information being abstracted from medical record)

C.	CLINICAL SIGNS (PHYSICAL EXAM)		
7.	What is the source of the information?		
	☐ Physical exam being performed in real time ☐ Medical record		
8.	Temperature: |___|___|**.**|___|°C ☐ Missing		
9.	Heart Rate: |___|___|___| beats per minute. ☐ Missing		
10.	Respiratory Rate: |___|___|breaths per minute ☐ Missing		
11.	What is the child's general condition?		
	☐ Well/Alert	☐ Restless/Irritable	☐ Lethargic or Unconscious	☐ Missing
12.	Assess the child's eyes and determine if they are:		

		☐ Normal *(skip to Q13)*	☐ Abnormally sunken		☐ Missing *(skip to Q13)*
	11a.	*If child's eyes are determined to be abnormally sunken, please ask the caregiver:* **Is the appearance of your child's eyes abnormal?**			
		☐ Yes *(abnormal for child)* ☐ No			

13.	Describe the child's ability to drink or breastfeed:				
	☐ Normal/Not Thirsty	☐ Drinks eagerly/Thirsty	☐ Drinks poorly/Unable to drink	☐ Missing	
14.	Using a thumb and forefinger, gently pinch up the child's skin on the abdominal wall and assess the skin's return to normal:				
	☐ Immediately	☐ 1 to <2 seconds (slowly)	☐ ≥2 seconds (very slowly)	☐ Missing	
15.	Dehydration assessment *(to be completed based on data in Q10-Q14 above)*				
	☐ <u>Severe dehydration</u> At least two of the following signs *(check all that apply)*: ☐ Lethargic or Unconscious ☐ Sunken eyes ☐ Drinks poorly/unable to drink ☐ Skin pinch goes back ≥2 seconds (very slowly)	☐ <u>Some dehydration</u> At least two of the following signs *(check all that apply)*: ☐ Restless/irritable ☐ Sunken eyes ☐ Drinks eagerly/Thirsty ☐ Skin pinch goes back 1 to <2 seconds (slowly)	☐ <u>No dehydration</u>	☐ Could not be determined based on information available	

D. CLINICAL EVENTS IN THE LAST 24 HOURS *(MEDICAL RECORDS AND/OR CAREGIVER INTERVIEW)*

16.	What is the source of the information?	☐ Medical record ☐ Caregiver report
17.	Number of unusually loose or watery stools passed in last 24 hours	|___|___| *(if <10, put "0" before digit)* ☐ Missing
18.	Of the unusually loose or watery stools passed in the last 24 hours, how many had visible blood in them?	|___|___|*(if <10, put "0" before digit)* ☐ Missing
19.	Number of vomiting episodes in last 24 hours	|___|___|*(if <10, put "0" before digit)* ☐ Missing
	REMINDER: Record any therapies initiated/completed in the Medical Management Form [CRF 04a] on a daily basis	

E. FORM COMPLETION

20.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
21.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
22.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
23.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: *To be completed after a child is enrolled in EFGH but is referred to another facility prior to their completion of the Discharge Form during their enrollment visit.*

Instructions: *Please complete this form for any children who are enrolled in EFGH (assigned a Participant ID) and who are referred to another facility prior to completion of the "Discharge Form". Note: For children who are referred, two Medical Management Forms may be completed.* Plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	Referral Information	
	1.	Participant ID	|___|___|___|___|___|___|___|
	2.	Date of Referral	|__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
	3.	Time of Referral	|___|___| : |___|___| *(hh : min, 24 hr)* ☐ Unknown
	4.	Is the child being referred to an EFGH recruiting site or a non-EFGH recruiting site?	
		☐ Yes, to an EFGH recruiting site	☐ No, not an EFGH recruiting site
	5.	What facility is the child being referred to?	
		☐ Name of EFGH recruiting site x	☐ Name of EFGH recruiting site x
		☐ Name of EFGH recruiting site x	☐ Name of EFGH recruiting site x
		☐	☐
		☐	☐
		☐ Other *(specify)*:_____	
	6.	Reason for referral *(check all that apply)*	
		☐ Requires specific treatments or services that are not available	☐ Requested by caregiver
		☐ Requires overnight stay	☐ Cost
		☐ Other *(specify)*:_____	
	7.	Diagnosis(es) when referred *(check all that apply)*:	
		☐ Anemia	☐ HIV
		☐ Sickle cell	☐ Urinary Tract Infection
		☐ Malaria	☐ Tuberculosis
		☐ Suspected sepsis	☐ Fever of unknown origin
		☐ Dysentery	☐ Acutely unwell, unknown cause
		☐ Diarrhea	☐ Other Gastroenteritis
		☐ Upper respiratory tract infection	☐ Meningitis/ encephalitis
		☐ Pneumonia	☐ Poisoning/ herbal intoxication
		☐ Other lower respiratory tract infections *(other than pneumonia)*	☐ Malnutrition
		☐ Asthma	☐ COVID-19

	☐ Unknown		☐ Other *(specify)*:_____	

B.	**VISIT TO THE FACILITY, COSTING INFORMATION, AND TRANSPORTATION HOME FROM THE FACILITY** *(Text in* **bold** *should be read verbatim,* plain text *is for prompts for study staff, and italics are instructions for study staff)*

8.	Is the caregiver able and willing to continue with the remaining interview questions?	
	☐ Yes	
	☐ No *(skip to Section C)*	
9.	**Did you miss any income-generating activities because of this child's health facility visit?**	
	☐ Yes	
	☐ No *(skip to Q12)*	
10.	**Approximately how much time have you missed from income generating activities?**	
	|____|____| hours <u>OR</u> |____|____| days	
11.	**What type of income generating activities?**	
	☐ Salaried work	☐ Hourly work
	☐ Non-wage earnings (e.g. trading, personal business, etc.)	☐ Other *(specify)*:_____
12.	**Did anyone else visit the child during the child's stay at the health facility?**	
	☐Yes	
	☐No *(skip to Q13)*	
	12a. **Approximately how many <u>adults</u> visited your child during his/her stay?** _____	
13.	**How much did your child's stay at the health facility cost you in total? This includes medical costs, transport, and household costs such as food and hotels.**	
	Total amount paid and/or owed *(in local currency)*: _____	☐ None *(skip to Q15)*
14.	**How much of those costs were spent on the following fees and materials? This includes money you've already spent or still owe.** *(check "Yes" for all costs and report amount paid or owed numerically in local currency. Leave row blank if the caregiver did not pay for the fee/material or does not recall. If respondent does not know exact cost, please ask for an estimate. Check "Unknown" if respondent cannot estimate amount.*	

	Clinical registration fee	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
	Lab tests or diagnostics	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
	Medical supplies <u>purchased in the facility</u> (e.g., needles, gloves)	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
	Medical supplies purchased <u>outside of facility</u> (e.g., needles, gloves)	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
	Doctor/nurse/health worker fees	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
	Medications administered during visit (e.g. antibiotics, multivitamins)	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown

		Medications to bring home (e.g. antibiotics, multivitamins)	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Food for yourself or other family members	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Lodging for yourself or other family members	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Childcare	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Other *(specify):* _____	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
	15.	**If your child becomes ill after discharge, will it be easy or challenging for you to seek care again at a health facility?**		
		☐ Easy *(skip to Q17)*		☐ Challenging
	16.	**Why will it be challenging to seek care again at a health facility?** *(check all that apply)*		
		☐ Money	☐ Religion	☐ Transport
		☐ Work	☐ Distance	☐ Caring for other children
		☐ Family members	☐ Quality of care	☐ Other *(specify):* _____
	17.	**What method of transportation do you and your child plan to use to travel home from the facility today?** *(check all that apply)*		
		☐ Walk	☐ Motorbike	☐ Private or shared car
		☐ Personal vehicle	☐ Shared van/bus/taxi	☐ Other *(specify):* _____

C.	**SCHEDULED FOLLOW UP VISIT DATES** *(to be completed by study staff and remind caregiver of scheduled visits)*	
	18.	Next scheduled Week 4 visit date:	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	19.	Next scheduled Month 3 visit date:	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	Please copy the scheduled follow up visit information into the Participant Information Card and give to caregiver.	
D.	**FORM COMPLETION**	
	20.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	21.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	22.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	23.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: *To be completed when a study participant who sought care at the study clinic (inpatient or outpatient) is ready to leave the facility.*

Instructions: *Please complete the following information for the child who is being discharged from the facility (for outpatient this means when the child is ready to leave the facility). Do not complete this form if a child was referred (complete Referral CRF (CRF 04e instead). If a participant is discharged during non-working hours, please aim to complete whatever questions possible with the medical records/facility logs available; otherwise, indicate if information was missing.* Text in **bold** should be read to study participants, plain text are prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	STATUS AT DISCHARGE	
1.	Participant ID	|___|___|___|___|___|___|___|
2.	What was the outcome of the child when leaving the facility/health center?	

☐ Improved or healthy *(skip to Q3)*	☐ No better/same as when presenting *(skip to Q3)*
☐ Worse *(skip to Q3)*	☐ Died in facility
☐ Unknown *(skip to Q3)*	☐ Other *(specify)*:_____*(skip to Q3)*
☐ Missing *(only applicable for participants discharged during non-working hours)*	

	2a.	If the child died, what was the date of death?	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* *(skip to Section E and complete CRF10a - Mortality CRF and CRF 11 - Study Close Out CRF)* ☐ Unknown/Missing
3.	Date of Discharge		|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Unknown/Missing
4.	Time of Discharge		|___|___| : |___|___| *(hh : min, 24 hr)* ☐ Unknown/Missing
5.	Has the child been discharged by the medical staff, or is the caregiver taking the child home against medical advice?		

☐ Discharged by clinician *(skip to Section B)*	☐ Self-discharge
☐ Unknown/Missing	

6.	Is the caregiver present?
	☐ Yes
	☐ No *(skip to Section B)*

7.	*Ask caregiver:* **What are the important factors in your decision to take the child from the hospital before it was recommended by your child's provider?** *(Read options and check all answers that apply)*	
	☐ Child recovered	☐ Caregiver needed to return to work
	☐ Cost of medical care too expensive	☐ Caregiver needed to return to domestic responsibilities
	☐ Transportation availability	☐ Poor quality care at health facility
	☐ Child not getting better	☐ Other *(specify)*:_____

B.	**FINAL DIAGNOSIS(ES) AT DISCHARGE**	
8.	Final diagnosis(es) at discharge *(check all that apply)*:	
	☐ Anemia	☐ HIV
	☐ Sickle cell	☐ Urinary Tract Infection
	☐ Malaria	☐ Tuberculosis
	☐ Suspected sepsis	☐ Fever of unknown origin
	☐ Dysentery	☐ Acutely unwell, unknown cause
	☐ Diarrhea	☐ Gastroenteritis
	☐ Upper respiratory tract infection	☐ Meningitis/ encephalitis
	☐ Pneumonia	☐ Poisoning/ herbal intoxication
	☐ Other lower respiratory tract infections *(other than pneumonia)*	☐ Malnutrition
	☐ Asthma	☐ COVID-19
	☐ Unknown/Missing	☐ Other *(specify)*:_____
	If caregiver not present, as indicated in Q6, skip to Section D.	

C.	**VISIT TO THE FACILITY, COSTING INFORMATION, AND TRANSPORTATION HOME FROM THE FACILITY** *(Text in* **bold** *should be read verbatim,* plain text *is for prompts for study staff, and italics are instructions for study staff)* *Note: If participant was referred from another EFGH facility (i.e. EFGH Facility A), answer Q9-Q17 based on the costs incurred during the facility visit where the child was referred-to (i.e. EFGH Facility B)*	
9.	**Did you miss any income-generating activities because of this child's health facility visit?**	
	☐ Yes	
	☐ No *(skip to Q12)*	
10.	**Approximately how much time have you missed from income generating activities?**	
	|_____|_____| hours OR |_____|_____| days	
11.	**What type of income generating activities?**	
	☐ Salaried work	☐ Hourly work
	☐ Non-wage earnings (e.g. trading, personal business, etc.)	☐ Other *(specify)*:_____

	12.	**Did anyone else visit the child during the child's stay at the health facility?**		
		☐Yes		
		☐No *(skip to Q13)*		
		12a.	Approximately how many <u>adults</u> visited your child during his/her stay? _____	
	13.	**How much did your child's stay at the health facility cost you in total? This includes medical costs, transport, and household costs such as food and hotels.**		
		Total amount paid and/or owed *(in local currency)*: _____		☐ None *(skip to Q15)*
	14.	**How much of those costs were spent on the following fees and materials? This includes money you've already spent or still owe.** *(check "Yes" for all costs and report amount paid or owed numerically in local currency. Leave row blank if the caregiver did not pay for the fee/material or does not recall. If respondent does not know exact cost, please ask for an estimate. Check "Unknown" if respondent cannot estimate amount.)*		
		Clinical registration fee	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Lab tests or diagnostics	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Medical supplies <u>purchased in the facility</u> (e.g., needles, gloves)	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Medical supplies purchased <u>outside of facility</u> (e.g., needles, gloves)	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Doctor/nurse/health worker fees	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Medications administered during visit (e.g. antibiotics, micronutrients)	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Medications to bring home (e.g. antibiotics, micronutrients)	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Food for yourself or other family members	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Lodging for yourself or other family members	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Childcare	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Transportation	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
		Other *(specify):* _____	☐ Yes, needed to pay for this	Amount: _____ ☐ Unknown
	15.	**If your child becomes ill after discharge, will it be easy or challenging for you to seek care again at a health facility?**		
		☐ Easy *(skip to Q17)*		☐ Challenging
	16.	**Why will it be challenging to seek care again at a health facility?** *(check all that apply)*		
		☐ Money	☐ Religion	☐ Transport
		☐ Work	☐ Distance	☐ Caring for other children
		☐ Family members	☐ Quality of care	☐ Other: _____

	17.	What method of transportation do you and your child plan to use to travel home from the facility today? *(check all that apply)*		
		☐ Walk	☐ Motorbike	☐ Private or shared car
		☐ Personal vehicle	☐ Shared van/bus/taxi	☐ Other *(specify)*: _____
D.	**SCHEDULED FOLLOW UP VISIT DATES** *(to be completed by study staff and remind caregiver of scheduled visits)*			
	18.	Next scheduled Week 4 visit date:	|__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	
	19.	Next scheduled Month 3 visit date:	|__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	
		Please copy the scheduled follow up visit information into the Participant Information Card and give to caregiver to take home (if caregiver is present).		
E.	**FORM COMPLETION**			
	20.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	
	21.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	
	22.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	
	23.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	

Purpose: *The diarrhea diary will be given to the caregivers of children enrolled in the EFGH study on the day of enrollment. Day 0 is filled out by both caregiver and study staff together on the day of enrollment for practice. The first entry into the diary (Day 1) will be completed on by the caregiver after the entry for Day 0. The diary will capture information about the diarrhea episode in the previous 24 hours leading up to presentation to the facility, during their enrollment visit, and after the child leaves the facility to document the full severity of the diarrhea episode. The caregiver or her designee (such as a school aged child also living in the house) will complete the form daily, for a 14-day period beginning on the date of enrollment. The diary will be collected from the caregiver during the first follow-up visit, at the end of the 14 day period if the enrollment hospitalization lasts 14 days or greater, or picked up during a home visit. While study staff may counsel and remind caregivers on how to complete the diary, study staff should not fill in blank information as the diary is intended to reflect caregiver report only.*

 PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):   OR write in Participant ID:

|___|___|___|___|___|___|___|

Instructions: *Please explain the following to the caregiver and work with the caregiver to fill out the first column "Day 0 - Previous 24 hours prior to Enrollment Visit" to reflect the child's signs and symptoms in the previous 24 hours leading up to presentation. The caregiver ALONE (not study staff) will then complete Days 1-14.*

- Day: Period from the sunrise of a day to sunrise of the next day.
    - Please do not count any symptoms twice.
    - For Day 0, you should count the symptoms in previous 24 hours prior to the enrollment visit
    - For Day 1, you should count the symptoms since enrollment up until the sunrise of the next day. Please note that this may not be a full 24 hours period.
    - For Day 2 and onwards, please count the symptoms from sunrise of that day to sunrise of the next day.
    - Please note the dates using the format day (01-31)– month (01-12) – year (2022 or 2023) *(For example June 1, 2022 would be written as: 01-06-2022)*
- Temperature: Refers to temperature collected either orally (thermometer inserted into the mouth), under the armpit, or forehead. Please note temperature taken on the forehead is DIFFERENT than if a child feels "hot to the touch."
    - If your child is still in the hospital and their temperature is being taken, that temperature reading can be reported.
    - If the study gave you a thermometer, please use it in the armpit of the child.
    - If the temperature is taken multiple times during the day, the highest should be recorded in the diary.
    - If you notice that your child is hot to touch on the forehead, please indicate that next to the appropriate box. Please answer this question even if you are also taking a thermometer reading.
- If your child has any of the signs shown in the figure, mark "X" in the box right to the figure for that day.
    - If your child is "normal" meaning s/he doesn't have any of the signs, make an "X" in the row corresponding to the smiling face(☺)
    - For "Medications", the smiley face (☺) indicates the child did <u>not</u> receive any ORS, Zinc supplements, or any antibiotics (ie absence of any medications)
    - For some symptoms (number of loose or watery stools and vomiting), please pay attention to the number of loose stools and vomiting and mark the box next to the highest number of loose stools or vomiting on that day.
- If you forget for a few days, try to start again on the correct day.
- Keep this form in a safe place and bring it to the health facility at the follow-up visit.

		Day 0 - Previous 24 hours prior to enrollment Visit	DAY 1 |_|_|-|_|_| - |2|0|2|_| * *May not be full 24—hour period*	DAY 2 |_|_|-|_|_| - |2|0|2|_|	DAY 3 |_|_|-|_|_| - |2|0|2|_|	DAY 4 |_|_|-|_|_| - |2|0|2|_|	DAY 5 |_|_|-|_|_| - |2|0|2|_|	DAY 6 |_|_|-|_|_| - |2|0|2|_|	DAY 7 |_|_|-|_|_| - |2|0|2|_|	DAY 8 |_|_|-|_|_| - |2|0|2|_|	DAY 9 |_|_|-|_|_| - |2|0|2|_|	DAY 10 |_|_|-|_|_| - |2|0|2|_|	DAY 11 |_|_|-|_|_| - |2|0|2|_|	DAY 12 |_|_|-|_|_| - |2|0|2|_|	DAY 13 |_|_|-|_|_| - |2|0|2|_|	DAY 14 |_|_|-|_|_| - |2|0|2|_|
Number of Abnormally Loose or Watery Stool																
	No loose or watery stool 😊 🚫															
	+															
Vomiting																
	No vomitting 😊 🚫															
	+															

		Day 0 - Previous 24 hours prior to enrollment Visit	DAY 1 I_I-I_I-I2I0I2I_I - I2I0I2I_I * *May not be full 24—hour period	DAY 2 I_I-I_I-I2I0I2I_I	DAY 3 I_I-I_I-I2I0I2I_I	DAY 4 I_I-I_I-I2I0I2I_I	DAY 5 I_I-I_I-I2I0I2I_I	DAY 6 I_I-I_I-I2I0I2I_I	DAY 7 I_I-I_I-I2I0I2I_I	DAY 8 I_I-I_I-I2I0I2I_I	DAY 9 I_I-I_I-I2I0I2I_I	DAY 10 I_I-I_I-I2I0I2I_I	DAY 11 I_I-I_I-I2I0I2I_I	DAY 12 I_I-I_I-I2I0I2I_I	DAY 13 I_I-I_I-I2I0I2I_I	DAY 14 I_I-I_I-I2I0I2I_I

Maximum Daily Temperature

	Not hot to touch															
	No thermometer reading															
		I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C	I_I_I.I_I°C
	Method of temperature collection (circle one [mouth, armpit, or forehead])															

Blood in Stool

	No blood in stool															

		Day 0 – Previous 24 hours prior to enrollment Visit	DAY 1 |_|-|_|-|_| - |2|0|2|_| * *May not be full 24—hour period*	DAY 2 |_|-|_|-|_| - |2|0|2|_|	DAY 3 |_|-|_|-|_| - |2|0|2|_|	DAY 4 |_|-|_|-|_| - |2|0|2|_|	DAY 5 |_|-|_|-|_| - |2|0|2|_|	DAY 6 |_|-|_|-|_| - |2|0|2|_|	DAY 7 |_|-|_|-|_| - |2|0|2|_|	DAY 8 |_|-|_|-|_| - |2|0|2|_|	DAY 9 |_|-|_|-|_| - |2|0|2|_|	DAY 10 |_|-|_|-|_| - |2|0|2|_|	DAY 11 |_|-|_|-|_| - |2|0|2|_|	DAY 12 |_|-|_|-|_| - |2|0|2|_|	DAY 13 |_|-|_|-|_| - |2|0|2|_|	DAY 14 |_|-|_|-|_| - |2|0|2|_|
	Blood in stool																
Medications																	
	No oral rehydration solution (ORS)																
	Oral rehydration soluation (ORS)																
	No antibiotics																
	Antibiotics																
	No zinc																
	Zinc																

Purpose: *To capture information about the enrolled participant at follow-up visits. Ideally this form is completed by the primary caregiver. If multiple people are with the child, ask to speak with the primary caregiver.*

Instructions: *Please complete this form for all enrolled participants at the Week 4 follow up visit and Month 3 follow up visit.* Text in **bold** should be read to study participants, plain text are prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	PARTICIPANT INFORMATION		
	1.	Participant ID:	|___|___|___|___|___|___|___|
	2.	Date of enrollment visit: *(for reference)*	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	3.	Date of follow up visit:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	4.	Time form is started:	|___|___| : |___|___| *(hh : min, 24:00 hr)*
	5.	EFGH country site:	

		☐ Bangladesh	☐ Kenya	☐ Malawi	☐ Mali
		☐ Pakistan	☐ Peru	☐ The Gambia	

B.	FOLLOW-UP VISIT INFORMATION

	6.	Follow up visit:	☐ Week 4 ☐ Month 3

7. What is the relationship of the respondent to the enrolled child?

☐ Biological mother	☐ Biological father
☐ Grandmother	☐ Grandfather
☐ Aunt	☐ Uncle
☐ Older sister	☐ Older brother

☐ Other *(specify):* _____

8. Is the respondent the primary caregiver?

☐ Yes

☐ No

9. Where is this visit being conducted?

☐ Health facility

☐ Home

☐ Over the phone *(only if home or health facility not possible, skip to Section E)*

10. Is the child available for physical exam by the medical team? *(ask only for home/clinic visits)*

☐ Yes *(skip to Section C)*

☐ No

11. *If no,* why not?

☐ Child has moved *(skip to Section E)*	☐ Child has passed away *(stop form, skip to Section L: Form completion), complete CRF 10a - Mortality CRF and CRF 11 Study Close Out CRF)*

		☐ Caregiver refused to let study staff see child *(skip to Section E)*	☐ Other *(specify)*: _____	
C.	**ASSESSMENT OF THE CHILD'S GENERAL CONDITION**			
	Ask this Section only if the child is available for physical exam by the medical team			
	12.	What is the child's general condition?		
		☐ Well/Alert	☐ Restless/Irritable	☐ Lethargic or Unconscious
	13.	Does the child appear unwell?		
		☐ Yes *(please complete CRF 08 - Unwell Child Form)*		
		☐ No		
D.	**CHILD ANTHROPOMETRY** *(complete this section only if the child is available for a physical exam by study team)*			
	14.	a.	What is the child's mid upper arm circumference (MUAC)? (1st measurement)	|___|___|.|___| (cm)
		b.	Arm from which MUAC is being measured *(please ensure the same arm is used to collect 1st, 2nd, and 3rd measurements)*	☐ Right ☐ Left
		c.	What is the child's mid upper arm circumference (MUAC)? (2nd measurement)	|___|___|.|___| (cm)
	If measurement 2 differs from measurement 1, subtract the lower measurement from the higher measurement and, if the difference is 0.3cm or greater, obtain a third measurement.			
		d.	What is the child's mid upper arm circumference (MUAC)? (3rd measurement, if applicable)	|___|___|.|___| (cm) ☐ Not applicable *(3rd measurement not indicated)*
		Comments:		
	15.	How is the child's weight being recorded?		
		☐ Adult scale, child only *(child is ≥24 months AND able to stand on the scale alone; skip to Q19)*		
		☐ Adult scale, child and caregiver together *(child is <24 months OR unable to stand on the scale alone)*		
	16.	a.	What is the weight of child and caregiver (1st measurement)	|___|___|___|.|___| (kg)
		b.	What is the weight of the caregiver alone (1st measurement)	|___|___|___|.|___| (kg)
		c.	What is the calculated weight of the child *(Q16a minus Q16b)*	|___|___|.|___| (kg)
	17.	a.	What is the weight of child and caregiver (2nd measurement)	|___|___|___|.|___| (kg)
		b.	What is the weight of the caregiver alone (2nd measurement)	|___|___|___|.|___| (kg)
		c.	What is the calculated weight of the child *(Q17a minus Q17b)* (2nd measurement)	|___|___|.|___| (kg)
	If measurement 2 (Q17c) differs from measurement 1 (Q16c), subtract the lower measurement from the higher measurement and if the difference is 0.2kg or greater, obtain a third measurement			

18.	a.	What is the weight of child and caregiver (3rd measurement)	|___|___|___|.|___| (kg) ☐ Not applicable *(3rd measurement not indicated)*
	b.	What is the weight of the caregiver alone (3rd measurement)	|___|___|___|.|___| (kg) ☐ Not applicable *(3rd measurement not indicated)*
	c.	What is the calculated weight of the child *(Q18a minus Q18b)* (3rd measurement)	|___|___|.|___| (kg) ☐ Not applicable *(3rd measurement not indicated)*
	Comments:		
19.	a.	What is the child's weight? (1st measurement)	|___|___|.|___|(kg)
	b.	What is the child's weight? (2nd measurement)	|___|___|.|___|(kg)
		If measurement 2 differs from measurement 1, subtract the lower measurement from the higher measurement and if the difference is 0.2 kg or greater, obtain a third measurement	
	c.	What is the child's weight? (3rd measurement, if applicable)	|___|___|.|___|(kg) ☐ Not applicable *(3rd measurement not indicated)*
	Comments:		
20.		How is the child's length *(if <24 months)* / height *(if ≥24 months)* being recorded?	
		☐ Recumbent length *(if <24 months)*	
		☐ Standing height *(if ≥24 months)*	
21.	a.	What is the length/height of the child? (1st measurement)	|___|___|.|___| (cm)
	b.	What is the length/height of the child? (2nd measurement)	|___|___|.|___| (cm)
		If measurement 2 differs from measurement 1, subtract the lower measurement from the higher measurement and if the difference is 0.5cm or greater, obtain a third measurement	
	c.	What is the length/height of the child? (3rd measurement, if applicable)	|___|___|.|___| (cm) ☐ Not applicable *(3rd measurement not indicated)*
	Comments:		

E.	**DIARRHEA/DYSENTERY RECOVERY AFTER LEAVING THE HEALTH FACILITY**
	Q22 through Q29 below relate to the period after the child was enrolled in the EFGH study (upon returning home from the health facility visit) and relate to the child's recovery from the illness they were enrolled with.

	These questions are ONLY to be asked at the Week 4 follow-up visit (or the Month 3 follow-up visit if the Week 4 visit was missed). Caregiver should answer the below questions based on memory rather than the diarrhea diary card.		
	22.	Was the diarrhea diary card returned?	
		☐ Yes	
		☐ No	
		☐ Not applicable *(follow up visit taking place by phone)*	
	23.	**Did your child continue to have diarrhea** *(defined as 3 or more unusually loose or watery stools in a 24 hour period)* **after leaving the health facility?**	
		☐ Yes	
		☐ No *(skip to Section F)*	
		☐ Don't know *(skip to Section F))*	
	24.	**When did the diarrhea end?** *Refer to calendar to determine date if # of days since leaving the facility (enrollment) was known but not exact date. The end date is the last day of diarrhea before a diarrhea-free period of two days or more.*	|___|___| -|___|___| - ___|___|___|___| *(dd-mm-yyyy)* ☐ Ongoing
	25.	**On the worst day of diarrhea since leaving the health facility, how many loose stools did the child have in one day** (24 hours)?	|___|___| loose stools *(if <10, put "0" before digit)*
	26.	**Did the child have blood in his/her stool during the diarrhea that continued after leaving the health facility?**	
		☐ Yes	
		☐ No *(skip to Q28)*	
		☐ Don't know *(skip to Q28)*	
	27.	**How many days did the child have blood in stool?**	|___|___| days *(if <10, put "0" before digit)*
	28.	**Did the child vomit any time during the episode of diarrhea that continued after leaving the health facility?**	
		☐ Yes	
		☐ No *(skip to Q29)*	
		☐ Don't know *(skip to Q29)*	
	28a.	**How many days did the child vomit?**	|___|___| days *(if <10, put "0" before digit)*
	28b.	**Thinking about the day when the child had the most vomiting, how many times did s/he vomit in the day (24 hours)?**	|___|___| *(if <10, put "0" before digit)*
	29.	**Did the child have a fever** (or feel hot to the touch) **during the diarrhea that continued after leaving the health facility?**	
		☐ Yes	
		☐ No *(skip to Section F)*	
		☐ Don't know *(skip to Section F)*	
	29a.	*If yes,* **what was the highest temperature?**	|___|___|. |___|⁰C ☐ Temperature not collected
	29b.	**How many days did s/he have the fever?**	|___|___| days
F.	**MEDICATIONS AFTER LEAVING THE FACILITY**		
	This section (Q30-Q33) is intended to capture what medications were used for the child's recovery from the diarrhea illness that led them to be enrolled in the EFGH study. These questions are only to be asked at the Week 4 follow-up visit (or the		

		Month 3 follow-up visit if the Week 4 visit was missed). Prescribed treatments to be ascertained from the Medical Management CRF and ideally, pre-filled in the first column below prior to conducting the interview (to prime the interviewee on what medications were prescribed). Medications used and days used are to be answered by the caregiver. Note there may be some medications used that were not prescribed and those should be captured as well.			
30.	Name of the medications originally <u>prescribed</u> for the child for the discharge period (*filled from Medical Management Form*)	Name of medications actually <u>taken</u> by the child during the discharge period *(including those not prescribed. Completed based on Caregiver report)*	**Among these medications <u>taken</u> by your child, did your child receive some or all of the medications for free?**	**Among these medications <u>taken</u> by your child, did you purchase some or all of the medications (at the facility or elsewhere)?**	**Among these medications <u>taken</u> by the child, how many days did your child eat or drink the medication?**
	☐ ORS	☐ ORS	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Unknown
	☐ Zinc	☐ Zinc	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
	☐ RUSF	☐ RUSF	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
	☐ RUTF	☐ RUTF	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
	☐ RUSF (locally made)	☐ RUSF (locally made)	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
	☐ RUTF (locally made)	☐ RUTF (locally made)	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
			Antibiotics		
	☐ Amoxicillin	☐ Amoxicillin	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
	☐ Azithromycin	☐ Azithromycin	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
	☐ Ampicillin	☐ Ampicillin	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
	☐ Augmentin/Co-amoxiclav	☐ Augmentin/Co-amoxiclav	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
	☐ Ceftriaxone	☐ Ceftriaxone	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know

		☐ Ciprofloxacin (Cipro)	☐ Ciprofloxacin (Cipro)	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Cefixime	☐ Cefixime	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Cefuroxime	☐ Cefuroxime	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Clarithromycin	☐ Clarithromycin	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Clindamycin	☐ Clindamycin	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Chloramphenicol	☐ Chloramphenicol	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Cotrimoxazole/ Septrin	☐ Cotrimoxazole/ Septrin	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Doxycycline	☐ Doxycycline	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Erythromycin	☐ Erythromycin	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Gentamicin	☐ Gentamicin	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Penicillin	☐ Penicillin	☐ Yes ☐ Don't know	☐ Yes ☐ Don't know	|___|___|days ☐ Don't know
		☐ Pyrazinamide	☐ Pyrazinamide	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Streptomycin	☐ Streptomycin	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Tetracycline	☐ Tetracycline	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Other1 *(specify):* _____	☐ Other1 *(specify):* _____	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know

		☐ Other2 *(specify):* _____	☐ Other2 *(specify):* _____	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Other3 *(specify):* _____	☐ Other3 *(specify):* _____	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		Antiprotozoals				
		☐ Albendazole	☐ Albendazole	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Mebendazole	☐ Mebendazole	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Metronidazole (Flagyl)	☐ Metronidazole (Flagyl)	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Other *(specify):* _____	☐ Other *(specify):* _____	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		Antimalarial				
		☐ Artemether lumefantrine	☐ Artemether lumefantrine	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Paludrine	☐ Paludrine	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Artesunate	☐ Artesunate	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Quinine	☐ Quinine	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Proguanil	☐ Proguanil	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		Other treatments (excluding analgesics)				
		☐ Other1 *(specify):* _____	☐ Other1 *(specify):* _____	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know
		☐ Other2 *(specify):* _____	☐ Other2 *(specify):* _____	☐ Yes ☐ No ☐ Don't know	☐ Yes ☐ No ☐ Don't know	|___|___|days ☐ Don't know

				☐ Yes	☐ Yes	|___|___|days
		☐ Other3 *(specify):* _____	☐ Other3 *(specify):* _____	☐ No ☐ Don't know	☐ No ☐ Don't know	☐ Don't know
	31.	**Thinking back to your child's stay at the health facility, how much did the visit cost you in total? This includes medical costs, transport, and household costs such as food and hotels.**				
		Total amount paid and/or owed *(in local currency)*: _____			☐ None *(skip to Q33)*	
	32.	**How much of those costs were spent on the following fees and materials? This includes money you've already spent or still owe.** *(check "Yes" for all costs and report amount paid or owed numerically in local currency. Leave row blank if the caregiver did not pay for the fee/material or does not recall. If respondent does not know exact cost, please ask for an estimate in local currency. Enter 999 if respondent cannot estimate cost.*				
		Clinical registration fee		☐ Yes, needed to pay for this		Amount: _____
		Lab tests or diagnostics		☐ Yes, needed to pay for this		Amount: _____
		Medical supplies purchased in the facility (e.g., needles, gloves)		☐ Yes, needed to pay for this		Amount: _____
		Medical supplies purchased outside of facility (e.g., needles, gloves)		☐ Yes, needed to pay for this		Amount: _____
		Doctor/nurse/health worker fees		☐ Yes, needed to pay for this		Amount: _____
		Medications administered during visit (e.g. antibiotics, multivitamins)		☐ Yes, needed to pay for this		Amount: _____
		Medications to bring home (e.g. antibiotics, multivitamins)		☐ Yes, needed to pay for this		Amount: _____
		Food for yourself or other family members		☐ Yes, needed to pay for this		Amount: _____
		Lodging for yourself or other family members		☐ Yes, needed to pay for this		Amount: _____
		Childcare		☐ Yes, needed to pay for this		Amount: _____
		Transportation		☐ Yes, needed to pay for this		Amount: _____
		Other *(specify):* _____		☐ Yes, needed to pay for this		Amount: _____
	33.	**Since leaving the health facility, about how much time have you missed from income-generating activities to care for the child while they were ill with the diarrhea episode they were enrolled with?**				
		|____|____| hours OR |____|____| days OR ☐ None				
G.		**NEW ILLNESS SINCE LAST SCHEDULED VISIT *(EITHER ENROLLMENT OR WEEK 4)***				
		The questions Q34 through Q62 below relate to period since this child's last scheduled visit (either Enrollment or Week 4) and excludes the diarrheal illness for which the child was enrolled in the EFGH study . If an Unwell Child CRF was completed for the participant, please reference the information from that CRF to complete this section.				
		New diarrhea/dysentery epsiodes since last visit				
	34.	**Since this child's last scheduled visit** *(either Enrollment or Week 4)*, **did your child develop a new episode of diarrhea, that is at diarrhea episode that started after at least 2 diarrhea free days?** *Note: Diarrhea episode is defined as diarrhea (3 or more unusually loose or watery stools in a 24 hour period). Use memory aid to facilitate remembering days.*				
		☐ Yes ☐ No *(skip to Q51)*				

		☐ Don't know *(skip to Q51)*
35.		How many new episodes of diarrhea did your child have since their last scheduled visit. *Note: A new episode is defined by diarrhea beginning after at least 2 diarrhea-free calendar days.*
		_____ *(range 1-10)*
	If the child had more than 1 new episodes of diarrhea during the relevant follow-up period (between Enrollment and Week 4 or between Week 4 and Month 3) ask the following questions about the <u>first</u> of those episodes. If the Week 4 visit was missed then the relevant follow-up period is defined as between Enrollment and Month 3.	
36.	**When did the diarrhea start?** *Refer to calendar to determine date if # of days ago known*	|___|___| -|___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
37.	**When did the diarrhea end?** *Refer to calendar to determine date if # of days ago known*	|___|___| -|___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Ongoing
38.	**Did the child have blood in stool during his/her diarrheal illness?** *(Use the memory aid to show pictures of each of these symptoms)*	
	☐ Yes ☐ No ☐ Don't know	
39.	**Did the child vomit at any time during the episode of diarrhea?**	
	☐ Yes ☐ No ☐ Don't know	
40.	**At any point during the diarrheal episode, did the child have any fever?** *(Fever meaning the child was hot to touch)*	
	☐ Yes ☐ No ☐ Don't know	
41.	**Did you seek care for the child's diarrhea outside your home?**	
	☐ Yes *(skip to Q42)* ☐ No	
	41a.	*If No to Q41,* **why not**? *(check all that apply then skip to Q51)*
		☐ Child did not seem to need care ☐ Clinic too far from home ☐ Unable to find transport ☐ Could not take time off from work ☐ Flood or bad weather ☐ Political unrest	☐ Cost for travel too high ☐ Cost for treatment too high ☐ Other child at home could not be left alone ☐ Not happy with clinic services in area ☐ Other *(specify)* _____
42.	**When did you first seek care for the child's illness?** *Refer to visual calendar aid carried by staff member to determine date relative to the date the episode started (as recorded in Q36).*	|___|___| -|___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
43.	**If you sought care for the child for this diarrheal illness where did you go** *(check all that apply)?*	
	☐ Traditional healer	☐ Religious healer

		☐ Drug seller	☐ Pharmacist
		☐ Community health worker	☐ Health outpost
		☐ Health facility (outpatient care)	☐ Health facility (inpatient care)
		☐ Other *(specify):* _____	
		If sought care at a health facility (either outpatient or inpatient), continue to Q44. Otherwise, skip to Q51.	
44.	**What was the name of the hospital or health center that you visited?**		
		☐ EFGH recruiting facility, specify facility ID: |___| ___|	☐ Other *(specify):* _____ ☐ Don't remember
45.	**When did you first visit the hospital or health center?** *Refer to visual calendar aid carried by staff member to determine date relative to the date the episode started.*	|___|___| -|___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as Q42	
46.	**Did the clinical team advise the child be hospitalized for treatment of diarrheal illness?**		
		☐ Yes ☐ No *(skip to Q51)*	
47.	**Was the child admitted** (ie at least an overnight stay) **for treatment of diarrheal illness**? *(This question is intended to differentiate between a child recommended to be admitted and actually admitted to the hospital)*		
		☐ Yes ☐ No *(skip to Q51)*	
48.	Date of admission:		
		|___|___| -|___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date in Q45 ☐ Don't remember	
49.	**How many days was the child admitted for?**	|___| ___| days ☐ Don't remember	
50.	Was a Hospital Record Abstraction CRF (CRF 09) was completed for this hospitalization?		
		☐ Yes	
		☐ No *(complete a Hospital Record Abstraction CRF (CRF 09))*	
		☐ No, child was admitted to a non-EFGH facility *(see Q44)*	
		New other (non-diarrheal) illnesses since last scheduled study visit	
51.	**Since this child's last scheduled visit** *(either Enrollment or Week 4)*, **did your child become ill with any illness besides diarrhea?**		
		☐ Yes ☐ No *(skip to Section H)* ☐ Don't know *(skip to Section H)*	
52.	*If yes,* **what was the illness your child had?**		
		☐ Cough, respiratory distress	
		☐ Febrile illness	
		☐ Other *(specify):* _____	
53.	**Did you seek any medical advice or treatment for this illness?**		

		☐ Yes
		☐ No *(skip to Section H)*
		☐ Don't know *(skip to Section H)*
	54.	*If yes,* **from whom did you seek advice about care for your child or where did you seek other medical treatment** *(not including the current clinic visit) (check all that were consulted)*

		☐ Traditional healer	☐ Religious healer
		☐ Drug seller	☐ Pharmacist
		☐ Community health worker	☐ Health outpost
		☐ Health facility (outpatient care)	☐ Health facility (inpatient care)
		☐ Other *(specify):* _____	

If sought care at a health facility (inpatient or outpatient), continue to Q55. Otherwise, go to Section H Immunization History.

	55.	**What was the name of the hospital or health center that you visited?**	
		☐ EFGH recruiting facility, specify facility ID: |___| ___|	☐ Other *(specify):* _____ ☐ Don't remember
	56.	**When did you first visit the hospital or health center?** *Refer to visual calendar aid carried by staff member to determine date relative to the date the episode started.*	|___|___| -|___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Don't remember
	57.	**Did the clinical team advise the child be hospitalized?**	
		☐ Yes ☐ No *(skip to Q61)*	
	58.	**Was the child admitted** (i.e, at least an overnight stay) **for treatment of the illness?** *(This question is intended to differentiate between a child recommended to be admitted and actually admitted to the hospital)*	
		☐ Yes ☐ No *(skip to Q63)* ☐ Don't know *(skip to Q63)*	
	59.	Date of admission:	
		|___|___| -|___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date in Q56 ☐ Don't remember	
	60.	**How many days was the child admiitted for?**	|___| ___| days OR ☐ Don't remember
	61.	**What was the diagnosis/diagnoses that your child received at the health facility or hospital?** *(check all that apply)*	

		☐ Diarrhea	☐ Dysentery
		☐ Gastroenteritis	☐ HIV
		☐ Anemia	☐ Urinary Tract Infection
		☐ Sickle cell	☐ Tuberculosis
		☐ Malaria	☐ Fever of unknown origin/Febrile illness
		☐ Suspected sepsis	☐ Pneumonia
		☐ Upper respiratory tract infection	☐ Meningitis
		☐ Other lower respiratory tract infections	☐ Poisoning/ herbal intoxication

		☐ Acutely unwell, unknown cause	☐ Severe acute malnutrition/ severe wasting
		☐ Asthma	☐ Moderate acute malnutrition/ moderate wasting
		☐ Other 1 *(specify)*:_____	☐ Other 2 *(specify)*:_____
		☐ None	☐ Don't know

	62.	Was a Hospital Record Abstraction CRF (CRF 09) completed for this hospitalization?
		☐ Yes
		☐ No *(complete a Hospital Record Abstraction CRF (CRF 09))*
		☐ No, child was admitted to a non-EFGH facility *(see Q55)*

H.	**IMMUNIZATION HISTORY** *(complete at Week 4 FU visit ONLY if immunization record was not available at Enrollment Visit)*

	63.	Was the child's immunization record not available at Enrollment and is available for abstraction now?
		☐ Yes
		☐ No *(skip to Section I)*
		☐ Not applicable *(skip to Section I)*
	64.	Using the immunization record, indicate how many doses of the following vaccines the child has received?
		(enter 0 if none, 9 if unknown. If a vaccine was given as part of a composite vaccine but not alone (e.g. measles as part of MMR or MR vaccine, mark "0" to the component (e.g. measles) and "1" to the composite (MMR)

Rotavirus vaccine	|___|	Bacille Calmette-Guerin (BCG)	|___|
Polio vaccine (OPV or IPV)	|___|	Rubella vaccine	|___|
Pentavalent vaccine (DPT+HiB+HBV)	|___|	HiB vaccine (Hemophilus influenzae)	|___|
S. pneumococcus vaccine (PCV)	|___|	Hepatitis A vaccine	|___|
Measles vaccine	|___|	Hepatitis B vaccine	|___|
MR vaccine (measles+rubella)	|___|	Typhoid fever vaccine	|___|
MMR vaccine (measles+mumps+rubella)	|___|	Varicella vaccine	|___|
Yellow fever vaccine	|___|	Meningococcal A vaccine	|___|
DPT vaccine (Diphteria+pertussis+tetanus)	|___|	Malaria vaccine (RTS,S)	|___|

	65.	How many doses of Vitamin A has the child received?	|__| *(enter 9 if unknown)*

I.	**IMMUNIZATION WILLINGNESS – WEEK 4 ONLY** *(complete only at Week 4 FU visit)*

	66.	When offered a new vaccine for your child, do you typically accept?
		☐ Yes, always *(skip to Q68)*
		☐ Sometimes
		☐ Never
	67.	What deters you from accepting new vaccines for your child? *(select one)*
		☐ Vaccines are too expensive
		☐ Vaccines are not available
		☐ Do not think vaccines are safe
		☐ Do not know about vaccines
		☐ Other *(specify)*: _____
	68.	If a new vaccine becomes available to prevent watery diary and bloody diarrhea, would you agree to use it?
		☐ Yes *(skip to visit-specific staff checks)*
		☐ No

		68a.	If no, which of the following reasons would deter you? *(select one)*
			☐ Vaccines are too expensive
			☐ Vaccines are not available
			☐ Do not think vaccines are safe
			☐ Do not know about vaccines
			☐ Other *(specify):* _____

J.	**STUDY STAFF CHECKS – WEEK 4 ONLY**		
	69.	*Please verify the following procedures were completed as part of the follow-up visit:*	
	Completed	Not completed	
	☐	☐	Follow up CRF (CRF 07) completed
	☐	☐	Child length/height, weight, and MUAC were collected and recorded in Section D of Follow up CRF (CRF 07)
	☐	☐	Dried blood Spot (DBS) collected, labelled as appropriate, and stored = *Applicable only to sites participating in immune response sub-study and in whom the caregiver agreed to have blood sample taken. If not participating select "Not applicable to this visit")*
	☐	☐	Diarrhea diary returned
	☐	☐	Diarrhea duration diary is reviewed with the caregiver and any missing or illegible information is clarified
	☐	☐	Participant is reminded of next scheduled follow up visit
	☐	☐	Appropriate reimbursements issued

K.	**STUDY STAFF CHECKS – MONTH 3 ONLY**		
	70.	*Please verify the following procedures were completed as part of the follow-up visit:*	
	☐	☐	Follow up CRF (CRF 07) completed
	☐	☐	Child length/height, weight, and MUAC were collected and recorded in Section D of Follow up CRF (CRF 07)
	☐	☐	Appropriate reimbursements issued
	☐	☐	Study Close Out CRF (CRF 10) completed

L.	**FORM COMPLETION**	
71.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
71.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
72.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
73.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To be completed when a study participant was deemed to be unwell during *Shigella* culture positive light contact; returned for a scheduled follow up visit and was determined to be unwell based on EFGH clinical team assessment; or the study participant sought care at the study clinic at a time other than the scheduled follow-up visits. Form to only be completed if child is physically present based on information ascertained, in real-time, during presentation.

Instructions: Please complete this form for all enrolled participants who seek care at an EFGH recruiting facility outside of their scheduled follow-up visits, who are deemed unwell during their scheduled follow-up visit, or who have been asked to return to the facility for assessment after receiving a *Shigella* culture positive result. Please also complete an AE form if the illness is definitely, probably, or possibly related to study participation. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	PARTICIPANT INFORMATION	
	1.	Participant ID: |__|__|__|__|__|__|__|
	2.	Date the child presented to the facility: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
	3.	Time form is started: |__|__| : |__|__| *(hh : min, 24:00 hr)*
	4.	EFGH country site:

	☐ Bangladesh	☐ Kenya	☐ Malawi	☐ Mali
	☐ Pakistan	☐ Peru	☐ The Gambia	

	5.	What are the circumstances that lead to this unwell assessment?
		☐ Child was identified to be unwell during a scheduled study follow up visit
		☐ Child returned for care because he/she was experiencing symptoms or was ill
		☐ Child was deemed unwell during *Shigella* culture positive light contact
		☐ Other *(specify)*: _____
	6.	**I'm sorry to hear your child isn't feeling well. What are the primary health concerns of your child today?** (*check all that apply*)

		☐ Fever/hotness of body	☐ Convulsing
		☐ Night sweats	☐ Excessive crying
		☐ Cough	☐ Ear problem
		☐ *If yes,* Cough up blood?	☐ Eye problem
		☐ Difficulty breathing/ wheeze	☐ Not drinking and/or not eating
		☐ Diarrhea	☐ Malaise
		☐ *If yes,* Blood in stool?	☐ Restless/irritable
		☐ Vomiting	☐ Rash/itching
		☐ Trauma	☐ Swelling of the lips
			☐ Other *(specify)*:_____
	7.	When did this illness begin? |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*

		If multiple concerns reported in Q6, answer based on the date the first illness began. Refer to calendar to determine date if # of days since illness began is known but not exact date	

B.	**MEDICAL EXAMINATION**			
	8.	What is the child's general condition?		
		☐ Well/Alert	☐ Restless/Irritable	☐ Lethargic or Unconscious
	9.	Assess the child's eyes and determine if they are:		
		☐ Normal *(skip to Q10)*	☐ Abnormally sunken	☐ Not recorded *(skip to Q10)*
		9a.	*If child's eyes are determined to be abnormally sunken and medical exam is being conducted in person, please ask the caregiver* **Is the appearance of your child's eyes abnormal?**	
			☐ Yes *(abnormal for child)*	
			☐ No	
	10.	Describe the child's ability to drink or breastfeed:		
		☐ Normal/Not Thirsty	☐ Drinks eagerly/Thirsty	☐ Drinks poorly/ Unable to drink
	11.	Using a thumb and forefinger, gently pinch up the child's skin on the abdominal wall and assess the skin's return to normal:		
		☐ Immediately	☐ 1 to <2 seconds (slowly)	☐ ≥2 seconds(very slowly)
	Please assess the following physical signs:			
	12.	Temperature *(using Exergen Thermometer)*	|___|___|.|___|°C	
	13.	Heart rate	|___|___|___|beats per minute	
	14.	Respiratory rate	|___|___|breaths per minute	
	15.	Cough	☐ Yes ☐ No	
	16.	Difficulty breathing	☐ Yes ☐ No	
	17.	Chest in-drawing	☐ Yes ☐ No	
	18.	Stridor	☐ Yes ☐ No	
	19.	Stiff neck	☐ Yes ☐ No	
	20.	Generalized rash	☐ Yes ☐ No	
	21.	Runny nose	☐ Yes ☐ No	
	22.	Convulsions	☐ Yes ☐ No	
	23.	Lethargy or Unconscious	☐ Yes ☐ No	
	24.	Chest auscultation signs suggestive of pneumonia	☐ Yes ☐ No	
	25.	Central cyanosis	☐ Yes ☐ No	
	26.	Oxygen saturation <90% (pulse oximetry)	☐ Yes ☐ No ☐ Not available	
	27.	Severe respiratory distress	☐ Yes ☐ No	
	28.	Palmar pallor	☐ Yes ☐ No	
	29.	Ear pain	☐ Yes ☐ No	
	30.	Pus drainage from ear canal	☐ Yes ☐ No	
	31.	Tender swelling behind the ear	☐ Yes ☐ No	
	32.	Signs of abscess	☐ Yes ☐ No	
	33.	Signs of oedema	☐ Yes ☐ No	

	33a.	*If yes:*		
		☐ Oedema on both feet/ankles *(mild)*		
		☐ Oedema on both feet/ankles, lower legs, hands, or lower arms *(moderate)*		
		☐ Generalized oedema, including both feet, legs, hands, arms, and face *(severe)*		

	34.	Tick all diagnoses applicable *(as determined by facility standard of care, check all that apply)*	
		☐ Diarrhea (watery)	☐ Diarrhea (dysentery)
		☐ Anemia	☐ HIV
		☐ Sickle cell	☐ Urinary Tract Infection
		☐ Malaria	☐ Tuberculosis
		☐ Suspected sepsis	☐ Fever of unknown origin/Febrile illness
		☐ Upper respiratory tract infection	☐ Pneumonia
		☐ Other lower respiratory tract infections	☐ Meningitis
		☐ Acutely unwell, unknown cause	☐ Poisoning/ herbal intoxication
		☐ Asthma	☐ Severe acute malnutrition/ severe wasting
		☐ Moderate acute malnutrition/ moderate wasting	☐ Soft tissue/skin infection
		☐ Other 1 *(specify)*: _____	☐ Other 2 *(specify)*: _____
			☐ None

	35.	What was the outcome of the illness visit?	
		☐ Child was hospitalized (*Complete Hospital Abstraction Form [CRF 09]*)	☐ Child was seen as an outpatient and returned home
		☐ Other *(specify)*:_____	
		Skip to Section D (Form Completion) unless unwell visit was due to child returning after a Shigella culture positive result and caregiver reporting the child being unwell or not yet recovered.	

C.	**MANAGEMENT FOLLOWING LIGHT CONTACT AND *SHIGELLA* CULTURE POSITIVE RESULT** *(only applicable to those participants whose Unwell Visit is because the child is returning after a Shigella culture positive contact)*

	36.	Was <u>new</u> *Shigella* treatment prescribed at the unwell visit for *Shigella*?
		☐ Yes
		☐ No *(skip to Section D: Form Completion)*

	37.	Name *(check box if prescribed)*	Dose prescribed *(circle unit)*	Prescribed Duration	Prescription filled
		☐ Ciprofloxacin (Cipro)	_____ (ml/mg) ☐ Unknown	|___|___| days ☐ Unknown	☐ Yes ☐ No ☐ Unknown
		☐ Azithromycin	_____ (ml/mg) ☐ Unknown	|___|___| days ☐ Unknown	☐ Yes ☐ No ☐ Unknown
		☐ Cotrimoxazole (Septrin)	_____ (ml/mg) ☐ Unknown	|___|___| days ☐ Unknown	☐ Yes ☐ No ☐ Unknown
		☐ Ceftriaxone	_____ (ml/mg) ☐ Unknown	|___|___| days ☐ Unknown	☐ Yes ☐ No ☐ Unknown

			_____ (ml/mg) ☐ Unknown	|___|___| days ☐ Unknown	☐ Yes ☐ No ☐ Unknown
		☐ Cefixime			
		☐ Other 1 *(specify):* _____	_____ (ml/mg) ☐ Unknown	|___|___| days ☐ Unknown	☐ Yes ☐ No ☐ Unknown
		☐ Other 2 *(specify):* _____	_____ (ml/mg) ☐ Unknown	|___|___| days ☐ Unknown	☐ Yes ☐ No ☐ Unknown
	38.	Were there any other recommended changes in the child's clinical management?			
		☐ Yes			
		☐ No *(skip to Section D: Form Completion)*			
	39.	Please describe those changes in the child's clinical management *(check all that apply)*			
		☐ Change in recommended fluids			
		☐ Zinc prescribed			
		☐ Nutritional therapy			
		☐ Other *(specify):* _____			
D.	**FORM COMPLETION**				
	40.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*		
	41.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*		
	42.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*		
	43.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*		

Purpose: *To abstract important information from the child's medical record every time the child is hospitalized at an EFGH recruitment facility. If a child is only seen as an outpatient, do not complete this form.*

Instructions: *Please abstract the following information from the child's medical record as soon as staff learn of a hospitalization. Please use a separate form for every hospital admission other than a hospital admission that occurred as part of the child's enrollment visit. Please also complete an AE form if the illness is definitely, probably, or possibly related to study participation.*

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.		PARTICIPANT INFORMATION	
	1.	Participant ID	|___|___|___|___|___|___|___|
	2.	Date of Enrollment:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	3.	Date of Form Completion:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	4.	EFGH country site:	
		☐ Bangladesh ☐ Kenya ☐ Malawi ☐ Mali	
		☐ Pakistan ☐ Peru ☐ The Gambia	

B.		ADMISSION INFORMATION	
	5.	Was the child admitted to either an inpatient ward or short-stay ward?	
		☐ Inpatient ward	
		Complete the following for inpatient ward admissions only.	
		Date admitted to inpatient ward:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
		Time admitted to inpatient ward:	|___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Unknown
		☐ Short-stay ward *(e.g. emergency room)*	
		Complete the following for short-stay ward admissions only.	
		Date admitted to short-stay ward:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
		Time admitted to short-stay ward:	|___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Unknown
	6.	What was the EFGH health facility ID for the facility that the child was admitted to? *(refer to EFGH facility list)*	
		|___|	

C.		DISCHARGE INFORMATION	
	7.	What was the outcome of the admission?	
		☐ Child was discharged	Date: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Unknown Time: |___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Unknown
		☐ Child was referred	Date: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Unknown Time: |___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Unknown
		☐ Child died	Date: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Unknown

		☐ Child absconded	Time: |___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Unknown
			Date: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Unknown
			Time: |___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Unknown

	8.	Final Diagnosis(es) *(check all that apply)*	
		☐ Diarrhea	☐ Dysentery
		☐ Gastroenteritis	☐ Anemia
		☐ Sickle cell	☐ HIV
		☐ Malaria	☐ Urinary Tract Infection
		☐ Suspected sepsis	☐ Tuberculosis
		☐ Upper respiratory tract infection	☐ Fever of unknown origin/Febrile illness
		☐ Other lower respiratory tract infections	☐ Pneumonia
		☐ Acutely unwell, unknown cause	☐ Meningitis
		☐ Asthma	☐ Poisoning/ herbal intoxication
		☐ Moderate acute malnutrition/ moderate wasting	☐ Severe acute malnutrition/ severe wasting
		☐ None	☐ Soft tissue/skin infection
		☐ Other 1 *(specify)*:_____	☐ Other 2 *(specify)*:_____

D.	**FORM COMPLETION**	
9.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
10.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
11.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
12.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To be completed when the staff learn a participant has passed away.

Instructions: Please complete this form for all participants who pass away. Note this form does <u>not</u> require a full caregiver interview. Please also complete an AE CRF if the mortality is definitely, probably, or possibly related to study participation. Please ensure a Study Close Out CRF is completed as soon as the staff are made aware of the death. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

A.	PARTICIPANT INFORMATION			
	1.	Participant ID:	|___|___|___|___|___|___|___|	
	2.	Date of form completion:	|___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)*	
	3.	EFGH country site:		
		☐ Bangladesh	☐ Kenya	☐ Malawi	☐ Mali
		☐ Pakistan	☐ Peru	☐ The Gambia	

B.	INFORMATION ABOUT THE DEATH	
	4.	How did the study staff learn of the child's death?
		☐ Caregiver attended regularly scheduled study visit and informed study staff
		☐ Caregiver alerted study staff of the death outside of regularly scheduled contacts
		☐ Study staff learned about the death from community members outside of health facility
		☐ Health facility staff informed study staff of the death
		☐ Child died while under EFGH clinical team's care
		☐ Other *(specify):* _____
	5.	Where did the death occur?
		☐ Health facility
		☐ Home
		☐ On the way to the health facility
		☐ Other *(specify):* _____
	6.	Is a death certificate or death notification form available?
		☐ Yes
		☐ No *(skip to Q10)*
	6a.	*If yes,* is the caregiver willing to share it or do you have access to it?
		☐ Yes
		☐ No *(skip to Q10)*
	7.	Date of death listed on death certificate or death notification form:
		|___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)* ☐ Missing
	8.	*Please transcribe the cause(s) of death listed on death certificate or death notification form*
		Immediate (1a): _____ ☐ Missing
		Intermediate (1b): _____ ☐ Missing
		Underlying (1c): _____ ☐ Missing

9.	Please note other significant conditions contributing to the death, but not related to the disease or condition causing it (2) *(then skip to Q15)* _____ _____ _____ _____ ☐ Missing	
10.	*If death certificate was <u>not</u> available,* approximately when did the death occur *(based on caregiver report or community knowledge)?* |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Unknown	
11.	If the death occurred in a health facility AND <u>no</u> death certificate is available: Is the a member of the treating clinical team (doctor, nurse, clinical officer) willing to participate in a brief interview?	
	☐ Yes *(Complete Section C. Treating Clinician Interview)*	
	☐ No *(skip to Section D)*	

C.	**TREATING CLINICIAN INTERVIEW**	
	The following section is intended to capture the open interview with the physician/clinician who was managing the child prior to their passing. Please listen closely to the physician's description of the events and enter them into the section below and then identify whether or not key terms were mentioned by the clinician. Check all terms mentioned by the physician in Q13.	
12a.	Staff ID of person conducting clinician Interview: |___|___|___|	
12b.	*Please ask the physician:* **Can you please tell me in your own words about the events that led to the death?** *Record detailed notes of response in English, Spanish, or French; use additional paper as needed. If needed, probe for additional details on when respondent recognized symptoms, changed management plans, what diagnostic tests were performed etc.*	
	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	
13.	Select any of the following words that were mentioned in the physician's narrative *(check all that apply)*:	

	☐ Abdominal pain	☐ Abdominal swelling
	☐ Bleeding or hemorrhage	☐ Cancer
	☐ Cough	☐ COVID-19/COVID
	☐ Dehydration	☐ Dengue fever
	☐ Diarrhea	☐ Fever
	☐ Heart problems	☐ Jaundice (yellow skin or eyes)
	☐ HIV/AIDS	☐ Malaria
	☐ Pneumonia	☐ Poisoning
	☐ Rash	☐ Seizure

		☐ Shortness of breath/ difficulty breathing	☐ Trauma/accident/injury
		☐ Typhoid	☐ Sepsis
		☐ None of the above were mentioned	☐ Don't know
		☐ Other key words *(specify 1-2):* _____	
	14.	Cause of death based on physician description	
		Immediate (1a): _____ ☐ Not applicable	
		Intermediate (1b): _____ ☐ Not applicable	
		Underlying (1c): _____ ☐ Not applicable	

D.	**CAREGIVER INTERVIEW**	
	15.	Is the caregiver willing to participate in a brief interview?
		☐ Yes *(when appropriate, proceed with Interview and complete Mortality Interview CRF [CRF 10b] in addition to the remaining question on this form)*
		☐ No *(Complete Study Close Out CRF [CRF 11] in addition to Section E)*

E.	**FORM COMPLETION**		
	16.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	17.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	18.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	19.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: *To be completed when a study participant passes away at a time that is acceptable to the caregiver*	

Instructions: *Please complete this form for all enrolled participants who pass away at an appropriate time (based on site team's discretion) and who agree to be interviewed.* Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

A.	PARTICIPANT INFORMATION				
	1.	Participant ID:	|___|___|___|___|___|___|___|		
	2.	Date of form completion:	|___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)*		
	3.	Time form is started:	|___|___| : |___|___| *(hh : min, 24:00 hr)*		
	4.	EFGH country site:			
		☐ Bangladesh	☐ Kenya	☐ Malawi	☐ Mali
		☐ Pakistan	☐ Peru	☐ The Gambia	

B.	INFORMATION ABOUT THE DEATH	
	5.	Did the caregiver give consent to the verbal autopsy interview?
		☐ Yes
		☐ No *(stop interview process, skip to Section E, Form Complete)*
	6.	How is the interview being conducted?
		☐ In person at home
		☐ In person at an EFGH facility
		☐ By phone
	7.	What was the timing of the death in relation to <u>scheduled</u> study follow up visits?
		☐Between Enrollment and scheduled Week 4 follow up visits *(i.e., Week 4 follow up visit did <u>not</u> occur)*
		☐Between scheduled Week 4 follow up visit and scheduled Month 3 follow up visit *(i.e., Month 3 follow up visit did <u>not</u> occur) (Skip to Section D)*
C.	DIARRHEA/DYSENTERY RECOVERY AFTER LEAVING THE HEALTH FACILITY *(complete only if death occurred between Enrollment and scheduled Week 4 Follow Up visit)*	
	Q10 through Q16 relate to the period after the child was enrolled in the EFGH study (upon returning home from the health facility visit) and relate to the child's recovery from the illness they were enrolled with. If the caregiver has returned the Diarrhea Diary, that can be used in conjunction with the caregiver's recall to answer the questions.	
	Please state to the caregiver: **We are so sorry to hear about your loss. Would you be willing to answer a few questions relating to the illness that led to your child's death? The interview will take approximately 10-15 minutes. If there are any questions you would prefer not to answer, you do not have to do so, and may stop the interview at any time.** *Note to staff: If at any point in the interview the caregiver wishes to stop, please ensure Section E is completed.*	
	8.	**Are you** *[the caregiver]* **willing to proceed with the interview?**
		☐ Yes ☐ No *(skip to Section E)*
	9.	Is the diarrhea diary card available?
		☐ Yes ☐ No

10.	Did your child continue to have diarrhea *(defined as 3 or more unusually loose or watery stools in a 24 hour period)* after leaving the health facility?
	☐ Yes ☐ No *(skip to Section D)* ☐ Don't remember *(skip to Section D)* ☐ Missing *(skip to Section D)*
11.	When did the diarrhea end? *Refer to calendar to determine date if # of days since leaving the facility (enrollment) was known but not exact date. Also refer to the daily diary if returned.*
	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Unknown
12.	On the worst day of diarrhea since leaving the health facility, how many loose stools did the child have in one day *(24 hours)*?
	|___|___| loose stools
13.	Did the child have blood in his/her stool during the diarrhea that continued after leaving the health facility?
	☐ Yes ☐ No *(skip to Q15)* ☐ Don't remember *(skip to Q15)*
14.	How many days since leaving the health facility did the child have blood in stool?
	|___|___| days *(if <10, put "0" before digit)*
15.	Did the child vomit any time during the episode of diarrhea that continued after leaving the health facility?
	☐ Yes ☐ No *(skip to Q16)* ☐ Don't remember *(skip to Q16)*

	15a.	How many days did the child vomit?	|___|___| days *(if <10, put "0" before digit)*
	15b.	Thinking about the day when the child had the most vomiting, how many times did s/he vomit in the day?	|___|___| times in the day *(if <10, put "0" before digit)*

16.	Did the child have a fever *(or feel hot to the touch)* during the diarrhea that continued after leaving the health facility?
	☐ Yes ☐ No *(skip to Section D)* ☐ Don't remember *(skip to Section D)*

	16a.	*If yes,* what was the highest temperature? |___|___|.|___|°C ☐ Temperature not collected
	16b.	How many days did s/he have the fever? |___|___| days *(if <10, put "0" before digit)*

D.	INTERVIEW
	The following section is intended to capture the open interview with the caregiver about events and conditions surrounding the participant's death. Please listen closely to the caregiver's description of the events and enter them into the section below and then identify whether or not key terms were mentioned by the caregiver. Check all terms mentioned by the caregiver in Q18.
17a.	ID of person conducting Interview: |___|___|___|
17b.	*Please ask the caregiver:* **Can you please tell me in your own words about the events that led to the death?**

	Record detailed notes of response in English, Spanish, or French; use additional paper as needed. If needed, probe for additional details on when respondent recognized symptoms, care sought, barriers to care, issues with transport, abnormalities, etc.	
	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	

	18.	Select any of the following words that were mentioned in the caregiver's narrative *(check all that apply)*:	
		☐ Abdominal pain	☐ Abdominal swelling
		☐ Bleeding or hemorrhage	☐ Cancer
		☐ Cough	☐ COVID-19/COVID
		☐ Dehydration	☐ Dengue fever
		☐ Diarrhea	☐ Fever
		☐ Heart problems	☐ Jaundice (yellow skin or eyes)
		☐ HIV/AIDS	☐ Malaria
		☐ Pneumonia	☐ Poisoning
		☐ Rash	☐ Seizure
		☐ Sepsis	☐ Shortness of breath/ difficulty breathing
		☐ Trauma/accident/injury	☐ Typhoid
		☐ None of the above were mentioned	☐ Don't know
		☐ Other key words *(specify 1-2):* _____	
	19.	Cause of death based on interview (only applicable if interviewer is medically trained and has completed WHO ICD training).	
		Immediate (1a): _____	
		Intermediate (1b): _____	
		Underlying (1c): _____	
		☐ Not applicable	
	Thank you for taking the time to talk with me at this difficult time. We are very sorry to hear about the loss of your child. Your answers will help us to better understand why your child was sick. Please let me know if you have any questions or concerns and please feel free to get in touch with me with any further questions. *END OF INTERVIEW.*		

E.	**FORM COMPLETION**		
	20.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	21.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	22.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	23.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To be completed when an enrolled participant is ready to be closed out of the study.

Instructions: *Please complete this form for all enrolled participants at the time of study close out.* Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	PARTICIPANT INFORMATION			
	1.	Participant ID:	|__|__|__|__|__|__|__|	
	2.	Date of form completion:	|__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	
	3.	EFGH country site:		
		☐ Bangladesh	☐ Kenya	☐ Malawi	☐ Mali
		☐ Pakistan	☐ Peru	☐ The Gambia	

B.	STUDY CLOSE OUT
	4. Check all the scheduled follow up visits that have occurred *(check all that have occurred)*:
	☐ Week 4
	☐ Month 3
	5. What is the reason for study close out?
	☐ Participant completed Month 3 follow up visit
	☐ Voluntary withdrawal by caregiver *(specify reason)*:

	☐ Planning to move out of study area	☐ Unhappy with study staff/procedures
	☐ Influence from another family member	☐ Unwilling to disclose/preferred not to state
	☐ Other *(specify)*: _____	

B.	
	☐ Eligibility revoked
	☐ Participant missed Month 3 follow up visit AND untraceable within 1 month of scheduled Month 3 follow up visit
	If lost to follow up, date of last known vital status of participant: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	☐ Participant died *(please complete Mortality Form [CRF 10a])*
	☐ Other reason *(specify)*: _____

C.	FORM COMPLETION	
	6. ID of person completing this form: |__|__|__|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	7. ID of person reviewing this form: |__|__|__|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	8. ID of person entering this form: |__|__|__|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	9. ID of person conducting data verification: |__|__|__|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Enterics for Global Health – *Shigella* Surveillance Study (EFGH)
Implementing Institution Name/Country Site
CRF 12 - *Shigella* Light Contact Form

Purpose*:* To track light contact with enrolled participants with a positive Shigella culture result and capture information about their health status, whether or not they were contacted by the study staff and invited to return to the facility, and outcome of light contact.

Instructions*:* Complete this form for any participants with a positive *Shigella* culture result.

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	**VISIT INFORMATION**		
	1.	Participant ID	|___|___|___|___|___|___|___|
	2.	Enrollment Date:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	3.	Date of Form Completion:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	4.	EFGH country site:	
		☐ Bangladesh	☐ Kenya
		☐ Malawi	☐ Mali
		☐ Pakistan	☐ Peru
		☐ The Gambia	
B.	**PARTICIPANT CONTACT INFORMATION**		
	5.	Did you successfully make contact with the participant's caregiver?	
		☐ Yes	
		☐ No *(skip to Q6)*	
	5a.	*If yes,* what was the date of contact	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	5b.	*If yes,* what method of contact was used?	
		☐ In-person at home	
		☐ In-person in the facility	
		☐ By phone	
		☐ Other *(specify):*_____	
	5c.	*If yes,* At the time of light contact, how was the child doing?	
		☐ Child has improved since enrollment in the study *(skip to Q7)*	
		☐ Child is doing the same as when the child was enrolled in the study* *(skip to Q7)*	
		☐ Child is doing worse* *(skip to Q7)*	
		☐ Learned that child died *(skip to Section D: Form Completion, complete CRF 11 - Study Close Out CRF and CRF 10a – Mortality CRF. Proceed with Mortality Interview if appropriate.)*	
		*If the child is doing the same and/or worse, invite child and caregiver back to the health facility for further assessment. If they return to the facility, please complete CRF 08 - Unwell Child CRF.	
	6.	How many attempts were made to contact the caregiver?	
		|___| attempts	

C		OUTCOME OF LIGHT CONTACT
	7.	What was the outcome of the light contact?
		☐ No further action by study staff, caregiver reported child's condition had improved
		☐ Caregiver agreed to bring participant to EFGH facility for Unwell Child Visit *(Complete CRF 08)*
		☐ Caregiver refused to bring participant to EFGH facility for Unwell Child Visit
		☐ Staff were not able to successfully contact the caregiver

D.		FORM COMPLETION	
	8.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	9.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	10.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	11.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: *To capture information about fecal sample collection at the recruiting sites (separate Specimen Accession RCRF to be completed by central laboratory).*

Instructions: *Complete this form for all enrolled participants at Enrollment Visit.*

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):   *PLEASE PLACE SPECIMEN ID LABEL HERE (OPTIONAL):*

A.	VISIT INFORMATION		
	1.	Participant ID	|___|___|___|___|___|___|___|
	2.	Enrollment Date:	|___|___| - |___|___| -	2	0 |___|___| (dd-mm-yyyy)
	3.	EFGH country site:	
		☐ Bangladesh	☐ Kenya
		☐ Malawi	☐ Mali
		☐ Pakistan	☐ Peru
		☐ The Gambia	

B.	RECTAL SWAB COLLECTION INFORMATION		
	4.	How many rectal swabs were collected?	
		☐ 0 rectal swabs	
		☐ 1 rectal swab *(dry for TAC)*	
		☐ 2 rectal swabs *(dry for TAC, mBGS)*	
		☐ 3 rectal swabs *(dry for TAC, mBGS, Cary-Blair, skip to Q5)*	
	4a.	If <3 swabs were collected, why?	
		_____	
		Skip to Section C if 0 rectal swabs were collected	
	5.	Date of swab collection: |___|___| - |___|___| -	2	0 |___|___| (dd-mm-yyyy)	
		☐ Date of collection is same as date of enrollment *(Q2)*	
	6.	Time of swab collection: |___|___| : |___|___| *(hh : min, 24:00 hr)*	
	7.	Did any of the rectal swabs collected have visible blood?	
		☐ Yes	
		☐ No	
	8.	<u>Rectal swab 1 (Dry swab for freezing)</u> ☐ Check if rectal swab 1 is missing *(skip to Section C)*	
	8a.	Where was the swab collected from?	
		☐ Directly from the child's rectum	
		☐ Whole stool sample *(only acceptable if direct swab is unable to be collected)*	
	8b.	Specimen ID: _____ ☐ Not applicable	
	9.	<u>Rectal swab 2 (mBGS transport media)</u> ☐ Check if rectal swab 2 is missing *(skip to Section C)*	

		9a.	Where was the swab collected from?
			☐ Directly from the child's rectum
			☐ Whole stool sample (*only acceptable if direct swab is unable to be collected*)
		9b.	Time of placement in media: |___|___| : |___|___| *(hh : min, 24:00hr)*
		9c.	Specimen ID: _____ ☐ Not applicable
	10.	Rectal swab 3 (Cary-Blair transport media) ☐ Check if rectal swab 3 is missing *(skip to Section C)*	
		10a.	Where was the swab collected from?
			☐ Directly from the child's rectum
			☐ Whole stool sample (*only acceptable if direct swab is unable to be collected*)
		10b.	Time of placement in media: |___|___| : |___|___| *(hh : min, 24:00 hr)*
		10c.	Specimen ID: _____ ☐ Not applicable

C.	**WHOLE STOOL COLLECTION INFORMATION**	
	11.	Was whole stool collected prior to the child leaving the health facility?
		☐ Yes
		☐ No *(skip to Section D; For The Gambia, Peru, Malawi, Pakistan and Bangladesh sites – instruct caregivers about home whole stool collection)*
		11a.	Was there any blood visible in the whole stool?
			☐ Yes
			☐ No
		11b.	Date of whole stool collection: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Date of collection is same as date of enrollment *(Q2)*
		11c.	Time of whole stool collection: |___|___| : |___|___| *(hh : min, 24:00 hr)*
		11d.	Specimen ID: _____ ☐ Not applicable
			For Bangladesh and the Gambia sites complete Q11e; all other sites, skip to Section D
		11e.	Time of placement in Cary-Blair media: |___|___| : |___|___| *(hh : min, 24:00hr)*

D.	**SAMPLE TRANSPORT INFORMATION**	
	12.	Date specimens placed in cool box: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Date of placement in cool box is same as date of enrollment *(Q2)*
	13.	Time specimens placed in cool box: |___|___| : |___|___| *(hh : min, 24:00hr)*
	14.	Date of departure from clinical site: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Date of departure is same as date of enrollment *(Q2)*
	15.	Time of departure from clinical site to lab: |___|___| : |___|___| *(hh : min, 24:00 hr)*

E.	**FORM COMPLETION**	
16.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
17.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
18.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
19.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

**Purpose*:* To capture information about home whole stool sample collection within 24 hours of the enrollment visit at the recruiting sites (separate Specimen Accession CRF to be completed by central laboratory). Only applicable to Bangladesh, The Gambia, Pakistan, Malawi, and Peru sites.*

**Instructions*:* Complete this form for enrolled participants that have a stool sample collected within 24 hours of the enrollment visit (i.e. at a home visit).*

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

PLEASE PLACE SPECIMEN ID LABEL HERE (OPTIONAL):

A.		VISIT INFORMATION	
	1.	Participant ID	|___|___|___|___|___|___|___|
	2.	Enrollment Date:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	3.	EFGH country site:	
		☐ Bangladesh	☐ The Gambia	☐ Pakistan
		☐ Peru	☐ Malawi	

B.		WHOLE STOOL COLLECTION INFORMATION	
	4.	Was whole stool collected within 24 hours after discharge from the enrollment visit to the health facility?	
		☐ Yes *(skip to 4b)*	
		☐ No	
	4a.	If No, why not? *(select one then skip to Section D)*	
		☐ Child did not produce whole stool within 24 hours of leaving health facility (no home whole stool collection)	
		☐ Study resources not available for home visit to collect sample (e.g. after hours, no staff available)	
		☐ Study staff cannot contact the caregiver or no one was home during home visit	
		☐ Other *(specify):* _____	
	4b.	Was there any blood visible in the whole stool?	
		☐ Yes	
		☐ No	
	4c.	Date caregiver reported whole stool passing: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*	
	4d.	Time caregiver reported whole stool passing: |___|___| : |___|___| *(hh : min, 24:00 hr; approximate to the nearest hour if the caregiver does not know)*	
	4e.	Method of whole stool collection:	
		☐ Staff retrieved whole stool sample from child's home	
		☐ Caregiver brought whole stool sample to clinical site or recruitment facility	
	4f.	Date of whole stool collection *(either date returned by caregiver or date retrieved at home by staff):* |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*	
	4g.	Time of whole stool collection *(either time returned by caregiver or time retrieved at home by staff):* |___|___| : |___|___| *(hh : min, 24:00 hr)*	

	4h.	Specimen ID: _____ ☐ Not applicable
	5.	When was the whole stool sample placed in a cool box?
		☐ Whole stool sample was placed in cool box upon pickup at home
		☐ Whole stool sample was placed in cool box upon receipt at clinical site or recruitment facility
		☐ Whole stool sample was placed in cool box at central laboratory
		☐ Other *(specify):* _____

C.	**SAMPLE TRANSPORT INFORMATION**	
6.	Date of departure from clinical site to central laboratory: |___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)* ☐ Not applicable, whole stool sample transported directly from home to central laboratory	
7.	Time of departure from clinical site to lab: |___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Not applicable, whole stool sample transported directly from home to central laboratory	

D.	**FORM COMPLETION**	
8.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
9.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
10.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
11.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*

Enterics for Global Health – *Shigella* Surveillance Study (EFGH)
Implementing Institution Name (Country Site)
CRF 14 - Blood Sample Collection Form

Purpose*: To capture information about blood sample collection at the recruiting sites (separate Specimen Accession form to be completed by central laboratory).*

Instructions*: Complete this form for all enrolled participants at Enrollment Visit and Week 4 visit (if blood collection is part of site protocol)*

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

PLEASE PLACE SPECIMEN ID LABEL HERE (OPTIONAL):

A.	VISIT INFORMATION		
	1.	Participant ID	|___|___|___|___|___|___|___|
	2.	Specimen ID	Specimen ID: _____ ☐ Not applicable
	3.	Visit Date:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	4.	Visit	☐ Enrollment ☐ Week 4 Follow Up
	5.	EFGH country site:	
		☐ Bangladesh	☐ Kenya
		☐ Malawi	☐ Mali
		☐ Pakistan	☐ Peru
		☐ The Gambia	
B.	BLOOD COLLECTION & TRANSPORT INFORMATION		
	6.	Was a finger/heel prick of blood collected from the participant?	
		☐ Yes *(skip to Q7)*	
		☐ No	
		6a.	If no, why?
			☐ Caregiver refused *(skip to Q12)*
			☐ Other (specify): _____*(skip to Q12)*
	7.	How many dried blood spots were completely filled?	
		☐ 5 *(skip to Q8)*	
		☐ 4	
		☐ 3	
		☐ 2	

		☐ 1
8.	Date of blood collection: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	
	☐ Date of collection is same as visit date *(Q2)*	
9.	Time of blood collection: |__|__| : |__|__| *(hh : min, 24:00 hr)*	
10.	Date of departure from clinical site: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*	
	☐ Date of departure is same as visit date *(Q2)*	
11.	Time of departure from clinical site to lab: |__|__| : |__|__| *(hh : min, 24:00 hr)*	

C. FORM COMPLETION

12.	ID of person completing this form: |__|__|__|	Date form completed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
13.	ID of person reviewing this form: |__|__|__|	Date form reviewed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
14.	ID of person entering this form: |__|__|__|	Date form entered: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
15.	ID of person conducting data verification: |__|__|__|	Date of data verification: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*

Purpose: *To capture information about protocol violations that occurred from the start of study (for participants, the start of the study refers to the date participant ID (PID) was assigned) until the end of the study duration.*

Instructions: *Please complete this form for all protocol violations. If multiple PIDs are affected by the violation, please submit one form per PID. Please note that only protocol violations (not deviations) are reported here. As a reminder, a protocol violation is defined as a consistent variation in practice from study protocol/SOPs that may affect participant safety, participant willingness to participate in the study, and/or integrity of the research or study data. Protocol violation is a subset of protocol deviation. Please also complete a Note to File if the violation affected more than one participant at the same time. Please consult the Protocol Deviation/ Violation SOP for additional details.*

A.	PARTICIPANT AND SITE INFORMATION			
	1.	Screening ID:	|___|-|___|-|___|___|___|___|-|___|___|___| *(Country ID - Facility ID - Sequential Screening # - Staff ID)*	
	2.	Participant ID:	|___|___|___|___|___|___|___| ☐ Not Applicable	
	3.	Date of screening:	|___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)*	
	4.	Date violation occurred:	|___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)*	
	5.	Date study staff was made aware of violation	|___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)*	
	6.	EFGH country site:		
		☐ Bangladesh	☐ Kenya	☐ Malawi	☐ Mali
		☐ Pakistan	☐ Peru	☐ The Gambia	
B.	PROTOCOL VIOLATION REPORTING			
	7.	Is the site PI aware of the violation?		
		☐ Yes			
		☐ No			
	8.	Was this event reported to the site-specific IRB?		
		☐ Yes			
		☐ No *(skip to Q10)*			
	9.	*If yes*, date reported to local IRB:	|___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)*	
	10.	Was this event entered in the Protocol Deviation/ Violations Log?		
		☐ Yes			
		☐ No			
	11.	Was the participant informed of the Protocol Violation?		
		☐ Yes			
		☐ No			
		☐ Not applicable			
C.	DESCRIPTION OF PROTOCOL VIOLATION			
	12.	Nature of violation *(check all that apply)*		
		☐ Consent not obtained or documented		☐ Consent obtained using outdated consent form	

	☐ Failure to provide a copy of signed consent form to the participant caregiver	☐ Enrolment of subjects that do not meet the inclusion/exclusion criteria
	☐ Undertaking of a study procedure not approved by IRB	☐ Breach in confidentiality that may pose an immediate threat to the participant or caregiver
	☐ Loss of laptop or study equipment that contains identifiable information about participant	☐ Failure to report a severe adverse event (SAE) to ethical review committees.
	☐ Other *(please specify):* _____	

13.	Brief summary of event (Description of event, location it occurred if relevant):	
14.	What steps have been taken to address this event?	
15.	What steps have been taken to prevent further occurrences?	

D.	**FORM COMPLETION**	
16.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
17.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
18.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
19.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: *To capture information about all adverse events (AE) definitely, probably, and possibly related to study participation occurring during the study participation period.*			
Instructions: *Complete this form for all adverse events definitely, probably, and possibly related to study participation occurring during the study participation period. If an event was NOT related to study participation this form does not need to be completed or entered in REDCap. Consult the Adverse Event SOP for other details including AE guidance and reporting procedures.*			

A.	**PARTICIPANT AND SITE INFORMATION**		
	1.	Screening ID:	|___|-|___|-|___|___|___|___|-|___|___|___| *(Country ID - Facility ID - Sequential Screening # - Staff ID)*
	2.	Participant ID: *(if applicable)*	|___|___|___|___|___|___|___| ☐ Not applicable (not enrolled)
	3.	Date of enrollment visit: *(if applicable)*	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Not applicable (not enrolled)
	4.	Date of onset of AE	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	5.	Time of onset of AE	|___|___| : |___|___| *(hh : min, 24:00 hr)*
	6.	Date of resolution of AE	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Not resolved
	7.	Time of resolution of AE	|___|___| : |___|___| *(hh : min, 24:00 hr)* ☐ Not resolved

B.	**AE DESCRIPTION AND REPORTING**		
	8.	Please describe the adverse event	
		Description of the adverse event here	
	9.	AE Severity	
		☐ Mild (Grade 1)	☐ Moderate (Grade 2)	☐ Severe (Grade 3)
		☐ Life threatening (Grade 4)	☐ Fatal (Grade 5)	
	10.	Relationship of AE to study procedures	

		☐ Definitely related	
		☐ Probably related	
		☐ Possibly related	
	11.	Outcomes Attributed to the Event	
		☐ Resolved without sequelae	☐ Resolved with sequelae
		☐ Recovering/Resolving	☐ Not Recovered/Not Resolved
		☐ Resulted in death	☐ Unknown
	12.	Is this a Serious AE?	
		☐ Yes	
		☐ No	
	13.	Was this event reported to the site-specific IRB?	
		☐ Yes	
		☐ No *(skip to Q15)*	
	14.	If yes, date reported	|___|___| - |___|___| - | 2 | 0 |___|___| (dd-mm-yyyy)
	15.	If Serious AE *(Q12)*, was the SAE communicated to EFGH coordination team within 24 hours of event awareness?	
		☐ Yes	
		☐ No	
		☐ Not applicable, AE not serious	
	16.	Are there any additional notes about the AE?	
		Comments and notes here	

C.	**FORM COMPLETION**	
	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Enterics for Global Health: *Shigella* Surveillance Study (EFGH)

Population Enumeration & Healthcare Utilization Survey Case Report Form Appendix

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03	Revisit Household for Healthcare Utilization Survey
04	Cluster Completion
20	Population Enumeration & HUS Protocol Violation

Purpose: *Population Enumeration*

Instructions: *Complete this form for each household/domestic structure in identified cluster that appears inhabited after the person able to give consent (head of household/primary caregiver/adult household member) has been asked to provide verbal consent – OR – if after three attempts, the head of household/primary caregiver/adult household member (herein referred to as "adult household member") has not been home or available to ask for verbal consent. Text in* **bold** *should be read to study participants, plain text is for prompts for study staff, and italics are instructions for study staff.*

A.	VISIT INFORMATION

1.	Date:	|___|___| -|___|___| - |2 | 0 |___|___| *(dd-mm-yyyy)*
2.	EFGH country site:	

☐ Bangladesh	☐ Kenya
☐ Malawi	☐ Mali
☐ Pakistan	☐ Peru
☐ The Gambia	

3.	Cluster number:	|___|___|___|
	3a.	Sub-cluster number *(applicable to Kenya and The Gambia only)*	|___| *(1-4)*

4.	Household identifier *(assigned if head of household/primary caregiver/adult household member have been asked for verbal consent - OR - if after three attempts, head of household/primary caregiver/adult household member have not been home or asked to consent)*:	|___|___| -|___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*	|___|___|___| *(Fieldworker ID)*	|___|___| *(Sequential number)*

5.	Did the study team approach the household?
	☐ Yes, met the adult household member *(conduct verbal consent)* ☐ Yes, adult household member is contactable by phone *(conduct verbal consent)* ☐ Yes, but adult household member was not home after three attempts and is <u>not</u> contactable by phone *(end of form)* ☐ Yes, but no one was ever home at each of the three attempts OR it appears or has been confirmed that no one is living in the home during the ~ 2 week enumeration period *(end of form)*
6.	Did the adult household member give verbal consent?
	☐ Yes ☐ No *(skip to form completion)* ☐ NA, adult household member/primary caregiver not able to provide consent *(skip to form completion)*
7.	What is the name of the _____ *(insert site-specific administrative unit)* that this house is within?
	|___|___|___| ☐ Other, specify: _____
8.	**How many people** *(including yourself, adults and children)* **currently live in the household?**
	|___|___|___|
9.	**Does a child under 5 years of age (<60 months) currently live in the household?**
	☐ Yes ☐ No *(skip to form completion)*

B.	CHILD INFORMATION							
10.	**How many children under 5 years of age (<60 months) currently live in the household**?				_____	*If 0, stop here. Questions below will be asked per each child under 5 years of age. The data system will automatically populate the number of rows below based on this answer.*		
11.	Child num	**What is the relationship of the person answering these questions to (name)?**	Is this person the primary caregiver of the child?	Child sex	Child Initials	Date of birth/age	Age (auto generated in real time and confirmed with the caregiver)	**Did this child experience diarrhea in the last two weeks** (14 days) – **that is 3 or more unusually loose or watery stools during a 24 hour period in the last 14 days?** *(only ask if the child is <60 months – automated question)*
	1	☐ Biological mother ☐ Biological father ☐ Adopted mother ☐ Adopted father ☐ Grandmother ☐ Grandfather ☐ Aunt ☐ Uncle ☐ Older sister ☐ Older brother ☐ Other, specify: _____	☐ Yes ☐ No	☐ Female ☐ Male	☐☐☐	|___|___| -|___|___| -___|___|___|___| *(dd-mm-yyyy)* ☐ Day Missing ☐ Month Missing ☐ Year Missing ____ months *(self report)*	____ months	☐ Yes ☐ No *(form complete)* ☐ Don't Know *(form complete)*
	X	☐ Biological mother ☐ Biological father	☐ Yes ☐ No	☐ Female ☐ Male	☐☐☐	|___|___| -|___|___| -___|___|___|___|	____ months	☐ Yes ☐ No *(form complete)*

	☐ Adopted mother ☐ Adopted father ☐ Grandmother ☐ Grandfather ☐ Aunt ☐ Uncle ☐ Older sister ☐ Older brother ☐ Other, specify: _____			*(dd-mm-yyyy)* ☐ Day Missing ☐ Month Missing ☐ Year Missing _____ months *(self report)*		☐ Don't Know (*form complete*)

If one or more children are between 6 to <36 months of age and had diarrhea in the last 14 days, continue. If not, skip to form completion.

C.	**Comments**

12. If there is anything unique about this visit, please record a description in the comments section. If this was a household that previously refused consent and then changed their mind and requested to participate (provided consent), it is required to indicate that information here and to include the original household identifier.

Purpose: *Healthcare utilization survey*

Instructions: *Complete the following questions for each child in the household between 6-35 months of age after consent is received. The questions should be answered by a household member who spends the most time with the child and is best able to recall symptoms related to the **most recent diarrheal episode (likely the primary caregiver)**. Diarrhea is defined as 3 or more loose stools in a 24 hour period. A diarrheal episode is diarrhea that began after at least 2 days without diarrhea. Use the memory aid and ask the caregiver to answer the following questions thinking about the most recent episode of diarrhea.* Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

A.	**VISIT INFORMATION**			
	1.	Date:	|___|___| -|___|___| - |2	0 |___|___| *(dd-mm-yyyy)*	
	2.	EFGH country site:		
		☐ Bangladesh	☐ Kenya	
		☐ Malawi	☐ Mali	
		☐ Pakistan	☐ Peru	
		☐ The Gambia		
	3.	Cluster number:	|___|___|___|	
	3a.	Sub-cluster number *(applicable to Kenya and The Gambia only)*	|___| *(1-4)*	
	4.	Household identifier *(same identifier as that assigned for the household enumeration)*:	|___|___| -|___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*	|___|___|___| *(Fieldworker ID)* |___|___| *(Sequential number)*

B.	**DIARRHEA SIGNS AND SYMPTOMS (*ODK will auto-generate this section for each eligible child*)**	
	5.	Child Initials & Age : *ODK to autopopulate the list of children with initials and age who had diarrhea reported in section B of Form 01 – Population Enumeration CRF*	|___|___|___| Child Initials |___|___| Age (months)
	6.	Who is answering the HUS questions on behalf of this child?	☐ Primary Caregiver of the Child ☐ Other Household Member
	7.	What is the relationship of the respondent to the child?	
		☐ Biological mother ☐ Biological father ☐ Adopted mother	
		☐ Grandmother ☐ Grandfather ☐ Aunt	
		☐ Uncle ☐ Older sister ☐ Older brother	
		☐ Other, specify: _____	
	8.	Did the adult household member and/or primary caregiver give informed consent for participation in the healthcare utilization survey?	
		☐ Yes, verbal consent was obtained for the healthcare utilization survey	
		☐ Yes, written informed consent was obtained for the healthcare utilization survey	
		☐ No, declined consent *(end of form)*	
		☐ No, primary caregiver is not available. Will revisit household to complete healthcare utilization survey *(end of form. Complete HUS Revisit Form upon revisiting household)*	

9.	**When did the diarrhea start?** *Refer to calendar to determine date if # of days ago known but not exact date*	|___|___| -|___|___| - ___|___|___|___| *(dd-mm-yyyy)*
10.	**When did the diarrhea end?** *Refer to calendar to determine date if # of days ago known but not exact date*	|___|___| -|___|___| - ___|___|___|___| *(dd-mm-yyyy)* ☐ Ongoing
11.	Duration of diarrhea by date calculation (auto-generated)	_____(days) *(Add suggested range 1 to 14 in ODK)*
12.	**On the worst day of diarrhea during this episode, how many loose stools did the child have in one day** (24 hours)?	_____loose stools
13.	**Did the child have any of the following symptoms during his/her diarrheal illness**? *(Use the memory aid to show pictures of each of these symptoms)*	
	Blood in stool: Irritable/less play: Sunken eyes: Wrinkled skin: Drinks eagerly, thirsty: Unable to drink or drank poorly: Lethargic, unconscious, or hard to stay awake:	☐ Yes ☐ No ☐ Don't Know ☐ Yes ☐ No ☐ Don't Know ☐ Yes ☐ No ☐ Don't Know ☐ Yes ☐ No ☐ Don't Know ☐ Yes ☐ No ☐ Don't Know ☐ Yes ☐ No ☐ Don't Know ☐ Yes ☐ No ☐ Don't Know
14.	**Did the child vomit at any time during the episode of diarrhea?**	
	☐ Yes ☐ No *(skip to Q15)* ☐ Don't know *(skip to Q15)*	
	14a. **How many days did the child vomit?**	_____(days) *(Add suggested range 1 to 14 in ODK)*
	14b. **Thinking about the day when the child had the most vomiting, how many times did s/he vomit in the day?**	_____
15.	**At any any point during the diarrheal episode, did the child have any fever?** (Fever meaning the child was hot to touch)	
	☐ Yes ☐ No *(skip to Q16)* ☐ Don't know *(skip to Q16)*	
	15a. *If yes,* **what was the highest temperature?**	_____ ⁰C ☐ Temperature not collected
	15b. **How many days did s/he have the fever?**	_____days
16.	**Did you seek care for the child's diarrhea outside your home?**	
	☐ Yes *(skip to Q17)* ☐ No	
	16a. *If No to Q16,* **why not?** _____ _____	
	(If did not seek care for child's diarrhea outside the home, form complete.)	
17.	**If you sought treatment or care for the child for this illness where did you go?** *(check all that apply)*	

		Facility	Date first visited
		☐ EFGH Facility X	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
		☐ EFGH Facility X	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
		☐ Other health facility (outpatient care)	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
		☐ Other health facility (inpatient care)	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
		☐ Other *(specify, check all that apply)*	

		☐ Traditional healer ☐ Drug seller ☐ Community Health worker ☐ Other *(specify):_____*	☐ Religious healer ☐ Pharmacist ☐ Health outpost

18.	What day of the child's diarrhea did the caregiver visit a hospital or health center? *(auto-generated in ODK;If today, "00" will be displayed)*	_____	
19.	**Did the clinical team at any care provider advise the child be hospitalized during this illness?**		
	☐ Yes ☐ No *(skip to Q21)*		
20.	**Was the child admitted to the hospital** (i.e. at least an overnight stay) **during this illness**?		
	☐ Yes ☐ No		
21.	**Did the child receive any of the following to treat the diarrhea**? *(check all that apply)*		

	Intravenous fluids	☐ Yes	☐ No	☐ Don't know
	A drinkable fluid made from a special packet called ORALITE or ORS	☐ Yes	☐ No	☐ Don't know
	Homemade fluid (such as thin watery porridge made from maize, rice, wheat, soup, sugar, salt water solution or yogurt-based drink)	☐ Yes	☐ No	☐ Don't know
	Antibiotic	☐ Yes *(specify)*	☐ No	☐ Don't know

If antibiotic was received, specify type received (check all that apply):

☐ Amoxicillin	☐ Azithromycin	☐ Artesunate	☐ Ampicillin
☐ Augmentin/ Co-amoxiclav	☐ Ceftriaxone	☐ Ciprofloxacin (Cipro)	☐ Cefuroxime
☐ Clarithromycin	☐ Clindamycin	☐ Chloramphenicol	☐ Cotrimoxazole (Septrin)
☐ Doxycycline	☐ Erythromycin	☐ Gentamicin	☐ Penicillin
☐ Pyrazinamide	☐ Streptomycin	☐ Tetracycline	☐ Unknown

☐ Other *(specify):_____*

Antisecretory or antiemetics	☐ Yes	☐ No	☐ Don't know
Zinc	☐ Yes	☐ No	☐ Don't know
Traditional medicine	☐ Yes	☐ No	☐ Don't know
None of the above	☐ Yes	☐ No	☐ Don't know

Purpose: To collect household wealth information at the Bangladesh site.

Instructions: Please complete this form for all households that are included in the Healthcare Utilization Survey at the Bangladesh EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

A.	WEALTH INDEX

1. **Does your household have a television?** ☐ Yes ☐ No

2. **Does your household have a refrigerator?** ☐ Yes ☐ No

3. **Does your household have an almirah/wardrobe?** ☐ Yes ☐ No

4. **Does your household have an electric fan?** ☐ Yes ☐ No

5. **What is the main material of the floor?** *(select one)*

   ☐ Cement   ☐ Earth/sand

   ☐ Other material

6. **What is the main material of the exterior walls?** *(select one)*

   ☐ Cement   ☐ Other material

7. **What is the main material of the roof?** *(select one)*

   ☐ Cement   ☐ Other material

B.	ADDITIONAL QUESTIONS

8. **Does your household have an oven?** ☐ Yes ☐ No

9. **Does your household have a motor bike?** ☐ Yes ☐ No

10. **Does your household have a car?** ☐ Yes ☐ No

11. **Does your household have an AC?** ☐ Yes ☐ No

12. **Does your household have a sewing machine?** ☐ Yes ☐ No

13. **Does your household have a bi-cycle?** ☐ Yes ☐ No

14. **Does your household have a dining table?** ☐ Yes ☐ No

15. **Does your household have a sofa?** ☐ Yes ☐ No

16. **Does your household have a radio?** ☐ Yes ☐ No

17. **Household ownership?**

    ☐ Own   ☐ Rented

    ☐ Occupied

18. **Source of drinking water**

    ☐ Own tap   ☐ Communal hand pump
    ☐ Own tube well   ☐ Bottled water

☐ Own well   ☐ Water vendor
☐ Own hand pump   ☐ Stored in reservoir
☐ Communal tap   ☐ Pond/canal/river
☐ Communal tube well   ☐ Shared tap/tube well/well in HH
☐ Others

19. **Shared latrine**   ☐ Yes   ☐ No

20. **Latrine type**

☐ Sanitary latrine with flush   ☐ Sanitary latrine without flush

☐ Non-sanitary/no water seal latrine   ☐ No latrine/use open space

C.	FORM COMPLETION

21. ID of person completing this form: |___|___|___|

Date form completed:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

22. ID of person reviewing this form: |___|___|___|

Date form reviewed:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

23. ID of person entering this form: |___|___|___|

Date form entered:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

24. ID of person conducting data verification: |___|___|___|

Date of data verification:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To collect household wealth information at The Gambia site.

Instructions: Please complete this form for all households that are included in the Healthcare Utilization Survey at The Gambia EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

A.	WEALTH INDEX

DETERMINE IF THE RESPONDENT LIVES IN AN URBAN OR RURAL AREA

☐ Urban   ☐ Rural

1. **Does your household have a sofa?**   ☐ Yes ☐ No

2. **Does your household have a wardrobe?**   ☐ Yes ☐ No

3. **Does your household have a television?**   ☐ Yes ☐ No

4. **Does your household have a refrigerator?**   ☐ Yes ☐ No

5. **Does your household have a DVD / VCD player?**   ☐ Yes ☐ No

6. **Does your household have a satellite dish?**   ☐ Yes ☐ No

7. **Does any member of your household own: a bicycle?**   ☐ Yes ☐ No

8. **What is the main source of drinking water for members of your household?** *(select one)*

   ☐ Public tap / Standpipe   ☐ Other water source

   ☐ Piped to yard

9. **What kind of toilet facility do members of your household usually use?**

   ☐ Flush to septic tank   ☐ Other toilet type

   ☐ Pit latrine w/o slab/ Open Pit

10. **What is the main material of the floor in your household?** *(select one)*

    ☐ Ceramic tile   ☐ Other floor material

11. **What is the main material of the exterior walls of your household?** *(select one)*

    ☐ Ceramic tile   ☐ Other wall material

12. **How many of the following animals does your household own: Cattle?**   ☐ None   ☐ 1 or more

13. **… Milk cows or bulls?**   ☐ None   ☐ 1 or more

14. **… Horses, donkeys, or mules?**   ☐ None   ☐ 1 or more.   ☐ 5 or more

15. **… Goats?**   ☐ None   ☐ 1 or more

16. **… Sheep?** ☐ None   ☐ 1 or more

B.	ADDITIONAL QUESTIONS

17. **Does your household have a functioning television?** ☐ Yes ☐ No

18. **Does your household have a functioning radio?** ☐ Yes ☐ No

19. **Does your household have a functioning refrigerator/fridge?** ☐ Yes ☐ No

20. **Does any member of your household own: a functioning motorcycle/scooter?** ☐ Yes ☐ No

21. **Does your household have functioning animal-drawn cart?** ☐ Yes ☐ No

22. **What is the main material of the roof in your household?** *(select one)*

☐ Thatch/Palm leaf   ☐ Metal/Tin/Cement

☐ Other roof material

23. **Does your household own any chicken, Guinea fowl, ducks, turkeys or geese?** ☐ Yes ☐ No

C.	FORM COMPLETION

24. ID of person completing this form: |___|___|___|
Date form completed:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

25. ID of person reviewing this form: |___|___|___|
Date form reviewed:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

26. ID of person entering this form: |___|___|___|
Date form entered:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

27. ID of person conducting data verification: |___|___|___|
Date of data verification:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To collect household wealth information for participants enrolled at the Kenya site.

Instructions: Please complete this form for all participants enrolled at the Kenya EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

A.	WEALTH INDEX

1. **Does your household have electricity?** ☐ Yes ☐ No *(skip Q14)*

2. **Does your household have a television?** ☐ Yes ☐ No *(skip Q15)*

3. **Does your household have a sofa?** ☐ Yes ☐ No

4. **Does your household have a cupboard?** ☐ Yes ☐ No

5. **Does your household have a DVD player?** ☐ Yes ☐ No *(skip Q16)*

6. **Does your household have a radio?** ☐ Yes ☐ No *(skip Q17)*

7. **Does your household have a table?** ☐ Yes ☐ No

8. **Does your household have a clock?** ☐ Yes ☐ No *(skip Q18)*

9. **What is the main material of the floor of your dwelling?** *(select one)*
   ☐ Cement   ☐ Other
   ☐ Earth/sand

10. **What is the main material of the external walls of your dwelling?** *(select one)*
    ☐ Dung/mud/soil   ☐ Other

11. **What is the main material of the roof of your dwelling?** *(select one)*
    ☐ Thatch/grass/makuti   ☐ Other

12. **What type of fuel does your household mainly use for cooking?** *(select one)*
    ☐ Wood   ☐ Other
    ☐ LPG/Natural gas

13. **What kind of toilet facility do members of your household usually use?** *(select one)*
    ☐ No facility/bush/field   ☐ Other

B.	ADDITIONAL QUESTIONS

14. **Does your household have a functioning electricity?** ☐ Yes ☐ No

15. **Does your household have a functioning television?** ☐ Yes ☐ No

16. **Does your household have a functioning DVD player?** ☐ Yes ☐ No

17. **Does your household have a functioning radio?** ☐ Yes ☐ No

18. **Does your household have a functioning clock?** ☐ Yes ☐ No

C.	FORM COMPLETION

19. ID of person completing this form: |___|___|___|
    Date form completed:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

20. ID of person reviewing this form: |___|___|___|
    Date form reviewed:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

21. ID of person entering this form: |___|___|___|
    Date form entered:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

22. ID of person conducting data verification:
    |___|___|___|
    Date of data verification:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To collect household wealth information at the Malawi site.

Instructions: Please complete this form for all households that are included in the Healthcare Utilization Survey at the Malawi EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

A.	WEALTH INDEX

1. **Does your household have electricity?** ☐ Yes ☐ No

2. **Does your household have a radio?** ☐ Yes ☐ No

3. **Does your household have a television?** ☐ Yes ☐ No

4. **Does your household have a bed with a mattress?** ☐ Yes ☐ No

5. **Does your household have a sofaset?** ☐ Yes ☐ No

6. **Does any member of this household own: a mobile phone?** ☐ Yes ☐ No

7. **Does any member of this household have a bank account?** ☐ Yes ☐ No

8. **What is the main material of the floor in your household?** *(select one)*

   ☐ Earth/sand   ☐ Cement

   ☐ Other floor material

9. **What is the main material of the roof in your household?** *(select one)*

   ☐ Thatch/palm leaf   ☐ Metal

   ☐ Other roof material

10. **What type of fuel does your household mainly use for cooking?** *(select one)*

   ☐ Wood   ☐ Other type of fuel

B.	FORM COMPLETION

11. ID of person completing this form: |___|___|___|
    Date form completed:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

12. ID of person reviewing this form: |___|___|___|
    Date form reviewed:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

13. ID of person entering this form: |___|___|___|
    Date form entered:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

14. ID of person conducting data verification:
    |___|___|___|
    Date of data verification:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To collect household wealth information at the Mali site.

Instructions: Please complete this form for all households that are included in the Healthcare Utilization Survey at the Mali EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

A.	WEALTH INDEX

1. **In your house, do you have electricity?** ☐ Yes ☐ No

2. **In your house, do you have a television?** ☐ Yes ☐ No

3. **In your house, do you have a bed?** ☐ Yes ☐ No

4. **In your house, do you have a fan?** ☐ Yes ☐ No

5. **In your house, do you have a cupboard** ☐ Yes ☐ No

6. **In your house, do you have a CD/DVD player?** ☐ Yes ☐ No

7. **In your house, do you have a refrigerator?** ☐ Yes ☐ No

8. **In your house, do you have a chair?** ☐ Yes ☐ No

9. **In your house, do you have a motorcycle or scooter?** ☐ Yes ☐ No

10. **In your house, do you have soap, washing powder, or ash/sand/dirt for washing your hands?** ☐ Yes ☐ No

11. **Does any member of this household have a bank account?** ☐ Yes ☐ No ☐ Don't know

12. **Where is your principal source of drinking water located?** *(select one)*

    ☐ Outside of the plot   ☐ Within the plot

13. **What is the distance to the principal source of drinking water?**

    ☐ Less than 30 minutes round trip   ☐ More than 30 minutes round trip

14. **Main material of exterior walls of the house?** *(select one)*

    ☐ Brick   ☐ Other

15. **Main material of roof of house?** *(select one)*

    ☐ Cement   ☐ Mud with wood

    ☐ Other

16. **Main material of floor of house?** *(select one)*

    ☐ Earth/sand floor   ☐ Ceramic tile floor

    ☐ Other

17. **In your house, what is the main fuel used for cooking?** *(select one)*

☐ Charcoal   ☐ Wood   ☐ Other

18. **Does your household own any pigs?**   ☐ Yes ☐ No

19. **Does your household own any camels or dromedaries?**   ☐ Yes ☐ No

20. **Does your household own any Guinea fowl, ducks, turkeys or geese?**   ☐ Yes ☐ No

B.	FORM COMPLETION

21. ID of person completing this form: |___|___|___|

Date form completed:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

22. ID of person reviewing this form: |___|___|___|

Date form reviewed:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

23. ID of person entering this form: |___|___|___|

Date form entered:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

24. ID of person conducting data verification:
|___|___|___|

Date of data verification:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To collect household wealth information at the Pakistan site.

Instructions: Please complete this form for all households that are included in the Healthcare Utilization Survey at the Pakistan EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

A.	WEALTH INDEX

1. **Does your household have a refrigerator?** ☐ Yes ☐ No

2. **Does your household have a washing machine?** ☐ Yes ☐ No

3. **Does your household have a sofa?** ☐ Yes ☐ No

4. **Does your household have a chair?** ☐ Yes ☐ No

5. **Does your household have an Almirah/cabinet?** ☐ Yes ☐ No

6. **Does your household have a computer?** ☐ Yes ☐ No

7. **Does your household have an internet connection?** ☐ Yes ☐ No

8. **Does your household have a bed?** ☐ Yes ☐ No

9. **Does any member of this household have a bank account?** ☐ Yes ☐ No

10. **What type of fuel does your household mainly use for cooking?** *(select one)*

    ☐ Wood ☐ Other

11. **What is the main material of the roof in your household?** *(select one)*

    ☐ Cement/RCC ☐ Other

12. **What is the main material of the walls in your household?** *(select one)*

    ☐ Cement ☐ Other

B.	FORM COMPLETION

13. ID of person completing this form: |___|___|___|

    Date form completed:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

14. ID of person reviewing this form: |___|___|___|

    Date form reviewed:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

15. ID of person entering this form: |___|___|___|

    Date form entered:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

16. ID of person conducting data verification: |___|___|___|

    Date of data verification:
    |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: To collect household wealth information at the Peru site.

Instructions: Please complete this form for all households that are included in the Healthcare Utilization Survey at the Peru EFGH site. Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.

A. WEALTH INDEX

1. **Does your household have a computer?** ☐ Yes ☐ No

2. **Does your household have a bookshelf?** ☐ Yes ☐ No

3. **Does your household have windows with curtains or blinds?** ☐ Yes ☐ No

4. **Does your household have a sofa?** ☐ Yes ☐ No

5. **What type of toilet does your household use?** *(select one)*

   ☐ Indoor connected to public sewer ☐ Other

6. **What type of material is the roof made of in your household?** *(select one)*

   ☐ Reinforced concrete ☐ Other

7. **What type of material are the walls made of in your household?** *(select one)*

   ☐ Brick or cement block ☐ Other

B. FORM COMPLETION

8. ID of person completing this form: |___|___|___|
Date form completed:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

9. ID of person reviewing this form: |___|___|___|
Date form reviewed:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

10. ID of person entering this form: |___|___|___|
Date form entered:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

11. ID of person conducting data verification: |___|___|___|
Date of data verification:
|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose: *Revisit the households that were placed on revisit list for Healthcare Utilization survey to assess eligibility of the child for Healthcare Utilization survey, obtain informed consent from the child's caregiver and conduct Healthcare Utilization survey.*

Instructions: *Complete the following questions for each child in the household that you are attempting to revisit. The questions should be answered by a household member who spends the most time with the child and is best able to recall symptoms related to the **most recent diarrheal episode (likely the primary caregiver)**. Diarrhea is defined as 3 or more loose stools in a 24 hour period. A diarrheal episode is diarrhea that began after at least 2 days without diarrhea. Use the memory aid and ask the caregiver to answer the following questions thinking about the most recent episode of diarrhea.* Text in **bold** should be read to study participants, plain text is for prompts for study staff, and *italics* are instructions for study staff.*

A.	VISIT INFORMATION		
	1.	Date:	|___|___| - |___|___| - |2 | 0 |___|___| *(dd-mm-yyyy)*
	2.	EFGH country site:	
		☐ Bangladesh	☐ Kenya
		☐ Malawi	☐ Mali
		☐ Pakistan	☐ Peru
		☐ The Gambia	
	3.	Cluster number:	|___|___|___|
	3a.	Sub-cluster number *(applicable to Kenya and The Gambia only)*	|___| *(1-4)*
B.	**REVISIT INFORMATION**		

		Household identifier *(same identifier as that assigned for the household enumeration) (select from filtered dropdown list by cluster in the data system)*:	|___|___| - |___|___| - | 2 | 0 |___|___|	|___|___|___|	|___|___|
	4.		*(dd-mm-yyyy)*	*(Fieldworker ID)*	*(Sequential number)*
			In the data system, select the Household ID where the child for whom you are repeating the visit lives and attempting to conduct the Healthcare Utilization survey and skip to Section D. If the Household ID is not listed, re-enter the original Household ID and complete Section C.		

C.		**CHILD INFORMATION**						

5.		**How many children under 5 years of age (<60 months) currently live in the household?**			_____	*If 0, stop here. Questions below will be asked per each child under 5 years of age. The data system will automatically populate the number of rows below based on this answer.*		

6.	Child num	**What is the relationship of the person answering these questions to (name)?**	Is this person the primary caregiver of the child?	Child sex	Child Initials	Date of birth/age	Age (auto generated in real time and confirmed with the caregiver)	**Did this child experience diarrhea in the last two weeks** (14 days) – **that is 3 or more unusually loose or watery stools during a 24 hour period in the last 14 days?** *(only ask if the child is <60 months – automated question)*
	1	☐ Biological mother ☐ Biological father ☐ Adopted mother ☐ Adopted father ☐ Grandmother ☐ Grandfather ☐ Aunt ☐ Uncle ☐ Older sister ☐ Older brother ☐ Other, specify: _____	☐ Yes ☐ No	☐ Female ☐ Male		|___|___| -|___|___| - ___|___|___|___| *(dd-mm-yyyy)* ☐ Day Missing ☐ Month Missing ☐ Year Missing ____ months *(self report)*	____ months	☐ Yes ☐ No (*form complete*) ☐ Don't Know (*form complete*)

X	☐ Biological mother ☐ Biological father ☐ Adopted mother ☐ Adopted father ☐ Grandmother ☐ Grandfather ☐ Aunt ☐ Uncle ☐ Older sister ☐ Older brother ☐ Other, specify: _____	☐ Yes ☐ No	☐ Female ☐ Male	☐☐☐	|___|___| -|___|___| - ___|___|___|___| *(dd-mm-yyyy)* ☐ Day Missing ☐ Month Missing ☐ Year Missing ____ months *(self report)*	____ months	☐ Yes ☐ No (*form complete*) ☐ Don't Know (*form complete*)

If one or more children are between 6 to <36 months of age and had diarrhea in the last 14 days, continue to Section D. If not, skip to Section E Form Completion.

D.	DIARRHEA SIGNS AND SYMPTOMS (*ODK will auto-generate this section for each eligible child*)		
7.	Did the adult household member and/or primary caregiver give informed consent for participation in the healthcare utilization survey?		
	☐ Yes, verbal consent was obtained for the healthcare utilization survey ☐ Yes, written informed consent was obtained for the healthcare utilization survey ☐ No, declined consent *(end of form)*		
8.	Child Initials & Age : *ODK to autopopulate the list of children with initials and age who had diarrhea reported in section C or in the previously completed Population Enumeration Form*	|___|___|___| Child Initials	|___|___| Age (months)
9.	Who is answering the HUS questions on behalf of this child?	☐ Primary Caregiver of the Child ☐ Other Household Member	
10.	What is the relationship of the respondent to the child?		
	☐ Biological mother	☐ Biological father	☐ Adopted mother
	☐ Grandmother	☐ Grandfather	☐ Aunt
	☐ Uncle	☐ Older sister	☐ Older brother
	☐ Other, specify: _____		
11.	**When did the diarrhea start?** *Refer to calendar to determine date if # of days ago known but not exact date*	|___|___| -|___|___| - ___|___|___|___| *(dd-mm-yyyy)*	
12.	**When did the diarrhea end?** *Refer to calendar to determine date if # of days ago known but not exact date*	|___|___| -|___|___| - ___|___|___|___| *(dd-mm-yyyy)* ☐ Ongoing	
13.	Duration of diarrhea by date calculation (auto-generated)	_____(days) *(Add suggested range 1 to 14 in ODK)*	
14.	**On the worst day of diarrhea during this episode, how many loose stools did the child have in one day** (24 hours)?	_____loose stools	
15.	**Did the child have any of the following symptoms during his/her diarrheal illness**? *(Use the memory aid to show pictures of each of these symptoms)*		
	Blood in stool:	☐ Yes ☐ No ☐ Don't Know	
	Irritable/less play:	☐ Yes ☐ No ☐ Don't Know	
	Sunken eyes:	☐ Yes ☐ No ☐ Don't Know	
	Wrinkled skin:	☐ Yes ☐ No ☐ Don't Know	
	Drinks eagerly, thirsty:	☐ Yes ☐ No ☐ Don't Know	
	Unable to drink or drank poorly:	☐ Yes ☐ No ☐ Don't Know	
	Lethargic, unconscious, or hard to stay awake:	☐ Yes ☐ No ☐ Don't Know	
16.	**Did the child vomit at any time during the episode of diarrhea?**		
	☐ Yes ☐ No *(skip to Q18)* ☐ Don't know *(skip to Q18)*		

	16a.	**How many days did the child vomit?**	_____(days) *(Add suggested range 1 to 14 in ODK)*
	16b.	**Thinking about the day when the child had the most vomiting, how many times did s/he vomit in the day?**	_____
17.		**At any any point during the diarrheal episode, did the child have any fever?** (Fever meaning the child was hot to touch)	
		☐ Yes ☐ No *(skip to Q18)* ☐ Don't know *(skip to Q18)*	
	18a.	*If yes,* **what was the highest temperature?**	_____ ⁰C ☐ Temperature not collected
	18b.	**How many days did s/he have the fever?**	_____days
18.		**Did you seek care for the child's diarrhea outside your home?**	
		☐ Yes *(skip to Q19)* ☐ No	
	18a.	*If No to Q18,* **why not?** _____ _____	
		(If did not seek care for child's diarrhea outside the home, form complete.)	
19.		**If you sought treatment or care for the child for this illness where did you go?** *(check all that apply)*	

	Facility	Date first visited
	☐ EFGH Facility X	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	☐ EFGH Facility X	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	☐ Other health facility (outpatient care)	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	☐ Other health facility (inpatient care)	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	☐ Other *(specify, check all that apply)*	

	☐ Traditional healer		☐ Religious healer
	☐ Drug seller		☐ Pharmacist
	☐ Community Health worker		☐ Health outpost
	☐ Other *(specify):*_____		

21.	What day of the child's diarrhea did the caregiver visit a hospital or health center? *(auto-generated in ODK;If today, "00" will be displayed)*	_____
22.	**Did the clinical team at any care provider advise the child be hospitalized during this illness?**	
	☐ Yes ☐ No *(skip to Q24)*	
23.	**Was the child admitted to the hospital** (i.e. at least an overnight stay) **during this illness?**	
	☐ Yes ☐ No	
24.	**Did the child receive any of the following to treat the diarrhea?** *(check all that apply)*	

		Intravenous fluids	☐ Yes	☐ No	☐ Don't know
		A drinkable fluid made from a special packet called ORALITE or ORS	☐ Yes	☐ No	☐ Don't know
		Homemade fluid (such as thin watery porridge made from maize, rice, wheat, soup, sugar, salt water solution or yogurt-based drink)	☐ Yes	☐ No	☐ Don't know
		Antibiotic	☐ Yes *(specify)*	☐ No	☐ Don't know

If antibiotic was received, specify type received (check all that apply):

☐ Amoxicillin	☐ Azithromycin	☐ Artesunate	☐ Ampicillin
☐ Augmentin/ Co-amoxiclav	☐ Ceftriaxone	☐ Ciprofloxacin (Cipro)	☐ Cefuroxime
☐ Clarithromycin	☐ Clindamycin	☐ Chloramphenicol	☐ Cotrimoxazole (Septrin)
☐ Doxycycline	☐ Erythromycin	☐ Gentamicin	☐ Penicillin
☐ Pyrazinamide	☐ Streptomycin	☐ Tetracycline	☐ Unknown

☐ Other *(specify)*:_____

		Antisecretory or antiemetics	☐ Yes	☐ No	☐ Don't know
		Zinc	☐ Yes	☐ No	☐ Don't know
		Traditional medicine	☐ Yes	☐ No	☐ Don't know
		None of the above	☐ Yes	☐ No	☐ Don't know

E.	**FORM COMPLETION**

25.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
26.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
27.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
28.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*

Purpose: *Document completion of all households in a cluster.*

Instructions: *Complete this form after all households in an identified cluster have been approached/visited and no further attempts will be made.*

A.	VISIT INFORMATION	
1.	Date:	|___|___| -|___|___| - |2 | 0 |___|___| *(dd-mm-yyyy)*
2.	EFGH country site:	
	☐ Bangladesh	☐ Kenya
	☐ Malawi	☐ Mali
	☐ Pakistan	☐ Peru
	☐ The Gambia	
3.	Cluster number:	|___|___|___|
3a.	Sub-cluster number *(applicable to Kenya and The Gambia only)*	|___| *(1-4)*
4.	Did the study team approach all households at least three times (if needed) and complete the PE and HUS CRF for each household in the cluster number noted above?	
	☐ Yes ☐ No; there are no household structures in satellite image and expected population size is zero ☐ No; it was not possible to visit all households due to extreme weather or safety concerns ☐ Other *(specify)*:_____	
5.	How many unique households were visited within this cluster?	|___|___|___|___|

Enterics for Global Health – *Shigella* Surveillance Study (EFGH)
Implementing Institution Name (Country Site)
Population Enumeration & HUS Protocol Violation Form

Purpose: *To capture information about Population Enumeration (PE) & Healthcare Utilization Survey (HUS)-related protocol violations that occurred from the start of study until the end of the study duration.*

Form Instructions: Please complete this form for all PE & HUS protocol violations. If multiple IDs are affected by the violation, please list the affected IDs in the relevant section. Please note that only protocol violations (not deviations) are reported here. As a reminder, a protocol violation is defined as a consistent variation in practice from study protocol/SOPs that may affect participant safety, participant willingness to participate in the study, and/or integrity of the research or study data. Protocol violation is a subset of protocol deviation.

Reporting Instructions: To Report a PE & HUS Protocol Violation, please email the completed form to efgh@uw.edu with the email subject "Site Name – PE & HUS Protocol Violation Report."

A.		SITE INFORMATION					
	1.	EFGH country site:					
		☐ Bangladesh	☐ Kenya		☐ Malawi		☐ Mali
		☐ Pakistan	☐ Peru		☐ The Gambia		
	2.	Date violation occurred:		__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*			
	3.	Date study staff was made aware of violation		__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*			
	4.	Date reported by email to EFGH Coordination team (efgh@uw.edu)		__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*			

B.		PROTOCOL VIOLATION REPORTING	
	5.	Is the site PI aware of the violation?	
		☐ Yes	
		☐ No	
	6.	Was this event reported to the site-specific IRB?	
		☐ Yes	
		☐ No *(skip to Q8)*	
	7.	*If yes*, date reported to local IRB:	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	8.	Was this event entered in the Protocol Deviation/ Violations Log?	
		☐ Yes	
		☐ No	
	9.	Was the participant informed of the Protocol Violation?	
		☐ Yes	
		☐ No	
		☐ Not applicable	

C.		DESCRIPTION OF PROTOCOL VIOLATION	
	10.	Nature of violation *(check all that apply)*	
		☐ Consent not obtained or documented	☐ Consent obtained using outdated consent form
		☐ Failure to provide a copy of signed consent form to the participant caregiver	☐ Administration of Healthcare Utilization Survey to household who did not meet the inclusion/exclusion criteria
		☐ Undertaking of a study procedure not approved by IRB	☐ Breach in confidentiality

	☐ Loss of tablet or study equipment that contains identifiable information about participant	☐ Other *(please specify):* _____ _____
11.	Who is affected by the violation? *(select one)*	
	☐ Individual	
	Enter Affected Household ID: |___|___| -|___|___| - | 2 | 0 |___|___| - |___|___|___| - |___|___| *(skip to Q13)*	
	☐ Site-wide	
	List affected Household IDs:	
12.	Brief summary of event (Description of event, location it occurred if relevant):	
13.	What steps have been taken to address this event?	
14.	What steps have been taken to prevent further occurrences?	

D.	FORM COMPLETION	
15.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
16.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Enterics for Global Health: *Shigella* Surveillance Study (EFGH)

Lab Case Report Form Appendix

Table of Contents

CRF Number	CRF Name
15	Specimen Accession
16	Stool Culture Results – Rectal Swab
16a	Shigella Serotyping & AST Results – Rectal Swab
17	Stool Culture Results - Whole Stool *(Gambia & Bangladesh only)*
17a	Shigella Serotyping & AST - Whole Stool

Purpose: *To capture specimen accession and storage information for all biological specimens collected in EFGH. Note: temperature excursions are asked separately for rectal swabs (asked only for rectal swab #1 as it is assumed all swabs are shipped together) and whole stools in case whole stool is shipped separate from swabs.*

Instructions: *Complete this form for all enrolled participants.*

PLEASE PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	PARTICIPANT INFORMATION			
	1.	Participant ID	|___|___|___|___|___|___|___|	
	2.	EFGH country site:		
		☐ Bangladesh	☐ Kenya	☐ Malawi	☐ Mali
		☐ Pakistan	☐ Peru	☐ The Gambia	
	3.	Enrollment facility ID:	|___|___|	
	4.	Visit specimens were collected at		
		☐ Enrollment *(complete all sections)*		
		☐ Week 4 *(complete Sections G & H only)*		
B.	RECTAL SWAB 1 (DRY) *(enrollment visit only)*			
	5.	Is there a dry rectal swab (swab 1) available for this participant?		
		☐ Yes		
		☐ No *(skip to Section C)*		
	6.	Date sample received at central lab:	|___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)*	
	7.	Time sample received at central lab:	|___|___| : |___|___| *(hh : min, 24:00 hr)*	
	8.	Specimen ID: _____ ☐ Not applicable		
	9.	What type of temperature monitor was used for the rectal swab shipment? *Note it is assumed that all rectal swabs utilize the same temperature monito*		
		☐ WarmMark		
		☐ 3M *(skip to Q11)*		
		☐ No monitor available *(skip to Q12)*		
	10.	Temperature excursion for 3 rectal swab shipment *(based on WarmMark monitor read):*		
		☐ Not reached *(no color change on WarmMark monitor)*		
		☐ Brief		
		☐ Moderate		
		☐ Prolonged		
		Answer Q10, then skip to Q12		
	11.	Temperature excursion for 3 rectal swab shipment *(based on 3M monitor read):*		
		☐ 0 (No excursion)		
		☐ 0-1 (30 minutes-9 hours)		
		☐ 2 (10-20 hours)		
		☐ 3 (21-30 hours)		
		☐ 4 (31-40 hours)		
		☐ 5 (41+ hours)		
	12.	Is the dry rectal swab (swab 1) acceptable for accessioning?		
		☐ Yes *(skip to Q13)*		

		☐ No, not acceptable for accessioning *(answer Q12a, skip to Section C)*	
		12a.	If not acceptable, why? *(select all that apply)*
			☐ Improperly labelled
			☐ Sample containers did not arrive tighly shut
			☐ Other *(specify)*: _____
	13.	Date rectal swab was placed in -80°C freezer:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	14.	Time rectal swab was placed in -80°C freezer:	|___|___| : |___|___| *(hh : min, 24:00 hr)*
		Comments *(optional)*:	

C.	**RECTAL SWAB 2 (MODIFIED BGS)** *(enrollment visit only)*	
	15.	Is there a mBGS rectal swab (swab 2) available for this participant?
		☐ Yes
		☐ No *(skip to Section D)*
	16.	Date samples received at central lab: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	17.	Time samples received at central lab: |___|___| : |___|___| *(hh : min, 24:00 hr)*
	18.	Specimen ID: _____ ☐ Not applicable
	19.	Is the mBGS rectal swab (swab 2) acceptable for accessioning?
		☐ Yes *(skip to Q20)*
		☐ No, not acceptable for accessioning
		19a. If not acceptable, why? *(select all that apply)*
		☐ Improperly labelled
		☐ Sample containers did not arrive tighly shut
		☐ Other *(specify)*: _____
		Comments *(optional)*:

D.	**RECTAL SWAB 3 (CARY-BLAIR)** *(enrollment visit only)*	
	20.	Is there a Cary-Blair rectal swab (swab 3) available for this participant?
		☐ Yes
		☐ No *(skip to Section E)*
	21.	Date samples received at central lab: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	22.	Time samples received at central lab: |___|___| : |___|___| *(hh : min, 24:00 hr)*
	23.	Specimen ID: _____ ☐ Not applicable
	24.	Is the Cary-Blair rectal swab (swab 3) acceptable for accessioning?
		☐ Yes *(skip to Q25)*
		☐ No, not acceptable for accessioning
		24a. If not acceptable, why? *(select all that apply)*
		☐ Improperly labelled
		☐ Sample containers did not arrive tighly shut
		☐ Other *(specify)*: _____
		Comments *(optional)*:

E.	**WHOLE STOOL SAMPLE** *(enrollment visit or within 24 hours [home collection- applicable to Bangladesh, The Gambia, Peru, Malawi, and Pakistan sites])*	
	25.	Is there a whole stool sample available for this participant?

		☐ Yes	
		☐ No *(skip to Section G)*	
		Specimen ID: _____ ☐ Not applicable	
	26.	Was the whole stool shipped together or separately from the rectal swab?	
		☐ Same shipment *(skip to Q32)*	
		☐ Different shipment	
	27.	Date samples received at central lab:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	28.	Time samples received at central lab:	|___|___| : |___|___| *(hh : min, 24:00 hr)*
	29.	What type of temperature monitor was used for the whole stool shipment?	
		☐ WarmMark	
		☐ 3M *(skip to Q31)*	
		☐ No monitor available *(skip to Q32)*	
	30.	Temperature excursion for whole stool shipment *(based on WarmMark monitor read):*	
		☐ Not reached *(no color change on WarmMark monitor)*	
		☐ Brief	
		☐ Moderate	
		☐ Prolonged	
		Answer Q30, then skip to Q32	
	31.	Temperature excursion for whole stool shipment *(based on 3M monitor read):*	
		☐ 0 (No excursion)	
		☐ 0-1 (30 minutes-9 hours)	
		☐ 2 (10-20 hours)	
		☐ 3 (21-30 hours)	
		☐ 4 (31-40 hours)	
		☐ 5 (41+ hours)	
	32.	Is the whole stool sample acceptable for accessioning?	
		☐ Yes *(skip to Q33)*	
		☐ No, not acceptable for accessioning *(answer Q32a then skip to Section F [Gambia and Bangladesh sites only] or Section G [other sites])*	
		32a.	If not acceptable, why? *(select all that apply) (answer Q32a then skip to Section F)*
			☐ Improperly labelled
			☐ Sample containers did not arrive tighly shut
			☐ Other *(specify):* _____
	33.	Number of vials of whole stool being stored: |___| *(1-5)*	
	34.	Weight of the 1ˢᵗ stored vial of stool *(back up qPCR sample):* |___|___|___| mg *(between 180-220mg)*	
	35.	Date whole stool was placed in -80°C freezer	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	36.	Time whole stool was placed in -80°C freezer	|___|___| : |___|___| *(hh : min, 24:00 hr)*
		Comments *(optional):*	
		Skip to Section G	
F.		**WHOLE STOOL SAMPLE FOR WHOLE STOOL CULTURE** *(Bangladesh and The Gambia sites only; enrollment visit stool only)*	
	37.	Is there a mBGS whole stool sample available for this participant?	

		☐ Yes	
		☐ No *(skip to Section G)*	
	38.	Date samples received at central lab:	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	39.	Time samples received at central lab:	|__|__| : |__|__| *(hh : min, 24:00 hr)*
	40.	Specimen ID: _____ ☐ Not applicable	
	41.	Is the whole stool sample acceptable for accessioning?	
		☐ Yes *(skip to Q43)*	
		☐ No, not acceptable for accessioning	
		42. If not acceptable, why? *(select all that apply)*	
		☐ Improperly labelled	
		☐ Sample containers did not arrive tighly shut	
		☐ Other *(specify)*: _____	
		Comments *(optional)*:	

G.	**DRIED BLOOD SPOT** *(enrollment & Week 4 visit only)*		
	43.	Is a dried blood spot (DBS) card available for this participant?	
		☐ Yes	
		☐ No *(skip to Section H)*	
	44.	Date samples received at central lab:	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	45.	Time samples received at central lab:	|__|__| : |__|__| *(hh : min, 24:00 hr)*
	46.	Specimen ID: _____ ☐ Not applicable	
	47.	Is the DBS acceptable for accessioning?	
		☐ Yes *(skip to Q48)*	
		☐ No, not acceptable for accessioning *(answer 47a, skip to Section H)*	
		47a. If not acceptable, why? *(select all that apply)*	
		☐ Improperly labelled	
		☐ Sample containers did not arrive tightly shut	
		☐ Other *(specify)*: _____	
	48.	Date DBS card placed in ~4°C storage:	|__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
	49.	Time DBS card placed in ~4°C storage:	|__|__| : |__|__| *(hh : min, 24:00 hr)*
		Comments *(optional)*:	

H.	**FORM COMPLETION**	
50.	ID of person completing this form: |__|__|__|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
51.	ID of person reviewing this form: |__|__|__|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
52.	ID of person entering this form: |__|__|__|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
53.	ID of person conducting data verification: |__|__|__|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Purpose*: To capture information about clinical microbiology results from <u>rectal swab</u> samples*

Instructions*: This form is to be completed as a final reporting of Shigella isolates and is to be completed for each child (even if no Shigella* was isolated)*. The related form (16a) is to be completed if Shigella is isolated.*

PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	SAMPLE INFORMATION	
	1.	Participant ID	|___|___|___|___|___|___|___|
	2.	Date form initated:	|___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)*
	3.	Time form initiated:	|___|___| : |___|___| *(hh : min, 24:00 hr)*
	4.	Time of inoculation onto primary media:	|___|___| : |___|___| *(hh : min, 24:00 hr)*
B.	LACTOSE FERMENTER	
	5.	Were lactose fermenter (LF) colonies isolated?
		☐ Yes
		☐ No *(skip to Q9)*
	6.	Confirm that up to 10 lactose fermenter colonies were stored at minus 80°C:
		☐ Yes *(skip to Q9)*
		☐ No
	5a.	If no, why not? _____
	7.	Date LF colonies were placed in minus 80°C freezer: |___|___| - |___|___| -	2	0 |___|___| *(dd-mm-yyyy)*
	8.	Time LF colonies were placed in minus 80°C freezer: |___|___| : |___|___| *(hh : min, 24:00 hr)*
C.	*SHIGELLA* ISOLATES *(complete based on final Shigella serotypes)*	
	9.	Number of unique *Shigella* serotypes: |___|___| *(0-20; if >0, complete form 16a. For each unique isolate, please fill out the serotype and AST results in form 16a)*
D.	FORM COMPLETION	

10.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
11.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
12.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*
13.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| -	2	0 |__|__| *(dd-mm-yyyy)*

Purpose*: To capture information about Shigella isolates from <u>rectal swab</u> samples*

Instructions*: This form is to be completed as a final reporting of Shigella isolates and is to be completed for each child from which Shigella was isolated. This form will be missing for children without Shigella isolated.*

PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	SAMPLE INFORMATION	
	1.	Participant ID	|___|___|___|___|___|___|___|
	2.	Date form initated:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	3.	Time form initiated:	|___|___| : |___|___| *(hh : min, 24:00 hr)*

B.	***SHIGELLA* ISOLATES** *(complete based on final # of unique Shigella isolates)*

Isolate 1

4.	Specimen ID of **1st** unique isolate: _____ ☐ Not applicable

5.	From which media was the 1st unique isolate grown:
	☐ Modified BGS
	☐ Cary-Blair
	☐ Both *(only tick "both" if exact same species, serotype, and zone sizes)*

6.	*Shigella* serogroup:
	☐ *S. dysenteriae* ☐ *S. flexneri* ☐ *S. boydii* ☐ *S. sonnei* ☐ <u>Undetermined</u>

6a. *S. flexneri* serotype:

☐ 1a	☐ 1b	☐ 1d	☐ 2a	☐ 2b
☐ 3a	☐ 3b	☐ 4a	☐ 4b	☐ 5a
☐ 5b	☐ 6	☐ X	☐ Y	☐ Non-typable

☐ Other *(specify)*:_____

7.	Date of 1st unique isolate recovery: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
8.	Time of 1st unique isolate recovery: |___|___| : |___|___| *(hh : min, 24:00 hr)*
9.	Date of AST test on 1st unique isolate: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of recovery *(Q7)*
10.	Time of AST test on 1st unique isolate: |___|___| : |___|___| *(hh : min, 24:00 hr)*
11.	Antibiotic susceptibility testing results:

Antibiotic	**Zone (mm)**	**Interpretation**	

	Antibiotic	Zone (mm)	MIC	Interpretation
	Ampicillin	|___|___|	☐ S ☐ I ☐ R	
	Azithromycin	|___|___|	☐ S ☐ I ☐ R	☐ Not interpretable (*obtain MIC*)
	Ceftriaxone	|___|___|	☐ S ☐ I ☐ R	
	Ciprofloxacin	|___|___|	☐ S ☐ I ☐ R	
	Nalidixic acid	|___|___|	☐ S ☐ I ☐ R	
	Pivemicellinam	|___|___|	☐ S ☐ I ☐ R	
	Trimethoprim/ sulfamethoxazole	|___|___|	☐ S ☐ I ☐ R	

12.	Azithromycin MIC *(if zone size is not interpretable)* |___|___|___|.|___|___|___| ☐ Not applicable
13.	Date 1st isolate was placed in minus 80 ºC freezer: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of recovery *(Q7)*
14.	Time 1st isolate was placed in minus 80 ºC freezer: |___|___| : |___|___| *(hh : min, 24:00 hr)*

Isolate 2

15.	Specimen ID of **2nd unique** isolate: _____ ☐ Not applicable
16.	From which media was the 2nd unique isolate grown:
	☐ Modified BGS
	☐ Cary-Blair
	☐ Both
17.	*Shigella* serogroup:
	☐ *S. dysenteriae* ☐ *S. flexneri* ☐ *S. boydii* ☐ *S. sonnei* ☐ Undetermined
	S. flexneri serotype:

☐ 1a	☐ 1b	☐ 1d	☐ 2a	☐ 2b
☐ 3a	☐ 3b	☐ 4a	☐ 4b	☐ 5a
☐ 5b	☐ 6	☐ X	☐ Y	☐ Non-typable

☐ Other *(specify)*:_____

18.	Date of 2nd unique isolate recovery: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
19.	Time of 2nd unique isolate recovery: |___|___| : |___|___| *(hh : min, 24:00 hr)*
20.	Date of AST test on 2nd unique isolate: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of recovery *(Q18)*
21.	Time of AST test on 2nd unique isolate: |___|___| : |___|___| *(hh : min, 24:00 hr)*
22.	Antibiotic susceptibility testing:

Antibiotic	Zone (mm)	MIC	Interpretation
Ampicillin	|___|___|	☐ S ☐ I ☐ R	
Azithromycin	|___|___|	☐ S ☐ I ☐ R	☐ Not interpretable (*obtain MIC*)
Ceftriaxone	|___|___|	☐ S ☐ I ☐ R	

	Ciprofloxacin	|___|___|	☐ S ☐ I ☐ R
	Nalidixic acid	|___|___|	☐ S ☐ I ☐ R
	Pivemicellinam	|___|___|	☐ S ☐ I ☐ R
	Trimethoprim/ sulfamethoxazole	|___|___|	☐ S ☐ I ☐ R

23.	Azithromycin MIC *(if zone size is not interpretable)* |___|___|___|.|___|___|___| ☐ Not applicable
24.	Date 2nd isolate was placed in minus 80 freezer: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of recovery *(Q18)*
25.	Time 2nd was placed in minus 80 freezer: |___|___| : |___|___| *(hh : min, 24:00 hr)*
	Note to lab staff: If >2 isolates, print appendix based on number of additional isolates and serotyping, AST, and storage fields will show up as repeating forms when entering into REDCap.

D.	FORM COMPLETION	
26.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
27.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
28.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*
29.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*

Appendix: *print out and complete this form for every nth isolate if >2 isolates recovered*

Isolate number: _____	
Specimen ID of isolate: _____ ☐ Not applicable	

From which media was the isolate grown:

☐ Modified BGS

☐ Cary-Blair

☐ Both

Shigella serogroup:

☐ *S. dysenteriae*　☐ *S. flexneri*　☐ *S. boydii*　☐ *S. sonnei*　☐ <u>Undetermined</u>

S. flexneri serotype:

☐ 1a	☐ 1b	☐ 1d	☐ 2a	☐ 2b
☐ 3a	☐ 3b	☐ 4a	☐ 4b	☐ 5a
☐ 5b	☐ 6	☐ X	☐ Y	☐ Non-typable

☐ Other *(specify)*:_____

Date of isolate recovery: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*

Time of isolate recovery: |___|___| : |___|___| *(hh : min, 24:00 hr)*

Date of AST test on isolate: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
　　　　　　　　　　　　☐ Same as date of recovery

Time of AST test on isolate: |___|___| : |___|___| *(hh : min, 24:00 hr)*

Antibiotic susceptibility testing:

Antibiotic	Zone (mm)	MIC	Interpretation
Ampicillin	|___|___|	☐ S ☐ I ☐ R	
Azithromycin	|___|___|	☐ S ☐ I ☐ R	☐ Not interpretable (*obtain MIC*)
Ceftriaxone	|___|___|	☐ S ☐ I ☐ R	
Ciprofloxacin	|___|___|	☐ S ☐ I ☐ R	
Nalidixic acid	|___|___|	☐ S ☐ I ☐ R	
Pivemicellinam	|___|___|	☐ S ☐ I ☐ R	
Trimethoprim/ sulfamethoxazole	|___|___|	☐ S ☐ I ☐ R	

Azithromycin MIC *(if zone size is not interpretable)* |___|___|___|.|___|___|___| ☐ Not applicable

Date isolate was placed in minus 80 freezer: |___|___| - |___|___| - | 2 | 0 |___|___|
　　　　　　　　　　(dd-mm-yyyy)　　☐ Same as date of recovery

Time isolate was placed in minus 80 freezer: |___|___| : |___|___| *(hh : min, 24:00 hr)*

Enterics for Global Health – *Shigella* Surveillance Study (EFGH)
Implementing Institution Name (Country Site)
CRF 17 - Stool Culture Results -Whole Stool

Purpose*: To capture information about clinical microbiology results from whole stool samples (only applicable in Bangladesh & The Gambia).*

Instructions*: This form is to be completed as a final reporting of Shigella isolates and is to be completed for each child (even if no Shigella was isolated) with a whole stool sample transported in Cary-Blair media in the Gambia and Bangladesh The related form (17a) is to be completed if Shigella is isolated.*

PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	**SAMPLE INFORMATION**		
	1.	Participant ID	|___|___|___|___|___|___|___|
	2.	Date form initiated:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	3.	Time form initiated:	|___|___| : |___|___| *(hh : min, 24:00 hr)*
	4.	Time of inoculation onto primary media:	|___|___| : |___|___| *(hh : min, 24:00 hr)*
B.	***SHIGELLA* ISOLATES** *(complete based on final Shigella serotypes)*		
	5.	Number of unique *Shigella* serotypes: |___|___|*(0-20). For each unique isolate, please fill out the serotype and AST results in form 17a*	
C.	**FORM COMPLETION**		

6.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*	
7.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*	
8.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*	
9.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*	

**Purpose*:* *To capture information about Shigella isolates from whole stool samples (only applicable in Bangladesh & The Gambia).*

**Instructions*:* *This form is to be completed as a final reporting of Shigella isolates from whole stool and is to be completed for each child from which Shigella was isolated. This form will be missing for children without Shigella isolated.*

PLACE PARTICIPANT LABEL HERE (OPTIONAL):

A.	**SAMPLE INFORMATION**		
	1.	Participant ID	|___|___|___|___|___|___|___|
	2.	Date form initiated:	|___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
	3.	Time form initiated:	|___|___| : |___|___| *(hh : min, 24:00 hr)*
B.	***SHIGELLA* ISOLATES** *(complete based on final # of unique Shigella isoaltes)*		

Isolate 1

4.	Specimen ID of **1ˢᵗ** unique isolate: _____ ☐ Not applicable	
5.	*Shigella* serogroup:	
	☐ *S. dysenteriae* ☐ *S. flexneri* ☐ *S. boydii* ☐ *S. sonnei* ☐ <u>Undetermined</u>	
	S. flexneri serotype:	

☐ 1a	☐ 1b	☐ 1d	☐ 2a	☐ 2b
☐ 3a	☐ 3b	☐ 4a	☐ 4b	☐ 5a
☐ 5b	☐ 6	☐ X	☐ Y	☐ Non-typable

☐ Other *(specify)*:_____

6.	Date of 1ˢᵗ unique isolate recovery: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
7.	Time of 1ˢᵗ unique isolate recovery: |___|___| : |___|___| *(hh : min, 24:00 hr)*
8.	Date of AST test on 1ˢᵗ unique isolate: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of recovery *(Q6)*
9.	Time of AST test on 1ˢᵗ unique isolate: |___|___| : |___|___| *(hh : min, 24:00 hr)*
10.	Antibiotic susceptibility testing results:

Antibiotic	Zone (mm)	Interpretation	
Ampicillin	|___|___|	☐ S ☐ I ☐ R	
Azithromycin	|___|___|	☐ S ☐ I ☐ R	☐ Not interpretable (*obtain MIC*)

		Antibiotic	Zone (mm)	MIC	Interpretation
		Ceftriaxone	|___|___|	☐ S ☐ I ☐ R	
		Ciprofloxacin	|___|___|	☐ S ☐ I ☐ R	
		Nalidixic acid	|___|___|	☐ S ☐ I ☐ R	
		Pivemicellinam	|___|___|	☐ S ☐ I ☐ R	
		Trimethoprim/ sulfamethoxazole	|___|___|	☐ S ☐ I ☐ R	

11.	Azithromycin MIC *(if zone size is not interpretable)* |___|___|___|.|___|___|___| ☐ Not applicable
12.	Date 1st isolate was placed in minus 80 freezer: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of recovery *(Q6)*
13.	Time 1st isolate was placed in minus 80 freezer: |___|___| : |___|___| *(hh : min, 24:00 hr)*

Isolate 2

14.	Specimen ID of **2nd unique** isolate: _____ ☐ Not applicable
15.	*Shigella* serogroup:

☐ *S. dysenteriae*	☐ *S. flexneri*	☐ *S. boydii*	☐ *S. sonnei*	☐ <u>Undetermined</u>

S. flexneri serotype:

☐ 1a	☐ 1b	☐ 1d	☐ 2a	☐ 2b
☐ 3a	☐ 3b	☐ 4a	☐ 4b	☐ 5a
☐ 5b	☐ 6	☐ X	☐ Y	☐ Non-typable

☐ Other *(specify)*:_____

16.	Date of 2nd unique isolate recovery: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
17.	Time of 2nd unique isolate recovery: |___|___| : |___|___| *(hh : min, 24:00 hr)*
18.	Date of AST test on 2nd unique isolate: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of recovery *(Q16)*
19.	Time of AST test on 2nd unique isolate: |___|___| : |___|___| *(hh : min, 24:00 hr)*
20.	Antibiotic susceptibility testing:

	Antibiotic	Zone (mm)	MIC	Interpretation
	Ampicillin	|___|___|	☐ S ☐ I ☐ R	
	Azithromycin	|___|___|	☐ S ☐ I ☐ R	☐ Not interpretable *(obtain MIC)*
	Ceftriaxone	|___|___|	☐ S ☐ I ☐ R	
	Ciprofloxacin	|___|___|	☐ S ☐ I ☐ R	
	Nalidixic acid	|___|___|	☐ S ☐ I ☐ R	
	Pivemicellinam	|___|___|	☐ S ☐ I ☐ R	

		Trimethoprim/ sulfamethoxazole	|___|___|	☐ S ☐ I ☐ R	
	21.	Azithromycin MIC *(if zone size is not interpretable)* |___|___|___|.|___|___|___| ☐ Not applicable			
	22.	Date 2ⁿᵈ isolate was placed in minus 80 freezer: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)* ☐ Same as date of recovery *(Q16)*			
	23.	Time 2ⁿᵈ was placed in minus 80 freezer: |___|___| : |___|___| *(hh : min, 24:00 hr)*			
C.	**FORM COMPLETION**				
	24.	ID of person completing this form: |___|___|___|	Date form completed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*		
	25.	ID of person reviewing this form: |___|___|___|	Date form reviewed: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*		
	26.	ID of person entering this form: |___|___|___|	Date form entered: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*		
	27.	ID of person conducting data verification: |___|___|___|	Date of data verification: |__|__| - |__|__| - | 2 | 0 |__|__| *(dd-mm-yyyy)*		

Appendix: *print out and complete this form for every nth isolate if >2 isolates recovered*

Isolate number: _____

Specimen ID of isolate: _____ ☐ Not applicable

From which media was the isolate grown:

☐ Modified BGS

☐ Cary-Blair

☐ Both

Shigella serogroup:

☐ *S. dysenteriae* ☐ *S. flexneri* ☐ *S. boydii* ☐ *S. sonnei* ☐ Undetermined

S. flexneri serotype:

☐ 1a	☐ 1b	☐ 1d	☐ 2a	☐ 2b
☐ 3a	☐ 3b	☐ 4a	☐ 4b	☐ 5a
☐ 5b	☐ 6	☐ X	☐ Y	☐ Non-typable

☐ Other *(specify)*:_____

Date of isolate recovery: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*

Time of isolate recovery: |___|___| : |___|___| *(hh : min, 24:00 hr)*

Date of AST test on isolate: |___|___| - |___|___| - | 2 | 0 |___|___| *(dd-mm-yyyy)*
☐ Same as date of recovery

Time of AST test on isolate: |___|___| : |___|___| *(hh : min, 24:00 hr)*

Antibiotic susceptibility testing:

Antibiotic	Zone (mm)	MIC	Interpretation
Ampicillin	|___|___|	☐ S ☐ I ☐ R	
Azithromycin	|___|___|	☐ S ☐ I ☐ R	☐ Not interpretable
Ceftriaxone	|___|___|	☐ S ☐ I ☐ R	
Ciprofloxacin	|___|___|	☐ S ☐ I ☐ R	
Nalidixic acid	|___|___|	☐ S ☐ I ☐ R	
Pivemicellinam	|___|___|	☐ S ☐ I ☐ R	
Trimethoprim/ sulfamethoxazole	|___|___|	☐ S ☐ I ☐ R	

Azithromycin MIC *(if zone size is not interpretable)* |___|___|___|.|___|___|___| ☐ Not applicable

Date isolate was placed in minus 80 freezer: |___|___| - |___|___| - | 2 | 0 |___|___|
(dd-mm-yyyy) ☐ Same as date of recovery

Time isolate was placed in minus 80 freezer: |___|___| : |___|___| *(hh : min, 24:00 hr)*