Surveillance for Multidrug-Resistant Gram-Negative Bacilli through the Healthcare-Associated Infections/Community Interface Emerging Infections Program

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I. Background

Gram-negative bacilli are common causes of healthcare and community infections. According the data from the National Healthcare Safety Network (NHSN) surveillance system, *Escherichia coli*, *Klebsiella pneumoniae*, and *Acinetobacter baumannii* were the 5th, 7th, and 9th most common causes of device-associated healthcare-associated infections in the United States in 2006 and 2007. In addition, *Enterobacteriaceae*, such as *E.coli* and *K. pneumoniae* are common causes of outpatient infections, particularly urinary tract infections.

The emergence of antimicrobial resistance has raised the importance of these organisms as a public health problem. Particularly concerning has been the emergence of extended spectrum beta-lactamases in the 1980's and 1990's. Organisms that produce these enzymes are nonsusceptible to commonly used extended-spectrum cephalosporins and beta-lactam/beta-lactamase inhibitor combinations leaving carbapenems as one of the few remaining effective antimicrobial classes. Fortunately, carbapenem resistance among *Enterobacteriaceae* has been uncommon until recently.

In 2001, a new carbapenamase was reported from a *K. pneumoniae* from North Carolina (designated *Klebsiella pneumoniae* carbapenemase or KPC). In the intervening 10 years, *Enterobacteriaceae* producing the KPC enzyme have spread widely, contributing to an increase in multidrug-resistant *Enterobacteriaceae* in the United States. In addition to the spread of KPC-producing *Enterobacteriaceae*, isolates of *E. coli* and *Klebsiella* species producing metallo-beta-lactamases (MBLs) have also been identified in the United States since 2009. Although uncommon in the United States, these enzymes are a frequent cause of carbapenem resistance throughout the world. MBLs that have been described among *Enteorbacteriaceae* in the United States include the New Delhi metallo-beta-lactamse (NDM), the Verona integrin-encoded metallo-beta-lactamase (VIM), and the "active on imipenem" (IMP) metallo-beta-lactamase. As both KPCs and MBLs are contained on highly mobile genetic elements these enzymes have the potential to spread rapidly and widely between *Enterobacteriaceae*. In addition, some *Enterobacteriaceae* may have other resistance mechanisms including producing a chromosomal extended-spectrum beta-lactamase or an AmpC beta-lactamase which when combined with a porin mutation can result in carbapenem-resistance.

Among *Acinetobacter*, multidrug resistance has also become an important problem. Data from NHSN suggests that nearly three-quarters of *Acinetobacter* isolates causing device and procedure-associated infections in intensive care units are multidrug resistant. In addition, in 2009, 66% of *Acinetobacter* were nonsusceptible to at least one carbapenem.

Few antimicrobials are currently available to treat carbapenem-resistant organisms and additional broad spectrum antimicrobial agents are estimated to be years away from approval; high levels of antimicrobial resistance in these strains has created substantial treatment challenges. Treatment issues have been compounded recently by the emergence of isolates that are resistant to all antimicrobials. The fact that *Enterobacteriaceae* are a common cause of infections in both healthcare and community settings suggests that treatment challenges might become even more complicated if carbapenem-nonsusceptible organisms move from healthcare settings, where they currently are primarily found, to outpatient settings.

Currently, national surveillance for gram-negative bacilli of epidemiologic importance (e.g., carbapenem-nonsusceptible strains) is limited. NHSN provides antimicrobial susceptibility results for organisms causing device and procedure infections; however, this data is limited to specific types of infections occurring primarily in hospitals. As the incidence and characteristics (e.g., move from inpatient to outpatient settings) of these organisms changes there is a need for more specific surveillance to better define the magnitude of the burden of these infections, to define the population at risk, and to inform prevention efforts.

II. Objectives

1. To evaluate the population-based incidence of carbapenem-resistance among common strains of *Enterobacteriaceae (CRE)* and carbapenem-nonsusceptibility among *Acinetobacter baumannii* complex (CRAB) and describe how the incidence changes over time.
2. To better characterize CRE and CRAB strains in sites submitting data in order to inform prevention efforts.
3. To describe known resistance mechanisms among a subset of carbapenem-resistant *Enterobacteriaceae.*

III. Surveillance Plan

A. Overview and Definitions

Two resistance phenotypes that will be evaluated in this surveillance system:

Species	Category	Carbapenem breakpoints
E. coli & *Klebsiella* species*, and *Enterobacter* species**	Carbapenem-resistant *Enterobacteriaceae*	Resistant to: imipenem (MIC[@] of ≥4), meropenem (MIC of ≥4), doripenem (MIC of ≥4) or ertapenem (MIC of ≥2
Acinetobacter baumannii§	Carbapenem-nonsusceptible *Acinetobacter baumannii*	Intermediate or resistant to: doripenem (MIC>1) imipenem (MIC of ≥8), or meropenem (MIC of ≥8)

**Klebsiella pneumoniae* and *Klebsiella oxytoca*
***Enterobacter aerogenes* and *Enterobacter cloacae* complex
Enterobacteriaceae breakpoints based on the 2015 CLSI breakpoints (M100-S25)
[@]MIC- Minimum inhibitory concentration
§ includes *A. baumannii*, *A. baumannii* complex, *A. calcoaceticus-baumannii* complex (including *A. calcoaceticus*). Breakpoints for doripenem based on FDA. Breakpoints for imipenem and meropenem based on the 2013 CLSI breakpoints (M100-S23)

Cases will be defined as carbapenem-resistant resistant *E. coli*, *Enterobacter* species (i.e., *Enterobacter aerogenes* and *Enterobacter cloacae* complex), *Klebsiella* species (i.e., *Klebsiella pneumoniae* and *Klebsiella oxytoca*), or carbapenem-nonsusceptible (intermediate or resistant) *Acinetobacter baumannii* complex isolated from normally sterile sites or urine from residents of the surveillance area. Cases will be identified through clinical microbiology laboratory data. Normally sterile sites include: blood, cerebrospinal fluid (CSF), pleural fluid, pericardial fluid, peritoneal fluid, joint/synovial fluid, bone, internal body site (lymph node, brain, heart, liver spleen, vitreous fluid, kidney, pancreas or ovary), muscle or other normally sterile site. Cultures designated as "fluid" shall be investigated as potentially sterile culture sites or urine; cultures designated as "tissue" with no specification (e.g. surgical specimens) will not be investigated. Isolation from solely non-sterile culture sites such as skin, wound, swabs, sputum, sinus, throat, eye (not including vitreous fluid), ear, abscess or drainage would not meet the case definition for this surveillance.

Isolates which undergo further confirmatory susceptibility testing (i.e. Kirby Bauer or E-Testing) at the clinical laboratory, should be excluded from surveillance if determine by confirmatory testing to no longer meet our case definition. Do not exclude isolates based on a negative modified Hodge test result or based on another non-molecular test for the presence of a Carbapenemase (i.e. CarbaNP) for this surveillance. Additionally, cases should not be excluded based on a molecular test for the presence of a Carbapenemase (i.e. PCR, Automated Molecular Assay). Testing performed at state public health laboratory or another EIP laboratory, **should not** be taken into consideration in determining case status.

Case-patients infections will be described based on the information obtained though medical record review and will be categorized based on the location of the culture collection and/or where the patient was on the fourth calendar day prior to culture.

B. Surveillance Areas

The total population of the surveillance area for this surveillance system is approximately 15million. The table below illustrates the population under surveillance for each participating EIP site as of January 2016.

	MuGSI Surveillance Population
CO	2,636,542 (5 county Denver area)
GA	3,975,130 (8 county Atlanta area)
MD	1,867,653 (3 county Baltimore area and Baltimore City)
MN	1,744,719 (2 metro Twin Cities counties)
NM	675,551 (1 county Albuquerque metro area)
NY	749,857 (1 county Rochester metro area)
OR	1,734,685 (3 county Portland area)
TN	1,618,979 (8 county Nashville metro area)
Total	**15,003,116**

Populations were obtained from the U.S. Census web site 12/29/2015 (http://quickfacts.census.gov/qfd/index.html), 2014 estimates.

C. Surveillance Strategy

Case finding is active, laboratory-based, and population-based. Since isolation of an isolate meeting the phenotypic case definitions from a normally sterile site or urine is essential to the case definition, every clinical laboratory that routinely processes specimens from residents of a surveillance area (including laboratories both within and outside the catchment area) will be routinely contacted for case identification.

Isolates meeting the phenotypic case definitions will be identified using clinical microbiology laboratory data, ideally using the primary antibiotic testing instrument directly. Each participating laboratory will regularly provide to the local EIP team line listings of all patients from whom isolates meeting the phenotypic case definitions have been isolated from a normally sterile site (Overview and Definitions) or urine. The first carbapenem-resistant *Enterobacteriaceae* of each species or carbapenem-nonsusceptible *Acinetobacter baumannii* complex per patient each 30 days will be eligible for inclusion in this evaluation. The initial culture

date will be the date the first culture was obtained. Additional positive cultures of surveillance organisms will be recorded as described below (Recurrent and Persistent Cases).

A case report form (Attachment 1) will be completed for each case meeting the criteria for inclusion described above. The process through which the case report form will be completed differs among the EIP sites but will primarily consist of review of the available medical records. The methods used by each EIP site will be detailed in writing and shared with CDC to ensure comparability of data collection among EIP sites. Any problems identified with data collection methods should be promptly identified and changes implemented and documented appropriately; the CDC HAIC MuGSI Surveillance Coordinator will be notified of any changes in data collection methods.

To assure complete, timely reporting and collection of isolates (before they are discarded by the laboratories), contact with microbiology laboratories will be frequent. Each site will establish regular reporting procedures for each laboratory (including laboratories both within and outside the catchment area). This can include receiving computer-generated/electronic line lists, phone calls, and/or paper reports. When a new laboratory is added to surveillance or a laboratory changes reporting practices (e.g. paper to electronic), surveillance personnel will carefully review the computer program and/or process used to generate the line list to ensure that the system will correctly identify cases.

D. Recurrent and Persistent Cases.

Case-patients who have already been assigned a state ID for any carbapenem-resistant *Enterobacteriaceae* species (i.e., *E. coli, K. pneumoniae, K. oxytoca, E. cloacae* complex, *E. aerogenes*) will be reported as a new case if a new culture from a sterile site or urine for that carbapenem-resistant *Enterobacteriaceae* is collected more than 30 days after the last positive culture and a new case report form will be completed. If the culture date is less than 30 days after the initial culture the case will be considered as having persistent disease and this will be indicated on the current case report form (CRF); a new case report form will not be filled out. This occurrence, additionally to be documented on the CRF, will be documented in the MuGSI Case Detection System as a "non-incident" episode (see Data collection, entry and analysis).

The same rules will apply for carbapenem-nonsusceptible *Acinetobacter baumannii* complex. However, patients with a carbapenem-resistant *Enterobacteriaceae* and a carbapenem-nonsusceptible *Acinetobacter* within 30 days of each other would count as two cases provided that each is more than 30 days from anisolate in the same category (i.e., *Enterobacteriacea*e *spp.* or *Acinetobacter baumannii* complex). The current MuGSI Case Detection System (CDS) will classify identified isolates correctly, sites are advised to enter in all isolates, reported to the EIP site, meeting the phenotypic case definitions into the MuGSI CDS so that isolates are correctly classified and the correct epidemiological information is obtained.

E. Data collection, entry and analysis

Data from laboratory line lists and case report forms will be entered into the MuGSI Data Management System (comprised of the MuGSI Case Detection System (CDS) and the MuGSI Case Management System (MuGSI-CM)); CDC will provide these systems to each participating EIP site. The MuGSI Data Management System is an online enterprise SQL-supported database with secure web and data servers at CDC. The MuGSI-CM's surveillance architecture has undergone certification and accreditation by the Office of the CDC Chief Information Security Officer (OCISO) for compliance with current information technology security policies and procedures. The format of the data entry, variables and data coding is standardized across all participating EIP

sites. Site-specific data (including personal identifier) will be saved to a local secure data server for utilization by local EIP staff and will not be transmitted to CDC.

Data analysis will be performed on a routine basis as well as specialized periodic or one time analyses. Primary analyses will evaluate the incidence of carbapenem-resistant *Enterobacteriaceae* and carbapenem-nonsusceptible *Acinetobacter baumannii* complex.

Specialized analysis will include:

- Antimicrobial susceptibility patterns of carbapenem-resistant isolates
- Incidence of specific mechanisms of carbapenem-resistance
- Assessing the contribution of community-onset isolates

All identified cases will be entered into the MuGSI Data Management System within two months of the month in which they were identified (i.e. the month from which the EIP site is notified about the case). Each entered case report form will be expected to be completed no later than 4 months after the month in which they are identified. For example a case that is identified in January should be entered into the data management system by March (and available for view at CDC by April 5th) and the case report from should be completed and entered by May (available for view at CDC by June 5th). All outstanding surveillance cases, from the previous calendar year's surveillance period, should be entered into the data management system by March of the following calendar year. All outstanding case report forms should be completed and entered by the June 5th of the following calendar year.

Each EIP site is encouraged to analyze their individual site data and share findings both with CDC and locally though local networks.

F. Surveillance Evaluation

A laboratory "check in" of *all* clinical laboratories that routinely process specimens from residents of a surveillance area, both within the surveillance area and those outside the catchment area, will be required yearly. Surveillance officers should contact all clinical laboratories to enquire about any changes that might have occurred to their Antibiotic Testing Instrument (including, but not limited to, changes in software of card types or introduction of new technology [e.g. MALDI-TOF MS]), assuming this is the primary method from which cases are being identified from the surveillance laboratory, what breakpoints the laboratory is currently using for Enterobacteriaceae and *Acinetobacter*, current methods for carbapenemase testing (including nucleic acid tests), and if the laboratory is performing any additional confirmatory tests to determine susceptibility to carbapenems. In the case where a surveillance laboratory is not using the MuGSI Antibiotic Testing Instrument queries, the surveillance officer must evaluate, using another method, that the surveillance laboratory is identifying all surveillance cases (e.g. confirmation annually that an ELR message still contains all organisms of interest). The methodology used for this "check in" should be discussed with the CDC MuGSI Surveillance Coordinator.

In addition to the laboratory "check in" every 2-3 years, each site should perform an evaluation of their overall surveillance catchment area to ensure they are capturing all MuGSI cases that could occur in the catchment area residents. This entails systematically assessing the catchment area to ensure that all laboratories that could regularly receive specimens from catchment area residents have been identified and approached about participating in MuGSI surveillance. Suggested methods of assessing the catchment area include use of: a physician survey (including assess urgent care centers or satellite clinics), the dialysis center survey/mapping project, a LTCF survey, a LTACH survey, and a hospital laboratory survey. For example surveys, please contact the CDC MuGSI Surveillance Coordinator. Coordinating this effort with other EIP programs that use

the same catchment area is also recommended.

Lastly guidance on improving data quality is in development with the HAIC Data Validation working group. Additional guidance is forthcoming.

G. Isolate Collection and Evaluation

As part of this surveillance project, carbapenem-resistant *Enterobacteriaceae* from sites will be collected in order to:

1. Better characterize the mechanism of resistance (i.e. carbapenamse production [KPC, NDM, OXA-48] associated with the organisms under surveillance
2. Validate antimicrobial susceptibility results from sites

This will be limited to carbapenem-resistant Enterobacteriaceae including *Klebsiella* species, *E. coli*, and *Enterobacter* species. Isolates will be evaluated using the following process:

1. Antimicrobial susceptibility testing including antimicrobials in the standard CDC panel (will at least include MICs for imipenem, meropenem, and ertapenem) with an MBL screen.
2. Carbapenem-nonsusceptible isolates will be tested using PCR for KPC, NDM and OXA-48
3. Carbapenem-nonsusceptible isolates that are MBL screen positive and NDM negative will undergo PCR for other carbapenemases (i.e. VIM, IMP)
4. As resources permit, isolates might be evaluated by whole genome sequencing

Each participating site will collect up to 120 isolates. Sites should enroll as many laboratories, serving the catchment area (and where it is geographically feasible to acquire isolate from the facility) as necessary to reach the goal of 30 isolates per quarter (beginning February, May, August, and November). These isolates will be submitted to CDC for testing. For more information regarding isolate collection and testing, please see the MuGSI Isolate Protocol.

IV. Project Personnel (subject to change)

Multi-site Gram-Negative Surveillance Initiative Staff:

Colorado: Wendy Bamberg MD, Sarah Jackson Janelle MPH
Georgia: Susan Ray MD, Jesse Jacob MD, Chris Bower MPH, Wendy Baughman MSPH
Maryland: Lucy Wilson MD ScM, Elisabeth Vaeth MPH, Katie Richards MPH
Minnesota: Ruth Lynfield MD, Paula (Snippes) Vagnone MT(ASCP),,, Catherine Lexau PhD MPH RN, Medora Witwer MPH
New Mexico: Joan Baumbach MD MDH MS, Erin Phipps DVM MPH, Nicole Kenslow, MPH, Emily Hancock, MPH, David Selvage, MHS PA-C
New York: Ghinwa Dumyati MD, Gary Holick PhD, Cathy Concannon MPHTennessee: Marion Kainer MD MPH, Daniel Muleta MBBS MPH, William Schaffner MD, Brenda Barnes RN CCRP, Jackie Mounsey RN
Oregon: Zintars Beldavs MPH, Maureen Cassidy MPH

CDC Personnel:

Primary Investigator: Alexander Kallen, MD, MPH

Secondary Investigators: Brandi Limbago, PhD, Maroya Walters, PhD ScM
Project Laboratory Leads: Maria Karlsson, PhD, Uzma Ansari, MS
Surveillance Coordinator: Sandra N. Bulens, MPH
Statistical Support: Yi Mu, PhD

V. Timeline

January 2016 – All participating sites will continue conducting surveillance for CRE and CRAB

VI. Protection of Human Subjects

This protocol has undergone ethical review at CDC and was determined not be to human subject research.

VII. HIPPA Privacy Issues

This surveillance project is considered to be public health disease surveillance under the HIPPA Privacy Rule and therefore is covered by the exception for public health-related activities.

Appendix 1: Data Collection Form

Patient ID: _____ Form Approved OMB No. 0920-0978

DEPARTMENT OF
HEALTH & HUMAN SERVICES
CENTERS FOR DISEASE CONTROL
AND PREVENTION
ATLANTA, GA 30333

2016 Multi-site Gram-Negative Surveillance Initiative (MuGSI)
Healthcare Associated Infection Community Interface (HAIC) Case Report

Patient's Name _____ Phone no. (_____) _____
(Last, First, MI)

Address _____ MRN _____

City _____ State _____ Zip _____ Hospital _____

— Patient identifier information is NOT transmitted to CDC —

1. STATE: ☐☐

2. COUNTY: _____

3. STATE ID: _____

4a. LABORATORY ID WHERE CULTURE IDENTIFIED: _____

4b. FACILITY ID WHERE PATIENT TREATED: _____

5. Where was the patient located on the 4th calendar day prior to the date of initial culture?
- ☐ Private residence
- ☐ LTCF Facility ID: _____
- ☐ LTACH Facility ID: _____
- ☐ Homeless
- ☐ Incarcerated
- ☐ Hospital Inpatient
  Was the patient transferred from this hospital? ☐ Yes ☐ No ☐ Unknown
  Facility ID: _____
- ☐ Other (specify): _____
- ☐ Unknown

6. DATE OF BIRTH: ☐☐/☐☐ ☐☐☐☐

7a. AGE: ☐☐☐

7b. Is age in day/mo/yr? ☐ Days ☐ Mos ☐ Yrs

8a. SEX:
- ☐ Male
- ☐ Female

8b. ETHNIC ORIGIN:
- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown

8c. RACE (Check all that apply):
- ☐ White
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Unknown

8d. WEIGHT: _____lbs _____oz OR _____kg ☐ Unknown

8e. HEIGHT: _____ft _____in OR _____cm ☐ Unknown

8f. BMI (Record only if ht and/or wt is not available): _____ ☐ Unknown

9. WAS PATIENT HOSPITALIZED AT THE TIME OF, OR WITHIN 30 CALENDAR DAYS AFTER, INITIAL CULTURE?
☐ Yes ☐ No ☐ Unknown

If yes: Date of admission ☐☐/☐☐/☐☐☐☐ **Date of discharge** ☐☐/☐☐/☐☐☐☐

10a. DATE OF INITIAL CULTURE ☐☐/☐☐/☐☐☐☐

10b. LOCATION OF CULTURE COLLECTION:

Hospital Inpatient	Outpatient	
☐ ICU	☐ Clinic/Doctors Office	☐ LTCF Facility ID: _____
☐ Surgery/OR	☐ Surgery	☐ LTACH Facility ID: _____
☐ Radiology	☐ Other Outpatient	☐ Autopsy
☐ Other Unit	☐ Dialysis Center	☐ Unknown
☐ Emergency Room	☐ Observational Unit/Clinical Decision Unit	

11a. Was the patient in the ICU in the 7 days *prior* to their initial culture?
☐ Yes ☐ No ☐ Unknown

11b. Was the patient in the ICU on the date of or in the 7 days *after* the initial culture?
☐ Yes ☐ No ☐ Unknown

12. PATIENT OUTCOME: ☐ Survived ☐ Died ☐ Unknown

If survived, transferred to:
- ☐ Private residence
- ☐ LTCF Facility ID: _____
- ☐ LTACH Facility ID: _____
- ☐ Unknown
- ☐ Other (specify): _____

If died, date of death: ☐☐/☐☐/☐☐☐☐

Was the organism cultured from a normally sterile site or urine, < calendar day 7 before death?
☐ Yes ☐ No ☐ Unknown

13a. ORGANISM ISOLATED FROM INITIAL NORMALLY STERILE SITE OR URINE:
Carbapenem-resistant:
- ☐ *Enterobacteriaceae (CRE):*
  - ☐ *E. coli*
  - ☐ *Enterobacter cloacae*
  - ☐ *Enterobacter aerogenes*
  - ☐ *Klebsiella pneumoniae*
  - ☐ *Klebsiella oxytoca*
- ☐ *A. baumannii (CRAB)*

13b. Was the initial culture polymicrobial?
☐ Yes ☐ No ☐ Unknown

13c. Was the initial isolate tested for carbapenemase?
☐ Yes
☐ No
☐ Labortory Not Testing
☐ Unknown

If yes, what testing method was used (check all that apply):
☐ Automated Molecular Assay (specify): _____
☐ CarbaNP ☐ E Test
☐ PCR ☐ Modified Hodge Test (MHT)
☐ Other (specify): _____
☐ Unknown

If tested, what was the testing result?
☐ Positive
☐ Negative
☐ Indeterminate
☐ Unknown

14. INITIAL CULTURE SITE:
☐ Blood ☐ Joint/synovial fluid
☐ CSF ☐ Bone
☐ Pleural fluid ☐ Urine
☐ Peritoneal fluid ☐ Other normally sterile site
☐ Pericardial fluid _____

URINE Cultures ONLY:
14a. How was the urine collected?
☐ Clean Catch
☐ In and Out Catheter
☐ Indwelling Catheter
☐ Condom Catheter
☐ Other: _____
☐ Unknown

URINE Cultures ONLY:
14b. Record the colony count for the organism indicated in Q13a:
_____
☐ Unknown

URINE Cultures ONLY:
14c. Signs and Symptoms associated with urine culture. Please indicate if any of the following symptoms were reported during the 5 day time period including the 2 calendar days before and the 2 calendar days after the day of initial culture:
☐ Altered mental status
☐ Acute pain, swelling or tenderness of the testes, epididymis or prostate
☐ Chills
☐ Cloudy
☐ Costovertebral angle pain or tenderness
☐ Dysuria
☐ Fever
☐ Frequency
☐ Hematuria
☐ Incontinence
☐ Leukocytosis
☐ Malodorous
☐ Purulent discharge
☐ Pyuria
☐ Retention
☐ Suprapubic tenderness
☐ Unspecified abdominal pain/tenderness
☐ Urgency
☐ Unknown
☐ Other (specify): _____
☐ None

15. Was the same organism (Q13a) cultured from a different sterile site or urine in the 30 days after the date of initial culture (of this current episode)?
☐ Yes ☐ No ☐ Unknown

If yes, source (check all that apply):
☐ Blood ☐ Joint/synovial fluid
☐ CSF ☐ Bone
☐ Pleural fluid ☐ Urine
☐ Peritoneal fluid ☐ Other normally sterile site _____
☐ Pericardial fluid

16. *Enterobacteriaceae* ONLY:
Were cultures of sterile site(s) or urine positive in the 30 days *prior* to the date of initial culture, for a DIFFERENT organism (Q13a)?
☐ Yes ☐ No ☐ Unknown ☐ NA

If yes, source (check all that apply):
☐ Blood ☐ Joint/synovial fluid
☐ CSF ☐ Bone
☐ Pleural fluid ☐ Urine
☐ Peritoneal fluid ☐ Other normally sterile site _____
☐ Pericardial fluid

If yes, indicate organism type and associated State ID for the incident closest to the date of initial culture:

Organism	State ID
E. coli	
Enterobacter cloacae	
Enterobacter aerogenes	
Klebsiella pneumoniae	
Klebsiella oxytoca	

16a. *A. baumannii* Cultures ONLY:
Were cultures of OTHER sterile site(s) or urine positive in the 30 days *prior* to the date of initial culture, for another *A. baumannii*?
☐ Yes ☐ No ☐ Unknown ☐ NA

If yes, source (check all that apply):
☐ Blood ☐ Joint/synovial fluid
☐ CSF ☐ Bone
☐ Pleural fluid ☐ Urine
☐ Peritoneal fluid ☐ Other normally sterile site _____
☐ Pericardial fluid

If yes, State ID for the organism closest to the date of initial culture:
_____

17a. Was this patient positive for the SAME organism in the *year prior* to the date of the initial culture (Q10a):
☐ Yes ☐ No (GO TO Q17c) ☐ Unknown (GO TO Q17c)

17b. If yes, specify date of culture and State ID for the first positive culture in the *year prior*:
☐☐/☐☐/☐☐☐☐
State ID: _____

17c. *Enterobacteriaceae* ONLY:
Was this patient positive for a MuGSI *Enterobacteriaceae* in the *year prior* to the date of initial culture (Q10a)?
☐ Yes ☐ No (GO TO Q18) ☐ Unknown (GO TO Q18) ☐ NA (GO TO Q18)

17d. If yes, specify organism, date of culture and State ID for the first positive *Enterobacteriaceae* culture in the *year prior* to the date of initial culture (Q10a):

Carbapenem-resistant *Enterobacteriaceae* (CRE):

- ☐ *E. coli*
- ☐ *Enterobacter cloacae*
- ☐ *Enterobacter aerogenes*
- ☐ *Klebsiella pneumoniae*
- ☐ *Klebsiella oxytoca*

Date of Culture: ☐☐/☐☐/☐☐☐☐

State ID: _____

18. Susceptibility Results: (please complete the table below based on the information found in the indicated data source). Shaded antibiotics are required to have the MIC entered into the MuGSI-CM system, if available.

Data Source	Medical Record		Microscan		Vitek		Phoenix		Kirby-Bauer		E-test	
Antibiotic	**MIC**	**Interp**	**MIC**	**Interp**	**MIC**	**Interp**	**MIC**	**Interp**	**Zone Diam**	**Interp**	**MIC**	**Interp**
Amikacin												
Amoxicillin/Clavulanate												
Ampicillin												
Ampicillin/Sulbactam												
Aztreonam												
Cefazolin												
CEFEPIME												
CEFOTAXIME												
CEFTAZIDIME												
CEFTRIAXONE												
Cephalothin												
Ciprofloxacin												
COLISTIN												
DORIPENEM												
ERTAPENEM												
Gentamicin												
IMIPENEM												
Levofloxacin												
MEROPENEM												
Moxifloxacin												
Nitrofurantoin												
Piperacillin/Tazobactam												
POLYMYXIN B												
TIGECYCLINE												
Tobramycin												
Trimethoprim-sulfamethoxazole												

19. TYPES OF INFECTION ASSOCIATED WITH CULTURE(S) *(check all that apply)*: ☐ **None** ☐ **Unknown**

- ☐ Abscess, not skin
- ☐ AV fistula/graft infection
- ☐ Bacteremia
- ☐ Bursitis
- ☐ Catheter site infection (CVC)
- ☐ Cellulitis
- ☐ Chronic ulcer/wound (not decubitus)
- ☐ Decubitus/pressure ulcer
- ☐ Empyema
- ☐ Endocarditis
- ☐ Meningitis
- ☐ Osteomyelitis
- ☐ Peritonitis
- ☐ Pneumonia
- ☐ Pyelonephritis
- ☐ Septic arthritis
- ☐ Septic emboli
- ☐ Septic shock
- ☐ Skin abscess
- ☐ Surgical incision infection
- ☐ Surgical site infection (internal)
- ☐ Traumatic wound
- ☐ Urinary tract infection
- ☐ Other _____

20. UNDERLYING CONDITIONS *(check all that apply)*: ☐ **None** ☐ **Unknown**

- ☐ AIDS/CD4 count < 200
- ☐ Alcohol abuse
- ☐ Chronic Liver Disease
- ☐ Chronic Pulmonary Disease
- ☐ Chronic Renal Insufficiency
- ☐ Chronic Skin Breakdown
- ☐ Congestive Heart Failure
- ☐ Connective Tissue Disease
- ☐ Current Smoker
- ☐ CVA/Stroke
- ☐ Cystic Fibrosis
- ☐ Decubitus/Pressure Ulcer
- ☐ Dementia/Chronic Cognitive Deficit
- ☐ Diabetes
- ☐ Hemiplegia/Paraplegia
- ☐ HIV
- ☐ Hematologic Malignancy
- ☐ IVDU
- ☐ Liver failure
- ☐ Metastatic Solid Tumor
- ☐ Myocardial Infarct
- ☐ Neurological Problems
- ☐ Obesity or Morbid Obesity
- ☐ Peptic Ulcer Disease
- ☐ Peripheral Vascular Disease (PVD)
- ☐ Premature Birth
- ☐ Solid Tumor (non metastatic)
- ☐ Spina bifida
- ☐ Transplant Recipient
- ☐ Urinary Tract Problems/Abnormalities

21. RISK FACTORS OF INTEREST ***(check all that apply)*****:** ☐ **None** ☐ **Unknown**

☐ Culture collected > calendar day 3 after hospital admission

☐ Hospitalized within year before date of initial culture:

If yes, enter mo/yr ☐☐/☐☐☐☐ OR ☐ Unknown

If known, prior hospital ID:_____

☐ Surgery within year before date of initial culture

☐ Current chronic dialysis: ☐ Peritoneal ☐ Hemodialysis ☐ Unknown

Hemodialysis Access: ☐ AV fistula/graft ☐ CVC ☐ Unknown

☐ Residence in LTCF within year before date of initial culture

If known, facility ID: _____

☐ Admitted to a LTACH within year before initial culture date

If known, facility ID: _____

☐ Central venous catheter in place on the day of culture (up to time of culture) or at any time in the 2 calendar days prior to the date of culture

☐ Urinary catheter in place on the day of culture (up to time of culture) or at any time in the 2 calendar days prior to the date of culture

If checked, indicate all that apply:

☐ Indwelling Urethral Catheter ☐ Suprapubic Catheter

☐ Condom Catheter ☐ Other: _____

☐ Any OTHER indwelling device in place on the day of culture (up to time of culture) or at any time in the 2 calendar days prior to the date of culture

If checked, indicate all that apply:

☐ ET/NT Tube ☐ Gastrostomy Tube ☐ NG Tube

☐ Tracheostomy ☐ Nephrostomy Tube ☐ Other: _____

☐ Patient traveled internationally in the two months prior to the date of initial culture.

Country:_____, _____, _____

☐ Patient was hospitalized while visiting country (ies) listed above

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22. Was case first identified through audit? ☐ Yes ☐ No ☐ Unknown	**23. CRF status:** ☐ Complete ☐ Pending ☐ Chart unavailable	**24. Date reported to EIP site:** ☐☐/☐☐/☐☐☐☐	**25. SO initials:** _____

26. Comments:

_____

_____

_____

_____

_____