It’s Time to Regulate Antimicrobial Stewardship Standards in Acute Care Settings

Emily Heil, PharmD, BCPS-AQ ID, AAHIVP
Conflict of Interest

• I have no conflicts of interest to disclose related to the content of this presentation
Objectives

• Describe the patient safety benefits of having an effective antimicrobial stewardship program in an acute care hospital

• Compare regulatory standards and policy changes related to antimicrobial stewardship in acute care settings
Antimicrobial (an-ti-mī-'krō-bē-əl)
destroying or inhibiting the growth of microorganisms and especially pathogenic microorganisms

Stewardship (ˈstü-ərd-ˌship)
the activity or job of protecting and being responsible for something
Antimicrobial Stewardship – What?

• Multi-disciplinary effort to provide the optimal selection, dose, and duration of an antibiotic

• Both a medication-safety and patient-safety initiative

• Minimize unintended consequences
  – Emerging resistance
  – Adverse drug events
  – *C. difficile*
  – Cost

• Goal: improve patient care and healthcare outcomes
FDA Antibiotic Approvals

<table>
<thead>
<tr>
<th>Period</th>
<th>Number of Approvals</th>
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<tbody>
<tr>
<td>1983-1987</td>
<td>16</td>
</tr>
<tr>
<td>1988-1992</td>
<td>14</td>
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<tr>
<td>1993-1997</td>
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<td>1998-2002</td>
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<td>2003-2007</td>
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<td>2008-2012</td>
<td>2</td>
</tr>
<tr>
<td>2013-2014</td>
<td>4</td>
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</table>
Antimicrobial Stewardship – Why?

- Antibiotics are a shared resource
- Antibiotics are misused in hospitals – up to 50% of use is unnecessary or inappropriate
- Antibiotics are a leading cause of ED visits for medication related adverse events
- Overuse contributes to antibiotic resistance and the growing *C. difficile* problem
- Improving antibiotic use is a public health imperative

MMWR Vol 63 March 2014.
JAMA 2016;316:2115-2125.
Antimicrobial Stewardship – Why?

• Done correctly, antimicrobial stewardship will
  – Help with regulatory compliance
  – Improve patient outcomes
  – Save money
  – Decrease resistance
  – Decrease *C. difficile* infections

LaRocco A. *Clin Infect Dis.* 2003;37:742-3
Antimicrobial Stewardship – Why in MD?

- Maryland has higher rates of antibiotic use compared to other states
- State level surveillance data indicates high-level resistance in gram negative bacteria in all 5 regions of the state
- Maryland is in the top 3 highest rates for community onset and healthcare onset C. difficile infection among 10 CDC Emerging Infections Program participating states

DHMH Status Report: Antibiotic Resistance in Maryland
Antimicrobial Stewardship – How?

• Front end: Formulary restriction and preauthorization
• Back end: Interventions after antimicrobials have been prescribed
• BOTH: Prospective audit with intervention and feedback

Supplemental Strategies

• Education, guidelines, clinical pathways
• Dose optimization via PK-PD
• De-escalation/Streamlining
• Combination therapy

• Antimicrobial order forms/order sets if CPOE
• IV-PO switch
• Computerized decision support
• Antimicrobial cycling

Dellit TH, et al. CID 2007;44:159-77
Auditing and Feedback

• Examples

  – Review patients on extended spectrum Beta-lactams and $3^{rd}/4^{th}$ generation cephalosporins at 72 hours and recommend de-escalation as appropriate
  – Review all cases of patients on ≥3 antibiotics
  – Utilize institution specific data to identify target service areas or medications for review
Prospective Audit

• Pre/post study of an intervention consisting of education and prospective feedback regarding antibiotic choice and duration for community acquired pneumonia

• Duration of antibiotic therapy decreased from median 10 to 7 days post intervention (P<0.001)

• Antibiotics were more frequently optimized (narrowed or modified based on susceptibility) in the intervention group (67% vs 19%)
Antimicrobial Stewardship

The Time Out

Take an antibiotic time out everyday on every patient and ask the following:
1. Does my patient have an indication for antimicrobial therapy?
2. Is my patient on the narrowest, most optimal treatment possible?
3. Can the antimicrobial be given orally?
4. Is it dosed correctly?
5. How long does my patient need antimicrobial therapy?
Antibiotic Restrictions

- Commonly used strategy to use formulary restrictions (with or without prior authorization) as a means to control expensive antimicrobials
- One institution observed a 32% decrease in total antimicrobial expenditures with no change in outcomes or length of stay over a year long period with implementation of pre-authorization on select antibiotics

## Restrictions & Pre-Authorizations

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
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</thead>
<tbody>
<tr>
<td>• Effective in decreasing targeted antibiotics</td>
<td>• May shift prescribing to alternative agents</td>
</tr>
<tr>
<td>• Can influenced future prescribing practices – education built into</td>
<td>• May be less acceptable to prescribers (loss of prescriber autonomy)</td>
</tr>
<tr>
<td>the process of discussing therapy choice</td>
<td>• May delay time to therapy for patients</td>
</tr>
<tr>
<td></td>
<td>• Effectiveness depends on skills of staff making recommendations</td>
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<td></td>
<td>and reviewing requests</td>
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</tbody>
</table>

Restrictions & Pre-Authorizations

• Examples
  – Mandating ID consults for specific drugs
  – Specific requirements that must be met for dispensing of certain drugs (‘checklist’)
  – Restricting empiric use of antibiotics most associated with *C. difficile* cases
Antibiotic Restrictions

• Prospective evaluation of an antimicrobial stewardship program
  – Goal to limit inappropriate use of 3rd generation cephalosporins
• 3 interventions evaluated over 7 years
  – Antibiotic choice, treatment duration, IV to PO switches
• Found significant reduction in the incidence of C. difficile in the National Nosocomial Infections Surveillance (NNIS) system hospitals of comparable size (p=0.002)

Antibiotic Restrictions

• Restrictive antibiotic policy banning routine use of ciprofloxacin and ceftriaxone at a 450 bed community hospital
• After 6 months, hospital acquired C. difficile decreased by 77%, ESBL rates decreased by 17%.
• Reductions were sustained at the three year follow up
# Guidelines and Clinical Pathways

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
<th>Examples</th>
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</thead>
<tbody>
<tr>
<td>• Improves prescribing adherence to national guidelines</td>
<td>• Requires time to develop and execute, plus educate in their use</td>
<td>• Protocols for empiric regimens for common infectious diseases – community acquired pneumonia, urinary tract infections, sepsis</td>
</tr>
<tr>
<td>• Can adapt national recommendations to hospital antibiogram and population</td>
<td>• Needs buy-in on therapy recommendations by all involved parties</td>
<td></td>
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<tr>
<td>• Multidisciplinary in development</td>
<td>• Adherence may be poor</td>
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</table>

Dose optimization

• Tailor therapy to individual patient characteristics, considering factors such as the organism, PK/PD of the antimicrobial
  – Pharmacy to dose vancomycin, aminoglycosides
  – Extended or continuous infusion beta-lactams
  – Alternate dosing regimens
STEWARDSHIP REGULATIONS
Timeline

2014
- CDC Core Elements for Acute Care Antibiotic Stewardship
- PCAST Combating Antibiotic Resistance Report

2015
- National Action Plan for Combating Antibiotic Resistant Bacteria
- TJC Stewardship Standards Presented for Public Comment

2016
- CMS Stewardship CoP Published in Federal Register
- Leapfrog adds Antibiotic Stewardship (by CDC Core Elements) to survey

2017
- TJC Standards Published
- Go-live for TJC
Core Elements of Hospital Antibiotic Stewardship Programs

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion

MARYLAND Patient Safety CENTER
CDC Core Elements of Hospital Antibiotic Stewardship Programs

1. Leadership Commitment
2. Accountability
3. Drug Expertise
4. Action
5. Tracking
6. Reporting
7. Education
1. Leadership Commitment

- Dedicating necessary human, financial and information technology resources
- Leaders establish ASP as an organizational priority
  - Accountability documents, budget plans, performance improvement plans, strategic plans
  - Reporting structure
- Budgeted financial support for antimicrobial stewardship activities
2. Accountability

• Identify a single leader responsible for program outcomes
  – Ideally an infectious diseases trained physician
3. Drug Expertise

- Identify a single pharmacist leader responsible for working to improve antibiotic use.
  - Ideally an infectious diseases trained pharmacist
  - Provide support for institutions to complete antimicrobial stewardship training programs in the absence of formal infectious diseases training
    - Society of Infectious Diseases Pharmacists Antimicrobial Stewardship Certificate Program
    - Making a Difference in Infectious Diseases Antimicrobial Stewardship Certificate Program
4. Action

• Antibiotic formulary restrictions
• Antibiotic time out
  – Evidenced-based antimicrobial usage
  – Right drug for the right patient for the right period of time
  – De-escalation of therapy
  – Duplicate coverage
  – Dose optimization
    • Maximize pharmacodynamic and pharmacokinetic aspects of antimicrobials
  – IV to PO conversions
• Implement policy requiring dose, indication and duration for all antibiotic orders
• Implementation of antibiotic guidelines
5. Tracking

- Aggregate antibiotic use data needed for benchmarking, tracking use patterns/trends, and regulatory reporting requirements
- Adverse effects of antibiotics (e.g., *C. difficile* rates)
- Rates of multi-drug resistant organisms
6. Reporting

• Prescriber level and unit level data
  – Reporting of prescriber practices back to end user, identify outliers
  – Routine reporting to leadership

• Publicity to staff and the public
7. Education

• Routine education at the time of hiring/initial privileging and periodically thereafter

• Education for patients and families
  – CDC Get Smart Week Tools

PRESERVE THE POWER OF ANTIBIOTICS

Antibiotic-resistant bacteria cause more than 2 million illnesses and at least 23,000 deaths each year in the United States. Antibiotic resistance occurs when germs no longer respond to the drugs designed to kill them. Inappropriate prescribing of antibiotics contributes to antibiotic resistance and is a threat to patient safety.

Healthcare Providers Can:
  • Prescribe correctly
    – Avoid treating viral syndromes with antibiotics, even when patients ask for them.
    – Pay attention to dose and duration: The right antibiotic needs to be prescribed at the right dose for the right duration.
    – Be aware of antibiotic-resistance patterns in your area so that you can always choose the right antibiotic.
    – Hospital and nursing home providers should reassess within 48 hours of starting the antibiotic, when the patient's culture results come back. Adjust the prescription, if necessary. Stop the prescription, if indicated.
  • Collaborate with each other and with patients
    – Talk to your patients about appropriate use of antibiotics.
    – Include microbiology cultures, when possible, when ordering antibiotics.
    – Work with pharmacists to ensure appropriate antibiotic use and prevent resistance and adverse events.
    – Use patient and provider resources offered by the Centers for Disease Control and Prevention (CDC) and professional organizations such as Society for Healthcare Epidemiology.
      • Provider Resources: http://www.cdc.gov/getsmart/
      • Patient Resources: http://www.cdc.gov/getsmart/community/for-patients/index.html
      • General Information: http://www.cdc.gov/drugresistance/protecting_yourself_families.html
  • Stop the spread
    – Follow hand hygiene and other infection control measures with every patient.
  • Embrace antibiotic stewardship
    – Improve antibiotic use in all facilities—regardless of size—through stewardship interventions and programs, which will improve individual patient outcomes, reduce the overall burden of antibiotic resistance, and save healthcare dollars.
    – Recognize and participate in CDC’s Get Smart About Antibiotics Week initiatives.
Timeline

- **2014**
  - PCAST Combating Antibiotic Resistance Report
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  - CMS Stewardship CoP Published in Federal Register

- **2017**
  - Go-live for TJC
  - TJC Standards Published

Go live for TJC
Executive Order -- Combating Antibiotic-Resistant Bacteria

EXECUTIVE ORDER

COMBATING ANTIBIOTIC-RESISTANT BACTERIA
By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby order as follows:

Sec. 5. Improved Antibiotic Stewardship. (a) By the end of calendar year 2016, HHS shall review existing regulations and propose new regulations or other actions, as appropriate, that require hospitals and other inpatient healthcare delivery facilities to implement robust antibiotic stewardship programs that adhere to best practices, such as those identified by the CDC. HHS shall also take steps to encourage other healthcare facilities, such as ambulatory surgery centers and dialysis facilities, to adopt antibiotic stewardship programs.
Timeline

- **2014**: PCAST Combating Antibiotic Resistance Report
- **2015**: CDC Core Elements for Acute Care Antibiotic Stewardship
  - National Action Plan for Combating Antibiotic Resistant Bacteria
- **2016**: TJC Stewardship Standards Presented for Public Comment
  - CMS Stewardship CoP Published in Federal Register
  - Leapfrog adds Antibiotic Stewardship (by CDC Core Elements) to survey
- **2017**: TJC Standards Published
  - Go-live for TJC
Medication Management Standard
MM.09.01.01

• Effective January 1, 2017
• Largely follows CDC Core Elements for Antimicrobial Stewardship
• The Standard: The hospital has an antimicrobial stewardship program based on current scientific literature
• Available at: https://www.jointcommission.org/assets/1/6/New_Antimicrobial_Stewardship_Standard.pdf
1. Leaders establish ASP as an organization priority
2. Staff and prescribers receive education on appropriate antimicrobial prescribing and antimicrobial resistance at the time of initial privileging and periodically thereafter
3. Education provided to patients and their families on appropriate antimicrobial use
4. The ASP teams includes the following
   – Infectious diseases physician
   – Infection preventionist(s)
   – Pharmacist(s)
   – Practitioner

   *Part-time, consultant staff and telehealth staff are acceptable members of the ASP team.*
MM.09.01.01 Elements of Performance

5. The ASP includes the CDC Core Elements
6. The ASP uses organization-approved multi-disciplinary protocols
7. The ASP collects, analyzes and reports data on program performance
8. QI/QA undertaken routinely to improve program
Timeline

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- CDC Core Elements for Acute Care Antibiotic Stewardship

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FEDERAL REGISTER

Vol. 81  Thursday,
No. 116  June 16, 2016

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services
42 CFR Parts 482 and 485
Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care; Proposed Rule
Proposed CMS Rule 482.42b: Infection control and antibiotic stewardship programs

• Expands Infection Prevention and Control (IPC) COP originally issued in 1986
  – Places ASP (ownership, resources, reporting) with infection control

• Designate an individual, ‘qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship’ as the program leader
  – Does not specify pharmacist vs MD
CMS Rule 482.42b

• Not prescriptive in which guidelines should be used for reference (e.g., CDC, IDSA/SHEA guidelines)

• “Promote evidence-based use of antibiotics” and “reduce the incidence of adverse consequences of inappropriate antibiotic use including, but not limited to, C. difficile infections and growth of antibiotic resistance in the hospital overall”
# CMS Rule 482.42b Estimates for ASP Staffing

<table>
<thead>
<tr>
<th>Hospital Beds</th>
<th>PharmD CMS FTEs*</th>
<th>MD CMS FTEs*</th>
<th>IT CMS FTEs*</th>
</tr>
</thead>
<tbody>
<tr>
<td>124 (average size)</td>
<td>0.25</td>
<td>0.1</td>
<td>0.05</td>
</tr>
<tr>
<td>300</td>
<td>0.6</td>
<td>0.25</td>
<td>0.1</td>
</tr>
<tr>
<td>600</td>
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<tr>
<td>800</td>
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</tr>
<tr>
<td>1000</td>
<td>2</td>
<td>0.8</td>
<td>0.4</td>
</tr>
</tbody>
</table>

*CMS recommendations represent *a minimum* and do not account for patient complexity
CMS Estimated Savings

- $1475 per bed in antibiotic costs saved
  – Savings accrue primarily to hospital
- $2216 - $5080 saved for each *C. difficile* case avoided (ASP + Infection Prevention assuming 50% effect reduction in CDI for combined IP/ASP)
  – Savings accrue to insurers and hospitals
Achieving Compliance

• Familiarize yourself with the CDC Core Elements for Antimicrobial Stewardship
• If you are starting from scratch, start small
• Utilize pre-existing resources and toolkits
  – Updated IDSA/SHEA Guidelines
  – National Quality Forum Antimicrobial Stewardship Playbook
  – CDC assessment tools
  – Institute for Healthcare Improvement Drivers and Change Package
The CMS/Joint Commission Dream Team

Stewardship Team

ID PharmD

IT Specialist

ID Physician

Infection Control

Microbiology
In the future

- Antimicrobial Use module of the National Healthcare Safety Network – reporting will be required
- Antibiotic use will be reported using the Standardized Antimicrobial Administration Ratio (SAAR)
CAAUSE: MD Campaign for Appropriate Antibiotic Use

- Formed January 2016
- Multidisciplinary collaborative
  - Acute care, long-term care, community, academia
- **Objective:** to encourage proper antibiotic use and decrease drug resistance rates in MD by broadly promoting antibiotic stewardship
- **Goal:** Work with Acute and LTC to develop programs prepared to meet the anticipated 2017 CMS Conditions of Participation as proposed by the CMS Proposed Rule 482.42
CAAUSE Stewardship Collaborative Activities

• Learning webinars/meeting
• Share successes/barriers with implementing stewardship
• Identify Physician/Pharmacist Leaders at each facility
• Identify metric and baseline for antibiotic usage
• Implement and Report: interventions, metrics and outcomes
• Prepare for anticipated CMS Conditions
• Stepwise implementation:
  – Year 1: Commitment letter, identify leaders, identify metrics and baseline
  – Year 2: Collect data, implement 1-2 interventions
  – Year 3: Continue activities, evaluate effectiveness
CAAUSE Collaborative Workgroups

- Antibiotic Timeout
- Vancomycin Dosing
- Asymptomatic Bacteriuria
Conclusions

• Antimicrobial Stewardship is an important public health initiative
• Regulations went live January 1, 2017
  – CDC Core Elements for Stewardship summarizes program goals well
• Target ‘low-hanging fruit’ at first
• No need to reinvent the wheel