Centers for Disease Control and Prevention Emerging Infections Program
Interviews of community-associated carbapenemase producing CRE cases
Interviewer Instructions

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Background

Purpose of this manual

The purpose of this manual is to describe the community-associated carbapenemase-producing CRE risk factor interview public health project in sufficient detail so that everyone who interviews participants uses consistent methodology, helping to ensure scientific reliability and validity of the project. Following the guidelines in the manual will also help to ensure that the patients being interviewed have the rights of confidentiality. After reading this manual, interviewers should be comfortable with the instructions and the health interview questionnaire.

Overview

The CDC-supported Emerging Infections Program (EIP) Multisite Gram-negative Surveillance Initiative (MuGSI) conducts population-based surveillance in several sites to monitor incidence of infections due to carbapenem-resistant Enterobacteriaceae (CRE) at the population level and tracks changes over time since 2012. Among risk factors of CRE acquisition, prior stays in hospitals or nursing homes are the most common. Sometimes documentation of previous healthcare exposures might be absent from medical records. In addition, community risk factors for acquiring CP-CRE that have been described in literature or uncovered during recent public health investigations, such as travel and occupation, are not reliably documented in medical records. One of MuGSI's objectives is to characterize epidemiologic characteristics of and risk factors for CRE. Therefore, to better characterize these, community-associated (CA) CP-CRE cases will be interviewed to better ascertain risk factors for acquiring CP-CRE.

Project Purpose and Objectives

This project will:

- 1. Validate case status as community-associated
- Identify other known potentially modifiable risk factors or sources for CP-CRE
 acquisition, such as international travel, previous use of antibiotics, occupation,
 exposure to animals, household contacts with risk factors for CRE acquisition,
 and other risk factors
- 3. Describe the epidemiology of community- associated CP-CRE and generate hypotheses for future research activities using EIP surveillance infrastructure.

Design and Population

The eligible CA CP-CRE cases will be identified via routine MuGSI surveillance conducted in surveillance catchment areas consisting of selected counties in California,

Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Tennessee, Oregon as outlined in the MuGSI protocol. Cases that are reported to the state health departments from areas outside the MuGSI catchment area may be interviewed by health department staff as part of regular health department response activities, but data from those cases will not be reported to CDC as part of MuGSI.

Participant (patient) enrollment

Refer to the MuGSI surveillance protocol, which provides details on the CRE case definition, description of surveillance data collection, epidemiological case classification, and definitions of incident versus persistent cases. Based on the information obtained through medical record review, incident CRE cases will be classified as community-associated if initial cultures were collected from a patient less than three calendar days after admission to a hospital; in a patient with no history of hospitalization, surgery, residence in a long-term care facility (LTCF) or residence in a long-term acute-care hospital (LTACH) in the year prior to date of culture; from a patient not on chronic dialysis at the time of culture collection; and from a patient without a urinary catheter or indwelling device in the 2 days prior to culture collection. Patients (or a legal proxy) from whom a CA CRE case has been identified as CP-CRE based on either clinical or public health laboratory testing will be interviewed after identification by an EIP site.

Interview guidelines

General Guidelines

Interviewer behavior, including voice inflection and pace, is crucial when introducing the project to respondents and gaining their cooperation. If interviewers sound bored or unprofessional during the introduction, respondents are not likely to want to complete an entire interview with them. Interviewers should avoid rushing through the introduction, or reading it in slow motion or ending every sentence as if it were a question. Finally, as much as possible, interviewers should refrain from nervous gestures ("um", giggling, and throat clearing) and make a special point of speaking slowly and clearly. In summary, interviewers should be serious, pleasant, self-assured, and their voice and words must convey their credibility.

Important Reminders Regarding Standardized Interviewing Technique

1. Read each question and response option exactly as written and in the order in which it appears in the questionnaire. This is vital for several reasons:

- Each question has been carefully constructed and pre-tested in order to obtain specific information and to be understood by the maximum number of respondents.
- It has been shown that people's answers are strongly influenced by the wording of a question and its location among others in the questionnaire.
- The wording and order of the questions has been designed to prevent respondent irritation and maximize respondent interest as well as reduce bias and measurement error.
- Administering a standardized questionnaire in a standardized fashion helps ensure that interviews conducted by many different interviewers in 10 states will yield comparable information.
- 2. Do not skip a question because the answer was given earlier or because you feel you may know the answer. In these situations, you can preface the question with something like "I know you just mentioned this, but I need to ask each question as it appears on the questionnaire," or "You have already touched on this, but let me ask you..." as appropriate.
- 3. Read slowly and pause long enough to allow a thoughtful response.
- 4. Read the entire question (including response options unless stated otherwise in your instructions) before accepting the respondent's answer.
- 5. If a respondent is confused, repeat the entire question or set of response options unless you are sure that only one part of it was missed or misunderstood. In particular, do not attempt to explain an item in your own words; it is better to code the response as "Don't know/Not sure" and go on to the next question.
- 6. As an interviewer, you must not direct the respondent toward an answer. Be sure to keep your voice neutral and use positive, non-leading feedback phrases (e.g. "I see" or "Thank you. That's important information" or "Thanks, its important to get your opinion on this," etc.)
- 7. If an answer is different from what you expect, don't remind the respondent of an earlier remark or try to force consistency. Simply write down what he or she tells you.
- 8. Use neutral cues or probes (i.e. "Could you tell me more about that?" or "Which would be closer to the way you feel?") to help the respondent give more complete answers to questions.

9. Finally, <u>familiarize yourself with the questionnaire</u>. The interview will flow more smoothly if you understand the skip patterns, know which sections must be filled out in advance, and practice reading the parts which are to be read aloud. Speak to the project coordinator if you have any questions.

Commonly asked questions from respondents

- 1. <u>How did you get my phone number?</u> We have your phone number because you tested positive for the CRE germ and we are contacting everyone with this disease who meets certain criteria.
- 2. Why can't you call someone else? It is important for the scientific validity of the project to get information from as many people as possible who had the CRE germ. If only some people participate, it becomes difficult to apply the findings of this project to all cases.
- 3. <u>How do I know this is a legitimate survey?</u> You may contact the project coordinator at (phone number) to verify the legitimacy of the project.
- 4. How do I know what I tell you will be kept in confidence? The interview/questionnaire is private, and no names will be associated with any reporting of results. Access to data is restricted to interviewers and researchers involved in the study. The project has undergone a formal ethics review to examine the safety to subjects, including privacy, and has been approved. We will only use information grouped with information from many other participants, without using names or other personal information. Any information collected that could identify you will be destroyed when the evaluation is done.
- 5. <u>How much does this project cost the taxpayer</u>? The project is implemented by the state and federal health agencies as part of their public health efforts. The goal is to find the cause of the illnesses which should save taxpayers money in the future.
- 6. Why can't you mail me the survey? The research team chose the telephone interviewing method for this project on the basis of cost, efficiency, and timeliness. For this project, subjects must be reached quickly in order to gather the most accurate information possible. Telephone interviews are quicker than mailed surveys and they also allow respondents a chance to ask questions and have their responses clarified.
- 7. What can I do about/to treat my CRE germ? Unfortunately, we are not medical providers and cannot provide recommendations for treatment. We can recommend you talk to your healthcare provider, or look for more information from the CDC

webpage: https://www.cdc.gov/hai/organisms/cre/index.html

Refusals to participate

In general, when interviewers sound professional and knowledgeable and give respondents the information necessary to make an informed decision, people will usually agree to participate. The following suggestions may help to further increase the participation rate: 1) Ask prospective respondents whether "now" is a convenient time to take the questionnaire, and if not, to indicate a better time. If, despite this, a prospective respondent refuses to participate, the interviewer should simply thank them and record this outcome on the call log. 2) It is helpful to anticipate the respondent who requires more information or is otherwise reluctant by anticipating common questions (above) and preparing answers to those questions in advance.

After the interview

Thank the person for their time and cooperation. Review the questionnaire to be sure you have clearly and accurately answered every question. If necessary, call the participant back to complete essential missing information, although limit calls to avoid irritation.

Confidentiality, Data Handling, and Analysis

The interview/questionnaire is confidential, and no names will be associated with the results. Access to data is restricted to interviewers and researchers involved in the project. The project has undergone a formal ethics review to examine the safety to participants, including confidentiality, and has been approved. Completed questionnaires will be reviewed and entered into a database at each site for analysis by an analytic team comprised of epidemiologists and statisticians from the sites and CDC.

Introduction to the Health Interview Form

The following questionnaire, **Community-Associated CP-CRE Interview**, is administered to patients with community-associated CP-CRE (CA CP-CRE) identified through the Emerging Infections Program (EIP) MuGSI surveillance system. The questions cover a variety of possible exposures, including international travel, previous use of antibiotics, occupation, exposure to animals, household contacts with risk factors for CRE acquisition, and other risk factors.

On the interview form, instructions for the interviewer to read aloud to the respondent are in **bold** and clarifying instructions for the interviewer only are **[bracketed and in bold].** The remainder of this document contains specific question-by-question instructions for conducting the interview.

Verbal agreement to participate

This project requires that participants are interviewed in a timely manner, and therefore, all participants are interviewed over the telephone. For persons 18 years of age or older, verbal agreement to participate will be obtained from all eligible participants. If a participant is a child <18 years of age, is deceased, or is unable to provide responses during the health interview (e.g. patient with dementia), a proxy interview with a surrogate (e.g. next-of-kin) will be attempted. Spanish-speaking cases will be contacted for interview using Spanish-speaking EIP personnel and translated materials. Other non-English speaking patients will not be interviewed for the project.

Call tracking and call log

Participants should be interviewed as soon as possible after specimen collection and verification of possible CRE from routine surveillance. Please note that participant interviews *must* occur within one year of the date of the incident specimen collection or the participant is ineligible for the project.

Participants: Before you start to fill out the call log form, please review MuGSI CRF data on demographics, outcomes, and underlying conditions to identify patients who may require interview with a proxy (i.e. children<18 years of age, deceased patients, and patients with dementia. Record the telephone number of the project participant (patient or proxy) for future reference. In attempting to reach the participant or proxy, a maximum of 10 attempts on at least 5 different dates using a valid phone number should be made before giving up on a potential case. At least one attempt should be made between 5-8 PM, and one weekend day. There is space to record the subject's request that you call back on a different day or time. It is not recommended that you leave a message on an answering machine during the first few attempts; however, you may do so after 2-3 attempts provided you are certain that you have the correct number and the machine identifies either the subject or the subject's household. Once a participant is enrolled, refuses, cannot answer questions, or you reach the maximum number of call attempts, enter the final outcome of the enrollment attempt in the enrollment log.

Participant Screening and Enrollment

The purpose of this activity is to first introduce yourself and the project to the potential enrollee and then to assess the individuals' eligibility for the project if he/she agrees to participate.

Telephone interview introductory script

The purpose of this form is to determine if the individual is available to hear more about the project and agrees to participate in an interview. Read the appropriate section: Section A: Answering machine, Section B: Cases, Section C: Cases (proxy version). At the end of Section A or Section B, if participant says *Yes* and agrees to participate in an interview, go to Section 1 of Enrollee Interview. If *No*, ask if you can call back at more convenient time, and if not, read: thank you very much for your time, and end call.

Section 1: Identifiers

This section will be filled out by EIP staff. Please pre-populate this information where possible before interviewing the patient. Refer to MuGSI CRF and CRF instructions for additional details of each element below.

- 1. Indicate Patient ID. This is a unique patient identifier assigned by the CDS. An individual will be assigned a Patient ID when an initial positive specimen that meets the incident case definition for MuGSI is entered in the CDS.
- 2. Indicate State ID. This is a case unique identifier assigned by the Case Detection System (CDS). Each positive specimen that is entered into the CDS will be assigned a State ID.
- 3. Indicate Provider ID. Enter the facility ID of the healthcare facility where the patient received initial treatment following his/her incident MuGSI specimen.
- 4. Indicate Lab ID. The laboratory ID refers to the hospital or reference laboratory where the initial specimen diagnostic test that identified a patient was performed.
- 5. Indicate Specimen ID. This is the accession number.
- 6. Indicate date of incident specimen collection. This is the date of collection of the first positive MuGSI specimen, for a single genus and species, from a normally sterile site or from urine. Use format: MM/DD/YYYY
- 7. Indicate the age. Age in years may be obtained from MuGSI CRE Case Report Form, but please verify participant's age during the interview.
- 8. Record the participant's biological sex of the case at birth (e.g., male or female) from the CRE Case Report Form before the start of the interview.

Before proceeding to Section 2: screening for healthcare exposures in the past year, please have a calendar in front of you. Please explain to the participant what kind of questions you will ask during the interview and how the interview will look like by reading aloud the script below in bold:

I will ask you questions	about [your/your child's] visits to healthcare, activities of people
living in your household	d, occupation, travel, other potentially relevant activities, and other
aspects of [your/your cl	hild's] health. It may be difficult to remember, but I would like your
best guess for each que	estion. I will be asking you about specific dates around the time
[you/your child] tested	positive for the CRE germ. For your reference, the germ was
identified from [you/you	ır child] on [incident specimen collection date]
at [facility]	During this interview, I will call the test for the CRE germ
-	"The questions I ask you will pertain to a time period up to three test for CRE. If you have a calendar, planner, or health records
(including things like m	edical bills or health insurance statements from that time), it may
be helpful to get those i	tems to help recall events. Do you need a minute to go get any of
these items?	

Section 2: Screening for healthcare exposures in the past year

This is the screening section before the start of an interview. The purpose of this section (Questions A-E) is to determine the patient's eligibility for the interview. This section will confirm the findings from medical record review that the MuGSI case is community-associated. Prior to asking these questions please identify on your calendar the patient's incident specimen collection date, which we call the date of a "positive test for CRE". Please ask all these questions in this section regardless if the patient said *YES* or *NO*.

- A. The purpose of this question is to determine whether the patient stayed overnight in a hospital in the U.S. or in another country in the 12 months before the positive test for CRE. Identify on your calendar the date 12 months before the positive test for CRE then ask the question. Overnight is meant to indicate admission to a facility for treatment. If a patient reports that they were in the emergency room overnight and then went home or stayed overnight in a hospital to visit a relative who was admitted, that is not considered admission to a healthcare facility. Hospitalization in a case <=12 months old for an uncomplicated birth is not considered a hospitalization. Hospitalization to an acute care hospital, long-term acute care hospital, and rehabilitation facility are considered hospitalizations. If the patient answers Yes, No, don't know, or Refused, continue to QB.
 - a. This question asks where the patient was hospitalized. The purpose of this question is to verify that the patient was indeed in a hospital and to also provide information so that the surveillance officer at the site can request records from that encounter if needed. Record the facility ID of the hospital here later.

- B. The purpose of this question is to determine whether the patient stayed overnight in a nursing home in the U.S. or in another country in the 12 months before the positive test for CRE. Identify on your calendar the date 12 months before the positive test for CRE then ask the question. Overnight is meant to indicate admission to a facility for treatment. If a patient reports that they stayed overnight to visit a relative who was admitted to a nursing home this is not considered admission to a nursing home. If the patient answers *Yes, No, don't know,* or *Refused,* continue to QC.
- C. The purpose of this question is to determine whether the patient had any surgery in the 12 months before the positive test for CRE. Identify on your calendar the date 12 months before the positive test for CRE then ask the question. Surgery must have occurred in an operating room (OR) where a surgeon makes at least one incision through skin or mucous membrane, including laparoscopic approach. This may include ambulatory surgery centers if the procedure takes place in an operating room. If the surgery did not occur in the operating room, this is not considered a surgery. The following are not considered a surgery: oral/dental surgery that takes place in a dentist office, surgical procedures that occur on the same day as culture collection, bed site procedure, such as paracentesis, insertion of central vascular catheter, suprapubic catheter, cardiac catheter or tracheostomy, even in performed in the OR. If the patient answers Yes, No, don't know, or Refused, continue to QD. If have doubts, please contact CDC coordinator for MuGSI definition of surgery.
 - a. If the patient said Yes, specify what kind of surgery did the patient have in the provided space. Reference CRF instructions to verify that the surgery reported qualifies under criteria of surgery for MuGSI. If not, change the answer to No and record additional details in the comments section. If the surgery mentioned by the patient falls under the criteria of surgery for MuGSI, then read the bolded text at the end of Section 2 and conclude the interview. If the surgery does not fall under criteria of surgery, continue the interview and go to Section 3: Healthcare exposures.
- D. The purpose of this question is to determine whether the patient was a chronic dialysis patient at the time of positive test for CRE. If prompted by those patients not familiar with the term dialysis, clarify that dialysis is a treatment for kidney failure that rids body of unwanted toxins, waste products and excess fluids by filtering patient's blood. When kidneys fail, the body may have difficulty cleaning blood and keeping system chemically balanced. If prompted further, tell the patient that this includes both hemodialysis and peritoneal dialysis and can be outpatient or

- inpatient dialysis. Identify on your calendar the date of positive test for CRE then ask the question. If the patient answers Yes, No, don't know, or Refused, continue to QE.
- E. The purpose of this question is to determine whether the patient had any medical devices at the time of the positive test for CRE or in the 2 days before the positive test for CRE. Clarify to the patient that for the purposes of this interview, a medical device is a device or medical equipment that are put in a patient's body to either give patient things, like food or medications or oxygen, or take things out, like collect blood or urine. Identify on your calendar the date of positive test for CRE then ask the question. MuGSI CRF instructions provide examples of medical devices in Appendix 2. Please note that a device that is implanted into the body and is contained completely within the body, for example a VP Shunt or a pacemaker, is not be considered a medical device for MuGSI surveillance. If you have doubts, please contact CDC surveillance coordinator for clarifications later. CDC MuGSI surveillance coordinator will maintain the list of devices mentioned by the patient in the appendix section of these instructions and will update as needed for your reference. If the patient answers Yes, continue to QEa and specify the type of device. If No, don't know, or Refused, continue the interview and go to Section 3: Healthcare exposures.
 - a. If the patient said *Yes*, specify what kind of device was used by the patient in the provided space. Reference CRF instructions to verify that the medical device reported qualifies under criteria of medical devices for MuGSI. If not, change the answer to *No* and record additional details in the comments section. If the device mentioned by the patient falls under the criteria for medical devices in MuGSI, then read the bolded text at the end of Section 2 and conclude the interview. If the device does not fall under criteria of medical devices, continue the interview and go to Section 3: Healthcare exposures.

Please note that there is a bolded text at the end of this section in the questionnaire which states that if the patient answered "YES" to any of the questions, then STOP the interview after saying "Thank you for your time. We are only interviewing people who have not had previous healthcare exposure in the past year. We will contact you if we have further questions." If the patient did not answer "YES" to any of the questions, then continue the interview and go to Section 3: Healthcare exposures.

Section 3: Healthcare exposures

The assessment of potential risk factors for CA CP-CRE starts in this section. The

purpose of this section (questions 1-11) is to ask if the patient had healthcare exposures at some point in the past that could be risk factors of CRE healthcare acquisition but either are further back in time than what the community associated CRE definition specifies, or are not part of the community associated CRE definition.

- 1. This question asks if the patient had any medical devices in the 12 months before the positive test for CRE. Remind the patient what is a medical device, if prompted. Question E prom the previous Section 2: "Screening for healthcare exposures in the past year" provides clarifications on medical devices. If Yes, ask what kind of device was used by the patient and specify in the provided space. If No, don't know, or Refused, continue the interview, and go to Q2.
- 2. This question asks if the patient ever stayed overnight in a hospital before the positive test for CRE. Overnight is meant to indicate admission to a facility for treatment. If a patient reports that they were in the emergency room overnight and then went home or stayed overnight in a hospital to visit a relative who was admitted, this is not considered admission to a hospital. Hospitalization in a case <=12 months old for an uncomplicated birth is not considered a hospitalization. Hospitalization to an acute care hospital, long-term acute care hospital, and rehabilitation facility are considered hospitalizations.</p>
 - a. If Yes, ask the patient when was his or her most recent stay in the hospital and record the most recent single date (month, day, year) that the patient was discharged from a hospital in the space provided. If the patient cannot remember the month and day of discharge, please record only the year. If No, don't know, or Refused, continue the interview, and go to Q3.
- 3. This question asks if the patient ever stayed overnight in a nursing home before the positive test for CRE. Overnight is meant to indicate admission to a facility for treatment. If a patient reports that they stayed overnight in a nursing home to visit a relative who was admitted, this is not considered admission to a nursing home.
 - a. If Yes, ask the patient when was his or her most recent stay in the nursing home and record the most recent single date (month, day, year) of discharge in the space provided. If the patient cannot remember the month and day of discharge from the nursing home, please record the year only. If No, don't know, or Refused, continue the interview, and go to Q4.
- 4. This question asks if the patient received dialysis in the 12 months before the positive test for CRE. If prompted by a patient not familiar with the term dialysis, clarify that dialysis is a treatment for kidney failure that rids the body of unwanted

toxins, waste products and excess fluids by filtering patient's blood. When kidneys fail, the body may have difficulty cleaning blood and keeping system chemically balanced. If prompted further, tell the patient that this includes both hemodialysis and peritoneal dialysis and can be outpatient or inpatient dialysis. Continue the interview, and go to Q5.

- 5. This question asks whether the patient went to a clinic or infusion center to have medications injected through the veins in the 12 months before the positive test for CRE. Clarify to the patient that medications commonly injected through the veins include those given for cancer chemotherapy and some antibiotics. If needed, clarify to the patient that an infusion clinic is a place outside of the hospital that provides medications through person's veins; chemotherapy is medication given for cancer treatment; antibiotics are medicines that fight infections caused by bacteria in humans and animals by either killing the bacteria or making it difficult for the bacteria to grow and multiply.
 - a. If *Yes*, ask what the reason was for visiting this clinic or facility and record the answer in the provided space. If *No*, *don't know*, or *Refused*, continue the interview, and go to Q6.
- 6. This question asks if the patient had any wounds that would not heal for more than two weeks, like a foot ulcer, in the 12 months before the positive test for CRE. If prompted, clarify to the patient that we are asking about the wound that compromises the skin, and that have not healed for at least two weeks. Wounds can be caused by external damage to intact skin and include surgical wounds, bites, burns, minor cuts and abrasions, and more severe traumatic wounds, such as lacerations and those caused by crush or gunshot injuries. Wounds can be caused by endogenous mechanisms associated with a predisposing condition that ultimately compromises the skin. These can be pressure ulcers (bed sores), diabetic ulcers, venous ulcers, and arterial ulcers. If the patient answers Yes, continue to Q7. If No, don't know, or Refused, skip Q7, Q8, Q9 and continue to Q10.
- 7. This question asks about who took care of the wound. Check all options that apply. If Self, Relative or Friend, Wound care specialist, Other, DK, or Refused, continue to Q8. If "Other," ask the patient to specify and record the answer in the provided space and then continue to Q8. Do not list names of people, only the relationship to the patient. Note that care of the wound includes care in a clinic, the hospital, patient's home. Wound care specialists can come from a variety of healthcare professions such as physicians, nurses, physical/occupational therapists, and pharmacists.

- 8. This question asks if wound care involved hydrotherapy or whirlpool therapy. If needed, clarify to the patient that hydrotherapy and whirlpool therapy are techniques that involve the use of water to aid with cleaning and healing of wounds, either by immersing a wound in water that flows around like a whirlpool, or by spraying the wound with water from a shower. If *Yes, No, don't know*, or *Refused*, continue the interview, and go to Q9.
- 9. This question asks if a wound VAC was used during the wound care. If needed, clarify to the patient that a wound VAC is a device consisting of a machine that connects to a dressing over a wound and sucks fluid out of the wound to help the wound heal more quickly. If Yes, No, don't know, or Refused, continue the interview, and go to Q10.
- 10. This question asks if the patient received any care from home healthcare providers in the 12 months before the positive test for CRE. Examples of home healthcare providers include visiting nurses or wound care providers. If *Yes* go to Q10a which asks to describe the services provided to the patient. If *No*, *Don't know*, or *Refused*, continue to Q11.
 - a. This question asks to describe the services given to the patient. Record the answer in the provided space. After you type the response in the provided space, continue to Q11.
- 11. This question asks if the patient had urinary procedures or other procedures where a doctor used a scope to look inside the bowel, stomach, lungs, etc. in the 12 months before the positive test for CRE. Some examples of procedures are colonoscopy, endoscopy, cystoscopy. If *Yes* go to Q11a which asks to specify the name of the procedure in the provided space.
 - a. This question asks to provide the name of the procedure in the provided space. After you type the response in the provided space, continue to Section 4: Travel.

Section 4: Travel

The purpose of this section (questions 12-14) is to ask the patient to provide some information about travel and/or residence outside of the United States. These questions collect information on travel within three years.

- 12. This question asks if the patient traveled or resided outside of the U.S. in the three years before the positive test for CRE. If *Yes* go to Q12a. If *No, Don't know,* or *Refused*, go to Section 5: Antibiotics.
 - a. Complete the table about the countries visited, list these countries and year(s) of travel to each country.
- 13. This question asks if the patient received any dental or medical care during travels outside of the U.S. in the 3 years before the positive test for CRE. Clarify to the patient that this includes but is not limited to dental cleanings or dental procedures, visits to outpatient clinics, overnight stays in hospitals, surgeries, endoscopies, cosmetic surgery, medication infusions, etc. If *Yes* go to Q13a-d and complete the table. If *No*, *Don't know*, or *Refused*, go to Section 5: Antibiotics.
 - a. This question asks to specify the country in the provided space. Specify the country and continue to Q13b.
 - b. This question asks about the type of care received. Read the list of types of dental/healthcare received and check all that apply. If *Other*, ask to specify in the provided space. Continue to Q13c.
 - c. Indicate year(s) that care was received. Continue to Q13d.
 - d. This question asks if getting the medical care was one of the reasons the patient travelled, in other words if this was a medical tourism. Check the appropriate checkbox. Continue to Section 5: antibiotics.

Section 5: Antibiotics

The purpose of this section (questions 14, 14a-b) is to ask the patient information about the use of antibiotics.

If needed, clarify to the patient that antibiotics are medicines that fight infections caused by bacteria in humans and animals by either killing the bacteria or making it difficult for the bacteria to grow and multiply.

Let the respondent know that it may be helpful for them to have their medical records or medication bottles in front of them to answer the next few questions. Allow time for the patient to gather these materials before beginning the next set of questions, if needed.

- 14. This question asks if the patient took antibiotics in the 12 months before the positive test for CRE. Give an example that people commonly take antibiotics for urinary tract infections, sore throats, sinus infections, boils or other skin infections, and for dentistry purposes. There are different groups of antibiotics, which are prescribed depending on a patient condition. If *Yes* go to Q14a-b, if *No*, *Don't know*, or *Refused*, go to Section 6: Occupation.
 - a. This question asks why the patient took the antibiotic. DO NOT read the list of responses to the patient. Mark a response for each medical condition separately. If the respondent does not specifically state a medical condition, leave the response missing; DO NOT assume the answer is "No". If the patient reports a reason that is not listed indicate *Other*, then record the reason for taking the antibiotic. Continue to Q14b.
 - b. Ask which antibiotics the patient took. Do not read the list of antibiotics. Check all that apply in the appropriate boxes.
 - The antibiotics are listed in alphabetical order, with brand and generic names of the same antibiotic listed in different boxes. This is done for the interviewer convenience to quickly locate the appropriate antibiotic on the list.
 - If more than one antibiotic was taken, record all of them. Note that there is space to specify two other antibiotics that are not included in the list. If the patient took more than two other antibiotics not included in the list, record the additional antibiotics in the Comments section at the end of the interview.
 - It may be helpful to have a pocket drug reference or internet access readily available to search for trade names and generic names, as the subject may answer with either name.
 - It may be helpful to ask if the patient has the bottle with the name of antibiotic.
 - If the subject when prompted is unsure of any of the antibiotics taken in those 12 months indicate don't know / refused on the form.
 - If the patient states that they took 2 or more drugs but is only certain of one of the drug names indicate the name of the known drug. For the unknown drug, mark as *Other*, then under *specify* mark 'UNK'.

 If an antibiotic name is uncertain, but the respondent gives an approximation of the name (says it was "cefo something") mark as Other, then under specify indicate "cefo something". Continue to Section 6: occupation.

Section 6: Occupation

The purpose of this section (questions 15-19) is to find out about the patient's occupation and related activities at the time of or in the 12 months before the positive test for CRE.

- 15. This question asks if the patient was employed at the time of the positive test for CRE. If Yes go to Q15a which asks to specify the patient's job in the provided space. Refer to standard list of occupations attached in the appendix to the interview questionnaire and type the name of the job. If No, Don't know, or Refused, continue to Q16.
- 16. This question asks if the patient worked or volunteered at a hospital, healthcare facility, or home health agency in the 12 months before the positive test for CRE. Volunteering can mean doing anything that requires the patient to enter a facility. Any amount of time spent working or volunteering in such a facility should be counted as "Yes." If Yes go to Q16a, Q16b, and Q16c and complete the table to record responses to these questions in a table. If No, Don't know, or Refused, continue to Q18.
 - a. This question asks about the patient's role there. Please refer to OMB categories in Appendix 1 and complete this part of a table later by including the appropriate category.
 - b. This question asks about healthcare facility type or organization where the patient worked. Refer to the facility types below the table, which include hospital, emergency department, doctor's office or clinic, dentist's office, long-term care facility, hemodialysis clinic, home health agency, ambulatory surgery center, other (specify). These facility types should be independently verified against EIP facility classification lists after receiving the name of the facility.
 - c. This question asks if the patient's job involved direct physical contact during care for patients. Explain to the patient that care for patients is the type of care that involves direct physical contact with the patient. Direct physical contact includes any actual physical contact such as a hug or hand holding.

Examples of occupations that provide care involving direct physical contact include nurse, technician, doctor, or any other occupation that involves providing healthcare to another person. Example of activity of providing care for patients with direct physical contact include touching the patient to help him or her get out of the chair, helping move the patient, inserting medical devices, providing medication. If there is a handshake, but the job does not involve providing care for patients, the answer should not be *No* to this question. If *Yes* go to Q17 which asks to describe the patient care duties in the space provided. If *No*, *Don't know*, or *Refused*, continue to Q18.

- 17. If respondent's job involved direct physical contact during care for patients in Q16C, ask the patient to describe direct physical contact during care for patients in the provided space. This is an open-ended question. If respondent's description does not include the following activities bathing the patient, assisting with toileting, assisting with other hygiene, and caring for the patient known to have CRE then ask for clarification on each of these activities and check *Yes, No, Don't know,* or *Refused.* Record the answer in the provided space and then go to question 17a.
 - a. This question asks about ages of persons for whom care was provided. Indicate age in years by checking the appropriate checkbox with the appropriate age range option. Because care can be provided for patients fitting into multiple age groups, several checkboxes can be checked.
- 18. This question asks if the patient worked or volunteered in a veterinary clinic or in another animal care facility in the 12 months before the positive test for CRE. Any amount of time spent working or volunteering in such a facility should be counted as "Yes." If Yes go to Q18a and 18b and complete the table to record responses to these questions in a table. These table has two parts: one part asks about a role, and the other part asks if the patient provided direct animal care. If No, Don't know, or Refused, continue to Section 7.
 - a. This question asks about the patient's role there. Please refer to OMB categories in Appendix 1 and complete this part of a table later. Examples of patient's roles from OMB categories may be as follows: veterinary assistants and laboratory animal caretakers (31-9096), veterinarians (29-1131), animal caretakers (39-2021), veterinary technologist or technician(29-2056) or other.
 - b. This question asks if the patient provided direct animal care. Explain to the patient that direct animal care is the type of care that involves direct physical

contact with the animal, for example touching the animal, holding or carrying the animal, bathing the animal, assisting with animal hygiene, caring for animal and other duties, involving physical contact with the animal. Examples of occupation with direct physical contact may include animal surgeon, wildlife veterinarian, Doctor of Veterinary Medicine, veterinary technician, veterinary assistant, or any other occupation that involves providing healthcare to animal. If *Yes* go to Q19 which asks to describe the animal care duties in the space provided. If *No*, *Don't know*, or *Refused*, continue to Section 7: agricultural and animal exposures.

19. This question asks to describe the animal care duties in the provided space including the types of animals cared for (e.g. cats, dogs, other pets, horses, cows). This question applies to respondents who said that they provided direct animal care duties in Q18b. Direct animal care involves activity such as touching the animal. This is an open-ended question with the text field. Examples of animal care duties include conducting physical exams on animals; providing medication, food, or water; cleaning and maintaining the animal's living environment (e.g., cage, enclosure); bathing or grooming the animal. Record the answer in the provided space and then go to Section 7: Agricultural and animal exposures.

Section 7: Agricultural and animal exposures

The purpose of this section (questions 20 and 21) is to ask the patient about agricultural and animal exposures in the 12 months before the positive test for CRE.

- 20. This question asks if the patient had any pets in the household in the 12 months before the positive test for CRE. Any amount of time having pets in the household should be counted as "Yes". If Yes go to Q20 a-e. If No, Don't know, or Refused, continue to Q21.
 - a. This question asks about the kind of pets the patient had. Read the list of pets and record the answer and the appropriate checkbox. Check all that apply. If *Other*, ask the patient to specify. Continue to Q20b.
 - b. This question asks if the patient's pet received any veterinary care in the 12 months before the positive test for CRE. If Yes, ask the patient about the type of healthcare the pet received. Read the list of types of healthcare and record the answer in the appropriate checkbox. Check all that apply. If Other, ask to specify in the provided space. Continue to Q20c.

- c. This question asks if the patient was ever told that the pet had CRE. If *Yes, No, don't know,* or *Refused,* continue the interview, and go to Q20d.
- d. This question asks if the patient's pet was imported into the United States from another country. If *Yes,* go to Q20e that asks to specify the country in the provided space and then go Q21; if *No, don't know,* or *Refused,* continue the interview, and go to Q21.
- e. This question asks to specify the country in the provided space. Record the answer in the provided space and then go to Q21.
- 21. This question asks if the patient lived or worked with livestock like cattle, sheep, goats, or other animals in the 12 months before the positive test for CRE. Any amount of time spent living or working with livestock should be counted as "Yes". This includes raising animals on premises, including raising backyard chickens, small pasture goats and other livestock. If Yes, go to Q21a that asks about the types of animals the patient lived or worked with. If No, don't know, or Refused, continue the interview, and go to Section 8: Household contacts.
 - a. This question asks the patient about the types of animals the patient lived or worked with. Read the list of animals and record the answer in the appropriate checkbox. Check all that apply. If *Other*, ask to specify in the provided space. Continue to Section 8: Household contacts.

Section 8: Household contacts

The purpose of this section (questions 22-26) is to ask the patient a few questions about activities of the patient's household members. Clarify to the patient that for the purposes of this interview members of household are persons who spent at least 50% of their nights in patient's household during the year before the positive test for CRE. Clarify to the patient that you will ask questions about members of patient's household during the 12 months before patient's positive test for CRE.

22. This question is designed to determine how many people live in the household. Because this number can change (e.g. one or more children are away at college), this question asks the respondent to count only those people who spent at least half (50%) of their nights in the home in the 12 weeks before the positive test for CRE. Be sure to have the respondent count himself or herself. If the answer is one, it means that the subject lives alone, then skip to Section 9: Other contacts.

- 23. This question asks if a member of patient's household was diagnosed with the CRE germ in the 12 months before the patient's positive test for CRE. If *Yes* go to Q23a. If *No, Don't know,* or *Refused,* continue to Q24.
 - a. This question asks if this was a family member who had CRE germ. Check *Yes, No, DK,* or *Refused* and then go to Q24.
- 24. This question asks if a member of patient's household stayed overnight in a hospital or nursing home in the 12 months before the patent's positive test for CRE. This includes any of the people referred to in Q22 (who spend ≥50% of nights in the household in the 12 months before the positive test for CRE). Overnight indicates admission to a healthcare facility. Staying in the emergency room for 12 hours overnight or staying overnight in a hospital to visit a relative who was admitted is not considered admission to a healthcare facility. Hospitalization in a case <=12 months old for an uncomplicated birth is not considered a hospitalization. Hospitalization to an acute care hospital, long-term acute care hospital, and rehabilitation facility are considered hospitalizations. If *Yes* go to Q24a. If *No*, *Don't know*, or *Refused*, continue to Q25.
 - a. This question asks the type of facility or facilities the member of the household stayed at. Record the answer in the appropriate checkbox. Check all that apply. Continue to Q25.
- 25. This question asks if a member of patient's household traveled or lived outside of the U.S. in the 12 months before the patient's positive test for CRE. If *Yes*, go to Q26, if *No*, *DK*, or *Refused*, skip to Section 9: Other contacts.
- 26. This question asks if the patient's household member received any dental or medical care during travels outside of the U.S. in the 12 months before the positive test for CRE. Clarify to the patient that this includes but not limited to dental cleanings or dental procedures, visits to outpatient clinics, inpatient hospitalizations, surgeries, endoscopies, cosmetic surgery, medication infusions, etc. If *Yes* go to Q26a-c and complete the table, if *No*, *Don't know*, or *Refused*, go to Section 9: Other contacts.
 - a. This question asks to specify the country in the provided space. Specify the country and continue to Q26b.
 - b. This question asks what type of care was received. Read the list of types of dental/healthcare received. Check all that apply. If *Other*, ask to specify in the provided space. Continue to Q26c.

c. This question asks if getting the medical care was one of the reasons the patient travelled, in other words whether this was a medical tourism. Check the appropriate checkbox. Continue to Section 9: Other contacts.

Section 9: Other contacts

The purpose of this section is to ask questions about people the patient might have been in close contact with other than members of the patient's household.

- 27. This question asks if the patient assisted someone outside the household with bathing, toileting, or moving around the house during the 12 months before positive test for CRE. Clarify to the patient that assisting with toileting includes contact with feces while changing the diaper in a child or adult. It does not include cleaning up in the bathroom unless the patient came into direct contact with feces during the cleaning process. If *Yes* go to Q27a, if *No*, *Don't know*, or *Refused*, go to Section 10: Activities and health.
 - a. This question asks if this person (who the patient has been in close contact with) stayed overnight in the hospital or nursing home during the 12 months before positive test for CRE. Overnight is meant to indicate admission to a facility for treatment. If a patient reports that they were in the emergency room overnight and then went home or stayed overnight to visit a relative who was admitted to a facility this is not considered admission to a healthcare facility. Hospitalization in a case <=12 months old for an uncomplicated birth is not considered a hospitalization. Hospitalization to an acute care hospital, long-term acute care hospital, and rehabilitation facility are considered hospitalizations. Continue to Section 10: Activities and health.
 - b. This question asks about the age of the person to whom assistance was provided. Indicate age in years by checking the appropriate checkbox with the appropriate age range option. Because assistance can be provided for patients fitting into multiple age groups, several checkboxes can be checked.

Section 10: Activities and health

The purpose of this section is to ask some questions about the patient's health at the time of or before the positive test for CRE.

28. This question asks if the patient needed help bathing, toileting, or moving around the house at the time of the positive test for CRE. Continue to Q29.

29. This question asks if the patient had repeated urinary tract infections in the 12 months before positive test for CRE. Clarify that repeated urinary tract infections are defined as two or more infections in six months or three or more infections in one year. Continue to Section 11: Final questions

Section 11: Final questions

The purpose of this section is to ask few final questions (30-37) before finishing the interview.

- 30. This question asks if the patient was born outside of the U.S. Tell the patient that we are asking this question because studies have shown that people who were born in another country are more likely to have antibiotic resistant bacteria. If *Yes* go to Q30a, if *No*, *Don't know*, or *Refused*, go to Q31.
 - a. This question asks to specify the country the patient was born in. Record the country in the provided space. Continue to Q31
- 31. This question asks the patient about how the patient thinks he/she got CRE germ. Record the answer in the provided space.
- 32. This question asks if there is anything else the patient would like to tell the interviewer. Record the answer in the provided space.
- 33. This question asks if the interviewer can call the patient back if there are further questions. Record the answer *Yes* or *No*.

Tell the patient that this was your last question. Thank the patient for his or her time and participation.

- 34. Record any comments about the interview that you feel were not captured elsewhere on the interview form.
- 35. Indicate if the interview was completed. If the interview was not completed, please explain in the space for comments (Q34).
- 36. Record the date of the interview (mm/dd/yyyy)
- 37. Please enter your initials as the interviewer.

Thank you!

Appendices

<u>Appendix 1: Health Interview Appendix—Job Codes (refer to: 2018 Standard Occupational Classification System (bls.gov))</u>

29-0000 Healthcare Practitioners and Technical Occupations

- 29-1000 Healthcare Diagnosing or Treating Practitioners
 - 29-1010 Chiropractors
 - 29-1011 Chiropractors
 - 29-1020 Dentists
 - 29-1021 Dentists, General
 - 29-1022 Oral and Maxillofacial Surgeons
 - 29-1023 Orthodontists
 - 29-1024 <u>Prosthodontists</u>
 - 29-1029 <u>Dentists</u>, All Other Specialists
 - 29-1030 Dietitians and Nutritionists
 - 29-1031 <u>Dietitians and Nutritionists</u>
 - 29-1040 Optometrists
 - 29-1041 Optometrists
 - 29-1050 Pharmacists
 - 29-1051 <u>Pharmacists</u>
 - 29-1070 Physician Assistants
 - 29-1071 Physician Assistants
 - 29-1080 Podiatrists
 - 29-1081 Podiatrists
 - 29-1120 Therapists
 - 29-1122 Occupational Therapists
 - 29-1123 Physical Therapists
 - 29-1124 Radiation Therapists
 - 29-1125 Recreational Therapists
 - 29-1126 Respiratory Therapists
 - 29-1127 <u>Speech-Language Pathologists</u>
 - 29-1128 Exercise Physiologists
 - 29-1129 Therapists, All Other
 - 29-1130 Veterinarians
 - 29-1131 <u>Veterinarians</u>
 - 29-1140 Registered Nurses
 - 29-1141 Registered Nurses
 - 29-1150 Nurse Anesthetists

- 29-1151 Nurse Anesthetists
- 29-1160 Nurse Midwives
 - 29-1161 Nurse Midwives
- 29-1170 Nurse Practitioners
 - 29-1171 Nurse Practitioners
- 29-1180 Audiologists
 - 29-1181 Audiologists
- 29-1210 Physicians
 - 29-1211 <u>Anesthesiologists</u>
 - 29-1212 Cardiologists
 - 29-1213 <u>Dermatologists</u>
 - 29-1214 Emergency Medicine Physicians
 - 29-1215 Family Medicine Physicians
 - 29-1216 General Internal Medicine Physicians
 - 29-1217 <u>Neurologists</u>
 - 29-1218 Obstetricians and Gynecologists
 - 29-1221 Pediatricians, General
 - 29-1222 Physicians, Pathologists
 - 29-1223 <u>Psychiatrists</u>
 - 29-1224 Radiologists
 - 29-1229 Physicians, All Other
- 29-1240 Surgeons
 - 29-1241 Ophthalmologists, Except Pediatric
 - 29-1242 Orthopedic Surgeons, Except Pediatric
 - 29-1243 <u>Pediatric Surgeons</u>
 - 29-1249 Surgeons, All Other
- 29-1290 Miscellaneous Healthcare Diagnosing or Treating Practitioners
 - 29-1291 Acupuncturists
 - 29-1292 Dental Hygienists
 - 29-1299 Healthcare Diagnosing or Treating Practitioners, All Other
- 29-2000 Health Technologists and Technicians
 - 29-2010 Clinical Laboratory Technologists and Technicians
 - 29-2011 Medical and Clinical Laboratory Technologists
 - 29-2012 Medical and Clinical Laboratory Technicians
 - 29-2030 Diagnostic Related Technologists and Technicians
 - 29-2031 Cardiovascular Technologists and Technicians
 - 29-2032 Diagnostic Medical Sonographers
 - 29-2033 Nuclear Medicine Technologists
 - 29-2034 Radiologic Technologists and Technicians
 - 29-2035 Magnetic Resonance Imaging Technologists
 - 29-2036 Medical Dosimetrists
 - 29-2040 Emergency Medical Technicians and Paramedics

- 29-2042 Emergency Medical Technicians
- 29-2043 Paramedics
- 29-2050 Health Practitioner Support Technologists and Technicians
 - 29-2051 Dietetic Technicians
 - 29-2052 Pharmacy Technicians
 - 29-2053 Psychiatric Technicians
 - 29-2055 Surgical Technologists
 - 29-2056 Veterinary Technologists and Technicians
 - 29-2057 Ophthalmic Medical Technicians
- 29-2060 Licensed Practical and Licensed Vocational Nurses
 - 29-2061 <u>Licensed Practical and Licensed Vocational Nurses</u>
- 29-2070 Medical Records Specialists
 - 29-2072 Medical Records Specialists
- 29-2080 Opticians, Dispensing
 - 29-2081 Opticians, Dispensing
- 29-2090 Miscellaneous Health Technologists and Technicians
 - 29-2091 Orthotists and Prosthetists
 - 29-2092 <u>Hearing Aid Specialists</u>
 - 29-2099 Health Technologists and Technicians, All Other
- 29-9000 Other Healthcare Practitioners and Technical Occupations
 - 29-9020 Health Information Technologists and Medical Registrars
 - 29-9021 Health Information Technologists and Medical Registrars
 - 29-9090 Miscellaneous Health Practitioners and Technical Workers
 - 29-9091 Athletic Trainers
 - 29-9092 Genetic Counselors
 - 29-9093 Surgical Assistants
 - 29-9099 Healthcare Practitioners and Technical Workers, All Other

31-0000 Healthcare Support Occupations

- 31-1100 Home Health and Personal Care Aides; and Nursing Assistants, Orderlies, and Psychiatric Aides
 - 31-1120 Home Health and Personal Care Aides
 - 31-1121 Home Health Aides
 - 31-1122 Personal Care Aides
 - 31-1130 Nursing Assistants, Orderlies, and Psychiatric Aides
 - 31-1131 Nursing Assistants
 - 31-1132 Orderlies
 - 31-1133 Psychiatric Aides
- 31-2000 Occupational Therapy and Physical Therapist Assistants and Aides
 - 31-2010 Occupational Therapy Assistants and Aides
 - 31-2011 Occupational Therapy Assistants
 - 31-2012 Occupational Therapy Aides
 - 31-2020 Physical Therapist Assistants and Aides

- 31-2021 Physical Therapist Assistants
- 31-2022 Physical Therapist Aides
- 31-9000 Other Healthcare Support Occupations
 - 31-9010 Massage Therapists
 - 31-9011 Massage Therapists
 - 31-9090 Miscellaneous Healthcare Support Occupations
 - 31-9091 <u>Dental Assistants</u>
 - 31-9092 Medical Assistants
 - 31-9093 Medical Equipment Preparers
 - 31-9094 Medical Transcriptionists
 - 31-9095 Pharmacy Aides
 - 31-9096 Veterinary Assistants and Laboratory Animal Caretakers
 - 31-9097 Phlebotomists
 - 31-9099 <u>Healthcare Support Workers, All Other</u>