Diagnostics to Drive Antibiotic Stewardship

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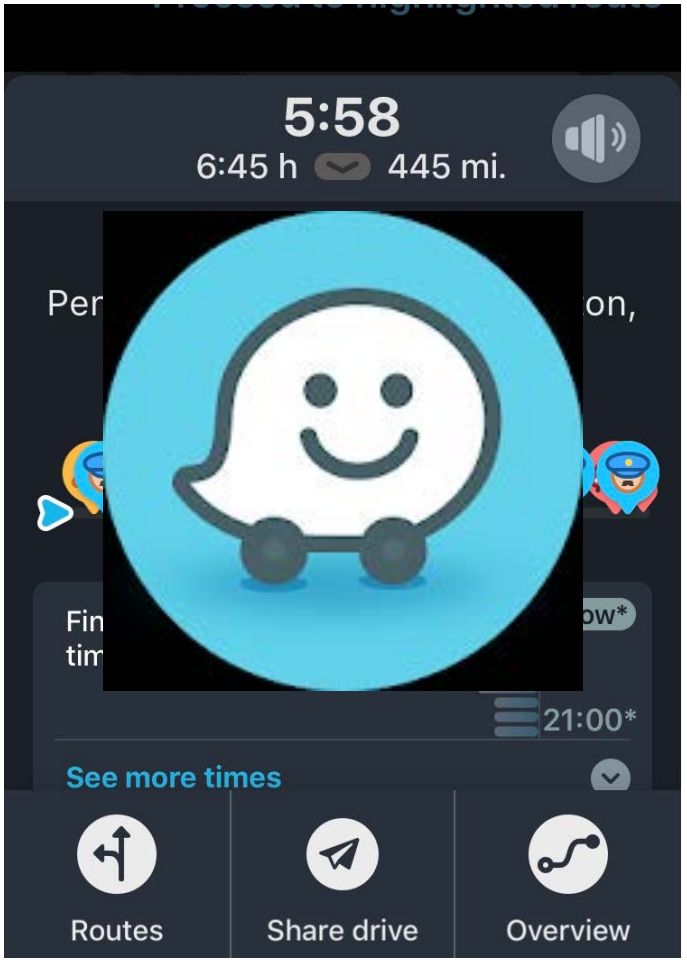
Disclosures

- Employed by Thermo Fisher Scientific is a leading manufacturer of diagnostic tests and laboratory equipment for the management of infectious diseases.
- Thermo Fisher, is participating in a coalition of multiple diagnostics companies committed to fighting infection and C-Diff

Objectives

- Create awareness of the ***value of laboratory diagnostics*** to help guide appropriate antimicrobial decisions for optimal patient outcome
- Connect the unique opportunity for currently available diagnostics in the PREVENTION of antimicrobial adverse events, such as resistance and c-difficile Infection
- Identify how Thermo Fisher Scientific, as part of a multiple diagnostic coalition is ***aligned with goals of the Peggy Lillis Foundation*** to bring awareness in the fight against infection, C-difficile and antibiotic resistance

Diagnostics: Driver or Navigator?



Antibiotic Use in the US: Should We be Concerned?

The New York Times

THE NEW OLD AGE

Older Americans Are Awash in Antibiotics

The drugs are not just overprescribed. They often pose special risks to older patients, including tendon problems, nerve damage and mental health issues.

By Paula Span

March 15, 2019

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DEADLY GERMS, LOST CURES

A Mysterious Infection, Spanning the Globe in a Climate of Secrecy

The rise of Candida auris embodies a serious and growing public health threat: drug-resistant germs.

April 6, 2019

- Two million Americans get antibiotic-resistant infections annually, the C.D.C. has reported, and 23,000 die from them—from 2010 data.
- More recent estimates from researchers at Washington University School of Medicine put the death toll at 162,000. Worldwide fatalities from resistant infections are estimated at 700,000.

https://www.nytimes.com/2019/03/15/health/antibiotics-elderly-risks.html

Antibiotic Use in the US: Should We be Concerned?

“Emma”

Antibiotic Stewardship: What is it?

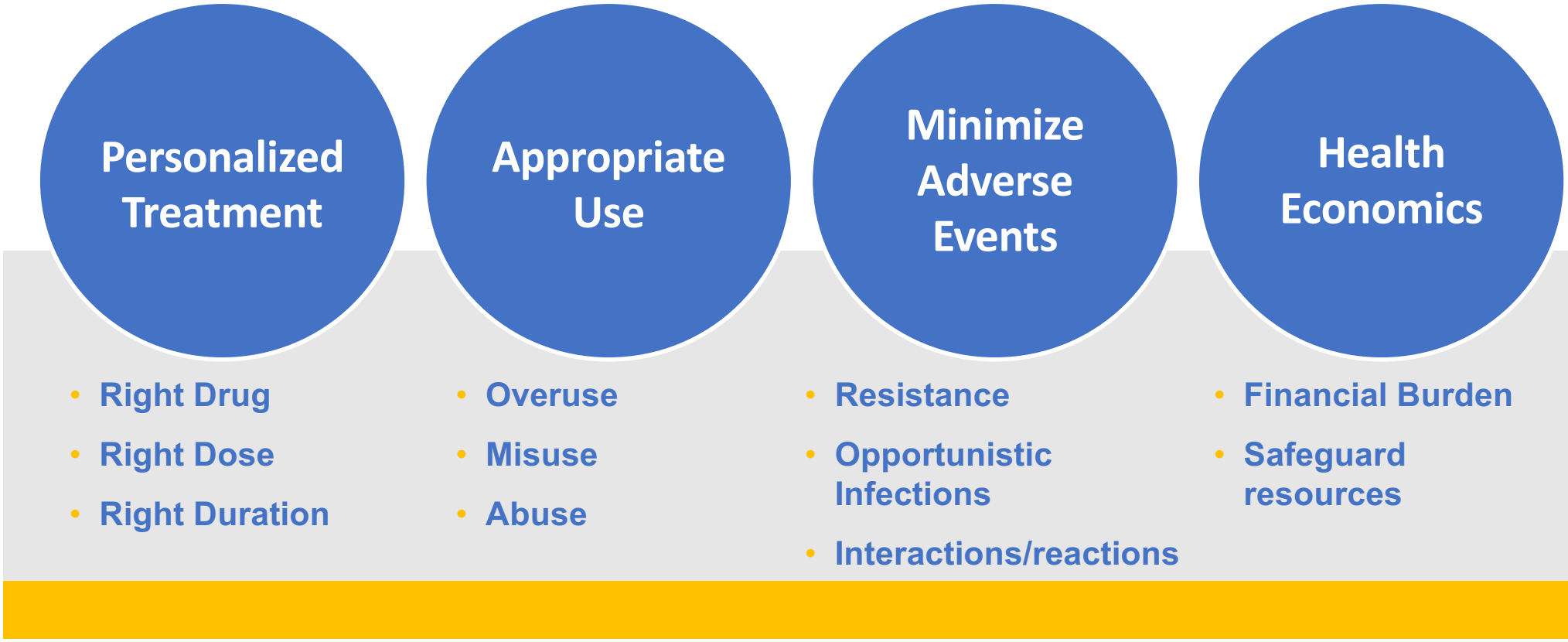
The conducting, supervising, or managing of something--
especially **: the careful and responsible management of something entrusted to one's care**

https://www.merriam-webster.com/dictionary/stewardship

"the optimal ***selection, dosage****, and* ***duration*** *of antimicrobial treatment that results in the* ***best clinical outcome*** *for the treatment or prevention of infection, with* ***minimal toxicity*** *to the patient and* ***minimal impact*** *on subsequent resistance."*

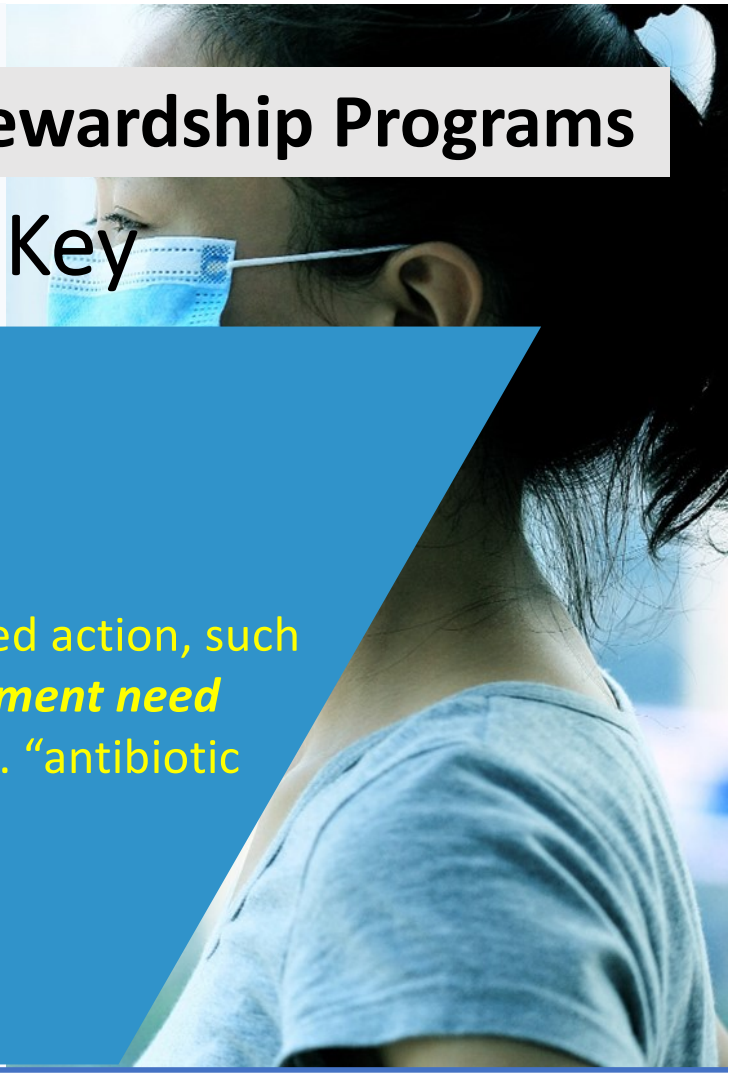
Jt Comm J Qual Improv. 2001;27(8):403-404

4 Primary Goals of Antibiotic Stewardship



Core Elements of Hospital Antibiotic Stewardship Programs

Resources & Education are Key

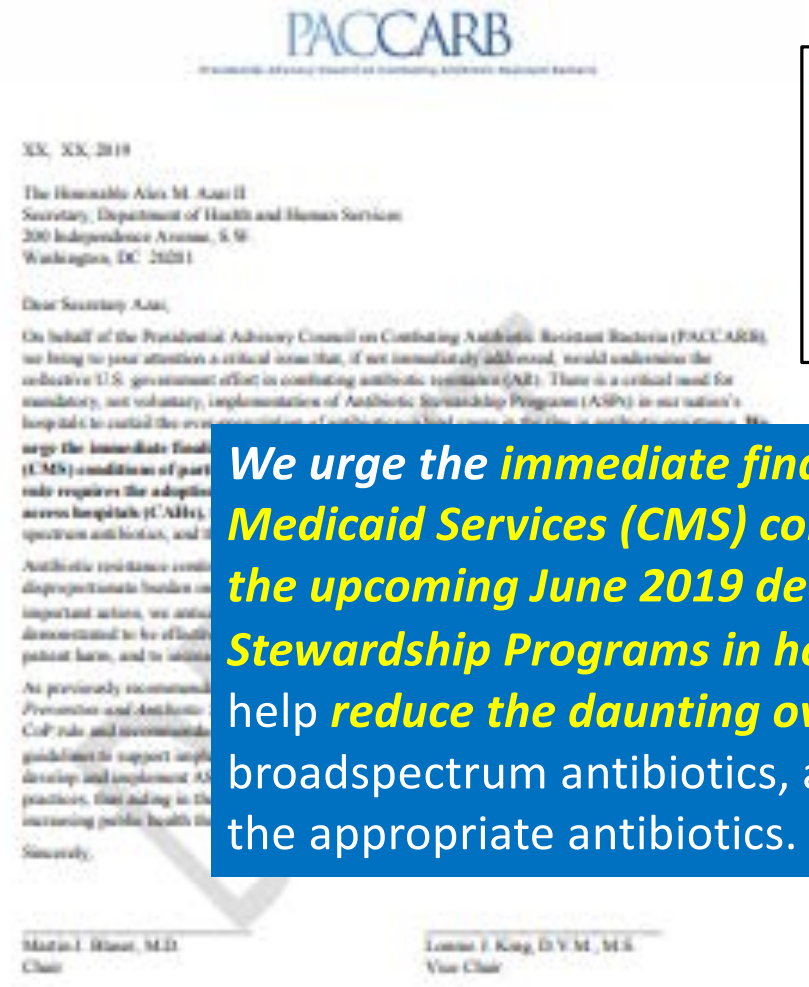


- **Leadership Commitment:**
- **Accountability**:
- **Drug Expertise**:
- **Action:**
  - Implementing at least one recommended action, such as ***systematic evaluation of ongoing treatment need*** after a set period of initial treatment (i.e. "antibiotic time out" at 48 hrs)
- **Tracking:**
- **Reporting**:
- **Education**:

OPPORTUNITY

https://www.cdc.gov/antibiotic-use/healthcare/implementation/core-elements.html

The Future of Antimicrobial Stewardship Programs?


PACCARB

XX, XX, 2019

The Honorable Alex M. Azar II
Secretary, Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Azar,

On behalf of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), we bring to your attention a critical issue that, if not immediately addressed, would undermine the collective U.S. government effort in combating antibiotic resistance (AR). There is a critical need for mandatory, not voluntary, implementation of Antibiotic Stewardship Programs (ASPs) in our nation's hospitals to curtail the ever-growing problem of antibiotic overuse. We **urge the immediate finali** **(CMS) conditions of part** **rule requires the adoptio** **access hospitals (CAHs),** spectrum antibiotics, and t

Antibiotic resistance contin disproportionate burden o important actions, we antici demonstrated to be of bot patient harm, and to minim

As previously recommend Prevention and Antibiotic CoP rule and recommend guidelines to support ASP develop and implement A practices, thus aiding in th increasing public health th

Sincerely,

Martin J. Blaser, M.D.
Chair

Lonnie J. King, D.V.M., M.S.
Vice Chair

April 8, 2019 - Virtual Public Meeting

PACCARB

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

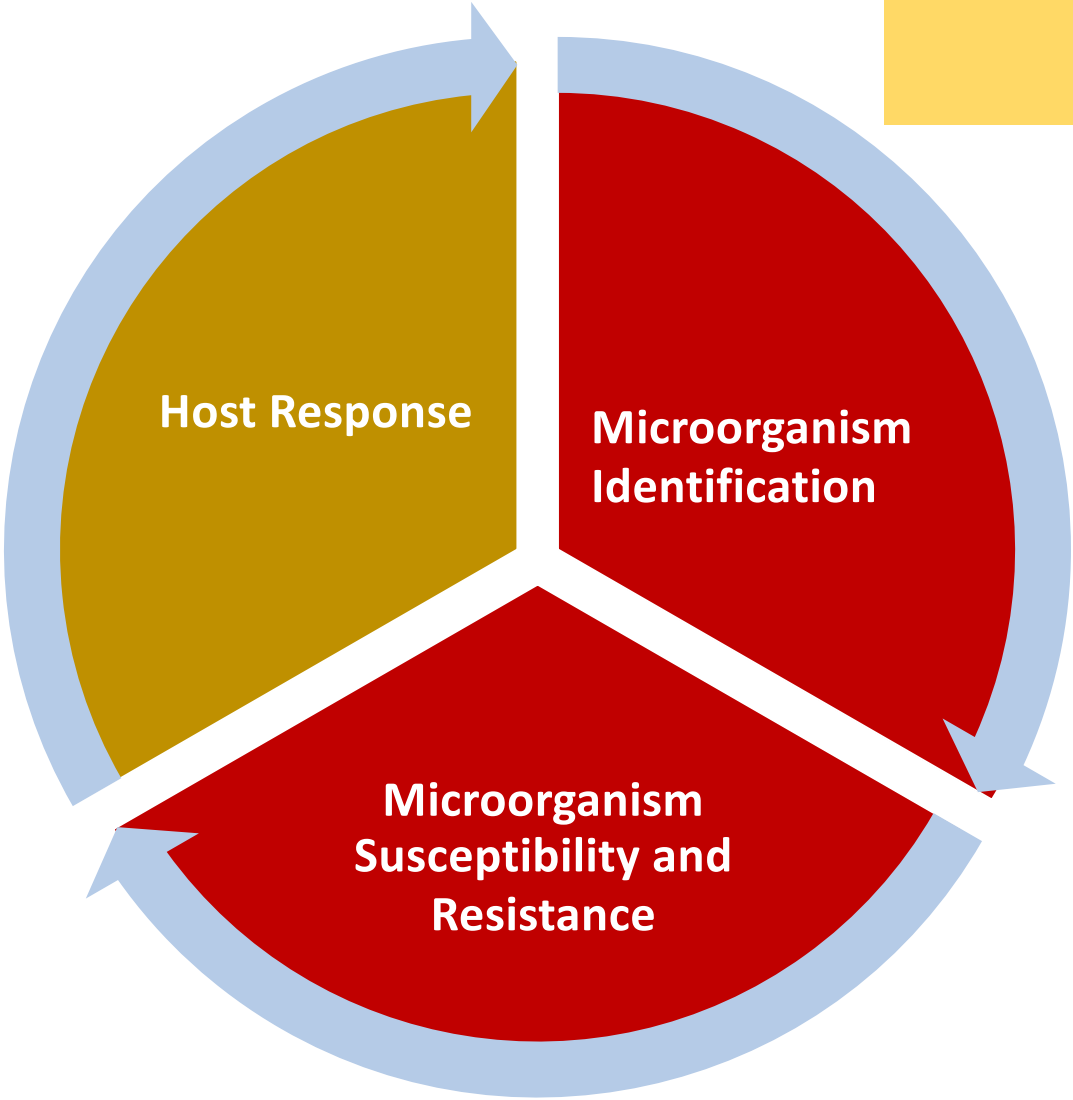
We urge the immediate finalization of the proposed Centers for Medicare and Medicaid Services (CMS) conditions of participation (CoP) rule, in advance of the upcoming June 2019 deadline. This rule requires the ***adoption of Antibiotic Stewardship Programs in hospitals***, especially critical access hospitals (CAHs), to help ***reduce the daunting overtreatment of patients*** with unnecessary broadspectrum antibiotics, and thereby, improve the care of patients receiving the appropriate antibiotics.

https://www.hhs.gov/ash/advisory-committees/paccarb/meetings/upcoming-meetings/april-8-2019-virtual-public-meeting/index.html

Thermo Fisher Scientific: What We Believe

- Antibiotic stewardship committees play a vital role in combatting antibiotic resistance while ensuring the best possible outcome for patients.
- They are in the best position to monitor and evaluate performance data, risk assessment, and evolving practices including new types of treatments and diagnostic tests.
- These include not only tests for pathogen detection and identification, but also FDA approved tests for the management of sepsis and safe discontinuation of antibiotics when they are no longer necessary.
- The proper use of available diagnostic tests is the easiest and quickest way to support antibiotic stewardship programs in the healthcare system.
- We support the implementation of antibiotic stewardship committees and other CMS efforts in addressing the national health issue of infectious disease for patients.

Goal of Diagnostics in Infection



Prevention of CDI: Can Diagnostics Fill a Gap?

1. **ISOLATE** AND INITIATE CONTACT PRECAUTIONS FOR SUSPECTED OR CONFIRMED CDI
2. **CONFIRM** CDI IN PATIENTS
4. DEVELOP **INFRASTRUCTURE** TO SUPPORT CDI PREVENTION
5. DEVELOP A FACILITY-SPECIFIC ***ANTIBIOTIC STEWARDSHIP*** PROGRAM
   - Implement the 7 Core Elements of Hospital Antibiotic Stewardship programs
   - Assess the appropriateness of antibiotic prescribing for agents that pose the highest risk for CDI, especially fluoroquinolones and 3rd and 4thgeneration cephalosporins
   - Evaluate antibiotic treatment of common infections such as urinary tract infection, upper respiratory infections, and community-acquired pneumonia to ensure it is in accordance with facility or national guidelines and facility antibiogram
   - Consider developing facility-specific treatment recommendations for common infections that include first- and second-line antibiotics
   - Consider restriction of antibiotics with highest risk for CDI

https://www.cdc.gov/hai/prevent/cdi-prevention-strategies.html

De-escalation of Antibiotics: Impact to C-Difficile Infection

BACKGROUND:

- Retrospective cohort study evaluated impact of de-escalation from antipseudomonal beta-lactams (APBL) within 48 hours of Enterobacteriaceae bloodstream infections (BSI) on 90-day risk of CDI.

METHODS:

- 808 Adult patients hospitalized for >48 hours for treatment of Enterobacteriaceae BSI
- Time to **CDI in patients who received >48 hours and ≤48 hours of APBL for empirical therapy of Enterobacteriaceae BSI**

RESULTS:

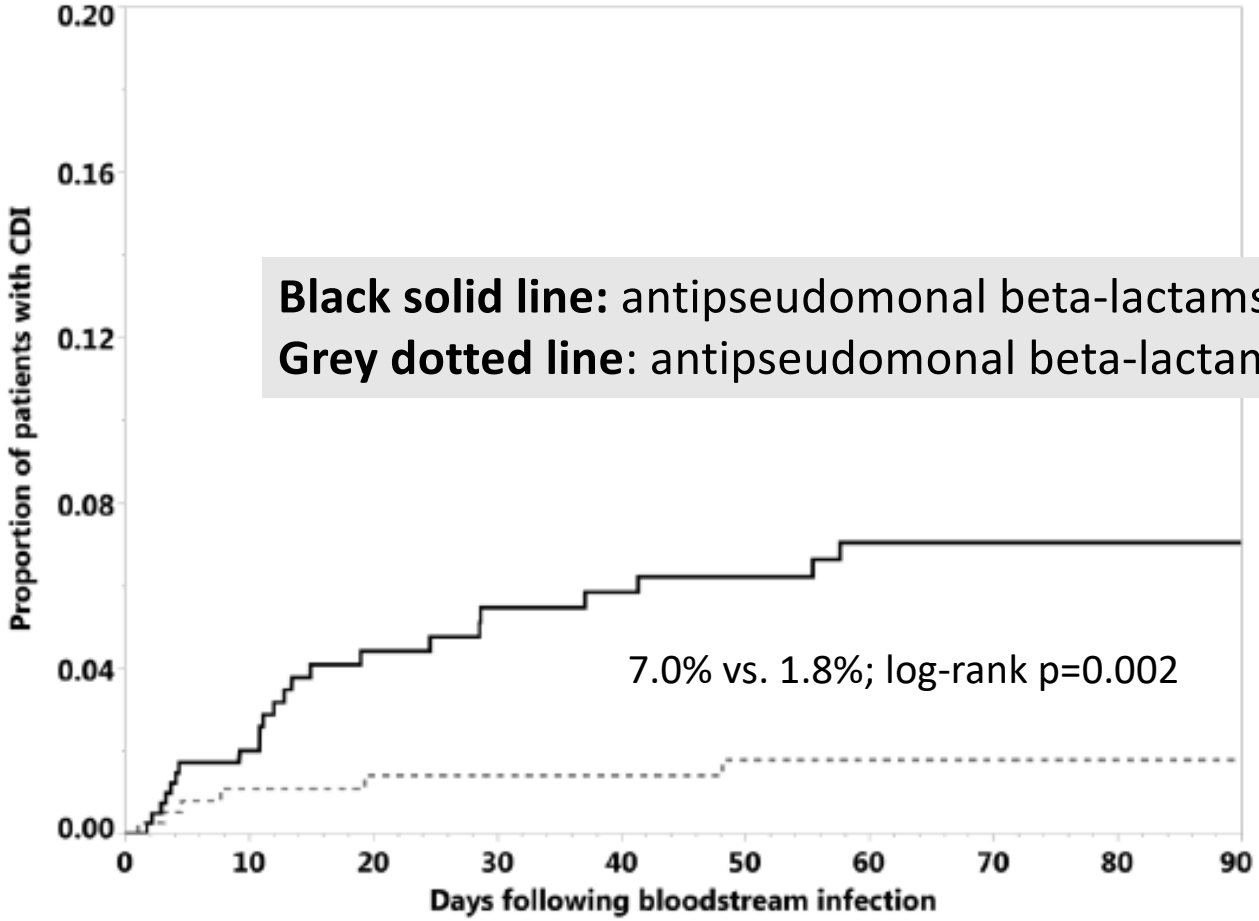
- **Incidence of CDI was higher in patients who received >48 hours than those who received ≤48 hours of APBL** (7.0% vs. 1.8%; log-rank p=0.002).
- After adjustment for propensity to receive >48 hours of APBL and other variables in the multivariable model, **receipt of >48 hours of APBL** (hazard ratio [HR] 3.38, p=0.006) and **end-stage renal disease** (HR 4.04, p=0.002) were **independently associated with higher risk of CDI.**

CONCLUSIONS:

- The empirical use of APBL for >48 hours was an independent risk factor for CDI. **Early de-escalation of APBL using clinical risk assessment tools or rapid diagnostic testing may reduce the incidence of CDI in hospitalized adults with Enterobacteriaceae BSI.**

Clin Infect Dis. 2018 Oct 12.

Kaplan-Meier curves of time to Clostridioides difficile infection based on duration of therapy with antipseudomonal beta-lactams



Clin Infect Dis. 2018 Oct 12

Impact of Procalcitonin (PCT)-Guided Antibiotic Management on Antibiotic Exposure and Outcomes: Real World Evidence

Michael R. Broyles, PharmD[1]
Department of Clinical Pharmacy and Laboratory Services, Five Rivers Medical Center, Pocahontas, AR, United States of America[1]

Table 2. Primary and Secondary Outcomes	Pre-PCT n=985	Post-PCT n=1167	Between-Group Difference (% Reduction)	P value
Primary Outcome				
Days of Therapy DOT, median (IQR)	17.0 (8.5-22.5)	9.0 (6.5-12.0)	-8.0 (47)	<0.001
Secondary Outcomes				
Hospital Mortality, n (%)	75 (7.6)	35 (2.9)	4.7% (62)	<0.001
30-day Hospital Readmission rate, n (%)	204 (22.4)	119 (11.1)	11.3% (50)	<0.001
C. difficile Infection*, n (%)	25 (2.5)	10 (0.9)	1.6% (64)	0.002
Adverse Drug Events from Antimicrobials*, n (%)	160 (16.2)	94 (8.1)	8.1% (50)	<0.001

*During hospitalization

Open Forum Infectious Diseases, Volume 4, Issue 4, Fall 2017, ofx213,https://doi.org/10.1093/ofid/ofx213

Coalition for Improving Sepsis and Antibiotic Practices

- We strongly support federal initiatives to deal with the public health crises of sepsis, infectious disease, and antibiotic stewardship.
- Many parts of the government are working on these issues, and they generally welcome input from concerned parties
- Congress recently asked the Medicare agency to report on its efforts to fight sepsis and use diagnostics to monitor infection
- Medicare responded that these issues are a priority and it is always looking to improve its policies
- At noon today, the President's Advisory Commission on antibiotics is holding a meeting to discuss what CMS is doing, and whether it could be doing
- Our Coalition hopes that CMS will be even more open to public input, such as by hosting a public conference on best practices for C-Diff and infection management
- We believe this is well-aligned with the goals of the Peggy Lillis Foundation to be sure the government is aware of these issues

Summary

- Antimicrobial Stewardship provides the vehicle for careful and responsible management of antimicrobial treatment
- Appropriate antimicrobial use maximizes treatment benefits while minimizing adverse events, such as resistance and C-difficile Infection
- Diagnostics help navigate the pathway to right drug, dose and duration
- Minimizing exposure to empiric antimicrobial duration may decrease the incidence of CDI
- Host response biomarkers, FDA approved for antibiotic stewardship, should be considered as part of a robust Antimicrobial stewardship program
- Guideline and Agency focus on current and emerging novel diagnostics for Antimicrobial Stewardship
- Continuation of Federal support for Antimicrobial Stewardship Programs

Thank you!