

The Crisis in Antibiotic Resistance

- In 1992, Harold Neu rang the alarm about antibiotic resistance and advocated.
 - -- Antibiotic Stewardship.
 - -- Development of New Antibiotics.
- The same warnings we hear today, but little action has taken place.

Warnings regarding the spread of Antibiotic Resistant Bacteria were made as early as 1992 but unfortunately, they were largely ignored.



Neu HC. The crisis in antibiotic resistance. Science. 1992 Aug. 21. 257(5073):1064-1073.

By 2002, Kentucky Had a MRSA Problem



"We have had little success in controlling these forms of resistance in part due to common misconceptions regarding the factors most responsible for the explosive spread of MRSA and VRE. Two such misconceptions are"

- "that MRSA and VRE are already well entrenched in the community and" (Misconception: MRSA was entrenched in the Community.)
- "these forms of resistance frequently develop de novo among susceptible strains in response to intensive antimicrobial pressure."
 (Misconception: MRSA commonly developed de novo in patients.)

"Unfortunately, these misconceptions undermine the importance of preventing patient-to-patient transmission within healthcare facilities as the primary means for controlling resistance."



McDonald, LC. Illicit Commerce Within Healthcare. The Spread of Antimicrobial Resistance in Louisville-Area Hospitals. Louisville Medicine 2002; 50: 235

USA Travelers - Risk Factor for MRSA



 Although the level of MRSA strains in Denmark is low, these strains do enter every year with patients arriving from countries where MRSA strains are frequent. It is, however, important that these strains, during the observation period, have not been allowed to spread in Danish hospitals.

If someone from the United States is hospitalized in Northern Europe, they are regarded high risk for MRSA



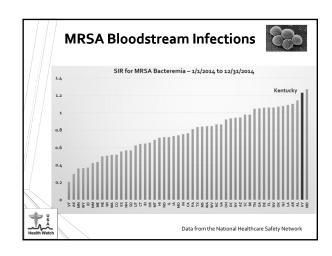
Rodahl VT and Knudsen AM. The decline of methicillin resistance among Danish Staphylococcus aureus strains. Infect Control Hosp Epidemiol. 1991; 12:79-82.

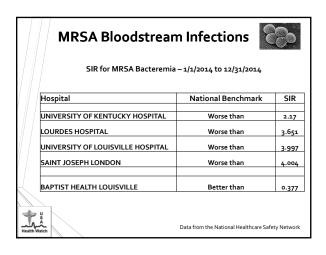
MRSA in 2012 > In the USA, 44% of Staph cultures are MRSA – From the CDDEP. Resistance of Staphylococcus aureus to Oxacillin (MRSA) in 2012 ** Resistant (Invasive isolates) 50 25 60 East South Central (Oxacillin (MRSA) in 2012 From the Center for Disease Dynamics, Economics & Policy

In 2014, Kentucky Still Has A Problem

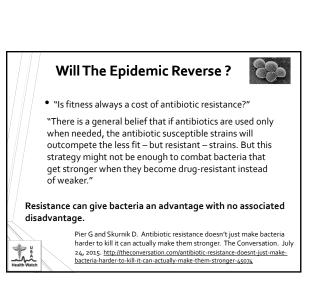
- 2012. In the region Kentucky resides, 62% of Staph Cultures were resistant to Methicillin.
- 2014. Kentucky has the second highest rate of MRSA bloodstream infections or bacteremia in the United States (Data is only available for 29 of 95 facilities).

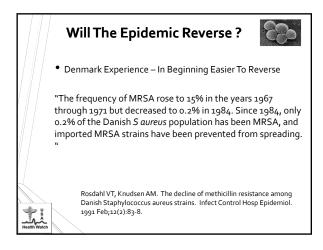


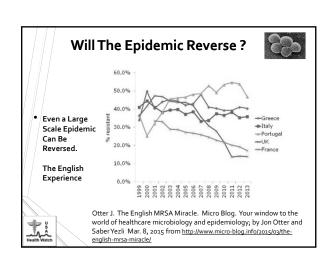


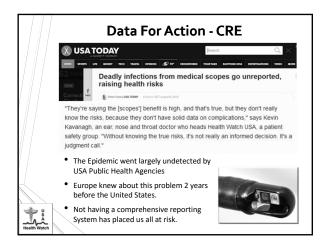


Unlike 2002, MRSA Infections & Carriers Are Ubiquitous. Hard to estimate the community's carrier rate. Data not good. The CDC reports 2%, but others report up to 6%.

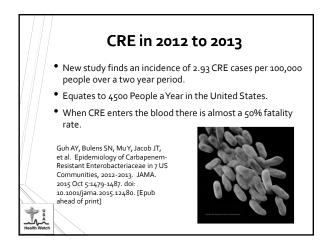


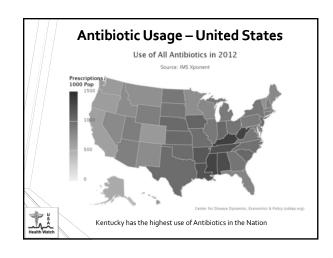


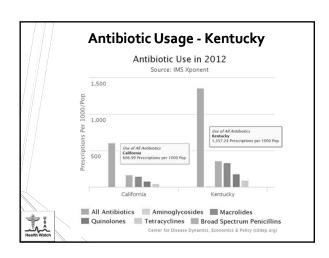


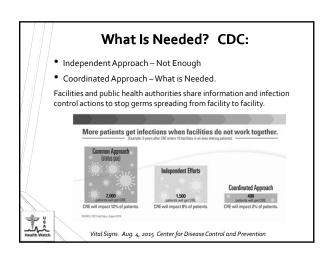












A Coordinated Approach Is Needed

KHN

Lack Of Cooperation Among Health Facilities Mars Antibiotic Resistance Fight, CDC Says

By Jordan Rau | August 4, 2015

• No single facility or facility type can solve this problem. It takes a coordinated approach.

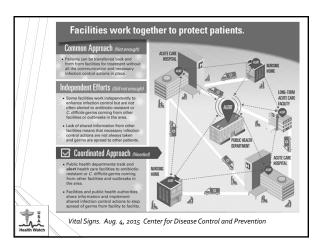
If there is a large environmental pressure (high prevalence in the community) from the pathogen, eventually it will get into the facility.

The Most Common Facilities Are Nursing Homes

"...there are between 1.6 and 3.8 million HAIs [health careacquired infections] in nursing homes every year. Annually, these infections result in an estimated 150,000 hospitalizations, 388,000 deaths, and between \$673 million and \$2 billion dollars in additional healthcare costs (Castle, et al. Nursing home deficiency citations for infection control, American Journal of Infection Control, May 2011; 39, 4)."



Proposed CMS Nursing Home Regulations: Docket ID: CMS-2015-0083. Agency: Centers for Medicare Medicaid Services (CMS)



State Health Department Coordination is Crucial

"CDC has received reports from NHSN users indicating that in some healthcare facilities, some of the decisions about what infections should be reported to NHSN are made by individuals who may choose to disregard CDC's protocol, definitions, and criteria or who are not thoroughly familiar with the NHSN specifications."

The Health Department Needs to Assure the Quality of Data.



Bell B, Conway P. Adherence to the Centers for Disease Control and Prevention's (CDC's) Infection Definitions and Criteria is Needed to Ensure Accuracy, Completeness, and Comparability of Infection Information. US Department of Health and Human Services. Washington, D.C. Oct. 8, 2015. Accessed on 12/2/2015 from http://www.healthwatchusa.org/downloads/2015/1008-nhsn-reporting.pdf

State Health Department Coordination is Crucial

- New KY Regulation One of the first in the nation to set up this coordinated approach. The regulation was approved months before the CDC's announced plan.
- Allows for coordination with the KY Dept. of Public Health.
 - ➤ All types of facilities
 - ➤ All types of highly resistant bacteria

Kentucky Department Of Public Health Coordination is Crucial

- Data for First Six Months of 2015
 - 1. CRE:
 - Two Outbreaks of CRE.
 - ≥ 28 Cases of Infection or Colonization of CRE in Hospitals ("emerging pathogen category").
 - 2. MRSA:
 - No outbreaks of MRSA
 - > 8 Cases of MRSA in Hospitals and 1 case in Nursing Homes ("emerging pathogen category").
- 3. C. Difficile
 - ➤ 1 Outbreak of C. Difficile
 - No Cases of C. Difficile ("emerging pathogen category").











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Ky. voices: Dr. Kevin Kavanagh says hospitals should act as Ky. falls on key infection ranking

June 17, 2015







By Kevin Kavanagh

At least twice a month we take our granddaughter to the Salato Wildlife Education Center in Frankfort. She loves animals, and the center is just the right size for a 3-year-old. She always runs to the first exhibit, which is also her favorite, the bald eagle.

Last month, the exhibit was empty and a note explained why: The eagle had developed an eve infection with a drug resistant bacteria and died.

The symbolism was striking. Superbugs are devouring our nation and even taking down the symbol of American greatness.

One of the most prevalent superbugs is MRSA which causes the deadly staph infection. Until recently, Kentucky had one of the highest rates of staph bloodstream infections in the nation. New data from the Centers for Disease Control's National Healthcare Safety Network show that our MRSA bloodstream infection rate has worsened; Kentucky is now



Salato's eagle, left, died of a drug-resistant infection; at right, the posting that informed visitors of the eagle's death.

dead last among the 50 states in controlling this deadly disease.

Kentucky's rate of infection is more than four times that of Vermont, the state with the lowest rate,

And let us not forget that data from the Center for Disease Dynamics, Economics & Policy indicate that the United States has the third worst rate of MRSA in staphylococcus aureus cultures in the industrial world. Only Malta and Israel are higher. The U.S. rate is 25 times higher than Northern Europe.

This is a far cry from the optimistic tone of a letter from the health care industry to state senators in Frankfort in January 2012, reporting "a dramatic 70 percent decrease in the hospital MRSA infection rate from January 2009 to December 2010" in Kentucky.

The most recent federal data showing Kentucky has the nation's highest rate of MRSA bloodstream infections is from July 1, 2013 to June 30, 2014. It is only available for 30 of Kentucky's 93 hospitals.

Two, Baptist Health Lexington and St. Elizabeth Medical Center, were top rated with better than expected results. But four outliers had poorer than expected results: The University of Kentucky, the University of Louisville, Saint Joseph London and Lourdes Hospital in Paducah.

Over the years, officials from UK, U of L and Saint Joseph Healthcare Systems have testified against legislative initiatives backed by Health Watch USA to control MRSA.

Saint Joseph Health System's chief medical officer testified on Feb. 10, 2011 before the Kentucky House Health and Welfare Committee against expanded public reporting of health-care associated infections by the Kentucky Department of Health. His testimony helped defeat a bill that would have enabled expanded collection of data and set the stage for better standards in infection control.

After testifying against infection-control reforms in Kentucky, the Saint Joseph official went on to become the chief clinical officer at the Texas hospital where an Ebola outbreak spread to its medical staff.

Many now agree that if the U.S. had enacted better and more specific standards for infection control, the Ebola outbreak in this country and ensuing infections of nurses might have been avoided. The lack of comprehensive data hindered the development of these standards.

London, the Laurel County seat, was also at the center of a Dec. 16, 2013 investigative report in USA Today entitled "Dangerous MRSA bacteria expanding into communities."

Unfortunately, based on what I think is faulty research, many institutions have gotten away from the technique of "seek and destroy" to confront these dangerous superbugs. Health Watch USA has published numerous manuscripts in the peer reviewed medical literature on this issue and we foresee a revitalization of surveillance.

A questionable trend aimed at confronting this epidemic is using the antiseptic chlorhexidine on every ICU patient every day. Two major drawbacks of this approach are the promotion of bacterial resistance and chlorhexidine's questionable effectiveness in the prevention of the two most common superbugs, C. difficile and MRSA.

I am sure that Kentucky's MRSA outliers will be quick to point out that they take care of riskier patients. But keep in mind the federal data are risk adjusted.

Kentucky's hospitals need to ask themselves if they should not be expanding their surveillance and isolation/decolonization techniques for MRSA. The Veterans Administration has had excellent results utilizing universal surveillance for MRSA and isolation of carriers. Maybe it is time to adopt this technique statewide.

Dr. Kevin Kavanagh of Somerset is board chairman of Health Watch USA.





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Needed: Greater Surveillance, New Norms in the Fight Against Antibiotic Resistance

Needed: Greater Surveillance, New Norms in the Fight Against Antibiotic Resistance

8 Oct 2015

Author: Kevin Kavanagh

The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria held its inaugural meeting in Washington, D.C on September 29, 2015. The meeting, which was webcast to the public, included presentations by infectious disease experts from across the United States. The conference was positive and upbeat and showcased the many initiatives the United States has under way to confront the epidemic of antimicrobial resistance.



One of the most impressive presentations was from a little-known agency called BARDA, the Department of Health and Human Services' Biomedical Advanced Research and Development Authority. Its mission is to develop and stockpile agents for use in public health emergencies. [1] BARDA has had 21 products approved by the FDA, and is currently supporting the development of six antibiotic products designed to quell highly resistant bacteria that are spreading around the globe, which military members are exposed to ever more frequently in overseas deployments. Among the most dangerous are carbapenem-resistant *Enterobacteriaceae* (CRE), which thrive even in the face of carbapenems, considered "last-resort" antibiotics.

Days after the CARB meeting, BARDA announced a contract to support development of CARBAVANCE, a combination antibiotic consisting of a carbapenem and a novel beta-lactamase inhibitor. The combination should be effective against the virtually untreatable CRE.

At this point, many would wonder just how common CRE infections are in the United States. And they would be as surprised (and dismayed) as I am that we have no good surveillance data on this major threat. The Centers for Disease Control and Prevention (CDC) has three agency initiatives for tracking resistant organisms. However, these systems—the National Healthcare Safety Network (NHSN), *Emerging Infections Program* (EIP) and the National Antimicrobial Resistance Monitoring System (NARMS)—are far from comprehensive. Even the flagship system, NHSN, tracks only a smattering of bacteria and none of the federal systems includes mandatory reporting of CRE. According to the Association for Professionals in Infection Control and Epidemiology (APIC), only 21 states have CRE reporting requirements, only some of which have started reporting. [2]

The best information I found on CRE comes from an investigative report from *USA Today* on CRE spread by retrograde duodenoscopes, which is disturbing on two counts. First, the reported growth in CRE infections spread by endoscopes appears to be increasing almost exponentially. [3] And second, the data come from *USA Today*, not a comprehensive federal tracking system—because the latter is nonexistent.

I'm not laying blame on any one or any agency; the allotted resources are scant **and** the expansion of any of these tracking systems would require a massive increase in operating budgets. At this point, the U.S. Congress has been unwilling to fund a truly workable tracking system. And of course, even if the system is built, it may not be used. Voluntary reporting has a dismal track record in the United States. Mandatory reporting will also be needed.

In the case of CRE, the lack of a comprehensive and uniform reporting system has created a situation that has placed the United States in the embarrassing predicament of detecting the CRE epidemic spread by endoscopes nearly two years after it was detected in Europe.[4]

The 21st Century Cures Act was passed by the U.S. House of Representatives in July 2015. This bill, like much of

1 of 3 10/9/2015 12:07 AM

the ongoing discussion in medicine on how we should confront this epidemic, stresses the need for new antibiotics. We've already seen that BARDA has a number of antibiotics under development or the in commercial pipelines that should be effective against some of the most resistant strains. The real question, however, is: Will any new antibiotic be used sparingly—only when truly needed—and its effectiveness conserved, or will we let history repeat itself with excessive use and the rapid development of bacteria resistant to it?

The 21st Century Cures Act does little to promote the stewardship that is the ultimate weapon against antibiotic resistance. What is missing is a clear statement that the development of last-resort antibiotics is just that: drugs that are exclusively to be used as a last resort, when there are no alternatives. The provisions in the bill could easily be construed as allowing the promotion of antibiotics based upon their cost effectiveness—i.e. if a drug is cost-effective, it should be used. [5] Instead, federal support should dictate that these antibiotics be reserved and used only when absolutely necessary.

Tracking and publicly reporting provider prescribing patterns should also be an element in safeguarding antibiotics of last resort. Provider utilization data are regularly collected by the drug industry for the purpose of marketing. Why can't we also have it to safeguard the public's health?

There is no question that federal dollars spent on antibiotic production without being tied to intense stewardship and utilization monitoring will be an expensive and futile process. We should take the opportunity afforded by new antibiotics from BARDA (and other sources) to mend our ways and adopt new norms for antibiotic use. Remember, insanity is doing the same thing over and over again and expecting a different result.

Dr. Kevin Kavanagh is the Board Chairman of Health Watch USA, a patient advocacy group based in Somerset, KY.

[1] CARB Meeting Part 8: Goal 4 Panel & Discussion. You Tube Play List for Presentations at Presidential Advisory Council for Antibiotic Resistant Bacteria (CARB). Sep. 29, 2015. https://www.youtube.com/playlist?list=PLrI7E8KABz1EP2ARlivq2Ag9RfCsFEL33

[2] State CRE Reporting Requirements. Association for Professionals in Infection Control and Epidemiology. Accessed on Oct. 3, 2015 from <a href="http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/Static_map - CRE.gif(http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/Static_map - CRE.gif(http://www.apic.org/Resource_/TinyMceFileManager/Adv

[3] Eisler, P. Deadly infections from medical scopes go unreported, raising health risks. USA Today. Aug. 21, 2015.

Accessed on Oct. 3, 2015 from: http://www.usatoday.com/story/news/2015/08/05/duodenoscope-infections-not-reported/29988165/)

[4] Peterson M, Terhune C. Scope maker warned Europe about contamination 2 years before L.A. infections. Los Angeles Times. Apr. 20, 2015. Accessed on Oct. 3, 2015 from http://www.latimes.com/business/la-fi-scope-overseas-warnings-20150421-story.html)

114th Congress 1st Session. H.R. 6. Subtitle G – Antibiotic Drug Development. To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes. Section 2121, page 129-130. And Section 2101, page 123-125. Accessed on Oct 3, 2015 from https://www.congress.gov/114/bills/hr6/BILLS-114hr6rfs.pdf

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2 of 3 10/9/2015 12:07 AM





Adherence to the Centers for Disease Control and Prevention's (CDC's) Infection Definitions and Criteria is Needed to Ensure Accuracy, Completeness, and Comparability of Infection Information

Issue: Ensuring data accuracy is critically important to both the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) for guiding prevention priorities and protecting patients. CDC and CMS require that all infections that meet the specified NHSN criteria and that CMS requires for incentive payment or public reporting purposes be reported to NHSN. CDC and CMS are issuing this communication to remind all hospitals of the importance of complete and accurate data for purposes of quality of care measurement and improvement.

Background: The CDC's NHSN is the nation's most comprehensive medical event tracking system used by more than 16,000 U.S. healthcare facilities in all 50 states, Washington, D.C., and Puerto Rico. Data from NHSN is used for tracking of healthcare-associated infections and guides infection prevention activities that protect patients. CMS and other payers use these data to determine incentives for performance and members of the public may use the data to select among available providers. Each of these parties relies on the completeness and accuracy of the data. CDC and CMS are fully committed to ensuring complete and accurate reporting, which is critical for protecting patients and guiding national, state, and local prevention priorities. Identifying infections and making sure that patients receive the highest quality of care is our top priority.

CDC has received reports from NHSN users indicating that in some healthcare facilities, some of the decisions about what infections should be reported to NHSN are made by individuals who may choose to disregard CDC's protocol, definitions, and criteria or who are not thoroughly familiar with the NHSN specifications. While there is no evidence of a widespread problem, CDC and CMS take any deviation from NHSN protocols seriously.

In some instances, these decisions may be made through a review process that overrules the decision of an infection preventionist or hospital epidemiologist to report an infection to NHSN, or clinicians may have departed from standard diagnostic practices to avoid reporting infections to NHSN, for example:

- Ordering diagnostic tests in absence of clinical symptoms. It has been reported that in some instances, when patients are admitted to a hospital, diagnostic microbiology tests are ordered even in the absence of clinical indications for testing, such as obtaining urine specimens for culture and sensitivity testing from patients who have no symptoms of a urinary tract infection. Many negative culture results are generated by this practice subjecting the patient to potentially unnecessary tests. On the occasion that a culture result is positive, the results are then used to assert that infections that first manifested themselves clinically many days later during hospitalization were present on admission and hence not reportable to NHSN.
- Discouraging the ordering of diagnostic tests in the presence of clinical symptoms. It has been reported that in some instances clinicians responsible for inpatient care in some hospitals may be discouraged from ordering diagnostic microbiology tests recommended by best medical practices (or

standards of care) to avoid test results that would make infections reportable to NHSN.

In either case, systematic underuse or overuse of diagnostic microbiology testing puts patients at risk. These practices can lead to use of antibiotics that is not necessary, such as treatment for bacterial colonization rather than infection, or antibiotic treatment that is not informed by culture results. When diagnostic tests are used inappropriately, clinicians lose the opportunity to modify antibiotic choice in response to antibiotic susceptibility testing results and make better informed decisions for patients. These practices could result in an increase in antibiotic resistant infections and adverse reactions among patients.

CDC and CMS underscore the importance of infection reporting by hospitals and other healthcare facilities for patient safety. All facilities should adhere to the NHSN protocol, definitions, and criteria to ensure the reliability and comparability of the data. The value of NHSN for prevention, public reporting, federal incentive payments to provide quality healthcare and protect patients depends on the completeness and accuracy of data reported to the system by NHSN users in healthcare facilities throughout the U.S. CDC works closely with healthcare professional organizations, state health departments, and the National Quality Forum in a broad-based, collaborative effort to ensure the NHSN protocol, definitions, criteria, and healthcare quality measure specifications are in accord with current clinical and laboratory practice. CMS regulations require that healthcare facilities, in submitting data to the system in fulfillment of CMS quality reporting programs, adhere to the NHSN protocols, definitions, and criteria and participate in CMS' validation process when selected for participation.

If a clinician thinks that there is a problem with the specified criteria, CDC would appreciate hearing those concerns. The agency continuously works to improve the definitions and criteria it maintains for infection surveillance, and in several instances, has refined its data collection instructions or clarified its definitions or criteria for identifying infections in response to issues brought to its attention by clinicians or hospitals. In the meantime, however, the hospitals must adhere to the existing protocols, definitions, and criteria to ensure that its data are comparable to that of other organizations and to avoid revocation of NHSN enrollment or other penalties for failure to report data that are required by CMS' incentive programs. CMS quality measure reporting programs require that a responsible official must acknowledge the accuracy of the data at the time of its submission. Hospital staff who become aware of deviations from NHSN's reporting protocols can utilize internal hospital or health system compliance processes to address the issue

CMS reminds hospitals that intentionally reporting incorrect data, or deliberately failing to report data that are required to be reported, may violate applicable Medicare laws and regulations. The Department of Health and Human Services' (HHS's) Office of Inspector General (OIG) protects the integrity of HHS programs, including Medicare and Medicaid. The Inspector General has the authority to exclude individuals and entities from participation in the Medicare, Medicaid, and other Federal healthcare programs and to impose Civil Monetary Penalties for certain misconduct related to Federal healthcare care programs. Hospital staff who become aware of intentional deviations from NHSN reporting protocols are encouraged to report their concerns to the OIG hotline.

Contacts: For questions about the content of this notice, please contact:

CDC Division of Healthcare Quality Promotion Policy Office

Phone: 404-639-4000

E-mail: DHQP_Policy@cdc.gov

For questions or concerns about the protocols, specifications, or criteria specified for any of the NHSN measures, please contact:

NHSN Helpdesk nhsn@cdc.gov

For more information about the OIG go to: https://oig.hhs.gov/. Suspected healthcare fraud and abuse can be reported to the OIG Hotline:

Phone: 1-800-HHS-TIPS (1-800-447-8477) Fax:

1-800-223-8164

E-mail: <u>HHSTips@oig.hhs.gov</u>

TTY: 1-800-377-4950 or https://oig.hhs.gov/fraud/

Mail: US Department of Health and Human Services

Office of Inspector General Attn: OIG Hotline Operations P.O. Box

23489

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Director, National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention (CDC)

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Centers for Medicare & Medicaid Services (CMS)

Table 1. Outbreaks* in Healthcare Facilities - Kentucky January 1 – June 30, 2015

Organism	Long Term Hospital Care Facility		Correctional Healthcare Facility	Outpatient Facility
Campylobacter spp.	0	1	0	0
Clostridium difficile	1	1	0	0
Carbapenem-resistant Enterobacteriaceae	2	0	0	0
GI illness, unspecified	3 [†]	15 [‡]	0	0
Influenza	0	44	0	0
Norovirus	1	8	0	0
Norovirus, suspected (unconfirmed)	0	1	0	0
Rotavirus	0	1	0	0
Respiratory illness, unspecified	0	2	0	0
Vancomycin-resistant Enterococcus	1	0	0	0
Total	8	74	0	0

^{*} Kentucky regulations (902 KAR 2:020) require any healthcare facility licensed under KRS Chapter 216B to immediately report any "unexpected pattern of cases, suspected cases, or deaths which may indicate a newly-recognized infectious agent, an outbreak, an emerging pathogen that may pose a threat to the public, an epidemic, [or] a non-infectious chemical, biological, or radiological agent" to the local health department where the facility is located or to the Department for Public Health. This table shows the number and type of Kentucky healthcare facilities that reported outbreaks occurring among patients, residents or staff of the facility under this regulation in 2015 by etiologic agent.

Table 2. Healthcare Facilities Reporting Cases of Emerging Pathogens of Public Health Importance Kentucky - January 1 – June 30, 2015

Organism	Hospital	Long Term Care Facility	Outpatient Facility	Other
Carbapenem-resistant Enterobacteriaceae (Escherichia coli)	2	0	0	0
Carbapenem-resistant Enterobacteriaceae (Klebsiella pneumoniae)	10	0	0	0
Carbapenem-resistant Enterobacteriaceae (other spp.)	16	0	0	0
Methicillin-resistant Staphylococcus aureus	8	1	0	2
Multi-drug resistant Acinetobacter	2	2	0	0
Vancomycin-resistant Enterococcus	1	0	0	0
Other MDRO	15	1	0	2

[¶] This table shows the number and type of facilities that have voluntarily reported cases of infection or colonization with certain pathogens of public health importance. Because hospitals may have reported more than one type of case, the columns do not necessarily sum to the total number of hospitals reporting. These voluntary reports are sometimes made by the facility that identifies the pathogen and may not reflect where the infection or colonization was acquired, since it may have been present on admission.

[†] Includes 1 healthcare facility that is licensed as a long term care facility but is housed in a hospital

[‡] Includes 1 healthcare facility that is primarily an assisted living facility but has floors licensed to provide personal care