

BEFORE THE INDIANA STATE DEPARTMENT OF HEALTH

**AN ADMINISTRATIVE RULES HEARING
LSA DOCUMENT #15-39**

HEARING OFFICER REPORT

This matter came before the duly appointed Hearing Officer, Manda Clevenger, on the 6th day of July, 2015, at 10:00 a.m., at the Indiana State Department of Health (ISDH), 2 North Meridian Street, Indianapolis, Indiana.

Notice of time and place of the hearing was given as provided by law by publishing on June 10, 2015, in the *Indianapolis Star* and the *Indiana Register*. Proof of publication of this notice has been received by the ISDH and the notice and proof are hereby incorporated into the record of this cause by reference and placed in the official files of the ISDH.

There were no oral statements. No written statements were submitted during the public hearing.

No one appeared to testify at the public hearing and no written comments were received at the public hearing. The record was left open until July 17, 2015.

WRITTEN STATEMENTS SUBMITTED DURING THE PUBLIC COMMENT PERIOD

Susan M. Kraska, RN, CIC
2015 APIC Indiana President
Association for Professionals in Infection Control and Epidemiology (APIC)

Ms. Kraska's comments are attached and incorporated by reference as **Exhibit 1**.

Mary Stepney, MT (ASCP)SM
Microbiology Specialist
The Medical Foundation – South Bend

Ms. Stepney's comments are attached and incorporated by reference as **Exhibit 2**.

The ISDH laboratory sent out an online survey to their list of Indiana laboratories in order to receive comments on a particular disease listed in the new rule (Carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE)). The ISDH laboratory received forty-seven hits to their online survey with twenty-seven (27) people completing the survey in its entirety. The twenty-seven (27) complete responses have been included in this hearing officer report.

**WRITTEN STATEMENTS SUBMITTED TO THE ONLINE SURVEY CONDUCTED
BY THE ISDH LABORATORIES**

Linda Rutherford
Reid Hospital

Ms. Rutherford's comments are attached and incorporated by reference as **Exhibit 3.**

Rhonda Brune
Adams Memorial Hospital

Ms. Brune's comments are attached and incorporated by reference as **Exhibit 4.**

Claudia Dant
Gibson General Hospital

Ms. Dant's comments are attached and incorporated by reference as **Exhibit 5.**

Julie L. Oliver
Henry County Hospital

Ms. Oliver's comments are attached and incorporated by reference as **Exhibit 6.**

Julie H. Voirol
DeKalb Health Laboratory

Ms. Voirol's comments are attached and incorporated by reference as **Exhibit 7.**

Carol Yager
Fayette Regional

Ms. Yager's comments are attached and incorporated by reference as **Exhibit 8.**

Audie Whitaker
Community Hospital Anderson

Mr. Whitaker's comments are attached and incorporated by reference as **Exhibit 9.**

Donna Sexton
St. Vincent Dunn

Ms. Sexton's comments are attached and incorporated by reference as **Exhibit 10.**

Jaime Redkey
St. Vincent Hospital 86th Street

Ms. Redkey's comments are attached and incorporated by reference as **Exhibit 11**.

Cheryl R. Houin
St. Joseph Regional Medical Center

Ms. Houin's comments are attached and incorporated by reference as **Exhibit 12**.

April Abbott
Deaconess Hospital

Ms. Abbott's comments are attached and incorporated by reference as **Exhibit 13**.

Pravin H. Patel, Ph.D.
Community Health Care System Munster

Mr. Patel's comments are attached and incorporated by reference as **Exhibit 14**.

Mary Schoaff MT (ASCP) ICP
Lutheran Hospital Fort Wayne

Ms. Schoaff's comments are attached and incorporated by reference as **Exhibit 15**.

Marijo Roiko
IU Health

Ms. Roiko's comments are attached and incorporated by reference as **Exhibit 16**.

Theresa Davison
Decatur County Memorial Hospital

Ms. Davison's comments are attached and incorporated by reference as **Exhibit 17**.

Mary Stepney
The Medical Foundation South Bend

Ms. Stepney's comments are attached and incorporated by reference as **Exhibit 18**.

Angie Hughes
Community Hospital of Bremen

Ms. Hughes' comments are attached and incorporated by reference as **Exhibit 19**.

Claire Roembke
Franciscan St. Francis Health

Ms. Roembke's comments are attached and incorporated by reference as **Exhibit 20**.

Eric Surface
Woodlawn Hospital

Mr. Surface's comments are attached and incorporated by reference as **Exhibit 21**.

John Sawatsky
IU Health Goshen Hospital

Mr. Sawatsky's comments are attached and incorporated by reference as **Exhibit 22**.

Leann Lawrence
Clark Memorial Hospital

Ms. Lawrence's comments are attached and incorporated by reference as **Exhibit 23**.

Mary P. McDonald
Terre Haute Regional Hospital

Ms. McDonald's comments are attached and incorporated by reference as **Exhibit 24**.

Sherry Robbins
IU Health Goshen

Ms. Robbins' comments are attached and incorporated by reference as **Exhibit 25**.

Jerry Wheatley
Memorial Hospital and Health Care Center Jasper

Mr. Wheatley's comments are attached and incorporated by reference as **Exhibit 26**.

Jean Knickerbocker
IUH La Porte Hospital

Jean Knickerbocker's comments are attached and incorporated by reference as **Exhibit 27**.

Vera Concho
Alverno Clinical Laboratory

Ms. Concho's comments are attached and incorporated by reference as **Exhibit 28**.

Bonny Lewis Van
Marion County Public Health Department

Ms. Lewis Van's comments are attached and incorporated by reference as **Exhibit 29**.

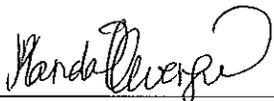
The following comment was received after the closure of the public comment period.

WRITTEN STATEMENT SUBMITTED AFTER THE END OF THE PUBLIC COMMENT PERIOD

Angela M. Toth
Associate, The Corydon Group

Ms. Toth's comments were received after the end of the public comment period, but are attached and incorporated by reference as **Exhibit 30**.

Dated at Indianapolis, Indiana this 9th day of September, 2015.



Manda Clevenger
Hearing Officer

Clevenger, Manda

From: Billman, Amanda
Sent: Thursday, June 25, 2015 10:15 AM
To: Clevenger, Manda
Subject: FW: APIC Indiana Comments on Final Rule
Attachments: Final Response letter to A Billman for July Hearing 2015 410 IAC 1 2-5.doc

Hey Manda,

See the attached document. I think Susan may have sent it to me because I put my e-mail address on the e-mail a few months back when we were trying to compile comments from LHDs and other partners.

Let me know if there is anything you may need from us.

Thanks!

~Mandy

From: Susan Kraska [<mailto:SKraska@beaconhealthsystem.org>]
Sent: Wednesday, June 24, 2015 4:40 PM.
To: Billman, Amanda
Cc: Pontones, Pamela
Subject: APIC Indiana Comments on Final Rule

Amanda,
I hope I have the correct email address for you? On behalf of APIC Indiana I wanted to make sure we submitted for the record our support of the changes to the 410 IAC Rule.

Best regards,
Susan

Susan Kraska, RN, CIC
Infection Prevention
Memorial Hospital of South Bend
615 North Michigan Street
South Bend, In 46601
574-647-3471 office
574-647-7328 fax
574-236-0531 pager
skraska@beaconhealthsystem.org
Don't Forget To Wash Your Hands!



Exhibit
#1



Ms. Amanda Billman
Surveillance and Investigations Division
Indiana State Department of Health
2 N. Meridian Street
Indianapolis, IN 46024

Re: Revision of Indiana State Department of Health 401 IAC 1-2.3 the Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories; hearing for proposed rule to add 410 IAC 1-2.5.

Dear Ms. Billman,

The Indiana Chapter of the Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide input for the revision of the Communicable Disease Reporting Rule and the inclusion of 410 IAC 1-2.5-86 Carbapenemase Producing-Carbapenem Resistant Enterobacteriaceae (CP-CRE) and the specific control measures recommended.

The Notice of Intent to Adopt a Rule was published in the Indiana Register on February 11, 2015 with the recommendation for CP-CRE reporting and specific control measures receiving preliminary approval for adoption of amendments and inclusion in the 410 IAC 1-2.5 proposed rule.

The revised Communicable Disease Rule will be presented at a public hearing dated July 6th, 2015 at 10:00 a. m. (LSA Document #15-39).

APIC supports adoption of the recommended rule 410 IAC 1-2.5-86 and the inclusion to the proposed revision of the Communicable Disease Reporting Rule 410 IAC 1.2-5.

We would like to thank ISDH for the opportunity to work with and provide assistance with this revision, and look forward to continuing these efforts to advance infection prevention and delivery of quality healthcare.

Sincerely,

Susan Kraska, RN, CIC

Susan M. Kraska, RN, CIC
2015 APIC Indiana President

Clevenger, Manda

From: Lovchik, Judith
Sent: Friday, July 03, 2015 8:28 PM
To: Clevenger, Manda
Subject: Fw: July 2, 2015 - Indiana Antibiotic Resistance Advisory Committee Agenda

She wants to make this a public comment.

From: Stepney, Mary <mstepney@sbfm.org>
Sent: Friday, July 3, 2015 12:46 PM
To: Lovchik, Judith
Cc: Matheson, Shelley; Madlem, Jyl
Subject: RE: July 2, 2015 - Indiana Antibiotic Resistance Advisory Committee Agenda

Feel free to submit. Thanks.

From: Lovchik, Judith [mailto:JLovchik@isdh.IN.gov]
Sent: Thursday, July 02, 2015 8:48 PM
To: Stepney, Mary
Cc: Matheson, Shelley; Madlem, Jyl
Subject: Re: July 2, 2015 - Indiana Antibiotic Resistance Advisory Committee Agenda

Thank you for making these suggestions, Mary. Did you know that the new rule for Communicable Disease Reporting is having public discussion/input on Monday at 10am at the 2N Meridian building in Indianapolis, 3rd floor? I know you probably can't make it, and I'm not sure there will be call in, but any written comments can be included. So I could submit these, or you could write something more formal.

We will discuss your suggestions and points and get back to you sometime soon, hopefully next week.

Judy

From: Stepney, Mary <mstepney@sbfm.org>
Sent: Thursday, July 2, 2015 8:05 PM
To: Lovchik, Judith
Cc: Matheson, Shelley; Madlem, Jyl
Subject: RE: July 2, 2015 - Indiana Antibiotic Resistance Advisory Committee Agenda

Great meeting! I did not want to extend the discussion with lab issues, but to Judy's question about labs knowing what to submit to ISDH, this is my take:

1. Until all commercial MIC panels and systems are updated to the 2010 breakpoints, one cannot be sure of what is being used in each micro lab
2. The presentation today was a good overview of the complexities of MDROs. The take-home message for me is that Infection Preventionists need to be aware of the mechanisms of resistance. I have heard IDs say the same thing, that mechanisms of resistance are for the IPs. However, the only mechanism that we report at the Medical Foundation is for carbapenemase producers (Y/N). IPs may institute contact precautions for infection prevention due to the MIC but not because of a reported mechanism of resistance. We can explain mechanisms as often as asked, but expecting nursing to remember along with everything else they have to do, for me, is not very realistic.

How much working knowledge of resistance mechanisms does Public Health expect of the community hospital IPs, particularly if their lab is unable to test?

3. Please demand a consensus on acronyms for what is reportable and sent to ISDH for epidemiology, before it becomes law. Once acronyms are used people forget what they mean and as Dr. Snyder mentioned, use them incorrectly. If it is all about the mechanism, then "CPO" takes the focus off resistance.
4. A suggestion to clarify for labs what isolates to submit, since the Hodge test is subjective and few labs will be adding cost with the Carba NP test:
Just looking at our ISDH MDRO reports (excluding all imipenem results and the meropenem=I), the ertapenem=R and meropenem=R isolates we submitted were all CREs but NOT carbapenemase producers. If we used that criteria for isolate submission, our lab would have sent you 46% fewer isolates in the past 8 months; that is assuming that all KPCs are resistant to both ertapenem and meropenem.

Hope this helps. Thanks for all that you do.

Have a great holiday weekend,

Mary

Mary Stepney, MT(ASCP)SM
Microbiology Specialist
The Medical Foundation
530 N. Lafayette
South Bend, IN 46601
(574)234-4176 ext. 1304
(574)236-6636 fax



CP-CRO Survey for CDR Public Comment

#5



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 3:12:39 PM
Last Modified: Wednesday, July 08, 2015 3:20:37 PM
Time Spent: 00:07:58
IP Address: 12.161.105.254

PAGE 2

Q1: Please enter the following demographic information:

Name	Linda Rutherford
Facility	Reid Hospital
Address	1100 Reid Parkway
City/Town	Richmond
State/Province	IN
ZIP/Postal Code	47374
Email Address	Linda.Rutherford@Reidhospital.org
Phone Number	765-983-3234

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

It is fine.

Q3: What changes and/or alterations would you suggest for the current definition?

Typically we also consider the resistance to third generation cephalosporins

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

We currently test for CRE

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

We currently test for CRE

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

Imipenem, Meropenem, Etp

Exhibit
#3

CP-CRO Survey for CDR Public Comment

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

Cost of sending the isolates to ISDH and the process which is now being utilized. It is difficult to reach anyone to provide an assigned number prior to sending the isolate.

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

CP-CRO Survey for CDR Public Comment

#7



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 3:02:31 PM
Last Modified: Wednesday, July 08, 2015 3:21:24 PM
Time Spent: 00:18:53
IP Address: 69.88.193.194

PAGE 2

Q1: Please enter the following demographic information:

Name	Rhonda Brune
Facility	Adams Memorial Hospital
Address	1100 Mercer Avenue
City/Town	Decatur
State/Province	IN
ZIP/Postal Code	46733
Email Address	rbrune@adamshealthnetwork.org
Phone Number	260-724-2145 ext 1600

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

The definition provided is only for CRE--not CRO. CRO would include non-Enterobacteriaceae isolates.

Q3: What changes and/or alterations would you suggest for the current definition?

If you would like ALL carbapenem resistant isolates--not just CRE-- sent for further evaluation, the definition should be changed to reflect that.

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

We send suspicious isolates out to a reference laboratory for confirmatory testing.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

More rapid confirmation.

Exhibit
#4

CP-CRO Survey for CDR Public Comment

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

Imipenem
Meropenem

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

xx

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#8



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 3:13:49 PM
Last Modified: Wednesday, July 08, 2015 3:26:04 PM
Time Spent: 00:12:14
IP Address: 208.103.1.136

PAGE 2

Q1: Please enter the following demographic information:

Name	Claudia Dant
Facility	Gibson General Hospital
Address	1808 Sherman Drive
City/Town	Princeton
State/Province	IN
ZIP/Postal Code	47670
Email Address	cdant@gibsongeneral.com
Phone Number	812-385-9292

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

we do not currently do a phenotypic test in-house, should we delay submission until getting confirmation test from our reference lab?

Q3: What changes and/or alterations would you suggest for the current definition?

suggest alternative for Modified Hodge test or send isolate without confirmation by phenotypic method.

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

it is not cost effective to do PCR or CarbaNP testing inhouse. We would need more training to do the modified Hodge test. Not being done now.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

we have had no isolates flagged for CRE in the 18 months we have been monitoring. Not sure it is economically feasible to do modified Hodge test.

Exhibit
#5

CP-CRO Survey for CDR Public Comment

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

2--ertapenem and meropenem

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:
when will this rule to final?

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#9



COMPLETE

Collector: Web Link 1 (Web Link)
 Started: Wednesday, July 08, 2015 3:05:43 PM
 Last Modified: Wednesday, July 08, 2015 3:29:33 PM
 Time Spent: 00:23:50
 IP Address: 74.112.113.12

PAGE 2

Q1: Please enter the following demographic information:

Name	Julie L Oliver
Facility	Henry County Hospital
Address	1000 N 16th St.
City/Town	New Castle
State/Province	IN Indiana
ZIP/Postal Code	47362
Email Address	joliver@hcmhcares.org
Phone Number	7655211147

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

We do not do Carbapenemase producing tests. If the carbapenem MICs ≥ 2 "AND" if R to any of the 3rd or 4th generation cephalosporins, we call "Possible CRE organism" and send out to reference lab for further testing. Your criteria does not mention cephalosporin sensitivity.

Q3: What changes and/or alterations would you suggest for the current definition?

Do we need to consider the sensitivity to the cephalosporins or just go by the carbapenem MICs?

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

As of this time, we do not do this confirmatory testing. We send out to reference lab and they send on to ISDH if positive. We could perform testing if required. However, we have so few isolates that we feel that it wouldn't be cost-effective for us at this time.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

We would need a test that uses reagents that have extremely long out dates due to the few numbers of organisms that we would perform this testing on. And it would need to be "time friendly" to perform due to only having one micro tech in the lab.



CP-CRO Survey for CDR Public Comment

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

We screen for only L+ organisms. We have had only about 4 positive CRE organisms since a little over a year. We use the Vitek 2 for AST testing.

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

I would love to have some updated information about CRE testing and screening. Perhaps some information on the different ways to test for carbapenemase production as well.

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

CP-CRO Survey for CDR Public Comment

#10



INCOMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 3:04:01 PM
Last Modified: Wednesday, July 08, 2015 3:32:44 PM
Time Spent: 00:28:43
IP Address: 208.80.28.139

PAGE 2

Q1: Please enter the following demographic information:

Name	Julie H. Voirol
Facility	DeKalb Health Laboratory
Address	1316 E. Seventh Street
City/Town	Auburn
State/Province	IN
ZIP/Postal Code	46706
Email Address	jvoirol@dekalbhealth.com
Phone Number	2609202613

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

Please define whether you are only looking at Enterobacteriaceae or all Carbapenem Resistant Organisms. We have isolated about 80 carbapenem resistant Pseudomonases this year. We have had 19 Klebsiella and E coli isolates with carbapenem MIC =>2 (some repeats) .We don't do phenotypic tests at this time.

Q3: What changes and/or alterations would you suggest for the current definition?

see #2. Please make it clear whether you will use additional criteria like the current ISDH CRE isolate submission guidelines that also require the organism to be resistant to 3rd generation cephalosporins. Are there limitations to potential CRE other than E coli and Klebsiella (such as Morganella, Proteus, Providencia) that may have intrinsic imipenem nonsusceptibility?

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

We don't have that capacity at this time.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

We are next to a long term respiratory care nursing home that will be expanding. We are willing to do whatever ISDH determines is the best for surviellance.

Exhibit
#7

CP-CRO Survey for CDR Public Comment

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

Imipenem, Doripenem, Ertapenem

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

If this rule change happens, I hope that the State is willing to staff ISDH with enough trained laboratorians to handle the large influx of work in a timely manner.

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

CP-CRO Survey for CDR Public Comment

#11  **INCOMPLETE**
Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 3:11:47 PM
Last Modified: Wednesday, July 08, 2015 3:32:56 PM
Time Spent: 00:21:09
IP Address: 69.160.157.66

PAGE 2

Q1: Please enter the following demographic information:

Name	Carol Yager
Facility	Fayette Regional
Address	1941 Virginia Ave
City/Town	Connersville
State/Province	IN
ZIP/Postal Code	47331
Email Address	caroly@fayetteregional.org
Phone Number	765-827-7789

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

Don't like the phenotypic test included

Q3: What changes and/or alterations would you suggest for the current definition?

What happened to resistant to all the 3rd gen cephalosporins and for non Kleb or E coli to be resistant to carbapenem other than imipenem

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

As a small lab, this is burdensome. Would not work for us.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

Our lab can screen and then send for confirmation. We are seeing very, very few CREs. At this time, our process works. The drawback is waiting for confirmation.

Exhibit #8

CP-CRO Survey for CDR Public Comment

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

ertapenem, imipenem, meropenem

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

Allow small labs to screen as currently-don't impose add'l testing (Hodge) that requires labor and supplies and is not frequently needed. ISDH should accept isolates screened to level lab is capable of.

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#12



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 3:32:41 PM
Last Modified: Wednesday, July 08, 2015 3:51:08 PM
Time Spent: 00:18:27
IP Address: 198.140.195.107

PAGE 2

Q1: Please enter the following demographic information:

Name	Audie Whitaker
Facility	Community Hospital Anderson
Address	1515 N. Madison Ave.
City/Town	Anderson
State/Province	IN
ZIP/Postal Code	46011
Email Address	audie.whitaker@ecommunity.com
Phone Number	765-298-5172

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

It's confusing. Organisms can meet the criteria above and still not have the gene for CRE. The pattern can be seen in AMP-c. It Confuses us when the ISDH reports back that an organism is negative. We have had specimens that tested positive on Hodge test, but turned out to not be CRE, but were Amp-c.

Q3: What changes and/or alterations would you suggest for the current definition?

Don't call it CRE unless it is positive for one of the genes that specifically codes for carbapenamases, such as KPC, NMD-1.

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

We can do Hodge testing, but at this time do not do CarbaNP, or Carba PCR.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

Better definition and clarification of what a CRE is and how to test for it.

Exhibit
#9

CP-CRO Survey for CDR Public Comment

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

Imipenem, meropenem, and ertapenem on all GNB's

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

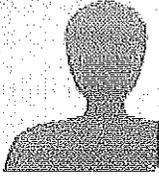
One of the confusing things for us is whether to isolate a patient if they fit the susceptibility pattern but do not have the gene for Carbapenemase production.

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

CP-CRO Survey for CDR Public Comment

#13



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 3:48:38 PM
Last Modified: Wednesday, July 08, 2015 3:51:59 PM
Time Spent: 00:03:21
IP Address: 198.186.64.22

PAGE 2

Q1: Please enter the following demographic information:

Name	Donna Sexton
Facility	St. Vincent Dunn
Address	1600 23rd Street
City/Town	Bedford
State/Province	IN
ZIP/Postal Code	47421
Email Address	dxsexton@stvincent.org
Phone Number	812.276.1301

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

Quote 1: language appears confusing.

Q3: What changes and/or alterations would you suggest for the current definition?

NA

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

Sent out to MACL

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

Immediate notification

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

NA

Exhibit
#10

CP-CRO Survey for CDR Public Comment

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

-

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#14



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 3:52:23 PM
Last Modified: Wednesday, July 08, 2015 3:56:07 PM
Time Spent: 00:03:44
IP Address: 198.186.64.22

PAGE 2

Q1: Please enter the following demographic information:

Name	Jaime Redkey
Facility	St. Vincent Hospital
Address	2001 W 86th Street
City/Town	Indianapolis
State/Province	IN
ZIP/Postal Code	46260
Email Address	jeredkey@stvincent.org
Phone Number	317-338-3685

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

I believe it matches the CDC definition, so it is fine

Q3: What changes and/or alterations would you suggest for the current definition?

Make sure it matches the CDC definition

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

Not sure; we have a contracted lab- MACL; I believe they should be able to

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

None

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

not sure

Exhibit
#11

CP-CRO Survey for CDR Public Comment

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

This should be sent to outside labs as well

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#15



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 3:43:03 PM
Last Modified: Wednesday, July 08, 2015 3:57:26 PM
Time Spent: 00:14:23
IP Address: 67.236.51.114

PAGE 2

Q1: Please enter the following demographic information:

Name	Cheryl R Houin
Facility	St Joseph Regional Medical Center
Address	1915 Lake Avenue
City/Town	Plymouth
State/Province	IN
ZIP/Postal Code	46563
Email Address	houinr@sjrhc.com
Phone Number	5749484279

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

How does MicroScan's KPC screening algorithm fit in?

Q3: What changes and/or alterations would you suggest for the current definition?

Give us five business days instead of three.

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

For my staff, the CarbaNP would work best.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

Rapid and simple phenotypic test.

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

Imipenem, Doripenem, Meropenem, and Ertapenem

Exhibit
#12

CP-CRO Survey for CDR Public Comment

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

x

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#17 **COMPLETE**



Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 3:33:08 PM
Last Modified: Wednesday, July 08, 2015 4:30:46 PM
Time Spent: 00:57:38
IP Address: 12.204.69.8

PAGE 2

Q1: Please enter the following demographic information:

Name	April Abbott
Facility	Deaconess Hospital
Address	600 Mary St.
City/Town	Evansville
State/Province	IN
ZIP/Postal Code	47747
Email Address	April.Abbott@Deaconess.com
Phone Number	812-450-2491

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

I suspect that many laboratories in Indiana do not possess the ability and/or expertise to correctly identify carbapenemases. What isolates are these laboratories supposed to send? Few laboratories currently perform Carba NP and the Modified Hodge has unacceptable specificity and specificity (specifically with NDM). Some laboratories may use molecular methods (e.g. Verigene) instead of phenotypic ones and would not meet this definition. An isolate with an ertapenem zone diameter of 22mm is susceptible.

Q3: What changes and/or alterations would you suggest for the current definition?

I am not sure I understand the goal of this requirement. If it is to capture epidemiological information about circulating strains then this will miss a significant amount of isolates, but I understand it is a fine balance so that every Enterobacter with a derepressed AmpC + porin mutation is not sent. Again, I would assume that a large number of laboratories stop with CRE and do not perform testing to identify CPO (I guess #4 will aid in determining this). I recommend inclusion of molecular methods. If the goal is to ultimately look more broadly at CREs, then I recommend looking at Oregon's CRE toolkit. <http://public.health.oregon.gov/DiseasesConditions/DiseasesAZ/Pages/disease.aspx?did=108> and finally, in the definition you are talking specifically about Enterobacteriaceae, but in the questions you refer to carbapenem-resistant organisms (which implies organisms beyond Enterobacteriaceae). I would like to see a push towards standardization of terms in the State.

Exhibit
#13

CP-CRO Survey for CDR Public Comment

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

We currently perform MHT along with other phenotypic methods (disk tests).

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

Education about CRE vs CPO vs MDRO vs CRO, etc. We need to work on standardization of terminology. We need better methods for detection (currently we use a panel that does not have the appropriate dilutions). We need more expertise on the bench to help with recognition of MDROs.

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

N = 3, ertapenem, meropenem, doripenem; likely to change to include imipenem and exclude doripenem next year.

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

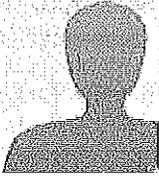
Again, I'm not sure I understand the goal of submitting these isolates given the focus on phenotypic identification at the clinical site (perhaps this is part of a larger initiative; I am not intimately familiar with the reporting rules here in Indiana yet). We routinely send isolates to the State Lab for confirmation of a possible carbapenemase, but I wouldn't consider them to actually be a carbapenemase-producing organism without molecular (or additional confirmation) which makes this definition a bit worrisome. The definition proposed will flag these isolates as CPO based on a flawed test (MHT) performed at the clinical location making it difficult to backtrack when the results do not confirm at the State Lab. This is difficult beast, so I commend ISDH for working towards addressing the need for better detection and epidemiological tracking.

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

CP-CRO Survey for CDR Public Comment

#19



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 3:36:43 PM
Last Modified: Wednesday, July 08, 2015 4:47:59 PM
Time Spent: 01:11:16
IP Address: 12.176.247.150

PAGE 2

Q1: Please enter the following demographic information:

Name	Pravin H Patel, Ph.D.
Facility	Community Health Care System
Address	901 MacArthur Blvd
City/Town	Munster
State/Province	In
ZIP/Postal Code	46375
Email Address	phpatel@comhs.org
Phone Number	219 836 7355

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

definition -Ok

Q3: What changes and/or alterations would you suggest for the current definition?

submission to sate lab - it will increase the workload

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

we perform Vitek and KB AST and 12 disk method as needed.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

none

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

we are finding about 10 isolates per month with KB and/or Vitek cards.

Exhibit
#14

CP-CRO Survey for CDR Public Comment

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

none

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#20



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 4:31:28 PM
Last Modified: Wednesday, July 08, 2015 4:50:00 PM
Time Spent: 00:18:31
IP Address: 64.184.93.139

PAGE 2

Q1: Please enter the following demographic information:

Name	Mary Shoaff MT(ASCP) ICP
Facility	Lutheran Hospital
Address	7950 West Jefferson Blvd
City/Town	Fort Wayne
State/Province	IN
ZIP/Postal Code	46804
Email Address	mshoaff@lhn.net
Phone Number	260-435-7370

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

OK mostly...see #3

Q3: What changes and/or alterations would you suggest for the current definition?

I would eliminate the "AND are positive for ...by a phenotypic test". I feel the phenotypic test is necessary only if older breakpoints are in use and a higher "S" MIC i.e.: "2" S for Ertapenem is observed. Any MIC greater does NOT need confirmatory phenotypic testing (I or R interps).

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

As noted in 3, we need to protect our limited laboratory resources and not require excessive manual testing--only perform MHT in the case of the "high" level "S" results.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

Analyzer software with breakpoints that match current CLSI guidelines. The FDA has not matched these in their latest revision.

Exhibit
#15

CP-CRO Survey for CDR Public Comment

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

Routinely 2: Ertapenem and Meropenem

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

Prefer a little more clarity in the definition:

...isolates include organisms "that test intermediate or resistant to one or more carbapenems"

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

CP-CRO Survey for CDR Public Comment

#21



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 6:46:31 PM
Last Modified: Wednesday, July 08, 2015 7:13:57 PM
Time Spent: 00:27:25
IP Address: 149.163.180.51

PAGE 2

Q1: Please enter the following demographic information:

Name	Marijo Roiko
Facility	IUHealth
Address	350 West 11th St
City/Town	Indianapolis
State/Province	IN
ZIP/Postal Code	46202
Email Address	mroiko@iupui.edu
Phone Number	3174916658

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

It is generally acceptable.

Q3: What changes and/or alterations would you suggest for the current definition?

(1) Carbapenemase-producing Enterobacteriaceae. Isolates include organisms that are non-susceptible to at least one carbapenem antibiotic with MIC ≥ 2 $\mu\text{g/ml}$ or zone diameter ≤ 22 mm

AND

Are positive for carbapenemase production by a phenotypic test (e.g., Modified Hodge, or Carba NP).

OR

Are non-susceptible to at least three carbapenem antibiotics with MIC ≥ 2 $\mu\text{g/ml}$ or zone diameter ≤ 22 mm

OR

Are positive for a carbapenemase gene marker.

Only one isolate that meets these criteria should be submitted if the same organism is repeatedly recovered from the same patient.

CP-CRO Survey for CDR Public Comment

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

We routinely perform the Modified Hodge test and our techs are comfortable with this test.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

A rapid, multiplex confirmatory test capable of processing multiple samples simultaneously would be great.

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

We routinely use the Vitek2 GN73 card which only includes meropenem.

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

none

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#22



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Thursday, July 09, 2015 6:22:02 AM
Last Modified: Thursday, July 09, 2015 7:06:20 AM
Time Spent: 00:44:18
IP Address: 216.8.213.146

PAGE 2

Q1: Please enter the following demographic information:

Name	THERESA DAVISON
Facility	DECATUR COUNTY MEMORIAL HOSPITAL
Address	720 NORTH LINCOLN STREET
City/Town	GREENSBURG
State/Province	IN
ZIP/Postal Code	47240
Email Address	theresa.davison@dcmh.net
Phone Number	812-663-1182

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

no opinion

Q3: What changes and/or alterations would you suggest for the current definition?

none

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

Our lab is small and does not perform the above tests. We have programmed our Vitek to flag susceptibility results that are suspect for CRE and those isolates are sent to ISDH for confirmation. In 2 years, we have submitted a total of 6 isolates.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

we need to continue sending suspect isolates to ISDH

Exhibit
#17

CP-CRO Survey for CDR Public Comment

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

Ertapenem, Imipenem

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

none

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#29



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Thursday, July 09, 2015 10:30:30 AM
Last Modified: Thursday, July 09, 2015 10:52:35 AM
Time Spent: 00:22:05
IP Address: 67.59.30.41

PAGE 2

Q1: Please enter the following demographic information:

Name	Mary Stepney
Facility	The Medical Foundation
Address	530 N Lafayette Blvd
City/Town	South Bend
State/Province	IN
ZIP/Postal Code	46601
Email Address	mstepney@sbfm.org
Phone Number	574-234-4176

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

This will reduce the number of organisms submitted, but have concerns about the false-positive and false-negative Modified Hodge tests.

Q3: What changes and/or alterations would you suggest for the current definition?

Ertapenem and meropenem resistant enterics would include all of the KPCs from our lab, based on recent review. Do not know how this compares to the Modified Hodge test.

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

We cannot add cost under current budget so PCR is out. Avoiding new products until after IQCP is implemented, so we will need to add the Modified Hodge test.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

??not sure what is being asked

Exhibit
#18

CP-CRO Survey for CDR Public Comment

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

ertapenem and meropenem always

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

CP-CRO designation will be even more confusing. If the focus is the mechanism of resistance for epidemiology then just CP. This will still beg the question, what about Pseudomonas, regardless of the final designation.

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#32



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Thursday, July 09, 2015 9:17:43 AM
Last Modified: Thursday, July 09, 2015 12:32:54 PM
Time Spent: 03:15:11
IP Address: 208.103.0.14

PAGE 2

Q1: Please enter the following demographic information:

Name	Angie Hughes
Facility	Community Hospital of Bremen
Address	1020 High Rd
City/Town	Bremen
State/Province	IN
ZIP/Postal Code	46506
Email Address	ahughes@bremenhospital.com
Phone Number	574-546-8093

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

I believe that very few labs are performing a phenotypic test for carbapenemase production. I feel this requirement in the definition would significantly reduce submissions.

Q3: What changes and/or alterations would you suggest for the current definition?

I would define a "Probable" or "Suspected" CRE.

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

I do not see our laboratory performing tests like this any time in the near future. Our volumes would not justify it.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

A reliable logarithm using the information from our Vitek2, however with so many potential variables, that seems highly unlikely.

Exhibit
#19

CP-CRO Survey for CDR Public Comment

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

Meropenem

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

I have no other comments.

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

CP-CRO Survey for CDR Public Comment

#34



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, July 08, 2015 3:01:26 PM
Last Modified: Thursday, July 09, 2015 1:08:36 PM
Time Spent: 22:07:10
IP Address: 199.189.61.37

PAGE 2

Q1: Please enter the following demographic information:

Name	Claire Roembke
Facility	Franciscan St. Francis Health
Address	8111 S. Emerson Ave
City/Town	Indianapolis
State/Province	IN
ZIP/Postal Code	46237
Email Address	claire.roembke@franciscanalliance.org
Phone Number	317-528-8973

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

It matches the hospital definition

Q3: What changes and/or alterations would you suggest for the current definition?

none

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

This follows our current procedure

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

Finding additional information regarding patients previous history at other facilities

Exhibit
#20

CP-CRO Survey for CDR Public Comment

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

K. pneumonia
E. coli
E. cloacae
P. mirabilis

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

Thank you for asking

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#35



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Friday, July 10, 2015 6:23:41 AM
Last Modified: Friday, July 10, 2015 6:54:08 AM
Time Spent: 00:30:26
IP Address: 208.103.1.92

PAGE 2

Q1: Please enter the following demographic information:

Name	Eric Surface
Facility	Woodlawn Hospital
Address	1400 E 9th St
City/Town	Rochester
State/Province	IN
ZIP/Postal Code	46975
Email Address	esurface@woodlawnhospital.com
Phone Number	574-224-1162

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

We have 2 or 3 CP class antibiotics on our AST panels. Requiring a phenotypic test will detrimental to our lab.

Q3: What changes and/or alterations would you suggest for the current definition?

delete phenotypic tests or provide us the supplies.

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

Some techs would be able to test, others would not. Could be a delay in obtaining results.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

subsidized phenotypic testing

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

ertapenem, imipenem, meropenem

Exhibit
#21

CP-CRO Survey for CDR Public Comment

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

We have sent < 5 isolates for confirmation since the start of the program. Having reagents to phenotype in house, would not be cost effective. A similar situation that holds true for BT screening. Small labs can not have reagents that will expire before using.

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

CP-CRO Survey for CDR Public Comment

#36



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Friday, July 10, 2015 9:21:27 AM
Last Modified: Friday, July 10, 2015 9:36:25 AM
Time Spent: 00:14:57
IP Address: 64.255.106.230

PAGE 2

Q1: Please enter the following demographic information:

Name	JOHN SAWATSKY
Facility	IUHEALTH GOSHEN HOSPITAL
Address	200 HIGH PARK AV
City/Town	GOSHEN
State/Province	IN
ZIP/Postal Code	46526
Email Address	jsawatsky@goshenhealth.com
Phone Number	574-364-1053

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

ok

Q3: What changes and/or alterations would you suggest for the current definition?

none

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

unable to do at this time

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

to prevent spread

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

ertapenem
meropenem

Exhibit
#22

CP-CRO Survey for CDR Public Comment

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

none

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#38



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Friday, July 10, 2015 12:46:38 PM
Last Modified: Friday, July 10, 2015 12:50:06 PM
Time Spent: 00:03:28
IP Address: 69.2.204.250

PAGE 2

Q1: Please enter the following demographic information:

Name	leann lawrence
Facility	clark memorial hospital
Address	1220 missouri ave
City/Town	jeffersonville
State/Province	in
ZIP/Postal Code	47130
Email Address	leann.lawrence@clarkmemorial.org
Phone Number	8122855868

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

i think it should be within 5 days of isolation

Q3: What changes and/or alterations would you suggest for the current definition?

see above

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

currently send out suspicious isolates for modified hodge

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

2- ertapenem, meropenem

CP-CRO Survey for CDR Public Comment

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#39



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Friday, July 10, 2015 1:34:55 PM
Last Modified: Friday, July 10, 2015 1:37:44 PM
Time Spent: 00:02:49
IP Address: 165.214.11.82

PAGE 2

Q1: Please enter the following demographic information:

Name	Mary p McDonald
Facility	Terre Haute Regional Hosp
Address	3901 S.7tn Street
City/Town	Terre Haute
State/Province	IN
ZIP/Postal Code	47802
Email Address	mary.mcdonald1@hcahealthcare.com
Phone Number	812-237-1610

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

none

Q3: What changes and/or alterations would you suggest for the current definition?

none

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

na

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

none

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

0

Exhibit
#24

CP-CRO Survey for CDR Public Comment

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

na

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#41



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Friday, July 10, 2015 1:56:23 PM
Last Modified: Friday, July 10, 2015 2:05:15 PM
Time Spent: 00:08:52
IP Address: 64.255.106.230

PAGE 2

Q1: Please enter the following demographic information:

Name	Sherry Robbins
Facility	IU Health Goshen
Address	200 High Park Avenue
City/Town	Goshen
State/Province	Indiana
ZIP/Postal Code	46526
Email Address	srobbins2@iuhealth.org
Phone Number	574-364-2864

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

It is okay as is.

Q3: What changes and/or alterations would you suggest for the current definition?

None.

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

We do not have the staffing resources to perform the phenotypic tests.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

Staffing resources. We send isolates to ISDH for confirmation.

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

2, ertapenem and meropenem.

Exhibit
#25

CP-CRO Survey for CDR Public Comment

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

None.

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#44



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Friday, July 10, 2015 2:46:28 PM
Last Modified: Friday, July 10, 2015 2:52:43 PM
Time Spent: 00:06:15
IP Address: 216.49.105.40

PAGE 2

Q1: Please enter the following demographic information:

Name	Jerry Wheatley
Facility	Memorial Hosp. & Health Care Ctr
Address	800 W 9th St
City/Town	Jasper
State/Province	IN
ZIP/Postal Code	47546
Email Address	jwheatle@mhhcc.org
Phone Number	812-996-0583

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

It's OK.

Q3: What changes and/or alterations would you suggest for the current definition?

None.

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

MHT Ok.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

Not of great need now, but in near future it would be good to have a fast and sensitive screening method.

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

3

Exhibit
#26

CP-CRO Survey for CDR Public Comment

PAGE 4

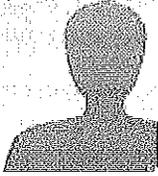
Q7: Please type any other comments you might have regarding the proposed rule change/definition:

None

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#45



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Friday, July 10, 2015 4:19:11 PM
Last Modified: Friday, July 10, 2015 4:25:36 PM
Time Spent: 00:06:24
IP Address: 206.51.109.225

PAGE 2

Q1: Please enter the following demographic information:

Name	Jean Knickerbocker
Facility	IUH La Porte Hospital
Address	1007 Lincolnway
City/Town	La Porte
State/Province	IN
ZIP/Postal Code	46350
Email Address	J.knickerbocker@lph.org
Phone Number	219-326-1234 ext 1519

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

We do not perform any phenotype tests. We get them so rarely, not sure how Vitek 2 identifies them.

Q3: What changes and/or alterations would you suggest for the current definition?

I don't know

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

We do not perform this test and would rely on whatever Vitek 2 gives us

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

We haven't had any in 2 years

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

Imipenim and ertapenam

Exhibit
#27

CP-CRO Survey for CDR Public Comment

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

no comments

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

#46



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Friday, July 10, 2015 5:30:08 PM
Last Modified: Friday, July 10, 2015 5:54:36 PM
Time Spent: 00:24:27
IP Address: 199.189.61.37

PAGE 2

Q1: Please enter the following demographic information:

Name	Vera Concho
Facility	Alverno Clinical Laboratory
Address	2434 Interstate Plaza Drive
City/Town	Hammond
State/Province	Indiana
ZIP/Postal Code	46324
Email Address	vera.concho@franciscanalliance.org
Phone Number	219-845-4023

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

I disagree, as it is any carbapenemase.

Q3: What changes and/or alterations would you suggest for the current definition?

You will need to define it so that Ertapenem is not included in the verbage or you will be getting more CRO isolates.

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

We currently do the Modified Hodge and Metallobetalacamase testing as indicated.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

We already perform the screening. A molecular method would be easier for the staff and generally more faster turn around time.

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#28

CP-CRO Survey for CDR Public Comment

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

Ertapenem, Imipenem Meropenem Doripenem are all tested by Microscan and Etest

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

I would not recommend implementation at this time.

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

CP-CRO Survey for CDR Public Comment

#47



COMPLETE

Collector: Web Link 1 (Web Link)
Started: Monday, July 13, 2015 9:53:06 AM
Last Modified: Monday, July 13, 2015 9:56:06 AM
Time Spent: 00:02:59
IP Address: 208.88.104.232

PAGE 2

Q1: Please enter the following demographic information:

Name	Bonny Lewis Van
Facility	Marion County Public Health Dept
Address	3838 N Rural Street
City/Town	Indianapolis
State/Province	IN
ZIP/Postal Code	46205
Email Address	bvan@MarionHealth.org
Phone Number	3172214672

PAGE 3

Q2: What is your opinion regarding the definition of Carbapenemase-producing Carbapenem-resistant Organisms (CP-CRO) as outlined above?

It is sound, and acceptable.

Q3: What changes and/or alterations would you suggest for the current definition?

Possibly specifically state that all generations of CLSI/FDA are acceptable?

Q4: What are your thoughts regarding the capacity of your clinical laboratory to perform this assessment of carbapenemase production (ie. by Modified Hodge, CarbaNP, or PCR)?

We do not perform this testing, nor do we have a need to.

Q5: What are, in your opinion, the biggest needs for CP-CRO detection in your facility?

We do not have a need, since this is an in-patient issue.

Q6: Based on testing capacity at your facility, how many carbapenems are currently being tested on your AST (Antimicrobial Susceptibility Testing) platform? Please indicate which ones.

none

Exhibit
#29

CP-CRO Survey for CDR Public Comment

PAGE 4

Q7: Please type any other comments you might have regarding the proposed rule change/definition:

na

PAGE 5

Q8: May we use your comments above as public comment to the rule change? Yes

Clevenger, Manda

From: Fox, Joseph R (ISDH)
Sent: Wednesday, September 09, 2015 11:20 AM
To: Clevenger, Manda
Subject: FW: HIV Reporting: Inconsistency in Indiana Code

Importance: High

From: Angela Toth [mailto:atoth@thecorydongroup.com]
Sent: Wednesday, September 09, 2015 10:24 AM
To: Fox, Joseph R (ISDH)
Subject: HIV Reporting: Inconsistency in Indiana Code
Importance: High

**** This is an EXTERNAL email. Exercise caution. DO NOT open attachments or click links from unknown senders or unexpected email. ****

Mr. Fox,

It has come to our attention that the Indiana Code and the Indiana Administrative Code are inconsistent regarding the required reporting of HIV cases. The language of 410 IAC 1-2.5-75 requires reporting of HIV cases to the local health officer while IC 16-41-2-3 requires reporting to the state department of health.

It is our opinion that the rules should be consistent and transparent. We simply would like to call this to your attention and are happy to be a part of any conversation you deem appropriate to make a fix to this inconsistency.

Thank you.



Angela M. Toth
Associate
The Corydon Group
125 West Market Street, Suite 300
Indianapolis, IN 46204
(317) 634-5963
Mobile: (317) 970-4135
www.thecorydongroup.com



Exhibit
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