Antibiotic Stewardship
Why We Must
How We Can

CAPT Arjun Srinivasan, MD
Associate Director for Healthcare Associated
Infection Prevention Programs
Division of Healthcare Quality Promotion
beu8@cdc.gov
Disclosures

• No financial disclosures.
• My talk today will focus on improving antibiotic use in hospital settings.
• There are equally important needs to improve antibiotic use in other healthcare settings - outpatient clinics, nursing homes and in agricultural settings.
• There is on-going work at CDC on these areas as well.
Why We Have to Improve Antibiotic Use

• Antibiotics are unlike any other drug, in that the use of the agent in one patient can compromise its efficacy in another.
• A lot of in-patient antibiotic prescriptions are unnecessary or sub-optimal.
• We are running out of antibiotics.
• Antibiotic misuse harms patients.
• Improving antibiotic has many benefits for patients and society.
Antibiotic Stewardship to Combat *C. difficile*

- 2014 meta-analysis on the impact of stewardship on *C. difficile* included 16 studies.
- Stewardship programs were significantly protective against *C. difficile*
  - Pooled risk ratio 0.48; 95% CI: 0.38, 0.62
- Restrictive interventions were most effective.
- Protection especially strong in geriatric settings.

Impact of Reductions in Antibiotic Prescribing on *C. difficile* in England

![Graph showing the impact of reductions in antibiotic prescribing on *C. difficile* infections in England.](image)

- **Cephalosporin doses**
- **Fluoroquinolone doses**
- **C. difficile in > 65 y.o.**

*Year*

http://www.hpa.org.uk/web/HPAweb&Page&HPAwebAutoListName/Page/1179745282388
*P. aeruginosa* susceptibilities before and after implementation of antibiotic restrictions (CID 1997;25:230)

P<0.01 for all increases
Stewardship optimizes patient safety: decreased patient-level resistance

Clinical Pulmonary Infection Score (CPIS)

- CPIS > 6: Antibiotics for 10-21 days
  - Ciprofloxacin for 3 days
  - Re-evaluate at 3 days
    - CPIS > 6: Treat as pneumonia
    - CPIS ≤ 6: Discontinue Ciprofloxacin

- CPIS ≤ 6: Randomize
  - Ciprofloxacin for 3 days
  - Standard Care (antibiotics for 10-21 days)

<table>
<thead>
<tr>
<th></th>
<th>Cipro</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotic duration</td>
<td>3 days</td>
<td>10 days</td>
</tr>
<tr>
<td>LOS ICU</td>
<td>9 days</td>
<td>15 days</td>
</tr>
<tr>
<td>Antibiotic resistance/superinfection</td>
<td>14%</td>
<td>38%</td>
</tr>
</tbody>
</table>

Study terminated early because attending physicians began to treat standard care group with 3 days of therapy.

Clinical outcomes better with antimicrobial management program

AMP = Antibiotic Management Program
UP = Usual Practice

The proven benefits of antibiotic stewardship programs have led to formal recommendations for their implementation:

- "CDC recommends that all hospitals implement an antibiotic stewardship program."
- American Hospital Association also recommends antibiotic stewardship programs as a "Top 5" intervention for hospitals.
Goals of Stewardship

• The primary goal of antibiotic stewardship is better patient care.
• Reducing antibiotic use and saving money are NOT the primary goals of antibiotic stewardship.
  – Optimized and fast empiric therapy for sepsis is an important part of antibiotic stewardship.
• They simply happen to be desirable side effects.
Where Do We Want to Be?

- Every hospitalized patient gets optimal antibiotic treatment.
- Every hospital in America has an active antibiotic stewardship program to accomplish that goal.
- Every stewardship program uses proven best practices.
How Do We Get There?

- Lessons learned from CLABSI prevention—what made that work?
- Well defined programs and interventions with education on implementing them.
- A strong, national measurement system.
- A national emphasis on solving the problem—including national goals.
- New policies to spur action.
- Research
A First Step- Defining Stewardship Programs

- It is hard to promote and measure implementation of antibiotic stewardship programs without a clear definition of what they entail.

- Previous definitions worked very well in large, academic hospitals, but were difficult or even impossible in smaller hospitals.

- We need to define what every hospital should do.
“Core Elements”

Core Elements of Hospital Antibiotic Stewardship Programs

http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html
Core Elements for Antibiotic Stewardship Programs

- Based on experience from successful stewardship programs in many types of hospitals.
- Attempts to define the “what” and leave flexibility on the “who”.
Core Elements for Antibiotic Stewardship Programs

- Leadership commitment from administration
- Single leader responsible for outcomes
- Single pharmacy leader
- Antibiotic use tracking
- Regular reporting on antibiotic use and resistance
- Educating providers on use and resistance
- Specific improvement interventions
Leadership Commitment

• There should be a formal expression of support for the stewardship program from the facility administration.

• Leadership must ensure that staff have time to implement the stewardship program.

• Financial support helps - a lot. But is not always imperative.
There should be a designated leader of the antibiotic stewardship program. 

Physicians have proven very effective in this role.

– Prescribing is a medical staff function

Pharmacy leadership is also critical.

Leadership by committee is not as effective.
Antibiotic Use Tracking

• Important to monitor antibiotic use to:
  • Find potential opportunities for improvement
  • Assess the effectiveness of stewardship efforts
  • CDC has developed the Antibiotic Use Option of the National Healthcare Safety Network to help with this.
    – Allows for electronic reporting of antibiotic use to help inform stewardship efforts.
Reporting and Education

• Stewardship programs need to feed data back to the hospital on:
  • Antibiotic use - process and outcome measures
  • *C. difficile*
  • Issues with resistance
Interventions to Improve Use

• Ultimately, specific interventions to improve the use of antibiotics are where the rubber meets the road for stewardship programs.
• There are many great examples.
• Hospitals should pick the ones that have most relevance to them.
What Is The Current Status of Antibiotic Stewardship Programs?

- To get a better picture of stewardship programs, CDC added questions to the 2015 annual facility survey of the National Healthcare Safety Network (covers hospital activities in 2014).

- Questions based on items outlined in CDC “Core Elements for Hospital Antibiotic Stewardship Programs.”
Percentage of U.S. acute care hospitals (n=4,184) reporting implementation of antibiotic stewardship by core element, 2014

- Leadership: 59.9%
- Accountability: 72.1%
- Drug Expertise: 87.2%
- Act: 93.8%
- Track: 78.1%
- Report: 67.5%
- Educate: 61.9%

Preliminary findings from NHSN 2015 Annual Facility Survey - Not for distribution
Findings on Antibiotic Stewardship in US Hospitals - NHSN Annual Facility Survey

- In 2014, 39.2% of US hospitals reporting having a stewardship program that meets all 7 CDC Core Elements.

- Factors associated with meeting all Core Elements
  - Bed size
  - Teaching Status
  - Leadership support (written > salary)
Percentage of acute care hospitals (n=4,184) implementing all seven of core elements of hospital antibiotic stewardship programs, National Healthcare Safety Network, 2014

AE, AP, AS, GU, VI data are not shown due to 7 or fewer hospital respondents but are included in the overall percentage.
Helping With Implementation

- Many hospitals have indicated they would like to have specific examples on ways to implement the core elements.
- CDC partnered with the National Quality Partnership of the National Quality Forum to do this.
  - National Quality Partnership brings together the roughly 400 member organizations of the NQF to work on quality improvement.
A Stewardship Playbook

- Playbook outlines specific actions that have been taken by other hospitals to implement the CDC Core Elements, barriers and solutions.

- Assembled by experts in stewardship from diverse settings as well as representatives from about 20 different professional organizations.

- Released in May 2015.

What Does It Look Like: Leadership Commitment

- **Examples of implementation:**
  - Issue formal board-approved statement on the importance of the ASP and include in annual report

- **Potential barriers and solutions:**
  - Low support of ASP by leaders- Refer to key national reports on importance of antibiotic stewardship and direct leaders to proposed regulatory requirements.

- **Tools and Resources:**
  - [Making the Business Case for ASP](#): Taking It to the C-Suite
Measuring In-patient Antibiotic Use - Current CDC Approach

- Broad (ideally national) assessments of aggregate use.
  - Emerging Infections Program point prevalence survey
  - Proprietary data from drug distributors.

- Facility specific assessments of antibiotic administration data
  - National Healthcare Safety Network Antibiotic Use option

- Detailed assessments of appropriate antibiotic use.
  - Emerging Infections Program antibiotic use assessment
National Healthcare Safety Network Antibiotic Use Option

- Captures electronic data on antibiotics administered, along with admission/discharge/transfer data.
- Calculates rates of administration for use:
  - By facilities to monitor interventions on single units or facility wide
  - To collect aggregate information on antibiotic use at a regional and national level
  - Eventually, to create antibiotic use benchmarks.
Challenges With Benchmarking Antibiotic Use

- Will require good benchmarking to help facilities know if they are outliers.
- The goal is not 100% or zero.
- Being an “outlier” does not necessarily mean there is a problem.
- Always have to be alert for unintended consequences.
Standardized Antibiotic Administration Ratio (SAAR)

- CDC’s 1st attempt at developing a benchmarking measure for antibiotic use.
- Similar in principle to the Standardized Infection Ratio (SIR).
- SAAR expresses observed antibiotic use compared to predicted use.
- CDC worked with many partners to develop the SAAR measure to try and make it most useful for stewardship.
Experts in stewardship suggested that a variety of different SAARs would be useful.

SAARs for different patient populations (adult, peds, ICU, non-ICU).

SAARs for different groups of antibiotics:
- Agents mainly for healthcare associated pathogens
- Agents mainly for community pathogens
- Agents active against MRSA
- Agents frequently use for surgical prophylaxis
- All agents
Key Points About the SAAR

- The SAAR is risk adjusted based only on facility characteristics (e.g. presence of ICUs, hospital size).
- We used facility and location characteristics to develop risk adjustment models for each SAAR category.
In January, 2016 The Standardized Antibiotic Administration Ratio was endorsed by the National Quality Forum.

- Approval was for public health surveillance and quality improvement only.

SAAR calculation is now available in the NHSN AU option so participating facilities can use this information.
Key Point About the SAAR

- The SAAR only helps direct stewardship efforts to locations and antibiotics where use appears to deviate from expected.
  - High use might be perfectly justified, low use might be harming patients.
- CMS has signaled its interest in exploring making the SAAR part of the hospital reporting and payment program.
Measuring Appropriate Use

- We all agree that the ultimate goal of stewardship is to improve appropriate use of antibiotics.
- It will be hard to measure progress towards that goal if we don’t have measures of appropriate use.
Assessing Appropriate Use

- CDC collaborated with partners to create assessment tools for appropriate use that hospitals can use for quality improvement.
  - Available on Get Smart for Healthcare website.
- The 2015-16 national antibiotic use point prevalence survey will include an assessment of appropriate use for 2 agents (vancomycin and quinolones) and 2 conditions (community acquired pneumonia and urinary tract infections)
National Goals and Policies - In-patient

- Before September 18, 2014.
- No national in-patient stewardship goals or policies.
  - Stewardship questions included as “non-citation” questions on Center for Medicare Services (CMS) in-patient infection control worksheet.
Why Are National Goals and Policies Important?

- Despite proven benefits, strong stewardship programs are not universal and not a high priority in many facilities.
- Not too different from where infection control was in the past.
- Certainly not the case for infection control now.
- National policies have elevated the profile of infection prevention.
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:

Section 1. Policy. The discovery of antibiotics in the early 20th century fundamentally transformed human and veterinary medicine. Antibiotics save millions of lives each year in the United States and around the world. The rise of antibiotic-resistant bacteria, however, represents a serious threat to public health and the economy. The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) estimates that annually at least two million illnesses and 23,000 deaths are caused by antibiotic-resistant bacteria in the United States alone.
Executive Order on Combating Antibiotic Resistant Bacteria

- Describes combating antibiotic resistance is a national security priority.
- Creates federal task force and Presidential advisory council to guide implementation of the national strategy.
- Mandates immediate federal action in areas relevant to resistance, including antibiotic stewardship.
NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Vision: The United States will work domestically and internationally and control illness and death related to infections caused by an bacteria by implementing measures to mitigate the emergence and resistance and ensuring the continued availability of therapeutics bacterial infections.

September 2014

NATIONAL ACTION PLAN FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA

MARCH 2015
National Strategy for Combating Antibiotic Resistant Bacteria- 2020 Goals

- All states will implement stewardship activities in healthcare settings.
- All federal facilities will have robust stewardship programs.
- 95% of hospitals will report antibiotic use data to NHSN.
- Reduce inappropriate use for monitored conditions/agents by:
  - 20% in-patient
  - 50% outpatient.
Key Developments in Stewardship: Resources

• The 2016 budget includes significant funding support for the President’s budget request for combating antibiotic resistance.
  – Stewardship is a key part of that request.

• Resources will support addressing key gaps in measurement and implementation and will greatly bolster capacity in state and local health departments to support resistance and stewardship efforts.
Key Developments in Stewardship: Incentives

• Starting in 2016, Anthem Healthcare added compliance with the CDC Core Elements to its Hospital Quality Incentive Program
  – More than 1000 hospital eligible for payments

• The Leapfrog Group proposing questions on CDC Core Elements for their annual survey.
  – Important influence for many C-suites.

• CMS has proposed that reporting antibiotic use to NHSN be part of Meaningful Use Stage 3.
Key Developments in Stewardship-Partnerships

• Society for Hospital Medicine launched “Fight the Resistance” campaign.

• Working with American Nurses Association to find ways to engage bedside nurses in stewardship.

• Working with the critical care community to explore stewardship opportunities in intensive care units.

• On-going work with many other partners.
Accreditation Standard from The Joint Commission

- Late in 2015, The Joint Commission proposed an accreditation standard for antibiotic stewardship in all healthcare facilities.
- The standard has 8 performance elements.
- They anticipate releasing the final standard this summer with compliance required in early 2017.
Accreditation Standard from The Joint Commission

- Element 1: Leaders establish antimicrobial stewardship as an organizational priority.
- Element 2: Educate staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and antimicrobial stewardship practices. Education occurs upon hire and annually thereafter.
Element 3: Educate patients, and their families as needed, regarding the appropriate use of antimicrobial medications, including antibiotics.
Accreditation Standard from The Joint Commission

- Element 4: The organization has an antimicrobial stewardship multidisciplinary team that includes the following members, when available in the setting:
  - Pharmacist(s)
  - Infection disease physician
  - Infection preventionist(s)

- Note: Part-time or consultant staff are acceptable as members of the antimicrobial stewardship multidisciplinary team.
Accreditation Standard from The Joint Commission

- **Element 5:** The organization’s antimicrobial stewardship program includes the following core elements:
  - Leadership commitment
  - Accountability
  - Drug expertise
  - Action
  - Tracking
  - Reporting
  - Education
Accreditation Standard from The Joint Commission

- **Element 6**: The organization’s antimicrobial stewardship program uses organization-approved multidisciplinary protocols.

- **Element 7**: The organization collects and analyzes data on its antimicrobial stewardship program, including antimicrobial prescribing and resistance patterns.

- **Element 8**: The organization takes action on improvement opportunities identified in its antimicrobial stewardship program.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482 and 485

[CMS-3295-P]

RIN 0938-AS21

Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs.
Hospital Conditions of Participation - Antibiotic Stewardship

- §482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.
- The hospital must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship.
Hospital Conditions of Participation - Antibiotic Stewardship

• (b) Standard: Antibiotic stewardship program organization and policies. The hospital
• must ensure all of the following:
• (1) An individual, who is qualified through education, training, or experience in
• infectious diseases and/or antibiotic stewardship, is appointed by the governing body as the leader of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership,
Hospital Conditions of Participation - Antibiotic Stewardship

• (2) An active hospital-wide antibiotic stewardship program must:

• (i) Demonstrate coordination among all components of the hospital responsible for:

• antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services.

• (ii) Document the evidence-based use of antibiotics in all departments and services of the hospital.
Hospital Conditions of Participation -
Antibiotic Stewardship

• (iii) Demonstrate improvements, including sustained improvements, in proper antibiotic use, such as through reductions in CDI and antibiotic resistance in all departments and services of the hospital.

• (3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use.

• (4) The antibiotic stewardship program reflects the scope and complexity of the hospital services provided.
Hospital Conditions of Participation - Antibiotic Stewardship

• (3) The leader of the antibiotic stewardship program is responsible for:

• (i) The development and implementation of a hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

• (ii) All documentation, written or electronic, of antibiotic stewardship program activities.
Hospital Conditions of Participation - Antibiotic Stewardship

• (iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the hospital’s infection prevention and control and QAPI programs, on antibiotic use issues.

• (iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.
Conclusions

- This is unprecedented, and absolutely critical, time for antibiotic stewardship.
- It’s always been a good idea. Now it’s a good idea that’s required.
- We need to do it, and we need to do it right.
- I would love to hear your thoughts on how we can support your efforts and what gaps need to be addressed.