Current Regulatory Landscape in Antibiotic Stewardship

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March 4, 2014 CDC Vital Signs Report

Improving antibiotic prescribing in hospitals
Key elements for improving the cycle of antibiotic prescribing practices

Morbidity and Mortality Weekly Report

March 7, 2014

Vital Signs: Improving Antibiotic Use Among Hospitalized Patients
Core Elements of Stewardship

- Accountability
- Drug expertise
- Appointing a single pharmacist leader
- Action
  - Implementing at least 1 recommendation
    - Antibiotic time-out
    - Prospective audit
    - Restriction
- Tracking
- Reporting
- Education

Key Elements

I. Federal leadership
II. Monitoring resistance
III. New antibiotics - Fundamental Research
IV. New Antibiotics - Clinical Trials
V. New Antibiotics - Commercial Development
VI. Human Stewardship
VII. Animal Stewardship
VIII. International Cooperation

REPORT TO THE PRESIDENT ON COMBATING ANTIBiotic RESISTANCE

Executive Office of the President
President’s Council of Advisors on Science and Technology
September 2014
September 18, 2014: Presidential Executive Order

- Section 5: Improved Antibiotic Stewardship
- 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 such as those identified by the CDC


National Action Plan

1. Slow the emergence and spread of resistant bacteria and infections
2. Strengthen national one-health surveillance efforts
3. Advance development and use of rapid and innovative diagnostic tests
4. Accelerate basic and applied antibiotic research and development for prevention, surveillance and control
5. Improve international collaboration and capacities
National Action Plan

Specific goals:
- Within 3 years:
  - Condition of participation from CMS in line with CDC Core Elements of Hospital Antibiotic Stewardship Programs
- By 2020:
  - Establishment of antibiotic stewardship programs in all acute care hospitals and improved antibiotic stewardship across all healthcare settings.
  - Reduction of inappropriate antibiotic use by 50% in outpatient settings and by 20% in inpatient settings.

https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf

June 2, 2015: White House!

- www.cdc.gov/features/antibioticuse/index.html
Antibiotic Stewardship Endorsements

- Alliance for the Prudent Use of Antibiotics
- American Academy of Pediatrics
- American Academy of Physician Assistants
- American Academy of Urgent Care Medicine
- American Medical Directors Assn.
- American Public Health Assn.
- American Society of Health System Pharmacists
- Assn. for Professionals in Infection Control and Epidemiology
- Assn. of State and Territorial Health Officials
- Center for Disease Dynamics, Economics & Policy
- Centers for Disease Control and Prevention
- Consumers Union
- Council of State and Territorial Epidemiologists

- Infectious Diseases Society of America
- Institute for Healthcare Improvement
- National Assn. of County and City Health Officials
- National Assn. of Directors of Nursing Administration in Long Term Care
- National Assn. of Public Hospitals
- Pediatric Infectious Disease Society
- Public Health Foundation
- Robert Wood Johnson Foundation
- Society of Hospital Medicine
- The Pew Charitable Trusts
- The Society for Healthcare Epidemiology of America
- Trust for America’s Health
- World Health Organization


So, where are we today????
Current State Stewardship Mandates

- **California (SB-1311)**
  - Each general acute care hospital, as defined in subdivision (a) of Section 1250, shall do all of the following by July 1, 2015:
    - (a) Adopt and implement an antimicrobial stewardship policy in accordance with guidelines established by the federal government and professional organizations. This policy shall include a process to evaluate the judicious use of antibiotics in accordance with paragraph (3) of subdivision (a) of Section 1288.8.

- **Missouri (MO-SB579)**
  - Additionally, this legislation requires Missouri hospitals and ambulatory surgical centers to establish antimicrobial stewardship programs for surveillance of use and resistance of certain antibiotics by Aug. 28, 2017. Mental health facilities are excluded from the antibiotic stewardship requirement. When federal Stage 3 “meaningful use” regulations take effect, hospitals and ambulatory surgical centers will report through the NHSN Antimicrobial Use and Resistance Module. Hospitals can learn more about establishing an effective antibiotic stewardship program by reviewing resources from the Centers for Disease Control and Prevention.

AR Patient Safety Atlas

[Map of antibiotic stewardship in acute care hospitals by state, 2014]

https://gis.cdc.gov/grasp/psa
ANTIBIOTIC STEWARDSHIP PLAYBOOK

• Represents input from more than 30 different groups who were part of the Antibiotic Stewardship Action Team.

• Is based on the CDC Core Elements for Hospitals Antibiotic Stewardship Programs.
  – Has specific suggestions for implementing the core elements and a special section on measurement in stewardship.

Key Developments in Stewardship: Policies

- July 2015: CMS released revised Conditions of Participation for nursing homes that include a requirement for stewardship programs.
  - CMS has signaled it is exploring doing the same for acute care hospitals.
- December 2015: The Joint Commission (TJC) issued proposed accreditation standards requiring antibiotic stewardship programs in all accredited facilities.
- January 2017: TJC began surveying on antimicrobial stewardship standards
CMS 2015 Proposed Rule for Long Term Care Facility Requirements

- The stewardship program would be part of the facility's infection prevention and control program.
- CDC has developed "Core Elements for Antibiotic Stewardship Programs in Long Term Care" to help with implementation.
- Requiring an antibiotic stewardship program that includes antibiotic use protocols and a system for monitoring antibiotic use.
- Designation of specific infection prevention and control officers (IPCOs).
- Written policies and procedures for the IPCP.
- Education or training related to the infection control program.

The Core Elements of Antibiotic Stewardship for Nursing Homes

APPENDIX B
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.

New Proposed Standards: Some are Not Waiting

Key Points:
• Fall in the Medication Management Section (MM)
• 8 Elements of Performance:
  • Leadership
  • Staff Education
  • Patient and Family Education
  • Stewardship Team (MD, RPh, IP)
  • CDC Core Elements
  • Protocols
  • Data
  • Action on improvement opportunities
New Incentives for Stewardship: Some are Not Waiting

• Starting in 2016, Anthem Healthcare added compliance with the CDC Core Elements to its Hospital Quality Incentive Program- more than 1000 hospital eligible.
• The Leapfrog Group is adding questions on CDC Core Elements to their annual survey.
  – Important influence for many C-suites.

Slide Courtesy of Arjun Srinivasan, MD
Core Elements:

Outpatient Stewardship
What About Measuring and Reporting Antibiotic Use

US Benchmarking Efforts

**CDC- Antimicrobial Use and Resistance module**

Objective: The primary objective of Antimicrobial Use option is to facilitate risk-adjusted inter- and intra-facility benchmarking of antimicrobial usage.

– Secondary objective: to evaluate trends of antimicrobial usage over time at the facility and national levels.

Primary metric: antimicrobial days/ 1000 days present

Data source: electronic MAR (with or without barcode medication administration)
Standardized Antibiotic Administration Ratio (SAAR)

\[
SAAR = \frac{\text{Observed (O) Antimicrobial Use}}{\text{Predicted (P) Antimicrobial Use}}
\]

- Predicted- Calculated by CDC based on predictive models based on nationally aggregated AU data
- Calculated for 5 different drug categories
- 4 different patient care locations
  - Adult/Pediatric medical, medical/surgical and surgical ICUs
  - Adult/Pediatric medical, medical/surgical and surgical wards

Antibiotic Groupings

- **Broad spectrum agents for hospital-onset/multi-drug resistant infections**
  - Amikacin, aztreonam, cefepime, ceftazidime, ceftazidime/avibactam, ceftolozane/tazobactam, colistimethate, doripenem, gentamicin, imipenem/clastatin, meropenem, piperacillin, piperacillin/tazobactam, polymixin B, ticarcillin/clavulanate, tigecycline, tobramycin
- **Broad spectrum agents predominantly used for community-acquired infections**
  - Cefotaxime, ceftriaxone, ciprofloxacin, ertapenem, gemifloxacin, levofloxacin, moxifloxacin
- **Anti-MRSA agents**
  - Ceftaroline, dalbavancin, daptomycin, linezolid, oritavancin, quinupristin/dalfopristin, tedizolid, telavancin, vancomycin
- **Agents for surgical site infection prophylaxis**
  - Cefazolin, cefotetan, cefoxitin, cefuroxime, cepalexin
- **All agents**
AU Option Submission Metrics*

• 295 facilities submitted at least one month of data
  - From 42 states (+AE & DC): AK, AL, AZ, CA, CO, CT, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, MT, NC, ND, NE, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SD, TN, TX, UT, VA, WA, WI
  - Bed size
    - Average = 226
    - Median = 187
    - Min/Max = 10, 1317
  - Teaching status
    - Teaching: 56%
      - Major teaching: 57%

*As of May 30, 2017

Yearly Submission into the AU Option*

*As of May 30, 2017
AR Option Submission Metrics*

- 39 facilities submitted at least 1 AR Event
  - From 12 states: CA, FL, IL, KS, LA, MD, MO, MT, SC, TN, TX, VA
  - Bed size:
    - Average = 245
    - Median = 209
    - Min/Max = 8, 1317
  - Teaching status:
    - Teaching: 51%
      - Major teaching: 65%

*As of May 30, 2017

Example Data

National Healthcare Safety Network
SAARs Table - All Standardized Antimicrobial Administration Ratios (SAARs) High-Level Indicators and High-Value Targets
As of April 13, 2016 and 12:32pm
Data Range: All AU, SAARs

All antimicrobials used in adult ICUs and wards

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Includes data for January 2014 and forward.
Data restricted to medical, medical/surgical and surgical locations.
Source of aggregate data: 2014 High-Value Data
Data contained in this report were last generated on March 13, 2016 at 12:32 AM.

Slide courtesy of Amy Webb, CDC
Current Output Options

NQF: Endorsed Measure

- April 2015:
  - Locations categories
    - Adult and pediatric
    - ICU and ward
  - Agent categories
    - Broad spectrum gram negative agents
      - Primarily active against community pathogens
      - Primarily active against hospital pathogens
    - Anti-MRSA agents
    - Agents primarily for surgical prophylaxis
    - All antibiotics
  - Includes plans to standardized (stay tuned!)
Why Is This Important?

• The items on the Measures Under Consideration list are the ones that CMS is considering making part of some type of reporting and/or payment program.
Hospital Inpatient Prospective Payment System 2017 Proposed Rule

• “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.”

Meaningful Use Stage 3

NHSN Meaningful Use Overview