Typhoid Fever Surveillance in Africa Program (TSAP)

Working Protocol ID: IVI-TSAP-01 v1.8

INTERNATIONAL VACCINE INSTITUTE
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AST</td>
<td>Antimicrobial susceptibility test</td>
</tr>
<tr>
<td>BNI</td>
<td>Bernhard Nocht Institute for Tropical Medicine, Hamburg, Germany</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention, Atlanta, USA</td>
</tr>
<tr>
<td>CRF</td>
<td>Case report form</td>
</tr>
<tr>
<td>EDTA</td>
<td>Ethylenediaminetetraacetic acid</td>
</tr>
<tr>
<td>ESBL</td>
<td>Extended spectrum beta lactamases</td>
</tr>
<tr>
<td>GCP</td>
<td>Good clinical practice</td>
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<tr>
<td>HCUS</td>
<td>Health care utilization survey</td>
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<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<td>IVI</td>
<td>International Vaccine Institute</td>
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<tr>
<td>LF</td>
<td>Laboratory form</td>
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<tr>
<td>MIC</td>
<td>Minimum inhibitory concentration</td>
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<tr>
<td>NICD</td>
<td>National Institute for Communicable Diseases, Johannesburg, South Africa</td>
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<tr>
<td>SOP</td>
<td>Standard operating procedure</td>
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<tr>
<td>TF</td>
<td>Typhoid fever</td>
</tr>
<tr>
<td>TSAP</td>
<td>Typhoid Fever Surveillance in Africa Program</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Preface

More detailed data on typhoid fever (TF) epidemiology, particularly in developing countries, are urgently needed. In November 2007, the World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE) on immunization endorsed the utilization of TF vaccines in regions where the disease is highly endemic, and recommended the strengthening of surveillance systems for TF, including sentinel site surveillance, and the development of reliable and appropriate diagnostics for use in developing countries. The WHO Position Paper on the use of TF vaccines states that decisions for use of typhoid vaccines should be based upon knowledge of the local epidemiological situation. It was noted that there is a need for more epidemiological data from African countries [1].

This protocol was developed by the International Vaccine Institute (IVI) in cooperation with scientists from multiple country sites with ongoing TF surveillance (Ghana, Kenya, South Africa, Tanzania), the United States Centers for Disease Control and Prevention (CDC), and the Bernhard Nocht Institute for Tropical Medicine (BNI) to establish standardized TF surveillance in multiple sites across sub-Saharan Africa. It describes project design and implementation of hospital-based surveillance of TF with a focus on Africa. This document contains standardized criteria for site selection, data management and collection, laboratory procedures and methodologies, and determination of catchment areas. This protocol also indicates the data and forms, which the participating sites will provide to the TSAP team at the IVI.

Acknowledgements

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I. Background and objectives

A. Background

Typhoid fever (TF), a systemic infection caused by *Salmonella enterica* serovar Typhi (S. Typhi), remains a problem of considerable concern in many low-income countries [1,2]. S. Typhi causes approximately 22 million symptomatic infections and 220,000 fatalities worldwide per year [3, 4]. Humans are known to be the only known hosts and natural reservoir of S. Typhi, and the disease occurs mainly in settings of poor hygiene caused by lack of adequate water supplies and unsafe environmental sanitation conditions.

Most data on morbidity and mortality associated with TF are from Asia, not Africa, which has had no comprehensive surveys on the burden of TF. To date, estimates of TF incidence rates are based on data from placebo arms of vaccine trials in Egypt and South Africa [5-8]. In 1990, a study from The Gambia reported 18% S. Typhi in 246 positive blood cultures [9] and in 1993 a study in the Ivory Coast revealed that bacteremia, including *S. enteriditis*, was more frequent among HIV-positive than in HIV-negative patients [10]. Although some studies in Ghana have addressed the epidemiology of TF [11-14], with the exception of a recent study [15], none has estimated the incidence of TF in the African setting due to lack of information about the health seeking behavior of ill persons and a well-defined coverage area for a hospital as a reliable denominator of incidence. Consistent data on TF incidence are urgently needed to identify endemic areas for vaccination trials and, subsequently, to implement vaccination strategies.

The uncertain distribution of TF in Africa currently limits the ability of national leaders to make evidence-based public health decisions regarding the deployment of TF vaccines. In the foreseeable future, other major causes of febrile illness (e.g., *Streptococcus pneumoniae* and *Haemophilus influenzae* type b) will likely decline due to the introduction of vaccines against these pathogens. Similarly, malaria now appears to be declining in many areas of sub-Saharan Africa [16-19]. Therefore, the relative importance of invasive *Salmonella* infections in Africa is likely to increase in the next few years.

The lack of credible data on TF in many African countries has also limited awareness of the disease among clinical and public health providers. Fever-related diseases are mostly diagnosed solely on the basis of clinical signs and symptoms. As a result, TF may be indistinguishable from other serious infections common to Africa such as malaria [20].
Fatal S. Typhi infections are frequently and incorrectly attributed to malaria due to the lack of widespread availability of bacteriological testing [14]. As a result of the non-specific clinical presentation of TF, definitive diagnosis depends on the isolation of S. Typhi from blood or bone marrow [21]. Bone marrow culture has a sensitivity of approximately 80%-95% [22] but is not an acceptable or practical standard procedure, leaving blood culture as the preferable diagnostic method. Presently, blood culture followed by microbiological identification is considered to be the practical gold standard diagnostic test for TF. Diagnostics based on serology, antigen detection, or DNA are available but lack sufficient sensitivity and specificity. The Widal test and others have very low specificity and offer virtually no diagnostic assistance in adolescents and adults because of the high prevalence of antibodies in healthy individuals over 10 years of age in endemic areas [23].

During the first week of illness, 60-80% of TF patients not previously treated with antimicrobials have the causative organism in their bloodstream [24]. However, even with good laboratory facilities, the organism cannot always be isolated because of antimicrobial use, insufficient volume of blood collected, or timing of specimen collection in relation to onset of disease. Historically, blood culture sensitivity for S. Typhi has ranged from 60% to 80% [22]. However, because factors that might impact the isolation of S. Typhi from blood are not routinely reported, Crump et al. chose to apply a conservative blood culture sensitivity of 50% to all conducted studies [3]. Gilman et al. reported that in a study looking at the isolation of S. Typhi, the sensitivity of bone-marrow culture was 90% and blood culture 40% [25].

Blood culture facilities are often limited to major hospitals in many developing countries, and consequently, access to appropriate diagnostic facilities is a limiting factor for typhoid diagnosis and surveillance. Therefore, a multi-country standardized TF surveillance program in sub-Saharan Africa is urgently needed.

**B. Objectives and expected outcomes**

The project will be implemented in collaboration with scientists and technical agencies (e.g., WHO, U.S. CDC, Institute Pasteur, and BNI). The objectives of this project are to establish sustainable surveillance for typhoid and paratyphoid fever and invasive non-typhoidal salmonellosis (NTS) by developing standardized guidelines for enteric fever surveillance in sub-Saharan Africa, by building capacity and leadership at each sentinel surveillance site, and by creating links with collaborators, governments, and other relevant partners. Once in place, the project should generate comparable enteric fever surveillance data in Africa that will be the basis for implementation of evidence-based public health interventions including immunization and the measurement and evaluation of vaccine impact following vaccine introduction.

**Objective**
To obtain comparable incidence data of enteric fever including invasive non-typhoidal *Salmonella* (NTS) infections in sub-Saharan Africa through standardized surveillance in multiple countries.

**Expected outcomes**

1. Standardization of surveillance criteria throughout all sentinel sites, including
   a. Inclusion criteria
   b. Appropriate diagnostic procedures in hospitals and laboratories
2. Standardization of data on enteric fever/NTS burden for all sentinel field sites in order to assess
   a. The burden of disease for multiple sites throughout sub-Saharan Africa.
   b. The distribution of antimicrobial resistance among *S. Typhi* and *S. Paratyphi* strains
3. Identification of risk factors associated with severe TF disease by
   a. Sex and age
   b. Region and season
   c. Clinical parameters
4. Improvement of current guidelines for empirical treatment in sub-Saharan Africa
5. Identification and definition of the population under surveillance (catchment area) to estimate the rate of enteric fever/NTS.

**II. Project design and implementation**

**A. Site selection criteria**

Within TSAP, two types of enteric fever surveillance site can be distinguished, namely those with existing febrile disease surveillance called Group 1 Sites (G1S) and those without existing febrile disease surveillance called Group 2 Sites (G2S). Both types of surveillance sites are covered by this protocol. Sites are located in sub-Saharan Africa and have existing evidence of enteric fever burden within the catchment area of the institution, expressed interest in participation in this program, and have the ability for sustainability (e.g., backed by their ministries), as well as the potential to develop enteric fever control and prevention policies and be early adopters of the typhoid vaccine. G1S have capacity (including laboratory capacity) to conduct febrile illness surveillance with the ability to isolate and identify *Salmonella* spp. from blood and stool cultures. G2S will be assisted by the program to develop febrile illness surveillance capacity. One site per country was selected using a standardized algorithm that evaluated the suitability of each site with regard to: i) ability to implement surveillance, ii) laboratory capacities that can be scaled up to include automated blood culture, iii) likelihood of determining a well-defined catchment population, and iv) anticipated burden of enteric fever/NTS based on available but non-standardized reports. Exception is the Kibera site in Nairobi, Kenya, where surveillance will be population-based. The difference to hospital-based settings, where the catchment
population of the respective health-care facility needs to be assessed using census and health-care utilization services (HCUS), the population of the population-based setting Kibera/Kenya is well-defined. This is part of an United States Centers for Disease Control/Kenya Medical Research Institute project and active home-visits are conducted in every household on a weekly basis and febrile patients will be encouraged to visit the local health care facility. The Kenyan CDC/KEMRI project has been approved by US CDC and local ethical review committees and TSAP will only collect data from their existing surveillance database. IVI IRB has been informed about this and provided “Acknowledgment of Receipt” on 2011/01/21.

Although sites will be classified as urban or rural, differences in national characteristics will not allow a single definition applicable to all countries. As a general guide, a site can be considered urban when the core of the area has a population density of at least 1,000 persons/mi² (386 persons/km²) and surrounding areas an overall density of at least 500 persons/mi² (173 persons/km²). All other sites can be considered rural [27]. A secondary analysis may be performed, applying local definitions of ‘urban’ and ‘rural’ [28].

B. Population serviced by sentinel health-care facility

In order to determine comparable incidences among participating study sites, exact data on the study health care facility’s catchment population need to be assessed. Contemporary hospital records (less than five years old) and census data will be used to estimate the population of the catchment area and to identify areas of from which febrile patients originate. The Health-Care Utilization Survey (HCUS, Appendix A), is needed to determine the health-seeking behavior of residents of the catchment area of the study health care facility. The combination of catchment population obtained from health-care facilities records or most recent census with data derived through the HCUS will help provide an estimate for the denominator in incidence calculations. Participants living outside of the catchment area will be excluded from the HCUS. Gender and age-stratified incidence rates will be calculated using the results of the HCUS.

C. Study subjects and inclusion criteria

All inpatients, regardless of age, admitted to the study hospital(s) with current fever or a subjective history of fever within the previous 72 hours will be considered for inclusion in the study.

All outpatients with current fever, regardless of age, who presents to the study hospital(s) will be enrolled. The enrollment of outpatients is limited by the capacity of the automated blood culturing machine(s) in place and the included number of inpatients. The maximum number of outpatients to be enrolled will be calculated as follows: (capacity of blood culturing machine) – (number of inpatients
enrolled. An algorithm to limit the enrollment of outpatients with current fever will be developed in close collaboration with IVI scientists and is site-specific.

Study subjects (in- and outpatients) will be eligible for participation if they meet the following criteria:

- The subject or his or her legal guardian provides informed consent.
- **Inpatients:**
  - The subject has a history of subjective fever within 72 hours or a tympanic temperature of ≥38°C (preferred mode of measurement) or an axillary temperature of >37.5°C or a rectal temperature of ≥38°C at admission.
- **Out-patients:**
  - The subject has a tympanic temperature of ≥38°C (preferred mode of measurement) or an axillary temperature of >37.5°C or a rectal temperature of ≥38°C at the moment of visiting medical facility.

**D. Enrollment procedures**

a) Screening, informed consent, and pre-test counseling

All patients will be assessed for need of emergency treatment and resuscitation in line with standard national guidelines for emergency triage and treatment by local staff. The following procedures will be performed by study staff during screening for determination of eligibility:

- Explanation of the study purpose and written informed consent process using two informed consent forms (ICFs), namely:
  - ICF1 for sites where no HIV testing is conducted.
  - ICF2 for sites where HIV testing is conducted although not specifically for TSAP (Appendix G).
- Written informed consent obtained
- Determination of the participant’s identity and area of residence; assignment of screening identification.

b) Clinical history and physical examination

Upon enrollment into the study a health-care provider will complete the recruitment form (Appendix C); assess basic clinical parameters and collect information on disease history, signs and symptoms, age and sex of the participant, and place of residence and record these on a standardized case report form (CRF; Appendix D). Medical care will be provided to patients in accordance with local treatment guidelines. Health-care personnel will take standardized clinical history, collect standardized data, and perform physical examinations.

c) Exposure measures
The main exposure variables to be measured are as follows: 1) pre-treatment of study participants with antimicrobial agents; 2) nutritional status of children <5 years old (weight, height), and 3) history of illness (fever, diarrhea, respiratory tract infection) during the prior three weeks. Clinical history, signs and symptoms, fever, body temperature will be assessed for all patients and recorded.

d) Discharge diagnosis
Following discharge, case notes and other available data will be reviewed by local staff, including a pediatrician and laboratory scientist in order to determine the most accurate discharge diagnosis, which will be recorded in the CRF (Appendix D).

e) Results dissemination
Results of all critical laboratory tests (e.g., blood culture, malaria film, antimicrobial susceptibility tests) will be communicated immediately to the medical team by a study team member. For most outpatients and many inpatients results will not be available to affect clinical care, but data will improve care of future patients. Inpatient care will be delivered in accordance with local guidelines and regulations.

f) Risk factor assessment
Patients identified with Salmonella infections (S. Typhi, S. Paratyphi and non-typhoidal Salmonella) will be visited or interviewed after discharge to assess risk factors (Appendix F). In all sites a case-control study matched by age, sex and neighborhood will be conducted and socioeconomic and exposure data will be univariably compared between the enteric fever and NTS infections by calculating the corresponding odds ratios with their p-values and their 95% confidence interval. Sites may decide to conduct risk factor assessment for other etiologies, e.g. Streptococcus pneumoniae and Staphylococcus aureus. If time and work capacity allows, some sites will be selected to conduct a matched case-control study to assess risk factors. A separate protocol will be provided to those sites.

E. Laboratory procedures

a. Sample collection. If inclusion criteria are met, samples will be collected immediately after a subject is enrolled and prior to treatment and sent to a laboratory together with the laboratory form (LF, Appendix E). Samples will be tested as follows:
   - Whole blood for blood culture, dry spot tests, and malaria slide preparation
   - EDTA-treated blood for DNA extraction and serology
   - Whole blood for bed side tests

b. Blood volumes. Blood volumes needed for blood culture and other tests for children and adults are
summarized in Table 1. A minimum of 1 ml and 1.5 ml of blood will be drawn from children (using butterfly) and adults, respectively, into a sterile syringe immediately after admission. Reasonable efforts will be made to obtain the target volume of blood depending on the subject’s distress level. For children, blood volume drawn will be determined by the child’s weight: ≤4 kg, 1 ml; 4 – 14 kg, ≤3 ml; 14 – 25 kg, ≤4.5 ml; >25 kg, ≤11 ml.

Table 1: Blood volumes required for culture and others tests for children and adults

<table>
<thead>
<tr>
<th>Volume obtained</th>
<th>Bottle type*</th>
<th>Blood culture (aerobic)</th>
<th>EDTA-tube</th>
<th>Bedside tests: Glucose, Hb, rapid tests, malaria slide, dry spot methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 ml</td>
<td>NA</td>
<td>Excluded from study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - 2 ml</td>
<td>P</td>
<td>1 ml</td>
<td>Remaining volume</td>
<td>1 drop / test</td>
</tr>
<tr>
<td>2 – 4.5 ml</td>
<td>P</td>
<td>Remaining volume</td>
<td>0.5 ml</td>
<td>1 drop / test</td>
</tr>
</tbody>
</table>

*NA, not applicable; P, pediatric bottle; A, adult bottle

<table>
<thead>
<tr>
<th>Volume obtained</th>
<th>Bottle type*</th>
<th>Blood culture (aerobic)</th>
<th>EDTA-tube</th>
<th>Bedside tests: Glucose, Hb, rapid test, malaria slide, dry spot methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1.5 ml</td>
<td>NA</td>
<td>Excluded from study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5 – 4.5 ml</td>
<td>P/A#</td>
<td>Remaining volume</td>
<td>0.5 ml</td>
<td>1 drop / test</td>
</tr>
<tr>
<td>4.5 – 8 ml</td>
<td>A</td>
<td>Remaining volume</td>
<td>0.5 ml</td>
<td>1 drop / test</td>
</tr>
<tr>
<td>8 – 11 ml</td>
<td>A</td>
<td>Remaining volume</td>
<td>1 ml</td>
<td>1 drop / test</td>
</tr>
</tbody>
</table>

*NA, not applicable; P, pediatric bottle; A, adult bottle
# Sites using closed system should use “A”, sites using a syringe for blood collection should use “P”

c. Blood culture. Blood will be collected using sterile techniques. For children up to 25kg (50lbs), pediatric bottles will be filled with a minimum of 1 ml blood (Table 1). Bottles will be weighed before and after blood collection to estimate the volume of blood inserted and blood volume will be recorded. At the laboratory, blood culture bottles will be assessed by appropriate automated blood culture instrument. Time to positivity will be recorded. Broth from positive bottles will be examined by direct methods (e.g., Gram stain). For identification of Salmonella spp. as well as other bacteria the Analytical Profile Index 20E (API-20E) and API-NH following TSAP laboratory SOPs will be used. Further identification will follow standard procedures for the identification of Salmonella.
spp. as recommended by the WHO and CDC [29]. Results of direct examination of broth and identity of all isolates from positive bottles found will be recorded in the laboratory form (Appendix E) and reported to clinical staff caring for patients (after excluding contaminants). Rates of contamination will be used to determine blood culture performance at the sites. All isolates will be frozen at -70°C using standardized cryotubes and subsequently evaluated by additional ASTs such as assessment of minimum inhibitory concentration (MIC) of appropriate antibiotics and extended-spectrum beta lactamases (ESBL) and genotyping. Plasma obtained from EDTA-treated blood will be frozen at -20°C for subsequent bacterial DNA extraction.

d. Antimicrobial susceptibility. Antimicrobial resistance testing will be conducted on-site using the Kirby-Bauer disk diffusion method, if the assay is well-established and standardized. The assay will be conducted at the reference laboratory at the National Institute for Communicable Diseases (NICD), in Johannesburg, South Africa.

e. Sample storage, shipment and reference laboratories. Samples from positive cultures as well as collected EDTA tubes (for culture-negative cases) and dry spot filter paper will be sent for confirmation and other tests as required to the reference laboratory at the National Institute for Communicable Diseases (NICD), Johannesburg, South Africa where the TSAP specimen repository will be established. At the Bernhard Nocht Institute for Tropical Medicine (BNI), Hamburg, Germany, further analyses, such as genotyping (of Salmonella isolates), confirmation of diagnosis, phylogenetics, and other test will be conducted as required. All samples sent to reference laboratories will be coded to prevent identification of the study subject. A separate standard operating procedure (SOP) will be developed for sample shipment.

f. Laboratory standardization. In order to standardize participating laboratories, all sites will be visited regularly and training courses will be provided. Reference samples will be provided to field sites to allow for a detailed assessment of laboratory procedures. Laboratory standardization will be described in separate SOP documents.

F. Ethical considerations

This protocol will undergo review by both the IVI Institutional Review Board and by local site-specific boards.

The specific procedures required for this study entail blood sampling by venipuncture or heel/finger prick. The staff will observe strict aseptic techniques and ensure subject safety. All waste will be disposed of as described in SOP protocols.
During and after the project, all data on subjects will be kept in strict confidence and will not be disclosed to a third party by any member of the study team. To achieve this, access to project computers will be restricted by the use of passwords and study data forms will be kept in a locked location. Confidential information stored on computers and paper forms will only be made available to co-investigators.
G. Potential direct benefits

For most outpatients and many inpatients results will not be available to affect clinical care, but data will improve care of future patients for enteric fever, NTS and other bacterial enteric pathogens. Additionally, findings from this program will contribute to public health knowledge and decision-making related to febrile illnesses in sub-Saharan Africa and provide better insight into the true incidence and prevalence of TF/NTS and other febrile illnesses in the area. Establishment of a sustainable surveillance and laboratory infrastructure will allow for better understanding of enteric fever epidemiology, which has not yet been fully described in this part of the world. Direct benefits include the opportunity to design a strategic approach to reduce the burden of invasive *Salmonella* infections by means of public health interventions, including vaccination, which will benefit the people of sub-Saharan Africa.

H. Site reporting to the IVI TSAP team

At a minimum, participating sites will share the following information and documents with the IVI:

- Data and other documents or sources obtained during estimation of catchment population.
- Dataset obtained during the conduct of HCUS Survey.
- Data recorded in the CRF and LF of study participants.
- All tests conducted in the laboratory, related to and relevant to the project, and their results including provision of specimens for additional testing at the reference laboratories and storage of specimens in the repository.
- All results of laboratory proficiency tests.
- If in mutual agreement, any other data or test results relevant to the TSAP.

I. Data management

Data sets from participating countries will be combined into a single platform for management and analysis at the IVI. A relational database will be designed in which the data will be uploaded into several tables. The relational database will allow data tables to be related by common variables. The goal of the relational database design is to generate a set of schemes that will allow the team to store information without redundancy and to retrieve information easily and accurately. Exploratory data analysis will be performed to identify all types of data errors, for example, form sequence number, duplication of data, range error, inconsistencies, and data linkage error. A monthly data summary (descriptive statistics of critical variables) will be produced. The local investigator and the IVI team will develop the system and manage the database.
The database management system will comply with the principles that govern biomedical research involving human subjects, the Declaration of Helsinki, and Good Clinical Practice (GCP). It will ensure participant confidentiality by not allowing users to link names with the history of medical events of the study participants. Access to the electronic database and hard-copy data will be restricted to authorized senior study personnel only.

All data documents, including systems documents, forms, logs of data flow, error outputs, error resolutions, and the process of data cleaning, will be kept in a locked file cabinet for future reference. Necessary measures will be taken so that forms are protected from hazards such as rot, insects, and theft. Since a database could be damaged or lost in many ways, backup files will be kept, and backups will be made regularly onto external storage devices. Multiple backups of at least the last three generations (an update in the database creates a new generation of database) of the database will be kept since errors found in a recent data set might require reviewing a previous copy of it. One backup copy will be kept in a geographically separate location. The logs of every backup will be maintained in a logbook that contains the database name, name of the person who conducted the backup, backup date, media name, and location of the media.

The study database will be the property of the local site and the IVI. Access to the database will be restricted to study personnel in order to safeguard the privacy of the study participants and to protect confidential and proprietary data. However, after reporting the primary objectives of the study, some data may be shared with other interested users under restricted conditions if at least one user is a member of the study personnel. Priority will be given to users who can provide interesting study concepts and a constructive data analysis plan. Any subsequent reporting of the shared data will require approval from the local site and the IVI.

**Statistical analyses**

The primary analysis of the study will be an estimation of the disease burden of enteric fever and other non-typhoidal *Salmonella* infections in sub-Saharan Africa. The numerator for the sentinel incidence rates will be determined by the number of blood-culture confirmed infections at the surveillance health care facility times five, since we are enrolling every fifth patient. The denominator will be obtained from the assessment of the catchment population and adjusted with the results of the HCUS (Appendix A). Incidence rates will be age-stratified. Risk factors such as age, gender, and treatment prior to admission will be assessed using multiple logistic regression. The possibility of making diagnoses based solely on clinical findings will be analyzed using multiple logistic regression analysis. A correlation analysis will try to assess seasonal patterns and the incidence of enteric fever/NTS. Antimicrobial susceptibility test-patterns will be analyzed in descriptive manner. All data will be analyzed using SAS (SAS Institute, North...
**J. Publication policy**

The IVI will prepare a summary manuscript reporting the enteric fever/NTS surveillance data from a multi-country perspective. The first author of the summary manuscript will be the person who has provided day-to-day coordination of the entire project; the last author will be the person who has provided scientific oversight of the project and who has taken the responsibility for the management of the entire project. Other authorships and their order will be determined based on individual contributions to the project.

Following publication of this initial article, individual sites, in collaboration with IVI epidemiologists, are encouraged to publish separate country-specific articles with IVI co-authorship. The project’s principal investigator and project coordinator will discuss publication scenarios with site representatives, help identify the lead scientists who will be responsible for drafting of the manuscript, and provide scientific oversight for each TSAP-related publication. Authorships and their order will be determined based on individual contributions to the project.

**M. Monitoring and evaluation of project progress**

The IVI will monitor project progress against the target outputs that will include the following:

- **Development of detailed work plans and timelines for each program component.** The IVI coordinators will work with country collaborators to develop and/or adjust study procedures.

- **Regular monitoring of field activities.** Monitoring of hospital activities will be provided by IVI coordinators who will work with country collaborators to monitor adherence to protocols and timelines for all aspects of the project, including adherence to GCP; recordkeeping; and laboratory testing. Additional monitoring will be performed by IVI’s Deputy Director General and Director General, as well as the Steering Committee of TSAP and the IVI Scientific Advisory Group, which will meet annually and report to the IVI Board of Trustees.

- **Quarterly review meetings.** The IVI’s Deputy Director General and IVI coordinators will review progress against the work plans and timelines for each quarter. They will also review the study progress, discuss problems encountered or anticipated, and possible solutions, adjust the work plan, as needed, and discuss planned activities for the next quarter.
References


28. CBER. http://cber.cba.ua.edu/asdc/urban_rural.html

**List of appendices**

Appendix A: Health Care Utilization Survey
   - Sub-appendix A1: Informed consent form
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Appendix B: Informed Consent Form 1

Appendix C: Recruitment Form

Appendix D: Case Report Form

Appendix E: Laboratory Form

Appendix F: Risk Factors Assessment

Appendix G: Informed Consent Form 2

Appendix H: Improvement of Febrile Disease Diagnostics through Capacity-Building in Africa (FEDIA)

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TSAP Appendix A: Health Care Utilization Survey

Acknowledgement
Appendix A of the Typhoid Fever Surveillance in Africa Program (TSAP) protocol was prepared in accordance to the WHO “Generic protocols for (i) hospital-based surveillance to estimate the burden of rotavirus gastroenteritis in children and (ii) a community-based survey on utilization of health care services for gastroenteritis in children and adapted accordingly (Source: http://www.who.int/vaccines-documents/DocsPDF02/www698.pdf).

Abbreviations
GPS  Global Positioning System
HCF  Health Care Facility
HCUS  Health Care Utilization Survey
SOP  Standard Operating Procedure
TSAP  Typhoid Fever Surveillance in Africa Program

Background
Appendix A shall be applied to several TSAP-participating countries. In order to determine comparable incidences among participating study sites, exact data on the study health care facility (HCF)’s catchment population need to be assessed.

In order to assess the catchment population, following steps need to be followed:

1) Contemporary study HCF records (less than five years old) and census data will be used to estimate the catchment area as well as the population of the catchment area.
2) The cluster sampling procedure will be applied to divide the catchment area into 30 clusters.
3) The standard formula of Henderson & Sundaresan (1982) will be used to calculate the number of interviews/ household visits, which need to be conducted in the catchment area.
4) The HCUS questionnaire will be used as data collection tool to determine the health-seeking behavior of residents in the catchment area of the study HCF.
5) The combination of population data obtained from HCF records or most recent census together with data derived through the HCUS will provide an estimate of the catchment population, which is needed as denominator for age- and gender-stratified incidence calculations.

Objectives
Objectives of the HCUS are:

1) To assess the catchment population of the study HCF, used as denominator for TF incidence calculations, and to adjust for residents not attending the study HCF in the catchment area.
2) To assess the appropriateness of the selected study HCF for febrile illness surveillance.
3) To collect data on the socio-economic status of the population in the catchment area.

Study design

1) Definitions
   Household: A household consists of a person or a group of related or unrelated persons who live together in the same dwelling unit, who acknowledge one male or female adult as the head of the household, who share the same housekeeping arrangements, who are considered to constitute one
unit, and who provide themselves with food or other essentials for living. A household may be located in a housing unit or in a set of collective living quarters such as a boarding house, a hotel, or a camp, may comprise the administrative personnel in an institution, or may be homeless. Collective living arrangements will not be considered as households.

**Respondent:**
The respondent is a person at the age of the country-specific legal age of majority who is a decision maker in a household and decides for other members of the same household which HCF to visit in case of e.g. febrile illness.

**Catchment area:** The catchment area is a certain area surrounding the study HCF selected for surveillance of febrile illness.

**Catchment population:** The catchment population of a study HCF is the population that seeks health care at this particular study HCF in case of febrile illness, and should be demographically well defined and geographically distinct from other HCFs. Ideally, the catchment population is stable during the surveillance period. In case the population is not stable, patterns of immigration, emigration, births, and mortality need to be considered.

2) **Methodology**

**Cluster sampling procedure and sample size calculation**
The catchment area may be defined administratively and geographically using a map to show administrative units and geographical boundaries. Where the catchment area of the study HCF in not clearly defined, factors such as the distance from the study HCF or the addresses on the admission records of patients admitted to the proposed study HCF will be considered. For urban and semi-urban settings, the catchment area of the study HCF may be composed of administrative units such as districts, whereas for rural settings, administrative units may be villages.

Ideally, 100% of inhabitants in the catchment area have good access to medical care at the selected study HCF and seek care at the study HCF in case of febrile illness. However, if the number of individuals in the catchment area who seek care at the study HCF is too low, consideration should be given to the enrollment of an additional HCF(s) in this area or the use of another population. An investigation could be conducted to assess the health seeking behavior of individuals in case of febrile illness at other HCFs in the study area.

The cluster sampling procedure is applied to divide the entire catchment area into 30 clusters, which are allocated proportionally to the population of administrative units in the catchment area. In order to estimate the population in the catchment area as well as of administrative units in the catchment area, contemporary HCFs’s records (less than five years old) and census data will be used. To make sure that the relative size of the clusters is approximately correct, only the most recent population data need to be used.

The number of households to be visited during the HCUS is calculated based on the standard formula of Henderson & Sundaresan (1982) and following assumptions: an alpha error of 0.05, a precision of 5%, a design effect of at least 2, and the proportion p of individuals expected to be treated with febrile illness at the HCF. The design effect is an adjustment factor for the cluster sampling procedure. Households, which will be visited during the HCUS, are randomly selected.
Since the TSAP-participating surveillance sites vary a lot, the determination of the catchment area and the application of the cluster sampling procedure as well as the selection procedure of households will be subject to careful considerations and discussions among IVI scientists and local collaborators.

**Study subjects and enrollment criteria**

All residents living in the catchment area will be considered for inclusion in the survey. Individuals with an unknown residence or residence outside of the catchment area will be excluded from the HCUS. The person who will provide written informed consent and answer the questions of the HCUS questionnaire, the respondent, has to be ≥ 15 years of age and be a resident in the catchment area.

The questionnaire (appendix 2) will always be administered to the adult decision-maker of the visited household. If the adult decision-maker is unavailable, an appointment for a return visit will be made and the interviewer will proceed to the next household. If the adult decision-maker cannot be reached when two further visits are made, the household will be replaced.

Enrollment of the respondent includes following steps:

- Determination of the respondent’s identity, age and area of residence.
- Explanation of the purpose of the survey to the respondent.
- Obtainment of written informed consent from the respondent using the informed consent form (Sub-appendix A1).
- Upon enrollment of the respondent, the interviewer will conduct the HCUS questionnaire (Sub-appendix A2).
- Upon completion of the questionnaire, the interviewer will thank the respondent and continue with the next eligible household.

**Data collection**

As data collection tool, a piloted, standardized, structured questionnaire with coded, open- and closed-ended questions (appendix 2) is administered once to the decision-maker of a household. For the purpose of comparison among TSAP-participating sites, the main elements of the questionnaire should not be modified. The questionnaire is divided into three major sections: (A) measurement of Global Positioning System (GPS) coordinates of each household and general information about the respondent, (B) health seeking behavior of members of the household, and (C) socio-economic information about the population in the catchment area. The exact procedure for completion of the questionnaire and measurement of GPS coordinates will be explained in a separate Standard Operating Procedure (SOP) and trained by IVI scientists.

**Data management**

Data of the HCUS will be entered twice, checked for coherency and consistency, and analyzed considering the survey design using the software FoxPro in order to obtain denominator data for age- and gender-stratified incidences. This means that since the study design uses the cluster sampling procedure, the effect of the cluster design has to be factored into the sample size. The denominator, the catchment population of the study HCF, will be calculated using results of questions 11 and 14 of the HCUS questionnaire. Other data from the HCUS questionnaire will be analyzed to gain additional insights into factors related to health seeking behavior for various clinical signs, reasons for seeking care at the study HCF in case of febrile illness as well as quality of health care provision at the study HCF, and
socio-economic characteristics of the population in the catchment area. GPS coordinates of enrolled households as well as of selected HCF(s) will be geographically displayed using the software GIS ArcMap. To ensure participant confidentiality, names will not be linked to the completed questionnaires. Access to hard-copies and the electronic database will be restricted to authorized personnel only and be kept in a locked location, where they are protected from hazards. To avoid loss of data derived from the HCUS, at least one backup file will be made from the electronic database.

**Ethical considerations**

This protocol will undergo reviews by both, the IVI Institutional Review Board and site-specific local boards. During and after the survey, all data on survey subjects will be kept in strict confidence and will not be disclosed to a third party by any member of the survey team. Strict confidence will be achieved by using passwords for access to survey computers and storage of survey data forms in a locked location. Confidential information stored on computers and paper forms will only be made available to co-investigators and IVI staff directly involved in the conduct of the HCUS.

**Potential direct benefits**

There are no direct benefits for participants. Indirect benefits for participants and the general population are that information on health care seeking behavior learned from this survey will help provide exact information on disease burden of febrile, infectious febrile diseases in the survey area and will help decision-makers to decide on appropriate control measures for the population living in the survey area.

Sub-appendix A1: Informed consent form
Consent to participate in the Health Care Utilization Survey

Name of local Principal and Co-investigator: [add name]
Name of Organization: [add name]
Name of Sponsor: International Vaccine Institute

Introduction You are invited to participate in this Health Care Utilization Survey (HCUS) because you live in the study area where we are conducting a research study to investigate the burden of diseases that cause fever, or hot body. This consent form should be read by you/ to you carefully and you should take your time to make your decision to participate. Please ask the survey staff to explain any words or information that you do not understand. Further information about the survey, including the nature of the survey, risks, benefits and inconveniences are listed below. After the procedure of the survey has been fully explained to you and if you agree to participate, you will be asked to sign this consent form. If you would like, we can provide you a copy of this form. [add name of local Principal and co-investigator] in collaboration with the International Vaccine Institute in Seoul, South Korea, conducts this survey.

What is the reason for this survey? We are conducting this survey to find out which health care facility you, your family and neighbors visit in case of fever. This information will help estimate how common fever is in your community and to find better ways to treat and prevent fever.

What do I have to do if I decide to participate? If you agree to participate, we will ask you some questions about you and your family, such as what your name is, the age and gender of your family members, and the occupation, ethnic group and education of the head of your household. We will also ask which health care facility your family will/ would visit in case of fever and what your family does to get help if anyone in your family is sick. Finally, we will measure the geographic location of your household.

What is the duration of my participation? The survey interview will take approximately 15 to 20 minutes.

What are the risks of this survey? There are no risks for participants. Asking above mentioned questions may make you or family members feel uncomfortable. You can refuse to answer any question or take a break at any time. You may stop participating in this survey at any time.

Are there benefits of participating in this study? If you agree to participate in this survey, there are no direct benefits for you, your family and neighbors. Indirect benefits are that information from this survey will help provide exact information on diseases which cause fever and lead to better understanding of how to treat and prevent fever for people in your community.

Will my information be kept confidential? All survey records that identify you and your family will be kept confidential. All information collected will be given code numbers and no name will be recorded. All paper files will be locked safely and computerized files will be password-protected; these files will only be accessible to authorized staff. Your name or any identifier will not be used in any publication or reports from this survey. Information that we collect about you and your family will only be shared with authorized members of the survey such as officials from ethics committees.

What are the costs? There are no costs for participants of this survey.

What about compensation? You will not be compensated for your participation in this survey.

What about my rights to decline participation or withdraw from the study? Participation in this survey is voluntary and you are free to refuse to participate in the survey or you can withdraw your consent at any time, without giving reasons and this will not involve any penalty.

Whom do I contact if I have questions? If you have any questions you may ask them now or later. If you wish to ask questions later, you may contact [add contact details of local Principal or Co-investigator].
Statement of consent
This consent form for participating in the HCUS has been read to me by me. The purpose, procedure, risks and benefits of this survey have been explained to me in detail. I have been allowed to ask questions, and my questions have been answered to my satisfaction by the survey staff. I have been told whom to contact if I have questions, want to discuss problems, or concerns. I have been told that I will be given a signed and dated copy of this consent form. I have been reassured that all information obtained as result of this survey will be confidential and used for the purpose of this survey by only the institutions participating in this survey.

I consent voluntarily to me and my family’s participation in this survey. I will follow the directions of the survey team and give them my full cooperation. I understand that I have the right to withdraw from the survey at any time.

RESPONDENT
Name of respondent:
______________________________________________________________

Signature/thumbprint of respondent:
______________________________________________________________

Date: __________/________/________ (DD/MM/YYYY)

IF RESPONDENT IS ILLITERATE
Add name of independent literate witness (if possible, this person should be selected by the respondent and must not have a connection to the survey team).

Name of witness:
______________________________________________________________

Signature of witness:
______________________________________________________________

Date: __________/________/________ (DD/MM/YYYY)

STUDY STAFF
I have read/ explained the survey to the above named respondent (witness if respondent is illiterate) in a language that the respondent understands well. I am certain that the respondent has understood the information and is allowing to be asked some questions.

Name of survey staff:
______________________________________________________________

Signature of survey staff:
______________________________________________________________

Date: __________/________/________ (DD/MM/YYYY)
Note: Sections marked with a star (★) will be further adapted

**Part B. HEALTH CARE UTILIZATION**

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<table>
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<tbody>
<tr>
<td>[1] Study site:</td>
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<td>[2] No. of cluster:</td>
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<tr>
<td>[3] Community/ District ★:</td>
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<td>[4] Address of household ★:</td>
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<td>[5] GPS coordinates of the household:</td>
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<td>(1) Altitude:</td>
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<td>(2) Longitude:</td>
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<td>(3) Latitude:</td>
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**Identification of the respondent**

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<tbody>
<tr>
<td>[6] Family name:</td>
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<td>[7] First name:</td>
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<td>[8] Phone number:</td>
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**What is the respondent’s relationship to the head of this household? ★**

1. O Head of household
2. O Spouse of head of household
3. O Son/ daughter of head of household
4. O Spouse of son/ daughter of head of household
5. O Brother/ sister of head of household
6. O Spouse of brother/ sister of head of household
7. O Mother/ father of head of household
8. O Mother/ father in law of head of household
9. O Granddaughter/ grandson of head of household
10. O Niece/ nephew of head of household
11. O Other, please specify ______________________________________________________________________

**Identification of interviewer**

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<td>Initials:</td>
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<td>Date of interview:</td>
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**How many members are living in this household on the day of visit?**

Number:   

**Please specify age and gender of each member of this household, including the respondent (<2 years of age in months; ≥2 years of age in years):**

**RESPONDENT**

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<td>Years</td>
<td>Gender:</td>
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### For questions 13 – 18 and 20, choose a TSAP facility or one of the subsequent codes

**CODES**

- **A** = Nowhere, self-treatment with traditional medicine
- **B** = Self-treatment with drugs bought over the counter
- **C** = Nowhere, self-treatment with leftover drugs bought in a pharmacy
- **D** = Traditional healer
- **E** = Pharmacy
- **F** = Private healthcare facility
- **G** = Governmental healthcare facility
- **H** = Nowhere, I don’t do anything

#### (A) <2years

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#### (B) ≥2 to <5years

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#### (C) ≥5 to <15years

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#### (D) ≥15years

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**For questions 13 – 18 and 20, choose a TSAP facility or one of the subsequent codes**

**CODES**

- **A** = Nowhere, self-treatment with traditional medicine
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- **C** = Nowhere, self-treatment with leftover drugs bought in a pharmacy
- **D** = Traditional healer
- **E** = Pharmacy
- **F** = Private healthcare facility
- **G** = Governmental healthcare facility
- **H** = Nowhere, I don’t do anything

#### (A) <2years

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#### (B) ≥2 to <5years

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#### (C) ≥5 to <15years

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#### (D) ≥15years

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HEALTH SEEKING BEHAVIOR

[21] Does the household have a health insurance?

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<thead>
<tr>
<th></th>
<th>(A) &lt;2years</th>
<th>(B) ≥2 to &lt;5years</th>
<th>(C) ≥5 to &lt;15years</th>
<th>(D) ≥15years</th>
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<tbody>
<tr>
<td>(A)</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>(B)</td>
<td>Yes</td>
<td>No</td>
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<td>No</td>
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<tr>
<td>(C)</td>
<td>Yes</td>
<td>No</td>
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<td>No</td>
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<tr>
<td>(D)</td>
<td>Yes</td>
<td>No</td>
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</table>

[22] If “Yes” in Q21, for which members of this household of following age groups does the insurance cover health expenses?

<table>
<thead>
<tr>
<th></th>
<th>(A) &lt;2years</th>
<th>(B) ≥2 to &lt;5years</th>
<th>(C) ≥5 to &lt;15years</th>
<th>(D) ≥15years</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>(B)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>(C)</td>
<td>Yes</td>
<td>No</td>
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<td>No</td>
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<tr>
<td>(D)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
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[23] In case a TSAP facility was selected in Q14 and/ or Q15, following questions will be posed to you because we want to know why members of this household seek care there.

<table>
<thead>
<tr>
<th></th>
<th>(A) &lt;2years</th>
<th>(B) ≥2 to &lt;5years</th>
<th>(C) ≥5 to &lt;15years</th>
<th>(D) ≥15years</th>
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<tbody>
<tr>
<td>(A)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>(B)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>(C)</td>
<td>Yes</td>
<td>No</td>
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<td>No</td>
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<tr>
<td>(D)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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</table>

[24] If “No” in Q23A, do members of this household choose the TSAP facility because the fee for the doctor’s visit is appropriate?

<table>
<thead>
<tr>
<th></th>
<th>(A) &lt;2years</th>
<th>(B) ≥2 to &lt;5years</th>
<th>(C) ≥5 to &lt;15years</th>
<th>(D) ≥15years</th>
</tr>
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<tbody>
<tr>
<td>(A)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>(B)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<td>(C)</td>
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<td>(D)</td>
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</table>

[25] If “No” in Q23B, do members of this household choose the TSAP facility because the fee for the doctor’s visit is appropriate?

<table>
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<th>(A) &lt;2years</th>
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<td>(D)</td>
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[26] If “No” in Q23C, do members of this household choose the TSAP facility because the fee for the doctor’s visit is appropriate?

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<td>(D)</td>
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[27] If “No” in Q23D, do members of this household choose the TSAP facility because the fee for the doctor’s visit is appropriate?

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<td>(C)</td>
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<td>(D)</td>
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[28] If “No” in Q23E, do members of this household choose the TSAP facility because the fee for the doctor’s visit is appropriate?

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[29] If “No” in Q23F, do members of this household choose the TSAP facility because the fee for the doctor’s visit is appropriate?

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<td>(F) Do members of this household choose the TSAP facility because of availability of drugs?</td>
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<th>(G) Do members of this household choose the TSAP facility because drugs are free of charge?</th>
<th>(A) &lt;2years</th>
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<th>(H) If “No” in Q23G, do members of this household choose the TSAP facility because expenses for drugs are appropriate?</th>
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<th>(I) Do members of this household choose the TSAP facility because of availability of diagnostic tests?</th>
<th>(A) &lt;2years</th>
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<th>(J) Do members of this household choose the TSAP facility because diagnostic tests are free of charge?</th>
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<th>(K) If “No” in Q23I, do members of this household choose the TSAP facility because expenses for diagnostic tests are appropriate?</th>
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<th>(L) Do members of this household choose the TSAP facility because the travel distance is appropriate?</th>
<th>(A) &lt;2years</th>
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<th>(M) Do members of this household choose the TSAP facility because the travel distance for severely sick persons is appropriate?</th>
<th>(A) &lt;2years</th>
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<th>(N) Do members of this household choose the TSAP facility because of short waiting time?</th>
<th>(A) &lt;2years</th>
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<th>(O) Do members of this household choose the TSAP facility because of availability of health service outside the working hours?</th>
<th>(A) &lt;2years</th>
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<th>(C) ≥5 to &lt;15years</th>
<th>(D) ≥15years</th>
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<th>(P) Do members of this household choose the TSAP facility because of availability of well-trained health service providers?</th>
<th>(A) &lt;2years</th>
<th>(B) ≥2 to &lt;5years</th>
<th>(C) ≥5 to &lt;15years</th>
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<th>(Q) Do members of this household choose the TSAP facility because of appropriate attitudes of health service providers?</th>
<th>(A) &lt;2years</th>
<th>(B) ≥2 to &lt;5years</th>
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<th>(R) Is there any other reason why members of this household choose the TSAP facility?</th>
<th>(A) &lt;2years</th>
<th>(B) ≥2 to &lt;5years</th>
<th>(C) ≥5 to &lt;15years</th>
<th>(D) ≥15years</th>
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Part C. SOCIO-ECONOMIC STATUS SURVEY

IVI-TSAP-01 v1.8, September 29, 2014
**EDUCATION**

24. Can the head of household read?  
   (1) ○ Yes  (2) ○ No  (3) ○ Don’t know

25. Can the head of household write?  
   (1) ○ Yes  (2) ○ No  (3) ○ Don’t know

26. How many years did the head of household go to school?  
   [ ] [ ] [year]  ○ Don’t know

27. What is the highest, completed education of the head of household?  
   (1) ○ Primary school  (2) ○ Secondary school  (3) ○ Post secondary education  
   (4) ○ Middle school  (5) ○ No answer applicable  (6) ○ Don’t know

**OCCUPATION**

28. What is the primary occupation of the head of household?  
   (1) ○ Farmer  (2) ○ Fisherman  (3) ○ Electrician  
   (4) ○ Plumber, Carpenter, Brick layer  (5) ○ Physician  (6) ○ Nurse, Technician  
   (7) ○ Teacher  (8) ○ Military, Marine  (9) ○ Security service  
   (10) ○ Factory worker  (11) ○ Restaurant worker  (12) ○ Housemaid  
   (13) ○ Driver  (14) ○ Hairdresser  (15) ○ Artist, Handcrafter  
   (16) ○ Shopkeeper  (17) ○ Trader  (18) ○ Street vendor  
   (19) ○ Unemployed  (20) ○ Tailor, Shoemaker  
   (21) ○ Other, please specify: ____________________________

**ETHNIC GROUP/ TRIBE**

29. What is the ethnic group/tribe of the head of household? *  
   Ethnic group/tribe *: ______________________________________

**WEALTH**

30. Does the primary occupation of the head of household provide the main source of steady/consistent income for this household? *  
   (1) ○ Yes  (2) ○ No

31. If “No” in Q 30, does any other member in this household have a steady/consistent income from any other source?  
   (1) ○ Yes  (2) ○ No

32. What is the primary construction material used for this house? *  
   (1) ○ Cement/Brick stone  (2) ○ Mud  (3) ○ Wood  (4) ○ No answer applicable

33. What is the type of this house? *  
   (1) ○ Owned  (2) ○ Supplied by employer  (3) ○ Rented  
   (4) ○ Other, please specify ____________________________

34. Does this household own any of the following (choose all that apply)?

<table>
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<tr>
<th>Item</th>
<th>(A) Radio</th>
<th>(B) Television</th>
<th>(C) Car</th>
<th>(D) Motorcycle</th>
<th>(E) Refrigerator</th>
<th>(F) Electricity</th>
<th>(G) Computer</th>
<th>(H) Internet</th>
<th>(I) Farmland</th>
<th>(J) Cow</th>
<th>(K) Sheep</th>
<th>(L) Mule</th>
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If “Yes”, number: ____________________________
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**Identification of reviewer**

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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(DD/MM/YYYY)</td>
</tr>
</tbody>
</table>
TSAP Appendix B: Informed Consent Form 1

Consent to participate in the Typhoid Fever Surveillance in Africa Program (TSAP)

Name of local Principal and Co-investigators: [add name]
Name of Organization: [add name]
Name of Sponsor: International Vaccine Institute

This section is for children >12 years of age only

We are looking into the number of people with hot bodies caused by germs in your area to try to prevent people from getting ill in the future. Please read or have study staff read this text to you. Take your time to decide to participate. After this, and if you agree to participate, you will be asked to sign this form. Then, you will be asked some questions about yourself, where you live and about how you keep yourself clean. After that, we will examine you, such as take your temperature and measure your weight, and we also take about two teaspoons of blood to study. This may make you feel uncomfortable. You do not have to be in this study. No one will be mad at you if you decide not to do this study. Even if you start, you can stop later if you want. You may ask questions about the study. Your treatment will not be affected whether you participate or not. Your participation does not cost you money and you will also not get any money.

If you decide to be in the study we will not tell anyone else what you say or do in the study. Even if your parents or teachers ask, we will not tell them about what you say or do in the study. Altogether, this will take about half an hour. Please go over the next sections with study staff and if there is anything you do not understand, just ask study staff to explain.

Introduction

You are asked to take part in this study because you live in the study area where we are conducting the Typhoid Fever Surveillance in Africa Program (TSAP). This consent form should be read by you/ read to you carefully and you should take your time to make your decision to participate. As study staff discusses this consent form with you, please ask him/ her to explain any words or information that you do not understand. Information of the study such as the nature of the study, risks, benefits, and inconveniences are listed below. After the study has been fully explained to you and if you agree to participate, you will be asked to sign this consent form. You will be offered a copy of this form to keep.

[add name of local PI and name or organization] in collaboration with the International Vaccine Institute in Seoul, South Korea, conducts the study.

What is the reason of this study?

We are conducting research to find out how common febrile illness, including typhoid fever, is in this study area. This information will help treat patients with severe febrile illness in the future and to decide on control measures against typhoid fever.

Typhoid fever is a bacterial infection. The disease is primarily transmitted by poor sanitation. Consumption of contaminated water and ingestion of raw or undercooked foods with germs are considered to be major risk factors for transmission of the bacteria. This disease can cause fever, headache, abdominal pain, diarrhoea and serious complications such as intestinal bleeding and perforation.

What do I have to do if I decide to participate?

If you agree to take part you will be asked some questions. We will ask for your/ your child’s name, age, gender, ethnic group as well as your/ your child’s current illness, and whether you/ your child received any medication during the last week. Some participants will be asked some additional questions about occupation, education, type of housing, about hygiene and sanitation, and handling of food.

We will then examine you/ your child and measure your/ your child’s body temperature, weight, height and length. A small blood sample (about two teaspoons) will then be taken from you/ your child. Your/ your child’s blood will be tested for bacterial infections and malaria. As soon as the results of these tests are available you and/or your doctor will be informed, however, this may be too late to affect treatment decisions of you/ your child. A small amount of
your/ your child’s blood will be used for determining the genetic sequence of bacteria and the assessment of other infections that might occur. This is very important to determine the origin of the pathogen as well as possible resistance against commonly used antibiotics and other drugs. This will help improve the treatment of future infections of other people with similar pathogens. As some of these tests require sophisticated diagnostic procedures and equipment, leftover blood will be stored and shipped to reference laboratories outside of [country]. In this case these results will not be available and will not affect your/ your child’s treatment.

**What is the duration of my participation?**
Blood collection will only take a couple of minutes, the interview and physical examination will take approximately 30 minutes. You/ your child might be visited at home for a later interview after your discharge from the hospital. This interview will take approximately 15 minutes.

**What are the risks of the study?**
Having a blood test can cause bruising or pain but other effects are unlikely and we will provide treatment if needed. If confidential information is revealed about you/ your child this could cause you distress but all information collected in the study will be kept confidentially. Taking blood or physical examination as well as asking above mentioned questions may make you/ your child feel uncomfortable. You/ your child may refuse any physical examination, taking blood or answering any question or may take a break at any time. You may stop the participation of you/ your child in this study at any time.

**Are there benefits of participating in this study?**
If you agree to take part in this study, the direct benefit for you/ your child is that febrile infections, possible other bacterial infections and your/ your child’s current malaria status are diagnosed. This may result in a better treatment of your/ your child’s disease in case you need to be hospitalized. However, this may be too late to affect treatment decisions of you/ your child if you are not hospitalized. Indirect benefits for you/ your child and the general population are that in the future the information learned from this study will improve the knowledge of typhoid fever, its modes of transmission, risk factors and appropriate treatment. Findings of this study will, moreover, contribute to future implementation of appropriate prevention and control measures for typhoid fever in this study area, other parts of your country, and in other African countries.

**Will my information be kept confidential?**
All study records that identify you will be kept confidential. All information collected in this study will be given code numbers and no name will be recorded. The key to this code numbers will be kept in a locked file and be only accessible to authorized staff. Your name or any identifier will not be used in any publication or reports from this study. Results of investigations or other information that we collect about you/ your child will only be shared with medical staff looking after you/ your child and authorized members of the study such as officials from ethics committees. Computerized files will be password-protected and paper files will only be locked safely and only accessible to authorized staff.

**What are the costs?**
All the investigations done for participants of this study will be free of charge but hospital care and treatments will be paid for in the usual way.

**What about compensation?**
You will not be compensated for your participation in this study.

**What about my rights to decline participation or withdraw from the study?**
If you decide not to be included in the study, the same tests will be available at the request of the medical team and your/ your child’s treatment will not be affected in any way. You are free to refuse to participate in the study or you can withdraw your consent at any time, without giving reasons and this will not involve any penalty or loss of benefits to which you/ your child are entitled such as proper care and treatment. Your access to treatment will not be dependent on your participation in the study.
Whom do I contact if I have questions?
If you have any questions you may ask them now or later. If you wish to ask questions later, you may contact [add contact details of local investigator].

Statement of consent
The “Consent to participate in the Typhoid Fever Surveillance in Africa Program (TSAP)” has been read to me/ I have read. The purpose and procedures, risks and benefits of this study have been explained to me in detail. I have been allowed to ask questions, and my questions have been answered to my satisfaction by the research staff. I have been told whom to contact if I have questions, want to discuss problems, or concerns. I have been told that I will be given a signed and dated copy of this consent form. I have been reassured that all information obtained as result of this study will be confidential and used for the purpose of this study only by the institutions participating in this study.
I consent voluntarily to my/ my child’s participation as a subject in this study. I will follow the directions of the study team and give them my full cooperation.
I understand that I have the right to withdraw from the study at any time, without any way affecting my child’s/ my own further medical care. If I/ my child will not participate in the study I/ my child will not involve any penalty or loss of benefits to which I/ my child are entitled.

For participant:

Name of participant: ______________________________________________________________

Name of parent/guardian (for children): ______________________________________________

Signature/thumbprint of participant or parent/guardian: _________________________________

Date: ___ / ___ / 20___

If participant or parent/guardian is illiterate:

Add name of independent literate witness (if possible, this person should be selected by the participant and should have no connection to the study team).

Name of witness: _________________________________________________________________

Signature of witness: ______________________________________________________________

Date: ___ / ___ / 20___

For the study staff:

I have read/explained the study to the above named participant (if adult)/ parent/guardian (if child) in a language that the participant understands well. I am certain that the participant has understood the information and is allowing a small amount of blood to be taken out of his/her own free will.

Name of study staff: ______________________________________________________________

Signature of study staff: ____________________________________________________________

Date: ___ / ___ / 20___

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### TSAP Appendix C: Recruitment Form

**Form Sl.#:__________________**

(To be filled by Data Management)

**Study label**

None

#### Recruitment Form

☐ Refusal, please specify reason for refusal: ____________________

### I. Study site information

1. **Reporting site**
   - This section will be adapted to each study site to include the hospital and/or health center name as options next to tick boxes.

2. **Date of visit**
   - (DD/MM/YYYY)

3. **Recruitment site**
   - Inpatient department
   - Outpatient department

4. **Multiple visits**
   - Has the participant been enrolled in TSAP before current visit?
     - Yes
     - No
     - Unknown
   - If Yes, specify month and year
     - (MM/YYYY)

### II. Participant information

1. **Informed consent obtained**
   - Yes
   - No

2. **Participant ID**

3. **Family name:**

4. **First name:**

5. **Gender**
   - Male
   - Female

6. **Date of birth**
   - (DD/MM/YYYY)
   - OR
   - Years
   - Months if ≤ 2 years of age

7. **Village/district [requires site-specific adjustment]**
   - Village/district 1
   - Village/district 2

8. **Phone number:**

9. **Address:**

10. **Since when has the participant lived at current house?**
    - (MM/YYYY)

11. **Ethnic group:** __________________________

### III. Complete if participant is a child (<18 years old)

1. **Mother’s name:**

2. **Father’s name:**

3. **Guardian’s name:**
**TSAP Appendix D: Case Report Form**

- **Form Sl.#:**
- **Study label:**

## Case Report Form

### I. Participant information

<table>
<thead>
<tr>
<th>Participant ID</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

### II. History of current illness

#### 1] Onset of illness (DD/MM/YYYY)

#### 2] Symptoms (check all that apply)

- History of Fever:
  - Yes
  - No
  - Unknown

  **IF YES:**
  - Character of fever: Continuous
  - Intermittent

  **Onset of fever:** (DD/MM/YYYY)

- Diarrhea:
  - Yes
  - No
  - Unknown

- Constipation:
  - Yes
  - No
  - Unknown

- Rash:
  - Yes
  - No
  - Unknown

- Headache:
  - Yes
  - No
  - Unknown

- Sore throat:
  - Yes
  - No
  - Unknown

- Cough:
  - Yes
  - No
  - Unknown

- Vomiting:
  - Yes
  - No
  - Unknown

- Abdominal Pain:
  - Yes
  - No
  - Unknown

#### 3] Medication prior to current medical evaluation (check all that apply)

- Antimalarials:
  - Yes
  - No
  - Unknown

- Analgesics:
  - Yes
  - No
  - Unknown

- Antibacterials:
  - Yes
  - No
  - Unknown

- State name if known:

#### 4] Contact with a person with fever within one week before onset of illness:

- Yes
- No
- Not remember

#### 5] Travel outside of local residence within one week before onset of illness:

- Yes
- No
- Not remember

### III. Physical examination

#### 1] Temperature on admission: °C

- Tympanic
- Axillary
- Rectal

#### 2] Weight:

- kg

#### 3] Height:

- cm

#### 4] Acute abdomen:

- Yes
- No
- Unknown

---

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### IV. Clinical appraisal

1) Participant admitted to hospital:

<table>
<thead>
<tr>
<th>Date of admission:</th>
<th>(DD/MM/YYYY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presumptive diagnosis at admission:</td>
<td></td>
</tr>
<tr>
<td>□ Gastrointestinal system infection (specify):</td>
<td>□ Fever of unknown origin</td>
</tr>
<tr>
<td>□ Central Nervous System Infection (specify):</td>
<td>□ Malaria</td>
</tr>
<tr>
<td>□ Respiratory Tract Infection (specify):</td>
<td>□ Urinary tract infection</td>
</tr>
<tr>
<td>□ Infection with another focus (specify):</td>
<td>□ Other (specify):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of discharge:</th>
<th>(DD/MM/YYYY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge diagnosis:</td>
<td></td>
</tr>
<tr>
<td>□ Gastrointestinal system infection (specify):</td>
<td>□ Fever of unknown origin</td>
</tr>
<tr>
<td>□ Central Nervous System Infection (specify):</td>
<td>□ Malaria</td>
</tr>
<tr>
<td>□ Respiratory Tract Infection (specify):</td>
<td>□ Urinary tract infection</td>
</tr>
<tr>
<td>□ Infection with another focus (specify):</td>
<td>□ Other (specify):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complications:</th>
<th>□ Yes</th>
<th>□ No</th>
<th>□ Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Clinical sepsis</td>
<td>□ Neurologic manifestations</td>
<td>□ Abscess (location):</td>
<td></td>
</tr>
<tr>
<td>□ Organ failure</td>
<td>□ Intestinal perforation</td>
<td>□ Other:</td>
<td></td>
</tr>
<tr>
<td>□ Adynamic Ileus</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Has a surgery been performed due to complications? □ Yes □ No □ Unknown

Outcome (Check all that apply):

<table>
<thead>
<tr>
<th>□ Recovered</th>
<th>□ Absconded</th>
<th>□ Lost to follow up</th>
<th>□ Died</th>
<th>□ Transferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Disabled</td>
<td>□ Ongoing treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Presumptive diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Gastrointestinal system infection (specify):</td>
</tr>
<tr>
<td>□ Central Nervous System Infection (specify):</td>
</tr>
<tr>
<td>□ Respiratory Tract Infection (specify):</td>
</tr>
<tr>
<td>□ Infection with another focus (specify):</td>
</tr>
</tbody>
</table>

Patient discharged from visit with a prescription for antibiotics: □ Yes □ No □ Unknown
2) Indicate treatment prescribed during visit or hospitalization (include ongoing treatment if any-check all that apply):

- Ampicillin
- Ciprofloxacin
- Gentamicin
- Chloramphenicol
- TMP-SMX
- Ceftriaxone
- Tetracycline
- Amoxycillin/clavulanic acid
- No treatment prescribed
- Other __________________________

3) Participant sent to lab for blood sample collection:

- Yes
- No
  If No, state reason: __________________________________________________________

V. Interviewer/Treating physician

[ ] All form sections completed

Name: ______________________
Signature: __________________

VI. Data entry

1st entry initials: ____________ (DD/MM/YYYY)

2nd entry initials: ____________ (DD/MM/YYYY)
### TSAP Appendix E: Laboratory Form

**Form Sl. #:__________________**  
*(To be filled by Data Management)*

**Laboratory Form**

- **Blood Sample** Not Collected, please specify reason: ____________________________

#### I. Participant and sample collection information (to be completed at Hospital/Clinic)

<table>
<thead>
<tr>
<th>1] Reporting study site [requires site specific adjustment]</th>
<th>2] Participant ID</th>
<th>Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study site 1</td>
<td></td>
<td>○ Male</td>
</tr>
<tr>
<td>Study site 2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>○ Pediatric</td>
<td></td>
</tr>
<tr>
<td>○ Adult</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5] Date and time sample taken</th>
<th>Participant’s date of birth OR Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>(DD/MM/YYYY)</td>
<td>(DD/MM/YYYY)</td>
</tr>
<tr>
<td>(hh:mm) AM PM</td>
<td>Age: years Months if ≤ 2 years of age:</td>
</tr>
</tbody>
</table>

Name of person completing this section of the form and date: ____________________________

<table>
<thead>
<tr>
<th>6] BC bottle barcode:</th>
</tr>
</thead>
</table>

#### II. Blood culture (BC) (to be completed at Laboratory)

<table>
<thead>
<tr>
<th>1] Date and time sample received in the lab</th>
<th>2] Date and time of incubation of inoculated BC bottle</th>
</tr>
</thead>
<tbody>
<tr>
<td>(DD/MM/YYYY)</td>
<td>(DD/MM/YYYY)</td>
</tr>
<tr>
<td>(hh:mm) AM PM</td>
<td>(hh:mm) AM PM</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3] Growth result</th>
<th>4] Identification of isolate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ Positive</td>
<td>○ Salmonella enterica - non–typhoidal (NTS)</td>
</tr>
<tr>
<td>○ Negative</td>
<td>○ Streptococcus pneumoniae</td>
</tr>
<tr>
<td></td>
<td>○ Haemophilus influenzae</td>
</tr>
</tbody>
</table>

**Gram Stain**

**Growth Characteristics**

**Blood agar:**

**MacConkey agar:**

**Identification tests - isolate 1**

<table>
<thead>
<tr>
<th>API:</th>
<th>Agglutinations reactions:</th>
<th>Other reactions:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Result: ____________________________
O Salmonella enterica – Typhi  O Staphylococcus aureus  O Others ____________________

5] Contamination Status:
O Definite Contamination  O Probable Contamination  O No Contamination  6] Microbank Position

7] Sensitivity testing methodology [requires site specific adjustment]
O BSAC  O CLSI  O Other:______________________________

Amoxicillin/Clavulanate  O S  O I  O R  Chloramphenicol  O S  O I  O R
Ampicillin  O S  O I  O R  Ciprofloxacin  O S  O I  O R
Ceftazidime  O S  O I  O R  Nalidixic Acid  O S  O I  O R
Ceftriaxone  O S  O I  O R  Trimethoprim/sulfa  O S  O I  O R

8] Second isolate identified  O Yes  Complete below  O No  Skip to section III

Identification tests - isolate 2

API: ____________________________  Agglutinations reactions: ____________________________  Other reactions: ____________________________

1] Identification of isolate:
O Salmonella enterica – non-typhoidal (NTS)  O Streptococcus pneumoniae  O Haemophilus influenzae
O Salmonella enterica – Typhi  O Staphylococcus aureus  O Others

2] Contamination Status:
O Definite Contamination  O Probable Contamination  O No Contamination

3] Microbank Position

4] Sensitivity testing methodology  [requires site specific adjustment]
O BSAC  O CLSI  O Other:______________________________

Amoxicillin/Clavulanate  O S  O I  O R  Chloramphenicol  O S  O I  O R
Ampicillin  O S  O I  O R  Ciprofloxacin  O S  O I  O R
Ceftazidime  O S  O I  O R  Nalidixic Acid  O S  O I  O R
Ceftriaxone  O S  O I  O R  Trimethoprim/sulfa  O S  O I  O R

Name, signature and date

III.  Malaria

1] Malaria film  O positive  O negative  O not done

2] Count  O /200 leukos  O /500 leukos  O /1,000 RBC

3] Species  O P. falciparum  O P. malariae  O P. ovale  O P. vivax

4] Gametocytes  O positive  O negative  O not done

5] Rapid Test*  O done  Indicate  O positive  O negative  O not done

Name, signature and date

*If routinely conducted at study site

IV.  Blood count (do not perform differential white blood count if manual count is required) [specific to site and method used AND optional]

<table>
<thead>
<tr>
<th>WBC</th>
<th>MCH</th>
<th>Basophils</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1000/μl)</td>
<td></td>
<td>(%WBC)</td>
</tr>
<tr>
<td>RBC</td>
<td>MCHC</td>
<td>Monocytes</td>
</tr>
<tr>
<td>(10⁶/μl)</td>
<td></td>
<td>(%WBC)</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hb</td>
<td></td>
<td>(g/dl)</td>
</tr>
<tr>
<td>Neutrophils</td>
<td></td>
<td>(%WBC)</td>
</tr>
<tr>
<td>Platelets</td>
<td></td>
<td>(1000/μl)</td>
</tr>
<tr>
<td>Hct</td>
<td></td>
<td>(%)</td>
</tr>
<tr>
<td>Eosinophils</td>
<td></td>
<td>(%WBC)</td>
</tr>
<tr>
<td>MCV</td>
<td></td>
<td>(fl)</td>
</tr>
<tr>
<td>Lymphocytes</td>
<td></td>
<td>(%WBC)</td>
</tr>
</tbody>
</table>

**V. HIV testing** (delete this section in countries not performing HIV testing) [specific to site]

HIV test performed:  
- [ ] done  
- [ ] positive  
- [ ] negative  
- [ ] unknown  
- [ ] not done

**Notes:**

---

**IVI-TSAP-01 v1.8, September 29, 2014**
TSAP Appendix F: Risk factors Assessment

Study site: ____________________________________________________________

Name of sampling unit: ________________________________________________

Identification of interviewee

Participant ID: __________________________________________________________

If possible, please provide latitude, longitude and altitude (GPS) of the place you live.

Latitude: W/ E [__]° [__]’ [__]” [__]° [__]’ [__]” Longitude: N/ S [__]° [__]’ [__]” [__]° [__]’

Altitude: □ < 500m □ ≥500m to 1,000m □ ≥1,000m to 1,500m □ ≥1,500m to 2,000m □ ≥2,000m

Household neighborhood: rural/urban/urban slum? □ Rural □ Urban slum □ Urban non-slum

Identification of interviewer

Name of interviewer: ____________________________________________________

Date of interview: [__] [__]/ [__] [__]/ [__] (dd/ mm/ yyyy)

Identification of reviewer

Name of reviewer: __________________________________________________________________________________________

Date of review: [__] [__]/ [__] [__]/ [__] (dd/ mm/ yyyy)

Occupation and Education

What is your main occupation?
□ Trader □ Driver □ Shopkeeper □ Vendor
□ Farmer □ Artisans □ Fishermen □ Nurse or health worker
□ Teacher □ Factory worker □ Housewife □ Food industry/catering
□ Unemployed □ No answer applicable

Do you have livestock such as poultries? □ Yes □ No

If “Yes”, what is the main drinking water supply of the livestock?
□ Inside tap □ Stand pipe □ Surface water □ Well □ No answer applicable

Can you read and write? □ Yes □ No

If “Yes”, which language?
□ French □ English □ Local language

What is the highest, completed education you have?
□ Primary school □ Post secondary education □ Middle school
□ Secondary school □ No education □ Unknown

For young children only: Does the child go to care facility/kindergarten? □ Yes □ No

For children and young adults only: Do you go to school? □ Yes □ No

What is your ethnic group/tribe? _________________________________________

What is your average household income (weekly or monthly depending on site)? _______________________

Housing, Hygiene, Sanitation and Food

Did you have contact to a person with fever during the past 7 days? □ Yes □ No

What is the main type of house you live?
□ Cement/Brick stone □ Mud house □ Wood □ No answer applicable
What is your main drinking water supply?
- [ ] Inside tap
- [ ] Stand pipe
- [ ] Surface water
- [ ] Well
- [ ] No answer applicable

What drinking water do you use mostly?
- [ ] Cooked
- [ ] Filtered
- [ ] Untreated
- [ ] Unknown

What water source do you use to wash vegetables and fruit?
- [ ] Inside tap
- [ ] Stand pipe
- [ ] Surface water
- [ ] Well
- [ ] No answer applicable

Where do you cook mostly?
- [ ] Inside kitchen/ In a room
- [ ] Outside/ open air
- [ ] No answer applicable

How do you prepare yourself mostly before handling food?
- [ ] Wash hands with soap and water
- [ ] Wash hands with water only
- [ ] Don’t wash my hands

Do you cover uncooked foods such as meat/ fish to store it for use in the next days?
- [ ] Yes
- [ ] No

How do you store fresh foods such as meat/ fish mostly to store it for use in the next days?
- [ ] Room temperature
- [ ] Refrigerator
- [ ] Freezer

Do/did you consume raw, unpasteurized milk and dairy products?
- [ ] Yes
- [ ] No

Do you consume raw, uncooked meat or eggs?
- [ ] Yes
- [ ] No

Does your household have an inside flush toilet?
- [ ] Yes
- [ ] No

If "No", where do you go to toilet mostly?
- [ ] Public toilet
- [ ] Next house
- [ ] Free range

How do you clean yourself mostly after visiting the toilet?
- [ ] Wash hands with soap and water
- [ ] Wash hands with water only
- [ ] Don’t wash my hands

Please provide the approximate distance from the place you live to the next sewer (meter): [__________]

Please provide the approximate distance from the place you live to the next garbage dump (meter): [__________]

Please provide the approximate distance from the place you live to the next water pump (meter): [__________]

How do you clean yourself mostly before eating?
- [ ] Wash hands with soap
- [ ] Wash hands with water only
- [ ] Wash only when my hands are dirty
- [ ] Don’t wash my hands

How many times per week do you eat outside your house?
- [ ] 0
- [ ] 1-3
- [ ] 4-5
- [ ] 6-7

How many times per week do you take food from a street vendor?
- [ ] 0
- [ ] 1-3
- [ ] 4-5
- [ ] 6-7

Data entry

1st data entry: Initials: ________________ Date: [__] [__]/ [__]/ [2] [0] [__] [__] (dd/ mm/ yyyy)

2nd data entry: Initials: ________________ Date: [__] [__]/ [__]/ [2] [0] [__] [__] (dd/ mm/ yyyy)
TSAP Appendix G: Informed Consent Form 2

Consent to participate in the Typhoid Fever Surveillance in Africa Program (TSAP)

Name of local Principal and Co-investigators: [add name]
Name of Organization: [add name]
Name of Sponsor: International Vaccine Institute

This section is for children >12 years of age only
We are looking into the number of people with hot bodies caused by germs in your area to try to prevent people from getting ill in the future. Please read or have study staff read this text to you. Take your time to decide to participate. After this, and if you agree to participate, you will be asked to sign this form. Then, you will be asked some questions about yourself, where you live and about how you keep yourself clean. After that, we will examine you, such as take your temperature and measure your weight, and we also take about two teaspoons of blood to study. This may make you feel uncomfortable. You do not have to be in this study. No one will be mad at you if you decide not to do this study. Even if you start, you can stop later if you want. You may ask questions about the study. Your treatment will not be affected whether you participate or not. Your participation does not cost you money and you will also not get any money.

If you decide to be in the study we will not tell anyone else what you say or do in the study. Even if your parents or teachers ask, we will not tell them about what you say or do in the study. Altogether, this will take about half an hour. Please go over the next sections with study staff and if there is anything you do not understand, just ask study staff to explain.

Introduction
You are asked to take part in this study because you live in the study area where we are conducting the Typhoid Fever Surveillance in Africa Program (TSAP). This consent form should be read by you/ read to you carefully and you should take your time to make your decision to participate. As study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not understand. Information of the study such as the nature of the study, risks, benefits, and inconveniences are listed below. After the study has been fully explained to you and if you agree to participate, you will be asked to sign this consent form. You will be offered a copy of this form to keep.

[add name of local PI and name or organization] in collaboration with the International Vaccine Institute in Seoul, South Korea, conducts the study.

What is the reason of this study?
We are conducting research to find out how common febrile illness, including typhoid fever, is in this study area. This information will help treat patients with severe febrile illness in the future and to decide on control measures against typhoid fever.

Typhoid fever is a bacterial infection. The disease is primarily transmitted by poor sanitation. Consumption of contaminated water and ingestion of raw or undercooked foods with germs are considered to be major risk factors for transmission of the bacteria. This disease can cause fever, headache, abdominal pain, diarrhoea and serious complications such as intestinal bleeding and perforation.

What do I have to do if I decide to participate?
If you agree to take part you will be asked some questions. We will ask for your/ your child’s name, age, gender, ethnic group as well as your/ your child’s current illness, and whether you/ your child received any medication during the last week. Some participants will be asked some additional questions about occupation, education, type of housing, about hygiene and sanitation, and handling of food. We will then examine you/ your child and measure your/ your child’s body temperature, weight, height and length. A small blood sample (about two teaspoons) will then be taken from you/ your child. Your/ your child’s blood will be tested for bacterial infections and malaria. As soon as the results of these tests are available you and/or your doctor will be informed, however, this may be too late to affect treatment decisions of you/ your child. A small amount of your/ your child’s blood will be used for determining the genetic sequence of bacteria and the assessment of other...
infections that might occur. This is very important to determine the origin of the pathogen as well as possible resistance against commonly used antibiotics and other drugs. This will help improve the treatment of future infections of other people with similar pathogens. As some of these tests require sophisticated diagnostic procedures and equipment, leftover blood will be stored and shipped to reference laboratories outside of [country]. In this case these results will not be available and will not affect your/ your child’s treatment.

Typhoid fever may affect people with a weakened immune system in a different way. For this reason, we also want to use already available information about your/ your child’s HIV status.

If you agree to share your/ your child’s HIV status with this study, please tick following box. ☐

What is the duration of my participation?
Blood collection will only take a couple of minutes, the interview and physical examination will take approximately 30 minutes. You/ your child might be visited at home for a later interview after your discharge from the hospital. This interview will take approximately 15 minutes.

What are the risks of the study?
Having a blood test can cause bruising or pain but other effects are unlikely and we will provide treatment if needed. If confidential information is revealed about you/ your child this could cause you distress but all information collected in the study will be kept confidentially. Taking blood or physical examination as well as asking above mentioned questions may make you/ your child feel uncomfortable. You/ your child may refuse any physical examination, taking blood or answering any question or may take a break at any time. You may stop the participation of you/ your child in this study at any time.

Are there benefits of participating in this study?
If you agree to take part in this study, the direct benefit for you/ your child is that febrile infections, possible other bacterial infections and your/ your child’s current malaria status are diagnosed. This may result in a better treatment of your/ your child’s disease in case you need to be hospitalized. However, this may be too late to affect treatment decisions of you/ your child if you are not hospitalized. Indirect benefits for you/ your child and the general population are that in the future the information learned from this study will improve the knowledge of typhoid fever, its modes of transmission, risk factors and appropriate treatment. Findings of this study will, moreover, contribute to future implementation of appropriate prevention and control measures for typhoid fever in this study area, other parts of your country, and in other African countries.

Will my information be kept confidential?
All study records that identify you will be kept confidential. All information collected in this study will be given code numbers and no name will be recorded. The key to this code numbers will be kept in a locked file and be only accessible to authorized staff. Your name or any identifier will not be used in any publication or reports from this study. Results of investigations or other information that we collect about you/ your child will only be shared with medical staff looking after you/ your child and authorized members of the study such as officials from ethics committees. Computerized files will be password-protected and paper files will only be locked safely and only accessible to authorized staff.

What are the costs?
All the investigations done for participants of this study will be free of charge but hospital care and treatments will be paid for in the usual way.

What about compensation?
You will not be compensated for your participation in this study.

What about my rights to decline participation or withdraw from the study?
If you decide not to be included in the study, the same tests will be available at the request of the medical team and
your/ your child’s treatment will not be affected in any way. You are free to refuse to participate in the study or you can withdraw your consent at any time, without giving reasons and this will not involve any penalty or loss of benefits to which you/ your child are entitled such as proper care and treatment. Your access to treatment will not be dependent on your participation in the study.

Whom do I contact if I have questions?
If you have any questions you may ask them now or later. If you wish to ask questions later, you may contact contact details of local investigator.

Statement of consent
The “Consent to participate in the Typhoid Fever Surveillance in Africa Program (TSAP)” has been read to me/ I have read. The purpose and procedures, risks and benefits of this study have been explained to me in detail. I have been allowed to ask questions, and my questions have been answered to my satisfaction by the research staff. I have been told whom to contact if I have questions, want to discuss problems, or concerns. I have been told that I will be given a signed and dated copy of this consent form. I have been reassured that all information obtained as result of this study will be confidential and used for the purpose of this study only by the institutions participating in this study. I consent voluntarily to my/ my child’s participation as a subject in this study. I will follow the directions of the study team and give them my full cooperation. I understand that I have the right to withdraw from the study at any time, without any way affecting my child’s/ my own further medical care. If I/ my child will not participate in the study I/ my child will not involve any penalty or loss of benefits to which I/ my child are entitled.

For participant:

Name of participant: ______________________________________________________________

Name of parent/guardian (for children): _______________________________________________

Signature/thumbprint of participant or parent/guardian: _________________________________

Date: ____ / ____ / 20____

If participant or parent/guardian is illiterate:

Add name of independent literate witness (if possible, this person should be selected by the participant and should have no connection to the study team).

Name of witness: ___________________________________________________________________

Signature of witness: __________________________________________________________________

Date: ____ / ____ / 20____

For the study staff:

I have read/explained the study to the above named -participant (if adult)/ parent/guardian (if child) in a language that the participant understands well. I am certain that the participant has understood the information and is allowing a small amount of blood to be taken out of his/her own free will.

Name of study staff: __________________________________________________________________

Signature of study staff: __________________________________________________________________

Date: ____ / ____ / 20____