Module 1
Healthcare Organization Infection Prevention and Control Programs: Essential Partners of Antimicrobial Stewardship Programs

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Case Scenario

The chief executive officer (CEO) of a large multihospital healthcare system recently returned from a leadership summit on the clinical and economic consequences of healthcare-associated infections (HAIs) where he heard about the growing incidence of infections due to multidrug-resistant organisms (MDROs) and their associated morbidities, mortalities, and costs. One particular session discussed the important role that antimicrobial overuse plays in the emergence of these infections and the impact an antimicrobial stewardship program (ASP) can have on reducing unnecessary drug use and costs associated with expensive, broad-spectrum therapies. The speaker also emphasized the importance that a relationship between a strong infection prevention and control program (IPC) and successful antimicrobial stewardship efforts can have on reducing MDROs.

After returning to his hospital, the CEO asked his leadership team to review the hospital system's existing programs regarding HAI reduction and to investigate the business and clinical case for implementing an ASP. You, as the associate director of the system's main hospital, are tasked with these analyses. Your first step is to gather all data on the burden of HAIs—in particular those due to antimicrobial-resistant pathogens—to assess the scope of the problem within the health system. You also want to gain insight on the clinical units and patient populations that have the highest burden of infections, the background of the HAI problem, and methods for prevention of these infections.

Introduction

The major impact that a successful ASP has on a healthcare organization rests on its ability to improve patient outcomes and reduce adverse events, including morbidity due to antibiotic-resistant pathogens (also known as MDROs) and *Clostridium difficile (C difficile),* organisms responsible for an increasing number of HAIs. MDRO infections and other HAIs lead to substantial patient morbidity, increased healthcare costs, prolonged hospitalization, and, most importantly, patient mortality.

A key partner in an organization's ASP—which seeks to reduce HAIs and the incidence of MDROs—is the organization's IPC program. IPC programs are in place at most healthcare organizations to encourage practices that prevent HAIs; systematically assess the burden of HAIs and MDRO infections; develop policies and practices to prevent HAI transmission; educate healthcare personnel (HCP), patients, caregivers, and visitors about infection prevention strategies; monitor adherence to recommended prevention practices; investigate outbreaks of HAIs; and prepare organizations for new infectious threats, such as novel MDROs or pandemic influenza. These efforts can synergize with those of an ASP to help reduce the burden of these infections. IPC programs often comprise infection preventionists (usually nursing personnel, many of whom are certified in IPC), physician epidemiologists, quality consultants, and data analysts.

This module will briefly review the magnitude and impact of HAIs and MDROs, the fundamentals of how pathogens (such as MDROs and *C difficile)* are transmitted, basic IPC measures to reduce such transmission, and the importance of linking the IPC program and ASP.

The Magnitude and Impact of Multidrug-Resistant Organisms and *C difficile*

For decades, the incidence of infections caused by strains of bacteria that are resistant to conventional antibiotics among hospitalized patients has remained high despite widespread efforts to control their spread.[1-3] MDROs, such as methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci, and multidrug-resistant gram-negative bacilli, once affected only the most critically ill patients; however, they have increasingly been identified as causing infections among an even larger population of considerably less-ill patients. In some instances, infections with resistant organisms (ie, MRSA) have been observed among patients in the community without prior healthcare contact.[4,5]

The prevalence and incidence of infections caused by MDROs continue to increase, and new MDROs have emerged for which there are limited to no effective therapeutic options, such as the carbapenem-resistant *Enterobacteriaceae* (CRE)[2] and the highly resistant bacteria that carry NDM-1 (New Delhi metallo-beta-lactamase).[6,7] MDROs have been associated with an increased risk of worsened clinical outcomes (including an increased risk of death and prolonged length of stay) and with higher costs of hospitalization in some patient populations.[8-14] The increase in the frequency of infections caused by MDROs, the higher risk of death associated with these pathogens, and the lack of promising novel pharmaceutical agents to treat these infections pose a significant challenge to the healthcare system.

Although not by definition an antibiotic-resistant organism, *C difficile* is another healthcare-associated pathogen that is often grouped with MDROs due to its rising incidence and substantial patient morbidity. *C difficile* is a spore-forming, toxin-producing organism that is part of the normal intestinal flora in about 3% of adults but which can cause illness ranging from self-limited diarrhea to severe colitis requiring colectomy.[15] *C difficile* is the leading cause of healthcare-associated diarrhea in adults. The incidence of *C difficile* infections has increased markedly over the past decade, and recent estimates of 333,000 cases of infection and 20,000 deaths annually have been proposed.[15-17] In 2000, a hypervirulent strain of the pathogen—the North American Pulsed Field Type 1 (027/BI/NAP1)—surfaced, which was associated with amplified virulent toxin production and higher complication rates. With the appearance of this and other hypervirulent strains, the incidence of community-onset *C difficile* infections and *C difficile* infections in those individuals who were previously at low risk (eg, no prior antimicrobial exposure, young age, lack of underlying comorbid illnesses) has also increased.[15,18,19] In addition, prior antibiotic use is one of the most important risk factors for developing *C difficile* infections,[15] thus highlighting the importance of ASPs in reducing the incidence of this pathogen.

The proliferation of MDROs and *C difficile* is believed to be largely driven by two major factors: antibiotic misuse or overuse and transmission of MDROs and *C difficile*.

Antibiotic Misuse and Overuse

Antibiotic misuse and overuse has the unintended (but ultimately predictable) consequence of selecting strains of bacteria that are able to evade the desired killing action of the drugs. These otherwise uncommon drug-resistant organisms—genetically equipped to survive exposure even to powerful antibiotics—can reproduce and ultimately dominate the population of bacteria colonizing and infecting vulnerable individuals. In the case of *C difficile*, in which the organisms find their niche in the colon, most antibiotics are not active against the pathogen but instead have the unintended side effect of killing normal beneficial bacteria that serve as the native flora of the gastrointestinal tract, thus allowing the spore-forming pathogen to promulgate.[19]

Antibiotic Misuse and Overuse (continued)

Strikingly, it has been estimated that ***as much as 50%*** of antibiotic use in hospitals is inappropriate.[20] Thus, antimicrobial stewardship efforts to reduce inappropriate utilization of antibiotics can have a marked impact on reducing selection pressure for the development of MDROs and the proliferation of *C difficile*. Targeting antibiotic therapy against identified pathogens, placing restrictions on prescribing key broad-spectrum agents, and avoiding the use of antibiotics in patients with suspected viral or noninfectious illnesses are strategies that will help reduce unnecessary antimicrobial prescription, MDRO colonization, and resultant HAIs.[21] (See Modules 2-5 for more information.)

Transmission of Multidrug-Resistant Organisms and *C difficile*

The second factor that has contributed to the prevalence of MDROs and *C difficile* is the transmission of these pathogens from individuals who are colonized or infected with these organisms to other persons. This "horizontal transmission" most often occurs in healthcare organizations. In addition, transmission is greatly facilitated by the intensity of contact between providers and patients, the number of patient-provider interactions, work flow, and human factor issues.

This transmission is further exacerbated by the failure of HCP and other persons to comply with even the most basic methods of infection prevention. These prevention measures are where an IPC program can impact the incidence of MDROs and *C difficile* infections the most. Implementing basic prevention measures, including isolation precautions and hand hygiene, can result in a reduction in the spread of MDROs and *C difficile* pathogens that cause HAIs.

Fundamentals of Infection Prevention and Control

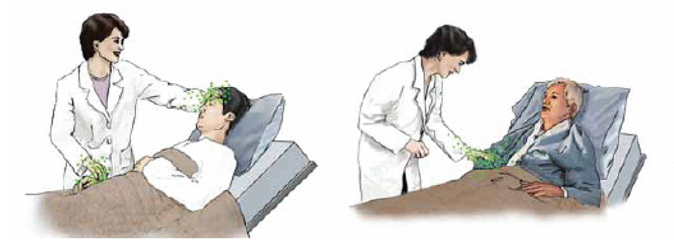
The specific routes by which pathogens such as MDROs and *C difficile* may be transmitted and the factors governing transmission in healthcare organizations can be quite complex and may be impacted by patient volume and comorbidities, the types of procedures performed at the organization, the physical characteristics and constraints of the organization, and the number and turnover rate of HCP. In general, the transmission of pathogens in healthcare organizations can be conceptually simplified to the following three major routes[22,23]:

1. Transmission via the animate environment: A healthcare worker's hands may become transiently contaminated with an MDRO or *C difficile* spores after having contact with a colonized or infected patient, then transfer the pathogen to another patient (see Figure 1-1A on page 5).
2. Transmission via the inanimate environment: Equipment, such as a stethoscope, becomes contaminated after contact with the skin or mucous membranes of a colonized patient and transfers the pathogen when it is used on another patient (see Figure 1-1B on page 5).
3. Transmission involving animate and inanimate environments: MDROs and *C difficile* are transmitted to surfaces and items in a colonized or infected patient's hospital room (eg, an infusion pump) first and are subsequently transferred to the hands of HCP who, in turn, transmit the pathogen to previously noncolonized patients (see Figure 1-1C on page 5).

Figure 1-1. Routes of Transmission for Pathogens in Health Care Organizations

A

Animate Transmission:
Patient A → Health Care Worker → Patient B



Source: Adapted from Pittet D, et al.: Evidence-based model for hand transmission during patient care and the role of improved practices. *Lancet Infect Dis* 6:641–652, Oct. 2006.

B

Inanimate Transmission:
Patient A → Health Care Worker's Stethoscope → Patient B

Source: Adapted from Pittet D, et al.: Evidence-based model for hand transmission during patient care and the role of improved practices. *Lancet Infect Dis* 6:641–652, Oct. 2006.

C

Interaction Between the Animate and Inanimate:
Patient A → Infusion Pump → Health Care Worker → Patient B

Source: Adapted from Pittet D, et al.: Evidence-based model for hand transmission during patient care and the role of improved practices. *Lancet Infect Dis* 6:641–652, Oct. 2006.

To prevent these various modes of transmission, the core prevention practices of hand hygiene, use of isolation precautions for colonized or infected patients, and attention to thorough environmental cleaning are essential. The following paragraphs elaborate on each of these practices.

Hand Hygiene

Because of the risk of transmitting MDROs and *C difficile* spores among patients or into the environment through the unwashed hands of frontline HCP, hand hygiene is ***the single most important IPC practice*** for preventing the transmission of these pathogens in hospitals and other healthcare organizations. Evidence-based guidelines describing the methods and indications for hand hygiene in healthcare have been widely disseminated.[24] Hand hygiene is a simple procedure that can be mastered even by schoolchildren.[25] However, even well-resourced organizations with engaged clinical and executive leadership routinely fail to maximize compliance with hand hygiene standards. Published interventions touting the success of a variety of initiatives to improve compliance failed to achieve hand hygiene rates greater than 70%.[26] Multiple barriers to full adherence of hand hygiene standards on the part of frontline clinicians and other HCP suggest that maximizing performance of this relatively straightforward behavior will require a more vibrant systems-based approach than has been applied previously. Following are some excellent resources to help guide organizations' hand hygiene programs:

- World Health Organization: *WHO Guidelines on Hand Hygiene in Health Care,*[27] http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf. Accessed December 2011.
- Centers for Disease Control and Prevention: *Guideline for Hand Hygiene in Health-Care Settings,*[28] http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf. Accessed December 2011.
- The Joint Commission: *Measuring Hand Hygiene Adherence: Overcoming the Challenges,*[29] http://www.jointcommission.org/assets/1/18/hh_monograph.pdf. Accessed December 2011.
- Joint Commission Center for Transforming Healthcare: *Hand Hygiene Project* and *Targeted Solutions Tool,*[30] http://www.centerfortransforminghealthcare.org/projects/display.aspx?projectid=5. Accessed December 2011.

Isolation Precautions

Colonized or infected patients are the primary source of MDRO and *C difficile* transmission in hospitals. Studies have shown that patients who are colonized with these organisms and who are placed in contact precautions (also called contact isolation) are much less likely to transmit these pathogens to other hospitalized patients.[23,31] For this reason, IPC guidelines recommend placing hospitalized patients found to be colonized or infected with an MDRO or with a *C difficile* infection in contact precautions. These precautions dictate that all HCP should wear barriers (ie, gloves and gowns) when entering a patient's room to reduce contamination of hands and clothing, use disposable dedicated equipment that is not shared with other patients, and place patients in private rooms, if available.[21,23,32] The following guidelines serve as excellent resources on the use of isolation precautions and other IPC strategies to reduce the MDRO and *C difficile* burden:

- Siegel JD, et al: 2007 Guideline for isolation precautions: Preventing Transmission of Infectious Agents in Health Care Settings. *Am J Infect Control.* 35 (Suppl 2):S165–164, Dec. 2007.[23] Also at http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html.
- Siegel JD, et al: *Management of Multidrug-Resistant Organisms In Healthcare Settings, 2006.*[33] http://www.cdc.gov/hicpac/mdro/mdro_toc.html.

Environmental Cleaning and Disinfection

The role that inanimate surfaces (fomites) play in the transmission of HAIs has been a topic of debate for decades. Prior to the 1970s, infection control personnel routinely sampled hospital surfaces for pathogens despite the lack of evidence to support this practice.[34] However, the inanimate environment remains an area of interest in light of studies demonstrating heavy contamination of hospital surfaces—such as bed linens, bed rails, and tabletops—with MDROs and *C difficile*.[35-38] Many organisms are able to live on inanimate surfaces for prolonged periods of time, and studies have shown that the hands of HCP are just as likely to become contaminated with these organisms whether they touch the skin of colonized patients or surfaces in their room.[39,40] In addition, several studies have demonstrated an inpatient's increased risk of acquiring an MDRO or a *C difficile* infection if the prior room occupant was also infected or colonized with these pathogens.[41,42]

Therefore, an important step in mitigating the impact of the inanimate environment in the transmission of MDROs and *C difficile* is to ensure that "high-touch" surfaces, such as doorknobs, bed rails, light switches, and wall areas around the toilet in the patient's room, are cleaned on a regular basis. The type of disinfectant that is used also may matter, as some agents may not effectively kill the spores of *C difficile*. For this reason, recent IPC guidelines recommend using chlorine-containing disinfectants (eg, bleach) or other sporicidal agents to clean the environment of patients infected with *C difficile* when increased organizational rates of this infection are present.[21] Monitoring cleaning performance is an important component of an organization's environmental services program, and numerous methods for such audits are available.[43] Additional information and guidance regarding environmental cleaning and disinfection strategies to reduce HAIs can be found in the following resources:

- Sehulster L, Chinn RY: Guidelines for environmental infection control in health-care facilities. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR Recomm Rep.* 52(RR-10):1–42, Jun. 6, 2003.[44] Also at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm. Accessed September 2011.
- Rutala WA. Weber DJ: Surface disinfection: Should we do it? *J Hosp Infect.* 48(Suppl A):S64-68, Aug. 2001.[45]
- Rutala WA, Weber DJ: Infection control: The role of disinfection and sterilization. *J Hosp Infect.* 1999; 43 Suppl:S43–55, Dec. 1999.[46]
- William Rutala's Disinfection and Sterilization Web site. http://www.disinfectionandsterilization.org/. Accessed September 2011.
- Carling PC, et al: Improving cleaning of the environment surrounding patients in 36 acute care hospitals. *Infect Control Hosp Epidemiol.* 29:1035–1041, Nov. 2008.[47]
- Carling PC, Bartley JM: Evaluating hygienic cleaning in health care settings: What you do not know can harm your patients. *Am J Infect Control*. 38(5 Suppl 1):S41–50, Jun. 2010.[43]

Key Components of Infection Prevention and Control Programs

Although no single IPC program model applies to all healthcare settings, several key components of IPC programs can maximize the effectiveness of an organization's HAI and MDRO prevention efforts and can work hand-in-hand with ASPs. Box 1-1 below lists the key components of IPC programs.

Box 1-1. Key Components of Infection Prevention and Control Programs

- **Clearly defined objectives and priorities**
- **HAI surveillance program**
- **Regular organizationwide risk assessments**
- **Partnership with the microbiology laboratory**
- **HAI prevention policies and procedures**
- **Infrastructure for robust education of HCP**
- **Monitoring of practices to assess compliance with prevention practices**
- **Adequate resources (personnel, data access and analysis, administrative support)**

First, an IPC program should have clearly delineated objectives and priorities that are detailed in scope yet are discretely defined. These goals may be based on organizationwide strategic plans, regulatory requirements (eg, publically reported outcomes), and high-risk patient populations or procedures.

Second, a robust surveillance program to track HAI and MDRO outcomes is essential. This program provides organizations with a clear understanding of the burden of specific infections and incidence trends over time in their facilities and allows them to assess the impact of their IPC programs. Standardized outcome definitions—such as those from the Centers for Disease Control and Prevention's National Healthcare Safety Network—that are applied consistently over time are crucial for valid comparisons of data. Lee et al provide an excellent overview of recommended practices for surveillance that identifies additional key components of HAI surveillance and IPC programs.[48]

Surveillance data also serve as one of the most primary links between IPC programs and ASPs, as the assessment of MDRO and *C difficile* incidences over time is an essential metric to gauge the impact of stewardship interventions.

Surveillance data should also be utilized to inform an organizationwide risk assessment, which is another key component of IPC programs. An MDRO risk assessment is a proactive exercise that systematically evaluates potential risks related to the burden of MDROs and that ranks these risks from high to low priorities using a predetermined scoring system. The goal of the risk assessment is to identify the highest risks for MDROs in an organization so that energy and resources can be directed toward these areas.

A risk assessment for MDROs might address invasive devices or procedures, employee infection prevention practices, the environment, education and communication, and other areas of performance. Ideally, the action plan to address the priority areas identified in the risk assessment will have a secondary impact on preventing other HAIs. For example, interventions to improve hand hygiene or increase compliance with appropriate isolation precautions that were targeted by a risk assessment have the potential also to reduce the transmission of infections from all types of organisms, not just MDROs. Likewise, addressing a risk to ensure the timely delivery of prophylactic preoperative antibiotics will have maximum effect if used for all surgical procedures, not just those currently under surveillance.

An organization's microbiology laboratory should be an important partner of the IPC program and ASP, and a close partnership between microbiology laboratory and IPC personnel is another key component of IPC programs. Data from microbiology testing are essential to develop an organizational antibiogram: an important tool for prescribing clinicians that denotes specific organism antimicrobial susceptibility results based on an institution's culture data. Antibiograms allow providers to select the antimicrobials that are most likely to target the predominant pathogens in their organization, thus potentially avoiding the use of ineffective agents. The microbiology laboratory can also assist with specialized testing during investigations of suspected HAI outbreaks and can provide a system to alert IPC personnel about the identification of a newly isolated MDRO, so that isolation precautions can be implemented rapidly.

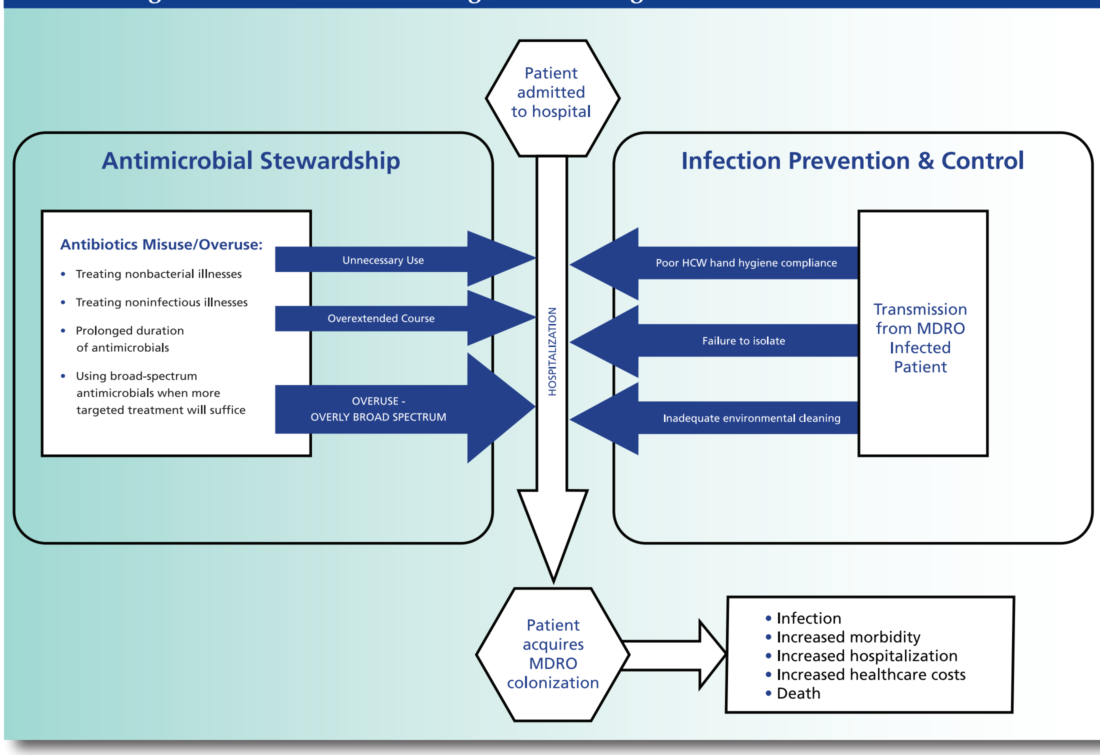
Because the impact of HAIs can be experienced at all levels of an organization—from the patients who become infected and the frontline caregivers who implement prevention strategies, to the administrative leadership focused on patient safety and organizational management—IPC program experts must provide clear leadership and guidance on HAI prevention efforts and must outline the expectations of all personnel with regard to HAI prevention. Clearly written policies and procedures must be put in place to facilitate prevention measures, and these policies should be reviewed and updated on a regular basis to ensure that they contain the latest evidence-based guidance. The policies and procedures should stipulate that all HCP should be regularly educated on the problem of HAIs and their methods of prevention in a manner that facilitates comprehension. Ensuring compliance with organizationwide IPC policies through practice audits and the implementation of tools to reinforce adherence (eg, rewarding top-performing units) is also important. It is also critically important that bedside providers be fully engaged in HAI prevention efforts, as this "ownership" of IPC by clinical staff has been a critical part of many successful HAI prevention programs. Finally, to maximize HAI reduction efforts, IPC policies should specify that an IPC program must be adequately resourced in terms of personnel specifically trained in IPC, access to data analysis systems and support, and administrative support.

Linking Antimicrobial Stewardship and Infection Prevention and Control Programs

As indicated previously, an organization's IPC program and ASP must be strategic partners in efforts to reduce HAIs (especially those due to MDROs and *C difficile*), as the core functions of the IPC program synergize with those of the stewardship program (see Figure 1-2 on this page).

Process and outcome surveillance data collected by IPC program personnel as part of HAI reduction efforts allow ASP leaders to assess the impact of their efforts in terms of direct patient outcomes. Together, outcome and process measures provide a comprehensive assessment of the incidence or prevalence of specific MDRO infections (outcomes) and the practices that may contribute to their development or their transmission in the organization (processes). The processes that are selected for metrics can range from hand hygiene compliance, environmental cleaning monitoring, education participation, to prescribing patterns.

Figure 1-2. Partnership Between Antimicrobial Stewardship and Infection Prevention and Control Programs to Minimize Multidrug-Resistant Organism Transmission



IPC program leaders also provide key information regarding MDRO transmission and specific circulating MDRO resistance patterns and also monitor for and recognize novel MDROs. In addition, IPC program leaders can share their knowledge about locations and patient populations in an organization that have high rates of MDRO infections so more intensive stewardship interventions can be used to help curb the spread of these pathogens in these areas. IPC program leaders also collaborate with laboratory, pharmacy, and other team members to plan and implement effective IPC interventions. Antimicrobial utilization data from the stewardship program are helpful to the IPC program, as these data provide insight into the factors contributing to MDRO emergence and because they may be used in other aspects of HAI surveillance (ie, prescribing an antimicrobial for a postsurgical patient may be a flag for the IPC program to assess the presence of a new surgical site infection).

The IPC program and ASP should partner with the organization's microbiology laboratory to gain further insight into the scope of an organization's MDRO and *C difficile* burden and to help develop timely communication systems for caregivers when MDROs are identified. Through this partnership, both programs can maximize the impact of their efforts to reduce the incidence of these troublesome healthcare-associated pathogens, which can lead to reduced patient morbidity and mortality and healthcare costs.

Additional Resources:

Association for Professionals in Infection Prevention and Control Elimination Guides:

- Methicillin-resistant *Staphylococcus aureus* in hospital settings, http://www.apic.org/downloads/MRSA_elimination_guide_27030.pdf. Accessed September 2011.
- Methicillin-resistant *Staphylococcus aureus* in long term care settings, http://www.apic.org/Content/NavigationMenu/PracticeGuidance/APICEliminationGuides/MRSA_in_LTC_09.pdf. Accessed September 2011.
- *Clostridium difficile*, http://www.apic.org/Content/NavigationMenu/PracticeGuidance/APICEliminationGuides/C.diff_Elimination_guide_logo.pdf. Accessed September 2011.
- Multidrug-resistant *Acinetobacter baumannii,* http://www.apic.org/Content/NavigationMenu/PracticeGuidance/APICEliminationGuides/AB_Guide.pdf. Accessed September 2011.

C difficile Guidelines:

Cohen SH, et al. Clinical practice guidelines for *Clostridium difficile* infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). *Infect Control Hosp Epidemiol*. 31:431–455, May 2010.

Business Case for Infection Control Programs:

Perencevich EN, et al. Raising standards while watching the bottom line: Making a business case for infection control. *Infect Control Hosp Epidemiol.* 28:1121–1133, Oct. 2007.

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Notes

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Module 2
Developing a Business Case for an Antimicrobial Stewardship Program

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Case Scenario

A hospital recently completed its strategic plan for the following fiscal year. Goals for improvement were identified, and each department was asked to list its top opportunities for improvement. The Infection Prevention and Control (IPC) Committee reported that the hospital was seeing a steady increase in the rate of multidrug-resistant organisms (MDROs). Furthermore, the Pharmacy Department and the Pharmacy and Therapeutics Committee reported that even with various strategies in place to ensure that antimicrobials were being used appropriately, annual increases in antimicrobial costs exceeded 10% per year. The greatest portion of the increase was related to increased antimicrobial use rather than cost increases, as antimicrobial costs represented 30% of the total pharmacy drug budget.

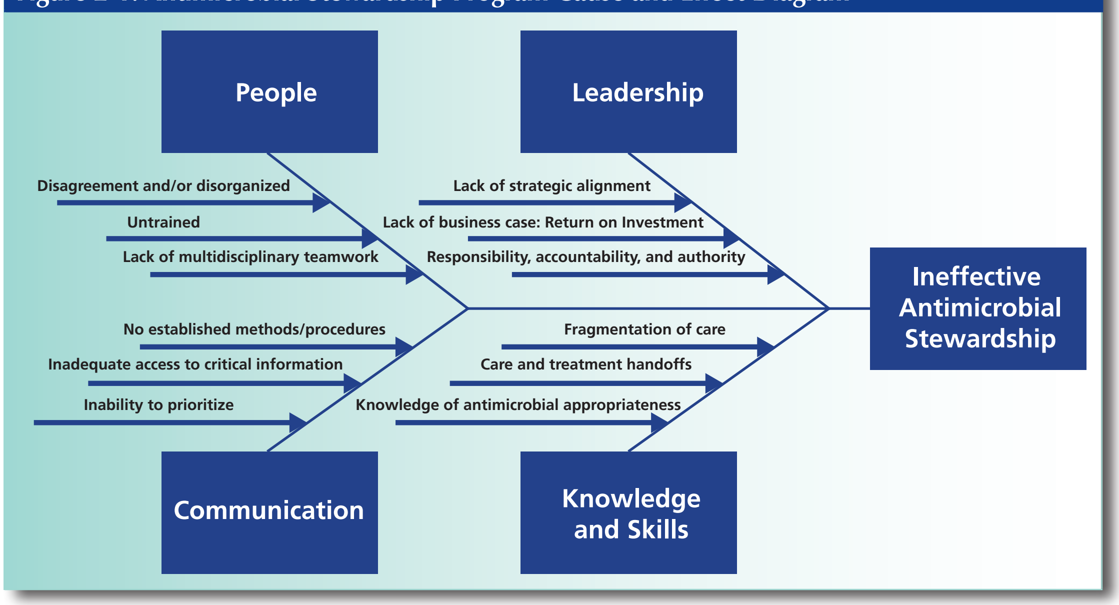
Additionally, the hospital was experiencing increased lengths of stay, primarily in intensive care units (ICUs). Benchmarking the hospital's MDRO rates with comparable hospitals indicated that the antimicrobial stewardship strategies the organization employed to this point had not been successful. Based on this disturbing information, the hospital administrators requested that an action plan be developed and a performance improvement team be created to address the issues of concern surrounding antimicrobial stewardship.

The team's assessment of the hospital revealed the following characteristics:

- *Fragmentation, redundancy, and gaps among clinical units addressing antimicrobial utilization*
- *Inconsistent alignment of the antimicrobial stewardship program (ASP) with approved organization strategic goals*
- *Inability to strategically prioritize approaches to reducing complications related to infections and to allocate resources to ensure appropriate antimicrobial utilization*
- *Difficulty creating accountability for antimicrobial utilization within the organization*
- *Difficulty communicating among healthcare providers responsible for antimicrobial utilization*
- *Inadequate access by clinical decision makers to critical information, such as defined daily doses and cost of antimicrobials*

After completing the assessment, the team created a cause and effect diagram to visualize the numerous variables that were affecting the hospital's ability to develop a successful ASP (see Figure 2-1 below).

Figure 2-1. Antimicrobial Stewardship Program Cause and Effect Diagram



This case study illustrates the need for clinical and administrative leaders of the Pharmacy Department and medical staff in the Infectious Disease Division (if available to the hospital) to collaborate to assess the current state of antimicrobial stewardship efforts and existing barriers and to begin developing a business case for an ASP.

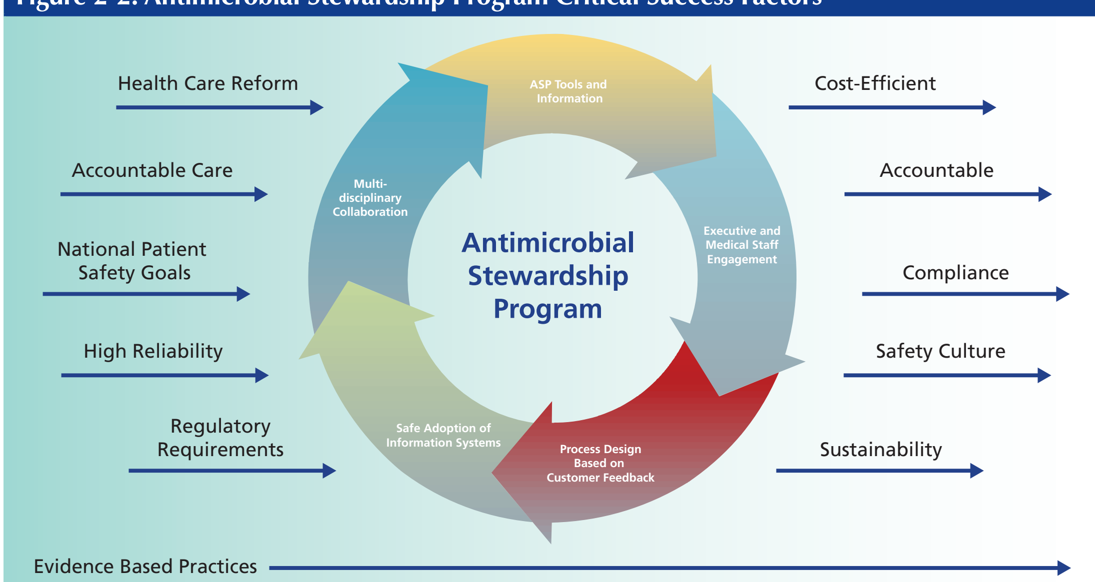
Introduction

Mandated by the Patient Protection and Affordable Care Act (ACA) of 2010, the Centers for Medicare & Medicaid Services' (CMS) Hospital Value-Based Purchasing Program marks the beginning of the end for healthcare's traditional volume-based business model. The new mandated model will change the existing culture in healthcare to focus on value rather than volume to determine payment incentives. Investing in technology, knowledgeable practitioners, and best practices, including antimicrobial stewardship, will be essential to realize better patient outcomes and resource utilization in the new era of healthcare.

The development of antimicrobial resistance has resulted in increased morbidity and mortality to patients and an increased cost to healthcare organizations. In 2007, The Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America published guidelines for developing institutional programs to enhance antimicrobial stewardship—an activity that includes choosing the appropriate antimicrobial, dose, route, and duration of antimicrobial therapy.[1] Effective antimicrobial stewardship combined with comprehensive IPC programs have been shown to limit the emergence and transmission of antimicrobial-resistant bacteria. In addition to potential clinical benefits, organizations and their leaders are also very interested in what is usually viewed as a secondary goal of antimicrobial stewardship: reducing healthcare costs without adversely affecting the quality of care. Therefore, it is important for healthcare organizations to note that effective ASPs can be financially self-supporting and can improve patient care.[1]

This module will highlight the background of the antimicrobial resistance problem, discuss the external factors that drive the need for change, and explain the components of a comprehensive business proposal for developing an ASP, all of which can lead to improved patient safety, care, and treatment, and to cost-efficient, sustainable, and accountable care. Figure 2-2 below lists the components that must be present in all ASPs and that will be described in this module: (1) ASP tools and information, (2) executive and medical staff engagement, (3) ASP process design and building the business case, (4) safe adoption of information systems, and (5) multidisciplinary collaboration for success.

Figure 2-2. Antimicrobial Stewardship Program Critical Success Factors



Developing a Business Case Proposal

Developing a business case proposal for an ASP should be the responsibility of the senior clinical executive. Although this individual may delegate the actual development of the proposal, he or she provides the appropriate oversight and support. To ensure that an optimal plan for developing a proposal is created, a process improvement team should be established if one does not already exist. The perspectives and input of key staff will be critical to designing a successful proposal and generating "buy-in."

A business case for a healthcare improvement intervention exists if the organization that invests in the intervention realizes a financial return on investment (ROI) in a reasonable time frame. This ROI may be realized as "bankable dollars" (profit), a reduction in losses for a given program or population, or avoided costs. In addition, a business case may exist if the investing organization believes that the intervention will positively affect organizational function and sustainability within a reasonable time frame.

A business case for an ASP should address the following important questions[2]:

- Will the proposed strategy for antimicrobial stewardship actually result in improved care?
- Is the improvement that an ASP will bring considered central to healthcare or an optional feature?
- Will revenue increase for the organization as a result of the ASP?
- What nonfinancial consequences of the improvement are important?

Factors to Consider When Making a Business Case for Antimicrobial Stewardship Programs

The Impact of Legislative and Accreditation Agencies on Healthcare Organizations

Several new legislative and reimbursement initiatives will dramatically change how hospitals will be reimbursed, and in the near future, these will be applied to other healthcare organizations as well. Organizations should consider these initiatives when developing their business case proposal for an ASP.

One component of this new legislation focuses on the concept of pay for performance, in which hospitals' reimbursement from CMS is directly tied to patient outcomes, adverse events, readmission rates, and other factors. One of these adverse events is healthcare-associated infections (HAIs). Inappropriate antimicrobial use can contribute to HAIs, particularly those caused by MDROs, and can lead to associated excess healthcare costs. One component of the pay-for-performance model is the Hospital Value-Based Purchasing Program. This program will make value-based incentive payments to acute care hospitals beginning in fiscal year (FY) 2013. According to this program, CMS will take away 1% of an organization's Medicare reimbursement and then give it back if the organization is above the mean of performance on specific measures, including those related to HAIs. Strong ASPs, with the potential to reduce infection risk, may help hospitals avoid receiving reduced Medicare payments.

Another component of the pay-for-performance model requires increased public reporting of organization and physician performance. Public reporting stimulates interest in quality and forms the basis of pay-for-performance programs. These programs are intended to strengthen the business case for quality improvement by encouraging organizations to invest in quality and by rewarding excellence with financial incentives. In addition, an organization's image and standing in a community may be affected by public reporting of quality data.

A strong ASP offers the organization an opportunity to demonstrate excellence. In a study conducted by CMS, financial incentives were shown to be capable of catalyzing quality improvement efforts among hospitals already engaged in public reporting.[3] As a result of the intertwining of improvement and finances, chief financial officers (CFOs) are also now becoming "Quality Champions."

In addition to national legislative requirements, hospitals and other healthcare organizations should consider requirements from organizations such as The Joint Commission when developing their ASP proposal. The Joint Commission's National Patient Safety Goal NPSG.07.03.01 requires healthcare organizations to implement evidence-based practices to prevent HAIs due to multidrug-resistant organisms.[4]

The Financial Impact of Inappropriate Antimicrobial Use

Antimicrobials used inappropriately will result in unnecessary exposure to medications, persistent or progressive infection, emergence of resistance, and increased costs, all of which are important factors to consider when an organization is trying to make a business case proposal for an ASP.[5] This rise in antimicrobial resistance related to inappropriate use of antimicrobials has been associated with increased patient morbidity and mortality.

Hospitals are important reservoirs for strains of bacteria resistant to antimicrobial drugs. It is estimated that approximately 5% of hospitalized patients experience an HAI.[6] The annual cost of these infections is estimated to be greater than $5 billion in the United States.[7-11] In one study, the excess costs of suspected infections associated with antimicrobial-resistant organisms was determined to be $6,767 per infection, while confirmed infections added $15,275 to the hospital stay.[6] As discussed previously, although healthcare organizations and providers are currently being paid for some patient complications, such as HAIs, ACA legislation stipulates that hospitals will no longer be reimbursed in the near future, and other healthcare organizations will soon follow suit. Therefore, it is critical for an organization's antimicrobial stewardship improvement team to identify and discuss the financial impact of inappropriate antimicrobial use on the organization.

Financial Benefits of Antimicrobial Stewardship Programs

The team preparing an ASP business case proposal needs to ensure that it clearly states the financial benefits of such a program.

First, an ASP should contain a systematic approach to antimicrobial use appropriateness. Studies have shown that improvement in the appropriate use of antimicrobials with ASPs reduces drug costs, length of stay, and infection-related mortalities, all of which have financial implications.[12] In the United States, ASPs have consistently demonstrated a 22%-36% reduction in antimicrobial use, with annual savings of $150,000-$900,000 in larger academic hospitals and smaller community hospitals.[7] The greater the extent of inappropriate usage that exists in an organization when starting a program, the more impact and cost savings an ASP can have. These savings in expenditures result from more appropriate use of antimicrobials, which includes minimizing exposure to those drugs, adjusting dosage, reducing redundant therapy, and targeting therapy to the likely pathogens. Studies have documented that using these strategies has resulted in cost savings of up to $500,000 per organization annually.[13] Therefore, the cost of implementing an ASP is more than justified by the return on investment. Sidebar 2-1 on page 6 lists strategies ASPs can use to reduce the costs associated with antimicrobials.

Sidebar 2-1. Reducing Antimicrobial Costs Through Antimicrobial Stewardship Programs

ASPs can help control antimicrobial costs using the following eight strategies:

1. **Education: Education programs can take two basic forms. The first involves direct interaction with prescribers, either through discussion about the antibiotic order or via a more formal educational program. The second employs utilization review with delayed feedback to prescribers regarding their pattern of prescribing.**

2. **Formulary restriction: Limiting the available agents on formulary is an effective means of prohibiting the use of newer, more expensive antibiotics in place of older, equally effective agents.**

3. **Pharmacy justification: This practice focuses on restriction policies that require approval of a designated physician or clinical pharmacist for the use of certain agents.**

4. **Formulary substitution or "Switch Therapy": Two types of switch therapies have been used: substituting a member of a class of agents for a "therapeutic equivalent" and changing to a different class of agents, usually with the aim of employing a less expensive oral regimen for a costly parenteral one.**

5. **Computer surveillance: The computer may be the ultimate tool healthcare organizations can use for antibiotic surveillance and education. The computerized entry of agents, such as antimicrobials, provides instantaneous feedback and education, and seamless alteration in the preference for certain agents.**

6. **Laboratory item-cost listing: Antimicrobial cost listing through susceptibility reports from the clinical microbiology laboratory provides a computerized feedback system that places the costs of the least expensive, most clinically relevant agent "online."**

7. **Purchase plans: Many organizations participate in group buying, or they negotiate with pharmaceutical manufacturers for better pricing on antimicrobials.**

8. **Multidisciplinary approaches, including preauthorization and consultation with an ASP team: Many organizations have a central methodology, but in fact, they really employ several different strategies to achieve control of antimicrobial use. The approaches involve input from various hospital services, including infectious diseases, clinical pharmacy, infection control, nursing, and, particularly, administration.**

Source: John JF Jr, Fishman NO. Programmatic role of the infectious diseases physician in controlling antimicrobial costs in the hospital. *Clin Infect Dis.* 24:471–485, Mar. 1997.

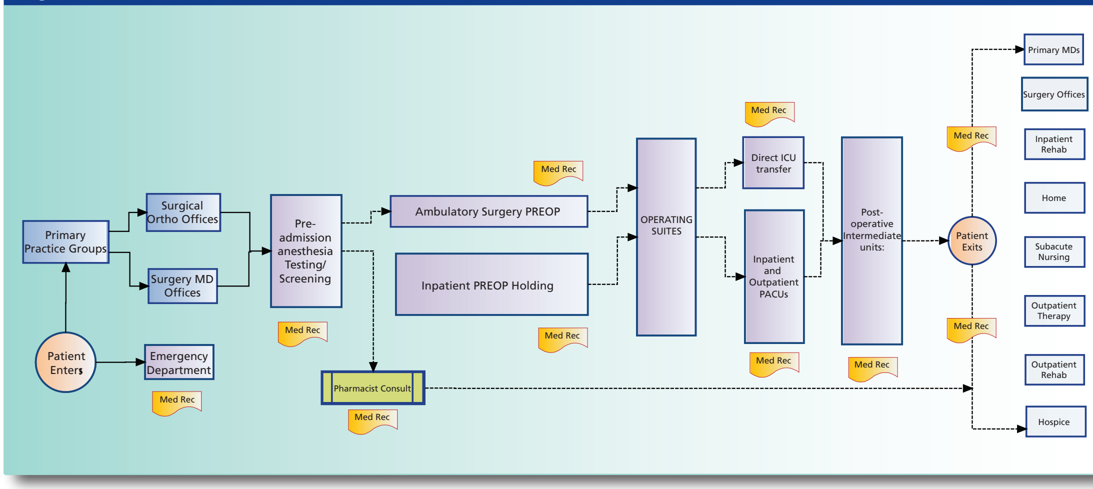
Transitions in Care

Yet another factor organizations should consider when developing their business case proposal for ASPs is transitions in care. Figure 2-3 on page 7 illustrates a typical continuum of care for a patient undergoing a surgical procedure. This figure highlights the potential risk points in the medication reconciliation process and the multitude of communication handoffs across the care continuum. The following key points in the figure are specific to antimicrobial stewardship issues during such transitions:

- There are multiple patient handoffs, each of which has the potential for communication breakdown about appropriate antimicrobials.
- There are multiple opportunities to introduce error within the medication reconciliation processes during each movement to a new care setting.
- Hospitals are now expending additional resources to coordinate postdischarge care in an effort to prevent readmission, some of which is due to patients' lack of understanding of their medications.
- The current healthcare environment is extremely complex and oftentimes fragmented, resulting in disciplines operating inconsistently with one another.

ASPs can help improve transitions in care by promoting communication effectiveness across disciplines, eliminating handoff errors, and facilitating the transfer of critical care plan information to postdischarge stakeholders.

Figure 2-3. Medication Reconciliation Failure Points in Care Transitions



When a patient transfers among different locations (or different levels of care in the same location), he or she may experience poor outcomes as a result of these risk points. One study showed that almost 20% of Medicare beneficiaries in the United States are readmitted to the hospital within 30 days of discharge.[14] The Medicare Payment Advisory Commission estimates that up to 76% of rehospitalizations may be preventable and that poor transitions in care can lead to patient safety issues, medication errors, and miscommunication, all of which endanger patients' lives, waste resources, and frustrate healthcare consumers.[15,16]

Organizational and Individual Barriers, and Resistance to Change

When developing an ASP business case proposal, it is important for an improvement team to identify potential organizational and individual barriers, and resistance to change. Organizations need stability and continuity to function effectively, yet this legitimate need for structure may lead to resistance. ASP champions must use the best data and information available to present a solid business case for this patient safety strategy and to position it as one of the top strategic priorities for senior leaders.

Physician groups are key stakeholders in ASPs. Their acceptance or resistance to potential changes that may occur with an ASP should be carefully considered. Metlay et al surveyed physicians about their attitudes and prescribing decisions when treating patients with community-acquired pneumonia (CAP).[17] The top three factors that influenced physicians' choice of drug were its efficacy in treating CAP, the severity of the patient's illness, and the physician's previous experience with and knowledge about the drug.[17] These factors should be addressed in ASP business case proposal recommendations. It is worth noting that in this study, the risk of contributing to the problem of antimicrobial resistance was ranked lowest of seven factors overall, including side effects, cost to patient, and ease of use (see Sidebar 2-2 below).[17] From this finding, a conclusion can be reached that educational efforts alone will not drive optimal use of antimicrobials in the community.[17] The survey also shows that it is possible for multidisciplinary team leaders to evaluate organizational readiness for change specific to antimicrobial stewardship.

Sidebar 2-2. Factors Influencing Physicians' Choice of Drug

1. **Efficacy in treating CAP**
2. **Severity of the patient's illness**
3. **Physician's previous experience with and knowledge about the drug**
4. **Side effects**
5. **Cost to patient**
6. **Ease of use**
7. **Risk of contributing to the problem of antimicrobial resistance**

Source: Metlay J. Tensions in antibiotic prescribing. *LDI Issue Brief*. 7:1–4, May 2002.

Barriers to Approvals and Implementation of Antimicrobial Stewardship Programs

In a survey of infectious diseases physician members of the Infectious Diseases Society of America (IDSA) Emerging Infections Network (EIN), lack of funding was cited as a key barrier for ASPs.[18] Also mentioned was the fact that administrators needed additional cost savings data for them to be able to support ASPs. In addition, the survey documented that although guidelines and editorials considered compensated participation by an infectious diseases physician in ASPs as critical, more than half of the respondents reported no direct compensation for ASP activities.[18] This lack of compensation may be another barrier that is detrimental to ASP approvals and implementation. The survey results listed the following seven barriers (in rank order) to a successful ASP[18]:

1. Insufficient resources, including funding, time, and people
2. Competing initiatives
3. Leaders unaware of the value of an ASP
4. Opposition from prescribers
5. Lack of information technology support and/or inability to get data
6. Other specialties antagonized by an ASP
7. Multiple infectious disease groups within a facility

The following eight approaches can be used to address these common barriers:

1. Acquire evidence-based data to ensure the success of an ASP.
2. Prioritize leadership strategic initiatives.
3. Establish a clear vision for antimicrobial stewardship.
4. Establish a multidisciplinary team.
5. Identify a lead physician champion.
6. Establish a business case and return on investment.
7. Justify the investment.
8. Pilot test the ASP for justification and seek administrative approval.

Although implementing an ASP is the right approach to prevent antimicrobial resistance for a variety of reasons, costs savings is one extremely important outcome that may be required by senior leaders to approve the program. The important role that leaders plays in ASPs is reinforced further by ranking "Hospital leadership not aware of the potential value of ASPs" as one of the top four barriers to effective ASPs in the IDSA EIN survey.[18]

Developing a Business Case Proposal for Antimicrobial Stewardship Programs

Core Components for Developing a Business Case Proposal for Antimicrobial Stewardship for Senior Leaders

To value and respect the time of senior leaders, it is important for the improvement team to create a strong yet succinct business case proposal for an ASP. Clinical leaders should involve the organization's Finance Department from the outset in the event the organization has a business case proposal template that needs to be followed.

The process of completing a business case analysis can be broken down into the following nine steps.[19]

Step 1: Frame the Problem and Develop Potential Solutions
The business case proposal should clearly define and explain the problem of antimicrobial resistance in the organization and how an ASP will address this issue. Highlighting the resistance problem and framing the benefits of the ASP around patient safety, quality, and cost-efficient care will add to the understanding of the business case and allow the ASP team to generate solutions based on evidenced-based practice and direct causes of organizational issues.

Step 2: Meet with Key Administrators
ASP leaders should schedule a meeting with key clinical and organizational leaders in which the ASP leaders provide data that demonstrate that the organization has a problem with antimicrobial resistance. The goals of the meeting are to accurately define the problem and to seek leadership support to conduct a multidisciplinary team analysis of the problem and propose potential solutions.

Step 3: Determine the Annual Cost of the Antimicrobial Stewardship Program
The estimated costs in the business case proposal should include the total costs incurred by the ASP; that is, variable and fixed costs. Identifying annual costs in the proposal is the reason the ASP team should schedule a meeting with the Finance Department, whose staff will be able to assist with this analysis.

Step 4: Determine Which Costs Can Be Lowered Through Reduced Infection Rates Resulting from the Antimicrobial Stewardship Program
The Finance Department can assist the ASP team to determine the "return on value" or the "return on investment" for the ASP, which should be included in the business case proposal. For example, the CFO in an organization may not allow the inclusion of "cost avoidance" as ongoing justification for an ASP. One example of cost avoidance can be a reduction in the number of infections associated with a particular diagnosis. For instance, if 500 coronary artery bypass graft (CABG) operations are completed at an organization annually, and the current surgical site infection (SSI) rate is 5%, then 25 CABG-related SSIs occur per year. A business case proposal, based on literature review, indicates that implementing an ASP can potentially reduce SSIs by more than 35% through targeted interventions, including improved prospective surveillance, reporting of rates to surgeons, and timing of perioperative antibiotics. Thus, if 25 CABG-related SSIs occur annually, an effective ASP could potentially prevent 9 of those. The "avoided costs" related to this reduction may or may not be permitted to be used by the CFO as justification for the ASP.

Step 5: Determine the Costs Associated with Healthcare-Associated Infections
As discussed earlier, HAIs are adverse events that can result from inappropriate antimicrobial use, and costs associated with these infections should be included in the business case proposal. Most leaders want to know the exact costs to the organization associated with the "problem" that is being presented in the proposal. Many studies describe the estimated costs of HAIs, and these can be used to project savings if no local data exist.[19,20] Generally, however, organizational leaders are less receptive to information from medical literature than from the organization's specific experiences and costs.

Step 6: Calculate the Financial Benefits of the Antimicrobial Stewardship Program

To complete a business case analysis, the estimated cost savings and other financial benefits that result from the ASP must be calculated after the total costs of the program have been deducted. In most situations, the data related to the cost of nonlabor resources, such as drugs and medical and surgical supplies, will come from administrative data, and a cost-to-charge ratio will be used in the organization. In the rare occasion that an organization uses a true cost-accounting system that defines actual cost, this approach should be employed, as it is much more accurate.

Step 7: Include Additional Financial or Health Benefits of the Antimicrobial Stewardship Program

Many IPC interventions have multiple benefits. For example, a contact isolation program developed in response to an outbreak of *Acinetobacter baumannii* infections can also reduce the rate of methicillin-resistant *Staphylococcus aureus* infections and vancomycin-resistant *Enterococcus* infections. Including possible additional financial or health benefits of an ASP in a business case proposal with supporting data that identify those expected benefits will make it easier for organization leaders to accept the premises of cost savings.

Step 8: Make the Business Case for the Antimicrobial Stewardship Program

The approach used to make the "pitch" for a business case to develop the ASP should be organization specific and address the unique needs of the organization.

Step 9: Prospectively Collect Cost and Outcome Data After the Antimicrobial Stewardship Program Is Implemented

It is imperative for an ASP team to collect intervention-specific outcome data and costs after an intervention is implemented, to compare the data prior to implementation, and to report the results to organization leadership on a regular basis. ASP leaders will decide from the program's outset which costs to measure. Potential approaches for evaluating the economic burden of HAIs in an organization include hospital charges, resources used, actual reimbursed charges, and hospital costs. Hospital costs include daily operating costs (sometimes called "fixed costs"), which do not vary based on patient volume, as well as the cost of drugs, tests, and other patient care-related activities (sometimes called "variable costs"), which are dependent on operational statistics, such as patient-days, admission, and clinic visits.[19]

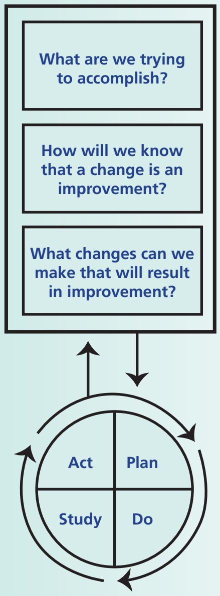
Use a Systematic Approach to Developing a Business Case Proposal

ASP leaders should use a systematic approach to the proposal development to ensure that at least the following questions are answered:

- What is antimicrobial stewardship?
- What is the purpose of antimicrobial stewardship?
- What is the background of the problem of antimicrobial stewardship as it relates to our patients?
- What are the primary functions (for example, reduction in development of MDROs) and secondary functions (for example, reduction in the costs of antimicrobials) of ASPs?
- What does the ASP cost, and how does this cost relate to achieving the main functions of the product (cost justification)?
- Are there alternatives to ASPs? If so, how much do those cost? How is antimicrobial stewardship unique?

A business case proposal should be built on data that define the problem. ASP leaders may want to consider using the Model for Improvement developed by Associates in Process Improvement and available on the Institute for Healthcare Improvement (IHI) Web site (see Figure 2-4 on page 11).[21] The model is a simple, yet powerful, tool to accelerate process improvement.

Figure 2-4. Model for Improvement



The Model for Improvement is composed of the following two parts[21]:

1. Three fundamental questions, which can be addressed in any order.
2. The Plan-Do-Study-Act (PDSA) cycle to test changes in real work settings. The PDSA cycle helps determine whether an implemented change is an improvement.

Dr. W. Edwards Deming popularized the PDCA cycle, otherwise known as the Shewhart cycle or the Deming Wheel's "Plan-Do-Check-Act" (later modified to "Plan-Do-Study-Act"). The PDCA/PDSA cycle is a basic scientific method for improvement that can be used to help develop ASP proposals.

An improvement team should complete the following activities when developing a business case proposal:

- Create a complete and reliable picture of patient safety issues by gathering data about adverse events, such as inappropriate antimicrobial use and any resulting injuries (harm).
- Use information from a cause and effect diagram (see page 2) an improvement team created to highlight key areas in the business case proposal.
- Recruit and include sponsors from senior management and middle management.
- Design metrics for reporting to senior leaders.
- Collaborate with and learn from other organizations that have designed business case proposals.
- Ensure that the ASP team leaders develop and assess basic process improvement skills and staff knowledge of process improvement.
- Ensure that leaders set expectations that improvement will be implemented quickly (days versus months) after the plan has been approved.
- Acknowledge that organizations may be reluctant to implement improvements if better quality is not accompanied by better payment or improved profit margins.
- Appreciate that without a business case for quality, it is unlikely organizations will move quickly and reliably to widely adopt proven quality improvements.

Business Case Proposal Formats

Typically, a proposal is a tool designed to persuade an organization to approve a request for funds or services. The goals of a proposal are to inform the reader of a problem or need, offer a solution(s), and provide a broad overview of how the proposed solution will work and how much it will cost.

An *informal* proposal can be very brief and used as a follow-up to a meeting. These proposals usually reiterate what was learned or uncovered in the meeting and provide a written overview of a solution. *Formal* proposals typically include cover letters, details of the major phases in a project, a project schedule, organizational duties, and a cost breakdown of the various components. Whether the initial format is formal or informal is organization or recipient dependent. Therefore, it is extremely important for ASP leadership to understand the type of proposal that will meet the expectations of senior leaders.

Business Case Proposal Content

Developing a business case proposal may appear to be minor undertaking, but it is actually quite significant. ASP leaders want senior leaders to understand that they have considered various options to solve or improve the antimicrobial resistance problem in their organization.

Although a variety of elements can be included in ASP business case proposals, all proposals should contain the same basic components: an explanation of why the team is conducting a project, its nature, how it will be implemented, the individuals who will be involved, where it will be carried out, how long it will take, how much it will cost, and the benefits to be realized (see Sidebar 2-3 below). The appendix on pages 16-17 provides an example of an ASP business case proposal.

Sidebar 2-3. Components of an Antimicrobial Stewardship Program Business Case Proposal

An ASP business case proposal should contain the following key components:

1. **Background of the antimicrobial resistance problem**
2. **Definition of the ASP**
3. **Benefits of the ASP**
4. **Implementation strategies**
5. **Composition and identity of the ASP team and stakeholders**
6. **Pilot testing logistics and time frame**
7. **Financial analysis**
8. **Recommendations**
9. **Next steps**
10. **Measurable outcomes**
11. **Time points of assessment**

More information about each of these elements is found in the business case proposal outline in the appendix.

All project proposals should be clearly written and organized so readers can follow a logical progression of thought from beginning to end. Due to the critically important nature of the proposal, assistance from such professionals as the organization's Public Relations and Marketing Department may be desirable. The ASP team may need to seek help to write the proposal based on their writing skills.

An executive summary (or summary of the entire proposal) should appear at the beginning of a proposal. Although it is the first section a reviewer will see, the executive summary should be written last to ensure that the writer fully understands what the proposal covers. The executive summary should cover a project's objectives, required resources, and methodology. The main function of the executive summary is to make it possible to quickly review the most important facts or points in the proposal without having to read through what may be a substantial amount of data.

Strategies for Fostering "Buy-in" for an Antimicrobial Stewardship Program Business Case

Buy-in can be defined as securing understanding, commitment, and a promise of future actions from others to support an ASP proposal. Buy-in is an essential emotional ingredient that is necessary for any ASP proposal to succeed. The following step-by-step approach can be beneficial when attempting to secure buy-in for a proposal:

1. *Set a goal and determine a buy-in objective:* What action do you want your audience to take regarding the proposal?
2. *Establish a strategic storyline:* To generate the action you want, what is the "big picture" or vision of a positive future you want your audience to see?
3. *Develop a storyline that targets the audience's agenda:* What are the audience's needs, wants, and future goals?
4. *Call the audience to action:* Ask for a commitment or first step toward the action you want.

Develop a Clear Mission

ASP leaders should ensure that the program has a mission statement that is concise and clear, and that addresses the perceived needs of the team, key personnel, and thought leaders. Leaders should also identify primary decision makers and key advisors (clinical and administrative leaders) and should meet with those key players early in the project prior to presenting the mission formally to solicit feedback and advice. Clear mission statements identify WHAT needs to be done, by WHOM, and by what target date (WHEN).

Use Outcomes Data

In addition, outcomes data can be included in the proposal to help persuade administrators and clinicians to support ASPs. (Additional data and metrics will be reviewed in Module 5.) Table 2-1 below shows some of the most useful outcomes data for administrative and clinical leaders (shown in decreasing rank order).

Table 2-1. Using Outcomes Data in an Antimicrobial Stewardship Program Business Case Proposal

Administrative Executive Leaders	Clinical Executive Leaders
Money saved	Improved outcomes
Reduced adverse drug events	Decreased antimicrobial resistance
Improved outcomes	Research
Decreased antimicrobial resistance	Reduced adverse drug events
Research	Reduced costs

Designate Champions

Another buy-in strategy is to identify staff "champions." When tackling process changes across an organization, the credibility of the intervention is critical. Getting competent and respected staff members from several key departments involved as advocates for a quality improvement project early in the process is a great way to provide the necessary credibility to get others on board and excited about the work.

Meet with Key Stakeholders

After completing a business case proposal, ASP leaders will want to verify and validate the content prior to submitting the proposal to senior leaders for approval. Meeting with key stakeholders will provide the opportunity to present the proposal, ensure ease of presentation, and validate strengths of the proposal for the stakeholders of the organization. Any stakeholder concerns and issues specific to support and engagement can be evaluated at this time. This is an important step in developing a business case proposal that is sometimes overlooked.

Address Barriers and Resistance to Change

It will be important for the multidisciplinary ASP team to proactively address potential system barriers and resistance from staff prior to introducing the business case to senior leaders.

From Proposal to Action Plan

After a business case proposal for an ASP has been developed and approved, it is time to develop an action plan. Action plans are necessary to pilot an improvement as an experiment and to determine future adjustments to the improvement. The action plan should contain very specific information about proposed changes. The following components can be developed into a brief outline to help develop an action plan that is easy to follow and that ensures accountability for achieving specific tasks by target deadlines:

- Identify strategies to reduce the risk of failure.
- Address responsibility for oversight of the implementation.
- Address ongoing measurement to determine the effectiveness of the actions.
- Create a time line for multiple actions.
- Set reasonable/attainable goals.
- Link goals to measurement.
- Select changes that have the highest potential to impact the entire organization.

Action plans should include the following components:

- Objectives of an ASP and the benefits anticipated from each objective
- Current status of antimicrobial utilization that will be affected by the objective
- Resources required to achieve objectives
- Impact of the ASP on other areas inside and outside the organization
- Timetable for achieving objectives
- Person(s) responsible for carrying out the objectives
- Evaluation and control processes

High reliability organizations (HROs) are those that consistently perform at high levels of safety over long periods of time.[22] HROs influence clinical and administrative leaders to work together collaboratively as one united team to solve problems. ASP leaders should consider reviewing eight steps from IHI for achieving patient safety and high reliability in their organizations.[23] These steps should align with the action plan for the ASP. The eight steps are as follows[23]:

1. Address strategic priorities, culture, and infrastructure.
2. Engage key stakeholders.
3. Communicate and build awareness.
4. Establish, oversee, and communicate system-level aims.
5. Track/measure performance over time, and strengthen analysis.
6. Support staff and patients/families impacted by medical errors.
7. Align systemwide activities and incentives.
8. Redesign systems and improve reliability.

Reporting Metrics to Senior Leaders

ASP leaders should share key metrics, such as the following, with senior leaders:

- What percentage of patients admitted to the hospital or treated by the hospital are experiencing an unintended antimicrobial event?
- What types of unintended events are patients experiencing at the organization?
- Where in the organization are patients experiencing these events?
- Are such events increasing or decreasing?
- What are the antimicrobial costs per patient-day and per admission before and after the implementation of an ASP?
- What type of comparison data (qualitative and quantitative) can be used to justify the ASP before and after implementation?
- What do benchmark data (qualitative and quantitative) with "like" organizations before and after implementation reveal?
- What is the impact of publicly reported data?

What Does Excellence Look Like?

A successful ASP is one that culminates in a change in leadership processes, cultural imperatives, and communication practices and is focused on patient-centered care. The following characteristics also demonstrate excellence in an ASP:

- Organizational vision that can be communicated in less than five minutes
- Work ethics match the vision
- Accountability for performance
- ASP values and organizational values are aligned
- Effective, two-way communication with key customers, partners, and stakeholders
- Key processes deliver optimal clinical, economic, and patient outcomes
- System in place to measure the value of the ASP

- Commitment to continuous quality improvement related to ASP processes
- Organizational goals for healthcare improvement are positively affected by the ASP across the continuum of care
- ASP processes and outcomes meet and exceed standards of regulatory and accrediting agencies
- Use of established best practices as a key component of the ASP strategy
- Technology is safely adopted into care processes

Conclusion

Antimicrobial resistance is one of the world's most pressing public health threats. Increased antimicrobial resistance is compromising the effectiveness of antibiotics and is associated with increased risk of hospitalization, length of stay, hospital costs, risk of ICU transfer, and patient mortalities and morbidities.

This module reviews the background of the problem of antimicrobial resistance, the subsequent resistance to change and barriers to successful implementation of ASPs, and the key components needed for writing and implementing a comprehensive ASP business case proposal. Antimicrobial resistance adversely impacts the health of patients in all types of healthcare organizations; therefore, organizations should develop a business case to justify an ASP in their facilities.

For an ASP business case proposal to be developed successfully, multidisciplinary teamwork is a necessary critical factor. Because of the need to provide safe, high-quality care to patients as well as to promote multiple financial, regulatory, and legislative benefits for the organization, ASPs should be considered mandatory for all healthcare organizations at this time.

Appendix
Antimicrobial Stewardship Program Business Case Proposal Outline

I. Executive summary

A. One-page description with power paragraphs stating what will be done, by whom, and by when

B. State the problem and the solution, including the benefits

II. Needs assessment

A. Review of literature

B. Review of internal data and experience

C. Establish a sense of urgency

III. Legal, regulatory, and accrediting assessment

A. Compliance

B. Miscellaneous

IV. Market analysis

A. Target population/primary decision makers

B. Current reimbursement for services

C. Key service characteristics and quality levels required

D. Environment assessment

E. Strengths, weaknesses, opportunities, and threats

F. Barriers to ASPs

G. Market and volume trends

V. Program service description

A. Scope of activities

B. Benefits provided or needs met

C. Types of patients served

D. Types of professionals involved

E. Rationale for the ASP

F. Customer expectations

G. Documentation/communication among providers

H. Previous experience

VI. Program management and organizational structure

VII. Financial analysis

A. Cost considerations

1. Direct

2. Indirect

3. Variable

B. Revenue considerations

C. Cost-avoidance considerations

D. Pro forma evaluation

VIII. Program evaluation

A. Criteria for service evaluation

1. Clinical outcomes

2. Economic outcomes

3. Humanistic outcomes

a. Quality of life

b. Satisfaction

B. Time frame for reviewing performance of ASP

IX. Marketing and promotional plan

X. Strategic planning process

A. Developing the strategic plan

1. Planning process

2. Participants

3. Strategic challenges and advantages

4. Planning horizon

B. Deploying the strategic plan (Action Plans)

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Notes

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Module 3
Initiating an Antimicrobial Stewardship Program

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Case Scenario

The medical director of infection prevention and control at Saint Somewhere Hospital (SSH) is concerned about an increase in cases of carbapenem-resistant enterobacteriaceae (CRE). Initially, these cases appear to have been imported from local long-term care facilities, but closer inspection reveals that some transmission is occurring within SSH. As part of a larger initiative to control CRE, the medical director wants to address antibiotic overuse, especially carbapenem use. Strategies that are presently in place include restricting a few expensive antibiotics for infectious-disease use only and the presence of a clinical pharmacist who works part-time with intensive care units (ICUs) and part-time with the infectious diseases (ID) section but who is not involved in approvals or other stewardship activities. The medical director discusses antimicrobial stewardship with the chair of the ID section and discovers that there is support for the idea, but presently, funding for clinician time does not exist. The chair presents the idea of antimicrobial stewardship to hospital leadership, and they are interested particularly in how this approach can help reduce pharmacy costs. The leadership team recommends that a formal proposal be developed, so they can consider the project. The chair of ID recommends you, a new physician in the ID section, to develop the proposal because you had shown interest in administrative work and antimicrobial stewardship during your interview.

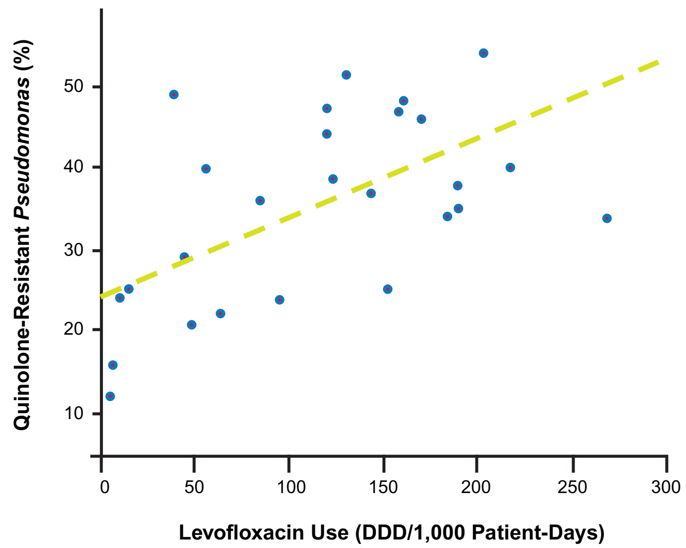
Introduction

An antimicrobial stewardship program (ASP) is an institutional antimicrobial management program—usually led by a pharmacist and a physician—that seeks to optimize antimicrobial use. Starting such a program can be a daunting task. From gaining administrative support and funding to winning over clinicians, the politics alone can stymie the development of an ASP. The tasks of setting goals, determining tactics, and choosing metrics can be equally challenging, despite help from guidelines.

Rationale for Antimicrobial Stewardship

Many clinicians used to see penicillin as a "silver bullet" that would eradicate most infections. This view is no longer held. Shortly after the introduction of antimicrobial therapy, resistance began to emerge, as did the knowledge that using antimicrobial agents encourages and selects for resistant bacteria. Antimicrobial resistance results in high costs, long hospital stays, and increased morbidity and mortality.[1-5] Despite these facts, antibiotics are routinely overused or misused, and it is estimated that approximately 50% of antimicrobial use in hospitals is unnecessary or inappropriate.[6,7] For example, Figure 3-1 on page 3 shows the correlation between increasing rates of fluoroquinolone-resistant *Pseudomonas* and increased use of levofloxacin.[8] Module 1 presents additional information about antimicrobial resistance.

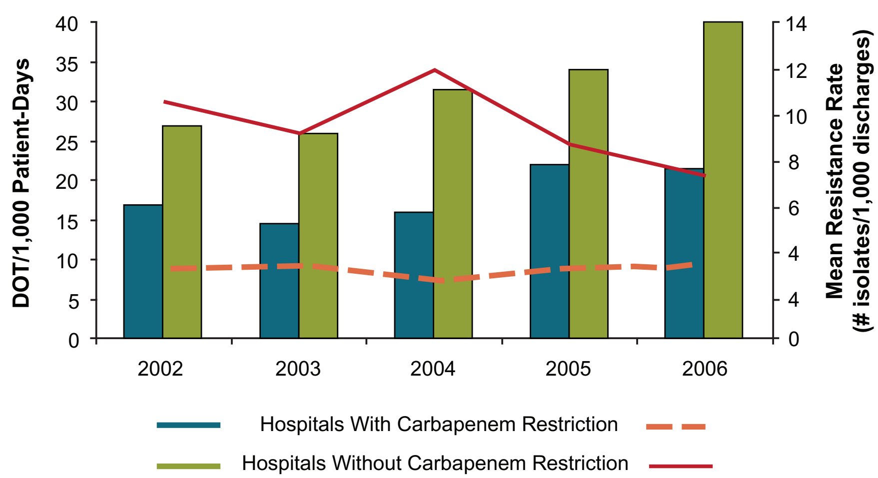
Figure 3-1. Graph Showing the Relationship Between Fluoroquinolone-Resistant *Pseudomonas* and Levofloxacin



As use of fluoroquinolones increases, the percentage of *pseudomonas* isolates resistant to fluoroquinolones increases proportionately.
Source: Polk RE, et al. Predicting hospital rates of fluoroquinolone-resistant *Pseudomonas aeruginosa* from fluoroquinolone use in US hospitals and their surrounding communities. *Clin Infect Dis.* 39:497–503, Aug. 15, 2004. Used with permission.

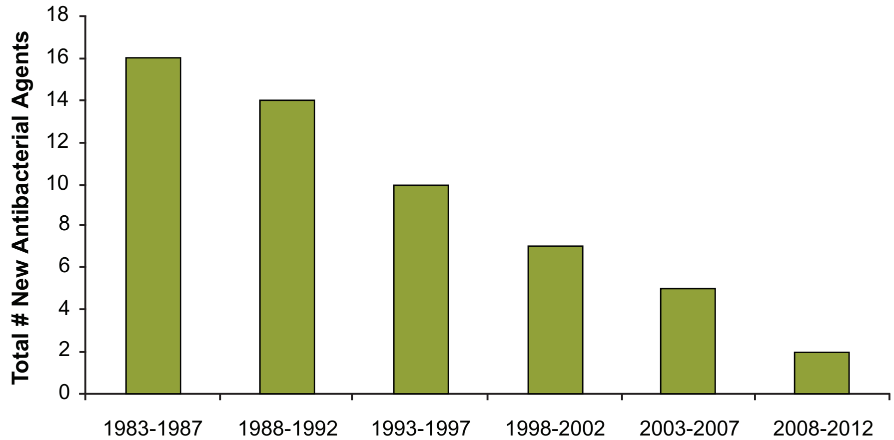
This example suggests that less antimicrobial use may reduce resistance, and there is evidence to support this relationship. Figure 3-2 below shows that hospitals that restricted carbapenems used lower quantities of this class of drugs and had lower rates of carbapenem resistance than hospitals that did not restrict carbapenem use.[9] With fewer and fewer antimicrobials being developed by pharmaceutical companies, protecting antimicrobial resources becomes even more important (see Figure 3-3 on page 4).

Figure 3-2. Relationship Between Carbapenem Restriction, Quantity Used, and Resistance



Hospitals with carbapenem restriction (n=8) have lower rates of carbapenem resistance than hospitals without carbapenem restriction (n=14).
Source: Pakyz AL, Oinonen M, Polk RE. Relationship of carbapenem restriction in 22 university teaching hospitals to carbapenem use and carbapenem-resistant *Pseudomonas aeruginosa. Antimicrob Agents Chemother.* 53:1983–1986, May 2009. Used with permission.

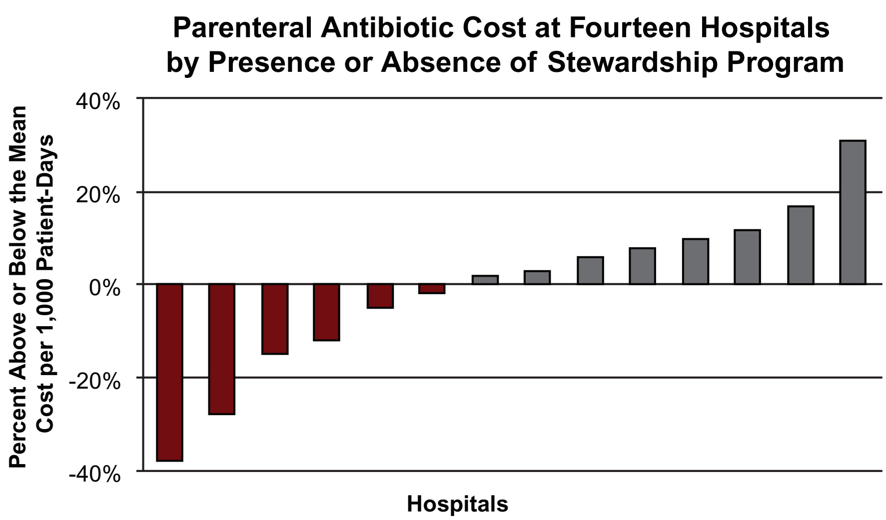
Figure 3-3. Number of Antimicrobial Agents Approved by the US Food and Drug Administration



This graph shows the number of new antimicrobials approved by the US Food and Drug Administration. Currently, there are only two new antimicrobials expected to be released between 2008 and 2012.
Source: Adapted from Infectious Diseases Society of America, et al. Combating antimicrobial resistance: Policy recommendations to save lives. *Clin Infect Dis.* 52(Suppl 5):S397–S428, May 2011. Used with permission.

In addition to slowing antimicrobial resistance, ASPs that improve antimicrobial prescribing and use patterns also have been shown to reduce *Clostridium difficile*-associated diarrhea and to decrease the risk of antimicrobial-resistant infections in hospital patients.[10-13] ASPs also have been shown to decrease antimicrobial utilization.[6,14-16] ASPs do not merely prevent bad outcomes, they also help increase cure rates by optimizing antimicrobial use and may also help reduce the cost of patient care.[14] For example, Figure 3-4 below shows the cost of parenteral antibiotics in 14 hospitals based on the presence or absence of an ASP. Finally, unnecessary antimicrobial use has its risks, as demonstrated by the 142,000 visits that were made to emergency rooms in 2008 for adverse reactions attributed to antimicrobials.[17]

Figure 3-4. Cost of Parenteral Antibiotics at Fourteen Hospitals



Cost of intravenous antibiotics is higher for hospitals that do not have antimicrobial stewardship programs.
Source: Carling PC, Fung T, Coldiron JS. Parenteral antibiotic use in acute-care hospitals: A standardized analysis of fourteen institutions. *Clin Infect Dis.* 29:1189–1196, Nov. 1999. Used with permission.

Antimicrobial stewardship also helps physicians balance their desire to do the right thing for their individual patients with the needs of the entire community of patients. Clinicians are familiar with the risk-benefit ratio and use it to help decide the course of action they should take when performing diagnostic testing or administering therapy. For example, when clinicians consider the needs of the patients they are treating, they may believe that using broader spectrum antimicrobial coverage than is indicated presents very low risks and high potential benefits. This problem is magnified by non-ID clinicians who have limited knowledge of antimicrobial therapy and ID. The clinicians' view of the risk-benefit ratio may change as they gain a better understanding of optimal antimicrobial therapy and as they consider the needs of the larger community. These are the goals of antimicrobial stewardship.

Antimicrobial agents are a category of medication that clinicians of all specialties feel comfortable prescribing, often without seeking consultation. Furthermore, failure to recognize the potential harm that can result from the overuse of antibiotics and failure to realize the urgency of this problem are real phenomena.[18] ASPs can address many of the problems associated with the use of antimicrobial agents by helping clinicians apply specialized, evidence-based knowledge to treat infections, optimize doses, and minimize toxicity, as well as by providing a community context for their use.

Initiating an Antimicrobial Stewardship Program

Identify Strategies to Improve Antimicrobial Stewardship

In 2007, the Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA) published guidelines to help hospitals develop ASPs.[6] The guidelines focus on presenting core and supplemental strategies that hospitals can use to optimize antimicrobial use. These strategies are based on evidence when possible and are based on expert opinion when there is little to no published evidence available. Table 3-1 on page 6 provides a summary of the core and supplemental recommendations in the guidelines, and Module 4 provides additional discussion about these strategies. It is important for ASP teams to consider which core and supplemental strategies they want to include in an ASP before they initiate this program, because the strategies the team chooses will impact the goals and resources needed to start the program. Furthermore, the clinical information and the means by which it can be accessed may significantly impact which strategies are employed in a program (see Module 4 and Module 5 for more information).

The core strategies make up the majority of the day-to-day workings of ASPs and are central to these programs. The core strategies include two methods to impact antimicrobial use in hospitals: a front-end approach, which is implemented before an agent is prescribed, and a back-end approach, which is used after an agent is prescribed. Module 5 contains additional discussions on the two approaches.

Table 3-1. Core and Supplemental Strategies from the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines

CORE STRATEGIES		
Strategy	**Rationale**	**Recommendation**
Prospective Audits (includes intervention and feedback to the prescriber)	Performed by infectious diseases physician or clinical pharmacist with infectious diseases training Can assist in reducing inappropriate use of antimicrobials Effective but time intensive	A-I
Antimicrobial Restriction (to ASP or infectious diseases approval only)	Can lead to immediate and significant reductions in use and cost of antimicrobials Role of preauthorization requirements has not been established and may shift use to other antimicrobial agents leading to increased resistance Where preauthorization is used – monitoring is necessary	A-II B-II B-III
SUPPLEMENTAL STRATEGIES		
Education	Provides foundation to influence prescribing behaviors and accept antimicrobial stewardship	A-III B-II
Guidelines and Clinical Pathways	Develop using multidisciplinary approach and local microbiological information (eg, resistance patterns to improve utilization); implement through education and provider feedback	A-I A-III
Antimicrobial Order Forms	Can be an effective component of a stewardship program and assist with practice guidelines	B-II
Streamlining or De-escalating Therapy	Used on the basis of microbiology culture reports and pharmacokinetic and pharmacodynamic drug characteristics; can result in decreased antimicrobial exposure and cost savings	A-II
Optimizing Antibiotic Dose	Based on the individual patient characteristics, causative organism, site of infection, and characteristics of the drug	A-II
Converting from Parenteral to Oral	Determined by patient condition; can decrease length of stay and costs	A-I

Source: Adapted from Dellit TH, et al. Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. *Clin Infect Dis.* 44:159–177, Jan. 15, 2007.

The front-end approach—often termed formulary restriction—refers to antimicrobial agents that have not been included on a hospital formulary or that require approval prior to prescription (preauthorization). ID physicians or ASPs develop a formulary and decide which drugs will require preauthorization. The front-end strategy is advantageous because it is relatively easy to implement after the agents on the formulary have been selected. Several studies have shown that this approach can reduce expenditures.[16] However, formulary restriction and preauthorization programs may have little effect on resistance because there is no follow-up after the antimicrobial is approved. Therefore, ASPs have little control over the duration of therapy and streamlining or de-escalation activities. In addition, clinicians often view this strategy as an infringement on their autonomy, especially in nonacademic settings. See Module 4 for more information about formulary restriction and preauthorization.

The back-end approach is often referred to as prospective audit and feedback. This strategy uses more resources than a front-end approach because it requires ASP clinical pharmacists or physicians to review prescriptions for targeted agents after they have been prescribed and to provide feedback to prescribers regarding the appropriateness of their use. This feedback usually is based on clinical-use criteria that have been approved previously by a Pharmacy and Therapeutics (P&T) Committee and/or the ID section. The back-end method is useful particularly for de-escalation and promotion of appropriate duration of therapy, which impacts resistance to a greater degree than formulary restriction alone. The obvious drawback to this approach is that it is more resource-intensive than a front-end approach. Formulary restriction and preauthorization requires ASP team members to answer inquiries requesting approval, and they can usually perform this duty while completing other tasks. Prospective audit and feedback, however, usually require dedicated time, which is proportional to the size and complexity of the hospital. For this reason, the net monetary gain for these programs is often less than that for formulary restriction and preauthorization. Module 4 presents additional information about prospective audit and feedback.

ASPs can consider using a hybrid program that implements both approaches. Formulary restriction and preauthorization may be better at saving money and optimizing doses, whereas a prospective audit and feedback program addresses resistance problems and improves overall antimicrobial use. Because each approach offers its own benefits, ASPs may find it worthwhile to restrict expensive and higher-risk drugs but to use prospective audit for selected drugs on specific units. For example, if daptomycin is being overutilized in the hematology/oncology unit, and carbapenem resistance is increasing in the surgical ICU, it may not be practical to perform a hospitalwide review of these agents, particularly if a real-time list of patients who are receiving these drugs cannot be obtained easily. Instead, ASPs can review carbapenem use in the surgical ICU and daptomycin use in hematology/oncology patients. A hybrid program may be useful for some hospitals; however, it is not standard practice at this time.

In addition to the front-end and back-end core strategies described previously, the IDSA/SHEA guidelines also provide supplemental strategies to help hospitals optimize antimicrobial use, and these strategies should be viewed as partners to the core strategies. For example, dose optimization is a supplemental strategy that can be incorporated into the formulary restriction or prospective audit core strategies. Another supplemental strategy focuses on interventions that transition patients from parenteral to oral drugs, which helps reduce costs, shortens length of stay, and allows clinicians to remove intravenous and peripheral catheters from patients more quickly. Other supplemental strategies are education based; for example, clinical pathways and order sets help clinicians optimize antimicrobial choices, and antibiograms based on recent local susceptibilities help guide empiric therapy. In addition, standardized prophylaxis regimens can promote appropriate antimicrobial use, prevent resistance, and help meet Surgical Care Improvement Project requirements.

Perform a Needs Assessment/Gap Analysis

To understand which of the strategies (front-end, back-end, or a combination) will work best for an ASP, team members should perform a needs assessment or gap analysis. These concepts may be familiar to many individuals, but they may not have encountered these tools in the context of antimicrobial stewardship. A needs assessment/gap analysis allows individuals to assess actual performance against potential performance or the present state compared to a desired state. This analysis should be performed at the planning stages of an ASP—prior to its implementation—and periodically thereafter. The main goals of this review are to identify key stakeholders in an ASP and their expectations, to identify the resources available to an ASP, and to understand the current state of antimicrobial use in the hospital.

Identify Key Stakeholders

Key stakeholders are individuals who have a vested interest in an ASP, whether they stand to benefit from the program, participate in the program, or provide funding for the program. ASP stakeholders typically include patients, hospital leaders, pharmacists, and physicians. ASP teams can identify stakeholders by starting with the individuals who will provide the resources to support the ASP, such as the finance staff. It is important for ASP teams to be aware of the expectations of finance staff. Module 2 describes how ASP team members can collaborate with the Finance Department when starting or implementing an ASP. Patients should also be considered as key stakeholders. Although patients do not contribute to improving the hospital's fiscal bottom line, they stand to gain the most from improved antimicrobial use.

Identify Resources

The number of full-time equivalents required by an ASP will be determined largely by the core strategies employed in the program. Physicians and pharmacists can perform ASP activities, and the amount of time they devote to a program and team members' expectations need to be clearly defined.

Consider Data

When planning an ASP, teams also need to consider the data that will be collected and analyzed in the program. Data that help an ASP team understand the current state of antimicrobial prescribing patterns and behaviors include antimicrobial-use metrics (eg, expenditure, dispensing, and administration data), number of patients who receive specific agents, aggregate microbiological data, information on admissions or hospital days, and data on adverse drug events.

Understanding what types of data are available may require contacting information technology services and, most likely, infection prevention and control and the microbiology laboratory. Electronic medical records (EMRs) provide data, and it is necessary to understand what information they do and do not contain. In addition, data mining programs provide consolidated data or alerts that can supplement data in EMRs, and some computer programs are capable of creating an antibiogram.

If a hospital does not have these resources already in place, the ASP team should investigate third-party vendors that provide these services to determine whether their product will provide the information required by the ASP. For example, ASPs need to measure drug utilization. (See Module 5 for information on calculating drug use.) Pharmacies usually can provide expenditure data and sometimes even aggregated dispensing data, but extracting actual administration data from an EMR provides better information. However, if the data are too unwieldy or time-consuming to analyze, using a less precise (and less costly), but simpler data source may be preferable. Knowing how much each drug costs—per day, per dose, and per course of therapy—also is useful data. Infection control can provide information about drug-resistance patterns or current infection prevention and control issues (as described in the case scenario).

Microbiology laboratories are important partners for ASPs, as they control how microbiological data are displayed to clinicians. Microbiology laboratories can help display results for some antimicrobials that are sometimes hidden. For example, it is common to hide results for all extended-spectrum beta-lactamase producers because drug susceptibility found in laboratory testing does not indicate success in clinical use. Microbiology laboratories also can make recommendations regarding therapy for multidrug-resistant pathogens.

Perform an Antimicrobial Use Evalution

ASPs need to understand the patterns of antimicrobial use in a hospital. Formal medication use evaluations are very useful, but time-consuming, and not practical for all antimicrobials. Basic metrics (such as days of therapy [DOT] or defined daily doses [DDD]) can be applied to utilization data instead. (Module 5 provides additional information on antimicrobial stewardship metrics, including how to calculate DOT and DDD.) Arranging these metrics according to floor or clinical service line is useful. If this is not possible, getting a snapshot one day a week for three weeks of the antimicrobials presently in use provides the same type of information. These use patterns begin to reveal the low-hanging fruit that ASPs can address. For example, a concerted and hospitalwide effort to reduce the use of antipseudomonal beta-lactams does not help units where the real problem is overuse of antifungal agents. Focusing on the real problems is a good way to preserve limited resources, and this is possible only if use patterns are mapped first.

Understand the Current State of Antimicrobial Stewardship

It is common for hospitals to have bits and pieces of antimicrobial stewardship taking place in different areas of the facility. It is also not unusual for different service lines to have different antimicrobial stewardship needs. A strategy that hospitals can use to understand the current state of stewardship in their organization is to perform an evaluation that provides a grade for each of the key strategies used for stewardship that are described in the IDSA/SHEA guidelines.[6]

Identify Priorities

After an ASP team performs a gap analysis and identifies required resources, it should prioritize the next steps. ASPs need to consider several factors. To implement either one of the core strategies described previously (formulary restriction or prospective audit), the ASP team should develop use criteria. For example, Figure 3-5 on page 10 presents use criteria for colistin. Use criteria documents should be accessible to help curb requests for approvals that are not likely to be successful. Use criteria documents for commonly used or targeted antibiotics should be vetted through ID clinicians, the Antimicrobial Stewardship Committee, the P&T Committee, the Medical Executive Committee, and similar governing bodies. ASPs are more credible when recommended and not-recommended uses for medications have been agreed on prior to their use.

Set Goals

Setting goals for a new ASP can be challenging. ASP team members should ask themselves a number of questions: How much can be accomplished in a year? What unexpected resources might be needed? Should the program focus on saving money to satisfy the administrators and pharmacy? Or should the program focus on optimizing patient outcomes and preventing antimicrobial resistance to win over clinicians and benefit patients? Can the program really affect resistance?

Figure 3-5. Sample Use Criteria for Colistin

COLISTIN (COLISTIMETHATE, POLYMYXIN E)

UCMC Recommended Uses

1. **Intravenous (IV):**
   a. Treatment of documented or suspected infections due to multidrug-resistant (MDR) gram-negative bacilli (eg, *Acinetobacter, Pseudomonas, Klebsiella*).
2. **Nebulized:**
   a. Treatment of pneumonias due to MDR gram-negative bacilli susceptible to colistin, as adjunctive therapy to systemic antibiotics.
   b. Chronic suppression in cystic fibrosis patients colonized with *Pseudomonas* that is resistant to or who have failed aerosolized tobramycin (Tobi®).

UCMC Non-Recommended Uses

1. Infections due to *Serratia, Proteus,* or *Providencia* spp. due to the lack of in vitro activity.
2. Anaerobic or gram-positive infections

Other Considerations

1. Colistin administration is associated with nephrotoxicity and neurotoxicity. Serum creatinine should be closely monitored in all patients receiving colistin. Concomitant use of other nephrotoxic agents should be avoided, if possible.

Dosing

Nebulization

1. 150 mg nebulized every 12 hours

Intravenous

1. Dosing should be based on ideal body weight or adjusted body weight if obese (ie, actual body weight >1.2 x ideal body weight).
2. The dosing of colistin in patients with renal insufficiency has not been well studied and there are wide variations in published recommendations.

Usual Dose	CrCl ≥75	74-50	49-30	29-10	<10*	HD*,†	CRRT
2.5 mg/kg	Q12H	50% Q12H		50% Q24H	50% Q24-48H		24H

*Disease severity, site of infection, and clinical response should be taken into consideration when selecting the dosing interval.
†Administer dose after dialysis.
CrCl=creatinine clearance; HD=hemodialysis; CRRT=continuous renal replacement therapy.

This sample comprehensive use criteria for colistin is from the author's hospital. These guidelines were approved by the P&T Committee and are used by the clinical pharmacist to make ASP recommendations; they may include uses not approved by the US Food and Drug Administration.
Source: The University of Chicago Medical Center. Used with permission.

When an ASP begins, there will be a lot of low-hanging fruit that are ripe for interventions. For example, improving safety, encouraging responsible antimicrobial use, optimizing duration of therapy, reducing drug expenditures, and preventing resistance should be included as possible goals of an ASP. When deciding on possible objectives, an ASP team should consider the following three questions: (1) Does it address one of my program goals? (2) Will I be able to measure outcomes or processes associated with this goal? (3) Do I have sufficient support and buy-in in the target clinical area? Programs that are just starting also should include developing standardization-of-use policies as a goal.

The magnitude of anticipated improvement in each area will depend on the available resources. Therefore, clarifying the specific goals of an ASP is an important tool to set appropriate expectations. For example, reducing the cost of antifungals, optimizing duration of therapy for common clinical syndromes, reducing toxicity due to aminoglycoside dosing, and reducing utilization of carbapenems are more manageable goals than those presented in the previous paragraph. Setting realistic goals also provides the direction necessary to determine the appropriate strategies to reach these goals and the appropriate metrics to monitor whether the goals have been attained. When selecting these metrics and strategies, it is important to revisit the goals to ensure that they are feasible.

Determine Metrics

Measuring the progress and success of an ASP is imperative to its longevity. The metrics selected should match the goals, and, to a certain extent, will impact the goals.

The most important priority of an ASP is to determine the method it will use to measure utilization. The two most common methods are DDD and DOT. DDD uses the World Health Organization's definition of a standard daily dose for an average-size adult with normal renal function. DOT counts the total days of therapy administered for a particular drug. Module 5 contains specific information on how to calculate DDD and DOT. An ASP team needs to decide how such methods will be used in the program.

However, measuring utilization is only part of the picture. Each program goal also needs a metric to ascertain whether it has been reached. For example, a log of near misses and reported adverse drug events can show whether an ASP has succeeded in its goal of promoting medication safety. Using process and outcome measures, such as measuring the proportion of drug levels at an appropriate time and within expected levels, can help an ASP evaluate the goal of optimizing dosing. If valid and easily measured metrics cannot be identified for a particular goal, it should be adjusted.

Choose Appropriate Tactics

An ASP team should choose the projects to work on based on the goals of the program, appropriate metrics, and available support. Success in the first year can be used to garner additional support in subsequent years. Therefore, as ASPs succeed, support and buy-in will grow, paving the way for more resource-intensive interventions. If time and resources are limited, an ASP's goals should be restricted to defined clinical areas or drugs. For example, restricting expensive or broad-spectrum agents combined with prospective audit and feedback on low-performing units maximizes available dedicated stewardship time. And by de-restricting broad-spectrum agents in areas where they are frequently indicated, pharmacists are free to help with other projects. Making the interventions more efficient by targeting them to the key clinical areas where change is needed most can help stretch thin resources.

Develop a Strategic Plan

A strategic plan will evolve as an ASP takes shape. Initially, the plan may be a working document or formal proposal to leadership requesting financial support. Eventually, the plan will evolve into a statement that clearly articulates the goals of an ASP and the metrics and tactics that will be used in the program. It also can be used to report the results realized by the program. It is prudent to revisit the strategic plan at each step in the development of the ASP.

The structure of this plan varies; however, it should focus on describing the goals of the ASP, the tactics that will be used to attain these, and the metrics that will be used to measure progress. Some ASPs structure this document like a business plan, starting with an executive summary or overview and following with a description of the ASP team and its role within a hospital. A statement of need justifying the ASP should also be included in the plan, as should a request for initial support and ongoing funding. The audience for this document can range from physicians on the antimicrobial subcommittee of the P&T Committee to chief executives. Module 2 includes additional information about developing an antimicrobial stewardship business plan and presents a sample plan.

Build an Antimicrobial Stewardship Team

The IDSA/SHEA guidelines recommend the personnel who should be tasked with leading an ASP.[6] The guidelines stipulate that it is highly desirable to have a clinical pharmacist and a physician lead the team because they bring different skills to the group.[6] The best-case scenario is for a clinical pharmacist who has advanced training in ID and a physician with extensive experience treating infections, often an ID specialist, to lead the program. However, this arrangement may not always be feasible, particularly in small hospitals in which only part of a clinical pharmacist's time may be devoted to stewardship. In such situations, it is essential for ASPs to be as efficient as possible and for supporting team members to provide as much help as possible.

Physicians and pharmacists are equal partners in successful ASPs, but they perform different duties. Clinical pharmacists usually perform day-to-day data collection and evaluate antimicrobials. They can provide recommendations regarding antimicrobial use only if criteria are clear and are established by an advisory committee. Physicians usually set goals, supervise interventions, and act as liaisons to medical staff. They also should be members of the P&T Committee or, preferably, leaders of an antimicrobial subcommittee, if one exists.

Medical staff committees, such as the P&T Committee, are usually responsible for creating policies that govern practice within a hospital. In essence, they provide oversight and are the voice of clinicians. An ASP's policies and initiatives will require the support of the Medical Executive Committee. ASP policies require thorough vetting by key players on the P&T and/or Medical Executive Committee to be successfully adopted and supported.

The core leaders of an ASP team usually are supplemented by additional physicians who serve on a larger Antibiotic Stewardship Committee. Representatives from key utilization areas (often ID, hematology/oncology, transplant, and critical care) should also be on the ASP. It is important for additional physicians to serve on the stewardship committee because their opinions help shape interventions and goals, but requests for their time should be minimal. Furthermore, their support of the ASP in their respective areas of practice helps provide a context for the interventions in these areas, which can lead to greater acceptability. These physicians also can help in the implementation of new policies and procedures because they have insight into the work flow in their areas of practice, and they have relationships with local physician leaders. It is vital for policies and interventions to be integrated into the existing work flow.

Other key members of an ASP may include information technology, infection prevention and control, and clinical microbiology staff; and these individuals should be integrated into the program.

Gain Support

As with any hospitalwide program, leadership support is important for an ASP to achieve success. In other words, if a hospital president or chief medical officer favors antimicrobial stewardship, others will follow, regardless of their own opinions. Leadership support is garnered through individual meetings and regular reporting of metrics. Leadership likes to promote and support successful programs, but they do not know whether a program is successful unless someone tells them. ASP team members should not wait for someone else to mention their achievements to leaders. To inform leaders about the success of their programs, team members should organize meetings in which they present reports that detail projected savings and evidence that the ASP met or exceeded its goals.

Pharmacies are usually willing to support ASPs and assist with funding efforts because they almost always reduce expenditures. In addition, ASPs can recoup the cost of the full-time equivalents devoted to this project.[18,19] In addition, one tertiary care center demonstrated that discontinuing its ASP cost the hospital more than $1million.[20] Multidrug-resistant gram-negatives are becoming more common, and studies have shown that ASPs can reduce the incidence of these bacteria in hospitalized patients over time.[12,21] ASPs may find it useful to pilot one or more interventions in defined clinical areas to demonstrate that they are effective. However, realistic timetables should be established, as savings on expenditures are realized relatively quickly, but positively affecting resistance can take years to manifest.

Although a glossy report is sure to impress leadership, getting clinicians to support and follow ASP advice is one of the biggest hurdles these programs face. Clinicians want to do what is best for their patients, and this sometimes leads to overly broad antimicrobial coverage and clinical inertia. In addition, clinicians sometimes view ASPs as trespassing on their autonomy. Nonetheless, clinicians often appreciate ASPs helping them to address safety issues and providing them with educational tools at the point of care. ASPs should seek out opinion leaders and ask how they can help these individuals streamline their practice with respect to antimicrobials.

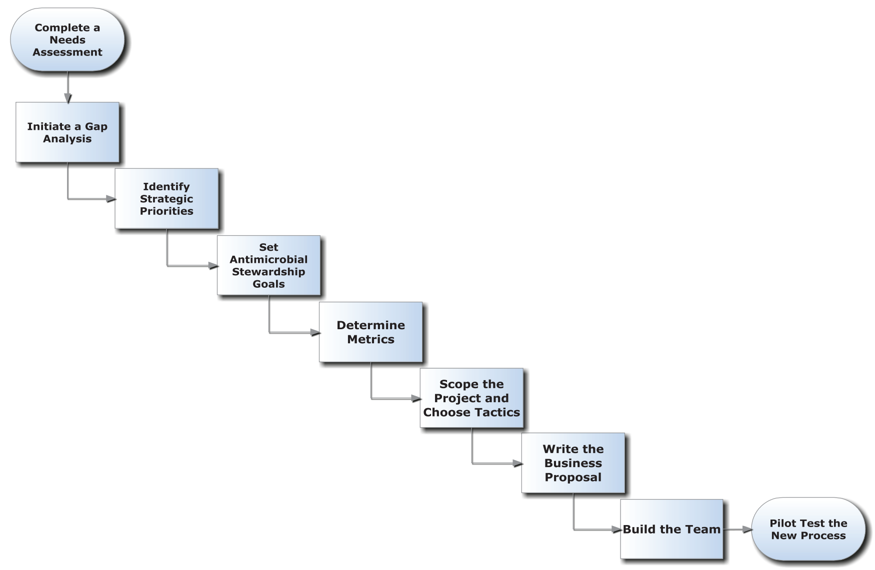
ASPs also should work hard to make the ASP interventions valuable to clinicians by incorporating convenient educational materials and useful advice. For example, formulary restriction programs are often unpopular with clinicians because they add to the work flow and limit antimicrobial choices. However, if use criteria are clearly stated and easily available, and if the approval process is quick and accompanied by evidence-based dosing information and suggestions about alternatives, they can become important sources of information for clinicians and essentially can become immediate curbside consultations.

Therefore, it is important to structure interactions correctly. For example, it is good policy to never "refuse" requested antimicrobials. Instead, an ASP can suggest an alternative agent based on use criteria that, in turn, are based on published literature. The tone used to communicate prospective audit and feedback information also must be considered carefully. The ASP cannot tell clinicians how to care for their patients any more than a consulting physician can. However, recommendations that are backed by evidence and that focus on optimizing therapy can overcome most opposition. ASPs report a very high rate of acceptance for recommendations. For example, one hospital reported an acceptance rate of 91%.[22]

Initiating an Antimicrobial Stewardship Program: A Performance Improvement Model

Although initiating an ASP is not necessarily considered an "improvement" project, it does represent the initiation of a new "design" for a hospital that will require a systematic methodology and implementation process for it to be successful and sustainable. Figure 3-6 below highlights the steps that a hospital should follow to start an ASP that were discussed in this module.

Figure 3-6. High-Level Process Map: "How to Get Started"



Following a systematic process enables teams to assess, plan, implement, and evaluate new processes while avoiding the application of a best-practice solution being placed on top of operational systems that may be broken.

Create a Current-State Process Map for Antimicrobial Use

The high-level steps required to create an ASP were discussed previously. The following "how to" steps can assist an ASP team to create a current- or present-state map for antimicrobial use within a well-defined area of clinical practice:

1. Assemble a team of eight individuals who are knowledgeable about a process.
2. The team will decide which current clinical area will be assessed and will develop the scope of the process map according to that area and its patient population.
3. Include at least one individual on the team who does not know the antimicrobial stewardship process. This individual is able to ask questions about why things happen in a specific way and can challenge the group to consider the rationale for why things have been created in a particular way.
4. Identify a facilitator who is neutral to the stewardship process who can assist with discussions as opposed to participating in actual discussions.
5. Consider six to eight high-level steps that occur within the stewardship process at least 80% of the time. The following steps provide an example:
    1. A physician admits a patient.
    2. The physician writes orders for an antimicrobial agent.
    3. Medications are administered.
    4. Care and treatment are provided.
    5. Laboratory tests are ordered and analyzed.
    6. Discharge orders are written.
    7. The patient is discharged.

   The team should agree on these steps. The first and last steps should be written in a circle, and the process steps should be written between these in a process-rectangle box. Triangles are drawn around areas where decisions need to be made, such as the type of antibiotic ordered. Connect each step with an arrow.
6. Ask each discipline to review and address the subprocesses, potential failures, and risk points that occur in each step.
7. After the process map is completed, the team that developed it should analyze it to determine not only what is working well but also what is not working well. Teams should primarily focus on points within the process that are risk points or potential failures, such as physician handoffs, team reporting, information flow within a medical record, and transfer of information to a community care provider.

Process mapping is a technique that makes work visible. A process map can show who is doing what, with whom, when, and for how long. It also shows the decisions that are made, the sequence of events, and any wait times or delays inherent in a process. There is no right or wrong way to build a process map. The process a team goes through to build the map is the critical success factor rather than what the actual map looks like. Process maps should be developed with paper and pen or flipchart and markers first. If the team attempts to use technical software or graphic programs while they are creating the map, not all the team members will be able to see and learn about the development process. ASP team members should ensure that they make time to plan the meeting; they bring flip charts, markers, and sticky notes; they establish ground rules for focused work; and they have fun!

Create a Project Charter

Because miscommunication can occur during team meetings, it is important for teams to develop a project charter. A project charter serves as an executive summary and is dynamic and ever changing, as new data are discovered about a given process. The charter can act as a source of information when a team member asks, "Why are we doing what we are doing?" A project charter can also help build consensus about the current state of a process, the desired future state of the process, and any other goals of the process. Therefore, the project charter is one of the primary tools that teams can use during the planning phase of a performance improvement project. To develop a project charter, team members should ask themselves the following questions and should record the answers:

1. What problem are we trying to address?
2. Who are the team members?
3. What is the scope of the problem or the area that we wish to study?
4. What is the current state of the process?
5. What is the dollar-equivalent benefit of the project?
6. Why is the project being done?
7. What are the goals of the project?

While the ASP team creates the project charter, team members also can begin to scope a potential performance improvement project, can think about strategic priorities and operational tactics, and can begin to reach consensus on defining a mission and vision for the project. Scoping a project means that the team will target a specific area, patient population, or antimicrobial agent, so that a pilot test can be run prior to fully deploying a new design for a process throughout a hospital. Figure 3-7 on page 16, presents a sample antimicrobial stewardship project charter.

Figure 3-7. Sample Antimicrobial Stewardship Project Charter

Project Charter: Antimicrobial Stewardship		Start	
Problem/Global Statement: Develop an Antimicrobial Stewardship Program by March 2012	Leadership Signoff: (CEO/COO) Sanction:______________		
Why is this project important? The purpose of the ASP is to optimize antimicrobial use, resulting in safe and appropriate dosing, responsible use of broad-spectrum agents, optimized duration of therapy, reduced antimicrobial expenses, and preventable antimicrobial resistance	Describe the patient benefit: Careful selection of antibiotic based on need, optimal duration of treatment, reduced resistance		
What will the project achieve? Elimination of fragmented care across units, multidisciplinary teamwork, prioritization of approaches, accountable partnership for ASPs, access to critical information for treatment decisions	Describe the organizational benefit: Teamwork, clearly defined treatment plans, reduced expenses, data-driven decision making		
What is the business case? (ROI) Safe, effective, and efficient patient care, performance improvement outcomes, reduced financial impact due to less inappropriate use of antimicrobial agents, and improved satisfaction of key stakeholders	Project Metrics:		
	Days of Therapy (DOT)		
Team Members:	Defined Daily Doses (DDD)		
Pharmacist:			
Lead Physician:	Stage:	Target Date:	Actual Date:
Infection Control Nurse:	Define (Plan)	Nov-11	
Epidemiologist:	Measure (Plan)	Dec-11	
Information Technologist:	Analyze (Do)	Jan-11	
Clinical Microbiology:	Improve (Check)	Feb-12	
Staff Nurse-Critical Care:	Control (Act)	Mar-12	
Administrator:			

Performance improvement teams should develop a charter at the initiation of a project and should revise it during the course of the project, as needed.

When thinking about performance improvement, teams might initially focus on using a Plan-Do-Study-Act cycle for each new initiative (see Module 2 for more information about this cycle). If possible, all initiatives should be pilot tested and evaluated before rolling them out to the entire hospital. In addition, the ASP should be monitored constantly to ensure its continued benefit/value. ASP leadership should be able to adjust resources for the program, as needed. For example, a project to switch from intravenous to oral antimicrobial administration may require a lot of work in the beginning but may be scaled back after clinicians become familiar with the idea and have been able to adjust their practices accordingly. Over time, they may be able to anticipate new ASP standards, such as those set by hospital policy, the P&T Committee, and the Infection Control Committee, and they may make changes on their own. For example, they will switch from administering linezolid intravenously to orally of their own accord. A performance improvement team should audit practice changes systematically to monitor whether practices start to falter; however, over time, the team can then begin to transfer resources into rolling out the new initiatives to the entire hospital.

Conclusion

Assembling the financial support, the team, and the plan for a new ASP is a manageable task that can be scaled to meet any hospital's needs. This module reviewed the key steps to starting an ASP and addressed practical concerns that teams need to consider when initiating such a program. While planning and implementing an ASP, concerns about finances, staffing, resources, and expected outcomes can appear to overshadow the clinical mission of the program; this objective must not be forgotten, however. The benefits of a successful ASP will be reaped by the patients of a hospital that takes on the challenge of antimicrobial stewardship.

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Notes

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Module 4
Creating Change: Using an Antimicrobial Stewardship Program to Improve Antimicrobial Usage

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Case Scenario

Fantastic Health Care (FHC) is a 350-bed community hospital located in a suburb of a large metropolitan area. There are two infectious diseases (ID) physicians who practice at FHC and three additional community hospitals in the area. Patients at FHC are cared for by a group of hospital-medicine specialists (hospitalists) and various private-practice physicians. The leadership of FHC would like to implement an antimicrobial stewardship program (ASP). However, the ID physicians have said that they do not have time to lead the program and that they are afraid that involvement in the program might decrease their number of consults. Individuals charged with implementing the ASP are wondering how to get all members of the medical staff "on the same page" regarding antimicrobial usage. Also, although they have a general sense that antimicrobial usage at FHC needs to be improved, they do not know how to identify the areas that need the most attention or the interventions and initiatives that would successfully address these areas.

Introduction

A formal ASP can be a very effective means of improving the use of antimicrobials within an institution. The Infectious Diseases Society of America/Society for Healthcare Epidemiology of America (IDSA/SHEA) guidelines provide useful recommendations regarding the structure and activities of ASPs.[1] However, these recommendations need to be adapted to the specific circumstances of individual hospitals. For example, what works best for FHC may not work as well for a large, academic medical center or even for another 350-bed community hospital that has a medical staff with a different approach to patient care.

In addition, the resources available for an ASP, the means to engage individual prescribers, and the key areas needing improvement may vary widely among different institutions. This module reviews the key strategies an ASP can use to positively impact the use of antimicrobials and discusses their applicability to different hospital settings. It also discusses how an ASP can focus its efforts by identifying and selecting the stewardship initiatives that will target the specific needs of their hospital. This module begins by considering a concept that is greatly feared by most clinicians: CHANGE.

Establishing a Culture of Change

The goal of an ASP is to improve the use of antimicrobials; therefore, it is assumed that at least some of the current practices within a hospital will need to change. Because many hospitals and individuals are often less than enthusiastic about embracing change, it is important for leadership to establish a culture that will help facilitate the improvement initiatives proposed by the ASP, particularly those that address changes in antimicrobial prescribing. According to Sbarbaro, "Changing physician behavior is considered by many to be an exercise in futility—an unattainable goal intended only to produce premature aging in those seeking the change. The more optimistic might describe the process as uniquely challenging."[2] Most individuals would agree that changing physician behavior can be "uniquely challenging"[2]; however, an ASP will have very limited success unless it is able to modify how physicians prescribe antimicrobials in specific situations. Sbarbaro suggests four key elements to generating change in physician behavior, including prescribing practices (see Sidebar 4-1 on page 3).[2] In addition, Module 2 discusses factors that influence physicians' drug choices.

Sidebar 4-1. Key Elements for Generating Change in Physician Prescribing Practices

1. Educational activities that require the direct involvement and focused attention of the physician, such as interactive, hands-on workshops
2. Documentation that a physician is an outlier—the odd man out—when compared to peers
3. Patient and peer feedback
4. Nationally developed guidelines, particularly when incorporated into the routine practice of leading physicians within a community and when strongly endorsed by local and national professional organizations

Source: Sbarbaro JA. Can we influence prescribing patterns? *Clin Infect Dis*. 33(Suppl 3):S240–S244, Sep. 15, 2001.

To help promote acceptance of ASP initiatives, it is important for hospitals to address misconceptions that physicians may have about the program. One common misunderstanding is that the goal of an ASP is to stop clinicians from using antimicrobials.[3] Although eliminating unnecessary antimicrobial use is an important objective of all ASPs, the primary goal of these programs is to improve patient outcomes through *optimizing* antimicrobial therapy, not by *eliminating* it. Optimizing therapy may involve reducing antibiotic use in some situations, but it may entail increasing antibiotic use in others. It is important for prescribers to view stewardship activities as helping with patient care rather than as intrusions or infringements on physician autonomy.[3] Establishing appropriate goals for an ASP and communicating these to the medical staff are essential steps to help address common misconceptions about these programs.

Role of the Antimicrobial Stewardship Committee

An Antimicrobial Stewardship Committee can be a valuable tool to help win the support of key physicians for an ASP. This committee is the sounding board for the ASP team members and the conduit for bidirectional communication with the medical staff. The committee usually also serves as a subcommittee of the Pharmacy and Therapeutics (P&T) Committee, providing a mechanism for ASP policies and procedures to become formal recommendations of the P&T Committee. Perhaps more importantly, an Antimicrobial Stewardship Committee meeting can allow ASP team members time to present local epidemiology and other scientific data that can influence treatment decisions and can provide a format to address the various misconceptions that may be held by certain prescribers. The input of physician committee members can also be an effective means of influencing prescribers, particularly outliers. In addition, the committee meeting provides a forum to discuss antimicrobial-use issues in the abstract rather than in connection with the treatment of a specific patient, which can often lead to a more emotional or confrontational interaction. And finally, because physicians on the committee are part of the decision-making process, they have ownership in ASP initiatives and can serve as helpful liaisons to their colleagues who are not committee members. This committee can be a powerful instrument for change, can help develop thought leaders who are respected by their peers, and can serve as a useful advisory board for the staff who participate in the day-to-day antimicrobial stewardship activities.

The committee should be composed of clinician stakeholders who come from diverse areas of the hospital and should include clinical services that have high antimicrobial utilization, including internal and hospital medicine, hematology/oncology, pulmonary/critical care, surgery, transplant surgery, and emergency medicine. In addition, representatives from clinical microbiology, pharmacy, and hospital epidemiology/infection control and prevention should be included on the committee. Other stakeholders may be considered, depending on which services or clinicians need to improve the most.

Members who are asked to participate on the committee should be well versed in evidence-based medicine and quality improvement. It is sometimes useful to include participants who might push back the most against stewardship activities, as they may be persuaded about the need for change more easily if they are active participants in the decision-making process. With time, the committee will bring problems regarding antimicrobial stewardship and potential solutions to these problems to the ASP team rather than vice versa.

Physician Leadership

For most hospitals, the support and collaboration of medical staff leadership is vital for the success of an ASP.[1] Although there are stakeholders in ancillary and administrative areas of a hospital who are interested in improving patient care, it is ultimately up to the medical staff to optimize patient care and to modify physician prescribing behavior. In most cases, it is advantageous for a physician to lead the ASP, and programs with physician leadership are more likely to succeed. The IDSA/SHEA guidelines for antimicrobial stewardship indicate that an ID physician should advocate and act as the program leader—and thus the chief champion of change—for the ASP.[1] However, many hospitals that need to improve antimicrobial utilization the most do not have an ID physician available. In addition, many hospitals share their ID consultant physician with other hospitals and organizations, and that physician might not have the time to invest in an ASP.

The physician team leader should have personal qualities that facilitate change (see Sidebar 4-2 below). These qualities should address the following "3 *c*'s," which are important when developing, implementing, and operating an institutional ASP:

1. *Conceptualization:* This term deals with understanding what needs to be done, why it needs to be done, and how to do it.
2. *Communication:* This word refers to ensuring that the prescribers of antimicrobials receive and understand the information gathered through conceptualization.
3. *Coercion:* Although this term sounds strong, it refers to exerting the pressure required to get things done within the hospital across all units and departments. It also applies to the necessary assertiveness that is sometimes required to modify physician prescribing behavior.

Sidebar 4-2. Personal Qualities of a Successful Antimicrobial Stewardship Team Leader

- **Strong leadership skills**
- **Assertive**
- **Good politician**
- **Effective communicator**
- **Uses evidence-based knowledge**
- **Respected by the medical staff**
- **Respected by hospital administration**
- **Familiar with stakeholder needs**
- **Experienced clinician who sees patients**

Although having an ID physician as a core member and leader of an ASP team is beneficial, it is not absolutely necessary, and these roles can be filled by another member of the medical staff. Hospitalists are well suited for these roles and can be integral to the leadership of the multidisciplinary ASP team.[3,4] Hospitalists have knowledge of the hospital because they support a wide range of services and may have fewer time constraints than a subspecialty physician. Additional training in anti-infective therapeutics may be useful for hospitalists, and this training is becoming increasingly available through professional societies, quality-improvement organizations, and public-health entities (see Table 4-1 below).

Table 4-1. Training Resources for Antimicrobial Stewardship

Organization	Contact Information	Comments
Centers for Disease Control and Prevention's Get Smart for Healthcare: Know When Antibiotics Work	http://www.cdc.gov/getsmart/healthcare	Web site has information, evidence, and advice about starting and maintaining an ASP. Also a resource for educational materials, tool kits, and best practice examples.
Society for Healthcare Epidemiology of America	http://www.shea-online.org	Offers several pertinent guidelines, workshops, training courses, and meetings.
Infectious Diseases Society of America	http://www.idsociety.org	Offers a workshop at its annual meeting, and an entire supplement of *Clinical Infectious Diseases* (August 1, 2011) is devoted to stewardship in community hospitals.
Making a Difference in Infectious Diseases Pharmacotherapy	http://www.mad-id.org/antimicrobial-stewardship-programs	Offers basic and advanced training in antimicrobial stewardship for pharmacists leading to a certificate of training.
Society of Infectious Diseases Pharmacists	http://www.sidp.org	Offers a course in antimicrobial stewardship for pharmacists leading to a certificate of training.
Institute for Healthcare Improvement	http://www.ihi.org	Offers periodic courses, training, and resources through Expedition series.
Medscape	http://www.medscape.org	CME on antimicrobial stewardship for community hospitals available for physicians.

Potential Antimicrobial Stewardship Improvement Initiatives and Interventions

Initiatives or interventions to optimize and improve antimicrobial use fall within three broad activity areas: (1) patient-specific, (2) physician-specific, and (3) general facility or systemwide. Table 4-2 below lists examples of potential activities for each activity area. A successful ASP often uses elements from each area, and each specific activity is chosen to meet the hospital's stewardship needs.

Potential evidence-based program activities to improve antimicrobial stewardship are listed in Table 4-3 on page 7. The IDSA/SHEA guidelines recommend using two fundamental, or core, strategies that have been implemented at numerous institutions with various levels of success.[1]

The first, prospective audit and feedback—sometimes termed a "back-end" approach to modifying antimicrobial therapy—is based on a prospective audit of antimicrobial use at the level of a single patient, with subsequent intervention and feedback to the provider. The second is a "front-end" approach based on formulary restriction that requires preauthorization to order previously designated antimicrobial agents. In addition to these two core activities, hospitals can use various supplemental strategies, including large-group and patient case–based education, guidelines and clinical pathways, antimicrobial order forms, computerized clinical decision support, and other strategies described in Table 4-3.

Table 4-2. Activities That Can Potentially Optimize and Improve Antimicrobial Use

Category	Activities
Patient-specific	• Prospective audit and feedback • Clinical decision support • Rapid diagnostic utilization • Microbiology laboratory selective reporting of susceptibilities • Identifying bug-drug mismatches • Culture-specific audit and feedback (eg, asymptomatic bacteriuria and tracheal colonization)
Physician-specific	• Formulary restriction/preauthorization • Antimicrobial-specific audit and feedback • Clinical decision support • Medication use evaluations (peer comparison) • One-on-one education • Antimicrobial order forms
General facility or healthcare system	• Education for large groups • Guidelines/pathway development • Care bundles or change bundles/packages (see page 11) • Benchmarking

Table 4-3. Potential Antimicrobial Stewardship Program Activities or Elements	
Prospective Audit and Feedback	
Advantages	• Proven in clinical studies to reduce and modify antimicrobial consumption, improve selected clinical outcomes, and decrease antimicrobial expenditures • One-on-one patient-centered education • Optimization of anti-infective pharmacology
Disadvantages	• Voluntary adherence by clinicians to suggestions • Resource intensive • Requires team member training and experience in anti-infective therapy
Comments	• "Back-end" approach • Requires identification and intervention for patients already started on antimicrobials • Interventions include changing, streamlining, de-escalation, pharmacodynamic/dose optimization, switching from intravenous (IV) to oral (PO) administration, and limiting duration of therapy
Formulary Restriction and Preauthorization	
Advantages	• Proven in clinical studies to reduce and modify antimicrobial consumption, improve selected clinical outcomes, and decrease antimicrobial expenditures • When coupled with infection prevention and control, effective in controlling outbreaks of resistant or secondary pathogens (such as *Clostridium difficile*)
Disadvantages	• Less appealing to clinicians • Loss of prescriber autonomy • Potential need for after-hours service • Time intensive • Potential for delay in administering antimicrobial
Comments	• "Front-end" approach • Requires formulary restriction or preauthorization to prescribe selected antimicrobial • Each intervention is a "mini-consult" and opportunity for an education intervention
Large-Group Education	
Advantages	• Can reach a large number of prescribers in a short period of time • Effective for communicating the need and rationale for subsequent stewardship interventions
Disadvantages	• Not particularly effective in changing prescribing behavior without other interventions • Rapid loss of knowledge
Comments	• Can take place during grand rounds or clinical staff meetings • Provides information to prescribers and clinicians regarding stewardship needs • Provides feedback about antimicrobial susceptibility and use data to clinicians

Table 4-3. Potential Antimicrobial Stewardship Program Activities or Elements (cont)

Guidelines and Pathways	
Advantages	• Limit variation in therapy of infectious diseases • Are evidence based • Assist with adherence to regulatory and third-party payer stipulations
Disadvantages	• Often not utilized unless combined with other stewardship strategies or elements
Comments	• Best if local data and conditions are used to adapt guidelines to a specific hospital
Computerized Physician Order Entry and Clinical Decision Support	
Advantages	• Shown in limited clinical studies to reduce and modify antimicrobial consumption, improve selected clinical outcomes, and decrease antimicrobial expenditures • Once established, can greatly assist with implementation of guidelines and best-evidence therapy • Can reduce adverse events related to antimicrobials
Disadvantages	• Resource intensive during design and implementation • Expensive • Not readily available
Comments	• Often entails modification of existing or purchasing additional information technology resources
Microbiology Interventions	
Advantages	• Potential to improve antimicrobial use and anti-infective therapy for individual patients
Disadvantages	• Not well studied
Comments	• Includes cascade reporting to "hide" antimicrobial susceptibilities that might promote suboptimal therapy (eg, fluoroquinolone susceptibility for invasive *Staphylococcus aureus* infections) • Assists with choices of automated susceptibility profile, communication about new testing protocols and changes to existing protocols, and preauthorization of susceptibility testing for unconventional antibiotics
Rapid Diagnostics	
Advantages	• Provide opportunity for early targeted therapy • Assist with de-escalation • Shown in very limited studies to decrease antimicrobial consumption and improve clinical outcomes
Disadvantages	• Not readily available • Expensive
Comments	• Includes polymerase chain reaction and antigen testing of clinical specimens or early culture growth with rapid turnaround of test results

Table 4-3. Potential Antimicrobial Stewardship Program Activities or Elements (cont)	
Measurement of Inflammatory Markers	
Advantages	• Measurement of c-reactive protein or procalcitonin in selected patients to assist with withholding of antimicrobials for nonbacterial infections and with duration of therapy for intensive care unit-related infections
Disadvantages	• Clinician nonadherence to guidelines based on laboratory results • Cost of testing
Comments	• Need to have clinician "buy-in" to follow results • Need for stewardship team to monitor and promote adherence to guidelines that use these laboratory markers to guide antimicrobial de-escalation or termination
Switch From IV to PO Administration	
Advantages	• May allow for discontinuing an IV access • Antimicrobial cost savings • Decreased length of stay
Disadvantages	• False perception by clinicians that IV antimicrobials are a good reason to justify continued hospitalization when confronted by third-party payers
Comments	• Consider for PO antimicrobials with good bioavailability in patients with a functioning alimentary tract • Identify patients (via computer-generated lists) who are on IV antimicrobials and are receiving other scheduled oral medications or a normal diet

Adapted from Ohl CA, Luther VP. Antimicrobial stewardship for inpatient facilities. *J Hosp Med.* 6(Suppl 1):S4–S15, Jan. 2011.

Prospective Audit with Intervention and Feedback

Prospective audit with intervention and feedback is a patient-specific approach that usually involves ASP team members who review initial or ongoing therapy and then intervene to provide feedback and suggested modifications to the medical-care provider to improve therapy. These activities can be performed by an ID physician, a clinical pharmacist, or a hospitalist with expertise in antimicrobial therapy. The aim is to provide patient-specific education and/or suggest changes to antimicrobial utilization to improve, streamline, and optimize therapy. Suggested modifications and interventions include discontinuing or changing one or more drugs (streamlining or de-escalation), switching from intravenous to oral drug administration, and shortening the duration of therapy. When appropriate, suggestions are sometimes made to escalate or intensify therapy to increase therapeutic efficacy.

Identifying patients for prospective audit and feedback efforts typically involves using computer surveillance to single out targeted antimicrobials or problematic usage. Examples include focusing on unnecessary treatment of asymptomatic bacteriuria, excessive duration of therapy for ventilator-associated pneumonia, or overzealous use of certain classes of antimicrobials. Many hospitals develop software that identifies potential patients for intervention. Propriety software that performs this function for the hospital epidemiologist and antimicrobial steward is also available.

Another potential prospective audit and feedback activity is to ensure that reports of patient-specific blood and sterile body fluid culture results are correctly matched to the patient's current antimicrobial therapy. This task allows the hospital to perform a daily review of the appropriateness of therapy for potentially serious infections. Some patients seen by the antimicrobial support team may be referred to an ID physician or another expert for a consult if their infections or therapy are too complicated for routine prospective audit and feedback recommendations.

A number of studies have demonstrated that prospective audit with intervention and feedback—as measured by reductions in inappropriate antimicrobial use—can improve antimicrobial stewardship, lower antibiotic consumption, and decrease infections due to *C difficile* or resistant pathogens.[5,6] Prospective audit with feedback is an effective core strategy a hospital can use to improve antimicrobial stewardship, particularly when other interventions are cumbersome or not well accepted by the medical staff.

Formulary Restriction and Preauthorization

The second major strategy hospitals can use to achieve antimicrobial stewardship goals involves antimicrobial formulary restriction. This physician-specific activity can be carried out in two ways: by omitting a particular antimicrobial agent from a hospital formulary or by requiring medical providers to obtain preauthorization before prescribing a restricted drug. To get authorization, a clinician who wants to prescribe a particular agent contacts a member of the stewardship team to obtain prescribing permission. A pager system, telephone calls, e-mails, or cell phone text messages are used most often to obtain preauthorization. It is important for hospitals to remember that when using a preauthorization system, the individual who grants permission needs to be respected and needs to have clinical experience, because each instance is in fact a "mini-consult" and creates an opportunity for patient-specific one-on-one education. Often, the provider or prescriber is not merely seeking authorization to use a drug that is otherwise restricted but is asking for suggestions as to which antimicrobial should be used. Studies have shown that effective interventions supporting antimicrobial stewardship initiatives were more accurately managed by clinical pharmacists than ID fellows in training.[7,8]

When deciding which antimicrobials will be restricted on a formulary, ASP team members should choose drugs that are used to treat complex infections or drugs that are—or have the potential to be—overused in certain infections for which there are alternatives. In addition, if local epidemiology or antibiograms show a particular problem pathogen, targeted restriction might be appropriate. For "workhorse" antimicrobials (ie, drugs that are over- or misused for several different infections), prospective audit and feedback may be a more effective strategy than restriction and preauthorization to reduce and modulate consumption.

Numerous studies have demonstrated that formulary restriction and preauthorization can effectively modulate antimicrobial use. These studies have documented reductions in antibiotic drug use—and often lower costs—after hospitals implement formulary restriction or preauthorization as part of antimicrobial stewardship.[4] It has been difficult to demonstrate additional benefits associated with this approach, although there is some support that it helps improve the antimicrobial susceptibilities of certain gram-negative pathogens.[8]

Supplemental Antimicrobial Stewardship Strategies

As mentioned earlier, Table 4-2 and Table 4-3 present a number of additional options to improve antimicrobial stewardship that supplement the two core strategies described previously.

Education is generally considered to be an essential component of an effective ASP, but it usually does not have a lasting impact on providers' behavior unless it is incorporated with other active interventions.[1] In particular, the large-group or grand-rounds type of education, in which an individual describes what needs to be done and why, typically does not engender permanent behavioral change. This educational mode might elicit some short-term behavioral modifications, but long-lasting change at the provider level requires consistent and repeated educational endeavors. Such large-group educational approaches are more effective and appropriate when used as a forum to describe or garner support for a new ASP or intervention rather than teaching a specific practice. One educational strategy that some hospitals have found useful is "academic detailing," which utilizes antimicrobial stewardship staff or other medical staff to educate physicians individually.[9]

Using an ASP as a mechanism to adapt national guidelines to local antimicrobial use and resistance patterns, then implementing these local guidelines or critical pathways, is another effective strategy hospitals can implement to improve antimicrobial stewardship. National guidelines generally enjoy widespread support, but they commonly lack specific information about how to implement recommendations at a given hospital or how to incorporate local data to make them relevant for decision making.

Information technology (IT) also can be adapted to healthcare delivery and prescriber support to improve antimicrobial stewardship. IT includes computer decision support and alert systems; computerized physician order entry; electronic medical records; electronic retrieval of treatment guidelines and clinical texts; data mining; and handheld tablet or smartphone applications that provide information on pathogens, diagnoses, medications, and treatments. In addition, computer-based surveillance and Web-based systems for antimicrobial approval, automated clinical decision support, and enhanced real-time communication between prescribers and other members of antimicrobial stewardship teams show promise for ASPs.

One strategy for improving antimicrobial stewardship not mentioned in the IDSA/SHEA guidelines, but which might become increasingly important in the future, is rapid molecular diagnostic testing. This testing method allows physicians to identify causative pathogens and rule out certain pathogens quickly, which should enable better decision making regarding which antimicrobial to administer. Using polymerase chain reaction (PCR) to test for respiratory viruses is one such promising strategy because it can potentially facilitate the discontinuation of antimicrobial therapy for infections due to viruses. PCR or fluorescence *in situ* hybridization also can allow for more rapid identification of blood culture pathogens, which facilitates antimicrobial streamlining or identification of blood culture contamination.

Using Change Bundles

Another physician-specific approach that can be used to improve antimicrobial therapy involves using a change bundle based on driver diagrams that examine the primary forces that affect antimicrobial decision making. The bundle concept was first proposed by the Institute for Healthcare Improvement and has been used to successfully develop several healthcare-associated infection interventions.[10] The change bundle contains a set of interventions that clinicians, nurses, and ancillary staff can follow to correctly administer antimicrobial therapy to individual patients. Examples of antimicrobial interventions include obtaining appropriate cultures prior to therapy, reconciling and adjusting antimicrobials at all care transitions or handoffs, and de-escalating antimicrobials at 72 hours. The goal of using change bundles is for clinicians to follow correct prescribing behavior without intervention from an ASP team member or other staff member. Antimicrobial stewardship change bundles will likely be available in the near future and appear to be promising additions to clinicians' tool kits to help them improve patient care.

Identifying Potential Targets

There are numerous improvement strategies an ASP may employ to improve antimicrobial stewardship and many areas of practice where these strategies may be employed. It is important for a hospital to select the improvement areas and interventions that are most appropriate to their individual facility. The following sections discuss the various sources of information that can help a hospital identify potential targets to improve its ASP:

- *Drug usage reports:* It is important for antimicrobial stewardship teams to monitor antibiotic usage. Usage reports can identify high-use and high-expense antimicrobials that may benefit from stewardship efforts. They can also identify areas of potential antimicrobial misuse (eg, an excessive amount of antipseudomonal antibiotics used in orthopedic patients). Module 5 provides additional information about these reports.
- *Microbiologic data:* These data can highlight unusual or increasing resistance patterns.
- *Published reports:* With the increased focus on antimicrobial stewardship, the number of published articles addressing important stewardship issues is growing. A possible area for investigation might be identified from a report of stewardship-program activities at another hospital or from researchers who report an area of potential antimicrobial misuse. For example, ASP team members who read an article in which a hospital frequently treated skin and soft-tissue infections (SSTIs) with excessively broad-spectrum antibiotics may be inspired to look at the practices associated with treating SSTIs at their own institution.[4]

- *Professional guidelines:* Various professional organizations periodically publish guidelines for the treatment of different ID. For example, many clinicians find the guidelines published by the IDSA particularly helpful.[1] A hospital may want to compare its antimicrobial use to that outlined in practice guidelines and develop initiatives to correct any inconsistencies.
- *Benchmarking:* Stewardship teams can identify potential areas for improvement by comparing antimicrobial use at their hospital to that of other similar facilities. Several hospital and health-system alliances have resources available for antimicrobial stewardship benchmarking. For example, one consortium allows members to compare many different antimicrobial usage measures, such as anti-infective cost by diagnosis-related group and the use of a specific antibiotic or group of antibiotics. Other medical consortiums are developing similar benchmarking resources. Ultimately, the National Healthcare Safety Network database, sponsored by the Centers for Disease Control and Prevention, will allow hospitals across the United States to benchmark their antimicrobial data. This reporting system is also developing an antimicrobial-use database that can integrate electronic hospital antimicrobial utilization data into a national comparative information system.
- *Medication use evaluations and other hospital investigations:* Evaluations that characterize the use of antimicrobials and/or the treatment of particular ID within hospitals often help identify areas that need improvement. Module 5 contains information about the medication use evaluation process.
- *Observations of pharmacists and other clinicians:* Clinicians who work in a hospital can serve as excellent sources of information about antimicrobial use within their facilities, and they should be encouraged to notify members of the ASP team about observations that concern them. These observations may concern potentially inappropriate antimicrobial prescribing habits or abnormal resistance patterns. It also may be informative to ask a clinical pharmacist about how antimicrobials are used in the areas in which they practice. For example, a pharmacist may be asked the following questions:
    - Are the physicians in your area of practice likely to de-escalate therapy based on culture results?
    - How often do these physicians treat asymptomatic bacteriuria?
    - What disease states appear to receive empiric therapy with an excessively broad spectrum of activity?
    - Are there physicians who are in particular need of assistance with these issues?

Selecting Improvement Initiatives

An ASP should use the following key factors to determine which initiatives it should pursue:

- *Impact:* An ASP should focus its efforts on initiatives that make a significant positive impact on the quality, safety, and/or cost of patient care. The clinical and economic impacts are sometimes evaluated separately because some interventions may have a huge clinical impact but a negligible financial impact (eg, ensuring that patients with *Staphylococcus aureus* bacteremia receive appropriate therapy), while others may have a significant financial impact but minimal clinical impact (eg, implementing a program to switch from intravenous to oral administration).
- *Political expediency:* Hospitals are political organizations, so individuals must be aware of the ramifications of certain decisions. For example, it is probably not wise for an ASP team to select a project that alienates half the medical staff. Teams instead should look for win-win initiatives—those that achieve the goals of the ASP as well as the goals of others who are involved in patient care. Political astuteness is an important quality of a successful stewardship program (this point is also reinforced in Module 2).

- *Resources required:* An ASP should choose initiatives that are consistent with the resources at their disposal. If a lack of resources is the main deterrent to the implementation of many important initiatives, the ASP should use this fact to try to obtain the necessary resources.
- *Ease of implementation:* Some initiatives are easier to implement than others, regardless of the hospital. An ASP should consider whether the potential benefits of the initiative are worth the effort. Figure 4-1 below provides a tool that can help an ASP decide which initiatives to pursue by assigning each a score, which allows them to be ranked. Although an ASP team does not need to adhere strictly to the prioritization of the initiatives based solely on the total score, the team can ascertain a general sense of the ideas that should be given the strongest consideration.

An ASP team should also realize that the program does not need to begin by implementing the "final version" of an initiative. Some programs may need to start out small and expand as resources and acceptance increase. For example, an ASP initially may include only 3 antimicrobials on its list of drugs that require preauthorization, although it would eventually like to restrict 10, or the team may be able to conduct prospective audit and feedback only for patients in intensive care units rather than for the entire hospital.

Figure 4-1. Antimicrobial Stewardship Initiatives Decision Matrix

	Key Factors					
Potential Initiative	Clinical Impact	Financial Impact	Political Expediency	Resource Requirements	Ease of Implementation	Total Score

An ASP can use this decision matrix to prioritize potential initiatives to help decide which ones it should implement. Potential initiatives are listed in the left-hand column. Key factors for each initiative are scored on a scale from 0 to 5 in the middle columns. The initiative in each row is then totaled in the right-hand column.

Overcoming Barriers

As with any large, multifaceted, and multidisciplinary initiative that relies on changing clinician behavior in healthcare facilities, barriers and obstacles will emerge. These hurdles usually develop during the planning and early implementation phases of an ASP, but they also can occur at any stage and even challenge well-established programs. Potential barriers to a successful ASP and possible solutions are listed in Table 4-4 on page 14. Community hospitals are more likely to encounter barriers related to financial and human resources, while all medical centers might run into opposition from medical staff that stems from a perceived loss of autonomy. It is important for an ASP team to remember that improving patient care ultimately is in the best interest of the patient, and barriers should therefore be removed. See Module 2 for a discussion of barriers to approvals and implementation of an ASP.

Table 4-4. Selected Potential Barriers to Antimicrobial Stewardship Programs	
Barrier	**Possible Solutions**
Lack of funding for personnel	• Create a business plan to present to hospital leadership to request additional funds. An ASP saves money and pays for itself (see Module 2 for more information about the business case for an ASP, including a sample business plan). • Implement an unfunded pilot for six months using available clinical pharmacist and physician-champion volunteers to show potential cost savings to justify the budget. • Use guidelines/clinical pathways or change bundles to affect physician prescribing. Monitor compliance with clinical pharmacists or nurses and communicate this information to medical staff leadership.
Inability to recruit an infectious diseases (ID) physician champion team leader	• Contract with an ID physician at another hospital to provide prospective audit and feedback using telemedicine and/or electronic medical records. • Contract with a hospitalist or other specialty clinician to fill this role.
Inability to recruit an ID clinical pharmacist	• Use or hire a non-ID clinical pharmacist and provide supplemental training. • Use clinical pharmacists in other specialty areas as extensions of the physician champion or sole ID clinical pharmacist.
Lack of medical staff/clinician support	• Work with medical staff leadership early in the process. • Enlist the help of the hospital quality/patient safety officer. • Enlist and develop thought leaders from "problem" specialties with help from the antimicrobial stewardship committee. • Employ large-group education that highlights problems with antimicrobial resistance or *C difficile* infections. • Rely more on prospective audit and feedback, which may be accepted better than formulary restriction.
Outlier physicians	• Measure and audit usage by these physicians. • Benchmark antimicrobial utilization by these physicians against other physicians in the practice or group. • Work with these physicians to understand their antimicrobial needs and patient usage. • Have the physician champion work with the outlier's medical staff department head or chief medical officer. • Work with the outlier's medical staff credentialing committee.
Inadequate information technology (IT) resources to obtain needed microbiology and drug utilization data	• Decrease the number of antimicrobials or the time period required for measurement. • Obtain an FTE portion for an IT staff member. • Include representatives on the hospital's clinical IT committee.
Small hospital that is part of a larger hospital system	• Use and adapt the resources and systemwide guidelines and policies of the larger system, and use a local physician champion and clinical pharmacist. • Concentrate on prospective audit and feedback rather than preauthorization. • Pick "low-hanging fruit," such as following up with patients admitted with pneumonia or urinary tract infections who are found to have alternative diagnoses without subsequent stopping of antibiotics.

It is usually better to avoid barriers than to run into them. Presenting the idea that an ASP serves as a patient advocate to the right audience may help team members succeed in dismantling barriers. Another approach to overcoming barriers is to network and share common problems and solutions with individuals who have developed and have staffed ASPs. ASP team members can network at local and national meetings and workshops and through various professional organizations and online resources, such as list serves, blogs, and online communities. Education and thought-leader development are other strategies that can be implemented prior to initiating an intervention, particularly if there is medical staff opposition. Preparing stakeholders for change before the change actually occurs is important.

Improving Antimicrobial Stewardship: A Performance Improvement Perspective

The appendix below, and on the pages following, describes how hospitals can use change management tools (developed by General Electric) to create change in an ASP to improve antimicrobial usage.

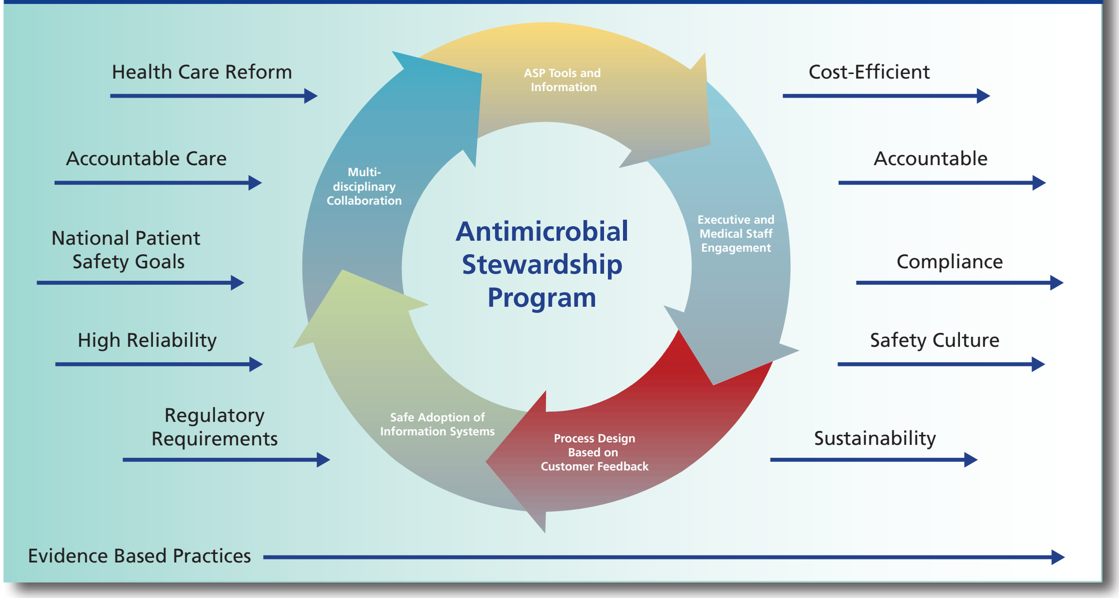
Conclusion

An ASP is charged with a difficult task: improving the usage of a class of medications that are ubiquitous within health care. To succeed in this critical endeavor, it is important for hospitals to tailor their stewardship efforts to the needs, personnel, and political structure of their institution. Employing a structure that incorporates strong physician leadership and an active Antimicrobial Stewardship Committee can enhance the program's effectiveness in accomplishing the difficult task of improving antimicrobial use. Interventions, strategies, and their targets should be selected to maximize the benefit within individual hospitals. Barriers will be encountered in most hospitals; therefore, ASPs need to be flexible, adaptable, and resilient to be successful.

Appendix
Change Acceleration Process Model

The conceptual model presented in Figure 4-2 below illustrates the various components present in all ASPs and depicts the numerous external and internal factors that can affect all hospitals and that can lead to change (see Module 2 for more information about this model). This module describes how hospitals can "execute" change in a variety of ways.

Figure 4-2. Antimicrobial Stewardship Program Critical Success Factors



This model conceptualizes factors that are critical to the success of ASPs and that can engender change.

The following four key factors are necessary to ensure success when implementing change within a hospital:

1. *Pressure for change:* Demonstrates the commitment of leadership and key stakeholders
2. *Clear, shared vision:* Allows individuals to share the need to improve patient care
3. *Capacity for change:* Requires resources, time, and money
4. *Action and performance:* Implemented through the Plan-Do-Study-Act or the Plan-Do-Check-Act cycle (see Module 2 for more information about these cycles)

The following sections describe how an ASP can use change models to improve antimicrobial stewardship.

Change Management and the Change Effectiveness Equation[12]

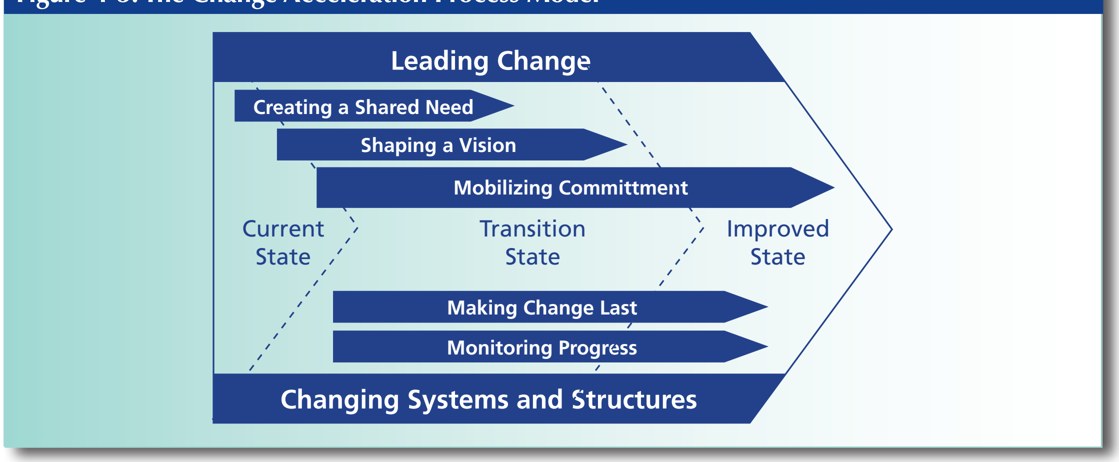
In the 1990s, the General Electric (GE) corporation investigated hundreds of projects and business initiatives to study change management best practices. One of their insights was that a high-quality technical strategy solution is insufficient to guarantee success. An astonishingly high percentage of failed projects had excellent technical plans, but the GE team found that failure was usually due to a lack of attention to the cultural factors that derail a project. GE defined failure as not achieving the anticipated benefits of a project.

The GE team also developed the Change Acceleration Process (CAP) model. As part of CAP, the GE team developed the Change Effectiveness Equation, $Q \times A = E$, as a simple way to describe change. Translated to English, this equation reads: The effectiveness (E) of any initiative is equal to the product of the quality (Q) of the technical strategy and the acceptance (A) of that strategy. In other words, paying attention to the people side of the equation is as important to the success of an initiative as the technical side. It is interesting to note that the team used a multiplicative relationship, meaning that if the acceptance factor is zero, the total effectiveness of the initiative will be zero, regardless of the quality of the technical strategy. Components of GE's CAP model can be applied to the creation of an ASP.

The Change Acceleration Process Model

The CAP model consists of the following seven key essential components that can be applied to an ASP[12] (see Figure 4-3 below):

Figure 4-3. The Change Acceleration Process Model



The Change Acceleration Process Model, adapted from General Electric, demonstrates a clear visual path for ASP teams to follow, as they journey to an improved state of antimicrobial stewardship. Source: Von Der Linn, B. Overview of GE's Change Acceleration Process (CAP). Change Management and Human Performance Technology. Jan. 25, 2009. http://bvonderlinn.wordpress.com/2009/01/25/overview-of-ges-change-acceleration-process-cap/ (accessed Nov. 1, 2011). Used with permission.

1. *Leading change:* Realistic, committed leadership throughout the duration of an initiative is essential for success. From a project management perspective, there is a significant risk of failure if hospital staff perceive a lack of commitment on the part of leadership.
2. *Creating a shared need:* The need for change must outweigh resistance to change. Compelling reasons to change should be present and should resonate not only with leadership but also with all stakeholders interested in antimicrobial stewardship (as identified throughout the modules). An ASP should create this shared need: Companies and healthcare organizations cannot fulfill their commitments or adapt well to change unless all leaders practice the discipline of execution at all levels.[13] Creating a shared need, breaking down tactics operationally, and gaining multidisciplinary support for change enables sustainability and successful execution.
3. *Shaping a vision:* Leadership should provide a clearly articulated vision that is widely understood and shared. This vision may be the single most critical factor ensuring a successful change initiative. Every journey should have a destination; otherwise, participants are merely wandering. The end product of that vision should be described in behavioral terms; ie, observable, measurable terms. The results should be expressed in terms of individual behavior, not financial terms.
4. *Mobilizing commitment:* After an ASP team gains leadership support, develops a compelling logic for change, and articulates a clear vision of the future, the necessary ingredients for success are present. The team can then develop support for the program to build momentum. If the team can leverage "early adopters" and pilot the project in areas with low resistance, it can learn from potential mistakes with partners who are forgiving.
5. *Making change last:* After completing successful antimicrobial stewardship improvement pilot projects, an ASP team should assess the factors that are helping and hindering a new process. The team should leverage early wins by transferring the knowledge and best practices gained in these pilots to the larger organization.
6. *Monitoring progress:* It is important for an ASP team to measure the progress of its change initiatives. The team should ask itself: *Is the change real? How will change be measured?* The team needs to set benchmarks, realize these, and celebrate success. Similarly, the team needs to establish accountability for a lack of progress in initiatives.
7. *Changing systems and structures:* Every hospital has underlying systems and structures, such as IT systems, training and education programs, systems to allocate resources, organizational design, and standard operating and workflow procedures. These systems are designed to support the current state of the hospital. After a change is implemented, a hospital should ensure that all systems align with the desired, future state of the hospital, so behavioral issues will not push the organization back to old systems and structures. To make change permanent, an ASP should systematically identify how systems and structures influence the behavior that it is trying to change and should modify these appropriately.

In summary, Dwight D. Eisenhower's quote clearly aligns with the core values and beliefs within the CAP model: "Leadership is getting others to do what you want them to do because they want to do it!" This approach can also be used to help ASPs succeed in their efforts to improve antimicrobial stewardship within hospitals.

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Notes

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Module 5
Measuring and Reporting Antimicrobial Stewardship Metrics

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Case Scenario

Pretty Good Care Hospital (PGCH) is a 350-bed community hospital that implemented an antimicrobial stewardship program (ASP) nine months ago. PGCH is paying for a 0.5 full-time equivalent (FTE) clinical pharmacist and a 0.25 FTE infectious disease physician to support the stewardship initiative. The director of pharmacy is charged with measuring the clinical and financial impact of the ASP and reporting this information to hospital administration and medical staff leadership. He has been asked specifically to explain why the recently published antibiogram failed to demonstrate a reduction in antimicrobial resistance, because this was supposedly one of the main reasons for implementing the ASP.

Introduction

The situation described above is fairly common in hospitals. As with most improvement initiatives within a hospital, participants in an ASP need to measure and report the impact of their initiatives. This chapter provides a brief discussion of common metrics related to antimicrobial stewardship and provides a framework for reporting these to hospital leadership. For all metrics discussed in this chapter, it is important to measure baseline data prior to the implementation of the various initiatives, so the impact of the ASP can be documented.

Measuring Antimicrobial Usage

Sources of Data

There are three main sources of data that hospitals can use to measure antimicrobial usage within their facilities: (1) the amount of drug purchased, (2) the amount of drug dispensed, and (3) the amount of drug charted as administered. The easiest of these for most hospitals to monitor is the amount of drug purchased. However, this is the least accurate reflection of the amount actually administered to patients, because purchases include drug that is wasted or expired. In addition, in many organizations, purchase data may include medications that are used outside of the inpatient setting (eg, ambulatory care clinics or home infusion centers). Purchase data also do not provide an accurate indication of the time frame of antimicrobial usage, because medications purchased in one time period might be used at another time. Using the amount of antimicrobials dispensed to gauge antimicrobial usage will provide more accurate data but will still overestimate usage, because these figures include medications that are lost or wasted.

With the advent of electronic medical records (EMRs), most hospitals can monitor the doses that are charted as administered to patients. This data source is considered to be the most appropriate one for tracking antimicrobial usage. Because dose administration ties antimicrobial usage to a specific patient at a specific point in time, it can also support a more detailed analysis of antimicrobial usage patterns.

Table 5-1 on page 3 summarizes the advantages and disadvantages of the three antimicrobial usage data sources.

Table 5-1. Sources of Antimicrobial Usage Data		
Sources	**Advantages**	**Disadvantages**
Doses Purchased	• Easy to obtain data	• Least accurate • May overestimate usage (may include wastage, expired, and usage in other areas) • Does not link usage to patient or time
Doses Dispensed	• Relatively easy to obtain data • More accurate than purchase data • Able to link usage to patient and day	• May overestimate usage (may include wastage and missing doses)
Doses Charted as Given	• Most accurate reflection of true antimicrobial usage • Links usage to patient and time, which supports a more detailed analysis of use	• Relies on accurate charting • Requires electronic medical records

Usage Metrics

The specific metric that best represents aggregate antimicrobial usage within a hospital is undetermined. Because normal dosing schedules vary among the different antimicrobials, the number of doses or total grams of antimicrobials used metrics provides little meaningful information. The most common method used to accurately reflect antimicrobial usage is the defined daily dose (DDD) promoted by the World Health Organization (WHO).[1] WHO defines DDD as "the assumed average maintenance dose per day for a drug used for its main indication in adults."[1] To estimate the total number of days of antimicrobial therapy, healthcare personnel should divide the total grams of each antimicrobial used for a given period of time by the WHO-defined DDD for the individual antimicrobials.

Table 5-2 below illustrates how the DDD methodology takes into account the different dosing regimens of various antimicrobials. For example, dividing the total grams of Drug A used (150 g) by the DDD (3 g) yields 50 DDDs of therapy. This method allows for a more accurate comparison with the usage of Drug B than comparing the number of doses or the grams of usage for each antimicrobial. Because DDD is a standardized unit of measure, it allows comparisons with antimicrobial usage in other hospitals and countries.

Table 5-2. Example of Defined Daily Dose (DDD) Methodology*		
Metric	**Drug A**	**Drug B**
Total doses	**150**	**50**
Total grams	**150**	**200**
DDD	**50 (150÷3)†**	**50 (200÷4)‡**

* This example is based on 10 patients receiving Drug A and Drug B for five days.
† Normal dose of 1 gram q8h; DDD = 3 g.
‡ Normal dose of 2 grams q12h; DDD = 4 g.

The DDD methodology is not without its drawbacks, however.[2,3] First, the dosage of many antimicrobials is reduced for patients with decreased renal function. In these cases, the DDD methodology underestimates the actual amount of antimicrobial exposure. This discrepancy is particularly important if the proportion of patients with renal insufficiency varies among the group of patients being compared. It is significant also when comparing the usage of an antimicrobial that requires renal dosing adjustment (eg, cefotaxime) with one that does not (eg, ceftriaxone). Second, the usage of certain antimicrobials that are dosed on patients' weights is misrepresented if their weights vary greatly from the "normal" population. Because the DDD methodology cannot be applied to pediatric patients, another drawback is that any aggregate antimicrobial use data that include these patients underestimates actual days of therapy. Finally, the DDD methodology provides an incorrect reflection of antimicrobial use if the typical dosing regimen of an antimicrobial differs from the WHO-defined DDD. For example, the DDD for oxacillin is 2 g; however, in the United States, this drug is commonly dosed 1 g or 2 g every four hours (6 g or 12 g daily dose).[4] Therefore, using the DDD methodology overestimates the usage of oxacillin by a factor of three or six.

An alternative measure of antimicrobial use has recently been proposed: using a direct measure of the days of therapy (DOTs).[2] One DOT represents "the administration of a single agent on a given day regardless of the number of doses administered or dosage strength."[2] Measuring the actual DOTs bypasses the errors introduced by renal and weight-based dosage adjustments, pediatric dosing, and "DDD versus typical dose" mismatch. However, because any number of antimicrobial doses given on a certain day is counted as a DOT, this measure may overestimate drug exposure in certain situations. For example, a patient is counted as receiving one DOT of nafcillin whether he or she is given a single dose or all six doses of an every-four-hour regimen.

Unlike DDDs, however, DOTs cannot be calculated from purchase data, and DOT methodology requires computerized pharmacy records at the individual-dose level. Table 5-3 below compares the advantages and disadvantages of the DDD and DOT methodologies.

Table 5-3. Comparison of Defined Daily Dose (DDD) and Days of Therapy (DOTs) Methodologies for Measuring Aggregate Antimicrobial Use

Measurement Method	Advantages	Disadvantages
Defined daily dose	• Allows standardized comparisons of aggregate antimicrobial use between hospitals in different locations and countries • Easy to derive from purchase data • Does not require computerized pharmacy records • Will change the estimate of drug use if the recommended daily dose is altered and the approved DDD does not change	• Will not accurately estimate DOTs when the administered daily dose is not equal to the DDD; therefore, it cannot be used to accurately compare relative use between different antimicrobial classes • Cannot be used in the pediatric population • Will underestimate use for drugs that require reduced dosage for renal impairment • Approved DDDs may change as new dosages are approved for existing drugs, which can create confusion when comparing use over time
Days of therapy	• Can be used to measure antimicrobial use in the pediatric population • Not influenced by changes in recommended DDDs • Not influenced by discrepancies between the DDD and the preferred daily dose • Allows benchmarking with the National Healthcare Safety Network	• Will overestimate use for drugs that are given in multiple doses per day • More difficult to measure without computerized pharmacy records

Adapted from Polk RE, et al. Measurement of adult antibacterial drug use in 130 US hospitals: Comparison of defined daily dose and days of therapy. *Clin Infect Dis.* 44:664–670, Mar. 1, 2007.

DOTs can be calculated for a specific antimicrobial from data files that contain every dose of the antimicrobial administered to each patient during the time period of interest. The following method can be used to calculate DOTs:

1. For each antimicrobial, obtain a data file that lists the date of administration and the account number of the patient to whom the antimicrobial was given.
2. Paste these data into a spreadsheet as shown in Table 5-4 below, so the date of administration is in column A and the patient account number is in column C.
3. Copy column A to column B, and change the format of the cells in column B to "number."
4. Multiply columns B and C, and display the product in column D. The result will create a unique number for each patient-day combination.
5. Remove the duplicates in column D. This action will remove entries related to when a patient received more than one dose of the antimicrobial on a given day.
6. Add the remaining entries in column D to provide the number of DOTs for the individual antimicrobial.

This method of calculating DOTs is valid only for antimicrobials that are given at least once a day. It provides inaccurate results if applied to antimicrobials that are given every 48 or 72 hours.

Table 5-4. Calculating Days of Therapy for an Individual Antimicrobial

A	B	C	D	
Date of Administration	Date Expressed as Number	Patient Account Number	Date Multiplied by Account Number	
12/14/2010	40526	8345	338189470	
12/15/2010	40527	8345	338197815	
12/16/2010	40528	8345	338206160	
12/16/2010	40528	8345	338206160	*Duplicate to be removed*
12/25/2010	40537	1234	50022658	
12/26/2010	40538	1234	50023892	
12/26/2010	40538	1234	50023892	*Duplicate to be removed*
12/27/2010	40539	1234	50025126	
12/27/2010	40539	1234	50025126	*Duplicate to be removed*
12/28/2010	40540	1234	50026360	
12/28/2010	40540	1234	50026360	*Duplicate to be removed*
12/29/2010	40541	1234	50027594	

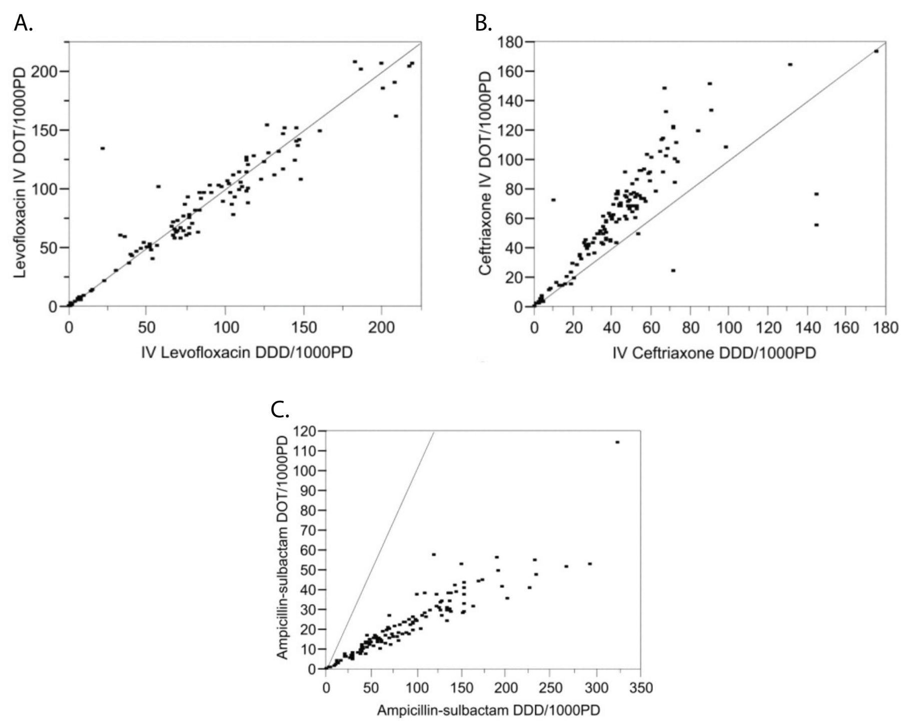
The date (expressed as a number) multiplied by the patient account number produces a date- and patient-specific number. Eliminating duplicates yields one entry per patient per day for the given antimicrobial, which is equivalent to a DOT for the given antimicrobial.

Polk et al[2] compared antibiotic use in 130 US hospitals as measured by the WHO-defined DDD and DOT methodologies. They examined the 50 most frequently used antibacterial drugs administered to adults discharged from the study hospitals from August 1, 2002, to July 31, 2003. The total mean number of DDDs per 1,000 patient-days and DOTs per 1,000 patient-days were not statistically different, although the correlation between them was poor ($r = 0.603$). There was good agreement between the two methodologies for antimicrobials, such as levofloxacin, in which the mean observed dose and the DDD were similar (see Figure 5-1A below).

However, the use for several antimicrobials as expressed by DDDs was significantly lower than the DOTs. This differential usage is illustrated in Figure 5-1B below, which depicts the use of ceftriaxone. This wide variation occurs because the WHO-defined DDD for ceftriaxone is 2 g, although the mean administered dose was actually 1.103 g.

For other antimicrobials, the usage determined by DDDs was significantly greater than that expressed by DOTs. This discrepancy is expressed dramatically in Figure 5-1C below, which depicts the use of ampicillin-sulbactam. The WHO-defined DDD for ampicillin-sulbactam is 2,000 mg. However, the average daily dose of ampicillin-sulbactam that was actually administered was 8,120 mg. Using the two methodologies resulted in a four-fold difference in the estimates of antimicrobial use of ampicillin-sulbactam.

Figure 5-1. Correlation of Defined Daily Dose (DDD) per 1,000 Patient-Days to Days of Therapy (DOTs) per 1,000 Patient-Days for Three Antibacterial Drugs at Individual Hospitals



These graphs depict the correlation of DDDs per 1,000 patient-days (PD) to DOTs per 1,000 PD for three antibacterial drugs at individual hospitals. Solid line = slope of 1.

A: Intravenous (IV) levofloxacin. When the administered daily dose is similar to the World Health Organization (WHO)-recommended DDD, estimates of aggregate antimicrobial use by DDDs per 1,000 PD and DOTs per 1,000 PD are not significantly different ($p = .614$; data are for 23 hospitals).

B: IV ceftriaxone. When the administered daily dose is lower than the WHO-recommended DDD, estimates of aggregate antimicrobial use by DDDs per 1,000 PD are significantly lower than estimates by DOTs per 1,000 PD ($p < .0001$; data are for 130 hospitals).

C: Ampicillin-sulbactam. When the administered daily dose is greater than the WHO-recommended DDD, estimates of aggregate antimicrobial use by DDDs per 1,000 PD are significantly greater than estimates by DOTs per 1,000 PD ($p < .0001$; data are for 128 hospitals).

Source: Polk RE, et al. Measurement of adult antibacterial drug use in 130 US hospitals: Comparison of defined daily dose and days of therapy. *Clin Infect Dis*. 44:664–670, Mar. 1, 2007. Used with permission.

It is important to understand the impact that changing dosing practices has on both methodologies as antimicrobial use is tracked over time. For example, more recent dosing recommendations for vancomycin have resulted in patients receiving higher daily doses.[5] This change in practice may be reflected by an increased number of DDDs, although the number of DOTs remains constant. Because it is not known which measure of antimicrobial exposure correlates better with the development of resistance, it may be advantageous to track DDDs and DOTs.

The use of DOTs to track the usage of antimicrobials has gained popularity/support from organizations. For example, this metric will be used by individual hospitals to measure and benchmark their antimicrobial usage in the new National Healthcare Safety Network (NHSN) program.[6] Therefore, hospitals should measure DOTs if they have the data to support it. Compiling usage data in three-month time units is appropriate for most internal monitoring purposes. Hospitals should be aware that benchmarking and sharing antimicrobial usage data in the NHSN program requires electronic patient-data capture and software interfaces. This program is currently being piloted in the United States and is expected to be widely available in late 2012.

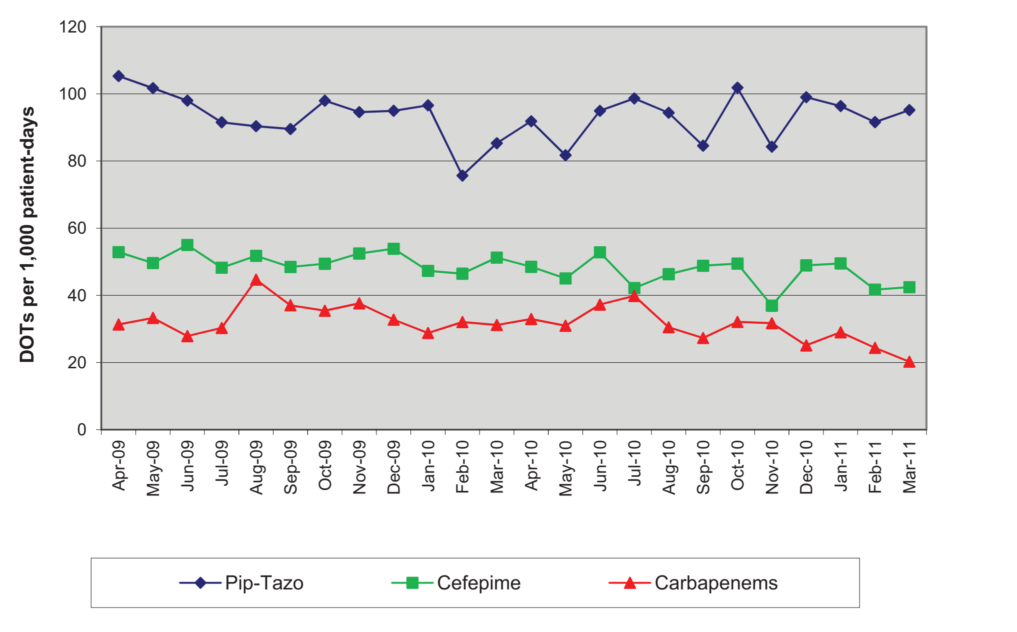
Because patient censuses can vary within and among hospitals, it is important to normalize the measure of antimicrobial use to reflect these variations. As demonstrated in the examples used previously, a commonly used normalization method is to express the measured amount of antimicrobial use (either DDDs or DOTs) per 1,000 patient-days. This metric allows usage to be tracked over time and compared with other institutions. However, it is essential for healthcare personnel to accurately define the patients who are included in the 1,000 patient-days. Including emergency department, day hospital, and/or observation patients in the calculation can have a significant impact on the results.

This metric assists not only in determining usage metrics for an entire hospital, it can also be very helpful when monitoring usage in specific subpopulations. The types of subpopulations that a hospital is able to analyze depend on the data elements captured in the hospital's medication administration database. Determining usage on a particular nursing unit, in a certain patient population (eg, oncology), or by a specific group of physicians can help identify major users of various antimicrobials and can help focus the various stewardship interventions. Tracking usage data in subpopulations over time can also help identify the causes of changes in antimicrobial usage patterns for the hospital (eg, determining the reason for a sudden increase in the use of a particular antimicrobial).

It is often helpful to classify the use of certain antimicrobials according to the route of administration. The oral (PO) form of most antimicrobials costs less than their intravenous (IV) counterparts. PO therapy can also allow IV catheters to be discontinued, thereby reducing the risk of catheter-associated bloodstream infections and facilitating earlier hospital discharge. Therefore, in situations in which the PO and IV routes of administering antimicrobials provide equal clinical efficacy, it is advisable to give PO therapy. Measuring the percentage of PO therapy for a particular antimicrobial can help identify potential cost savings opportunities, track the effectiveness of a hospital's IV to PO initiatives, and document cost savings associated with those initiatives.

As Burke first stated in 1998, antimicrobial use often resembles a balloon.[7] As a balloon is squeezed in one area, it expands in another. Similarly, as use of one antimicrobial decreases, use of another antimicrobial may increase. Healthcare personnel might be alarmed by an increase in the use of a certain antimicrobial and be encouraged by reduction in the use of another. However, when viewed together, these changes may simply represent a shift between two similar antimicrobials and may not result in a net change in total antimicrobial exposure. This type of shift in therapy can be particularly common if a drug shortage hinders the availability of a particular antimicrobial. For this reason, analyzing key groups of antimicrobials can provide a more accurate view of antimicrobial use within a hospital than merely monitoring individual agents. Figure 5-2 on page 8 presents a sample of usage data for three different antimicrobials commonly used to empirically cover gram-negative pathogens.

Figure 5-2. Use of Agents Prescribed for Empiric Coverage of Gram-Negative Pathogens

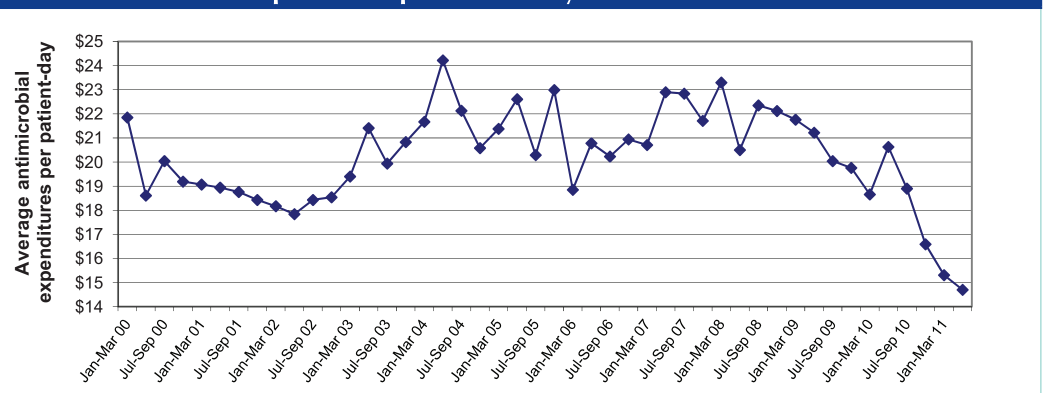


Usage of three beta-lactam antimicrobials commonly used to empirically cover gram-negative organisms is plotted over time. This type of analysis shows whether changes in the usage of a single antimicrobial are offset by a reciprocal change in another. (Pip-Tazo: piperacillin-tazobactam)

Financial Metrics

Although the primary goals of antimicrobial stewardship are improved clinical outcomes and reduced antimicrobial resistance, hospital administrators are also interested in the financial impact of such programs, because they require monetary support to be successful. Therefore, it is essential for hospitals to measure the economic impact of ASPs. Two common metrics used to monitor anti-infective expenditures are antimicrobial costs per patient-day and antimicrobial costs per admission. The same caveats mentioned for usage metrics apply to these financial metrics: The specific anti-infectives included in cost figures and the patient populations included in the denominator have to be clearly defined. Figure 5-3 below illustrates how antimicrobial costs per patient-day can be tracked over time. As with usage data, compiling data in three-month time units is appropriate for most situations.

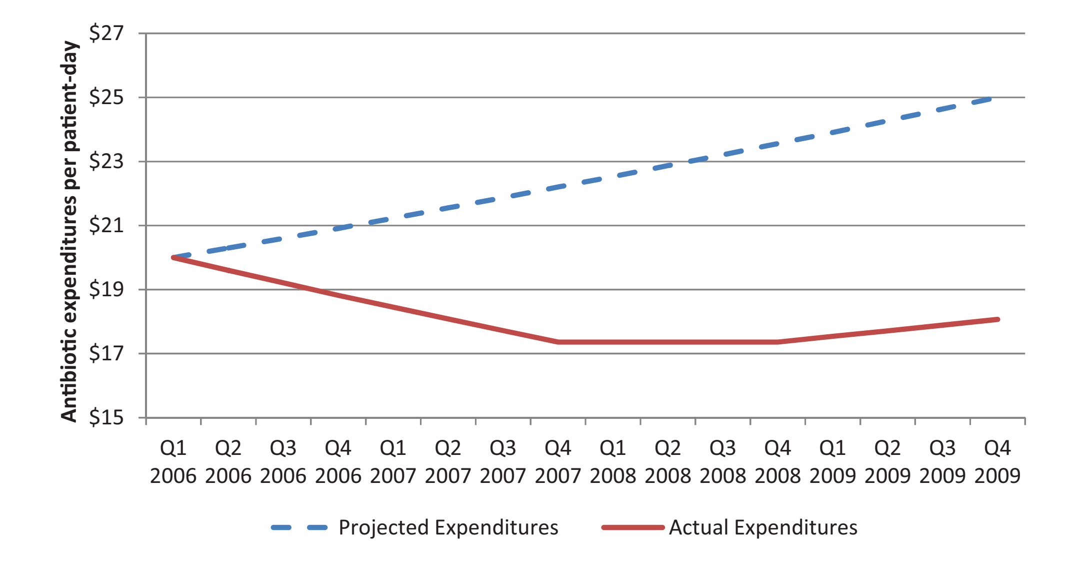
Figure 5-3. Antimicrobial Expenditures per Patient-Day



Longitudinal antimicrobial costs are expressed by graphing the average antimicrobial expenditures per patient-day for each quarter over time.

It is not unusual for the reduction in anti-infective expenditures to level off after an ASP has been in operation for a few years. However, this does not mean the program no longer has a favorable influence on antimicrobial expenditures. Figure 5-4 below illustrates that it can help to compare actual antimicrobial expenditures with those that are projected based on inflation or usage trends. In this example, although actual expenditures did not continue to decline after the first two years of the ASP, considerable savings compared with projected costs were still realized. It is also important to note that if an effective ASP is discontinued, anti-infective expenditures may start increasing toward preprogram levels.[8,9]

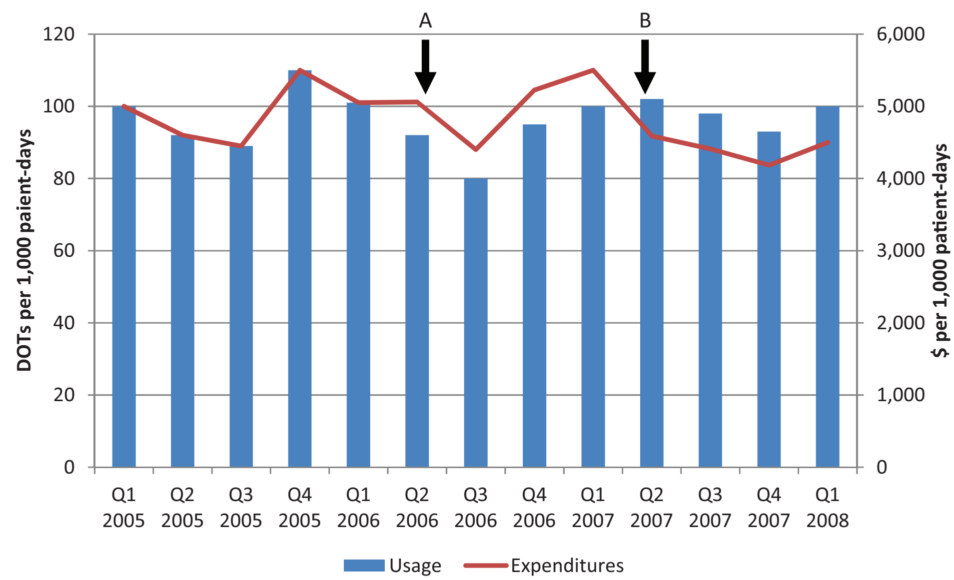
Figure 5-4. Comparing Actual and Projected Expenditures



The solid line illustrates that a hospital had an 8% annual decrease in actual expenditures during the first two years of an ASP, followed by a slight increase in expenditures. The dashed line presents projected expenditures based on 6% annual inflation. Although actual expenditures did not continue to decline after the first two years of the ASP, the hospital still had considerable savings compared with projected costs.

It may be helpful to correlate usage and financial metrics for individual antimicrobials or a class of antimicrobials. For example, Figure 5-5 on page 10 shows the DOTs per 1,000 patient-days and the expenditures per patient-days for Antimicrobial X. Variations in usage and expenditures are fairly proportional, with two exceptions. At point A, expenditures increased out of proportion to usage, primarily due to new national guidelines that recommend higher doses of Antimicrobial X for numerous infections. At point B, expenditures appear to decline in relationship to usage due to a decrease in the purchase price of Antimicrobial X.

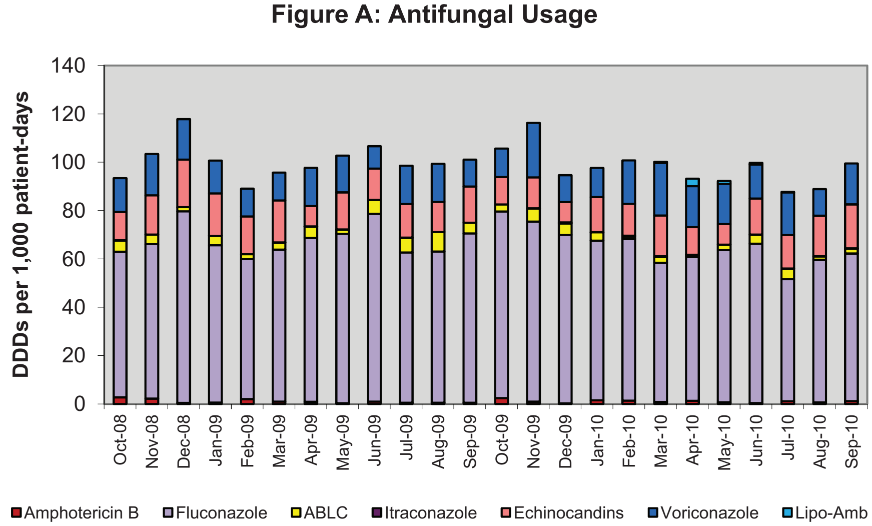
Figure 5-5. Displaying Usage and Cost Data for Antimicrobial X

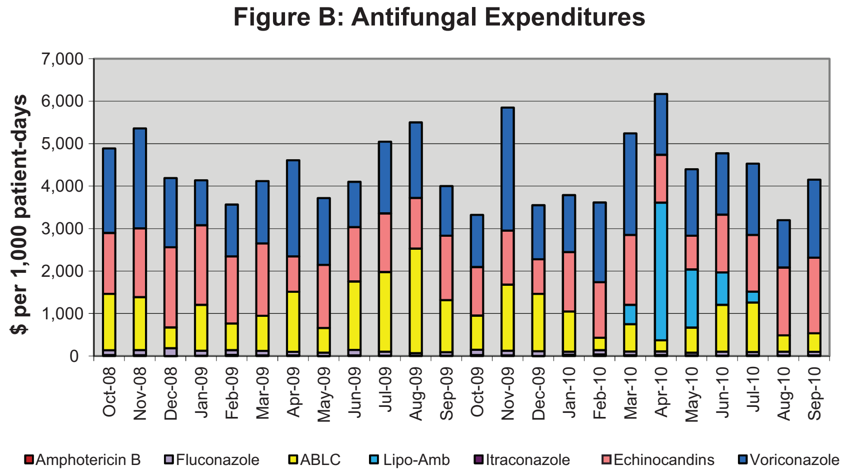


This graph displays the usage and cost data for Antimicrobial X. At point A, expenditures are increased in proportion to usage secondary to prescribers using higher doses of Antimicrobial X. At point B, expenditures are decreased in proportion to usage secondary to a reduction in the purchase price of Antimicrobial X.

Comparing usage and expenditures graphs also can highlight the main agents that contribute to antimicrobial expenses. For example, comparing Figure 5-6A and Figure 5-6B on page 11 demonstrates that although fluconazole is the most frequently used antifungal agent at a particular hospital, it contributes only slightly to total antifungal expenditures.

Figure 5-6. Antifungal Usage and Expenditures





This graph plots the usage of antifungal agents (expressed as DDDs per 1,000 patient-days; Figure A) and expenditures for antifungal agents (expressed as dollars per 1,000 patient-days; Figure B) for individual drugs and the medication class over time. ABLC: amphotericin B lipid complex; Lipo-Amb: liposomal amphotericin B).

Process Measures

Process measures can help document the impact and effectiveness of an ASP and can reflect the state of stewardship within a hospital. The following ASP process measures have been proposed to governmental and regulatory bodies for use in measurement programs, including the Centers for Medicare & Medicaid Services:

- An indication is provided with each antimicrobial start.
- A process is in place to review a selected course of antimicrobial therapy within 72 hours of initiating therapy.
- A process is in place to review selected episodes in which blood cultures grow organisms to ensure that patients are receiving optimal antimicrobial therapy.
- Antimicrobials are not prescribed to treat patients with asymptomatic bacteriuria.
- Cultures are obtained before new antimicrobials are administered for sepsis or systemic inflammatory response syndrome.

The goal of using these measures is to inform and motivate quality improvement efforts for the use of all antimicrobial agents in acute care hospitals.

It is important for hospitals to measure the impact of ASPs on process measures. It is not enough just to develop guidelines for treating various infections or using certain antimicrobials. A robust ASP also will measure adherence to these guidelines and will respond to areas that need improvement. These activities usually are accomplished by performing a medication use evaluation (MUE),[10] an activity familiar to most pharmacy departments. Sidebar 5-1 below explains the process for conducting an MUE.

Sidebar 5-1. Medication Use Evaluation Process

1. ***Determine the data collection method:*** **MUEs can be conducted retrospectively or in "real time." Real-time data collection allows reviewers to access all data sources without requiring the Medical Records Department to "pull charts." It also allows clarification of ambiguous entries in the medical record and even permits reviewers to record missing data points themselves, if necessary. However, real-time data collection requires data to be recorded on a daily basis. Retrospective data collection is less time sensitive, because it allows reviewers to collect data at any time. In addition, reviewers do not need to wait to accrue a certain number of patients who meet study criteria; they can just go back in time to obtain a large enough patient sample.**
2. ***Determine the patient-identification method:*** **It is usually fairly easy to identify patients who are receiving a particular antimicrobial. Most hospital data systems can produce a report of all new orders for a specific antimicrobial (to support real-time data collection) or a list of patients who received a specific antimicrobial during a certain time period (to support retrospective data collection). For hospitals without this level of informatics support, pharmacists could keep lists of all new orders for the antimicrobial of interest, although this introduces a memory step into the process. However, it can be more challenging to identify patients who have a particular infection. Because diagnostic codes are not assigned until patient discharge, obtaining a list of patients based on diagnosis-related groups can support retrospective, but not real-time, data collection.**
3. ***Select the sample size:*** **The goal of most MUEs is to obtain a general idea of antimicrobial use in a particular area or to identify an area needing improvement. Therefore, the sample size for an MUE does not necessarily have to be as large as sample sizes in articles for peer-reviewed publications. The sample size of most MUEs will be influenced by the time required to collect data on each patient and the available human resources to collect this data.**
4. ***Select data to collect and outcomes to assess:*** **Usually, demographic data are collected so as to allow evaluation of whether the outcome of interest differs among various patient groups. For example, data could indicate that guidelines are not being followed by a particular group of physicians or for a certain type of patient. When choosing the data elements to collect, it is advantageous to select elements that are readily available within an EMR and that do not require extensive reading of progress notes or paper flow sheets.**
5. ***Perform a chart review:*** **This step is usually the rate-limiting step in evaluating process measures. Unfortunately, most stewardship teams do not have the time to gather and analyze all the data they would like to. Therefore, the elements to be measured need to be chosen carefully.**
6. ***Analyze the data:*** **Data should be analyzed to reflect the outcomes of interest and to identify areas for improvement.**
7. ***Respond to results:*** **In most hospitals, the results of the MUE should be reported to the stewardship team, which will determine how to respond to the data. Eventually, the MUE and subsequent response should be reported to the Pharmacy and Therapeutics Committee.**

When analyzing the impact of ASPs, it is important to realize that implementing guidelines sometimes may significantly influence antimicrobial prescribing, even though an MUE might show that the level of strict adherence to the guidelines was less than what was desired. For example, Hanzelka et al studied the impact of institution-specific sepsis guidelines on adequacy of initial antimicrobial therapy.[11] Although the rate of strict adherence to the new sepsis guidelines was relatively low, implementation of these guidelines was associated with an overall change in the selection of antimicrobials for sepsis and a significant improvement in the adequacy of empiric therapy, from 68% to 85%.

Stewardship team members should document their activities and should report these to hospital administration and medical staff leadership. Interventions at the patient level (eg, de-escalating a patient's antimicrobial therapy) can be captured in many ways. Many proprietary clinical surveillance systems have a mechanism to record interventions made by clinicians, or interventions can be recorded using a documentation tool developed by the hospital. However, many important stewardship activities (eg, guideline implementation and educational initiatives) are directed at the level of the hospital rather than individual patients. Because the documentation tools mentioned previously would not capture these activities, they should be recorded separately and summarized in an annual report (see the "Annual Report" section on page 15).

Outcome Measures

Other than using the financial metrics mentioned previously, it can be difficult for hospitals to use true outcome measures that capture the impact of an ASP. Outcome measures tend to fall into two categories: (1) clinical outcomes related to interventions within a targeted area of practice and (2) measures that reflect a reduction in the "collateral damage" associated with the use of antimicrobials.

Clinical outcome measures can include metrics, such as length of hospital stay, cure of an infection, mortality, adequacy of initial therapy, and antimicrobial-free days. These types of measures usually are assessed after the implementation of initiatives related to a specific disease or area of practice. For example, Wrenn et al reported that the implementation of institution-specific hospital-acquired pneumonia (HAP) guidelines was associated with an increase in adequacy of initial therapy for HAP at their hospital from 45% to 69%.[12] The major barrier to assessing clinical outcome measures is the tremendous amount of time required to collect the data. As mentioned in the discussion of MUEs, most hospitals do not have the human resources required to collect the data for all the clinical outcomes they would like to measure.

Ideally, a reduction in the inappropriate use of antimicrobials will result in a decrease in the collateral damage associated with antimicrobial usage—specifically *C difficile* infections, adverse effects related to antimicrobials, and antimicrobial resistance. Therefore, institutions should consider collecting data related to these outcomes.

C difficile infections are associated with antimicrobial use.[13,14] It is fairly easy to determine the rate of *C difficile* infections from the number of positive toxin assay tests reported from the laboratory. However, there are several caveats. First, hospitals must be careful to eliminate duplicate positive tests. As with all diagnostic tests, the number of positive results reported will be influenced by the number of tests that are ordered, as well as the sensitivity and specificity of the assay.

Although it is intuitive that using fewer antimicrobials will result in fewer antimicrobial-related adverse events, it is very difficult for a hospital to document this relationship in a suitable manner. On the surface, it appears to be relatively easy to calculate the number of reported adverse drug events (ADEs) that were associated with antimicrobials and to track this value over time. However, most ADEs within a hospital are discovered through self-reporting, and reported episodes are believed to greatly underestimate the number of true events. Therefore, any change in the number of antimicrobial-associated ADEs is likely to be related to a change in reporting practices rather than reflecting a true change in the number of events. In fact, most hospitals are trying to increase their number of reported ADEs.

In addition, it is difficult to know how to normalize these data. Should the number of ADEs be divided by the total number of patients admitted, the number of patient-days, or the number of patients treated for infections? Finally, an increase in antimicrobial-associated ADEs may actually reflect an improvement in antimicrobial use rather than a deterioration. For example, due to the increasing resistance of several gram-negative organisms, some guidelines are recommending empiric combination therapy that includes aminoglycosides.[15] The increased use of aminoglycosides may be associated with increased nephrotoxicity; however, it may also result in increased adequacy of initial therapy, which has been associated with improved mortality. Because of these factors and other confounding factors, it is not recommended that ASPs expend the effort to track antimicrobial-associated ADEs at this time.

Measuring antimicrobial resistance is very important, because combating increasing resistance is one of the main reasons for antimicrobial stewardship. An antibiogram is the most commonly used method to report the susceptibility of various bacteria to specific antimicrobials. Guidelines for developing an antibiogram have been published by the Clinical and Laboratory Standards Institute.[16] Hospitals should be aware of certain caveats when reviewing antibiograms. First, the source of the isolates included in the antibiogram needs to be understood. For example, antibiograms can summarize susceptibility data from inpatients or outpatients only, inpatients and outpatients combined, or patients from a particular unit or area of a hospital (eg, critical care or oncology). It is also important to look at the number of isolates for each pathogen included in the antibiogram. Pathogens with a higher number of isolates are encountered more frequently than those with low numbers, and if there is a low number of isolates for a particular pathogen, a change in the susceptibility of one or two isolates could dramatically affect the percentage susceptible number reported in the antibiogram.

Second, most antibiograms are compiled on an annual basis. Although this time frame may be adequate to let practitioners know about the general susceptibilities of bacteria in their hospital, it is probably not sensitive enough to quickly detect an outbreak of infections due to resistant clones of pathogens. For this reason, some hospitals compile antibiogram data on a "rolling" six-month basis. For example, data from the previous January through June are reported in July; data from the previous February through July are reported in August, and so on. This approach is feasible only for large hospitals that have a significant number of isolates to allow six months of data to be meaningful.

Another issue is that traditional antibiograms list susceptibilities to individual antimicrobials only and do not provide much assistance in determining the impact of combining different antimicrobials. For example, an antibiogram might show that a particular bacterium has 70% susceptibility to Drug A and 80% susceptibility to Drug B, but it will not show the bacterium's susceptibility to combining Drug A and Drug B. Determining the susceptibilities of antimicrobial combinations requires a more in-depth analysis. Although this can be a time-consuming process, it can provide information that is very helpful when designing empiric antimicrobial regimens for certain diseases. For example, when analyzing the bacteria that caused HAP at their hospital, Beardsley et al[17] demonstrated that very little additional gram-negative activity was gained by adding a fluoroquinolone to a beta-lactam antimicrobial, such as piperacillin-tazobactam or cefepime, even though this combination was recommended by national HAP guidelines.[13] It was only the addition of amikacin that greatly increased the likelihood of covering gram-negative HAP pathogens. These data were incorporated into the hospital's HAP guidelines.

Although some studies have demonstrated the favorable impact of ASPs on antimicrobial resistance,[18–20] this outcome is often very difficult to document. The development and spread of resistance is a very complicated process that is influenced by many factors (eg, infection prevention and control practices, antimicrobial use within and outside the institution, colonization status of patients admitted to the hospital, and patient immune status). In addition, it may take years for the impact of a particular intervention on antimicrobial resistance to become apparent. During this protracted period of time, it is common for a number of other changes to be implemented that coincide with the antimicrobial stewardship interventions, which make assessments of causality difficult and biased.

Annual Report

As mentioned previously, it is important to keep healthcare personnel within a hospital informed of the efforts of an ASP. One method to accomplish this is an annual report. ASP team members can use the following template to develop an antimicrobial stewardship annual report:

1. Introduction: Provide a brief overview of the purpose and goals of the ASP.
2. Antimicrobial usage data (eg, DOTs or DDDs normalized for 1,000 patient-days): Team members may want to limit this data only to high-profile antimicrobials or antimicrobials that have been targeted by various stewardship initiatives.
3. Financial metrics (eg, antimicrobial expenditures per patient-day and per admission): Include current data and compare it to a preprogram baseline and the previous year. Provide graphs of metrics over time similar to Figures 5-3 or 5-4.
4. Summary of patient-level interventions: Team members may list the number of each major type of intervention (eg, number of therapy de-escalations and number of antimicrobial regimen changes to cover an "uncovered" pathogen) and the total number of interventions.
5. Summary of activities: Provide a brief summary of completed, ongoing, and planned initiatives.
6. Outcomes of initiatives: Provide examples of outcomes, such as improved clinical outcomes and decreased use of a particular antimicrobial.

Improving Antimicrobial Stewardship: A Performance Improvement Perspective

The previous sections described the recommended metrics that hospitals should use in their ASPs. The following sections now turn to the measurement phase of the performance improvement process. A critical component of a successful ASP is the hospital's ability to build an infrastructure that will support safe, effective, and efficient antimicrobial stewardship across all systems and processes. This means that the hospital has determined that antimicrobial stewardship will align with strategic priorities, and, therefore, the organization will consistently maintain resources that systematically support performance improvement. To achieve this goal, a measurement system consisting of structure, process, and outcome metrics should be in place.

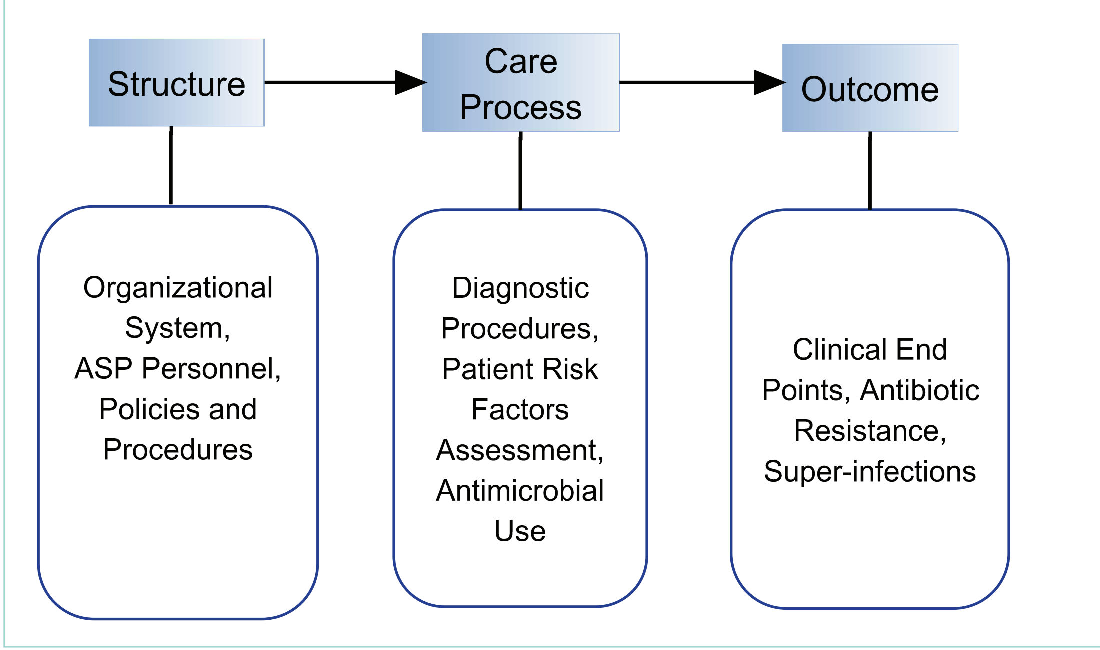
The interdisciplinary antimicrobial stewardship team should have a set of structure, process, and outcome metrics that will be monitored regularly through the hospital executive leadership quality improvement process, the Pharmacy Department, and the Pharmacy and Therapeutics Committee. Specific hospital policies and procedures that align with evidence-based practices should be in place and should be accessible to all disciplines. Tools to assist clinicians in their assessment, management, and documentation of clinical processes, and education of stakeholders can facilitate these activities.

A major challenge in healthcare today is the implementation of systems that deliver clear and reliable information—or provide a systematic flow of information—particularly handoffs that may be verbal or electronic. The current state of antimicrobial use and infection prevention, and control methods may be assessed using an ASP survey (such as the one available at http://www.abxstewardship.com/), which may include assessing the degree to which all disciplines have access to medical records, generate information that should be communicated, and carry out individualized care plans across the various transitions of care within and outside a hospital. As described in Module 3, an alternative approach might consist of using a current-state process map to identify potential process failures and opportunities for performance improvement. After process failures are identified within a given process map, available or new metrics can be determined.

Donabedian Structure

Donabedian's structure-process-outcome model (see Figure 5-7 below) has long served as a unifying framework for examining health services and assessing patient outcomes.

Figure 5-7. The Donabedian Model of Patient Safety



This diagram illustrates the Donabedian model of patient safety, adapted for antimicrobial stewardship. Adapted from Donabedian A. *The Definition of Quality and Approaches to Its Assessment. Explorations in Quality Assessment and Monitoring.* Ann Arbor, MI: Health Administration Press, 1980.

Donabedian's model proposes that each of the three components—structure, process, and outcome—directly influences subsequent components (indicated by the arrows in the model), meaning that structure affects process, which ultimately influences the overall outcomes. Although the process and outcome measures discussed previously are traditionally used in performance improvement projects, it is also important to consider whether a system's infrastructure is in place to ensure efficient and effective processes, which promote sustainable outcomes.

Structure measures analyze the presence or absence of system structures that enable clinicians to manage a given process effectively. In the case of antimicrobial stewardship, structure measures might include the presence of key personnel, adequate training, updated policies and procedures, and the presence of an antimicrobial stewardship interdisciplinary team. In the absence of a well-built system structure, clinicians may have difficulty avoiding human error because of system variation across units, departments, and services, and are often confused as to why given process and outcome measures are not improving. Hospitals should analyze all three measure types to ensure that a standardized process for antimicrobial stewardship exists in their facilities.

Table 5-5 on page 17 presents sample structure, process, and outcome metrics for monitoring antimicrobial stewardship.

Table 5-5. Sample Structure, Process, and Outcome Metrics for Monitoring Antimicrobial Stewardship		
Structure Metrics	**Process Metrics**	**Outcome Metrics**
Interdisciplinary ASP team in place	**Use of treatment guidelines**	**Clinical end points (cure, mortality, length of stay)**
MUE in place	**Review of sterile body fluid cultures**	**Antimicrobial expenditures per patient-day**
Regularly updated antibiogram	**Therapy assessed/revised in response to culture data**	***C difficile* infection rate**
Strategic alignment with leadership support	**Compliance with stewardship policies**	**Antimicrobial resistance**
Data management process in place	**Guideline adherence**	**Use of targeted antimicrobials**

Data Collection Process

Although establishing metrics is very important, it is just as critical to understand the method that will be used to collect data and whether the information collected will be as precise and accurate as necessary. A measurement system is the complete process used to collect data and is comprised of the people, methods, equipment, and technology employed in the data collection process.

The ability to measure processes and resources necessary for an ASP accurately and precisely is critical for making decisions that affect and/or influence an ASP. The measurement system must be implemented and improved before baseline data are collected.

To ensure the accuracy and precision of a measurement system needed to collect data on the current-state process, the ASP team should consider answering the following questions:

- Do we have the data we need?
- What type of data is involved?
- How will the data be collected?
- Are the data accurate and precise enough for us to be able to determine if a change to a process actually improved the process?
- How will the data be analyzed?
- How will the data analysis be used to help the ASP team improve patient care?

Carefully considering what data need to be collected, by what process, by whom, the time frame for collecting the data, and double-checking that a precise and accurate data collection method is in place will lead to a successful measurement system, that is considered reliable to measure the effects of clinical changes and to optimize patient outcomes.

Conclusion

ASPs use a variety of metrics to help hospitals evaluate the effectiveness of antimicrobial stewardship initiatives and to identify areas requiring additional intervention. ASPs are encouraged to use data to help engage prescribers to improve antimicrobial use and to highlight the benefits these programs provide to their hospitals.

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Notes

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