Antimicrobial Stewardship: Building the Case and Overcoming the Barriers in Your Institution

Presented as a Midday Symposium at the 45th ASHP Midyear Clinical Meeting and Exhibition

Wednesday, December 8, 2010
Anaheim, California
Please be advised that this activity is being audio recorded for archival purposes and, in some cases, for repurposing of the content for enduring materials.
Antimicrobial Stewardship: Building the Case and Overcoming the Barriers in Your Institution

**AGENDA**

11:30 a.m. – 11:35 a.m.  Welcome and Introduction
Craig Martin, Pharm.D., BCPS
*Activity Chair*

11:35 a.m. – 12:10 p.m.  Antimicrobial Stewardship Programs: Why Now?
Craig Martin, Pharm.D., BCPS

12:10 p.m. – 12:40 p.m.  Making the Case and Overcoming Barriers to Antimicrobial Stewardship Programs
Steven B. Cano, M.S., B.S.Pharm.

12:40 p.m. – 1:15 p.m.  The Role of the Pharmacist: Best Practices for Maintaining Effective Antimicrobial Stewardship Programs
Robert C. Owens, Jr., Pharm.D.

1:15 p.m. – 1:30 p.m.  Closing Remarks and Discussion
All Faculty

**FACULTY**

**Craig Martin, Pharm.D., BCPS, Activity Chair**
Pharmacist Specialist, Infectious Diseases
Associate Professor
University of Kentucky College of Pharmacy
University of Kentucky Health Care
Lexington, Kentucky

**Steven B. Cano, M.S., B.S.Pharm., FASHP**
Senior Director of Pharmacy, Chief Pharmacy Officer
Cambridge Health Alliance
Cambridge, Massachusetts

**Robert C. Owens, Jr., Pharm.D.**
Director, Antimicrobial Stewardship Program
Medical Pharmacy Specialist, Infectious Diseases
Maine Medical Center
Portland, Maine
Clinical Assistant Professor
University of Vermont, College of Medicine
Burlington, Vermont
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Craig Martin, Pharm.D., BCPS

Dr. Martin declares that he has no relationships pertinent to this activity.

Steven B. Cano, M.S., B.S.Pharm., FASHP

Mr. Cano declares that he has no relationships pertinent to this activity.

Robert C. Owens, Jr., Pharm.D.

Dr. Owens declares that he has served as a consultant for Theradoc.

Ron DeChant, M.S., B.S.Pharm.

Mr. DeChant declares that he has no relationships pertinent to this activity.
ANTIMICROBIAL STEWARDSHIP: BUILDING THE CASE AND OVERCOMING THE BARRIERS IN YOUR INSTITUTION

ACTIVITY OVERVIEW

Antimicrobial stewardship programs – why are they needed in health systems especially at this time? The focus of this symposium is to provide an overview of antimicrobial resistance and other consequences of inappropriate antimicrobial use, the goals of antimicrobial stewardship, and elements of an effective antimicrobial stewardship program. The role of the pharmacist in developing and implementing a multidisciplinary antimicrobial stewardship program in conjunction with infection prevention and control efforts in the institutional setting will be presented. Faculty will discuss how to make the case for a stewardship program and how to build a business plan. Potential barriers to the implementation process of antimicrobial stewardship programs (e.g., a lack of information technology, misperceptions about program goals) and strategies for overcoming such barriers will be presented. An automated audience response system will be utilized to facilitate active learning and application of knowledge to practice.

ACTIVITY OBJECTIVES

At the conclusion of this knowledge-based educational activity, participants should be able to

- Describe the relationship between inappropriate antimicrobial use and antimicrobial resistance, hospital-acquired infections, morbidity, mortality, hospital length of stay, and health care costs.
- List at least three elements of an effective antimicrobial stewardship program.
- Discuss the role of the pharmacist in developing and implementing an effective multidisciplinary antimicrobial stewardship program.
- Identify several potential barriers to implementing antimicrobial stewardship programs and suggest ways to overcome such barriers.
- Discuss how to make the case and build a business plan to launch an antimicrobial stewardship program.
CONTINUING EDUCATION ACCREDITATION

The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity provides 2.0 hours (0.2 CEUs) of continuing pharmacy education credit (ACPE activity #204-000-10-483-L01P).

Attendees must complete a Continuing Pharmacy Education Request online and may immediately print their official statements of continuing pharmacy education credit at the ASHP Learning Center at http://ce.ashp.org following the activity.

Complete instructions for receiving your statement of continuing pharmacy education online are on the next page. Be sure to record the six-digit session code announced during the activity.

Available soon at http://ashpmedia.org/symposia/steward

So that this educational activity can be shared with a wider audience, a Web-based version of it is being developed. Encourage your pharmacist colleagues who were unable to attend the Midyear to look for this free online continuing pharmacy education activity beginning in March 2011.

Please note that individuals who claim CPE credit for the live symposium are ineligible to claim credit for the Web-based activity.
Instructions for Processing CPE online at http://ce.ashp.org

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http://ce.ashp.org

1. Log in to the ASHP Learning Center using your e-mail address and password.  
   If you have not logged in to the new ASHP Learning Center (launched August 2008) and are not a member of ASHP, you will need to set up an account by clicking on “Become a user” and following the instructions.

2. Once logged in to the site, click on “Process Meeting CE.”

3. If you are a registered attendee at the ASHP Midyear Clinical Meeting, click on the start button to the right of ASHP Midyear Clinical Meeting 2010.
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4. Click on the click here link to view sessions associated with the day of the activity. This activity was held on Wednesday, December 8, 2010.

5. Enter the session code (e.g., A12345 and note that the letter is case sensitive) which was announced during the activity, and select the number of hours equal to your participation in the activity.

6. Click submit to receive the attestation page.

7. Confirm your participation and click submit.

8. New this year, complete the overall Midyear evaluation and click the “finish” button. You will then be able to view and print your transcript.

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Craig Martin, Pharm.D., BCPS
*Activity Chair*
Pharmacist Specialist, Infectious Diseases
Associate Professor
University of Kentucky College of Pharmacy
University of Kentucky Health Care
Lexington, Kentucky

Craig Martin, Pharm.D., BCPS is an Associate Professor of Pharmacy and Internal Medicine at the University of Kentucky College of Pharmacy. He is the clinical pharmacist for the University of Kentucky Health Care's Antimicrobial Stewardship Program. The program provides patients of the UK Chandler Medical Center with appropriate, cost-effective antimicrobial therapy through formulary management and patient-specific interventions. Dr. Martin serves as a lecturer on infectious diseases and counter-terrorism in the first, second, and third professional year curriculum. He also provides experiential education to fourth professional year students through the antimicrobial management and infectious diseases rotations.

Dr. Martin received his Doctor of Pharmacy degree from the University of Kentucky College of Pharmacy in 1999 and completed an Infectious Disease Specialty Residency at UK in 2002.

Dr. Martin is a recipient of American Society of Health-System Pharmacists' (ASHP) Best Practice Award (2004), the Society of Infectious Diseases Pharmacists' "Outstanding Clinical Practice" award (2005), and the 2010 Kentucky Society of Health-System Pharmacy's "Pharmacist of the Year" award.
Craig Martin, Pharm.D., BCPS, Activity Chair

PRESENTATION
Antimicrobial Stewardship Programs: Why Now?

OVERVIEW
Antimicrobial resistance in nosocomial and community-associated pathogens is at an all-time high. In addition, the development and approval of novel antimicrobial agents with activity against multidrug resistant pathogens is at its lowest point in decades. Antimicrobial Stewardship has been heralded as a manner by which pharmacists and other clinicians can attempt to maximize the effectiveness of available antimicrobial agents and minimize the further proliferation of resistance. In this session, we will begin to answer the question “Why now?” is the most appropriate time for hospitals to invest in antimicrobial stewardship.

LEARNING OBJECTIVES
At the conclusion of this knowledge-based educational activity, participants should be able to
- Understand the balance between broad spectrum therapy and the need for de-escalation and conservative antimicrobial use.
- Discuss methods to promote appropriate antimicrobial use in an effort to maximize positive outcomes and minimize environmental impact.
- List examples of methods to improve antimicrobial use in your institution.
Antimicrobial Stewardship Programs: Why Now?

Craig Martin, Pharm.D., BCPS-ID
UK HealthCare
University of Kentucky College of Pharmacy
Lexington, Kentucky

Objectives

- Understand the balance between broad spectrum therapy and the need for de-escalation and conservative antimicrobial use
- Discuss methods to promote appropriate antimicrobial use in an effort to maximize positive outcomes and minimize environmental impact
- List examples of methods to improve antimicrobial use in your institution

Background

- We are in an unprecedented era of antimicrobial need
- We need to be creative in preserving our current antimicrobial agents
- Pharmacists are uniquely positioned to assist in these efforts
The Critical Balance

Importance of appropriate empiric therapy

Effect of broad-spectrum therapy on resistance

A Disturbing Trend

SulfA, BLa, Gm, Chloramphenicol
TCN, MAC, Vanc, Rif, FQ, TMP
No new classes, modification of existing agents,
SulfA, BLa, GM
TCN resistant E. aureus
MIRSA
VRSA
VISA in Veteran
MIRSA (Traveller)
MDR S. aureus
KPC
MBL
New Entities
Limited PCN resistant S. aureus
MRSA
VRE
VISA in 7 states


VRSA
LZD-R
S. aureus
MDR Pseudomonas

Half of US and European companies ended drug discovery (BMS, Lilly, Wyeth, GSK, etc)

New Antibacterials Approved by FDA

Boucher et al. Clin Inf Dis 2009

See page 18 for enlarged view
Hypothetical Situation

• A pharmaceutical manufacturer develops a new antimicrobial targeted to multi-drug resistant (MDR) gram negative organisms.

• It is more expensive than many formulary agents, but may provide coverage of more pathogens.

• How is your Pharmacy & Therapeutics Committee (P&T) likely to handle it?

Based on the previous scenario, how is your P and T Committee likely to handle it?

a. Place on formulary with no restriction
b. Place on formulary with criteria-based restriction
c. Place on formulary with approval necessary
d. Do not place on formulary

Guiding Tenets of Antimicrobial Use

• For severe infections, start broad
  – If you get it wrong, you’re in trouble
• Get it in the patient quickly
• De-escalation of therapy is a necessity
  – The right drug is always the narrowest spectrum agent that produces a successful response and causes the least significant adverse effects and the least collateral damage
• Treat for the most appropriate length of time, then stop
Does your hospital have an Antimicrobial Stewardship Program (ASP) ?

a. Yes
b. No

Which best describes your ASP pharmacist’s training?

a. General residency / fellowship
b. ID specialty residency / fellowship
c. No residency; no formal ID training
d. Short-term training program (e.g. certificate)
e. We don’t currently have an ASP program

Antimicrobial Stewardship Guidelines: A Summary

- Multidisciplinary problem that cannot be solved unilaterally
- Core members (should be compensated)
  - ID Physician
  - ID trained Pharmacist
- Additional members
  - Microbiologist
  - IT Specialist
  - IC Professional and/or Epidemiologist

Collaborative Antimicrobial Stewardship

Dellit et al. CID 2007.
Antimicrobial Stewardship Guidelines

- Core Strategies
  - Prospective audit with intervention and feedback
  - Formulary restriction with preauthorization
- Supplemental Strategies
  - Education
  - Guidelines and clinical pathways
  - Antimicrobial cycling
  - Antimicrobial order forms
  - Combination therapy
  - Streamlining or de-escalation of therapy
  - Dose optimization
  - Parenteral to oral conversion

Dellit et al. CID 2007.

Moving from “Restriction” to “Facilitation”

- Letter submitted to AJHP by Martin et al. (in press)
  - Programs with a heavy-handed restriction approach may inadvertently be doing a disservice to patients
  - We should be focusing more on getting the right drug to the patient rather than merely restricting drugs
  - The only dose of a drug proven to save lives is THE FIRST ONE

Prospective Audit/Feedback in Smaller Institutions

- Glenwood Regional Medical Center (Monroe, LA): 120 bed community hospital
- ID Specialist (part-time), Clinical Pharmacist, Infection Control, Microbiology
- Concurrent chart review 3 days/week
- Targeted patients
  - Multiple antibiotics
  - Prolonged antibiotics
  - High-cost antibiotics
- Initial pushback from medical staff
- 69% recommendation acceptance
- 19% reduction in antibiotic expenditures ($177k)

LaRocco et al. CID 2003.
Beyond Restriction to Appropriate Use Promotion:
Antifungal Use in Stem cell transplant (SCT) / Leukemia

UK HealthCare

Guidelines for Management of antifungal agents in adult immunocompromised hosts: circumferential antifungal stewardship.

Suspected Candidiasis Guidelines

- Note: Immunoocompetent patients.
- Decision: echinocandin or fluconazole?
- Collaboration: Novel lab methods PNA FISH (peptic nucleic acid fluorescence in situ hybridization)

Antimicrobial Stewardship:
Honest Assessment of Our Current State

- Does a good job of promoting the idea that antimicrobial use matters to society (at least to inpatients)
- Does a poor job of talking about community use
- Does a poor job of talking about individual patients (timing, selection, etc.)
Antimicrobial Stewardship: Now and Into the Future

• Collaboration with clinical microbiology to incorporate novel diagnostics
  – PNA FISH
  – PCR (polymerase chain reaction) for MRSA (methicillin resistant Staph aureus) and other pathogens
• Multidisciplinary collaboration for IT solutions on diagnosis, evaluation, and treatment of sepsis and other diseases
• Focusing less on restriction, and more on facilitation
• Taking the battle into the community

Antimicrobial Stewardship Programs: Why Now?

• Because antimicrobial overuse/misuse affects resistance
• Because antimicrobial resistance is at unprecedented levels
• Because antimicrobial stewardship programs are typically financially self-supporting (although this should be a secondary goal)
• Because there's ample evidence that it's the right thing to do
A Disturbing Trend

- Sulfa, BLs, AGs, Chloramphenicol
- TCN, MAC, Van, RIF, FQs, TMP
- No new classes. Modification of existing agents.
- LZD, DAP, TIG
- New Entities Limited

PCN-resistant S. aureus

MRSA

VRE

VISA in 7 states

MDR Pseudomonas

ZD-R S. aureus

LZD-R

S. aureus

MDR

Pseudomonas

UK HealthCare:
Suspected Candidiasis Guidelines

- Note: Immunocompetent patients.
- Decision: echinocandin or fluconazole?
- Collaboration: Novel lab methods
  PNA FISH (peptic nucleic acid fluorescence in situ hybridization)

Candida Score >2.5

- Yes (Start echinocandin)
  - Cx/FISH (-), pt improves (cont. echinocandin)
  - Cx/FISH (-), no improvement (DC echinocandin)
  - Cx/FISH (+), Flu-S species (change to fluconazole)

- No (No antifungal therapy)
  - Cx/FISH (+), Flu-R species (cont. echinocandin)
  - Continue to evaluate

- Candida Score ≤2.5
  - Cx/FISH (-), pt improves (cont. echinocandin)
  - Cx/FISH (-), no improvement (DC echinocandin)
  - Cx/FISH (+), Flu-S species (cont. echinocandin)
  - Cx/FISH (+), Flu-R species (cont. echinocandin)
  - Continue to evaluate

Half of US and Japanese companies end drug discovery (BMS, Lilly, Wyeth, GSK, PG, etc)
SELECTED REFERENCES AND RESOURCES


SEL F – A S S E S S M E N T   Q U E S T I O N S

1. Which of the following is a CORE antimicrobial stewardship strategy?
   - a. Parenteral to oral conversion.
   - b. Antimicrobial cycling.
   - c. Formulary restriction with preauthorization.
   - d. Antimicrobial order forms.

2. Which of the following is TRUE regarding antimicrobial stewardship in smaller institutions?
   - a. There are no published accounts of successful programs in smaller institutions.
   - b. The only published accounts of programs in smaller institutions involved a 5 day per week dedicated ID pharmacist.
   - c. Successful, part-time antimicrobial stewardship initiatives have been published.

3. Which of the following is a strength of current antimicrobial stewardship initiatives?
   - a. The promotion of the idea that antimicrobial use is important on a population level.
   - b. The reduction of antimicrobial use in the community.
   - c. Promoting the prompt initiation of antimicrobial therapy.

Answers

1. c
2. c
3. a
Antimicrobial Stewardship: Building the Case and Overcoming the Barriers in Your Institution

Steven B. Cano, M.S., B.S.Pharm., FASHP
Senior Director and Chief Pharmacy Officer
Cambridge Health Alliance
Cambridge, Massachusetts

Steven B. Cano, M.S., B.S.Pharm., FASHP, is Senior Director of Pharmacy and Chief Pharmacy Officer for the Cambridge Health Alliance (CHA) in the Boston Metro-North region. The CHA comprises three hospitals, the Cambridge Public Health Department, more than 20 primary care/ambulatory care sites, and Network Health, a growing Medicaid health plan. The CHA Department of Pharmacy manages operations in three hospitals and a retail pharmacy, conducts drug research activities, maintains a strategic partnership with the University of Rhode Island College of Pharmacy for undergraduate teaching, and coordinates pharmacist-managed pharmacotherapy clinics. Prior to his current position, Mr. Cano was Director of Pharmacy at Saint Vincent Hospital in Worcester, Massachusetts, for 17 years and Director of Pharmacy at Humana Hospital Mountain View in Denver, Colorado, for 5 years.

Mr. Cano received a degree in biology from Wichita State University and a Bachelor of Science degree in pharmacy from the University of Kansas. He completed a combined Master of Science in Hospital Pharmacy degree and accredited hospital pharmacy residency program at the University of Kansas Medical Center. Mr. Cano has published over 20 articles and book chapters, and he has presented lectures to multidisciplinary national audiences. His professional interests include continuous quality improvement applied to the medication-use process, antimicrobial stewardship, medication safety, and outcomes research, and efforts to promote pharmaceutical care. Mr. Cano is a MassExcellence (Baldrige performance excellence criteria) senior examiner and was a faculty member for The Competitive Edge: Advanced Experiential Training in Outcomes Research program through ASHP. He is an Adjunct Professor of Pharmacy Practice at the University of Rhode Island College of Pharmacy. Mr. Cano has been active in pharmacy organizations in Kansas, Colorado, and Massachusetts, and was honored as Health-System Pharmacist of the Year in Massachusetts in 1995. Mr. Cano is a Fellow of ASHP.

In 1992, while at Saint Vincent Hospital, Mr. Cano established one of the first antimicrobial stewardship programs in the country. Aspects of the program included daily rounding with an ID physician / pharmacist team, antimicrobial order forms, extensive antibiotic use restriction policies, guidelines and protocols for antibiotic management by the clinical pharmacist. The antimicrobial stewardship team developed and deployed a unique multi-attribute utility theory model for structured formulary decision making. A 30% reduction in antibiotic expense was realized and maintained after the first year of the program. Mr. Cano was involved in the implementation of a similar program at the Cambridge Health Alliance in 2004.
OVERVIEW

Over the past twenty years, health care organizations have demonstrated the positive impact antimicrobial stewardship programs (ASPs) have on clinical and economic outcomes. Three years ago, the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America issued guidelines for the development of formal ASPs. Currently, it is unclear the extent to which these programs have been deployed nationally, however, ongoing concerns related to antimicrobial misuse, increasing antimicrobial resistance, and a lack of effective new agents in the drug development pipeline have lead to a focus on ASP implementation. Pharmacy and infectious diseases leaders are being challenged to ensure that their organizations have formal ASPs in place to protect patients.

Organizations that desire optimal antimicrobial use must prepare for a journey that begins with an understanding of the issues. Once pharmacy and infectious diseases leaders commit to a program of antimicrobial stewardship, a variety of barriers to implementation must be recognized and addressed. The case for antimicrobial stewardship can best be built locally through the development of a formal business plan. Upon approval and successful implementation, ASPs can thrive with the proper teamwork, funding, and accountability mechanisms in place.

LEARNING OBJECTIVES

At the conclusion of this knowledge-based educational activity, participants should be able to

- Discuss the essential elements of an antimicrobial stewardship business plan.
- Identify the status of your particular organization vis-a-vis the antimicrobial stewardship journey.
Making the Case and Overcoming Barriers to Antimicrobial Stewardship Programs

Steven Cano, M.S., B.S.Pharm.
Senior Director of Pharmacy / Chief Pharmacy Officer
Cambridge Health Alliance
Cambridge, Massachusetts

Objectives

• Discuss the essential elements of an antimicrobial stewardship program (ASP) business plan.

• Identify the status of your particular organization vis-a-vis the antimicrobial stewardship journey.

What is the status of antimicrobial stewardship (ASP) in my institution?

a. No ASP and no plans to pursue one
b. No ASP but we need to establish one
c. We are discussing the need for an ASP
d. Our ASP is not very effective
e. We have an ASP and it is highly regarded
The Journey . . .

- Enlightenment
- Commitment
- Justification
- Implementation
- Optimization

The Burning Platform

Challenge to Pharmacy Leaders

- Even though antimicrobial stewardship . . .
  - Is not required by The Joint Commission
  - Is not mentioned in the ASHP 2015 objectives
  - Is not measured directly in various national clinical pharmacy surveys

- We have a professional responsibility to demonstrate leadership!
Pharmacy – An Essential Ingredient . . .
• Pharmacy is an essential member of team based care delivery
• Medical specialty group support includes . . .
  – Society of Critical Care Medicine
  – National Association of Epilepsy Centers
  – United Network of Organ Sharing
  – Society of Hospital Medicine
  – Committee on the Future of Emergency Care in the United States Health System. Board on Health Services and Institute of Medicine
  – Infectious Diseases Society of America


Barriers to Establishing ASPs
• Lack of funding
• Shortage of adequately trained ID physicians and pharmacists
• Lack of pharmacy leadership supporting / managing ASP
• Lack of infectious diseases support
• Competition for funding with other hospital programs
• Communications with antagonizing colleagues


Did you (or will you) use a formal business plan to justify your ASP?

a. Yes, it was (or will be) very helpful
b. Yes, but it was not (or will not be) very helpful
c. No, it was not (or will not be) worth the effort
d. Unsure

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Building the Case

- Need for cost analysis of new programs
- New programs need to demonstrate return on investment (ROI) over reasonable time period
- Current situation is likely costing institution unnecessary dollars
- Clinical issues make timely program implementation compelling
- A formal business plan is essential

ASP Business Plan

- Needs assessment
- Market analysis
- Legal, regulatory, and accreditation assessment
- Program/service description
- Program management and organization
- Financial analysis
- Program evaluation
- Marketing and promotional plan
- Recommendations

Needs Assessment

- Review of literature
  - Antimicrobial resistance
  - Practice research, guidelines, and success stories
- Review of internal data and experience
  - Antibiotic budget
  - Impact of antibiotic misuse
  - Internal pharmacy success stories
- Share the burning platform
Market Analysis

• Target population and primary decision makers
• Environmental assessment (SWOT analysis)
• Market trends
  – Survey of competitor hospitals
  – National trends
• Volume trends
  – Changing services
  – Changing utilization trends

Legal, Regulatory, and Accreditation Assessment

• Compliance
  – Legal
  – Regulatory and licensure
  – Accreditation
  – Practice standards
• Collaborative drug therapy management
• Miscellaneous
  – Certification and credentialing
  – Risk management

Program / Service Description

• Scope of activities
• Benefits provided or needs met
• Types of patients served
• Types of professionals involved
• Rationale for the ASP
• Customer expectations
• Documentation / communication among providers
• Previous experiences (both successes and disappointments)
Most successful ASPs are managed . . .

a. By a pharmacy manager
b. By the Chief of Infectious Diseases
c. Through a collaborative Pharmacy / Infectious Diseases effort
d. Depends on the local circumstances
e. Unsure

Program Management and Organization

• Organization / reporting relationship should reflect strongest institutional reporting base
• Relationship to other programs and related organizations should be highlighted
• Responsibility, capability, and expertise should be detailed for . . .
  – Management
  – Physicians
  – Pharmacists
  – Others

Program Management and Organization (cont’d)

• Any anticipated contractual relationships (e.g., physician champion) should be disclosed
• All important expenses should be fully recognized
  – Staffing requirements
  – Training requirements
  – Other important expenses
• Key impacted work processes should be noted
The primary motive for implementing an ASP is . . .

- a. Clinical quality improvement
- b. Economic improvement
- c. Both clinical and economic improvements are possible
- d. Unsure

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Financial Analysis

- Cost considerations
  - Direct
  - Indirect
- Revenue considerations
- Cost avoidance considerations
- Formal economic evaluation
- Pro forma evaluation

Impact of Multidisciplinary Antibiotic Management Program

- 7 years of experience in a 200-bed community teaching hospital in Boston
- ID pharmacist (1.0 FTE) / ID physician (0.25 FTE) team
- Review and feedback approach focusing on 3rd generation cephalosporins, aztreonam, fluoroquinolones, imipenem
- Antibiotic use measured by defined daily dose / 1000 patient-days
- Outcome: $243,000 – 293,000 reduction in annual antibiotic costs
- Cost of program: $43,000 annually

Antimicrobial Cost Control in a Community Teaching Hospital

- 900-bed community teaching hospital in Dallas
- ASP team:
  - ID pharmacist (1.0 FTE)
  - ID physician (0.2 FTE)
  - Microbiologist (0.25 FTE)
- Program components:
  - Provider education
  - Automatic IV-→PO conversion
  - Automatic stop order policy
  - Restriction policies

Cost of program: ASP team salaries

Program Evaluation

- Criteria for service evaluation
  - Clinical outcomes (including microbiologic)
  - Economic outcomes
  - Humanistic outcomes
    - Quality of life / functional status
    - Satisfaction
- Relevant process indicators
- Timeframe for reviewing ASP performance
- Criteria for program termination if necessary

Clinical / Economic Outcomes of Pharmacist-Managed Aminoglycoside or Vancomycin Therapy

- Retrospective review of almost 200,000 Medicare patients
- In hospitals without a pharmacist-managed protocol:
  - Length of stay 12% longer
  - Total Medicare charges 6% higher
  - Drug and laboratory charges 8% higher
  - Hearing loss 46% higher
  - Renal impairment 34% higher
  - Death rates 7% higher

Clinical / Economic Outcomes of Pharmacist-Managed Antimicrobial Prophylaxis in Surgical Patients

- Retrospective review of more than 240,000 Medicare patients
- In hospitals without a pharmacist-managed protocol:
  - Length of stay 10% longer
  - Total Medicare charges 3% higher
  - Drug charges 7% higher
  - Surgical site infections 34% higher
  - Death rates 52% higher


Evidence to Support Team Approach to Antimicrobial Stewardship

- ID physician/clinical pharmacist team since 1993
- Comparison by blinded ID physician review

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<td>Clinical cure rate</td>
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<td>Treatment failure rate</td>
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<td>Appropriate choice of antimicrobial</td>
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p < 0.05 for all 3 outcome measures


Marketing and Promotional Plan

- Physicians and other providers
- Patients
- Payors
- Other stakeholders
  - Administration
  - Finance

- “What’s in it for me?”
Recommendations

- Approve the program
- Project positive financial return to secure pilot and/or full program funding
  - Physician resources
  - Pharmacist resources
  - Clinical decision support resources
- Address legal, regulatory, and accreditation issues
- Position program to ensure maximum administrative support, exposure, and accountability
- Conduct formal ASP strategic planning process

ASP Strategic Planning Process

- Leadership
- Developing the strategic plan
  - Formal process involving key stakeholders
  - Strategic challenges and advantages
  - Short-term and longer-term planning horizons
- Deploying the strategic plan
  - Action plans
  - Required resources
  - Performance projections, benchmarks, and measures

Essential Elements of an Effective Antimicrobial Stewardship Program

- Committed pharmacy, infectious diseases and organizational leadership
- Structured program, established through formal approval process, and managed through ongoing multi-disciplinary participation
- Adequate number of competent clinicians
- Performance metrics that document program impact
Lessons Learned - Critical Success Factors

• Teamwork wins
  – Primary team: Pharmacy and Medicine (ID)
  – Laboratory / microbiology / information technology support is critical
• Up-front program funding is optimal
• Clinical outcomes are of primary importance, but understand measurement difficulties
• Economic outcomes are of secondary importance, but ASPs are typically self-funding
• ASP team must be accountable
Antimicrobial Cost Control in a Community Teaching Hospital

- 900-bed community teaching hospital in Dallas
- ASP team:
  - ID pharmacist (1.0 FTE)
  - ID physician (0.2 FTE)
  - Microbiologist (0.25 FTE) team
- Program components:
  - Provider education
  - automatic IV→PO conversion
  - automatic stop order policy
  - restriction policies
- Cost of program: ASP team salaries

SELECTED REFERENCES AND RESOURCES

   Editorial.

2. Owens RC, Shorr AF, Deschambeault AL. Antimicrobial stewardship: shepherding

   management program conducted during 7 years. Infect Control Hosp Epidemiol.


5. Bond CA, Raehl CL. Clinical and economic outcomes of pharmacist-managed

6. Bond CA, Raehl CL. Clinical and economic outcomes of pharmacist-managed
   antimicrobial prophylaxis in surgical patients. Am J Health-Syst Pharm. 2007;
   64:1935-42.

   33:289-295.
SELF–ASSESSMENT QUESTIONS

1. Which of the following is not a step on the journey to getting the most from your antimicrobial stewardship program?
   a. Optimization.
   b. Implementation.
   c. Commitment.
   d. Reevaluation.
   e. Enlightenment.

2. Which of the following is a frequent barrier to establishing antimicrobial stewardship programs?
   a. Competition for funding with other hospital programs.
   b. The lack of new antimicrobial agents being introduced to the market.
   c. The Pharmacy department's desire to implement other types of clinical programs.
   d. Oversupply of infectious diseases physicians.
   e. Uncertainty of the impact of the pharmacist on antimicrobial use.

3. With regard to building the case for antimicrobial stewardship programs, which of the following statements is not true?
   a. Across virtually all hospitals, new programs need to demonstrate or project a return on investment.
   b. Many hospitals without formal programs are able to demonstrate optimal clinical and economic outcomes related to antibiotic use.
   c. A formal business plan is highly recommended when trying to justify a program.
   d. The clinical impact of a program is more important than the financial impact.
   e. Programs are not yet required by the Joint Commission or the Centers for Medicare and Medicaid Services.

Answers
1. d
2. a
3. b
Antimicrobial Stewardship: Building the Case and Overcoming the Barriers in Your Institution

Robert C. Owens, Jr., Pharm.D.
Director, Antimicrobial Stewardship Program
Clinical Pharmacy Specialist, Infectious Diseases
Department of Pharmacy Services and Division of Infectious Diseases
Maine Medical Center
Portland, Maine

Robert C. Owens, Jr, Pharm.D is the Director of the Antimicrobial Stewardship Program and Clinical Pharmacy Specialist in Infectious Diseases for the Department of Pharmacy Services and Division of Infectious Diseases at Maine Medical Center in Portland, Maine. He is a Clinical Assistant Professor in the Department of Medicine at the University of Vermont, College of Medicine in Burlington and serves as a faculty member of the Infectious Diseases Fellowship Program at Maine Medical Center. He is also a Clinical Assistant Professor, Tufts University, School of Medicine in Boston, Massachusetts.

Dr. Owens received his Pharm.D. at Mercer University School of Pharmacy in Atlanta, Georgia. He completed his residency in clinical pharmacy practice at DeKalb Medical Center in Atlanta and went on to complete his fellowship training in Infectious Diseases at Hartford Hospital in Hartford, Connecticut.

Dr. Owens’ research interests include antimicrobial pharmacokinetics and pharmacodynamics, antimicrobial stewardship (serves on the IDSA/SHEA Guideline Committee in this area), C. difficile infection, health outcomes and economics, as well as antimicrobial therapy in the geriatric population. He has functioned as the principle investigator and co-investigator on numerous Phase I-IV studies since 1995 and has over 125 abstracts and publications in the peer-reviewed literature including journals such as the New England Journal of Medicine and Clinical Infectious Diseases. He has recently served as the editor-in-chief of two books on antimicrobial stewardship (2005, Marcel Dekker) and antimicrobial resistance (2007, Informa Healthcare). In 2006, he and coauthors received the “Infectious Diseases Pharmacotherapy Impact Paper of the Year award” by the Society of Infectious Diseases Pharmacists. The antimicrobial stewardship program run by Drs. Owens and Stogsdill, has won two Paul M. Cox, Jr., Memorial medical quality awards at Maine Medical Center (2003, 2006).

Dr. Owens has served as a member of the CLSI subcommittee on inpatient medication use and appointed as consultant to the Anti-Infective Advisory Committee of the FDA (SGE status) in 2006, and consultant for Reuter’s Health in 2008. He is a member of the editorial boards of Pharmacotherapy, Diagnostic Microbiology and Infectious Diseases, The Open Drug Safety Journal, and the Tarascon Pocket Pharmacopeia and serves as an ad hoc reviewer for numerous other professional journals.
Antimicrobial Stewardship: Building the Case and Overcoming the Barriers in Your Institution

Robert C. Owens, Jr., Pharm.D.

PRESENTATION

The Role of the Pharmacist: Best Practices for Maintaining Effective Antimicrobial Stewardship Programs

OVERVIEW

After the approval and implementation of an Antimicrobial Stewardship Program (ASP), pharmacists are uniquely positioned to help ensure the long-term success of this important initiative. In order to maintain the program's energy and momentum, the pharmacist, along with other members of the team, must assure the efficient use of resources, strategic planning, and reporting of successes and challenges. This presentation will discuss strategies to maintain an effective ASP in your health care system.

LEARNING OBJECTIVES

At the conclusion of this knowledge-based educational activity, participants should be able to

- Give several examples of simple initiatives that can be successful in the early phases of an antimicrobial stewardship program.
- Describe the importance of tracking antimicrobial use on a long-term basis.
- Discuss the importance of individualizing antimicrobial stewardship interventions based on your institution’s landscape.
The Role of the Pharmacist: Best Practices for Maintaining Effective Antimicrobial Stewardship Programs

Robert C. Owens Jr., Pharm.D.
Director, Antimicrobial Stewardship Program
Division of Infectious Diseases
Maine Medical Center
Portland, Maine

Disclosures/Biases
I do not believe in automatic stop orders for antibiotics.
I do not believe in antibiotic restriction as the primary means of “stewardship” with what we currently know about this strategy.

“Must Haves” for Larger and Smaller Hospitals

<table>
<thead>
<tr>
<th>Administrative Support</th>
<th>Basic Resources…</th>
</tr>
</thead>
<tbody>
<tr>
<td>JCAHO, CDC Get Smart for Health Care, Visibility of Public Reporting</td>
<td>ID Physician Optimal: Not always possible in smaller hospitals, Consider others with interest in antibiotics, or outsourcing expertise</td>
</tr>
</tbody>
</table>

Physician Champion
Dedicated Pharmacist time
Collaboration and Role of the Pharmacist
Continuation, Advancement of Knowledge…1990s-Current

Clinical Pharmacists
Clinical Pharmacist & ID Physician
Operationalize

Research
Patients
Focus on Patient Safety (Randomized Trial)

Continuation, Advancement of Knowledge…1990s-Current

Clinical Pharmacists
Clinical Pharmacist & ID Physician
Operationalize

Research
Patients
Focus on Patient Safety (Randomized Trial)

However, Procrustean (or, One Size Fits All) Strategy Will Not Work!
Look at Local Resistance Patterns, Antimicrobial Utilization, Expenditures

Did We Run Aground?
The likelihood of a 'stealth' nuclear submarine running aground is supposed to be as likely as a Loch Ness monster sighting but that is what happened off of Scotland's Isle of Skye where the HMS Astute became stuck for several hours, until it was helped to deeper waters from, among other vessels, a tugboat.

http://www.sfgate.com/blog/stew/detail entry_id=522302?ts
2017072318
How does your institution track antimicrobial use?

a. Defined daily dose
b. Days of therapy
c. Purchases $
d. Other
e. Do not track
Outcome Measurement of Certificate Program

Certificate Program
Augusta, ME

Pre-Program Survey
3 Months Post-Program Survey
6 Months Post-Program Survey
One Year Post-Program Survey

Certificate

Inpatient Stewardship Strategies: 10,000 ft View

Restriction — expert advice
CPOE/Abx Order form
CDSS — expert systems

Rapid Diagnostics in progress
Traditional Culture in progress
Audit/Feedback

De-escalation
IV-Oral
STOP abx

Antimicrobial Order
Microbiological Data Trickling in (Gram Stain), Imaging studies, etc...

Do You Know What You're Spending to Treat Resistant Organisms?

- Expenditures for drug classes used to treat resistant organisms greatly increased from 2004 to 2007.
- In contrast, expenditures for older drug classes (e.g., penicillins, fluoroquinolones) decreased over the same period.

- Carbapenems
- Anti-MRSA Drugs
- Glycopeptides
- Penicillins
- Fluoroquinolones
Coordinating Increased Compliance with CMS Core Measures for Pneumonia

Role of the Pharmacist

If "No" is checked, the algorithm questions appear.

Work to Improve CMS Core Measures (Correct Antibiotic, Correct Timing)

New appearance of order set on Form Open. The first question the clinician must answer is if there is any diagnostic uncertainty of pneumonia. – a simple Yes or No click.

See page 52 for enlarged view
Creatinine clearance information will be available looking back 7 days.

If there is a MRSA health issue and drug allergies, the information will auto-populate.

Clicking on the MLM button will open up the guidelines.

Front End Interventions (Example)


See page 52 for enlarged view

See page 53 for enlarged view
Research Paper

Impact of a Computerized Clinical Decision Support System on Reducing Inappropriate Antimicrobial Use: A Randomized Controlled Trial

JESSINA C. MCGREGOR, PHD, ELIZABETH WEEKES, PHARM.D, GRAEME N. FORREST, MBBS, HAROLD C. STANDIFORD, MD, ELI N. PERENCEVICH, MD, MS, JOY P. FURUNO, PhD, ANTHONY D. HARRIS, MD, MPH

Computerized Decision Support Led to More Patients Capable of Being Intervened Upon by the ASP

So... some might be wondering where to start?

See page 53 for enlarged view

See page 54 for enlarged view
Outcome Measures: Antimicrobial Stewardship Program Combined With Infection Control Interventions on Epidemic CDI

Antibiotic Intervention Period

Use of Targeted Abx

Bars represent CDI


See page 54 for enlarged view

Clostridium difficile Infection by CDC definition
January 2005 – February 2010

See page 55 for enlarged view

Outcome Measures: Antibiotic Use Reduction (over 7 years)


Reduction in CDAD (p=0.002)

See page 55 for enlarged view
Example Solution:
Antibiotic start times now default for quinolones from the 0900 standard to 1100 and 2300 for ciprofloxacin orally.

Dosed adequately (>10mg/kg):
- Underweight patients: 100%
- Normal weight patients: 93.9%
- Overweight patients: 27.7%
  - And only 3.3% of patients receiving <10mg/kg had their dose changed within first 24 hours

We Can Do a Better Job of Minimizing Unnecessary Antimicrobial Use
Point Prevalence Survey of Antimicrobial Duplication
- 39% received 2 or more antibiotics
- 77% of cases contained unnecessary redundant therapy, resulting in excessive use of antibiotics
- Receiving unnecessary, redundant therapy considered a “medication error”
- This is a ripe opportunity for intervention

If you have an ASP, which is most important to the justification of your program?

a. Expenditures on antimicrobials.
b. Reduction in resistance rates
c. Improved clinical parameters (e.g. LOS, etc.)
d. All of the above
e. None of the above
Adequately Trained Resource Challenges

Current Landscape
- 2007 ASP Guidelines left "purposefully" vague
  "ID trained pharmacist" given the number of training programs
  vs. number of hospitals
- 2009: ID Pharmacist Training Position Statement: PGY 1
  Residency + ID residency (PGY2) programs (Pharmacotherapy 2009)
- ID Fellowship programs
- Or, Pharmacists learn "on the job" with adequate accessibility to
  mentors (1970s-forward); Optimally with supplemental
  certificate-type training (2008-current)
Anatomy of Success

For pharmacist as a team member:
Keep it “simple” especially at first…

Interventional technique
Documentation tool
Specific objectives

Anatomy of Success

Hand holding…

What Do I Take Away from This?
Perceived Barriers to Implementation of ASPs

- Strategies We Have Previously Employed
  - Previous restrictive strategies used by many to “control” antibiotic use
  - Overcoming barriers: Prospective audit with feedback (gives control back to the prescriber, taking ownership, sharing risk)
- Neither physicians or pharmacists alone have skill sets that are optimal for ASPs, but BOTH together = Unbeatable!
  - Pharmacodynamics, Infectious disease, Lab interpretations, moving isolated interventions to programmatic interventions is not easy but requires time, politics, knowledge, measuring outcomes
- Communication, Communication, Communication…
- Business case
  - ROI for even small hospitals and early programs has been demonstrated
  - ROI for seasoned programs can be best characterized by benchmarking
If “No” is checked, the algorithm questions appear.

Creatinine clearance information will be available looking back 7 days.

If there is a MRSA health issue and drug allergies, the information will auto-populate.
Clicking on the MLM button will open up the guidelines.

Research Paper

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Computerized Decision Support Led to More Patients Capable of Being Intervened Upon by the ASP

Outcome Measures: Antimicrobial Stewardship Program Combined With Infection Control Interventions on Epidemic CDI

Clostridium difficile Infection by CDC definition
January 2005 – February 2010

Number of Cases

2007 rate 1.1 per 1000 patient days

Outcome Measures: Antibiotic Use
Reduction (over 7 years)

Parenteral antibiotic use, cost per 1,000 patient-days, and Medicare Case Mix Index (MCCMI)


Reduction in CDAD (p=0.002)
### Antibiotic Surveillance Report

**Maine Medical Center**

**Antibiotic Surveillance Report**

**Jan-14-2007 05:03**

**042575490003**  ....continued  Adm. Date: 2007/01/03 18:59

- **Allergy:** No Known Allergies
- **Bun:** 29
- **Creat:** 2.1
- **WBC:** 7.7
- **Bld Cult:** NO GROWTH AT 48 HOURS
- **Height:** 182.9
- **Weight:** 88.10 kg

#### Antibiotic Orders

<table>
<thead>
<tr>
<th>Start Date/Time</th>
<th>Status</th>
<th>Stop Date/Time</th>
</tr>
</thead>
</table>

- **1/10/07 001BHNSHKY**  
Piperacillin/Tazobactam Inj - 2.25 Gm, IV INFUSION, q6h, Infuse via syringe pump.  
  - Ordered  
  - 1/10/07 8:47

- **1/13/07 001BH5Z3FH**  
Metronidazole Inj - 500 mg, in 100 ml NS, q6h, Infuse over 60 min. Do not refrigerate  
  - Ordered  
  - 1/13/07 13:22

#### Nutrition Orders

<table>
<thead>
<tr>
<th>Start Date/Time</th>
<th>Status</th>
<th>Stop Date/Time</th>
</tr>
</thead>
</table>

- **1/11/07 001BHQOSSJ**  
  Diet, diabetic(D), 1800 cal(18) - Renal(G), start now on Jan-11-2007, continue until d/c'd  
  - Ordered  
  - 1/11/07 15:45

### Antibiotic Surveillance Report

**Maine Medical Center**

**Antibiotic Surveillance Report**

**Jan-14-2007 05:03**

**046247560006**  ....continued  Adm. Date: 2007/01/03 10:18

#### Antibiotic Orders

<table>
<thead>
<tr>
<th>Start Date/Time</th>
<th>Status</th>
<th>Stop Date/Time</th>
</tr>
</thead>
</table>

- **1/10/07 001BMZSC**  
  Imipenem Inj - 500 mg, IV INFUSION, q6h, IN 100ml NS over 30 minutes  
  - Ordered  
  - 1/10/07 5:00

- **1/10/07 001BPHWQ**  
  Metronidazole Inj - 500 mg, in 100 ml NS, q6h, Infuse over 60 min. Do not refrigerate  
  - Ordered  
  - 1/11/07 0:00

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SELECTED REFERENCES AND RESOURCES


SELF– ASSESSMENT QUESTIONS

1. Which of the following is a TRUE statement regarding Infectious Diseases (ID)-trained pharmacists?
   a. Must have completed a PGY1 and PGY2 in ID.
   b. Certificate/training programs have become necessary to fill the void of ID residency-trained pharmacists.
   c. Must have completed an ID fellowship.
   d. It is not reasonable for community hospitals to have an ID-trained pharmacist on staff.

2. Which of the following is a FALSE statement regarding antimicrobial expenditures from 2004-2007?
   a. Expenditures for fluoroquinolones decreased.
   b. Expenditures for penicillins decreased.
   c. Expenditures for carbapenems increased.
   d. Expenditures for anti-MRSA drugs decreased.

3. According to a study published by Valiquette et al, in 2007, antimicrobial interventions:
   a. Increased the rate of Clostridium difficile infection (CDI).
   b. Decreased the rate of CDI, when implemented in conjunction with enhanced infection control practices.
   c. Decreased the rate of CDI, when implemented alone.
   d. Had no effect on the rate of CDI.

Answers

1. b
2. d
3. b