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"antimicrobial resistance is a problem of international proportion"

Antimicrobial Stewardship Programs

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This knowledge-based activity is targeted for all pharmacists and is acceptable for 1.0 hour (0.1 CEU) of continuing education credit. This course requires completion of the program evaluation and at least a 70 percent grade on the program assessment questions. ACPE Universal Activity Number (UAN): 0048-0000-12-009-H04-P

Objectives:

After completion of this program, the reader should be able to:

- 1. Identify ways in which Antimicrobial Stewardship Programs (ASPs) are utilized to decrease microbial resistance.
- 2. Comprehend the multiple and interconnected roles of various health care professionals associated with ASPs.
- Recognize the significant decrease in current research and development of antimicrobial agents by major pharmaceutical companies and its impact on the need to properly utilize available antibiotics.
- 4. List strategies that can be established to create and run an effective institutional ASP.
- 5. Examine how the quality of patient health has been improved as a result of successful implementation of ASPs in a variety of health care settings.

Abstract

Antimicrobial Stewardship Programs (ASPs) are becoming increasingly prevalent in the United States as concerns continue to mount regarding antimicrobial resistance and the lack of new, novel antibiotics being introduced. There are a multitude of factors that have contributed to the escalation in antimicrobial resistance, with some of the more common concerns being overly broad antimicrobial coverage and prolonged antimicrobial treatment amongst others. While antimicrobial resistance is a problem of international proportion, each health care institution remains responsible for assessing its own protocols pertinent to

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antimicrobial usage. ASPs have had unparalleled success in achieving their goals due to the collaboration of health care personnel, informatics, data collection, and effective policies being employed. While the pharmaceutical industry struggles with the development of novel antimicrobials, ASPs are a critical component to promote the continued efficacy of currently available antimicrobials.

A considerable number of strategies have been established to implement and manage an effective institutional ASP, including educational programs, the development of institutional antimicrobial and disease state guidelines, prior approval for certain broad-spectrum agents, post-prescription review, and computer-based decision support. However, resources are often limited thus creating barriers for institutional ASP success. Some common barriers include a lack of fundraising, inadequate or absent diagnostic facilities, poor data collection, variation in data collection, a lack of communication among various health care professionals and a lack of cooperation among health care facilities.

ASPs have the potential to reduce antimicrobial resistance evolution and therefore improve patient outcomes. The involvement of multiple health care professionals, including pharmacists, is imperative to the success of an ASP.

Introduction

Inappropriate prescribing, overuse of antimicrobial agents and even appropriate antibacterial use have resulted in multidrugresistant organisms, elevated medical care costs and adverse events.¹ On a universal level, there is a growing concern of increased antimicrobial resistance which has led to the development of ASPs. An ASP is defined by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) as "a system of personnel, informatics, data collection, and policy/procedures that promotes the optimal selection, dosing, and duration of therapy for antimicrobial agents throughout the course of their use."² Furthermore, the World Health Organization (WHO) defines optimal antibiotic prescriptions as "the costeffective use of antimicrobials which maximizes their clinical therapeutic effect, while minimizing both drug-related toxicity and the development of antimicrobial resistance."³ As seen by the definitions of ASPs and optimal prescriptions, preventing antimicrobial resistance truly involves all sections of health care, especially pharmacy.

Nonetheless, there exists a significant gap between the presence of novel candidates in the latter stages of the "US drug-development pipeline" and the increasing number of resistant microorganism strains.

Impetus for the Development of ASPs

Pharmaceutical advancements in drug development of novel antimicrobials have been steadily declining. The number of new antibacterial drugs approved for marketing in the United States continues to decrease⁷ (Figure 1). It is important to recognize that it is not only the number of antimicrobials in the drug-development pipeline, or the number of antimicrobials that have been recently approved, but also the quality of novel drugs developed with new mechanisms of action.

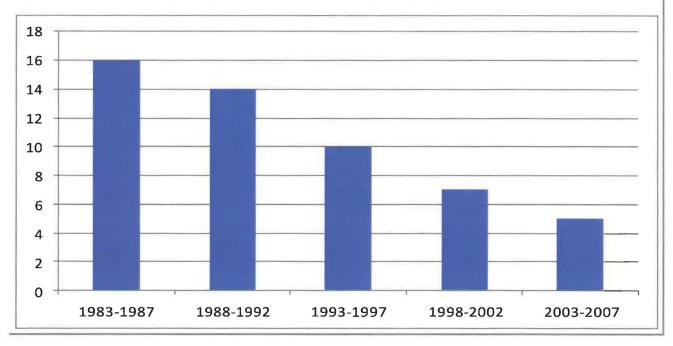


Figure 1. New antibacterial agents approved in the US, 1983–2007, per 5-year period^{5,6,7}

The decrease in research and development for antimicrobial agents by major pharmaceutical companies has not gone unnoticed, and is highlighted when current treatment options become susceptible to resistant microorganisms. The IDSA and the Antimicrobial Availability Task Force (AATF) have expressed concern over this issue.⁴ Nonetheless, there exists a significant gap between the presence of novel candidates in the latter stages of the "US drug-development pipeline"⁴ and the increasing number of resistant microorganism strains. For example, the quantity of β -lactamases has greatly increased—in 1970, there were 13 of these enzymes known, 282 in 1999, and 532 in 2004.⁴

The Role of ASPs

Approximately 60 percent of hospitalized patients in the United States receive at least one dose of an antimicrobial agent. In 2002, there were approximately 1.7 million health care-associated infections (HAIs) in the United States, which resulted in about 98,987 fatalities. Many of the HAIs were caused by pathogens resistant to antimicrobial agents.² Alarmingly, more people now die of MRSA infection in U.S. hospitals than of HIV/AIDS and tuberculosis com-

"More people now die of MRSA infection in U.S. hospitals than of HIV/AIDS and tuberculosis combined."

bined.⁵ Additionally, many of the therapeutic options for these pathogens are limited, sometimes forcing prescribers to use older drugs often associated with increased risk of toxicity. Furthermore, the number of elderly patients, individuals undergoing surgery, transplantation, and other procedures continues to increase making the average patient more susceptible to these infections due to their immunocompromised status.⁵

As it becomes clear that antimicrobial resistance is an increasingly troublesome reality, the roles of ASPs today become ever more significant in the health care world. The primary goal of ASPs is to increase the quality of patient care, while the secondary goal involves reducing health care costs.² Additionally, ASPs are aimed at being able to successfully use current antimicrobial agents in the future by limiting overuse and misuse of antimicrobials today, thus minimizing antimicrobial resistance.¹ The use of ASPs can decrease medication errors pertaining to antimicrobials, such as preventing duplicate antimicrobials or avoiding the prescribing of unneeded antimicrobials.⁸ Ultimately, infections that arise from multidrug-resistant (MDR) pathogens increase the length of illness and hospital stays.⁹ Efficient ASPs should monitor the proportions of antimicrobial agents used in patient populations to ensure there is some diversity in the prescribed drugs for specific indications. This monitoring will aid in avoiding the development of resistance to antibiotic classes as a whole.¹ Additionally, ASPs encourage the streamlining or the de-escalating of therapy in the earliest possible stages of a treatment, the transfer to oral treatment from parenteral treatment, the administration of antimicrobial agents over the correct length of time and the administration of the correct dose. In many institutions without ASPs, the ability to tailor a medication regimen from the initial broad-spectrum therapy is neglected even when microbiologic data becomes available. Similarly, "spiraling empiricism" occurs when broad-spectrum antibiotics are quickly and haphazardly administered when a patient does not improve health after the initial therapy. Likewise, the probability of encountering a MDR pathogen is enhanced when antimicrobial treatment is administered for too long of a time period. As a result of ASPs, these issues can be minimized.² Inevitably, lower medical costs are

another "bottom-line"¹ goal of ASPs without compromising the standard of care administered to the patient.¹

In order for an ASP to be effective in achieving the goals described above, it is imperative that appropriate health care professionals are actively involved. There can be several combinations of participants that prove to be effective, but the fundamental staffing involved in an ASP usually includes an infectious disease physician, clinical pharmacist, and infection control personnel. The ASP pharmacist works closely with the microbiology laboratory who provides patient-specific cultures and vital susceptibility information.¹ An emergency medicine clinical pharmacist (EPh) can play a significant role in an antibiotic stewardship program, by reconsidering empiric antimicrobial treatment before the patient leaves the emergency room (since a patient is normally started on an IV broad-spectrum antibiotic after arrival in the emergency room before a culture is taken).¹⁰

Several strategies have been established to create and manage an effective institutional ASP, but there are basic principles that are crucial for success. Some common, baseline items that are present in the majority of successful ASPs include educational resources, the development of guidelines incorporating both local and national concerns, prior approval, post-prescription review and computer-based decision support.¹ Also, ASPs are most effective when they incorporate local guidelines into national guidelines by taking into consideration the prescribing and resistance patterns of antimicrobial agents in a certain region. Two proven strategies for incorporating ASPs are the "back-end"² and "front-end"² approaches. The "front-end"² approach includes formulary restriction and preauthorization (e.g., phone calls to the stewardship team) for restricted antimicrobial agents. The negative effect of this strategy is a possible delay in the administration of "stat" antimicrobials. The "back-end"² approach, also known as the prospective audit, involves the antimicrobial support team, including the infectious disease clinical pharmacist, to give feedback with suggestions to the prescriber based on institutional guidelines, patient specific information and culture results.² Common interventions include de-escalating or discontinuing one or more medications, switching from an intravenous to oral dosage form, and recommending a short-term duration of therapy. Additional strategies include educational programs, antimicrobial order forms, and computer systems with clinical decision support (such as computerized physician order entry). Overall, it is important for each institution to build an effective ASP based on available resources, personnel and various local factors.²

Although many health care settings have successfully implemented an ASP, there are a number of barriers that may be encountered including a lack of fundraising and physician participation, an insufficient number of infectious disease physicians and pharmacists, inadequate or absent diagnostic facilities, poor data collection, variation in data collection, a lack of communication among various health care professionals and a lack of cooperation among health care facilities.^{8,11} An underlying issue that has a prominent role in the lack of physician participation is that only approximately 18 percent of infectious disease physicians that participate in ASPs are reimbursed for their services.¹ These sorts of obstacles are especially true for smaller institutions with limited budgets and personnel. In order to overcome these problems, it is suggested that executive planning and continued education programs be implemented to increase the cooperation among health care professionals to augment their clinical knowledge base dealing



with steps to decrease and prevent antimicrobial resistance.¹¹ Therefore, educational programs directed at health care professionals can have a significant impact on the awareness of antimicrobial resistance, and the necessary procedures that need to be considered in their area of practice.

Impact of ASPs

There are numerous examples of successful implementation of ASPs to combat certain drug resistant pathogens and to improve the quality of patient care in a variety of specific health care settings. For example, an ASP was initiated in 2002 at the Vanderbilt University Hospital surgical trauma and intensive care units. The data collected as a result of this ASP spanned over an eight-year period. Over this time period, there were 1,794 Gram negative pathogens isolated. As a result of the initiation of the ASP, the percentage of infections due to MDR pathogens decreased from 34.7 percent in 2002 to 8.5 percent in 2008. Because resistant Gram negative infections are associated with about three times the health care costs compared to antimicrobial susceptible Gram negative infections, the implementation of the ASP resulted in decreased overall health care costs.¹²



Similarly, at John Hopkins Children's Medical and Surgical Center, a 175-bed hospital, an antimicrobial stewardship campaign was implemented. As a result, there was an 11.6 percent decrease in the number of doses of restricted antimicrobial agents dispensed. In addition, there was a 40 percent reduction in the number of telephone calls from the pharmacy when restricted antimicrobial use occurred. This was in large part due to the increased communication and educational programs offered to prescribers of the antimicrobial stewardship campaign. Additionally, there was a \$370,069 decrease in the projected costs associated with restricted antimicrobial agents.¹³

A clinical trial evaluated the effectiveness of an ASP by comparing an intervention group (a pharmacist involved in antimicrobial stewardship) compared to a control (no antimicrobial stewardship pharmacist).

The role of the stewardship pharmacist was to utilize prospective audit for the basis of interventions, to monitor the cultures of the patients, and to educate health care personnel of the program. In this study, there were 442 antibiotic orders for 160 patients. A total of 168 interventions by the antimicrobial stewardship pharmacist were performed, with a 91 percent acceptance rate by the prescribing physician. Compliance of all quality indicators, as a result of the ASP, rose to 54 percent compared to the baseline 16 percent of the control group. The quality indicators, together forming the primary outcome measure of this study, included documented indication for antibiotic therapy, appropriate cultures collected, appropriate empirical therapy and antimicrobial selection based on institutional and national guidelines, and appropriate de-escalation.¹⁴

ASPs are currently being implemented in settings beyond the hospital and inpatient facilities in order to incorporate a "full cycle of care." An ASP should not end once a patient is discharged, but should transition to the outpatient setting. For example, the Cleveland Clinic formed the community-based parenteral anti-infective therapy program (CoPAT). Under this program, an infectious disease consultation is mandated for any patient that is discharged to another facility or to the patient's home. During this consultation, infectious disease clinicians review laboratory results and also schedule follow-up appointments. Follow-up visits are thought to decrease readmissions, which is a major concern since 34 percent of Medicare patients discharged from hospitals are rehospitalized within 90 days, adding an additional \$17.4 billion to overall Medicare costs. Demonstrating the importance of the follow-up visits, over one-half of these re-hospitalized patients were not scheduled for a follow-up visit. Overall, the Cleveland Clinic's initiative to expand their ASP program beyond their inpatient facility is aimed at improving patient health and is an area of future expansion of ASPs.¹⁵

Conclusion

Antimicrobial resistance is a major health care-associated predicament. Without proper preventative measures, such as the implementation of ASPs, patient health could be severely compromised. Likewise, the use of current antimicrobial agents must be monitored in an attempt to prevent resistance due to inappropriate prescribing, length of treatment, and over-prescribing. ASPs have been proven to be efficacious in a variety of formats, especially when institutional guidelines based on local patterns are combined with national guidelines. Additionally, the involvement of multiple health care professionals, including pharmacists, is an imperative part of an ASP improving patient care and decreasing antimicrobial

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ASK AN EXPERT

During our research on ASPs, we had the opportunity to interview Jason Pogue, PharmD, BCPS-ID, a clinical pharmacist (infectious diseases) at Sinai-Grace Hospital, Detroit Medical Center and author of several leading articles in this area of practice.^{16,17}

Q: Why do you think ASPs are important to our health care system?

JP: Antimicrobial resistance has been recognized by the World Health Organization (WHO) as one of the top three current threats to human health. As the antimicrobial pipeline falls further behind the pace of antimicrobial resistance development, ASPs become even more vital to health care in order to preserve the antimicrobials we currently have.

Q: When formulating budget appropriations, do you believe health care institutions consider these developments in antimicrobial resistance to be of vital importance?

JP: Firstly, when strictly focusing on the bottom line, since infections involving multidrug-resistant organisms are so costly, antimicrobial resistance is to be avoided at all costs. Recently the government and other payers are not reimbursing treatment of health care-associated infections, leaving the institution to shoulder the financial burden. This makes health care facilities carefully consider, develop, and utilize an ASP to combat the development of antimicrobial resistance. Furthermore, drug resistant pathogens often require new, broader spectrum drugs for treatment, which are extremely expensive. Therefore, hospitals consider antimicrobial resistance as a priority concern when developing a budget. Even though all health care institutions desire to run an effective ASP, since ASPs have been proven to improve patient outcomes and lower overall health care costs, the lack of adequate resources needed up front may restrict many institutions from seeing the full effect of a complete ASP.

Q: IDSA has attempted to combat the lack of development in the antimicrobial pipeline by introducing the 10 x '20 Initiative calling for the development of ten novel antibiotics by the year 2020. Is this realistic?

JP: Considering the current state of antimicrobial development, this goal is lofty and may be unlikely. Most new antibiotics in development are not novel, but rather are more diverse derivatives of current antibiotics since they do not have a new mechanistic target. While these derivatives can lower the cost of current treatment, they are not considered novel development.

Currently, the two major antibiotics that work to fight Acinetobacter baumannii are ampicillin-sulbactam and imipenen. This microbe, by innate nature, is resistant to many antibiotics. However, it is becoming increasingly resistant to ampicillinsulbactam and imipenen. The susceptibility of this organism to the two antibiotics decreased from 89 percent to 40 percent and 99 percent to 42 percent, respectively. Currently, there are not any new drugs to combat this organism, only leaving older medications as treatment options, which have an increased number of side effects. For example, colistin can be used, but causes nephrotoxicity in 40 percent of the patients. Therefore, many deleterious outcomes can occur due to the inability to utilize the first line therapy. Also, as resistance develops, the length of hospital stay and mortality rates increase, which highlights the importance of ASPs.

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Assessment Questions—Antimicrobial Stewardship Programs

1. Which is NOT a reason for concern dealing with the spread of antimicrobial resistance?

- A. Decrease in research and development of antimicrobial agents by major pharmaceutical agents
- B. Administration of the correct dose
- C. Over-prescribing antibiotics
- D. Inappropriate and/or prolonged use of broadspectrum antimicrobial coverage

2. All of the following are benefits of successful ASPs EXCEPT:

- A. Decrease in overall health care costs
- B. Ability for institutions to decrease the number of staff health care professionals
- C. Improved patient quality of care
- D. Decrease length of hospital stay

3. The primary goal of an ASP is to:

- A. Decrease overall health care costs
- B. Increase the quality of patient care
- C. Decrease the number of antimicrobial agents needed to be stocked in the pharmacy
- D. Increase the need for improved laboratory resources and machinery

4. ASPs encourage all of the following EXCEPT:

- A. Transfer of parenteral treatment to oral treatment
- B. Off-cycle antibiotic prescribing
- C. Streamlining or de-escalating antibiotic therapy immediately when appropriate
- D. More than one of the above

5. Which term correctly describes an event when broadspectrum antibiotics are quickly and haphazardly administered if a patient does not improve health after the initial therapy?

- A. Antibiotic cycling
- B. Spiraling empiricism
- C. Stat treatment
- D. Multi-drug resistant medication therapy

6. Common participants involved in the operation of a successful ASP include all of the following EXCEPT:

- A. Information technology staff
- B. Infectious disease physician
- C. Clinical pharmacist
- D. Physical therapist

7. Common strategies that are present in successful ASPs include all of the following EXCEPT:

- A. Prescription approval
- B. Educational resources for the involved health care professionals
- C. Post-prescription review
- D. Exclusive use of national guidelines

8. A strategy for incorporating an ASP that includes formulary restriction and preauthorization for the use of restricted antimicrobial agents is known as:

- A. Front-end approach
- B. Back-end approach
- C. "Stat" approach
- D. Guideline approach
- 9. This strategy for incorporating an ASP, also known as the prospective audit, utilizes interventions and feedback by an infectious disease clinical pharmacist to make suggestions to the prescriber:
 - A. Front-end approach
 - B. Back-end approach
 - C. Computerized physician order entry
 - D. Formulary restriction/preauthorization

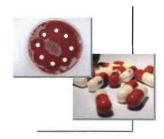
10. Common barriers facing the implementation of an efficacious ASP include all of the following EXCEPT:

- A. Inadequate or absent diagnostic facilities
- B. Communication among health care facilities and health care professionals
- C. Poor data collection
- D. Insufficient number of infectious disease physicians and pharmacists

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| The program met the stated goal | s and objectives: | | | | | |
| Identify ways in which Antimicrobial Stewardship Programs (ASPs) are utilized to decrease microbial resistance. | | 1 | 2 | 3 | 4 | 5 |
| Comprehend the multiple an care professionals associat | d interconnected roles of various health ed with ASPs. | 1 | 2 | 2 3 4 | | 5 |
| of antimicrobial agents by | rease in current research and development major pharmaceutical companies, and its perly utilize available antibiotics. | 1 | 2 | 3 | 4 | 5 |
| List strategies that can be est institutional ASP. | ablished to create and run an effective | 1 | 2 | 3 | 4 | 5 |
| | tient health has been improved as a result of of of ASPs in a variety of health care settings. | 1 | 2 | 3 | 4 | 5 |
| The program met your educational needs. | | 1 | 2 | 3 | 4 | 5 |
| Content of the program was interesting. | | 1 | 2 | 3 | 4 | 5 |
| Naterial presented was relevant to my practice. | | 1 | 2 | 3 | 4 | 5 |
| comment/Suggestions for future | programs: | | | | | |

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| | Answers to Assessment Q | stions—Please Circle Your Answer | |
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