Advancing Antimicrobial Stewardship

Illinois Summit on Antimicrobial Stewardship
July 12, 2016

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Disclosures

• Commercial interest
  – Speaker for Premier
  – Planning for a collaborative at Vizient
Objectives

- Describe the current regulatory environment
- Define various implementation tools that are available or forthcoming
- Discuss antimicrobial stewardship implementation challenges
Pretest Question 1

• What percentage of US hospitals reported antibiotic stewardship programs with all 7 of CDCs Core Elements?
  – 10%
  – 20%
  – 40%
  – 100%
Pretest Question 2

• True or False: CMS will require every US acute care hospital and nursing home to have an antibiotic stewardship program as a condition of participation.
Pretest Question 3

• True or False: California is the only state that has proposed legislation on antibiotic stewardship.
Pretest Question 4

• True or False: Hospitals with similar characteristics should have the exact same framework for their antibiotic stewardship programs.
Antimicrobial Stewardship

- Stewardship is the responsible overseeing and protection of something considered worth caring for and preserving
  - Antimicrobials are worth preserving
  - Not synonymous with restriction
Antimicrobial Stewardship Program (ASP)

• Promotes appropriate use of antimicrobials by selecting the appropriate agent, dose, duration and route of administration

• Objective:
  – Optimize the utilization of antimicrobial agents in order to:
    • Minimize acquired resistance
    • Improve patient outcomes and toxicity
    • Reduce treatment costs
ASP Prevalence in US Hospitals

• Not new concept –
  – Sir Alexander Fleming addressed in 1945 Noble Prize acceptance speech
Sir Alexander Fleming

“The time may come when penicillin can be bought by anyone in the shops. Then there is the danger that the ignorant man may easily underdose himself and, by exposing his microbes to non-lethal quantities of the drug, educate them to resist penicillin.”

Nobel lecture, 1945
ASP Prevalence in US Hospitals

• Not new concept
  – Sir Alexander Fleming addressed in 1945 Noble Prize acceptance speech
  – Documented ASPs since 1970s in US hospitals

Percent of Hospitals with Antibiotic Stewardship Programs by State, 2014*

Antibiotic stewardship programs ensure patients get the right antibiotics at the right time for the right duration

*A hospital stewardship program is defined as a program following all 7 of CDC core elements of antibiotic stewardship programs.

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

Source: CDC’s NHSN Survey

Nationally, 39.2% of all hospitals have stewardship programs (1642 of 4184); the national goal is 100% of hospitals by 2020.
ASPs Prevalence in US Hospitals

- Not new concept
  - Sir Alexander Fleming addressed in 1945 Noble Prize acceptance speech
  - Documented ASPs since 1970s in US hospitals

- ~40% hospitals have an ASP according to CDC’s NHSN (meet all 7 core elements)

- What about the rest and standardization?

ANTIBIOTIC RESISTANCE THREATS in the United States, 2013

Antibiotic Threats in the US, 2013

Foreword by Dr. Tom Frieden, MD, MPH, Director of CDC:

• Antimicrobial resistance is one of our most serious health threats
• The loss of effective antibiotics will undermine our ability to fight infectious diseases, manage infectious complications
• Efforts to prevent include proven public health strategies:
  • Immunization
  • Infection control
  • Protecting the food supply
  • Antibiotic stewardship
  • Reducing person-to-person spread through screening, treatment and education
• Dr. Tom Frieden: CDC recommends every hospital adopt an ASP with seven core elements

• Dr. John Combes (VP of American Hospital Association):
  – In support of CDC recommendation
Core Elements:

- Leadership Commitment
- Accountability
- Drug Expertise
- Action
- Tracking
- Reporting
- Education
September 18, 2014

• White House announced a national effort to combat antibiotic resistance in bacteria.

• Three key items released on that day:
  – Report from the President’s Council of Advisors on Science at Technology (PCAST)
  – National Strategy for Combatting Antibiotic Resistant Bacteria
  – Executive Order

• Stewardship prominent in all three
(1) **CMS should use reimbursement incentives to drive antibiotic stewardship.**

- By the end of 2017, CMS should have Federal regulations (Conditions of Participation) in place that will require U.S. hospitals, critical access hospitals, and long-term care and nursing home facilities to develop and implement robust ASPs that adhere to best practices.

NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Vision: The United States will work domestically and internationally to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria by implementing measures to mitigate the emergence and spread of antibiotic resistance and ensuring the continued availability of therapeutics for the treatment of bacterial infections.

September 2014
National Strategy for Combating Antibiotic Resistant-Bacteria (CARB): Goals

- Slow the development of resistant bacteria and prevent transmission
- Strengthen surveillance
- Advance development of new diagnostics
- Accelerate research and development for new antibiotics, other therapeutics and vaccines
- Improve international collaboration in combating resistance
National Strategy

• 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% inpatient and 50% outpatient
• CDC and AHRQ will expand research
The White House
Office of the Press Secretary

For Immediate Release

Executive Order -- Combating Antibiotic-Resistant Bacteria

EXECUTIVE ORDER

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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

• Signed 9/18/14 by President Obama mandates action to protect existing antibiotics and spur the creation of new ones by 2020 — moves the administration called critical given how rapidly many bacteria are becoming resistant to current drugs

Executive Order on CARB

• Describes combating antibiotic resistance is a national security priority
• Creates federal task force and Presidential advisory council to guide implementation of the national strategy
• Addresses various areas relevant to resistance, including stewardship
White House Summit on Antibiotic Stewardship: June 2015

• >150 organizations present
• Both animal and health sectors; public and private entities
• Each organization had to submit how they are committed to addressing CARB Strategy

https://www.whitehouse.gov/the-press-office/2015/06/02/fact-sheet-over-150-animal-and-health-stakeholders-join-white-house-effo
Antibiotic stewardship integrated within pharmacy and infection prevention and control (IPC):

• Expanding pharmacy medication reviews to include antibiotics for monthly review; reviews also occur for all new admissions/re-admissions, (§ 483.45)
• Antibiotic use protocols and monitoring included in IPC (§ 483.80)
• Integrating IPC and antibiotic stewardship into QAPI activities (§ 483.75)

CMS Proposed Rule: Reform of Requirements for LTCFs

• Proposed July 2015
• 7000+ comments submitted awaiting CMS response

Hospital Stewardship Programs as a Condition of Participation?

- The President has instructed CMS to review regulations and consider proposing new regulations to advance antibiotic stewardship.
- CMS has indicated that it is considering this step for acute care hospitals, just as they have already done for nursing homes.

Slides borrowed from Arjun Srinivasan, SHEA Spring 2016 Meeting
• “In the future, we are considering proposing the NHSN Antimicrobial Use measure to advance national efforts to reduce the emergence of antibiotic resistance by enabling hospitals and CMS to assess national trends of antibiotic use to facilitate improved stewardship by comparing antibiotic use that hospitals report to antibiotic use that is predicted based on nationally aggregated data.”
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

• The draft went out for field review (public comment) in late 2015, early 2016.

• They are currently reviewing comments to make decisions about next steps
What Now?

• Unprecedented time for antibiotic stewardship
• National strategy for advancing stewardship as a key part of combating resistance
• Now comes the hard part of putting reports and strategies into action
California is an Antimicrobial Stewardship Leader
California Senate Bill 739

“By January 1, 2008, [CDPH] shall take all of the following actions to protect against health care associated infections (HAI) in general acute care hospitals statewide:

– (4) Require that general acute care hospitals develop a process for evaluating the judicious use of antibiotics, the results of which shall be monitored jointly by appropriate representatives and committees involved in quality improvement activities.”

Health & Safety Code § 1288.8(a) (2006)
Assessment of ASPs in California Acute Care Hospitals

- 220 (52%) hospitals participated web-based survey May 2010 – March 2011
- ASP definition non-specific:
  - ASP strategy identified
  - Personnel dedicated to ASP
- Representativeness:
  - Rural, regional variation similar
  - Teaching status high (57% vs. 15%) and bed size higher than median (201-300 vs. 140)

Assessment of ASPs in California Acute Care Hospitals

- 213 hospitals
  - 50% (105) current ASP
  - 30% (64) planning ASP
  - 17% (36) no ASP
    - 33% pharmacist antimicrobial oversight

- 128 hospitals
  - 23% influenced to start ASP by SB 739
California Senate Bill 1311 (Hill)


- Signed by Governor Brown September 29, 2014
California Senate Bill 361

• **1275.4.** (a) On or before January 1, 2017, each skilled nursing facility, as defined in subdivision (c) of Section 1250, shall adopt and implement an antimicrobial stewardship policy that is consistent with antimicrobial stewardship guidelines developed by the federal Centers for Disease Control and Prevention, the federal Centers for Medicare and Medicaid Services, the Society for Healthcare Epidemiology of America, or similar recognized professional organizations.

• **Signed October 10, 2015**
CDC Core Elements of ASPs in Nursing Homes

• Adaptation of Core Elements for Hospital ASPs into practical ways to initiate or expand antibiotic stewardship activities in nursing homes

• Nursing homes are encouraged to work in a step-wise fashion, implementing one or two activities to start and gradually add new strategies from each element over time

http://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html
California Senate Bill 27 (Hill)

14401. Beginning January 1, 2018, a medically important antimicrobial drug shall not be administered to livestock unless ordered by a licensed veterinarian through a prescription or veterinary feed directive, pursuant to a veterinarian-client-patient relationship that meets the requirements of Section 2032.1 of Title 16 of the California Code of Regulations.

https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill_id=201520160SB27
• **14402.** (a) Beginning January 1, 2018, a medically important antimicrobial drug may be used when, in the professional judgment of a licensed veterinarian, the medically important antimicrobial drug is any of the following:
  – (1) Necessary to treat a disease or infection.
  – (2) Necessary to control the spread of a disease or infection.
  – (3) Necessary in relation to surgery or a medical procedure.

• (b) A medically important antimicrobial drug may also be used when, in the professional judgment of a licensed veterinarian, it is needed for prophylaxis to address an elevated risk of contraction of a particular disease or infection.

• (c) A person shall not administer a medically important antimicrobial drug to livestock solely for purposes of promoting weight gain or improving feed efficiency.

• (d) Unless the administration is consistent with subdivision (a), a person shall not administer a medically important antimicrobial drug in a regular pattern.
California Senate Bill 27 (Hill)

• Approved by Governor Brown 10/10/2015

https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill_id=201520160SB27
California remains only state with legislation regarding judicious use of antibiotics
California remains only state with legislation regarding judicious use of antibiotics.
Missouri SB 579

19. No later than August 28, 2017, each hospital, excluding mental health facilities as defined in section 632.005, and each ambulatory surgical center as defined in section 197.200, shall in consultation with its medical staff establish an antimicrobial stewardship program for evaluating the judicious use of antimicrobials, especially antibiotics that are the last line of defense against resistant infections. The hospital's stewardship program and the results of the program shall be monitored and evaluated by hospital quality improvement departments and shall be available upon inspection to the department. At a minimum, the antimicrobial stewardship program shall be designed to evaluate that hospitalized patients receive, in accordance with accepted medical standards of practice, the appropriate antimicrobial, at the appropriate dose, at the appropriate time, and for the appropriate duration.
20. Hospitals described in subsection 19 of this section shall meet the National Healthcare Safety Network requirements for reporting antimicrobial usage or resistance by using the Center for Disease Control's Antimicrobial Use and Resistance (AUR) Module when regulations concerning stage 3 of Medicare and Medical Electronic Health Record incentive programs promulgated by the Centers for Medicare and Medicaid Services' that enable the electronic interface for such reporting are effective. When such antimicrobial usage or resistance reporting takes effect, hospitals shall authorize the National Healthcare Safety Network, or its successor, to disclose to the department facility-specific information reported to the AUR Module. Facility-specific data on antibiotic usage and resistance collected under this subsection shall not be disclosed to the public, except the department may release case-specific information to other facilities, physicians, and the public if the department determines on a case-by-case basis that the release of such information is necessary to protect persons in a public health emergency.
21. The department shall make a report to the general assembly beginning January 1, 2018, and on every January first thereafter on the incidence, type, and distribution of antimicrobial-resistant infections identified in the state and within regions of the state.
Missouri SB 579

- Requires antibiotic stewardship programs in hospitals and ASCs
- Requires all hospitals to report to CDC’s NHSN AUR module
- Passed by Senate and House
- Delivered to Governor on May 25, 2016

http://www.house.mo.gov/billtracking/bills161/jrnpdf/jrn056.pdf#page=55
Antimicrobial Stewardship Implementation
Guidelines for the Development of an Institutional ASP

- Developed by professional societies (Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA))
- *Clinical Infectious Diseases* 2007
- Team, elements of an ASP including strategies and measurement, research priorities and future directions

ASP Implementation

• Menu of interventions/strategies
• Customizable with application in every healthcare setting including limited resource settings:
  – Lack of funding/personnel
    • Eg. some community hospitals

US ASP Infrastructure Varies

• In a national survey, of 406 US healthcare providers, 206 (51%) respondents reported working in a hospital with an ASP
  – Of these, 71% included ID physicians, 59% ID pharmacists, and 51% IPs
  – Hospitals with an ASP were 3x more likely to have an ID consultation service or an ID pharmacist than hospitals without an ASP

ASP Core Competencies

• Published November 25, 2014 in *Infection Control Hospital Epidemiology* jointly by SHEA, IDSA, SIDP, MAD-ID, NFID, PIDS
  – Stakeholders including physician, pharmacist, IP, microbiologist, hospital administration

SHEA/IDSA: ASP Implementation Guidelines

• Revised guidelines take a practical approach by offering pragmatic advice and endorsing programs tailored to each institution’s unique situation
• Focus on individual interventions
• Expert panel weighed strength of each recommendation and the quality of evidence behind it.
• 28 recommendations are offered

26. In nursing homes and skilled nursing facilities, we suggest implementation of antimicrobial stewardship strategies to decrease unnecessary use of antimicrobials and improve clinical outcomes [Good practice recommendation]

- Comment: Implementing ASPs at nursing homes and SNFs is important and must involve point-of-care providers to be successful. The traditional physician-pharmacist team may not be available on-site and facilities might need to investigate other approaches to review and optimize antibiotic use, such as obtaining infectious diseases expertise through telemedicine consultation.

AHRQ’s Nursing Home Implementation Guide

• Guide = Four AHRQ projects to develop individual toolkits
  – Two on communication and clinical decision-making about potential infections
  – Two on antibiograms

• Guide is comprehensive

Guide to Long-Term Care Antimicrobial Stewardship

• Includes multiple strategies and toolkits on how to:
  – Implement, monitor, and sustain an ASP
  – Determine if a potential infection should be treated
  – Select the right antibiotic
  – Educate and engage residents and family members

Suspected UTI SBAR

[Nursing Home Name]__________________________________________________________

[Street]__________________________________________________________

[City, State, Zip]__________________________________________________________

Resident Name__________________________________________________________

Name__________________________________________________________

Facility Phone/Fax__________________________________________________________

Date/Time

How was information provided to clinician? [ ] Phone [ ] Fax [ ] In Person [ ] Other

S – Situation (Use this information to complete Section A&R)

[ ] I am contacting you about a suspected UTI for above resident.

Current assessment (check all that apply):

[ ] Increased urgency
[ ] Rigors (shaking, chills)
[ ] Increased frequency
[ ] Delirium (sudden onset of confusion, disorientation,
[ ] Hematuria

Vital Signs: BP ___________________________ Pulse ________________ Resp. rate ________________ Temp. ________________

Resident complaints (check all that apply):

[ ] Dysuria (painful, burning, difficult urination)
[ ] Suprapubic pain
[ ] Costovertebral tenderness (flank pain/tenderness)

Recent Urinalysis Results (Within the last 10 days) If Available:

UA results that were obtained on ___________ (date) due to ______ (reason).

The results accompanying this communication are as follows:

B – Background

Indwelling catheter: [ ] NO [ ] YES

Incontinence: [ ] NO [ ] YES If yes, is this new/worsening? [ ] NO [ ] YES

Active diagnoses (especially, bladder, kidney/gastrointestinal conditions):

Specify: ____________________________________________________________

Advance directives for limiting treatment (especially antibiotics): [ ] NO [ ] YES

Specify: ____________________________________________________________

Medication Allergies: [ ] NO [ ] YES

Specify: ____________________________________________________________

The resident is on Warfarin (Coumadin®): [ ] NO [ ] YES

The resident is diabetic: [ ] NO [ ] YES

A – Assessment (check boxes and determine recommendation)

Resident with indwelling catheter:

[ ] Fever of 100°F (38°C) or repeated temperatures of 99°F (37°C)?
[ ] New costovertebral tenderness
[ ] Rigors
[ ] New delirium
[ ] Hypotension

Any one of the above present

Resident without indwelling catheter:

[ ] Acute dysuria alone: OR
[ ] Single temperature of 100°F (38°C), or repeated temperatures of 99°F (37°C) AND at least one new or worsening of the following:

[ ] Urgency
[ ] Suprapubic pain
[ ] Frequency
[ ] Gross hematuria
[ ] Costovertebral angle tenderness
[ ] New/worsening urinary incontinence

R – Recommendation

[ ] Protocol criteria ARE met.

According to our understanding of best practices and our facility protocols, the resident may have a urinary tract infection and need a prescription for an antibiotic agent.

[ ] Protocol criteria ARE NOT met.

According to our understanding of best practices and our facility protocols, the information is insufficient to indicate an active urinary tract infection. The resident does NOT need an immediate prescription for an antibiotic, but may need additional observation.

Physician/NP/PA Orders

How were orders provided to clinician?: [ ] Phone [ ] Fax [ ] In Person [ ] Other

Ordered UA (with C & L if indicated)

Would you like to initiate any of the following?

[ ] Encourage 4 ounces of cranberry juice TID.
[ ] Record fluid intake

Assess vital signs, including temp., every ______ hours for ______ hours

Notify Physician/NP/PA if symptoms worsen or if unresolved in ______ hours

Other: ____________________________________________________________

[ ] Initiate the following antibiotics

Specify: ____________________________________________________________

[ ] Other, specify: ____________________________________________________________

Physician/NP/PA signature: __________________________ date/time:

Telephone order received by: __________________________ date/time:

Resident without indwelling catheter:
- Acute dysuria alone; OR
- Single temperature of 100°F (38°C), or repeated temperatures of 99°F (37°C)* AND at least one new or worsening of the following:
  - urgency
  - suprapubic pain
  - frequency
  - gross hematuria
  - costovertebral angle tenderness
  - new/worsening urinary incontinence

If none of the above criteria are met, protocol criteria are NOT met.

According to our understanding of best practices and our facility protocols, the information is insufficient to indicate an active urinary tract infection. The resident does NOT need an immediate prescription for an antibiotic, but may need additional observation.

CDC and the National Quality Partnership of the National Quality Forum

• Developed an Antibiotic Stewardship Playbook
  – Represents input from >30 stakeholders
  – Based on the CDC Core Elements for Hospital Antibiotic Stewardship Programs
  – Has specific suggestions for implementation and a special section on measurement
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

www.qualityforum.org/NQP/Antibiotic_Stewardship_Playbook.aspx
Other Implementation Challenges

• The NHSN hospital survey demonstrated that smaller hospitals are having a hard time implementing the core elements:
  – 25% of hospitals <50 beds vs 55% in >200 beds
• But about 100 critical access hospitals did report implementing all 7 elements.
• How can we disseminate their experience?
• State based collaboratives seem to be very helpful
Conclusions
Antimicrobial Stewardship

- Antimicrobial stewardship is recognized as a priority in US healthcare facilities
  - Will be required for CMS reimbursement
- Antibiotic Use and Resistance measures will be required and reported to CDC’s NHSN
- Every healthcare provider can act as an antimicrobial steward
- There are opportunities to reduce antimicrobial use in every US institution
Go Forth as Antibiotic Stewards

• Stewardship is the responsible overseeing and protection of something considered worth caring for and preserving
  – Antibiotics are worth protecting, especially for future generations
  – If we did not have antibiotics, modern medicine would not be possible:
    • Burn treatment, chemotherapy, transplantation
YOU ARE THE NEXT CLASS OF DRUG-RESISTANT BACTERIA. AS HUMANS CONTINUE TO ABUSE AND OVERUSE ANTIBIOTICS, YOUR RANKS WILL SWELL. SO, GO OUT THERE AND MUTATE! AND REMEMBER: THAT WHICH DOES NOT KILL US MAKES US STRONGER!!
Questions/Comments

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Post-Test Question 1

• What percentage of US hospitals reported antibiotic stewardship programs with all 7 of CDCs Core Elements?
  – 10%
  – 20%
  – 40%
  – 100%
Answer to Post-Test Question 1

• Answer: 40%
  – In 2014, 40% of US hospitals reported meeting all 7 Core Elements to CDC’s NHSN
Post-Test Question 2

- True or False: CMS will require every US acute care hospital and nursing home to have an antibiotic stewardship program as a condition of participation.
Answer to Post-Test Question 2

• **Answer: True**
  - CMS has already proposed regulations to require antibiotic stewardship programs in long-term care facilities and are currently revising the regulations based on public comments.
  - We are awaiting release of the proposed regulations for acute care hospitals.
Post-Test Question 3

- True or False: California is the only state that has proposed legislation on antibiotic stewardship.
Answer to Post-Test Question 3

• Answer: False.
  – Missouri has passed Senate Bill 579 which is now with the Governor awaiting his signature that requires all hospitals and ASCs to have an antibiotic stewardship program.
Post-Test Question 4

• True or False: Hospitals with similar characteristics should have the exact same framework for their antibiotic stewardship programs.
Answer to Post-Test Question 4

• **Answer: False**
  
  Every healthcare facility must evaluate available antibiotic stewardship strategies as a menu of interventions and determine what the needs are locally before determining how best to implement an institution-specific antibiotic stewardship program.