Foodborne Diseases Active Surveillance Network
(FoodNet)
Surveillance Protocol, 2004
# Foodborne Diseases Active Surveillance Network (FoodNet)  
## Active Surveillance Protocol

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I. ACTIVE SURVEILLANCE OBJECTIVES

1. Determine the incidence and clinical consequences of foodborne diseases in the United States

2. Monitor change in incidence in foodborne diseases over time

II. INTRODUCTION

The Foodborne Diseases Active Surveillance Network (FoodNet) is the principal foodborne disease component of the Centers for Disease Control and Prevention's (CDC's) Emerging Infections Program (EIP). FoodNet is a collaborative project among CDC, the eleven EIP sites, the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), and the United States Food and Drug Administration (FDA). FoodNet augments, but does not replace, longstanding activities at CDC, USDA, FDA, and in states to identify, control, and prevent foodborne disease hazards.

FoodNet is a sentinel network that is producing more stable and accurate national estimates of the burden and sources of specific foodborne diseases in the United States through active surveillance and additional studies. Enhanced surveillance and investigation are integral parts of developing and evaluating new prevention and control strategies that can improve food safety and health. Ongoing FoodNet surveillance is
being used to document the effectiveness of new food safety control measures, such as
the USDA–FSIS Pathogen Reduction and Hazard Analysis and Critical Control Point
(PR/HACCP) systems, in decreasing the number of cases of foodborne diseases that
occur in the United States each year.

III. ACTIVE SURVEILLANCE DATA–LABORATORY CONFIRMED CASES

A. CASE DEFINITION
Isolation of laboratory-confirmed *Campylobacter, Cryptosporidium, Cyclospora*,
Shiga toxin-producing *E. coli* (including *E. coli* O157), *Listeria, Salmonella, Shigella, Vibrio*, and *Yersinia* from a resident of the catchment area during a given time period
(e.g., calendar year)

B. DATA COLLECTION
FoodNet personnel within each site contact each clinical laboratory within that site’s
catchment area either weekly or monthly, depending on the laboratory size. Sites
ascertain all laboratory-confirmed cases (see section titled “Case Definition”) of
infection from stool, and sites also ascertain all laboratory-confirmed cases from
urine, blood, cerebrospinal fluid, or other sterile sites (e.g., bone, joint fluid, or
peritoneal fluid). Of note, isolates from urine were not included in FoodNet
surveillance from 1996 to 1998, *Cryptosporidium* and *Cyclospora* were not included
in FoodNet surveillance in 1996 and 1997, and non-O157 Shiga toxin-producing *E. coli* were not included in 1996 and 1999. Additionally, each clinical laboratory within that site’s catchment area should be audited at least twice per year (see section titled “Clinical Laboratory Audit”) to evaluate the completeness of case ascertainment.

A person with the same pathogen isolated 2 or more times from the same specimen source within a thirty day period (regardless of calendar year) will be identified as a duplicate and the second isolation will be excluded from the active dataset. Persons with the same pathogen isolated from the same specimen source within 31 to 365 days of the original culture (regardless of calendar year) will be classified as a carrier and the second isolation will be excluded from the active dataset.

Of note, it is possible that a resident within the FoodNet catchment area may become ill, seek medical care and submit a specimen, but that the specimen may be sent to a clinical laboratory that is geographically outside the FoodNet surveillance area. FoodNet attempts to ascertain such cases by contacting the larger diagnostic reference laboratories that are likely to receive specimens from residents of the FoodNet sites. Those clinical laboratories outside the surveillance area that have been identified as having received specimens from FoodNet residents are then added to the list of clinical laboratories that are routinely contacted by FoodNet surveillance officers within each site.
Once a case has been identified, FoodNet personnel within each site complete a Case Report Form and/or enter the data directly into an electronic database. The Case Report Form should serve as a template for the information to be collected. If the appropriate information is being captured, a hard copy of the Case Report Form does not necessarily need to be completed. There is one Case Report Form for bacterial pathogens (Appendix I) and one Case Report Form for parasitic pathogens (Appendix II). Definitions for these variables can be found in Appendix III. The information from these forms is compiled by each site within an electronic database (see section titled “Database Structure”).

In 2004, there were two major changes to the data collected by FoodNet. First, FoodNet began identifying whether a case was part of a foodborne outbreak and, if so, what the Electronic Foodborne Outbreak Reporting System (EFORS) number of that outbreak was. Second, FoodNet began collection international travel history for cases. The exposure window asked varied depending on the pathogen. For *Salmonella Typhi* and *Listeria*, cases were questioned about travel in the previous 30 days before their isolation date. For *Cryptosporidium* and *Cyclospora*, cases were questioned about travel in the previous 15 days before their isolation date. For all other FoodNet pathogens, cases were questioned about travel in the 7 days before their isolation date.
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C. DATABASE STRUCTURE

FoodNet surveillance data should be housed in an electronic data management system. Historically, FoodNet sites have used the Public Health Laboratory Information System (PHLIS) to store data on-site and to transmit data to CDC. In 2002, FoodNet personnel determined that PHLIS was not necessarily the best method for storing and transmitting data for FoodNet purposes. FoodNet will eventually switch to the National Electronic Disease Surveillance System (NEDSS) and is currently developing a Foodborne Program Area Module (PAM). We hope these changes will be implemented in 2004.

Until NEDSS is implemented, each site has developed a method for data storage and transmission that meets the needs of that site. California, Connecticut, Georgia, Minnesota, and Tennessee have and will continue to use PHLIS to store FoodNet data until NEDSS is implemented. Colorado, Maryland, New York, New Mexico, and Oregon use state-based data structures that are NEDSS compliant to store FoodNet data. All FoodNet sites transmit data on a monthly basis to a secure FTP website at CDC.

Regardless of the data structure (i.e., PHLIS, a NEDSS-compliant state developed system, NEDSS), data should contain the same basic information. Variable names, definitions, and legal values can be found in Appendix IV.
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D. DATA TRANSMISSION

FoodNet surveillance data are transmitted to CDC on a monthly basis. An email is sent out a few weeks before the Steering Committee conference call reminding sites of the deadline for monthly data submission. Steering Committee calls are held on the second Thursday of each month. It is strongly encouraged that sites follow this deadline as a lack of timeliness delays the monthly review and analysis of data. Year-to-date numbers should be submitted with each transmission. FoodNet sites are requested to post their data on the secure FoodNet FTP site and inform the appropriate CDC surveillance officer when these data have been posted. After these data are downloaded from the FTP site, the file is deleted from the site.

E. DATA MANAGEMENT AT CDC

A patient with multiple isolates will require one or several Case Report Forms, depending on the situation.

A. Time Frame: If a patient has been identified as a duplicate as described above, a new Case Report Form is not needed. For example, if *Salmonella* is isolated from two stools specimens in the same week, only enter the first isolate into the database. This will be counted as one case in any analyses. If a patient has been identified as a carrier as described above, a new Case Report Form is needed. For example, if *Salmonella* is isolated from stool on the first of the month and a second *Salmonella* is isolated from stool on the fifteenth of the following month, enter both stools into the database.
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B. Multiple Sites: If the patient has the same pathogen isolated from different specimen sources, regardless of the time, then a new Case Report Form is needed for each source. For example, if *E. coli* O157 is isolated from blood and stool, enter both into the database. This will be counted as one case in analysis and the more invasive specimen will be used for analysis.

C. Multiple Specimens: If the patient has multiple pathogens, or the same pathogen with different serotypes, isolated from the same source, regardless of time, then a new Case Report Form is required for each pathogen. For example, if *Campylobacter* and *Shigella* are isolated from stool, then enter both pathogens into the database. These will be counted as two cases in analysis.

F. DATA CLOSE-OUT

Preliminary data close-out begins in January and continues into February in time for the annual FoodNet Morbidity and Mortality Weekly Report (MMWR) which is published in the April. Final data close-out begins in late June and continues into July. During preliminary and final data close-outs, each site works with a CDC surveillance officer to reconcile case counts between CDC and the sites.

By mid-June, sites should have all cases for the previous year entered into their databases, these data should be sent to CDC (in that data transmission, each site should also provide information on a summary of the case counts, the number of
carriers, whether carriers are included in these data, and whether duplicates are included in these data). After these data are received, a CDC surveillance officer will begin checking cases counts (i.e., CDC case counts compared to individual site cases counts). By middle of July, CDC and each site should have reconciled final case counts. Each site should send an official email stating their final counts, by pathogen, for that year.

Once CDC and the sites have agreed on the case count numbers, CDC surveillance officers will review these data. Any data that may seem errant will be flagged and the site will be asked to verify the data point. If changes to the data are necessary, the data should be resubmitted and case counts should be re-verified.

G. DATA QUALITY

Surveillance officers at CDC perform monthly checks of all surveillance data to ensure quality and completeness. In this process, the surveillance officers run frequencies on the data to look for any outlying data points (e.g., AGE=129 years). If any outlying data points are identified or if there are questionable data points, CDC will contact the site and request a correction or verification. For a correction to be utilized, data corrections must be made at the site and cleaned data must be retransmitted.
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In particular, the surveillance officer will focus on accuracy of Salmonella serotyping data and accuracy and completeness of the State Laboratory Identification Number (SLABSID) (see section titled “FoodNet/NARMS integration”). The CDC surveillance officer will contact sites on a prospective basis, about inaccuracies or incomplete information. Changes made to the data at the sites will be captured during the next monthly transmission.

Additionally, the FoodNet Performance Standards (Appendix V) have been developed to assess completeness and accuracy of FoodNet data. Twice a year, these standards are evaluated and feedback is provided to the sites. Performance standards are reviewed annually at the Coordinators Meeting and revised as appropriate.

H. FOODNET/NARMS INTEGRATION

The National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS) was established in 1996 within the framework of the CDC's Emerging Infections Program's (EIP) Epidemiology and Laboratory Capacity Program.

NARMS collaborators include CDC, FDA, and all state and selected local health departments. The primary objective of NARMS is to monitor antimicrobial resistance among Salmonella, E. coli O157, and Shigella. Participating sites forward every twentieth non-Typhi Salmonella, E. coli O157, and Shigella isolate as well as every Salmonella Typhi, Listeria, and Vibrio isolate to CDC. Once the isolates arrive at CDC, microbiologists test them for susceptibility against 17 antimicrobial agents.
NARMS and FoodNet personnel at CDC have been working towards linking data from both surveillance systems, thus integrating susceptibility data from NARMS with patient data from FoodNet. Eventually, the goal is to also integrate data from the National Molecular Subtyping Network for Foodborne Disease Surveillance, also known as PulseNet, to improve the power of all 3 surveillance programs.

For FoodNet and NARMS data to be linked, each isolate must have a unique identifier, which is the State Laboratory Identification Number (FoodNet variable: SLABSID). We encourage FoodNet epidemiologists to communicate with the NARMS microbiologists in each state to make sure that FoodNet data and NARMS isolates from the same patient are identified by the same State Laboratory Identification Number. At CDC, surveillance epidemiologists will prospectively monitor monthly FoodNet data submissions to ensure the correct State Laboratory Identification Number format is being submitted. If a case is submitted with an incorrect State Laboratory Identification Number format, the case will be “flagged” by the FoodNet application and CDC FoodNet personnel will contact the appropriate site to request a correction.

I. CLINICAL LABORATORY AUDIT

Regular clinical laboratory audits are a fundamental requirement of FoodNet active surveillance of laboratory confirmed cases. To ensure that all cases of diseases under surveillance are being reported and to ensure that any change in incidence is not due to surveillance artifacts, audits of every clinical laboratory within the FoodNet

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surveillance area must be performed at least twice per year. However, if a laboratory routinely reports all culture results via computer printouts, there is no need to repeat the audit, as this method itself meets the criteria for an audit. Hospital visits and/or phone calls may still be necessary to collect information missing from the Case Report Form.

The primary data source at every reporting site (usually a laboratory log slips/log book or computer printout that lists all isolates) should be reviewed for pathogens under surveillance, and compared to the list of cases reported prospectively to the surveillance coordinator. A Case Report Form should be completed on all newly identified cases that have not been entered into the surveillance database. Audits should be performed every January and July for the previous 6 months. Cases identified by audit should be submitted following the FoodNet case ascertainment guidelines used for cases obtained through non-audited methods. Complete Case Report Forms on both “audit” cases and any other outstanding cases should be entered into the computer database by March 1 and September 1 for the audited six-month period. If complete Case Report Forms cannot be entered into the database by these deadlines, basic demographic information such as age, sex, race and county of residence should be entered into the database for these pending cases.
Acceptable methods for auditing a laboratory include:

- Physical visit by an agent of the state (e.g., FoodNet/state employee, academic partner) to the laboratory to review, in person, the laboratory testing log slips/log books (onsite review). If used, this method must include personal review of every possible positive laboratory test result from the laboratory being audited.

- Review of a computer generated line list of all laboratory data, with documentation that the program used to generate the computer generated list will include every case potentially fitting the FoodNet surveillance definition from that laboratory.

- Review of an electronic database of cases received electronically or in hard-copy from clinical laboratories, with documentation that the program used to generate the database will include every case potentially fitting the FoodNet surveillance definition from that laboratory.

Unacceptable methods for an audit include:

- Sending a list of FoodNet cases to the clinical laboratories for the laboratories to review and indicate whether FoodNet site has counted all cases
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- Review of a list of “cases” or positive test results generated by hand, or by review of computer reports, from laboratory personnel, infection control, or other hospital staff.

- Review of cases or positive reports set aside or sent in by laboratory personnel, infection control staff, or other hospital staff.

J. ADDITIONAL COMMENTS ON SELECTED PATHOGENS UNDER SURVEILLANCE

1. Shiga toxin-producing E. coli

As FoodNet has gained a better understanding of surveillance for Shiga toxin-producing E. coli (STEC), the classification for STEC cases has changed. From 1996-1999, surveillance was only conducted for E. coli O157. In 2000, surveillance was expanded in some states to non-O157 STEC and cases were classified into two categories: “E. coli O157” and “E. coli other.” In 2001, STEC cases were classified into two categories: “E. coli O157” and “Shiga toxin-producing E. coli non-O157”. Beginning in 2002, STEC cases were classified into three categories: “E. coli O157”,

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“Shiga toxin-producing *E. coli* non-O157”, and “STEC O-Antigen Undetermined.”

The classification of STEC into these categories depends upon a number of factors, including whether the isolate was biochemically identified as *E. coli*, the *E. coli* O antigen number, the H antigen number, and the results of the Shiga Toxin Test (Appendix VI).

Isolates are classified as "*E. coli* O157" when a laboratory confirms the expression of the O antigen 157 and either the expression of H antigen 7 or the production of Shiga toxin. Isolates are classified as "STEC nonO157" when a state public health laboratory confirms that the isolate does not express O antigen 157 and that it does produce Shiga toxin. These isolates should be forwarded to CDC for serotyping. If CDC confirms the expression of some other O antigen (e.g., O111, O26), then that O antigen number should be entered, by the state, into the database. Finally, isolates are classified as "STEC O Antigen Undetermined" if a state public health laboratory confirms the production of Shiga toxin and rules out the expression of O antigen 157, and, after testing at CDC, an O antigen cannot be determined.
2. *Listeria*

In FoodNet, *Listeria* cases are unique from other pathogens in that additional information, including pregnancy status as well as fetal outcome, is collected.

Additionally, the Council of State and Territorial Epidemiologists (CSTE) adopted a *Listeria* case surveillance position statement at their 2003 annual meeting. In this initiative, CSTE recommends prospective, routine interviewing of all listeriosis cases, using a standardized questionnaire, of all patients with culture-confirmed listeriosis. As a result, FoodNet sites began collecting these in 2004. Until this activity can be incorporated into the NEDSS program area module for foodborne diseases, this will be a paper-based reporting system. (Appendix VII) There will be a data entry screen in NEDSS for the *Listeria* Case Report Form.

3. *Salmonella*

FoodNet attempts to record complete *Salmonella* serotype information. In January 2003, CDC adopted the Kauffman White scheme of *Salmonella* serotyping (prior to 2003 the modified Kauffman White scheme was used). *Salmonella* serotype information is submitted to FoodNet during monthly data transmissions. This information is updated as additional laboratory testing is completed. For a list of serotype designations which
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vary between the modified Kauffman White scheme and the Kauffman
White scheme. Additionally, the documents found in Appendix VIII and
Appendix IX will help elucidate *Salmonella* serotype designation.

Surveillance for *Salmonella* Typhi infections is conducted as part of
routine FoodNet surveillance. In addition to this routine activity, an
additional Case Report Form (Appendix X) for every *S.* Typhi case should
be completed. The person originally reporting the illness (e.g., a health
care provider) should complete the report and send it to both state
surveillance personnel and CDC’s Foodborne and Diarrheal Disease
Branch at the provided address.

4. *Vibrio*

Surveillance for *Vibrio* infections is conducted as part of routine FoodNet
surveillance. An additional Case Report Form (Appendix XI) for every
*Vibrio* case should be completed. The person originally reporting the
illness (e.g., a health care provider) should complete the report and send it
to state surveillance personnel and to CDC’s Foodborne and Diarrheal
Disease Branch at the provided address.
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5. **Yersina**

FoodNet began collection *Yersinia* species information in 2003. An attempt has been made to ascertain this information for the 1996-2002 *Yersinia* data.

V. **ACTIVE SURVEILLANCE DATA – HUS CASES**

Population-based surveillance for Hemolytic Uremic Syndrome (HUS) was initiated in FoodNet to monitor long term trends in this important outcome of Shiga toxin-producing *Escherichia coli* (STEC) infection, to identify STEC strains that cause HUS in the United States and monitor changes in their frequency over time, and to establish a platform for conducting future studies of HUS pathogenesis and treatment.

The HUS surveillance system is based on reporting by pediatric nephrologists who are requested to promptly report all cases of HUS to the FoodNet HUS surveillance officer within each site. Additionally, several FoodNet sites review hospital discharge data to ascertain pediatric and adult cases of HUS. Review of hospital discharge data is done on a retrospective basis and these data are often not available until 6 months after the end of the calendar year.
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There are three forms associated with HUS surveillance. The first form, the Case Report Form (Appendix XII), should be completed to collect demographic information and data needed to confirm the diagnosis of HUS. Data for the Case Report Form may be collected by interviewing the attending physician, their designee, and/or by reviewing the patient’s medical record. The second form, the Microbiology Report Form (Appendix XIII), collects information on specimens that may have been obtained as part of regular medical care. The third form, the Chart Review Form (Appendix XIV), collects information on the outcome and complications of the patient’s acute illness. Data from these three forms are entered by each site into an Epi Info database using customized data entry screens. In addition to transmitting the data to CDC on a monthly basis, data are transmitted when a case is identified or new information is obtained for a reported case.

For more detailed information on how to conduct HUS surveillance, please review the “Active surveillance for Hemolytic Uremic Syndrome (HUS) Protocol” (Appendix XV).

Serologic testing for *E. coli* O157 and/or *E. coli* non-O157 antigens is available at CDC. Because the serologic test is not FDA approved and because the cost of analyzing a single specimen is prohibitive, state health department partners should not expect that results will be available in real time and should not use the results for clinical purposes. States requesting this service should submit sera to the Foodborne and Diarrheal Diseases immunology laboratory.
VI. DATA USAGE

FoodNet data belong to individual sites that submit these data. You may use these data as you choose and you are encouraged to use these data to provide feedback to the clinical laboratories, physicians, and other relevant persons within your site.

If you would like to use FoodNet data from more than one site or you would like a CDC author on your site-specific abstract/manuscript, you must follow the Foodborne Diseases Active Surveillance Network (FoodNet) Data Use Policy (Appendix XVI) and the Foodborne Diseases Active Surveillance Network (FoodNet) Protocol Development and Publication Policy (Appendix XVII).

K. LEADERSHIP AND PARTICIPATION

Since FoodNet is a collaborative effort, it is important to have participation and leadership from all those involved, including the state partners. Leadership and participation in FoodNet are measured in several ways. First, each month the FoodNet Steering Committee, including CDC, USDA, FDA and state partners, has a conference call that serves to update all stakeholders on recent FoodNet activities. On these calls, the Steering Committee discusses, among other items, any administrative issues, special studies (e.g., case-control studies), votes on potential proposals for sharing/analyzing the
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data, etc. Each FoodNet site should have at least one representative on the Steering Committee call.

Second, leadership and participation in the FoodNet Working Groups is encouraged. The Working Groups are established at the annual Vision Meeting and focus on the priorities set by the Steering Committee. Finally, each site is encouraged to annually submit at least one FoodNet abstract to a national meeting.
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Appendix I: Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Bacterial Form

Appendix II: Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Parasitic Form

Appendix III: Foodborne Diseases Active Surveillance Network (FoodNet) Variable Definitions

Appendix IV: Documentation of FoodNet Variables

Appendix V: FoodNet/NARMS Performance Standards, 2003

Appendix VI: FoodNet Criteria for Classification of Shiga toxin-producing E. coli (STEC)

Appendix VII: Listeria Case Report Form

Appendix VIII: Salmonella serotyping

Appendix IX: Overview of Salmonella Serotype Designation

Appendix X: Salmonella Typhi case report form

Appendix XI: Cholera and other Vibrio Illness Surveillance Report

Appendix XII: Hemolytic Uremic Syndrome (HUS) Case Report Form

Appendix XIII: Hemolytic Uremic Syndrome (HUS) Microbiology Report Form

Appendix XIV: Hemolytic Uremic Syndrome (HUS) Chart Review Form

Appendix XV: Active surveillance for Hemolytic Uremic Syndrome (HUS) Protocol

Appendix XVI: Foodborne Diseases Active Surveillance Network (FoodNet) Data Use Policy

Appendix XVII: Foodborne Diseases Active Surveillance Network (FoodNet) Protocol Development and Publication Policy
## Appendix I: Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Bacterial Form

**Local Case ID (Medical Record #):** ____________________________

**Isolated Bacteria:** _______________________________

**Patient’s name:** ____________________________________________

**Address:**

- Number/ Street: ____________________________
- City: ____________________________
- State: ____________________________
- ZIP: ____________________________

**Phone No:** (       )  _______ - _____________

### Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Form

- **PHLIS ID # (Patient-Specimen):** ❏❏❏❏❏❏❏❏❏❏❏❏❏❏❏

- **Local ID:** ❏❏❏❏

### 1) COUNTY

(residence of patient):

- ____________________________
- ____________________________

### 2) SEX:

- Male ❏
- Female ❏
- Unknown ❏

### 3) DATE OF BIRTH:

- month
- day
- year

### 4) RACE : (original categories)

- ☐ White
- ☐ Black
- ☐ American Indian/ Native Alaskan
- ☐ Unknown
- ☐ Asian or Pacific Islander

### 4a) RACE : (additional FN categories)

- ☐ Asian
- ☐ Pacific Islander or Native Hawaiian
- ☐ Multi-racial
- ☐ Other

### 5) ETHNICITY:

- ☐ Hispanic
- ☐ Non-Hispanic
- ☐ Unknown

### 6) SPECIMEN COLLECTION DATE

- month
- day
- 200__

### 7) AGE: ____________

- years

### 8) IF < 1 YEAR, AGE:

- months

### 9) SUBMITTING LAB:

- ____________________________

### 9a) SUBMITTING PHYSICIAN:

- ____________________________

- Phone: (       )  _______ - _____________

### Informant: ____________________________

(10) SOURCE OF SPECIMEN:

- ☐ Stool
- ☐ Blood
- ☐ CSF
- ☐ Urine
- ☐ Unknown
- ☐ Other site (specify):

### 11) ISOLATED BACTERIA:

- ☐ *Salmonella* (serogroup______)  serotype_______________________)
- ☐ *Shigella*  (serogtype/species___________________________)
- ☐ *Campylobacter* (species_______________________________)
- ☐ *E. coli*

- Biochemically identified?  Yes ❏
- No ❏
- Unknown ❏

- O157 positive?  Yes ❏
- No ❏
- Unsure/Not Tested ❏

- O antigen number ________

- H7 positive?  Yes ❏
- No ❏
- Unsure/Not Tested ❏

- H Antigen Number ________

- Isolate non-motile?  Yes ❏
- No ❏
- Unsure/Not Tested ❏

- Shiga toxin-positive?  Yes ❏
- No ❏
- Unsure/Not Tested ❏

- National database PFGE Pattern _______________

- ✗ Other Bacteria (specify):_____________________

### Pregnant?  Yes ❏
- No ❏
- Unknown ❏

### Outcome of Fetus?

- ☐ Abortion/stillbirth
- ☐ Induced abortion
- ☐ Live birth/neonatal death
- ☐ Survived-clinical infection
- ☐ Survived-no apparent illness
- ☐ Unknown
### A. Hospital Follow-up:

13) **PATIENT STATUS AT THE TIME OF SPECIMEN COLLECTION:**
   - [ ] Hospitalized (go to 15)
   - [ ] Outpatient (go to 14)

14) **IF OUTPATIENT, WAS THE PATIENT SUBSEQUENTLY HOSPITALIZED?**
   - [ ] Yes (go to 15)
   - [ ] No (go to 15c)
   - [ ] Unknown (go to 15c)

16) **OUTCOME:**
   - [ ] Alive
   - [ ] Dead
   - [ ] Unknown

16a) **HOW WAS THIS INFORMATION (from #16) DETERMINED?**
   - Patient / relative contacted
   - Physician contacted or chart review / medical records review
   - Did not follow up
   - County provided information

15) **IF PATIENT WAS HOSPITALIZED** (that is, if answered "Hospitalized" to #13 or "Yes" to #14):

   **Hospital name:** ____________________________
   **Date of admission:** _____ / _____ / 200___
   **Date of discharge:** _____ / _____ / 200___

15a) **TRANSFERRED TO ANOTHER HOSPITAL?**
   - [ ] Yes
   - [ ] No
   - [ ] Unknown

15b) **IF YES, TRANSFER HOSPITAL NAME:**

15c) **HOW WAS THE INFORMATION (from #13, 14, or 15) DETERMINED?**
   - [ ] Patient / relative contacted
   - [ ] Physician contacted or chart review / medical records review
   - [ ] Did not follow up
   - [ ] County provided information

18) **DID THE PATIENT TRAVEL WITHIN THE LAST**
   - 30 days if infected with S. Typhi or Listeria
   - 7 days if infected with other bacterial pathogen

18a) **Date of departure from the U.S.:** _____ / _____ / 200___
   **Date of return to the U.S.:** _____ / _____ / 200___

### B. Health Department Follow-up:

If the isolate was further characterized by the State Lab, please update #11.

17) **DID THE STATE LAB RECEIVE THE ISOLATE?**
   - [ ] Yes
   - [ ] No
   - [ ] Unknown

17a) **If Yes, STATE LAB ISOLATE ID NUMBER:**

19) **WAS CASE FOUND DURING AN AUDIT?**
   - [ ] Yes
   - [ ] No
   - [ ] Unknown

20) **WAS THE CASE PART OF AN OUTBREAK?**
   - [ ] Yes (go to 20a)
   - [ ] No
   - [ ] Unknown

20a) **IF OUTBREAK RELATED, WAS IT A FOODBORNE OUTBREAK?**
   - [ ] Yes (go to 20b)
   - [ ] No
   - [ ] Unknown

20b) **EFORS NUMBER:** ____________________________

21) **WAS CASE ENROLLED IN THE CASE-CONTROL STUDY?**
   - [ ] Yes
   - [ ] No
   - [ ] Unknown

22) **IS CASE REPORT COMPLETE?**
   - [ ] Yes
   - [ ] No

22a) **DATE CASE REPORT COMPLETED:**
   **month** / **day** / 200___

22b) **INITIALS OF PERSON COMPLETING CASE REPORT:**

Comments

________________________________________________________________________________________

________________________________________________________________________________________

________________________________________________________________________________________

Revised 2/6/04
Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Form

**Appendix II: Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Form**

**Patient’s name:** [Name]

**Address:** [Address]

**Phone No:** [Phone Number]

---

**1) COUNTY**
(residence of patient):

---

**2) SEX:**
- Male
- Female
- Unknown

**3) DATE OF BIRTH:**

---

**4) RACE** (original categories):
- White
- Black
- American Indian/ Native Alaskan
- Unknown
- Asian or Pacific Islander

**4a) RACE** (additional FN categories):
- Asian
- Pacific Islander or Native Hawaiian
- Multi-racial
- Other

**5) ETHNICITY:**
- Hispanic
- Non-Hispanic
- Unknown

**6) SPECIMEN COLLECTION DATE**

---

**7) AGE:**

---

**8) IF < 1 YEAR, AGE:**

---

**9) SUBMITTING LAB:**

---

**9a) SUBMITTING PHYSICIAN:**

---

**Informant:**

---

**Date Report Received in Lab:**

---

**10) SOURCE OF SPECIMEN:**
- Stool
- GI Aspirate
- Small Bowel Biopsy
- Unknown
- Other site (specify):

---

**11) ISOLATED PARASITIC ORGANISM:**

- **Cryptosporidium**
  - How identified? (Please check all that apply):
    - Wet mount, not stained
    - Wet mount, temporary stain, type: [Type]
    - Acid fast, type: [Type]
    - FA (Direct immunofluorescence)
    - ELISA, specify immunoassay method: [Method]
    - PCR
    - Other, please specify: [Specify]

- **Cyclospora**
  - How identified? (Please check all that apply):
    - Wet mount, not stained
    - Wet mount, temporary stain, type: [Type]
    - Wet mount, autofluorescence
    - Acid fast, type: [Type]
    - Safranin, type: [Type]
    - PCR
    - Other, please specify: [Specify]
A. Hospital Follow-up:

13) PATIENT STATUS AT THE TIME OF SPECIMEN COLLECTION:
☐ Hospitalized (go to 15) ☐ Unknown (go to 15c)
☐ Outpatient (go to 14)

13a) OISD (Other immunosuppressive diseases):
☐ Yes ☐ No ☐ Not available

14) IF OUTPATIENT, WAS THE PATIENT SUBSEQUENTLY HOSPITALIZED?
☐ Yes (go to 15) ☐ No (go to 15c) ☐ Unknown (go to 15c)

15) IF PATIENT WAS HOSPITALIZED
(that is, if answered “Hospitalized” to #13 or “Yes” to #14):
Hospital name: ____________________________
Date of admission: ____ / ____ / 200__  
month   day
Date of discharge: ____ / ____ / 200__
month   day

15a) TRANSFERRED TO ANOTHER HOSPITAL?
☐ Yes ☐ No ☐ Unknown

15b) If Yes, TRANSFER HOSPITAL NAME:
_____________________________________________

15c) HOW WAS THE INFORMATION (from #13,14, or 15) DETERMINED?
☐ Patient / relative contacted
☐ Physician contacted or chart review / medical records review
☐ Did not follow up
☐ County provided information

16) OUTCOME: ☐ Alive ☐ Dead ☐ Unknown

16a) HOW WAS THIS INFORMATION (from #16) DETERMINED?
Patient / relative contacted
Physician contacted or chart review / medical records review
☐ Did not follow up
☐ County provided information

B. Health Department Follow-up:

If the isolate was further characterized by the State Lab, please update #11.

17) DID THE STATE LAB RECEIVE THE ISOLATE?
☐ Yes ☐ No ☐ Unknown

17a) If Yes, STATE LAB ISOLATE ID NUMBER:
___________________________________________

18) DID THE PATIENT TRAVEL WITHIN THE LAST 15 DAYS?
☐ Yes (go to 17a) ☐ No ☐ Unknown

18a) Date of departure from the U.S.: ____ / ____ / 200__
month   day
Date of return to the U.S.: ____ / ____ / 200__
month   day

19) WAS CASE FOUND DURING AN AUDIT?
☐ Yes ☐ No ☐ Unknown

20) WAS THE CASE PART OF AN OUTBREAK?
☐ Yes (go to 20a) ☐ No ☐ Unknown

20a) IF OUTBREAK RELATED, WAS IT A FOODBORNE OUTBREAK?
☐ Yes (go to 20b) ☐ No ☐ Unknown

20b) EFORS NUMBER: ____________________________

21) IF AVAILABLE, PLEASE INDICATE:

Date of illness onset: ____ / ____ / 200__ ☐ Not Available
month   day
Date of diarrhea onset: ____ / ____ / 200__ ☐ Not Available
month   day

22) WAS CASE ENROLLED IN THE CASE-CONTROL STUDY?
☐ Yes ☐ No ☐ Unknown

If No, Reason: ____________________________
Reason Code: ____________________________

Comments __________________________________________
________________________________________

23) IS CASE REPORT COMPLETE? ☐ Yes ☐ No

23a) If Yes, DATE CASE REPORT COMPLETED:
____ / ____ / 200__
month   day

23b) INITIALS OF PERSON COMPLETING CASE REPORT: ________

Comments __________________________________________
________________________________________

Revised 2/6/04
Appendix III: Foodborne Diseases Active Surveillance Network (FoodNet) Variable Definitions

The variables listed are from the Case Report Form, which is a hard copy based on the Public Health Laboratory Information System (PHLIS) Foodborne Illness Module. Numbered variables on the Case Report Form are included in the PHLIS Foodborne Illness Module. Unnumbered variables are provided at site request to help track patients and specimens.

**PHLIS ID Number:** During data entry, the PHLIS program automatically assigns the ID number. The first eight digits correspond to the site ID, [SITE_ID], the next 9 digits are the patient ID, [PAT_ID] and the next three are the specimen ID. The specimen ID distinguishes between multiple specimens for a case, i.e. from different sources or different days. The last 2 digits are the aliquot ID which is used when a single specimen is split for multiple tests. PHLIS will permit multiple specimens per patient through the structure of its relational database. Information on the algorithm to be used with multiple samples per patient is provided in the Case Ascertainment Instructions.

**Local Case ID:** [LOCAL_ID] Case medical record number

**[SNAPDATE]:** Date PHLIS data was uploaded to Foodnet for each site

**Patient name, address, and phone number:** Personal identifiers will be entered into the database but will be encrypted during data transmission to the CDC. City, [CITY] State, [STATE] and ZIP code [ZIPCODE] will be transferred to CDC unencrypted. Data at lower sites, such as Grady Hospital in Atlanta or the Oakland Office in California, will be unencrypted when received in the higher site.

**County [COUNTY]:** This records the patient's county of residence. This will be used to determine whether or not the individual resides within the catchment area and therefore whether the individual will be included in the data. *Protocol for homeless cases:* Enter 'homeless' in the address field, '99999' as the zip code, leave the city field blank, and enter the appropriate county from where the case was reported.

**Sex [SEX]:** Male, Female, or Unknown

**Date of Birth [DOB]:** Month/Day/Year

**Race [RACE]:** If known (white, black, American Indian/Native Alaskan, Asian/Pacific Islander) or unknown. *Race-additional census categories:* This is a new question for 2002 to capture more specific data on race. The pick list includes Asian, Pacific Islander/Native Hawaiian, Multi-racial, and Other. These additional choices have been added as part of FoodNet to all isolate modules for compliance with the new census categories. This question will be skipped if the answer to "Race" is White, Black, American Indian/Native Alaskan, or Unknown. Otherwise you will be prompted to fill in this variable.

**Ethnicity [ETHNICITY]:** If known (Hispanic, Non-Hispanic, unknown)

**Specimen date [SPECDATE]:** Month/Day/Year of specimen collection. If this information is unavailable, please provide "Date received in laboratory" in the appropriate field [DT_RCVD].

**Age/Age in months [AGE_YR, AGE_MNTH, AGE_DAYS]:** PHLIS will calculate this information, given the "Date of Birth" and the "Specimen date". This age is in years. If the patient is less than one year old, age in months is used. If the patient is less than 1 month old, age in days is used.

**Submitting Lab/Phone:** This list of hospital and reference labs will be in picklist format in the module. **The module does not have the picklist installed for each site.** The picklist is created by the user during data entry. In the PHLIS module, at the variable "Submitting lab", hit the insert key to add to the picklist and type the name of the hospital or reference lab. The phone number will not be entered into PHLIS. [SUBLAMNM]

**Submitting Physician/Phone/Address:** This information is not transmitted to the CDC but was requested by the sites in order to follow up isolates sent to reference labs.

**Source of Specimen [SPECRSRCE]:** Site from which specimen was collected, including stool, urine, blood, CSF, or other sterile site such as bones or joints.
Appendix III: Foodborne Diseases Active Surveillance Network (FoodNet) Variable Definitions

- **Isolated Bacteria and Confirmed Parasites [ISOLATE]:** The list of bacteria includes *Salmonella*, *Shigella*, *Campylobacter*, *E. coli* (STEC), *Vibrio*, *Listeria monocytogenes*, and *Yersinia enterocolitica*. The list of parasites include Cryptosporidium and Cyclospora.

- Once the bacteria is selected, a second picklist of serotype, if known, is provided for: [SEROTYPE]

- *Shigella: [SHIGSERO]*
- *Campylobacter: [CAMPSPEC]*
- *Vibrio: [VIBROSPC]*
- *Yersinia*
- *Listeria: [LISTSERO]*

- Additional variables on *Salmonella* serogroup and serotype are also provided: [SAL_GRP, SAL_SERO]

- If the bacterial pathogen is *E. coli* (STEC) or *Listeria*, additional information is requested:

  **E. coli / STEC**
  
  - Biochemically identified as *E. coli*? [BIOID] Yes, No, Unsure/not tested, Unknown
  - O157 positive? [O157POS] Yes, No, Unsure/not tested, Unknown
  - O antigen number [OANTIGNO] ###
  - H Antigen Number [ECOLANT] If H antigen positive, provide H antigen number ##.
  - Isolate non-motile? [NONMOTIL] Yes, No, Unsure/not tested
  - Shiga toxin Positive: [SHIGTPOS] If *E. coli* is Nonmotile, was it Shiga-like toxin producing? Yes, No, Unsure/Not tested

  **Listeria**
  
  - Pregnant? [PREGNANT] Yes, No, Unknown
  - Outcome of Fetus? [FOUTCOME] Abortion/stillbirth, Induced abortion, Live birth/neonatal death, Survived-clinical infection, survived - no apparent illness, unknown

  **Specimen ID number (accession #):** This information is **not transmitted** to the CDC but was requested by the sites to track specimens by the accession number from the lab sample.

  **Date received in laboratory:** This information is required only if the Specimen Collection Date is unavailable. Month, Day, and Year the specimen was received in the laboratory. [DT_RCVD]

  * Patient Status at time of specimen collection [PSTATCOL]: Was the patient an inpatient, an outpatient, or unknown. An ER collection is counted as an outpatient. For ER discharges with no follow-up, ‘subsequent hospitalization’ and ‘outcome’ will be coded as ‘unknown’.

  **If outpatient, was patient subsequently hospitalized [OPATHOSP]:** Outpatients who are hospitalized within 7 days of specimen collection, should be counted as ‘yes’. If we cannot find out if case was subsequently hospitalized, make no assumptions and enter ‘unknown’.

  **If hospitalized, please provide the following information:**
  
  - Hospital name [HOSPNAME], Date of admission [HDTOFADM], Date of discharge [HDTOFDIS], if transferred to another hospital [XFR2OHOS], and the name of the hospital to which the patient was transferred [XFRHOSNM]. Patient ID number is the medical record number or chart number of the hospitalized patient. This variable is not included in the PHLIS module because it is a patient identifier. It is included on the Case Report Form in order to follow up the hospitalized patients. A picklist can be created for the "Hospital name" in the same way as for "Submitting lab".

  **How was the information determined? [HINFODET]:** How information from questions 13, 14, or 15 were determined. Choices are patient or relative contacted, physician contacted or chart review/medical records review, did not follow up, or county provided information.
Appendix III: Foodborne Diseases Active Surveillance Network (FoodNet) Variable Definitions

Outcome [OUTCOME]: Alive, Dead, Unknown. If outpatient, death within 7 days of culture confirmation date, if hospitalized, follow-up until patient is discharged or dies. If hospitalization is <7 days, data from hospital discharge will still be used for ‘outcome’.

How was the information determined? [OINFODET]: How information from question 16 was determined. Choices are patient or relative contacted, physician contacted or chart review/medical records review, did not follow up, or county provided information

Did the state receive the isolate?: [STLABRIS] Did the hospital or reference lab forward the isolate, yes, no, or unknown?

* If yes, isolate number: [SLABSID] Each state lab should assign a unique isolate ID number. This isolate ID number will be used to link isolates forwarded to CDC by state health departments for anti-microbial testing.

Case found during an audit? Yes, no, or unknown

Case in case-control study? [CASE_IN] Yes, no, or unknown (Only for cases of pathogens for which we are conducting an ongoing case control study.)

If no, reason case is not enrolled in case control study [REASON]: Only for cases of pathogens for which we are conducting an ongoing case control study. If surveillance case was not enrolled as a case in the case control study, reason why excluded. Choices may vary by study, but will usually include: not reachable after 15 calls, do not have home phone, non English speaker, unable to answer questions, did not have diarrhea, no onset of diarrhea, diarrhea onset > 10 days before collection, outbreak associated, unable to interview within 21 days of collection, refused, not in catchment area, immunocompromised, not selected in random sample, chronic carrier, family member with positive culture/bloody diarrhea, unable to contact patient, outside of study time period, no control was found, or other reason.

Is case report complete? [CASRPTC] Yes, no, or unknown: CDC can track the number of completed forms with this variable. A case report form will be complete if all known variables are provided.

* Complete, Date, Initials [CASRPTCD, CASRPTCI]: When the case report form is complete, the person completing the form should initial and date the form. No may be entered in the PHLIS module, but this information will be updated to yes once the form is complete or all information available is collected

* Must enter data into PHLIS module
## Appendix IV: Documentation of FoodNet Variables

<table>
<thead>
<tr>
<th>PHLIS Variable's Name</th>
<th>PHLIS Variable's Data Type</th>
<th>PHLIS Variable's Data Length</th>
<th>FoodNet Variable's Data Type</th>
<th>Variable Description</th>
<th>Potential Answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>RES1XHX</td>
<td>Character</td>
<td>1</td>
<td>Character</td>
<td>race- additional categories</td>
<td>A [Asian], M [Multi-Racial], O [Other], P [Pacific Islander or Native American]</td>
</tr>
<tr>
<td>AGE_Mo</td>
<td>Character</td>
<td>2</td>
<td>Numeric</td>
<td>age of patient in months if patient is less than 1 year old</td>
<td></td>
</tr>
<tr>
<td>AGE_YRS</td>
<td>Character</td>
<td>3</td>
<td>Numeric</td>
<td>age of patient in years</td>
<td></td>
</tr>
<tr>
<td>ALIQUOT_ID</td>
<td>Character</td>
<td>2</td>
<td>Character</td>
<td>aliquot id</td>
<td></td>
</tr>
<tr>
<td>RES1X1R</td>
<td>Character</td>
<td>10</td>
<td>Character</td>
<td>was the ecoli biochemically identified as <em>E.coli</em></td>
<td>No, Not Tested, Unknown, Yes</td>
</tr>
<tr>
<td>RES1DDF</td>
<td>Character</td>
<td>15</td>
<td>Character</td>
<td><em>Campylobacter</em> species</td>
<td>bubulus, coli, cryaerophilia, doylei, fetus,</td>
</tr>
<tr>
<td>RES1XAP</td>
<td>Character</td>
<td>1</td>
<td>Character</td>
<td>case in case-control study?</td>
<td>No, Unknown, Yes</td>
</tr>
<tr>
<td>RES1X47</td>
<td>Character</td>
<td>7</td>
<td>Character</td>
<td>is case report complete?</td>
<td>No, Yes</td>
</tr>
<tr>
<td>RES1X48</td>
<td>Date YYMMDD8.</td>
<td>Date</td>
<td>Date</td>
<td>date case report form was completed</td>
<td>No, Yes</td>
</tr>
<tr>
<td>RES1X49</td>
<td>Character</td>
<td>3</td>
<td>Character</td>
<td>initials of person completing case report form</td>
<td></td>
</tr>
<tr>
<td>CITY</td>
<td>Character</td>
<td>15</td>
<td>Character</td>
<td>city</td>
<td></td>
</tr>
<tr>
<td>COUNTY</td>
<td>Character</td>
<td>20</td>
<td>Character</td>
<td>county of residence</td>
<td>* see census document</td>
</tr>
<tr>
<td>BIRTHDATE</td>
<td>Date YYMMDD8.</td>
<td>Date</td>
<td>Date</td>
<td>date of birth</td>
<td></td>
</tr>
<tr>
<td>RES1X1B</td>
<td>Date YYMMDD8.</td>
<td>Date</td>
<td>Date</td>
<td>date specimen received in laboratory (only if specimen collection date unavailable)</td>
<td></td>
</tr>
<tr>
<td>RES1X1Q</td>
<td>Character</td>
<td>2</td>
<td>Character</td>
<td>what is the H antigen number?</td>
<td>1-999</td>
</tr>
<tr>
<td>ENTRY_DATE</td>
<td>Date YYMMDD8.</td>
<td>Date</td>
<td>Date</td>
<td>date entered</td>
<td></td>
</tr>
<tr>
<td>ETHNIC</td>
<td>Character</td>
<td>1</td>
<td>Character</td>
<td>ethnicity</td>
<td>H (Hispanic), N (Non-Hispanic), U (Unknown)</td>
</tr>
<tr>
<td>RES1XFA</td>
<td>Character</td>
<td>3</td>
<td>Character</td>
<td>outcome of fetus?</td>
<td>1 (Survived, no apparent illness) 2 (Survived, clinical infection)</td>
</tr>
<tr>
<td>FIRST_NAME</td>
<td>Character</td>
<td>12</td>
<td>Character</td>
<td>patient's first name, encrypted when arrives at cdc</td>
<td>should be blank or encrypted</td>
</tr>
<tr>
<td>RES1DEA</td>
<td>Character</td>
<td>20</td>
<td>Character</td>
<td>IF O157, was it H7 antigen positive?</td>
<td>No, Unsure/Not Tested, Yes</td>
</tr>
<tr>
<td>RES1X3L</td>
<td>Date YYMMDD8.</td>
<td>Date</td>
<td>Date</td>
<td>date of hospital admission</td>
<td></td>
</tr>
<tr>
<td>RES1X3M</td>
<td>Date YYMMDD8.</td>
<td>Date</td>
<td>Date</td>
<td>date of hospital discharge</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix IV: Documentation of FoodNet Variables

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<tr>
<th>PHLIS Variable's Name</th>
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<th>PHLIS Variable's Data Length</th>
<th>FoodNet Variable's Data Type</th>
<th>Variable Description</th>
<th>Potential Answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>RES1XH4</td>
<td>Character</td>
<td>55</td>
<td>Character</td>
<td>how hospital information was obtained?</td>
<td>County provided information, Did not follow-up, Patient or relative contacted, Physician contacted or chart/medical records/death cert</td>
</tr>
<tr>
<td>RES1X3J</td>
<td>Character</td>
<td>30</td>
<td>Character</td>
<td>Hospital name</td>
<td></td>
</tr>
<tr>
<td>RES1XHY</td>
<td>Character</td>
<td>7</td>
<td>Character</td>
<td>Is the case international travel related?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>DISEASE_D</td>
<td>Character</td>
<td>15</td>
<td>Character</td>
<td>name of pathogen isolated</td>
<td>Campylobacter, E. coli 0157, Cryptosporidium, Cyclospora, Listeria, Salmonella, Vibrio, Yersinia, Shigella, STEC O Ag Undet, STEC Non O157</td>
</tr>
<tr>
<td>LAB_NUMBER</td>
<td>Character</td>
<td>12</td>
<td>Character</td>
<td>local aliquot ID</td>
<td></td>
</tr>
<tr>
<td>LAST_NAME</td>
<td>Character</td>
<td>25</td>
<td>Character</td>
<td>patient's last name, encrypted when arrives at cdc should be blank or encrypted</td>
<td></td>
</tr>
<tr>
<td>RES1XH9</td>
<td>Character</td>
<td>10</td>
<td>Character</td>
<td>Listeria serotype</td>
<td>1/2A, 1/2B, 1/2C, 3A, 3B, 3C, 4B, Unknown, Untypeable</td>
</tr>
<tr>
<td>LOCAL_ID</td>
<td>Character</td>
<td>16</td>
<td>Character</td>
<td>case medical record number</td>
<td></td>
</tr>
<tr>
<td>RES1X1N</td>
<td>Character</td>
<td>7</td>
<td>Character</td>
<td>was the isolate non-motile?</td>
<td>No, Unknown, Yes</td>
</tr>
<tr>
<td>RES1DE9</td>
<td>Character</td>
<td>20</td>
<td>Character</td>
<td>was the ecoli O157 positive?</td>
<td>No, Unsure/Not Tested, Yes</td>
</tr>
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<td>RES1X1P</td>
<td>Character</td>
<td>3</td>
<td>Numeric</td>
<td>what is the O antigen number?</td>
<td>1-999</td>
</tr>
<tr>
<td>RES1XH5</td>
<td>Character</td>
<td>60</td>
<td>Character</td>
<td>how outcome information was obtained?</td>
<td>County provided information, Did not follow-up, Patient or relative contacted, Physician contacted or chart/medical records/death cert</td>
</tr>
<tr>
<td>RES1X3I</td>
<td>Character</td>
<td>7</td>
<td>Character</td>
<td>if outpatient, was patient subsequently hospitalized?</td>
<td>No, Unknown, Yes</td>
</tr>
<tr>
<td>RES1DDH</td>
<td>Character</td>
<td>7</td>
<td>Character</td>
<td>outbreak related?</td>
<td>No, Unknown, Yes</td>
</tr>
<tr>
<td>RES1WYH</td>
<td>Character</td>
<td>7</td>
<td>Character</td>
<td>outcome of patient</td>
<td>Alive, Dead, Unknown</td>
</tr>
<tr>
<td>PATIENT_ID</td>
<td>Character</td>
<td>9</td>
<td>Character</td>
<td>patient id number generated by phlis</td>
<td></td>
</tr>
<tr>
<td>RES1XFB</td>
<td>Character</td>
<td>3</td>
<td>Numeric</td>
<td>If listeria isolate, was patient pregnant?</td>
<td>1 (Yes), 2 (No)</td>
</tr>
<tr>
<td>RES1X3H</td>
<td>Character</td>
<td>12</td>
<td>Character</td>
<td>patient status at time of collection</td>
<td>Hospitalized, Outpatient, Unknown</td>
</tr>
<tr>
<td>RACE</td>
<td>Character</td>
<td>1</td>
<td>Character</td>
<td>race</td>
<td>I-Native American</td>
</tr>
<tr>
<td>RES1X4B</td>
<td>Character</td>
<td>2</td>
<td>Character</td>
<td>Salmonella serogroup</td>
<td></td>
</tr>
<tr>
<td>RES1764</td>
<td>Character</td>
<td>60</td>
<td>Character</td>
<td>Salmonella serotype</td>
<td></td>
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<tr>
<td>GENDER</td>
<td>Character</td>
<td>1</td>
<td>Character</td>
<td>sex</td>
<td>M (male), F (female), U (unknown)</td>
</tr>
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<td>RES1DDW</td>
<td>Character</td>
<td>60</td>
<td>Character</td>
<td>Shigella species</td>
<td>boydii, dysenteriae, flexneri, sonnei, unknown</td>
</tr>
</tbody>
</table>
### Appendix IV: Documentation of FoodNet Variables

<table>
<thead>
<tr>
<th>PHLIS Variable's Name</th>
<th>PHLIS Variable's Data Type</th>
<th>PHLIS Variable's Data Length</th>
<th>FoodNet Variable's Data Type</th>
<th>Variable Description</th>
<th>Potential Answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>RES1X1O</td>
<td>Character</td>
<td>10</td>
<td>Character</td>
<td>If <em>E. coli</em> was it shiga-like toxin producing?</td>
<td>No, Not Tested, Unknown, Yes</td>
</tr>
<tr>
<td>SITE_ID</td>
<td>Character</td>
<td>10</td>
<td>Character</td>
<td>site id number generated by phlis automatically (location/number of computer where data was entered)</td>
<td>** (see table at bottom)</td>
</tr>
<tr>
<td>RES1X3R</td>
<td>Character</td>
<td>30</td>
<td>Character</td>
<td>state lab id</td>
<td>^ see FN/NARMS linking table for correct format (should be unique for each case)</td>
</tr>
<tr>
<td>SPEC_ID</td>
<td>Character</td>
<td>3</td>
<td>Character</td>
<td>specimen id number generated by phlis</td>
<td></td>
</tr>
<tr>
<td>DATE_TAKEN</td>
<td>Date</td>
<td>YYMMDD</td>
<td>Date</td>
<td>specimen collection date</td>
<td></td>
</tr>
<tr>
<td>SOURCE</td>
<td>Character</td>
<td>60</td>
<td>Character</td>
<td>site from which specimen was collected</td>
<td>Abscess, Blood, CSF, Other, Stool, Unknown, Urine</td>
</tr>
<tr>
<td>STATE</td>
<td>Character</td>
<td>2</td>
<td>Character</td>
<td>state</td>
<td>CA, CO, CT, GA, MD, MN, NM, NY, OR, TN</td>
</tr>
<tr>
<td>RES1XAD</td>
<td>Character</td>
<td>7</td>
<td>Character</td>
<td>did the hospital or reference lab forward the isolate?</td>
<td>No, Unknown, Yes</td>
</tr>
<tr>
<td>LAB_NAME</td>
<td>Character</td>
<td>25</td>
<td>Character</td>
<td>name of submitting laboratory</td>
<td></td>
</tr>
<tr>
<td>RES1XGI1</td>
<td>Memo</td>
<td>350</td>
<td>Memo</td>
<td>Underlying causes or associated illness</td>
<td>AIDS, Alcohol Abuse, Artherosclerotic Cardiovascular Disease (ASCVD/CAD), Asthma, Blunt Trauma, Burns, Cirrhosis, CSF Leak (2 trauma/surgery), Diabetes Mellitus, Emphysema/COPD, Heart Failure/CHF, HIV Infection, Hodgkin's Disease, Immunoglobulin Deficiency, Immunosuppressice Therapy (steriods, chemotherapy, radiation), IVDU, Leukemia, Multiple Myeloma, Nephrotic Syndrome, Organ Transplant, Other Illness, Other Malignancy, Penetrating Trauma, Renal Failure/Dialysis, Sickle Cell Anemia, Splenectomy/asplenia, Surgical Wound (post operative), Systemic Lupus Erythematosus (SLE), Unknown, Varicella</td>
</tr>
</tbody>
</table>
### Appendix IV: Documentation of FoodNet Variables

<table>
<thead>
<tr>
<th>PHLIS Variable's Name</th>
<th>PHLIS Variable's Data Type</th>
<th>PHLIS Variable's Data Length</th>
<th>FoodNet Variable's Data Type</th>
<th>Variable Description</th>
<th>Potential Answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>RES1XAQ</td>
<td>Character</td>
<td>2</td>
<td>Character</td>
<td>reason not in case-control study?</td>
<td>01 [Non-English/non-Spanish speaker], 10 [No surrogate available], 11 [Unable to answer questions], 12 [Physician did not allow patient contact/physician refused], 02 [Case refused], 03 [Case not reachable after 15 calls], 04 [Do not have home phone], 05 [Outbreak associated], 06 [Unable to interview within 30 days of collection due to laboratory issues], 07 [Unable to interview within 30 days of collection due to county health], 08 [Unable to interview within 30 days of collection due to other], 09 [Not in catchment area]</td>
</tr>
<tr>
<td>RES1XHZ</td>
<td>Date</td>
<td>YYMMDD8.</td>
<td>Date</td>
<td>Date of departing from U.S.</td>
<td></td>
</tr>
<tr>
<td>RES1XI0</td>
<td>Date</td>
<td>YYMMDD8.</td>
<td>Date</td>
<td>Date of returning to U.S.</td>
<td></td>
</tr>
<tr>
<td>RES1X7P</td>
<td>Character</td>
<td>24</td>
<td>Character</td>
<td>Vibrio species</td>
<td>algimoltylicus, cholerae, cincinnatiensis, damsela, fluvialis hollisae, mimicus, parahaemolyticus, vulnificus, unknown</td>
</tr>
<tr>
<td>RES1X3N</td>
<td>Character</td>
<td>7</td>
<td>Character</td>
<td>transferred to another hospital?</td>
<td>No, Unknown, Yes</td>
</tr>
<tr>
<td>RES1X3O</td>
<td>Character</td>
<td>30</td>
<td>Character</td>
<td>name of transfer hospital</td>
<td></td>
</tr>
<tr>
<td>RES1XFC</td>
<td>Character</td>
<td>24</td>
<td>Character</td>
<td>Yersinia species</td>
<td>aldovae, bercovieri, enterocolitica, frederiksenii, intermedia, kristensenii, mollaretii, pestis, philomiragia, pseudotuberculosis, rohdei, ruckeri</td>
</tr>
<tr>
<td>ZIP</td>
<td>Character</td>
<td>9</td>
<td>Character</td>
<td>zipcode</td>
<td></td>
</tr>
</tbody>
</table>
Surveillance
1. Case follow-up
   a. Percent of cases with “unknown” hospitalization (hospitalization within 7 days of culture collection date)  
      Target: <= 50% unknown
   b. Percent of outpatient/ER cases with “unknown” outcome  
      (If outpatient, death within 7 days of culture collection date; if hospitalized, follow-up until patient is discharged or dies)  
      Note: See attached sheet for additional information.  
      Target <= 50% unknown
   c. Percent of hospitalized cases with “unknown” outcome  
      Target <=15% unknown

2. Timeliness - median days from culture collection to data entry in PHLIS/state system  
   (In MD, NY, CO, and GA, a variable will be added into PHLIS to allow monitoring of this standard.)  
   Target: <= 15 days

3. HUS surveillance - measure of participation  
   Target: Report to CDC at least once per month

4. Outbreak surveillance - measure of participation  
   Target: Summary report to CDC at least once per month  
   Target: Report 85% of outbreaks to CDC within 2 weeks of ‘Date first case became ill’  
   FoodNet will determine method for measuring this standard.  
   Target: Finalize 70% of reports within 2 months of first onset  
   Coordinators proposed to revise because current standard is not measurable.

NARMS
5. Isolate submission - percent of cases which should have had an isolate submitted, that did have an isolate submitted, 2 month lag time allowed  
   Target: Every 20th non-Typhi Salmonella in surveillance  
   Every 20th E. coli O157 in surveillance  
   1 Campylobacter isolate per week  
   Every 20th Shigella in surveillance  
   All Salmonella Typhi in surveillance  
   All Listeria monocytogenes in surveillance  
   All Vibrio in surveillance
Appendix V: FoodNet/NARMS Performance Standards, 2003

PulseNet
6. PFGE testing - percent of cases which should have had a PFGE pattern submitted, that did have a PFGE pattern submitted
   Target: All *E. coli O157*, *Salmonella Typhimurium*, and *Listeria monocytogenes* in surveillance
   FoodNet will add a timeliness factor to this standard once a method for measuring it is established.

7. Isolates received at state laboratory from clinical labs
   a. Target: >= 85% *E. coli O157* in surveillance
      Target: >= 85% *Salmonella* in surveillance
      Target: >= 95% *Listeria monocytogenes* in surveillance
      Target: >= 90% *Vibrio* in surveillance
   b. Target >= 95% of bacterial isolates (except *Campylobacter*) will have serotype/species information entered into the FoodNet system

Case-control studies
8. Percent of cases eligible for case-control studies which were enrolled
   Target: >= 50% enrollment of eligible cases in surveillance
   (“eligible” as defined in methods for each study)
   a. Percent of cases enrolled in *Listeria* case-control study
      Target: >= 85% of cases enrolled with >=2 controls
   b. Percent of cases enrolled in *cryptosporidium* case-control study (for sites participating in *Cryptosporidium* case-control study)
      Target: >= 85% of cases enrolled with 2 controls

Leadership
9. Participation
   a. Percent of Steering Committee conference call with site representative
      Goal: Representatives from each site should attend 100% of calls
   b. Percent of Data-Sharing conference call with site representative
      Goal: Representatives from each site should attend >= 5 of 6 (83%) calls per year

10. Number of 1st authored abstracts submitted yearly to national meetings
    Goal: Each site should submit >= 1 FoodNet abstract (site specific or aggregated data) per year to a national meeting
11. Target of 100% of Vibrios reported through FoodNet surveillance will be reported to FDDB on appropriate surveillance form in timely fashion. (“timely fashion” still to be determined)

12. Target of ___ % of Vibrio isolates received at state lab will be sent to CDC.

13. Target of capturing *Listeria* serotype information in FoodNet database in timely fashion so as to be useful for sites (for example in identifying clusters). (“timely fashion” still to be determined)

14. Target of 100% completion of ‘State Lab ID’ variable in FoodNet surveillance for isolates submitted to NARMS and PulseNet.
ADDITIONAL INFORMATION FOR PERFORMANCE STANDARD #1

1.) Hospitalization for any reason during the 7 day window will be recorded as a ‘yes’.
   (If >7 day window is used, CDC FoodNet can subset data to include only those with 7 day window.)

2.) If hospitalization is <7 days, data from hospital discharge will still be used for ‘outcome’.

3.) ER visits are considered ‘outpatient’. For ER discharges with no follow-up, ‘subsequent hospitalization’ and ‘outcome’ will be coded as ‘unknown’.

4.) ER Chart requests that are not fulfilled will be coded as ‘unknown’.

5.) FoodNet Case report form will be modified to reflect changes.
Appendix VI: FoodNet Criteria for Classification of Shiga toxin-producing E. coli (STEC)

1. Biochemically identified as E.coli (BioID)
   - Yes
     - O157 Positive? (O157/pos)
       - Yes
         - O Antigen Number (O AntigNo) = 157
           - STEC=O157
             - H7 Ag Positive? (Hantpos)
               - Yes
                 - H Antigen (EcoliAnt) = 7
                   - STEC O157
                     - Shiga Toxin Test (ShigToxpos)
                       - Yes
                         - No Unsure/Missing Not Tested
                       - No
                         - STEC O Ag Undet
                           - Encounter Database
               - No
                 - H Antigen (EcoliAnt) = not 7
                   - STEC nonO157
                     - Shiga Toxin Test (ShigToxpos)
                       - Yes
                         - No Unsure/Missing Not Tested
                       - No
                         - STEC O Ag Undet
                           - Encounter Database
       - No
         - O Antigen Number (O AntigNo) = blank or not 157
           - STEC nonO157
             - Shiga Toxin Test (ShigToxpos)
               - Yes
                 - STEC O Ag Undet
                   - Encounter Database
               - No
                 - Shiga Toxin Test (ShigToxpos)
                   - No Unsure/Missing Not Tested
               - No
                 - STEC nonO157
                   - STEC O Ag Undet
                     - Encounter Database
   - No
     - Not Tested/Unsure/Missing

*Flags indicate coding*
Please obtain information from children > one month of age and adults. In the event of a fetal or neonatal (<1 month of age) infection the mother is considered the case-patient and the mother’s food consumption history should be collected.

**CASE INFORMATION**

<table>
<thead>
<tr>
<th>Patient’s name:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s address:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phone numbers:</td>
<td>(h)</td>
<td>(w)</td>
</tr>
</tbody>
</table>

**DOB (mm/dd/yyyy):**

<table>
<thead>
<tr>
<th>Ethnicity (check all that apply)</th>
<th>Race (check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Hispanic/Latino</td>
<td>[ ] American Indian/Alaska Native</td>
</tr>
<tr>
<td>[ ] Non Hispanic/Latino</td>
<td>[ ] African American/Black</td>
</tr>
<tr>
<td>[ ] Unknown</td>
<td>[ ] Asian</td>
</tr>
<tr>
<td></td>
<td>[ ] White</td>
</tr>
<tr>
<td></td>
<td>[ ] Native Hawaiian/Pacific Islander</td>
</tr>
</tbody>
</table>

**State of residence:**

<table>
<thead>
<tr>
<th>State (laboratory) ID No</th>
<th>PulseNet Pattern Numbers:</th>
<th>CDC Outbreak (EFORS) ID No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ascl: GX6A16.________</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Apal: GX6A12.________</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other enzyme:________</td>
</tr>
</tbody>
</table>

**PREGNANCY ASSOCIATED CASES AND NEONATAL INFECTIONS (<1 MONTH OF AGE)**

**PREGNANCY ASSOCIATED CASE?** [ ] Yes [ ] No [ ] Unknown.

*If No, skip to ‘CASES NOT ASSOCIATED WITH PREGNANCY’.*

**If Yes,**

Did the mother have culture-confirmed listeriosis during pregnancy? [ ] Yes [ ] No [ ] Unknown

What type of infection did the pregnant woman have?

- [ ] Bacteremia/Sepsis
- [ ] Meningitis
- [ ] Febrile gastroenteritis
- [ ] Amnionitis
- [ ] No symptoms
- [ ] Unknown
- [ ] Other, specify________

**Type of specimen collected on woman:** [ ] Blood [ ] Stool [ ] CSF [ ] None [ ] Other, specify________

**Date specimen collected (mm/dd/yyyy):**

What was the outcome of the pregnancy? [ ] Still pregnant [ ] Miscarriage [ ] Stillbirth [ ] Preterm delivery (live birth) [ ] Term delivery (live birth) [ ] Other, specify________

**Was the mother hospitalized for her listeriosis illness?** [ ] Yes [ ] No [ ] Unknown

*If yes,*

**Date of admission (mm/dd/yyyy):**

**Date of discharge (mm/dd/yyyy):**

**Name of Hospital:**

**What was the mother’s outcome?** [ ] Survived [ ] Died [ ] Unknown

**FETAL AND NEONATAL (<1 MONTH OF AGE) INFECTIONS**

**Did the fetus or neonate have culture-confirmed listeriosis?** [ ] Yes [ ] No [ ] Unknown

*If yes,*

**What type of infection did the child have?**

- [ ] Meningitis
- [ ] Bacteremia/Sepsis
- [ ] Granulomatosis infanti-septicum
- [ ] Unknown
- [ ] Other, specify________

**Type of specimen collected on child:**

[ ] Blood [ ] Stool [ ] CSF [ ] Placenta [ ] Other, specify________

**Date specimen collected (mm/dd/yyyy):**

**Child’s DOB (mm/dd/yyyy):**

<table>
<thead>
<tr>
<th>Child’s Outcome:</th>
<th>[ ] Survived</th>
<th>[ ] Died</th>
<th>[ ] Unknown</th>
</tr>
</thead>
</table>

**CASES NOT ASSOCIATED WITH PREGNANCY**

**Did the fetus or neonate have culture-confirmed listeriosis?** [ ] Yes [ ] No [ ] Unknown

*If yes,*

**What type of infection did the child have?**

- [ ] Meningitis
- [ ] Bacteremia/Sepsis
- [ ] Febrile gastroenteritis
- [ ] Unknown
- [ ] Other, specify________

**Type of specimen collected:**

[ ] Blood [ ] Stool [ ] CSF [ ] Other, specify________

**Date specimen collected (mm/dd/yyyy):**

**Type of infection:**

- [ ] Bacteremia/Sepsis
- [ ] Meningitis
- [ ] Febrile gastroenteritis
- [ ] Unknown
- [ ] Other, specify________

**Was patient hospitalized?** [ ] Yes [ ] No [ ] Unknown

*If yes,*

**Date of admission (mm/dd/yyyy):**

**Date of discharge (mm/dd/yyyy):**

**Name of Hospital:**

**Case-patient’s Outcome:**

<table>
<thead>
<tr>
<th>[ ] Survived</th>
<th>[ ] Died</th>
<th>[ ] Unknown</th>
</tr>
</thead>
</table>
Salmonella serotyping

Patricia Fields PhD
National Salmonella Reference Lab
Foodborne and Diarrheal Diseases Branch
CDC
September 12, 2003

What is serotyping?

- The “first-generation” subtyping method
- Phenotypic characterization of strains based on the immunologic reactivity of two surface structures:
  - Lipopolysaccharide (O antigen)
  - Flagellin protein (H antigen)
- In Salmonella, includes species and subspecies identification
  - Isolates of different subspecies can have the same O and H antigens

Schematic Representation of Salmonella Serotype Antigens

Salmonella taxonomy

- Two species of Salmonella
  - Salmonella enterica
  - Salmonella bongori (formerly subspecies V)
- Salmonella enterica is further divided into 7 subspecies
  - Designated by roman numerals
  - 99% of human isolates are subspecies I
  - Subspecies II, IIIa, IIIb, IV, VI
  - Subspecies IIIa and IIIb used to be genus Arizonae
- Subspecies VII recognized but not used for the purpose of serotype designation
- Species/subspecies typically determined by biochemical testing

Salmonella enterica subspecies

<table>
<thead>
<tr>
<th>Subspecies</th>
<th>V. enterica</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>enterica</td>
</tr>
<tr>
<td>II</td>
<td>salmonae</td>
</tr>
<tr>
<td>IIIa</td>
<td>arizonae</td>
</tr>
<tr>
<td>IIIb</td>
<td>diarizonae</td>
</tr>
<tr>
<td>IV</td>
<td>houtenae</td>
</tr>
<tr>
<td>VI</td>
<td>indica</td>
</tr>
</tbody>
</table>

Differentiating Salmonella subspecies

Salmonella O antigen

- Outermost portion of lipopolysaccharide (LPS)
- Carbohydrate antigen
- Different sugars and different linkages between sugars produce the different antigens

Salmonella O Antigens

- “O Group” antigens are the most important for determining serotype
- 46 O serogroups (encoded by the rfb region)
- O groups initially designated by capital letters
- Ran out of letters … started using numbers
- Now: all O Groups are designated by numbers
- Letter designations still commonly used
- These O groups represent about 97% of human isolates
Appendix VIII: *Salmonella* serotyping

**Salmonella O Antigens (cont)**
- 11 additional O antigens that are not encoded by the *rfb* region
- Found in specific O groups
- Most can be variable within a given serotype, so are less important for serotype determination
- Typically encoded by extra-chromosomal elements
- One encoded on a plasmid
- Several encoded by bacteriophages
- Others likely to be encoded by bacteriophages, too

**Salmonella H antigen**
- Flagellin, the flagellar filament
- A protein antigen
- Variation in the middle surface-exposed portion of the protein
- *Salmonella* is unique in having 2 different H antigens:
  - Phase 1
  - Phase 2
- The 2 flagellin genes are coordinately expressed—one is off when other is on
- Some serotypes are “monophasic”—have only one flagellar antigen

**Salmonella H Antigens**
- 119 H antigens (Phase 1 & Phase 2)
- Typically designated by lower case letters
  - 1, 2, 1, 5, 1, 7, etc are the notable exceptions
- Ran out of letters … started using numbered z’s
  - z₄, z₆, z₁₀, z₁₅, etc.
- Typically, no antigenic relationships between “z” antigens
- Some H antigens are antigenically related
- Related antigens referred to as “complexes”
- Typically, have one antigen in common plus secondary antigens
- 1 complex, G complex, E complex, EN complex, z₄ complex

**Genomic location of genes encoding serotype antigens**

**Subspecies II – VI serotypes are designated by a formula**

"Group O:48" or "Group Y"

IV 48: g, z51: -*

Subspecies O  Phase 1  “monophasic” antigens

* *Salmonella* IV 48: g, z51: - was formerly known as *S.* Marina.

**Designation of Salmonella Serotypes**
- Designated according to the conventions of the Kauffmann-White Scheme
  - Established 1929
  - 44 serotypes in 1934
  - 2,523 serotypes in 2001
- Kauffmann-White Scheme maintained by Institut Pasteur
  - Published every five years
  - Updated annually

**Distribution of Salmonella O Groups**

**Subspecies I serotypes are designated by a name or a formula**

*S.* Typhimurium

"Group O:4" or "Group B"

<table>
<thead>
<tr>
<th>O antigen</th>
<th>Phase 1 Phase 2 H antigens</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 4, [5], 12 : i : 1,2</td>
<td></td>
</tr>
</tbody>
</table>

Subspecies O antigen  Phase 1  Phase 2  H antigens

<table>
<thead>
<tr>
<th>O antigen</th>
<th>Phase 1 Phase 2 H antigens</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 4, 12 : i : 1,2</td>
<td></td>
</tr>
<tr>
<td>1, 4, 12 : i : 1,2</td>
<td></td>
</tr>
<tr>
<td>1, 4, 12 : i : 1,2</td>
<td></td>
</tr>
</tbody>
</table>

*Typhimurium var. O 5* or var. Copenhagen
Appendix VIII: Salmonella serotyping

Examples of Serotype Designations
- *Salmonella enterica* subspecies *enterica* serotype Typhimurium
- *Salmonella* serotype Typhimurium
- *Salmonella* ser. Typhimurium
- *Salmonella* ser. Typhi
- *Salmonella enterica* subspecies houtenae serotype 48:g,z51:-
- *Salmonella enterica* serotype IV 48:g,z51:-
- *Salmonella enterica* serotype IV 48:g,z51:-
- *Salmonella enterica* serotype IV 48:g,z51:-
- “CDC preferred” designation

Serotype Variants: Unable to detect one or both H antigens
- Monophasic variants
  - *Salmonella* I 4,5,12:i:---
  - *Salmonella* I 4,12:i:---
  - *Salmonella* I 4,[5],12:i:---
  - *Salmonella* I Group B:i:---
  - *Salmonella* I Group O:4:i:---
- “Salmonella Group B i monophasic”
- Nonmotile variants
  - *Salmonella* I 4,5,12:i:--- (or I 4,5,12:nonmotile)
- Other serotypes also produce monophasic variants!

Serotype Variants: Unable to detect O antigen
- Rough strains (no longer express O antigen)
  - *Salmonella* I O rough:i:1,2
- Mucoid strains (capsule blocks O antigen detection)
  - *Salmonella* I O mucoid:i:1,2

Rough strains (no longer express O antigen)
- *Salmonella* I O rough:i:1,2
- Mucoid strains (capsule blocks O antigen detection)
- *Salmonella* I O mucoid:i:1,2

Rough strains (no longer express O antigen)
- *Salmonella* I O rough:i:1,2
- Mucoid strains (capsule blocks O antigen detection)
- *Salmonella* I O mucoid:i:1,2

Rough strains (no longer express O antigen)
- *Salmonella* I O rough:i:1,2
- Mucoid strains (capsule blocks O antigen detection)
- *Salmonella* I O mucoid:i:1,2
Appendix IX: Overview of *Salmonella* Serotype Designation

1) *Salmonella* Taxonomy
The genus *Salmonella* divided into two species, *Salmonella enterica* and *Salmonella bongori*.

*Salmonella enterica* is further subdivided into 6 subspecies that are designated by names or Roman numerals. The Roman numerals are simpler and more commonly used. Subspecies IIIa and IIIb were historically considered a separate genus, *Arizonae*, and are still sometimes referred to by this name.

<table>
<thead>
<tr>
<th><em>Salmonella enterica</em> subspecies</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
</tr>
<tr>
<td>II</td>
</tr>
<tr>
<td>IIIa</td>
</tr>
<tr>
<td>IIIb</td>
</tr>
<tr>
<td>IV</td>
</tr>
<tr>
<td>VI</td>
</tr>
</tbody>
</table>

*Salmonella bongori* was originally designated *S. enterica* subspecies V. It has since been determined to be a separate species of *Salmonella*. However, for simplicity and convenience, these strains are commonly referred to as “subspecies V” for the purpose of serotype designation.

2) *Salmonella* Serotype Antigens
*Salmonella* serotype is based on the immunoreactivity of two surface structures, O antigen and H antigen.

**O antigen** is a carbohydrate antigen (also called a polysaccharide) that is the outermost component of LPS (lipopolysaccharide). It is a polymer of O subunits; each O subunit is typically composed of four to six sugars depending on the O antigen. Variation in O antigen results from variation in the sugar components of the O subunit, from variation in the nature of the covalent bond between the sugars of the subunit, and from variation in the nature of the linkage between the O subunits that form the O antigen polymer. O antigens are designated by numbers and are divided into O serogroups or O groups. O groups are designated by the primary O factor(s) that are associated with the group. Many of the common O groups were originally designated by letter and are still commonly referred to by letter (e.g., *S*. Typhimurium belongs to Group O:4 or Group B, *S*. Enteritidis belongs to group O:9 or Group D1; *S*. Paratyphi A belongs to Group O:2 or Group A).

**Additional O factors** are associated with some O groups and are often variably present or variably expressed. Table 1 lists the O groups and the additional O antigens that may be present in serotypes of that group. When multiple O factors are present, they are listed sequentially and separated by commas.

**H antigen** is a protein antigen called flagellin; multiple flagellin subunits make up the filament component of the flagella. The ends of flagellin are conserved and give the flagella its characteristic filament structure. The antigenically variable portion of flagellin is the middle region, which is surface-exposed. *Salmonella* is unique among the enteric bacteria in that it can express two different flagellin antigens. Typically, this is coordinated so that only one antigen is expressed at time in a single bacterial cell. The two antigens are referred as Phase 1 and Phase 2. “Monophasic” isolates are those that
Appendix IX: Overview of *Salmonella* Serotype Designation

Salmonella serotypes express only a single flagellin type. These occur naturally in some serotypes (e.g., *S. Enteritidis*, *S. Typhi*, most subspecies IIIa and IV serotypes), or can occur through the inactivation of the gene encoding the Phase 1 or Phase 2 antigen.

Table 2 lists the H antigens of *Salmonella*. Some antigens are composed of multiple factors, which are separated by commas; for example, the second phase antigen of *S. Typhimurium* is composed of factors 1 and 2, which is represented as “1,2”. Related antigens are grouped into complexes.

3) *Salmonella* Serotype Identification

*Salmonella* serotypes are typically identified in a cascade of tests. First, an isolate is identified and the subspecies is determined, typically by biochemical testing. O antigens and H antigens are detected in independent agglutination assays using antisera that react with groups of related antigens or a single antigen. Both H antigens can sometimes be detected in a single culture, particularly for older strains or for isolates that have been passed multiple times. When only one H antigen is detected, the isolate is inoculated onto the top of a tube of phase reversal media, a semisolid media containing antisera to the H antigen that has already been identified. Organisms expressing the previously detected H antigen are immobilized by the added antisera and grow only at the top of the tube. Organisms expressing the second H antigen are able to move away from the top of tube, evidenced by growth throughout the tube. The second H antigen is then determined using organisms recovered from the bottom of the phase reversal media.

4) *Salmonella* Serotype Designation

All *Salmonella* serotypes can be designated by a formula. Additionally, subspecies I serotypes are given a name (e.g., Typhimurium, Enteritidis, Typhi, etc).

The typical format for a serotype formula is:
Subspecies [space] O antigens [colon] Phase 1 H antigen [colon] Phase 2 H antigen

**Examples:**

I 4,5,12:i:1,2 (S. Typhimurium)
I 4,12:i:1,2 (S. Typhimurium)
I 9,12:g,m:- (S. Enteritidis)
II 47:b:1,5 (S. II 47:b:1,5)
IV 48:g,z,51:- (S. IV 48:g,z,51:-)
IIIb 65:(k):z (S. IIIb 65:(k):z)

**Other conventions:**

* Some O and H factors are variably present. This is indicated in the generic serotype formula by underline when the factor is encoded on a bacteriophage (e.g., 1) or by square brackets (e.g., [5]) when the antigen is variably present. For an individual isolate, if the variable factor is detected it is included in the formula without additional notation. If the variable factor is not detected, it is not listed in the formula. Weakly recognized antigens are indicated by parentheses (e.g., (k) ).

* The absence of an H antigen is indicated by a minus sign (“-“) for the particular phase. For example, the “monophasic Group B” isolates that are becoming more common in the US are designated as “S. I 4,5,12:i:- ” or “S. I 4,12:i:- ”. Nonmotile isolates (express no H antigen) are indicated by minus signs in both phases, but can also be designated by “NM” or “nonmotile” in place of the H antigens.
Appendix IX: Overview of *Salmonella* Serotype Designation

* Isolates that do not express O antigen (rough isolates) or express a capsule that prevents immunologic detection of the O antigen (mucoid isolates) are indicated by “O-rough” or “Mucoid” in place of the O antigen.
* Rarely, isolates express a third H antigen that is noted by a colon followed by the antigen after the Phase 2 H antigen (e.g., S. II 13,23:b:[1,5]:z42, formerly S. Acres)

5) *Salmonella* Serotype Statistics

There were 2501 *Salmonella* serotypes as of 2001; approximately 60% belong to subspecies I. In the US, approximately 99% of reported human isolates belong to subspecies I. The “top 10” serotypes account for approximately 74% of all isolates reported in the US; the “top 100” serotypes account for about 98% of all isolates. Among the top 100 serotypes, only S. IV 48:g,z51:- (formerly S. Marina), S. IV 50:z4,z23:- (formerly S. Flint), S. IV 6,7:z4,z24:- (formerly S. Kralendyk), and S. IV 16:z4,z32:- (formerly S. Chameleon) are not subspecies I. Among the non-subspecies I isolates, subspecies IV isolates are the most common, followed by subspecies II, IIIa, and IIIb. Subspecies VI and *S. bongori* isolates are very rare.

6) Additional Reading

[http://jcm.asm.org/cgi/reprint/38/7/2465.pdf]


For questions or additional information, please contact Patti Fields [(404) 639-1748; pifl@cdc.gov]

According to the Bacteriological Code, the legitimate species name for *S. enterica* is *S. choleraesuis*, and there are a few other differences from the nomenclature described. The official taxonomic designations are confusing and proposals to change them are currently under consideration. The taxonomy described here is used by most laboratories worldwide, including the CDC.
### Table 1. Antigens associated with *Salmonella* O serogroups

<table>
<thead>
<tr>
<th>O Group (number designation)</th>
<th>O Group (letter designation)</th>
<th>Antigens present in all serotypes</th>
<th>Additional antigens that may be present in some serotypes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>A</td>
<td>2, 12</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>B</td>
<td>4, 12</td>
<td>1; 5; 27</td>
</tr>
<tr>
<td>7</td>
<td>C1</td>
<td>6, 7</td>
<td>14; (Vi)</td>
</tr>
<tr>
<td>8</td>
<td>C2</td>
<td>8</td>
<td>6; 20</td>
</tr>
<tr>
<td>9</td>
<td>D1</td>
<td>9, 12</td>
<td>1; (Vi)</td>
</tr>
<tr>
<td>9, 46, 27</td>
<td>D2</td>
<td>9, 46</td>
<td>none</td>
</tr>
<tr>
<td>9, 46, 27</td>
<td>D3</td>
<td>9, 12, 46, 27</td>
<td>1</td>
</tr>
<tr>
<td>3, 10</td>
<td>E1</td>
<td>3, 10</td>
<td>15; 15, 34</td>
</tr>
<tr>
<td>1, 3, 19</td>
<td>E4</td>
<td>1, 3, 19</td>
<td>10; 15</td>
</tr>
<tr>
<td>11</td>
<td>F</td>
<td>11</td>
<td>none</td>
</tr>
<tr>
<td>13</td>
<td>G</td>
<td>13</td>
<td>1; 22; 23</td>
</tr>
<tr>
<td>6, 14</td>
<td>H</td>
<td>6, 14</td>
<td>1; 24; 25</td>
</tr>
<tr>
<td>16</td>
<td>I</td>
<td>16</td>
<td>none</td>
</tr>
<tr>
<td>17</td>
<td>J</td>
<td>17</td>
<td>none</td>
</tr>
<tr>
<td>18</td>
<td>K</td>
<td>18</td>
<td>6; 14</td>
</tr>
<tr>
<td>21</td>
<td>L</td>
<td>21</td>
<td>none</td>
</tr>
<tr>
<td>28</td>
<td>M</td>
<td>28</td>
<td>none</td>
</tr>
<tr>
<td>30</td>
<td>N</td>
<td>30</td>
<td>none</td>
</tr>
<tr>
<td>35</td>
<td>O</td>
<td>35</td>
<td>none</td>
</tr>
<tr>
<td>38</td>
<td>P</td>
<td>38</td>
<td>none</td>
</tr>
<tr>
<td>39</td>
<td>Q</td>
<td>39</td>
<td>none</td>
</tr>
<tr>
<td>40</td>
<td>R</td>
<td>40</td>
<td>1</td>
</tr>
<tr>
<td>41</td>
<td>S</td>
<td>41</td>
<td>none</td>
</tr>
<tr>
<td>42</td>
<td>T</td>
<td>42</td>
<td>1</td>
</tr>
<tr>
<td>43</td>
<td>U</td>
<td>43</td>
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</tr>
<tr>
<td>44</td>
<td>V</td>
<td>44</td>
<td>1</td>
</tr>
<tr>
<td>45</td>
<td>W</td>
<td>45</td>
<td>none</td>
</tr>
<tr>
<td>47</td>
<td>X</td>
<td>47</td>
<td>1</td>
</tr>
<tr>
<td>48</td>
<td>Y</td>
<td>48</td>
<td>none</td>
</tr>
<tr>
<td>50</td>
<td>Z</td>
<td>50</td>
<td>none</td>
</tr>
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</tr>
<tr>
<td>53</td>
<td></td>
<td>53</td>
<td>1</td>
</tr>
<tr>
<td>54 (provisional)</td>
<td>54</td>
<td>21; 3; 3,15; 4,12; 8,20; 6,7</td>
<td></td>
</tr>
<tr>
<td>55</td>
<td></td>
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</tr>
<tr>
<td>56</td>
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<td>none</td>
</tr>
<tr>
<td>67</td>
<td></td>
<td>67</td>
<td>none</td>
</tr>
</tbody>
</table>
## Appendix IX: Overview of *Salmonella* Serotype Designation

### Table 2. H (flagellar) antigens of *Salmonella*

<table>
<thead>
<tr>
<th>Complex</th>
<th>Antigens</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 complex:</td>
<td>1,2,5,7,16,27</td>
</tr>
<tr>
<td>EN complex:</td>
<td>e,n,x,e,n,x,z15,e,n,z15</td>
</tr>
<tr>
<td>G complex:</td>
<td>f,g,f,g,m,t,f,g,s,f,g,t,g,m,g,m,p,s,g,m,q,g,m,s,g,m,s,t,g,m,t,g,p,g,p,s,g,p,u,g,q,g,s,q,g,s,t,g,t,g,z51,g,z62,g,z63,g,z85,m,p,t,u,m,t</td>
</tr>
<tr>
<td>L complex:</td>
<td>l,v,l,w,l,z13,l,z13,z28,l,z28</td>
</tr>
<tr>
<td>Z4 complex:</td>
<td>z4,z23,z4,z23,z32,z4,z24,z4,z32</td>
</tr>
</tbody>
</table>

Other antigens (not part of a complex):

- a
- b
- c
- d
- e,h
- i
- k
- (k)
- r
- r,i
- y
- z
- z6
- z10
- z29
- z35
- z36
- z36,z38
- z38
- z39
- z41
- z42
- z44
- z47
- z50
- z52
- z53
- z54
- z55
- z56
- z57
- z60
- z61
- z64
- z65
- z67
- z68
- z69
- z71
- z81
- z83
- z87
- z88
Appendix X: *Salmonella* Typhi Case Report Form

Can be accessed at:  http://basis1.cdc.gov/BASIS/masompb/forms/eforms/DDD/563
Appendix XI: Cholera and other Vibrio Illness Surveillance Report

<table>
<thead>
<tr>
<th>1. First three letters of patient's first name:</th>
<th>V. cholerae O1</th>
<th>V. cholerae O139</th>
<th>V. cholerae non-O1, non-O139</th>
<th>V. parahaemolyticus</th>
<th>V. vulnificus</th>
<th>Other species identified</th>
<th>Date specimen collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>State:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>County/Parish:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex: M, F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race/Ethnicity:</td>
<td>White (not Hispanic), Black, Hispanic</td>
<td>Hispanic, Asian, Pacific Islander</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occupation:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Date of birth:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Source of specimen:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Specimen collected:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. Were other organisms isolated from the same specimen that yielded Vibrio? If yes, list:

9. Was the identification of the species of Vibrio (e.g., V. cholerae, V. parahaemolyticus, etc.) confirmed at the State Public Health Laboratory? If yes, list:

10. Complete the following information if the isolate is V. cholerae O1 or O139:

- Source of isolation: (check one)
  - Activated sewage
  - Domestic water
  - Food
  - Food handler
  - Other

- Antigen detection: (check one)
  - C toxin
  - O139 toxin
  - Other

- Isolation data: (check one)
  - Isolated
  - Not isolated
  - Not done

- ELISA results: (check one)
  - Positive
  - Negative
  - Other

- Other (specify):

CDC 82.71 REV 07/2000 (Page 1 of 4) CHOLERA AND OTHER VIBRIO ILLNESS SURVEILLANCE REPORT
# Appendix XI: Cholera and other Vibrio Illness Surveillance Report

## II. CLINICAL INFORMATION

<table>
<thead>
<tr>
<th>Patient ID:</th>
<th></th>
</tr>
</thead>
</table>

### 1. Date and time of onset of first symptom:

- [ ] Ui: ___
- [ ] Day: ___
- [ ] Mo: ___
- [ ] Yr: ___

### 2. Symptoms and signs:

- [ ] Fever: ___
- [ ] Headache: ___
- [ ] Muscle pain: ___
- [ ] Diarrhea: ___
- [ ] Vomiting: ___
- [ ] Rectal bleeding: ___
- [ ] Abdominal cramps: ___

### 3. Any sequelae? (e.g., amputation, skin graft, etc.):

- [ ] Yes: ___

### 4. Admitted to a hospital for this illness? (yes):

- [ ] Yes: ___
- [ ] No: ___

### 5. Did patient die? (yes):

- [ ] Yes: ___
- [ ] No: ___

### 6. Did patient receive any of the following medications or vaccines in the 30 days prior to the illness onset?

#### a. Antibiotics

<table>
<thead>
<tr>
<th>Antibiotics</th>
<th>Yes: ___</th>
<th>No: ___</th>
</tr>
</thead>
</table>

#### b. Other medications

- [ ] [ Specify: ]

## III. EPIDEMIOLOGIC INFORMATION

### 1. Did this case occur as part of an outbreak?

- [ ] Yes: ___
- [ ] No: ___

### 2. Did the patient travel outside his/her home state in the 7 days before illness began?

- [ ] Yes: ___
- [ ] No: ___

#### a. City/State/Country

<table>
<thead>
<tr>
<th>City/State/Country</th>
<th>Days: ___</th>
</tr>
</thead>
</table>

#### b. Date Left

<table>
<thead>
<tr>
<th>Date Left</th>
<th>Days: ___</th>
</tr>
</thead>
</table>

### 3. Please specify which of the following seafoods were eaten by the patient in the 7 days before illness began. (Multiple times, most recent)
### Appendix XI: Cholera and other Vibrio Illness Surveillance Report

#### III. Epidemiologic Information (Cont.)

<table>
<thead>
<tr>
<th>Date of exposure</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of exposure</td>
<td>Yes</td>
<td>No</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

Additional comments:

- If the patient was exposed to water, indicate type:
  - Salt water
  - Fresh water
  - Other (specify)

- If there was exposure to water, indicate body:
  - Oral
  - Integumentary
  - Respiratory
  - Other (specify)

#### 5. If patient was infected with V. cholerae O1 or O139, or both of the following risk factors were present:

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If isolate is Vibrio cholerae O1 or O139 please answer questions 5-8.

#### 6. If patient had traveled to foreign country:

- Yes
- No

#### 7. If patient was exposed to other Vibrio species:

- Yes
- No

If domestically acquired illness due to any Vibrio species is suspected to be related to seafood consumption, please complete section IV (Seafood Investigation).

#### ADDITIONAL INFORMATION or COMMENTS

- Person completing form:
  - Name:
  - Title/Agency:
  - Date:
  - Telephone:

- CDC Use Only:
  - Source:
  - Comment:

- CDC Isolate No.

---

Public Health Service Act of 1944, as amended.

CDC 82-745 REV 07/2000 (Page 1 of 3) CHOLERA AND OTHER VIBRIO ILLNESS SURVEILLANCE REPORT (OVER)
Appendix XI: *Cholera* and other *Vibrio* Illness Surveillance Report

### IV. SEAFOOD INVESTIGATION SECTION

**Vibrio species:**

For each seafood ingestion investigation, please complete as many of the following questions as possible.

(Include additional pages section IV if more than one seafood type was ingested and investigated.)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Type of seafood (e.g., clam)</td>
<td></td>
</tr>
<tr>
<td>Date consumed</td>
<td></td>
</tr>
<tr>
<td>Time consumed</td>
<td></td>
</tr>
<tr>
<td>Amount consumed</td>
<td></td>
</tr>
</tbody>
</table>

If patient ate multiple seafoods in the 7 days before onset of illness, please note why this seafood was investigated (e.g., consumed as implicated in outbreak investigation).

2. How was this fish or seafood prepared?  
   - Raw  
   - Baked  
   - Boiled  
   - Fried  
   - Steamed  
   - Other (specify):  

3. Was seafood imported from another country?  
   - Yes  
   - No  
   - If yes, specify:  

4. Was this fish or shellfish harvested by the patient or a friend of the patient?  
   - Yes  
   - No  
   - If yes, specify:  

5. Where was this seafood obtained?  
   - Seafood market  
   - Seafood restaurant  
   - Other (specify):  
   - Address:  

6. Name of restaurant, seafood type, or food store:  
   - Tel.:  
   - Address:  

7. If ceftriaxone, cefotaxime, or metronidazole were given, how were they distributed to the retail outlet?  
   - Included in the order  
   - Delivered separately  
   - Other (specify):  

8. Date restaurant or food outlet received seafood:  
   - No.  
   - Day  
   - Mo.  

9. Was this restaurant or food outlet inspected as part of this investigation?  
   - Yes  
   - No  

10. See shipping tags available from the suspect lot?  
    - Yes  
    - No  

11. Shippers who handled suspected seafood:  
    - Include container numbers if available:  

12. Source(s) of seafood:  

13. Harvest site:  
    - Date:  
    - Mo.  
    - Day  
    - Year  
    - Status:  
      - Approved  
      - Conditioned  
      - Prohibited  
      - Other (specify):  

14. Physical characteristics of harvest area as close as possible to harvest date:  
    - Maximum ambient temp:  
    - Surface water temp:  
    - Salinity (ppt):  
    - Total rainfall (months prior 5 days):  
    - Fecal coliform count:  

15. Was there evidence of improper storage, cross-contamination, or holding temperature at any point?  
    - Yes  
    - No  
    - If yes, specify details:  

Person completing section IV:  

Date:  

Title/Agency:  

Tel.:  

CDC 2019 REV 07/2006 (Pages 1 of 2)  

*CHOLERA AND OTHER VIBRIO ILLNESS SURVEILLANCE REPORT*
Appendix XII: HUS Case Report Form

Hemolytic Uremic Syndrome Surveillance
State Department of Health

Case Report Form

Instructions: Complete the following by interviewing the attending physician and/or reviewing patient’s medical record.

I. PATIENT IDENTIFICATION

1A. Patient name _______________________________ 2A. Date of birth __/__/__

3A. Parent/guardian _______________________________ 4A*. Medical Rec # __________

5A. Address ___________________________________________________________________________________

6A. Phone home (____) _________ 7A. Phone work (____) _________ 8A. County of residence ________________

9A*. Sex ☐ Female ☐ Male

10A. Ethnicity ☐ Hispanic ☐ Non-Hispanic ☐ Unknown

11A. Race ☐ White ☐ Asian / Pacific Islander ☐ Black ☐ American Indian / Alaska Native ☐ Other _____________________ ☐ Unknown

12A. Are you completing this form for a case identified by ICD9 code review of hospital discharge data?
☐ no (skip to 14A) ☐ yes

13A. Has this case been previously reported (either through the provider network or other source)?
☐ no ----> Complete questions marked by an asterisk (*) on forms A, B, and C
☐ yes ----> Stop here. Staple this form to patient’s original report, and update database, changing answers for this and the previous question (12A and 13A only) to “yes”

II. HOSPITAL INFORMATION

14A. Person reporting case ____________________________________________ 15A. Phone (____) __________

16A. Attending physician ______________________________________________ 17A. Phone (____) __________

18A*. Hospital Name ____________________________ 19A*. Phone (____) __________

20A*. Date of admission or transfer to this facility __/__/____

21A*. Date of discharge or transfer from this facility __/__/____ ☐ Still hospitalized

22A. Institution transferred to (if applicable) ____________________________

23A. Institution where first hospitalized (if different) ____________________

24A. Date of initial hospitalization (if different) __/__/____

25A. Physician, initial hospitalization (if different) ________________________ 26A. Phone (____) _________
### Appendix XII: HUS Case Report Form

#### III. CLINICAL INFORMATION

27A*. Date of HUS diagnosis ___/___/____

28A*. Did patient have diarrhea during the 3 weeks before HUS diagnosis? .......... □ yes □ no □ unsure

- **if yes** 29A*. Date of diarrhea onset ___/___/____
- 30A. Did stools contain visible blood at any time .......... □ yes □ no □ unsure
- 31A. Was diarrhea treated with antimicrobial medications .......... □ yes □ no □ unsure
  - **if yes** 31A-1. Type of antimicrobial ______________________________________
  - 31A-2. Was patient treated with antimicrobial medications for any other reason than diarrhea during the 3 weeks before HUS diagnosis? .......... □ yes □ no □ unsure
  - **if yes** 31A-3. Type of antimicrobial ______________________________________
  - 31A-4. Reason(s) _______________________________________________________

Other medical conditions present during 3 weeks before HUS diagnosis:

- 32A*. Urinary tract infection ............................................................................ □ yes □ no □ unsure
- 33A*. Respiratory tract infection ................................................................... □ yes □ no □ unsure
- 34A*. Pregnancy ................................................................................................ □ yes □ no □ unsure
- 35A*. Malignancy................................................................................................ □ yes □ no □ unsure
- 36A*. Transplanted organ or bone marrow...................................................... □ yes □ no □ unsure
- 37A*. HIV infection............................................................................................ □ yes □ no □ unsure

Laboratory values within 7 days before and 3 days after HUS diagnosis:

- 38A*. Highest serum creatinine................................................................. ______ mg/dL □ not done
- 39A. Highest serum BUN ............................................................................ ______ mg/dL □ not done
- 40A. Highest serum amylase .......................................................................... ______ U/L □ not done
- 41A. Highest WBC ........................................................................................... ______ K/mm³ □ not done
  - or Lowest hematocrit .................................................................................... ______ % □ not done
- 43A*. Lowest platelet count ............................................................................ ______ K/mm³ □ not done

Other laboratory findings within 7 days before and 3 days after HUS diagnosis:

- 44A*. Blood smear with microangiopathic changes (i.e., schistocytes, burr cells, helmet cells or red cell fragments) ................................ □ yes □ no □ unsure □ not done
- 45A*. Blood in urine by dipstick..................................................................... □ yes □ no □ unsure □ not done
- 46A*. Protein in urine by dipstick.................................................................... □ yes □ no □ unsure □ not done
- 47A*. RBC in urine by microscopy................................................................... □ yes □ no □ unsure □ not done

48A. Patient’s blood type_______ □ unknown

---

### To be completed by health department

49A. How was patient's illness first identified by health department?

- □ Report of HUS case by a participating* physician or service
- □ Report of HUS case by a non-participating physician or service
- □ Routine O157 surveillance
- □ Other, describe __________________________

*member of active HUS surveillance network

50A. Is this case outbreak related? ........................................ □ yes □ no □ unsure______

51A. Status of report □ initial □ Update □ Complete

52A. Date ____/____/_____ 53A. Completed by (initials)__________________________

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Revised 12/18/2003
Appendix XIII: HUS Microbiology Report Form

Hemolytic Uremic Syndrome Surveillance
State Department of Health

Microbiology Report Form

Instructions: Complete by contacting microbiology laboratory at each institution where patient was treated. Complete one composite form for all laboratories.

1B. Patient name ________________________________________________________
    2B. Date of birth ____/____/___

3B*. Was stool specimen obtained from this patient ...........................................
    □ yes □ no □ unsure

If no, go to question 26B

4B. Laboratories where stool(s) tested

<table>
<thead>
<tr>
<th>Name</th>
<th>City/State</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
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<td></td>
</tr>
</tbody>
</table>

5B. Was stool tested for Shiga toxin ......................................................
    □ yes □ no □ unsure

If yes
6B. Methods(s)/kit(s) used_______________________________________________

7B. Result...............................................
    □ positive □ negative □ unsure

8B. Collection date 1st specimen tested:   ____/____/____

9B. Collection date 1st positive specimen: ____/____/____

10B*. Was stool cultured for E. coli O157?............................................
    □ yes □ no □ unsure

If no    skip to question #6
If yes
11B. Collection date 1st specimen tested for O157   ____/____/____

12B. Methods used
    □ culture on sorbitol-MacConkey agar
    □ other, describe___________________________________

13B. Was E. coli O157 isolated?............................................................
    □ yes □ no □ unsure

If yes
14B. Collection date 1st positive specimen:   ____/____/____

15B. Result of H antigen testing (check one):
    □ H7 positive    □ other H, specify:____
    □ H7 negative
    □ unsure or not tested
    □ non-motile

16B. Was non-O157 Shiga toxin-producing E. coli isolated....................
    □ yes □ no □ unsure

If yes
17B. Serotype: O:____ H:____ □ non-motile □ unknown

18B. Collection date 1st specimen tested:   ____/____/____

19B. Collection date 1st positive specimen:   ____/____/____

Revised 12/18/2003
Appendix XIII: HUS Microbiology Report Form

20B. Other pathogen isolated from stool......................................................☐ yes  ☐ no  ☐ unsure

if yes  21B. Pathogen #1____________________ Specimen collection date ___/___/____

22B. Pathogen #2____________________ Specimen collection date ___/___/____

If O157 or other STEC was isolated, complete the following based on health department records:

23B. Disposition of isolate
☐ Sent to state laboratory (reference # ________________________)
☐ Sent to CDC
☐ Sent to other reference laboratory (specify ___________________)
☐ Discarded

24B. Identity of isolate confirmed by state Public Health Laboratory
☐ yes
☐ no
☐ unsure
☐ not tested

Comment____________________________________________________

25B. PHLIS reference number:________________________________________________________

26B. Has patient serum been tested for antibodies to O157 or other STEC?.............. ☐ yes  ☐ no  ☐ unsure

if yes  27B. Serogroup O157  Titers : IgG 1:____  Interpretation ☐ positive  ☐ negative  ☐ borderline
        IgM 1:____  Interpretation ☐ positive  ☐ negative  ☐ borderline

28B. Serogroup O111  Titers : IgG 1:____  Interpretation ☐ positive  ☐ negative  ☐ borderline
        IgM 1:____  Interpretation ☐ positive  ☐ negative  ☐ borderline

29B. Serogroup O26  Titers : IgG 1:____  Interpretation ☐ positive  ☐ negative  ☐ borderline
        IgM 1:____  Interpretation ☐ positive  ☐ negative  ☐ borderline

30B. Status of report  ☐ initial  ☐ update  ☐ complete

31B. Date ___/___/____

32B. Completed by (initials) __________
Appendix XIV: HUS Chart Review Form

Hemolytic Uremic Syndrome Surveillance
State Department of Health

Chart Review Form
Instructions: Complete after patient has been discharged; use hospital discharge summary, consultation notes and DRG coding sheet. Complete one composite form for all institution where hospitalized.

1C. Patient name ___________________________________________  _____________________ 2C. Date of birth ___/___/____

3C. Hospitals admitted ______________________________________ Phone (____) ____________
Date admitted above:____/____/___       Date discharged above:____/____/___

__________________________________________________________________________ Phone (____) ____________
Date admitted above:____/____/___       Date discharged above:____/____/___

__________________________________________________________________________ Phone (____) ____________
Date admitted above:____/____/___       Date discharged above:____/____/___

__________________________________________________________________________ Phone (____) ____________
Date admitted above:____/____/___       Date discharged above:____/____/___

4C. Date of first admission:____/____/___  5C. Date of last discharge:____/____/___

Did any of the following complications occur during this admission:

<table>
<thead>
<tr>
<th></th>
<th>Date of onset</th>
</tr>
</thead>
</table>
| 8C* | Pneumonia.......................................................... | □ yes □ no □ unsure 9C. if yes ___/___/
| 10C* | Seizure.............................................................. | □ yes □ no □ unsure 11C. if yes ___/___/
| 12C* | Paralysis or hemiparesis........................................ | □ yes □ no □ unsure 13C. if yes ___/___/
| 14C* | Blindness..................................................................... | □ yes □ no □ unsure 15C. if yes ___/___/
| 16C* | Positive blood culture........................................... | □ yes □ no □ unsure 17C. if yes ___/___/

if yes, Pathogen(s) isolated:
__________________________________________________________

18C* | Other major neurologic sequelae .......................... | □ yes □ no □ unsure 19C. if yes ___/___/

if yes, Describe: ____________________________________________

Were any of the following procedures performed during this admission:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>20C*</td>
<td>Peritoneal dialysis..............................................</td>
</tr>
<tr>
<td>21C*</td>
<td>Hemodialysis......................................................</td>
</tr>
</tbody>
</table>

Transfusion with:

<p>| | |</p>
<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>22C.</td>
<td>packed RBC or whole blood.................................</td>
</tr>
<tr>
<td>23C.</td>
<td>platelets............................................................</td>
</tr>
<tr>
<td>24C.</td>
<td>fresh frozen plasma............................................</td>
</tr>
</tbody>
</table>

25C* | Plasmapheresis ................................................... | □ yes □ no □ unsure  |

26C | Laparotomy or other abdominal surgery*..................... | □ yes □ no □ unsure  |

*other than insertion of dialysis catheter

27C | if yes to surgery, Describe: ____________________________ |

28C*. Condition at discharge.............................................. | □ dead □ alive  |

29C | if dead, Date deceased: ___/___/____ |

30C* | if alive, Requiring dialysis................................... | □ yes □ no □ unsure |

31C* | With neurologic deficits...................................... | □ yes □ no □ unsure |

32C. Status of report □ initial □ update □ complete

33C. Date ___/___/___  34C. Completed by (intials)________

Revised 12/03/2003
Appendix XV: Active Surveillance for Hemolytic Uremic Syndrome (HUS) Protocol

I. OBJECTIVES
1. Determine the incidence of HUS using population-based surveillance
2. Monitor long term trends in STEC infection using HUS incidence as a marker
3. Identify STEC strains that cause HUS in the United States and monitor changes in their frequency over time
4. Establish a platform for conducting future studies of HUS pathogenesis and treatment

II. BACKGROUND
Hemolytic uremic syndrome (HUS) is a life-threatening illness characterized by hemolytic anemia, thrombocytopenia, and acute renal failure. Approximately 90% of HUS cases in the United States are caused by infection with Shiga toxin-producing Escherichia coli (STEC). Although E. coli O157:H7 (O157) is the most easily and most frequently isolated, many other STEC serotypes can also cause HUS.

Efforts to control STEC infections and develop effective therapies for HUS have been hampered by the absence of reliable surveillance data. Rapidly changing culturing practices make it difficult to know if STEC infections are becoming more or less common in any given area. The role of non-O157 STEC as a cause of HUS in the United States is largely unexplored. Finally, attempts to evaluate new treatments for HUS have been hindered by the rarity of reported cases in any given area.

Active surveillance in defined populations will allow determination of the incidence rate of HUS and whether that rate is changing. Linking microbial diagnosis to this active surveillance will allow differentiation of illness caused by O157 and by other STECs, and therefore will both provide a way to validate O157 surveillance data and a way to detect increases in illness caused by other STECs.

III. METHODS
A. General
The HUS surveillance system will be based on specialty provider networks comprised of pediatric nephrologists. The system will be introduced as a component of the Foodborne Diseases Active Surveillance Network (FoodNet).

B. Personnel
Participating sites will appoint one or more persons to serve as the local HUS surveillance officer.

C. Case finding
1. Sites will establish a practitioner reporting network that includes all pediatric nephrologists practicing within the catchment area. These practitioners will be
Appendix XV: Active Surveillance for Hemolytic Uremic Syndrome (HUS) Protocol

asked to report promptly all cases of HUS. The HUS surveillance officer will contact these practitioners monthly to identify any unreported cases.

2. Where available, hospital discharge data tapes will be reviewed annually to evaluate completeness of reporting for pediatric cases and to identify cases of HUS among adults (defined here as persons ≥ 18 years old). A protocol will be developed for reporting cases identified retrospectively through hospital discharge data tapes.

3. All patients <18 years old who receive treatment for acute HUS within the catchment area will be entered into the surveillance system, regardless of state of residence or how they were identified by the health department. Cases residing outside the United States should not be entered.

4. Although a practitioner network is not being established to identify cases of HUS among adults (≥ 18 years old), surveillance officers may learn of such cases nevertheless. These cases should be evaluated and reported in the same manner as pediatric cases, provided there is a history of an associated diarrheal illness.

D. Case Reporting

1. General
   a. The period of hospitalization is defined as the time during which the patient is continuously hospitalized for an acute illness leading to a diagnosis of HUS. Transfers between hospitals are considered part of the same hospitalization.
   b. The Case ID number will be assigned using the year of HUS diagnosis (first 4 digits), the state FIPS code (next 2 digits), and a sequential case number (last 3 digits). For example, the third case in California during 2000 would be assigned # 2000-06-003
   c. Data will be entered by each site into a database using the HUS data entry screens in Epi Info. The data will be transmitted to CDC as an e-mail attachment when a case is identified or new information is obtained for a reported case.

2. Case Report Form:
   a. This form collects demographic information and data needed to confirm the diagnosis of HUS. It should be completed as soon as possible after the case is identified.
   b. The information may be collected by interviewing the attending physician, their designate (e.g., infection control nurse), and / or by reviewing the patient's medical record. If the patient has been transferred between hospitals, it may be necessary to contact the referring (or receiving) physician. This
Appendix XV: Active Surveillance for Hemolytic Uremic Syndrome (HUS) Protocol

should be done even if the referring physician does not work within the formal FoodNet catchment area.

3. Microbiology Report Form
   a. This form collects information on specimens that may have been obtained as part of regular medical care.
   b. Upon learning of the case, the HUS surveillance officer will complete a composite form by contacting the microbiology laboratory at all institutions where the patient is or has been hospitalized during the course of the acute illness. If the patient is still hospitalized, the officer will contact the laboratory periodically until the patient is discharged to identify any subsequent specimens.
   c. One copy of the microbiology reporting form may be completed for each laboratory testing a stool specimen from the patient. This includes clinical reference labs, public health labs and laboratories located outside the formal catchment area. However, only one summary form should be entered into the database.

4. Chart Review Form
   a. This form collects information on the outcome and complications of the patient's acute illness.
   b. Following discharge of the patient, the HUS surveillance officer should obtain a copy of the hospital discharge summary, consult notes, and the diagnostically related groups (DRG) coding sheet and use these to complete the form.
   c. One composite summary form should be completed for all institutions where the patient was admitted during the hospitalization period, including any hospitals located outside of the formal EIP/FoodNet catchment area.

E. Laboratory Testing
Serologic testing for O157 and/or non-O157 antigens is available at CDC. States requesting this service should submit sera to the foodborne and diarrheal diseases immunology laboratory.
CDC’s Emerging Infections Program
Foodborne Diseases Active Surveillance Network (FoodNet)
Data Use Policy

I understand that I am responsible for the integrity and management of these datasets. The datasets will not be provided to a third party without the permission of the FoodNet Steering Committee. In the spirit of collaboration, I agree to keep the FoodNet Steering Committee informed of the results of analyses. In accordance with the FoodNet publication guidelines, I will not distribute the results of these analyses, electronically or otherwise, in the form of a poster, abstract, manuscript, report, press release, or other public presentation without the approval of the FoodNet Steering Committee.

If you have any questions about the data use policy, please contact FoodNet at 404-371-5465 or mailto: foodnet@cdc.gov.

http://www.cdc.gov/foodnet
Appendix XVII: Foodborne Diseases Active Surveillance Network (FoodNet) Protocol Development and Publications Policy

Guidelines for publication of manuscripts, abstracts, or other external releases of scientific data: The FoodNet publication policy applies to all manuscripts, abstracts, or external releases of scientific data in which FoodNet collaborates or which are supported, in whole or in part, through CDC’s EIP.

1. **Data from one site (site-specific projects or one site’s data from a multi-site project):** Sites are encouraged to review their data frequently and to discuss interesting findings with the FoodNet Steering Committee. Although FoodNet Steering Committee approval is not required before a site (or a site and CDC) initiates an abstract, manuscript, or other external release of scientific data that is based on site-generated data, sites are strongly encouraged to inform the Steering Committee of such investigations prior to submission or external release. If the next FoodNet Steering Committee meeting is scheduled after the deadline for submission or external release of data, committee members may be contacted individually by telephone or e-mail. Sharing of such information will reduce duplicative efforts and may lead to useful additional collaborations.

2. **Aggregate data:** CDC, sites, USDA, and FDA are encouraged to review the aggregate data (defined as data from ≥2 sites) frequently and discuss interesting findings with the FoodNet Steering Committee. The FoodNet Steering Committee will ensure that aggregate data are analyzed and published in a timely and equitable manner, and will ensure high scientific standards.

   a. Proposals for data analysis and external releases of scientific data may be initiated by individuals at CDC, any of the sites, USDA, or FDA. Such proposals should be made available to the FoodNet Steering Committee at least 1 week prior to the next Steering Committee call (usually the second Thursday of the month). Leadership of any given project is open to discussion by the Steering Committee.

   b. The FoodNet Steering Committee will designate a “Study Team,” usually of five or fewer (representing at least three sites) persons, to work on creating a study protocol. The person who presents the proposal to the FoodNet Steering Committee will usually be a member of the Study Team and, with FoodNet administrative support, will arrange the first meeting or conference call.

   c. At the first meeting or conference call, the study team will determine the “Team Leader.” The Team Leader, with FoodNet administrative support, must be willing and able to lead protocol and questionnaire development, and schedule and conduct meetings or conference calls. If the original Team Leader is unable to continue in a leadership role, or if another team member emerges as the leader (for example, by heading the protocol development), a leadership change may occur. If such a change is endorsed by the Study Team, the change may proceed. If there is disagreement within the Study Team about such a change, the matter will be resolved by the FoodNet Steering Committee. Other changes in Study Team personnel will be handled by the Study Team with the Steering Committee resolving any disagreements.

   d. The Team Leader will be the principal investigator (PI). The decision of who is to be PI will be made no later than the initiation of the project or
Appendix XVII: Foodborne Diseases Active Surveillance Network (FoodNet) Protocol Development and Publications Policy

study. The PI will have the right of first refusal to be lead author or presenter of primary work (that is, publication or presentation).

e. The Study Team will select an “Analytic Team,” which might be a subset of the Study Team or might include other FoodNet staff from CDC, USDA, FDA, or the sites.

f. The final study design and questionnaire will be made available to each site, CDC, FDA, and USDA for comment before the study or analysis proceeds.

3. **Dataset distribution:** Once a proposal has been approved by the steering committee, the appropriate dataset will be forwarded to each collaborator of the Analytical Team. A data release agreement must be signed at the time of receipt of the dataset and will be kept on file at CDC.

4. **Authorship:**
a. All manuscripts and abstracts that include unpublished data from FoodNet will include at least one author from CDC, unless CDC declines. All manuscripts and abstracts that include unpublished data from a site in FoodNet will include at least one author from that site, unless that site declines. Additional authors from a site or CDC should reflect significant contributions made by these persons, as described in the "Uniform requirement of manuscripts submitted to biomedical journals" (NEJM 1991;324:424-428). The Study Team will be the nucleus of the author list, unless a Team member declines. The lead author will determine the order of authorship. The Steering Committee will resolve any differences of opinion in this listing.

b. “FoodNet Working Group” will be included as the last entry on the authorship line in all publications and an asterisk or footnote will refer to “Foodborne Diseases Active Surveillance Network Working Group” and a listing of names.

c. Every publication in which FoodNet collaborates or which is supported wholly or in part through FoodNet should acknowledge the project name in the manuscript text. A sample sentence might be “This work was conducted by the FoodNet project of the Emerging Infections Program Network.” Publications should also acknowledge financial support by referring to the CDC Emerging Infections Program cooperative agreement number and by acknowledging support from other agencies as appropriate.

d. All manuscripts or abstracts that include data from FoodNet will follow CDC clearance guidelines, which include that all authors have time to review and comment on manuscripts and abstracts before they are put into clearance, and all manuscripts or abstracts are cleared by CDC.

5. **Timelines:** Timelines for the development of major publications will be drafted by the PI and will be listed on the Publications Spreadsheet. These timelines can include deadlines for analysis, abstract submission for a national meeting, outline of paper, first draft, draft acceptable for clearance, and final paper for submission. If deadlines are not met, the Steering Committee can open the paper to leadership by other investigators.