

A Cohort Study of the Impact of Resistance on Clinical Outcome Among non-Typhi *Salmonella* Serotypes

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A Cohort Study of the Impact of Resistance on Clinical Outcome Among non-Typhi *Salmonella* Serotypes

I. Project Overview

Title: A Cohort Study of the Impact of Resistance on Clinical Outcome Among non-Typhi *Salmonella* Serotypes

Protocol summary / Purpose of study

The purpose of this study is to investigate the impact of infection with non-Typhi Multi-Drug Resistant (MDR) *Salmonella* on clinical outcome. Non-Typhi MDR *Salmonella* includes *Salmonella* with resistance or reduced susceptibility to clinically important antimicrobial agents. The population in this study resides in the catchment area of the Centers for Disease Control and Prevention's (CDC) Foodborne Diseases Active Surveillance Network (FoodNet), which includes approximately 40 million persons (14 percent of the U.S. population¹). The study will be carried out by (i) identifying subjects with non-Typhi MDR *Salmonella* infections isolated from stool or a normally sterile site, (ii) interviewing them, and (iii) if hospitalized, extracting information about clinical course from their medical records.

Investigators/Collaborators/Funding

Investigators include National Antimicrobial Resistance Monitoring Surveillance (NARMS) and FoodNet staff in the 10 FoodNet sites and CDC. Collaborators include epidemiologists at the USDA and FDA. Funding for this study will be provided as part of the CDC Emerging Infections Program.

Investigators and Roles

Role	Name	Affiliation(s)	Responsibilities
Principal Investigator	Fred Angulo, DVM, PhD	FDDB/DBMD/NCID	Administrator
Clinician Investigator/ Epidemiologist	Tom Chiller, MD, MPH	FDDB/DBMD/NCID	Study design and data analysis
Clinician Investigator/ Epidemiologist	Ezra Barzilay, MD	FDDB/DBMD/NCID	Study design and data analysis
Epidemiologist	Julie Choudhuri, RN, MSPH	FDDB/DBMD/NCID	Study design and data analysis
FoodNet sites:	CA, CO, CT, GA, MD, MN, NM, NY, OR, TN	CA Dept of Health Services, Berkeley, CA CA EIP, Oakland, CA CDC, Atlanta, GA CO Dept of Public Health and Envr, Denver, CO CT Dept of Public Health, Hartford, CT CT EIP, New Haven, CT GA Div of Public Health, Atlanta, GA GA EIP, Atlanta, GA MD Dept of Health and Mental Hygiene, Baltimore, MD MD EIP, Baltimore, MD MN Dept of Health, Minneapolis, MN NM Dept of Health, Albuquerque, NM NM EIP, Albuquerque, NM NYS Dept of Health, Albany, NY OR Dept of Human Services, Portland, OR TN Dept of Health, Nashville, TN	Subject enrollment Questionnaire Chart Abstraction
		FDA	Study design and data analysis
	Myra Gardner	USDA	Study design and data analysis

II. Introduction

Background/ Justification

Recent data indicate 1.4 million non-Typhi *Salmonella* infections occur each year in the United States, resulting in 15,000 hospitalizations and 400 deaths. The economic burden of non-Typhi *Salmonella* infections encompasses outpatient provider visits (office and emergency), hospitalizations, and lost time at work. Most enteric *Salmonella* infections are short-lived and self-limiting. However, *Salmonella* can manifest invasively as a serious bloodstream infection or meningitis.

Antimicrobials may reduce the severity of illness and be life saving for persons with enteric fever, invasive infection, very young or old age, or immunocompromising conditions. Practitioners commonly treat *Salmonella* with fluoroquinolones (e.g., ciprofloxacin) in adults and extended-spectrum cephalosporin (e.g., ceftriaxone) in children. Yet the prevalence of antimicrobial resistant organisms is on the rise, which increases the risk for treatment failure in human infections.

NARMS, initiated in 1996, conducts nationwide surveillance for antimicrobial resistance in enteric bacteria. A representative sample of non-Typhi *Salmonella* isolates (every 20th) is forwarded from public health laboratories to the CDC's NARMS laboratory. Results from NARMS surveillance have described several critical trends. Recently, NARMS reported the emergence of a highly multi-drug resistant strain of *Salmonella* Newport, resistant to 9 or more antibiotics. Furthermore, there has been increasing resistance in other non-Typhi *Salmonella* to clinically important antibiotics, extended spectrum cephalosporins and quinolones, both first line therapy for many enteric infections.

It is important to understand and describe the human health consequences of drug resistant infections caused by non-Typhi *Salmonella*. However, few studies have looked at clinical outcomes of *Salmonella* infections with respect to drug-resistance. A Danish cohort study linked quinolone-resistant *Salmonella* Typhimurium to a higher risk for invasive illness or death in comparison to pan-

susceptible infections². In a recent retrospective study linking NARMS and FoodNet data, patients with antimicrobial-resistant Non-typhoidal *Salmonella* infections were more likely to experience a bloodstream infection and hospitalization than those infected with a pan-susceptible organism³. These findings prompted us to hypothesize that people infected with multi-drug resistant *Salmonella* will experience more severe and costly outcomes than those with pan-susceptible infections. Additionally, using DT104 strains there are studies in the scientific literature that show that the burden of the severity of clinical outcomes is attributed to the strain's phenotypic resistance and not its serotype (Martin, Lee Health Canada). This will be the first U.S. study to prospectively examine in detail the medical consequences of drug resistant non-Typhi *Salmonella* infections

Definition of Resistance

We define a strain of non-Typhi *Salmonella* serotype as pansusceptible if it does not exhibit resistance or reduced susceptibility to any antimicrobial agents tested. *Salmonella* strains are commonly defined as multi-drug resistant (MDR) if they exhibit resistance to three or more classes of antibiotics. For the purposes of this study, we will define MDR *Salmonella* strains as those that exhibit resistance to five or more classes of antibiotics. Two instances of MDR strains warrant further characterization: pentaresistant strains are those that exhibits resistance to five classes of antibiotics, (a classic example being strains that exhibits the phenotype ACSSuT with resistance to ampicillin, chloramphenicol, streptomycin, sulfamethoxazole and tetracycline) and heptaresistant strains that exhibit resistance to seven or more classes of antibiotics. The latter, when they include resistance to extended spectrum cephalosporins and fluoroquinolones, will be defined as strains of Clinically Important Resistance (CIR).

Objectives

The study's primary objective is to determine and compare severity of clinical outcome measured as a composite score (defined later in the proposal) among infections with pansusceptible or MDR non-Typhi *Salmonella* strains.

The clinical outcomes studied are:

- Diarrhea
- Duration of diarrhea
- Invasive symptoms (bloody diarrhea)
- Duration of fever (number of hours between onset of fever and defervescence)
- Mean time to defervescence from the onset of antimicrobial therapy (number of hours from onset of antimicrobial therapy to defervescence)
- Intravenous antimicrobial therapy
- Treatment failure
- Total duration of antimicrobial therapy
- Duration of antimicrobial therapy after discharge, if hospitalized
- Hospitalization
- Duration of hospital stay
- Intensive Care Unit stay
- Duration of stay in the Intensive Care Unit
- Vasopressor support (e.g., to improve renal output or blood pressure)
- Invasive procedures (e.g., including central line placement and endotracheal intubation)
- Diagnosis of subsequent co-morbidities (e.g., sepsis, endocarditis, meningitis, septic metastases, renal failure)
- Mortality

For the purpose of analysis:

- Fever is defined as rectal temperature above 100.4°F (38.0°C), oral temperature above 99.5°F (37.5°C) or axillary temperature above 99.0°F (37.2°C).
- Defervescence is defined as the time marking 24 hours from the time the core temperature was less than the equivalent of 100.4 degrees F (38.0 degrees Celsius) rectal.
- Treatment failure is defined as failure to defervesce within 48 hours from the onset of antimicrobial therapy. For the cases that do not report core temperatures or chart abstraction fails to produce records of core temperature, a change of antibiotic to a different class will be regarded as a sign of treatment failure.

This study also aims to identify persons considered at higher risk for resistant non-Typhi *Salmonella* infections based on their age, immune status, and site from which *Salmonella* was isolated. High risk for *Salmonella* infections are persons aged <5 or >65 years, having a chronic medical condition, or having an immunosuppressive condition. Within this study, an immunosuppressive condition is defined as the presence of any of the following: human immunodeficiency virus (HIV) infection, systemic lupus erythematosus, rheumatoid arthritis, leukemia or non-skin cancer, end-stage renal disease, bone-marrow/organ transplant, insulin-requiring diabetes, radiation therapy, or receipt of an immune-suppressing medication (including cancer chemotherapy, oral or injectable steroids, methotrexate, etc.).

III. Procedures/Methods

Design

The study design is a prospective, multi-center cohort study. The cohort will be identified through FoodNet, an active surveillance network, for a 12-month period.

Study Population

The study population will include those cases with laboratory-confirmed non-Typhi *Salmonella* residing in any of the 10 FoodNet states. The sites include all or part of the following states: California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee. Cases will be enrolled as they are detected by the FoodNet site's public health laboratory.

NARMS routinely receives 1/20 (5%) of non-Typhi *Salmonella* isolates from participating public health laboratories in the United States. We propose that states maintain their sampling schemes and if allowed by the state's capacity, enhance it to either 1/4, 1/5, or 1/10 of all their non-Typhi *Salmonella* isolates. These isolates will be forwarded to the CDC for antimicrobial susceptibility testing and other microbial characterization tests. Once non-Typhi *Salmonella* is isolated by the state public health or reference laboratory, study eligibility will be determined by epidemiologists at the state level.

The following sampling scheme illustrates a projection of study cases and charts abstractions for each participating state. Attrition will occur due to NARMS isolates being duplicates, carriers, out of surveillance catchment, and perishing during shipping.

FoodNet Site	FoodNet Cases*	Sampling Scheme	Estimated # of Study Cases	Prevalence of Hospitalization (based on FoodNet)	Estimated # Chart Abstractions
CA	466	1/10	47	17.65%	8
CO	247	1/4	62	14.63%	9
CT	393	1/5	79	24.43%	19
GA	1982	1/20	99	24.71%	24
MD	794	1/10	79	31.45%	25
MN	575	1/5	115	23.44%	27
NM	370	1/5	74	19.47%	14
NY	394	1/5	79	20.56%	16
OR	372	1/20	19	20.16%	4
TN	798	1/10	80	33.82%	27
Total	6019	--	732	--	169

Attrition Rate

10%

659**Mean Hospitalization Rate****23.35%**

* Based on 2003 FoodNet surveillance data

Inclusion criteria

Eligible study participants are persons of any age, residing within a FoodNet catchment area during the 12-month study period, and having a non-Typhi *Salmonella* serotype isolated from stool or a normally sterile site.

Exclusion criteria

Patients will not be included in the study if:

- i. the non-Typhi *Salmonella* serotype isolate is not available for further characterization;
- ii. they have a documented pre or co-existing infection defined as infection from a different enteric pathogen or site within 30 days of their non-Typhi *Salmonella* culture;
- iii. they do not speak English or Spanish;

- iv. they are not reachable after at least 15 telephone attempts (3 attempts each for 5 days, at least 1 day being a weekend and at least 1 attempt each day occurring between 5:00 and 9:00 pm), or within 85 days of culture date;
- v. they do not have a telephone number available for their primary residence;
- vi. they reside outside of the FoodNet catchment area;
- vii. they refuse to be interviewed;
- viii. a guardian or surrogate is not available for interviewing;

Records will be kept documenting why patients were excluded from study (Appendix C).

Number of participants expected / Sample size

Data from the National Antimicrobial Resistance Monitoring System, 1996 through 2001, indicates that

- Approximately 12% of non-Typhi *Salmonella* isolates are resistant to 5 or more classes of antimicrobial agents, which is consistent with the proposed definition of MDR *Salmonella*.
- Approximately 2% of non-Typhi *Salmonella* isolates are resistant to extended spectrum cephalosporins, while 0.2% are resistant to fluoroquinolones. These cases will fall under the definition of CIR *Salmonella*
- Approximately 72% of non-Typhi *Salmonella* isolates are pansusceptible⁴.

According to the sampling scheme (assuming a 10% dropout), we will collect 659 non-Typhi *Salmonella* isolates. Based on the prevalence data above, we expect to identify:

- 79 cases with MDR non-Typhi *Salmonella* infection
- 13 cases with CIR non-Typhi *Salmonella* infection
- 474 cases with pansusceptible non-Typhi *Salmonella* infection
- 93 cases with resistance to one or two classes of antimicrobials that do not meet the definition of MDR non-Typhi *Salmonella* infection.

Power Calculations

We will rank clinical outcomes according to their severity. Next, we will combine them to develop a new weighted scoring mechanism/scale. This will enhance our ability to detect differences in clinical severity through an aggregate effect. Due to biological variations, we may not capture illness severity by comparing a single clinical outcome (e.g., fever or no fever). However, we can powerfully detect degrees of medical severity by incorporating plausible, cumulative clinical outcomes. This innovative scale is to be developed, but a simplified example would be:

- mild:* x duration of fever or diarrhea;
- moderate:* x duration of fever or diarrhea + hospitalization/ no-ICU stay;
- severe:* x duration of fever or diarrhea + hospitalization/with ICU stay;
- very severe:* x duration of fever or diarrhea + hospitalization/with ICU stay + endotracheal intubation or vasopressor support.

Based on currently available methodologies, we know that the sample size necessary to detect significant differences in aggregated clinical outcomes (i.e. as part of a summative clinical score) at a given power, is lower than the sample size required by any of the individual outcomes. Therefore, in order to estimate sufficient sample size for this study, we based our power calculations on a single clinical outcome (hospitalization).

We know the overall prevalence of resistance to one or more antimicrobial agents among non-Typhi *Salmonella* serotypes to be approximately 28%.

Assuming

- Hospitalization prevalence of 23% among patients with *Salmonella*
- An odds ratio of 1.8 for hospitalization of patients with pansusceptible versus resistant *Salmonella*³
- 10% dropout

Then, enrolling 640 patients would provide sufficient power to detect a difference with 80% power and 95% confidence within 1 year.

Enrollment of Study Population

Once aware of a non-Typhi *Salmonella* isolate, sites will review their internal databases to determine if the case has a pre or co-existing infection, and is to be excluded. Eligible cases will be interviewed by telephone two weeks from the specimen collection date, after informed consent is obtained. Interviewers will be experienced, trained public health personnel and blinded to the patient's resistance status. The study staff will contact the patient (if patient \geq 18 years of age), patient's caretaker (if patient < 18 years of age or unable to interview independently), or surrogate (if deceased). If the patient is still hospitalized, the researcher will wait one week until attempting contact again to allow time for discharge from the hospital and the clinical outcome to occur. A standardized questionnaire will be administered (Appendix A).

State statutes and regulations allow health departments the authority to review medical information when relevant to public health disease prevention and control activities. If hospitalized, available medical records of eligible patients will be reviewed by trained public health staff at the state level, using a structured chart extraction questionnaire (Appendix B). Chart review is a normal surveillance activity for state health departments. The first admission with stool or other sterile site culture-confirmed non-Typhi *Salmonella* infection will be identified. Subsequent hospital admissions and visits will also be used to complete the questionnaire.

Cases may be enrolled as early as 14 days and no later than 85 days after specimen collection date. Every effort will be made to serotype isolates and interview as soon as possible.

Questionnaires

The questionnaire (Appendix A) covers demographic characteristics, clinical history, specific exposures, and antimicrobial history. Interviews will be conducted in English or Spanish, depending on the preference of the person being interviewed. A Spanish version of the questionnaire has been translated by a certified professional translator, and back translated to English by a native speaker. The project staff member will administer the questionnaire to all persons who are ≥ 18 years of age after obtaining appropriate consent (Appendix C2), and to a parent, guardian, or caregiver for persons < 18 years of age or persons unable to independently be interviewed (e.g., developmentally delayed, suffering from dementia). In addition, for persons < 18 and > 13 years of age, verbal assent will be obtained (Appendix C3). A surrogate should be interviewed, when possible, if a patient is deceased. The interviewers will be blinded to the subjects' non-Typhi *Salmonella* antimicrobial resistance status, minimizing the introduction of bias.

Medical records are reviewed by state health departments in accordance with their state statutes as normal surveillance activities. Hospital charts will be reviewed for all patients to determine the patient's clinical course and duration of illness and hospitalization. A chart extraction questionnaire (Appendix B) will cover laboratory results, medical procedures, type of antimicrobial therapy before and during hospitalization, clinical response to therapy (e.g., time to defervescence), and clinical or microbiologic relapse- to obtain measures for severity of clinical outcome. Only state-assigned identifiers will be documented on the chart abstraction form (Appendix B).

Bacteriologic isolates /Laboratory studies

The NARMS laboratory at CDC will conduct antimicrobial susceptibility testing on all *Salmonella* isolates received for patients in the cohort. The CDC performs susceptibility testing with a semi-automated system (Sensititre, TREK Diagnostic Systems, Westlake, OH). The partial range minimum inhibitory concentration (MIC) will be determined for 14 antimicrobial agents: amikacin, ampicillin, amoxicillin-clavulanic acid, ceftriaxone, cephalothin, chloramphenicol, ciprofloxacin,

gentamicin, kanamycin, nalidixic acid, streptomycin, sulfamethoxazole, tetracycline, and trimethoprim-sulfamethoxazole. National Committee for Clinical Laboratory Standards (NCCLS) interpretive criteria will be used when available⁵.

Informed consent

Subject interviews: For participants ≥ 18 years of age or emancipated minors, verbal consent will be obtained and documented on the consent form (Appendix C2). For persons <18 years of age or persons unable to independently be interviewed (e.g., developmentally delayed, suffering from dementia), verbal consent will be obtained from a parent, guardian, or caretaker and verbal assent from the minor case-patient (Appendix C3). If deceased, staff will attempt to interview a surrogate. The consent and verbal assent forms have been translated into Spanish by a native speaker and back-translated to English by a different native speaker to ensure accuracy. A copy of the consent form read to the patient, with their response noted and signed by the interviewer, will be kept with each completed questionnaire. Staff will mail the interviewee a copy of the consent form.

As patient or proxy interviews will be conducted over the phone, requiring signed consent would substantially reduce participation. This study requests a waiver of documentation of consent under 45 CFR 46.117.c(2), because the study presents no more than minimal risk of harm to participants and signed consent would not normally be required outside of the research context. Only questionnaire data, medical records review, and existing specimens are involved. No procedure for which written consent is normally required outside of the research context is involved. The waiver of documentation of informed consent will not adversely affect the rights and welfare of participants.

Confidentiality

All information will be kept confidential in locked cabinets in locked offices with limited access and electronic information on password-protected computers in a password-protected database. Only the databases will be forwarded to CDC. Protected health information (name, address, etc.) will not be forwarded to the CDC or included in any published materials relating to this study. The primary unique identifier attached to each isolate, is the state laboratory isolate ID number, already an established practice for identifying laboratory isolates sent to the CDC. This number will be used to merge laboratory, questionnaire, and chart abstraction data. Study staff should also enter the Public Health Laboratory Information System (PHLIS) or any other local unique identifier that would optimize linking between case information and lab results. The assignment of a unique state lab ID number permits the removal of all personal identifiers and ensures confidentiality.

Risks and benefits

The study participant will expend minimal time and effort, consisting of a twenty-minute phone interview. There will be no reimbursement and participants will receive no direct benefit from the study. There is no penalty for not participating. There is no risk to the patient or the patient's caretaker except for minimal potential loss of privacy. Steps described above under "confidentiality" minimize this potential loss of privacy.

Data handling / Analysis

Completed case questionnaires will be reviewed and coded by study staff at each site, and information entered into a local database. We propose that states send some of the initial questionnaires to the CDC to aid in-group discussion of questions and problems. At the completion of the study, each state will forward their databases of study information to CDC where the data will be aggregated and analyzed. Only state-assigned isolate or case identifiers will accompany the data.

Analysis will be conducted by an analytic team comprised of epidemiologists and statisticians in collaboration with NARMS and FoodNet staff.

The primary analysis will compare the clinical outcomes observed among cases with:

- i. MDR non-Typhi *Salmonella* infection to those of cases with pansusceptible non-Typhi *Salmonella*;
- ii. CIR non-Typhi *Salmonella* serotypes to those of cases with pansusceptible non-Typhi *Salmonella* infections.

In addition, the study will look for variations of clinical outcomes among subgroups with reference to age, sex, and immune status.

IV. References

1. FoodNet 2002 Annual Report
http://www.cdc.gov/foodnet/annual/2002/2002executive_summary.pdf
2. Helms M, Simonsen J, Molbak K. Quinolone resistance is associated with increased risk of invasive illness or death during infection with *Salmonella* serotype Typhimurium. *J Infect Dis.* 2004 Nov 1;190(9):1652-4.
3. Varma JK, Molbak K, Barrett TJ, Beebe JL, Jones TF, Rabatsky-Ehr T, Smith KE, Vugia DJ, Chang HG, Angulo FJ. Antimicrobial-Resistant NonTyphoidal *Salmonella* is associated with excess bloodstream infections and hospitalizations. *J Infect Dis.* 2005 Feb 15;191(4):554-561.
4. NARMS 2001 Annual Report:
<http://www.cdc.gov/narms/annual/2001/table/0119.htm>
5. Clinical and Laboratory Standards Institute. Performance standards for antimicrobial susceptibility testing: informational supplement. M100-S15. Wayne (PA); The Committee; current.

APPENDIX A

A Cohort Study of the Impact of Resistance on Clinical Outcome Among non-Typhi *Salmonella* Serotypes CASE QUESTIONNAIRE

SECTION 1: CASE IDENTIFIERS

State Laboratory Isolate ID Number* _____ **Site ID** _____

*Please note this is mandatory to identify and link cases by

PHLIS ID Number _____ Other patient or specimen ID _____
(CA, CT, GA, MN)

Specimen Collection Date ____/____/____ →→ **FILL IN ON PAGE 6**
MM DD YY

Specimen Source: (CIRCLE ONE) stool / blood/ urine/ cerebrospinal fluid (CSF)/ OTHER: _____

County _____ State Initials _____

DOB ____/____/____
MM DD YY

Gender of case

Male..... 1

Female..... 2

(IF DON'T KNOW/ NOT SURE, ASK DURING INTERVIEW)

BEFORE YOU CONTACT CASE, HAVE A CALENDAR IN FRONT OF YOU

SECTION 2: HEALTH QUESTIONS

PART 1. SCREENING QUESTIONS

[You have/your child has] been diagnosed with a Salmonella infection. I would like to begin with several questions about [your/ your child's] infection. Because I will be asking about specific dates around the time of [your/ your child's] diagnosis, it may be helpful for you to have a calendar or day planner in front of you. Do you need a few minutes to go get one?

1. Were you ever told by your doctor or nurse that [you/your child has] have a *Salmonella* bloodstream infection or a positive blood culture for *Salmonella*?

- Yes..... 1
- No..... 2
- Don't know/Not sure..... 7
- Refused..... 9

2. For what reason did you [go/ take your child] to a health care provider's office or laboratory where [you/ your child] provided the specimen that yielded *Salmonella*?

- Felt sick/ symptoms of illness..... 1
- No symptoms–Testing required by employer..... **GO TO Q.23**..... 2
- No symptoms–Testing required for immigration..... **GO TO Q.23**..... 3
- No symptoms–Testing required by health department... **GO TO Q.23**..... 4
- No symptoms—Routine urine test **GO TO Q.23**..... 5
- Other **PLEASE SPECIFY** _____ 6

PART 2. HISTORY OF ILLNESS AND MEDICAL CARE

3. On what date did [you/ your child] first notice symptoms of illness because of this *Salmonella* infection?
 (If respondent is unsure of the date, prompt with the date specimen was collected and ask them to provide their best estimate when illness began.)

____/____/____
 mo day yr (= ONSET DATE – write this date on calendar)

Don't know/Not sure..... 777777
 Refused..... 999999

4. What was the first symptom that [you/ your child] had? ([DO NOT READ]. CHOOSE ONLY ONE.)

- Fever..... 1
 - Chills..... 2
 - Nausea 3
 - Vomiting..... 4
 - Abdominal Pain or cramping..... 5
 - Achy joints or muscles..... 6
 - Fatigue..... 7
 - Headaches..... 8
 - Diarrhea 9
 - Bloody stool/diarrhea..... 10
 - Other (e.g. 'sweats', anorexia)..... 11
- SPECIFY _____

5. During [your/ your child's] illness, did [you/ your child] have any of the following symptoms?
PLEASE READ EACH SYMPTOM.

		Yes	No	DK	Refuse
A	Chills	1	2	7	9
B	Nausea	1	2	7	9
C	Vomiting	1	2	7	9
D	Abdominal Pain or cramping	1	2	7	9
E	Achy joints or muscles	1	2	7	9
F	Fatigue or excessive tiredness	1	2	7	9
G	Headaches	1	2	7	9
H	Diarrhea (>3 loose stool in 24 hours)	1	2	7	9
	→→IF YES... →When did the diarrhea start?	____/____/____ mo day yr Enter 777777 for Don't know 999999 for Refused			
	→What was the most number of stools in a 24-hour period?	_____ # stools			
	→Still having diarrhea?	1	2	7	9
I	→→IF NO to "Still Having Diarrhea"... How many days did the diarrhea last?	_____ # days			
	Blood in stools or bloody diarrhea	1	2	7	9
J	Other	1	2	7	9
	→→IF OTHER, please specify (e.g. 'sweats', anorexia):				

6. After [you/ your child] became ill, did you ever check a temperature with a thermometer?

- Yes..... 1
- No..... **Go to Q. 10**..... 2
- Don't know/Not sure..... **Go to Q. 10**..... 7
- Refused..... **Go to Q. 10**..... 9

7. Did [you/ your child] ever have a temperature reading of 100.4 degrees Fahrenheit (38.0 degrees Celsius) or higher?

- Yes..... 1
- No..... **Go to Q. 10**..... 2
- Don't know/Not sure..... **Go to Q. 10**..... 7
- Refused..... **Go to Q. 10**..... 9

8. Please recall the date of that first temperature reading above 100.4 degrees F or above (38.0 degrees C)?

____/____/____ (= **FEVER DATE – write this date on calendar**)
 MM DD YY

- Don't know/Not sure..... 7
- Refused 9

9. If [you/your child] ever had a fever, can you recall the date [you/ your child] went more than 24 hours without a fever?

____/____/____ (= **DEFERVESCENCE DATE – write this date on calendar**)
 MM DD YY

- Does not apply 000000
- Don't know/Not sure..... 777777
- Refused..... 999999

Now I'm going to ask you about outpatient visits related to this illness. Please distinguish the number of hospital emergency department from other types of clinic visits. Do not include telephone contact with a healthcare professional.

10. How many times did [you/ your child] visit a doctor or other health professional at a **clinic, urgent care, or doctor's office** for this illness or complications related to this illness?

- __ __ outpatient clinic or urgent care or doctor's office visits
- Don't know/Not sure..... 77
- Refused..... 99

11. How many times did [you/ your child] visit a doctor or other health professional at a **hospital emergency department** for this illness or complications related to this illness?

- __ __ hospital emergency department visits
- Don't know/Not sure..... 77
- Refused..... 99

12. How many times did [you/ your child] visit any **other type of outpatient health care facility (including alternative medicine)** for this illness or complications related to this illness?

PLEASE SPECIFY (e.g., herbalist, acupuncture) _____

___ other outpatient facility visits
 Don't know/Not sure..... 77
 Refused..... 99

13. During the course of your illness, did [you/ your child] ever receive an intravenous (I.V.) catheter? (**Read the following if further explanation is needed: A needle is inserted into a vein usually in the hand or arm, and a small tube remains for the purpose of giving fluid or medicine through).**)

Yes..... 1
 No..... **Go to Q. 14.**..... 2
 Don't know/Not sure..... **Go to Q. 14.**..... 7
 Refused..... **Go to Q. 14.**..... 9

→→**IF YES**, Did [you/ your child] receive intravenous (I.V.) fluids for rehydration?

Yes..... 1
 No..... 2
 Don't know/Not sure..... 7
 Refused..... 9

14. [Were you / Was your] child admitted to the hospital overnight for this illness?

Yes..... 1
 No..... **Go to Q. 19.**..... 2
 Don't know/Not sure..... **Go to Q. 19.**..... 7
 Refused..... **Go to Q. 19.**..... 9

15. How many times [were you / was your] child admitted to the hospital for this illness?

___ times
 Don't know/Not sure..... 77
 Refused..... 99

16. Please tell me the names and dates of each hospital [you were/ your child was] admitted to for this illness?

(IF ADMITTED TO SAME HOSPITAL TWICE, LIST HOSPITAL NAME TWICE)

Hospitalization #1

Hospital Name/CODE: _____ Dates _____ to _____
Address: _____
City, State: _____
Phone: _____

Hospitalization #2

Hospital Name/CODE: _____ Dates _____ to _____
Address: _____
City, State: _____
Phone: _____

Hospitalization #3

Hospital Name/CODE: _____ Dates _____ to _____
Address: _____
City, State: _____
Phone: _____

→→ COMPLETE “HOSPITAL FOLLOW-UP” FORM FOR EACH HOSPITALIZATION

17. On what date did [you/ your child] first enter the hospital for this illness?

____/____/____
 MM DD YY

18. How many nights [were you/ was your child] hospitalized for this illness?

___ ___ nights

Don't know/Not sure..... 777777
 Refused..... 999999

19. After [your/your child's] illness began, did [you/ your child] begin any antibiotics? Please also include any antibiotic given at your health care provider's office, like an injection.

Yes..... 1
 No..... **Go to Q. 23**..... 2
 Don't know/Not sure..... **Go to Q. 23**..... 7
 Refused..... **Go to Q. 23**..... 9

20. I am going to ask you some questions about the antibiotics [you/your child] took. If you still have prescription bottles/packages, please get them.
- What is the name of the antibiotic(s) [you/your child] took after [you/your child] became ill? As a reminder, [you/ your child] became ill on _____ (ONSET DATE)
 - Did you/your child start this antibiotic before or after [you/ your child] gave the specimen to your health care provider, which yielded *Salmonella*? As a reminder, [you/your child] submitted this specimen on _____ (SPECIMEN DATE).
 - What date did [you/your child] start taking the antibiotic(s)?
 - Are [you/your child] still taking the antibiotic(s)? (If YES, record as 777777 under “STOP DATE?”)
 - (If not still taking antibiotic) What date did [you/ your child] stop taking the antibiotic(s)?
 - (If not still taking antibiotic) Did [you/ your child] miss any doses of the antibiotics?

CIRCLE ANTIBIOTIC ON LIST. [DO NOT READ].

→→If not still taking←←

Antibiotic Name (A)		Start before or after specimen collection? (B)	Start Date? (C) (999999 if unknown)	Stop Date? (D,E) (777777 if still taking, 999999 if unknown)	Miss any dose of antibiotics? (F)
Don't Remember Name	99	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Amoxicillin	1	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Amoxicillin/Clavulanate	2	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Ampicillin	3	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Augmentin	4	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Azithromycin	5	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Bactrim	6	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Biaxin	7	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Ceclor	8	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Cefaclor	9	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Cefadroxil	10	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Cefdinir	11	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Ceftin	12	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Cefixime	13	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Cefuorixime	14	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Cefzil	15	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Cefprozil	16	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Cephalexin	17	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Cephradine	18	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Ciprofloxacin or Cipro	19	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Clarithromycin	20	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)
Cleocin	21	Before (1) After(2) DK(7)			Y(1) N(2) DK(7) REF(9)

CIRCLE ANTIBIOTIC ON LIST. [DO NOT READ].**→→If not still taking←←**

Antibiotic Name (A)		Start before or after specimen collection? (B)			Start Date? (C) (999999 if unknown)	Stop Date? (D,E) (777777 if still taking, 999999 if unknown)	Miss any dose of antibiotics? (F)
Clindamycin	22	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Dapsone	23	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Doxycycline	24	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Duricef	25	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Erythromycin	26	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Erythromycin/sulfa	27	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Flagyl	28	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Floxin	29	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Fosfomycin	30	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Gatifloxacin	31	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Keflex	32	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Keftab	33	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Levofloxacin	34	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Levoquin	35	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Metronidazole	36	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Monurol	37	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Norfloxacin or Norflox	38	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Ofloxacin or Oflox	39	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Omnicef	40	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Pediazole	41	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Penicillin or Pen VK	42	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Septra	43	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Sparfloxacin	44	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Suprax	45	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Tequin	46	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Tetracycline	47	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Trimox	48	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Trimethoprim/Sulfa	49	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Zagam	50	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
Zithromax or Z-Pak	51	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
OTHER – SPECIFY	52	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)
OTHER – SPECIFY	53	Before (1)	After(2)	DK(7)			Y(1) N(2) DK(7) REF(9)

21. While [you were/ your child was] taking antibiotics, did the doctor change the antibiotic or tell [you/ your child] to stop taking the antibiotic early?

- Yes..... 1
- No..... **Go to Q. 23**..... 2
- Don't know/Not sure..... **Go to Q. 23**..... 7
- Refused..... **Go to Q. 23**..... 9

22. Please think back-- Why were the antibiotics stopped early or changed?

[Read answers only if necessary]

- Rash/ allergic reaction 1
- Adverse reaction (e.g. drug interaction, kidney failure)..... 2
- (PLEASE SPECIFY)** _____
- Continued fever..... 3
- No improvement in symptoms 4
- A specialist or new doctor changed it..... 5
- Doctor received lab results..... 6
- Other reason: **(PLEASE SPECIFY)** _____

SECTION 2: EXPOSURES

PART 1. PRIOR MEDICATION USE / PAST MEDICAL HISTORY

Count 4 weeks back from onset date. For asymptomatic individuals, use the specimen collection date. You will ask about the time period between onset date and 4 weeks before the onset date. For example, if the ONSET DATE is April 30, ask about the time April 2 to April 30.

Next, I would like to ask you a few questions about you/ your child’s medication use.

- 23. In the 4 weeks before [your/ your child’s] diagnosis with *Salmonella* or illness began, that is between (read appropriate dates) did [you/ your child] receive any of the following types of treatments or take any of the following types of medications?

PLEASE READ EACH MEDICATION/TREATMENT.

		Yes	No	DK	Refuse
A	Any oral or intravenous (IV) steroid, such as prednisone	1	2	7	9
B	Any immune-suppressing medication, such as Cyclosporine, FK 506 (tacrolimus), or Methotrexate	1	2	7	9
C	Any type of Insulin	1	2	7	9
D	Any form of chemotherapy	1	2	7	9
E	Any form of radiation therapy	1	2	7	9
F	Any anti-diarrhea medication, such as Pepto-Bismol, Immodium, or Kaopectate	1	2	7	9
G	Any acid-reducing pills, such as Pepcid, Zantac, or Prilosec (both over-the-counter and prescription).	1	2	7	9

- 24. In the four weeks before [your/your child’s] illness began, did [you/ your child] take any antibiotics, even if just one dose?

- Yes..... 1
- No..... **Go to Q. 28**..... 2
- Don’t know/Not sure..... **Go to Q. 28**..... 7
- Refused..... **Go to Q. 28**..... 9

- 25. Why [were you/ was your child] taking this antibiotic? [**DO NOT READ**].

- Ear, sinus, upper respiratory infection 1
- Bronchitis or pneumonia..... 2
- Urinary tract infection..... 3
- Skin infection..... 4
- Acne..... 5
- Prophylaxis or Preventive (e.g.: travel, exposure to meningitis, dental work)..... 6
- Other (**SPECIFY** _____) 7
- Don’t Know..... 8
- Refused..... 9

26. How did you obtain the antibiotic [you were/ your child was] taking before [you were/ your child was] diagnosed with *Salmonella*?

- Left over in medicine cabinet..... 1
- Borrowed from friend/relative..... 2
- Prescribed by doctor recently..... 3
- Other..... 4

SPECIFY _____

- [Do not read]** Don't Know..... 7
- [Do not read]** Refused..... 9

27. I am going to ask you some questions about the antibiotics [you/ your child] took. If you still have the prescription bottle or package, please get it now. (**Interviewer: code your answers on the chart**).

- a. What is the name of the antibiotic [you/ your child] took before you became ill with *Salmonella*?
- b. [Were you / Was your child] taking this within the 5 days before [you/ your child] became ill with *Salmonella*?
- c. [Were you / Was your child] taking this the day before [you/ your child] became ill? By day, I am referring to the 24 hrs before illness began.
- d. What date did [you/ your child] start taking the antibiotic? (**IF “STILL TAKING”, enter 777777 under “Stop Date?”**)
- e. When did [you/ your child] stop taking the antibiotic?
- f. (**If not still taking antibiotic**) Did [you/ your child] miss any doses of antibiotics?
[Do not read] all the options.

CIRCLE ANTIBIOTIC ON LIST. [DO NOT READ].**→→If not still taking←←**

Antibiotic Name (A)		Taking 5 days before becoming ill? (B)				Taking the day before becoming ill? (C)				Start Date? (D) <small>(999999 if unknown)</small>	Stop Date? (E) <small>(777777 if still taking, 999999 if unknown)</small>	Miss any dose of antibiotics? (F)
Don't Remember Name	99	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Amoxicillin	1	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Amoxicillin/Clavulanate	2	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Ampicillin	3	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Augmentin	4	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Azithromycin	5	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Bactrim	6	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Biaxin	7	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Ceclor	8	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Cefaclor	9	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Cefadroxil	10	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Cefdinir	11	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Ceftin	12	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Cefixime	13	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Cefuorixime	14	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Cefzil	15	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Cefprozil	16	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Cephalexin	17	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Cephadrine	18	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Ciprofloxacin or Cipro	19	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Clarithromycin	20	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Cleocin	21	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Clindamycin	22	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)
Dapsone	23	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1) N(2) DK(7) REF(9)

CIRCLE ANTIBIOTIC ON LIST. [DO NOT READ].**→→If not still taking←←**

Antibiotic Name (A)		Taking 5 days before becoming ill? (B)				Taking the day before becoming ill? (C)				Start Date? (D) (999999 if unknown)	Stop Date? (E) (777777 if still taking, 999999 if unknown)	Miss any dose of antibiotics? (F)			
Doxycycline	24	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Duricef	25	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Erythromycin	26	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Erythromycin/sulfa	27	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Flagyl	28	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Floxin	29	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Fosfomycin	30	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Gatifloxacin	31	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Keflex	32	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Keftab	33	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Levofloxacin	34	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Levoquin	35	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Metronidazole	36	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Monurol	37	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Norfloxacin or Norflox	38	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Ofloxacin or Oflox	39	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Omnicef	40	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Pediazole	41	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Penicillin or Pen VK	42	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Sepra	43	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Sparfloxacin	44	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Suprax	45	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Tequin	46	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Tetracycline	47	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Trimox	48	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Trimethoprim/Sulfa	49	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Zagam	50	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
Zithromax or Z-Pak	51	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
OTHER – SPECIFY	52	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)
OTHER – SPECIFY	52	Y(1)	N(2)	DK(7)	REF(9)	Y(1)	N(2)	DK(7)	REF(9)			Y(1)	N(2)	DK(7)	REF(9)

Now I would like to ask you some very general questions about [your/ your child's] health. We would like to know about [your/ your child's] medical history. Some of these questions are of a sensitive nature. You do not need to answer the questions if you are uncomfortable.

28. As far as you know, have you ever been told by a physician that [you have/your child has] any of the following medical conditions?

PLEASE READ EACH CONDITION AND RECORD YES / NO / DK / REFUSE.

		Yes	No	DK	Refuse
A	Diabetes	1	2	7	9
B	Kidney Disease	1	2	7	9
	→→ IF YES , [Are you/Is your child] on dialysis or awaiting dialysis?	1	2	7	9
C	Organ or Bone Marrow Transplant	1	2	7	9
D	Stomach Ulcer Disease	1	2	7	9
E	Stomach Surgery	1	2	7	9
F	Liver Disease, including Hepatitis C	1	2	7	9
G	Chronic Diarrhea	1	2	7	9
H	Leukemia or Cancer (not skin cancer)	1	2	7	9
I	Sickle Cell Disease (not sickle cell trait)	1	2	7	9
J	Lupus	1	2	7	9
K	Rheumatoid Arthritis	1	2	7	9
L	Any other immune compromising condition	1	2	7	9

→→PLEASE SPECIFY _____

PART 2. TRAVEL HISTORY (INCLUDING DOMESTIC)

I would like to ask you some questions about any travel [you/ your child] may have done in the 10 days before [you/ your child] became ill.

29. In the 10 days before [your/ your child’s] illness began, did [you/ your child] travel outside of the United States?

- Yes..... 1
- No..... **Go to Q. 31**..... 2
- Don’t know/Not sure..... **Go to Q. 31**..... 7
- Refused..... **Go to Q. 31**..... 9

→→**IF YES**, Where did [you/your child] travel to and when did [you/ your child] travel?

Country _____ Dates _____ **to** _____
 Country _____ Dates _____ **to** _____
 Country _____ Dates _____ **to** _____

30. Did [you/ your child] seek traveler’s health advice from a doctor’s office, traveler’s health clinic, immunization clinic, or health department before you left?

- Yes..... 1
- No..... 2
- Don’t know/Not sure..... 7
- Refused..... 9

31. In the 10 days before [you/ your child’s] illness began, did [you/ your child] travel within the U.S. outside of your/your child’s home state?

- Yes..... 1
- No..... **Go to Q. 32**..... 2
- Don’t know/Not sure..... **Go to Q. 32**..... 7
- Refused..... **Go to Q. 32**..... 9

→→**IF YES**, which states did [you/your child] travel to in those 10 days?

CIRCLE ALL THAT APPLY.

- | | | | | | | | | | | | | |
|----|----|----|----|----|----|----|----|----|----|----|----|----|
| AL | CA | DC | IA | KS | MD | MO | ND | NM | OK | SC | UT | WI |
| AK | CO | FL | ID | KY | ME | MS | NE | NV | OR | SD | VA | WV |
| AR | CT | GA | IL | LA | MI | MT | NH | NY | PA | TN | VT | WY |
| AZ | DE | HI | IN | MA | MN | NC | NJ | OH | RI | TX | WA | |

SECTION 3: DEMOGRAPHICS

Now I would like to ask you a few questions about [your/your child's] community and family. Some of these questions may be personal but they help us figure out how to prevent these infections. You may refuse to answer any of these questions.

32. What is [your/your child's] race?

[Read only if necessary, respondent may choose more than one race]

White.....	1
Black or African American.....	2
American Indian or Alaskan Native.....	3
SPECIFY PRINCIPAL TRIBE _____	
Asian Indian.....	4
Chinese.....	5
Filipino.....	6
Japanese.....	7
Korean.....	8
Vietnamese.....	9
Native Hawaiian.....	10
Guamanian or Chamarro.....	11
Samoan.....	12
Other Pacific Islander.....	13
Other Asian.....	14
SPECIFY _____	
Some other race.....	15
SPECIFY _____	
[Do not read] Don't know/Not sure.....	77
[Do not read] Refused.....	99

33. [Are you/ Is your child] of Hispanic or Latino origin?

Yes.....	1
No.....	2
Don't know/Not sure.....	7
Refused.....	9

34. **(If case ≥ 18 or emancipated minor)** What is the highest grade of school you completed?
(If case < 18) What is the highest grade or year of school completed for the oldest parent or guardian?

[Read if necessary]

Less than 1 st grade.....	1
1 st through 8 th grade (Elementary).....	2
9 th through 12 th grade (No Diploma).....	3
High school graduate: high school diploma or the equivalent (GED).....	4
Some college but no degree.....	5
Associate degree in college.....	6
Bachelor's degree (for example: BA, AB, BS).....	7
Master's degree (for example: MA, MS, Meng, MSW, MBA).....	8
Doctorate degree (for example, MD, DVM, PhD, JD).....	9
Technical degree SPECIFY _____	
Other SPECIFY _____	

[Do not read] Don't know/Not sure.....	77777
[Do not read] Refused.....	999999

35. Which of the following places best describes where [you/your child] live(s)?

[Please Read]

- City or urban area..... 1
- Suburban area 2
- Town or village..... 3
- Rural area, but not on a farm..... 4
- On a farm..... 5
- Don't know/Not sure..... 7
- Refused..... 9

[Do not read]

[Do not read]

36. Which of the following best describes [your/your child's] current home?

[Please Read]

		Yes	No	DK	Refuse
A	Apartment building / Flat/ Condominium	1	2	7	9
B	Townhome / Duplex	1	2	7	9
C	Free-standing house	1	2	7	9
D	Mobile Home or trailer	1	2	7	9
E	Other? →→IF YES, SPECIFY _____	1	2	7	9

37. What is [your/ your child's] zip code? ____ _

- Don't know/Not sure..... 777777
- Refused..... 999999

38. At the time that [you/ your child] became ill, did [you/your child] have any form of medical or health insurance that paid some or all of your medical bills?

- Yes..... 1
- No..... **Go to Q. 39**..... 2
- Don't know/Not sure..... **Go to Q. 39**..... 7
- Refused..... **Go to Q. 39**..... 9

→→ IF YES, Please describe [your/ your child's] health insurance. You may consult your insurance card for information or make more than one choice.

[Please Read]

		Yes	No	DK	Refuse
A	Health Maintenance Organization (HMO), Preferred Provider Organization (PPO)	1	2	7	9
B	Private Insurance	1	2	7	9
C	Medicaid	1	2	7	9
D	Medicare	1	2	7	9
E	Other?	1	2	7	9
→→IF OTHER, PLEASE SPECIFY: _____					

39. Did this infection interfere with [your/your child's] ability to perform [your/your child's] usual daily activities such as housework, going to school or going to work?
- Yes..... 1
 - No..... 2
 - Don't know/Not sure..... 7
 - Refused..... 9
 - IF YES**, How many days of usual activities did [you/your child] miss? ___ ___ days
 - Don't know/Not sure..... 7
 - Refused..... 9

If the person with the Salmonella illness is LESS THAN AGE 18, SKIP to Q41. Otherwise, continue to Q40.

40. Did you have a paid job at the time you got sick?
- Yes..... 1
 - No..... 2
 - Don't know/Not sure..... **Go to Q. 41**..... 7
 - Refused..... **Go to Q. 41**..... 9
 - IF YES**, Did you miss any days from your paid job due to this illness?
 - Yes..... 1
 - No..... 2
 - Don't know/Not sure..... **Go to Q. 41**..... 7
 - Refused..... **Go to Q. 41**..... 9
 - IF YES**, How many days did you miss from your paid job due to this illness?
 ___ ___ **days** (ROUND TO THE NEAREST WHOLE DAY)
 - Don't know/Not sure..... 7
 - Refused..... 9

This is my last question. This information, though of a sensitive nature, is very important for us to collect so we may estimate how much Salmonella infections cost people in the U.S.

41. Now I am going to read you a list of income categories. Please stop me when a category best describes your total household income, before taxes, in 2004. Was it ...
- [Please Read]**
- Less than \$15,000..... 1
 - \$15,000 up to \$25,000..... 2
 - \$25,000 up to \$40,000..... 3
 - \$40,000 up to \$55,000..... 4
 - \$55,000 up to \$75,000..... 5
 - \$75,000 up to \$100,000..... 6
 - More than \$100,000..... 7
 - [Do not read]** Don't know/Not sure..... 77
 - [Do not read]** Refused..... 99

Closing Statement: *That was my last question. Thank you very much for your time and cooperation.*

SECTION 4: CASE/INTERVIEWER INFORMATION

Date of interview ____/____/____
 MM DD YY

Time of interview _____ AM PM
 (circle one)

Name of interviewer _____

Interviewed in **English/Spanish**
 (circle one)

Case Status?

- a. Alive..... 1
- b. Dead..... 2 →→ DATE (____/____/____)
- c. Unknown..... 7 MM DD YY

Whom did you interview?

- Case 1
- Mother..... 2
- Father..... 3
- Guardian..... 4
- Nurse, nurse’s aid, trained caregiver..... 5
- Family Member (e.g., spouse, adult child)..... 6 →→SPECIFY _____
- Other..... 7 →→SPECIFY _____
- Don’t Know/Not Sure..... 9

Do you need to complete a hospital follow-up form?

- Yes..... 1
- No..... 2

APPENDIX B

A Cohort Study of the Impact of Resistance on Clinical Outcome Among non-Typhi *Salmonella* Serotypes HOSPITALIZATION FOLLOW-UP

State Laboratory Isolate ID Number _____ Site ID _____

PHLIS ID Number (CA, CT, GA, MN) _____ Other patient or specimen ID # _____

Hospital Name or Code: _____ ←FILL IN FROM CASE QUESTIONNAIRE, Q16

Hospitalization Number: _____ ←FILL IN FROM CASE QUESTIONNAIRE, Q1

Name of Chart Reviewer _____

1. Were you able to complete a “Hospitalization Follow-Up” form for this hospitalization?

- Yes..... 1
- No..... 2

→→IF NO, why were you not able to complete a “Hospitalization Follow-Up” form?

- Hospital information unknown..... 1
- Hospital information incorrect..... 2
- Hospital refused access to records..... 3
- Records at hospital unavailable..... 4

SPECIFY _____

- Other..... 5

SPECIFY _____

2. What was the date of admission for this hospitalization?

____/____/____
MM DD YY

- Don't know/Not sure..... 777777
- Refused..... 999999

3. What was the date of discharge for this hospitalization?

____/____/____
MM DD YY

- Don't know/Not sure..... 777777
- Refused..... 999999

4. Admission Diagnoses: **List all the diagnoses that were given as an indication for this hospitalization.**

	Diagnosis/Condition
1	
2	
3	
4	
5	

5. Admission Vital Signs: **Leave blank if unknown.**

Temperature _____ **(CIRCLE) Celsius or Fahrenheit**
 Systolic Blood Pressure _____ **mmHg**
 Diastolic Blood Pressure _____ **mmHg**
 Heart Rate _____ **beats/min**
 Respiratory Rate _____ **breaths/min**
 Weight _____ **(CIRCLE) Pounds or Kg**

6. Admission laboratory studies: **Leave blank if unknown.**

Lab Test		RESULT	Units
Sodium	Na		mEq/L or _____
Potassium	K		mEq/L or _____
Chloride	Cl		mEq/L or _____
Bicarbonate	HCO ₃ / CO ₂		mEq/L or _____
Blood Urea Nitrogen	BUN		mg/dL or _____
Creatinine	Cr		mg/dL or _____
Albumin	Alb		g/DL or _____
White Blood Cells	WBC		Per mm ³
Percent Neutrophils	%Segs/PMNs		%
Hematocrit	Hct		%
Platelets	Plt		Per mm ³

HOSPITAL COURSE—LABORATORY STUDIES

7. Highest WBC recorded: _____ Per mm³

8. Was a blood culture performed during this hospitalization?

- Yes..... 1
- Don't know/Not sure..... **Go to Q. 9**..... 7

→→IF YES, what were the results of the blood culture?

- Growth..... 1
- No Growth..... 2
- Unknown..... 9

→→IF "GROWTH", complete results below for each pathogen isolated?

PATHOGEN #1: _____

(if serotype unknown enter serogroup)

Antimicrobial	Results			
	Sensitive	Intermediate	Resistant	Unknown
Penicillin	Sensitive	Intermediate	Resistant	Unknown
Ampicillin	Sensitive	Intermediate	Resistant	Unknown
Ceftriaxone	Sensitive	Intermediate	Resistant	Unknown
Ciprofloxacin	Sensitive	Intermediate	Resistant	Unknown
Erythromycin	Sensitive	Intermediate	Resistant	Unknown
Gentamicin	Sensitive	Intermediate	Resistant	Unknown
Sulfa	Sensitive	Intermediate	Resistant	Unknown
Tetracycline	Sensitive	Intermediate	Resistant	Unknown
Trimethoprim-Sulfa	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown

PATHOGEN #2: _____

Antimicrobial	Results			
Penicillin	Sensitive	Intermediate	Resistant	Unknown
Ampicillin	Sensitive	Intermediate	Resistant	Unknown
Ceftriaxone	Sensitive	Intermediate	Resistant	Unknown
Ciprofloxacin	Sensitive	Intermediate	Resistant	Unknown
Erythromycin	Sensitive	Intermediate	Resistant	Unknown
Gentamicin	Sensitive	Intermediate	Resistant	Unknown
Sulfa	Sensitive	Intermediate	Resistant	Unknown
Tetracycline	Sensitive	Intermediate	Resistant	Unknown
Trimethoprim-Sulfa	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown

PATHOGEN #3: _____

Antimicrobial	Results			
Penicillin	Sensitive	Intermediate	Resistant	Unknown
Ampicillin	Sensitive	Intermediate	Resistant	Unknown
Ceftriaxone	Sensitive	Intermediate	Resistant	Unknown
Ciprofloxacin	Sensitive	Intermediate	Resistant	Unknown
Erythromycin	Sensitive	Intermediate	Resistant	Unknown
Gentamicin	Sensitive	Intermediate	Resistant	Unknown
Sulfa	Sensitive	Intermediate	Resistant	Unknown
Tetracycline	Sensitive	Intermediate	Resistant	Unknown
Trimethoprim-Sulfa	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown
Other _____	Sensitive	Intermediate	Resistant	Unknown

HOSPITAL COURSE—PROCEDURES/THERAPIES

9. Was a central venous catheter (temporary or permanent) placed during this hospitalization?
PLEASE NOTE: This is different from a peripheral intravenous catheter in that it would be placed at the internal jugular (IJ), subclavian (SC or chest), or femoral veins.

- Yes..... 1
- No..... 2
- Don't know/Not sure..... 7

10. Did the patient receive any antibiotics during this hospitalization?

- Yes..... 1
- No..... 2
- Don't know/Not sure..... 7

→→IF YES, please complete antibiotic administration form at end of questionnaire.

11. Was the patient hospitalized in an intensive care or step-down unit?

- Yes..... 1
- No..... **Go to Q. 15**..... 2
- Don't know/Not sure..... **Go to Q. 15**..... 7

12. If hospitalized an in intensive care or step-down unit, how many nights were spent in ICU?

- _____ nights
- Don't know/Not sure..... 7

13. Was the patient intubated (endotracheal tube) or placed on a ventilator?

- Yes..... 1
- No..... 2
- Don't know/Not sure..... 7

14. If hospitalized in an intensive care unit, did the patient receive any vasopressor medications?

Includes dopamine (Inotropin), dobutamine (Dobutrex), epinephrine (Adrenaline), norepinephrine (Levophed).

- Yes..... 1
- No..... 2
- Don't know/Not sure..... 7

DISCHARGE HISTORY

- 15. Were antibiotics prescribed for the patient on discharge?
 - Yes..... 1
 - No..... 2
 - Don't know/Not sure..... 7

→→IF YES, complete antibiotic administration form at end of questionnaire. Code “# Days Received” column with “7777” if antibiotic was given on discharge only.

- 16. Where did the patient go after discharge from the hospital?
 - Home..... 1
 - Transferred to Another Hospital..... 2
 - Assisted Living Facility (e.g. board and care)..... 3
 - Skilled-nursing facility/rehabilitation /nursing home..... 4
 - Deceased..... 5
 - Other..... 6
 - SPECIFY** _____
 - Don't Know..... 7

→→IF “DECEASED” What was/were the cause(s) of death listed on the death certificate?

ANTIBIOTICS RECEIVED DURING HOSPITALIZATION OR PRESCRIBED ON DISCHARGE

Antibiotic Name		Prescribed on Discharge?	# of Days Received (777777 if unknown duration or prescribed as discharge medication)	Ever Administered Intravenously?
Amikacin or Amikin	60	Yes(1) No(2) DK(7)		Yes(1) No(2) DK(7)
Amoxicillin	1	Yes(1) No(2) DK(7)		N/A
Amoxicillin/Clavulanate	2	Yes(1) No(2) DK(7)		N/A
Ampicillin	3	Yes(1) No(2) DK(7)		Yes(1) No(2) DK(7)
Ampicillin/Sulfbactam	61	Yes(1) No(2) DK(7)		N/A
Ancef	62	Yes(1) No(2) DK(7)		N/A
Augmentin	4	Yes(1) No(2) DK(7)		N/A
Azithromycin	5	Yes(1) No(2) DK(7)		Yes(1) No(2) DK(7)
Aztreonam	63	Yes(1) No(2) DK(7)		N/A
Bactrim	6	Yes(1) No(2) DK(7)		Yes(1) No(2) DK(7)
Biaxin	7	Yes(1) No(2) DK(7)		N/A
Ceclor	8	Yes(1) No(2) DK(7)		N/A
Cefaclor	9	Yes(1) No(2) DK(7)		N/A
Cefadroxil	10	Yes(1) No(2) DK(7)		N/A
Cefazolin	64	Yes(1) No(2) DK(7)		N/A
Cefdinir	11	Yes(1) No(2) DK(7)		N/A
Cefepime	65	Yes(1) No(2) DK(7)		N/A
Cefixime	13	Yes(1) No(2) DK(7)		N/A
Cefotaxime	66	Yes(1) No(2) DK(7)		N/A
Cefotetan or Cefotan	67	Yes(1) No(2) DK(7)		Yes(1) No(2) DK(7)
Cefprozil	16	Yes(1) No(2) DK(7)		N/A
Ceftazidime	68	Yes(1) No(2) DK(7)		N/A
Ceftin	12	Yes(1) No(2) DK(7)		N/A
Ceftriaxone	69	Yes(1) No(2) DK(7)		N/A
Cefuorixime	14	Yes(1) No(2) DK(7)		Yes(1) No(2) DK(7)
Cefzil	15	Yes(1) No(2) DK(7)		N/A
Cephalexin	17	Yes(1) No(2) DK(7)		N/A
Cephradine	18	Yes(1) No(2) DK(7)		N/A
Ciprofloxacin or Cipro	19	Yes(1) No(2) DK(7)		Yes(1) No(2) DK(7)
Claforan	70	Yes(1) No(2) DK(7)		Yes(1) No(2) DK(7)
Clarithromycin	20	Yes(1) No(2) DK(7)		N/A
Cleocin	21	Yes(1) No(2) DK(7)		N/A
Clindamycin	22	Yes(1) No(2) DK(7)		Yes(1) No(2) DK(7)
Dapsone	23	Yes(1) No(2) DK(7)		N/A
Doxycycline	24	Yes(1) No(2) DK(7)		Yes(1) No(2) DK(7)
Duricef	25	Yes(1) No(2) DK(7)		N/A
Erythromycin	26	Yes(1) No(2) DK(7)		Yes(1) No(2) DK(7)
Erythromycin/sulfa	27	Yes(1) No(2) DK(7)		N/A
Flagyl	28	Yes(1) No(2) DK(7)		Yes(1) No(2) DK(7)
Floxin	29	Yes(1) No(2) DK(7)		N/A
Fortaz	71	Yes(1) No(2) DK(7)		N/A
Fosfomycin	30	Yes(1) No(2) DK(7)		N/A
Gatifloxacin	31	Yes(1) No(2) DK(7)		N/A
Gentamicin or Garamicin	72	Yes(1) No(2) DK(7)		N/A

ANTIBIOTICS RECEIVED DURING HOSPITALIZATION OR PRESCRIBED ON DISCHARGE

Antibiotic Name		Prescribed on Discharge?			# of Days Received <small>(77777 if unknown duration or prescribed as discharge medication)</small>	Ever Administered Intravenously?
Imipenem/Cilastatin	73	Yes(1)	No(2)	DK(7)		N/A
Keflex	32	Yes(1)	No(2)	DK(7)		N/A
Keftab	33	Yes(1)	No(2)	DK(7)		N/A
Levofloxacin	34	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
Levoquin	35	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
Maxipime	74	Yes(1)	No(2)	DK(7)		N/A
Meropenem or Merrem	75	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
Metronidazole	36	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
Monurol	37	Yes(1)	No(2)	DK(7)		N/A
Nafcillin	76	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
Nebcin	77	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
Norfloxacin or Norflox	38	Yes(1)	No(2)	DK(7)		N/A
Ofloxacin or Oflox	39	Yes(1)	No(2)	DK(7)		N/A
Omnicef	40	Yes(1)	No(2)	DK(7)		N/A
Oxacillin	78	Yes(1)	No(2)	DK(7)		N/A
Pediazole	41	Yes(1)	No(2)	DK(7)		N/A
Penicillin or Pen VK	42	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
Piperacillin	79	Yes(1)	No(2)	DK(7)		N/A
Piperacillin/Tazobactam	80	Yes(1)	No(2)	DK(7)		N/A
Primaxin	81	Yes(1)	No(2)	DK(7)		N/A
Rocephin	82	Yes(1)	No(2)	DK(7)		N/A
Sepra	43	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
Sparfloxacin	44	Yes(1)	No(2)	DK(7)		N/A
Suprax	45	Yes(1)	No(2)	DK(7)		N/A
Tequin	46	Yes(1)	No(2)	DK(7)		N/A
Tetracycline	47	Yes(1)	No(2)	DK(7)		N/A
Ticarcillin or Ticar	83	Yes(1)	No(2)	DK(7)		N/A
Ticarcillin/Clavulanate	84	Yes(1)	No(2)	DK(7)		N/A
Timentin	85	Yes(1)	No(2)	DK(7)		N/A
Tobramycin	86	Yes(1)	No(2)	DK(7)		N/A
Trimethoprim/Sulfa	49	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
Trimox	48	Yes(1)	No(2)	DK(7)		N/A
Unasyn	87	Yes(1)	No(2)	DK(7)		N/A
Vancomycin	88	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
Zagam	50	Yes(1)	No(2)	DK(7)		N/A
Zinacef	89	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
Zithromax or Z-Pak	51	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
Zosyn	90	Yes(1)	No(2)	DK(7)		N/A
OTHER – SPECIFY	52	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
OTHER – SPECIFY	53	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)
OTHER – SPECIFY	54	Yes(1)	No(2)	DK(7)		Yes(1) No(2) DK(7)

Emerging Infections Program

A Cohort Study of the Impact of Resistance on Clinical Outcome Among non-Typhi *Salmonella* Serotypes

ADMINISTRATIVE PACKET

- ✓ Phone Script Introduction
- ✓ Case Consent
- ✓ Verbal Assent
- ✓ Log of Attempts to Call Cases
- ✓ Case Outcomes Form

A Cohort Study of the Impact of Resistance on Clinical Outcome Among non-Typhi *Salmonella* Serotypes

INTRODUCTION

QUESTION 1

[To person answering the phone if an adult, otherwise ask for an adult] Hello, my name is _____. I'm calling from the _____ Health Department. I am looking for the home of (case's name), is this the correct telephone number?

___ YES

**IF AGE \geq 18 YEARS OLD OR EMANCIPATED MINOR, GO TO QUESTION 2
IF AGE < 18 YEARS OLD (NOT EMANCIPATED), GO TO QUESTION 6
IF CASE KNOWN TO BE DECEASED, GO TO QUESTION 11**

___ NO

Thank you very much, but I seem to have dialed the wrong number.

STOP. Confirm telephone number and begin script again.

___ Does **not** speak English or Spanish

Thank you for your time.

We can only interview someone who speaks English or Spanish.

STOP.

FOR AGE \geq 18 YEARS OLD OR EMANCIPATED MINOR BY YOUR STATE'S DEFINITION

QUESTION 2

May I please speak with (case's name)?

___ YES, already on phone.

GO TO Q3.

___ YES, not on phone

After case comes to the phone, GO TO Q3

___ YES, but not home now

When would be a good time to call back to reach (case's name)?

List day and time on Log of Call Attempts to Find Cases

Thank you very much for your time.

STOP.

___ NO, not able to speak to him/her

GO TO Q5

QUESTION 3

I am calling because we were notified that you were diagnosed with *Salmonella*. The Health Department follows up on all cases of *Salmonella*. The illness can be very serious and so we are also carrying out research with the Centers for Disease Control and Prevention. We want to know how *Salmonella* affects different people in order to prevent future infections.

First, have you or another family member already spoken with someone else from the health department about this infection?

___ YES

We are conducting this survey as part of a national study of Salmonella infections, in cooperation with the Centers for Disease Control and Prevention (CDC) in Atlanta. Even though some of the questions will be similar to ones you have been asked before, we need to ask them in the same way to each person who had this infection.

___ NO

It is possible that someone else from the health department may contact you at a later time.

___ Don't know/Not sure

We are conducting this survey as part of a national study of Salmonella infections, in cooperation with the Centers for Disease Control and Prevention (CDC) in Atlanta. You may have been asked similar questions before, but we need to ask them in the same way to each person who had this infection. Someone from the health department may also contact you at a later time.

QUESTION 4

Before I proceed any further I need to make sure that you live in one of the counties involved in the study. Could you please tell me what county you currently live in? (County).

___ Case lives in catchment area.

GO TO START

___ Case does not live in catchment area

Thank you very much, but we are only interviewing individuals who live within certain counties or states.

STOP.

QUESTION 5

We are conducting a health study, and their participation in this study is very important. Why am I not able to speak with (case's name) ?

___ Does not speak English or Spanish

List language on Log of Call Attempts to Find Cases.

___ Other, (specify) _____

IF CASE DECEASED... GO TO Q11

IF CASE INCOMPETENT/UNABLE TO ANSWER QUESTIONS FOR SELF → GO TO Q17

IF CASE STILL HOSPITALIZED → List day and time on log of call attempts and state:

‘I’m sorry. We would like to call back when (case's name) is feeling better.

We’ll try again next week. Thank you very much for your time.

STOP.

FOR AGE ≤ 18 YEARS OLD (NOT EMANCIPATED MINOR)

QUESTION 6

May I please speak with the parent or guardian of (case's name) ?

___ YES, already on phone.

GO TO Q7.

___ YES, not on phone

After parent or guardian comes to phone... GO TO Q7.

___ YES, but not home now

When would be a good time to call back to reach (case's name) 's parent or guardian?

List day and time on Log of Call Attempts to Find Cases

Thank you very much for your time.

STOP.

___ NO, not able to speak to him/her

GO TO Q10.

QUESTION 7

I am calling because we were notified that (case's name) was diagnosed with *Salmonella*. The Health Department follows up on all cases of *Salmonella*. The illness can be very serious and so we are also carrying out research with the Centers for Disease Control and Prevention. We want to know how *Salmonella* affects different people in order to prevent future infections.it.

First, have you or another family member already spoken with someone else from the health department about this infection?

___ YES

We are conducting this survey as part of a national study of *Salmonella* infections, in cooperation with the Centers for Disease Control and Prevention (CDC) in Atlanta. Even though some of the questions will be similar to ones you have been asked before, we need to ask them in the same way to each person who had this infection.

___ NO

It is possible that someone else from the health department may contact you at a later time.

___ Don't know/Not sure

We are conducting this survey as part of a national study of *Salmonella* infections, in cooperation with the Centers for Disease Control and Prevention (CDC) in Atlanta. You may have been asked similar questions before, but we need to ask them in the same way to each person who had this infection. Someone from the health department may also contact you at a later time.

QUESTION 8

Before I proceed further I need to make sure that (case's name) lives in one of the counties involved in the study. Could you please tell me what county (case's name) currently lives in? (County).

Case lives in catchment area.

GO TO Q. 9

Case **does not** live in catchment area

Thank you very much, but we are only interviewing individuals who live within certain counties or states.

STOP.

QUESTION 9

Is (case's name) hospitalized at this time?

NO, case not currently hospitalized.

GO TO START

YES, case still hospitalized.

List day and time on log of call attempts and state

"I'm sorry. We would like to call back when (case's name) is feeling better. We'll try again next week. Thank you very much for your time.

STOP.

QUESTION 10

We are conducting a health study, and their participation in this study is very important. Why am I not able to speak with (case's name)'s parent or guardian?

Does not speak English or Spanish

List language on Log of Call Attempts to Find Cases.

Emancipated minor.

GO TO Q.3.

Other, list _____

Thank you very much for your time.

STOP.

FOR DECEASED CASES

QUESTION 11

We understand that (case's name) has passed away. Is that correct?

YES

I would like to offer my condolences to you and your family. . .

GO TO Q12

NO

I'm sorry for the misunderstanding . . .

GO TO Q2QUESTION 12

The _____ health department is conducting a health study about (case's name)'s recent illness. Who can best answer health questions on behalf of (case name)?

If Name Given . . . GO TO Q13

If "No/I don't know", SAY:

Thank you for your time.

STOP.

QUESTION 13

May I please speak with (surrogate's name) ?

___ YES, already on phone.

GO TO Q14.

___ YES, not on phone

After surrogate comes to phone... GO TO Q14.

___ YES, but not home now

When would be a good time to call back to reach (surrogate's name) ?

Thank you very much for your time.

List day and time on Log of Call Attempts to Find Cases

STOP.

___ NO, not able to speak to him/her

GO TO Q16

QUESTION 14

I am calling because we were notified that (case's name) was diagnosed with *Salmonella*. The Health Department follows up on all cases of *Salmonella*. As this illness can be very serious, we are also carrying out research with the Centers for Disease Control and Prevention. We want to know how *Salmonella* affects different people in order to prevent future infections.

First, have you or another family member already spoken with someone else from the health department about this infection?

___ YES

We are conducting this survey as part of a national study of *Salmonella* infections, in cooperation with the Centers for Disease Control and Prevention (CDC) in Atlanta. Even though some of the questions will be similar to ones you have been asked before, we need to ask them in the same way each time.

___ NO

It is possible that someone else from the health department may contact you at a later time.

___ Don't know/Not sure

We are conducting this survey as part of a national study of *Salmonella* infections, in

cooperation with the Centers for Disease Control and Prevention (CDC) in Atlanta. You may have been asked similar questions before, but we need to ask them in the same way to each person every time. Someone from the health department may also contact you at a later time.

QUESTION 15

Before I proceed further I need to make sure that (case's name) lived in one of the counties involved in the study. Could you please tell me what county (case's name) lived in? (County).

Case lived in catchment area.

GO TO START

Case did not live in catchment area

Thank you very much, but we are only interviewing individuals who live within certain counties or states.

STOP.

QUESTION 16

We are conducting a health study, and their participation in this study is very important. Why am I not able to speak with (surrogate's name) ?

Does not speak English or Spanish

List language on Log of Call Attempts to Find Cases.

Other, (specify) _____

Thank you very much for your time.

STOP.

FOR PERSONS UNABLE TO INDEPENDENTLY BE INTERVIEWED

QUESTION 17

May I please speak with the caregiver of (case's name) ?

YES, already on phone.

GO TO Q18.

YES, not on phone

After caregiver comes to phone... GO TO Q18.

YES, but not home now

When would be a good time to call back to reach (case's name) 's caregiver?

List day and time on Log of Call Attempts to Find Cases

Thank you very much for your time.

STOP.

NO, not able to speak to him/her

GO TO Q21

QUESTION 18

I am calling because we were notified that (case's name) was diagnosed with *Salmonella*. The Health Department follows up on all cases of *Salmonella*. The illness can be very serious and so we are also carrying out research with the Centers for Disease Control and Prevention. We want to know how *Salmonella* affects different people in order to prevent future infections.

First, have you or another family member already spoken with someone else from the health department about this infection?

___ YES

We are conducting this survey as part of a national study of Salmonella infections, in cooperation with the Centers for Disease Control and Prevention (CDC) in Atlanta. Even though some of the questions will be similar to ones you have been asked before, we need to ask them in the same way to each person who had this infection.

___ NO

It is possible that someone else from the health department may contact you at a later time.

___ Don't know/Not sure

We are conducting this survey as part of a national study of Salmonella infections, in cooperation with the Centers for Disease Control and Prevention (CDC) in Atlanta. You may have been asked similar questions before, but we need to ask them in the same way to each person who had this infection. Someone from the health department may also contact you at a later time.

QUESTION 19 Before I proceed further I need to make sure that (case's name) lives in one of the counties involved in the study. Could you please tell me what county (case's name) currently lives in? (County) .

___ Case lives in catchment area.

GO TO Q 20.

___ Case does not live in catchment area

Thank you very much, but we are only interviewing individuals who live within certain counties or states.

STOP.

QUESTION 20

Is (case's name) hospitalized at this time?

___ NO, case not currently hospitalized.

GO TO "START" (below)

___ YES, case still hospitalized.

List day and time on log of call attempts and state

I'm sorry. We would like to call back when (case's name) is feeling better. We'll try again next week. Thank you very much for your time.

STOP.

QUESTION 21

We are conducting a health study, and their participation in this study is very important. Why am I not able to speak with (case's name)'s caregiver?

___ Does not speak English or Spanish

List language on Log of Call Attempts to Find Cases.

___ Other, list _____

Thank you very much for your time.

STOP.

START

Read consent form as written.

After consent documented, go to QUESTIONNAIRE. If the case-patient is a child aged < 18 years, and not emancipated, then read ‘verbal assent’ to the child after reading the consent.

A Cohort Study of the Impact of Resistance on Clinical Outcome Among non-Typhi *Salmonella* Serotypes CASE CONSENT

[Flesch-Kincaid reading level: grade 7.3]

In recent years, we have seen that some antibiotics used to treat bacterial infections, like *Salmonella*, no longer work well. Many *Salmonella* are becoming resistant to antibiotics. The <state> Department of Public Health and the Centers for Disease Control and Prevention (CDC) are conducting a research study to learn about *Salmonella* infections which are and are not resistant to antibiotics. These illnesses can be very severe. We want to know how they affect different people in order to prevent them.

We were notified about (case’s name) ’s illness because <state> ’s laws require that all *Salmonella* infections be reported to the health department. I’d like to ask you questions about [your/ your child’s] illness. The questions should take about 20 minutes. Being in this study is voluntary. You may refuse to answer any questions **without penalty or loss of benefits to which [you are/ your child is] otherwise entitled**. You may stop at any time. All of your responses will be handled in a confidential manner to the extent allowed by law. We will limit the loss of your privacy by removing your name and personal identifiers from the information you give us today. We will also keep your information locked with minimal access only by the study staff. There is no direct benefit to [you/ your child] or others for being in the study, but it will help us learn more about other people who will be affected by *Salmonella*. There is no penalty for not being in the study. There is also no risk to [you/ your child], except your discomfort with some of the questions that may be of a sensitive nature. Often, bacteria isolated from a laboratory specimen (e.g., stool, blood) are sent to the health department. If (case’s name) gave the doctor a laboratory specimen, the bacteria from that specimen may have been sent to the health department. We will combine the information from this interview with test results from [your/ your child’s] laboratory specimen. We will be combining the information from this interview with information routinely collected by the health department. Additionally, if [you were/ your child was] hospitalized, we will obtain information about [your/ your child’s] illness and treatment from [your/ your child’s] medical record.

If you have questions about this study or you feel that you may have been harmed by this study, you may call Ezra Barzilay, MD at the CDC at 404-371-5465. If you have questions about your rights as a participant in this research study, please contact the office of CDC’s Deputy Associate Director for Science at 1-800-584-8814. If you call, please leave a brief message including your name, phone number, and mention that you are calling in reference to CDC protocol #4634. Someone will return your call as soon as possible. Locally, here in (catchment state) , you may contact (local researcher) at (local number) if you have questions about the study.

I will be happy to mail a copy of this consent form as well as information about *Salmonella* and food safety if you would like. (Record mailing information separately)

Do you have any questions before I begin? May I begin?

(Verbal consent given) YES NO

Interviewer signature _____

**Please attach this consent to the questionnaire used to interview the case/parent/caregiver.
IF CASE-PATIENT AGED 13-17, PLEASE OBTAIN VERBAL ASSENT.
OTHERWISE, CONTINUE TO QUESTIONNAIRE.**

**A Cohort Study of the Impact of Resistance on Clinical Outcome
Among non-Typhi *Salmonella* Serotypes
VERBAL ASSENT (AGES 13-17)**

IF CASE-PATIENT IS AGED 13-17 years old, document verbal assent.

We are calling because the (state's name) health department was notified about your recent illness. Your [parent/guardian] has agreed to answer some questions about your illness. We will use the information to help us understand and prevent this type of illness in others. There is no right or wrong answer to these questions and participation is voluntary. There is no risk or benefit to you. Your name and facts will be kept private as much allowed by law. Your [parent/guardian] may refuse to answer any questions and can stop the survey at any time. Do you have any questions for me?

Do you understand and agree with the decision to participate?

(Verbal assent given) YES NO

Date / /

Interviewer signature _____

Please attach this consent to the questionnaire used to interview the case/parent/caregiver

A Cohort Study of the Impact of Resistance on Clinical Outcome Among non-Typhi *Salmonella* Serotypes LOG OF ATTEMPT TO CALL CASES

State Laboratory Isolate ID Number _____ Site ID _____
 PHLIS ID Number _____ Other patient or specimen ID _____
(CA, CT, GA, MN)

Case's name _____
 Case's Phone # _____
 Alternate # _____
(If more than one telephone number, circle telephone number of primary residence)

Log of attempts:

Date/	Time	Time	Time	Time	Time
-------	------	------	------	------	------

Day 1 ____/____ ____ ____ ____ ____
 Day 2 ____/____ ____ ____ ____ ____
 Day 3 ____/____ ____ ____ ____ ____
 Day 4 ____/____ ____ ____ ____ ____
 Day 5 ____/____ ____ ____ ____ ____
 Day 6 ____/____ ____ ____ ____ ____
 Day 7 ____/____ ____ ____ ____ ____
 Day 8 ____/____ ____ ____ ____ ____
 Day 9 ____/____ ____ ____ ____ ____
 Day 10 ____/____ ____ ____ ____ ____

If hospitalized, note here the date one week later in which to call case again:

Date: _____
 Date: _____
 Date: _____

At least 15 phone attempts must be made
 3 attempts each x 5 days
 3 attempts must be on a weekend
 1 attempt on a weekday must be between 5-9pm

Language needed: _____

Call back at _____ (day) _____ (time)
 Call back at _____ (day) _____ (time)
 Call back at _____ (day) _____ (time)
 Call back at _____ (day) _____ (time)

Interview Completed? Yes No

**Attach this form to the interview questionnaire
 Make sure to update patient tracking information in PHLIS**

PLEASE COMPLETE FOR ALL NON-ENROLLED CASES OF NON-TYPHOIDAL SALMONELLA

A Cohort Study of the Impact of Resistance on Clinical Outcome Among non-Typhi *Salmonella* Serotypes NON-ENROLLED CASE OUTCOMES

State Lab Isolate ID Number _____ Site ID _____
 PHLIS ID Number _____ Other patient or specimen ID _____
 (CA, CT, GA, MN)
 County _____
 State _____

Before you attempted to contact patient, did you deem the patient eligible for the study?
 Yes..... 1
 No..... 2
 →→IF NO→ Why was the patient not eligible?
 Not in catchment area..... 1
 No telephone or other contact information available..... 2
 Excluded because of state-specific selection criteria..... 3
 Found out about case > 85 days after specimen collection..... 4
 Other..... 9
SPECIFY _____

Did you contact the patient or their surrogate?
 Yes..... 1
 No..... 2
 →→IF NO→ Why did you not contact the patient?
 Telephone number incorrect or non-working..... 1
 Patient/Surrogate not reachable after 15 telephone attempts..... 2
 Other..... 9
SPECIFY _____

After contacting the patient or their surrogate, did you complete a questionnaire?
 Yes..... 1
 No..... 2
 →→IF NO→ Why did you not complete the questionnaire?
 Non-English, Non-Spanish speaker..... 1
 Patient/Surrogate refused to be interviewed..... 2
 Patient not able to answer questions and no surrogate available..... 3
 Surrogate not able to answer questions..... 4
 Patient had pre or co-existing infection with other enteric bacteria 6
 Patient or surrogate unable to estimate when illness began..... 7
 Patient or surrogate interrupted and stopped interview after it began..... 8
 Other..... 9
SPECIFY _____