Navigating the New Antimicrobial Stewardship Regulations

Sondra Davis¹, Collin Verheyden², Mandelin Cooper³,
and Devak Desai⁴

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Abstract

Purpose: Many health care facilities are navigating their way through the new antimicrobial stewardship standards and guidelines. The purpose of this article is to provide information for health care facilities to improve patient care. **Summary:** New regulations and guidelines surrounding antimicrobial stewardship have prompted facilities to review their process related to antimicrobial stewardship. In setting up a program, there are many factors to consider including involving key personnel, obtaining leadership support, identifying an infectious disease physician to chair or cochair the committee, and meeting agenda, metrics, and educational needs. **Conclusion:** Antimicrobial stewardship plays a vital role in both our hospital and community setting. Pharmacists are uniquely positioned to improve optimal patient care through rounding, review of patients' chart, and contribute to the improvement of antimicrobial stewardship by working with a multidisciplinary team. These efforts may improve the utilization of antimicrobial agents.

Keywords

antimicrobial stewardship, antimicrobial development, antimicrobial management, antimicrobial stewardship program, anti-infective medications, antibiotics, implementation, antimicrobial regulations

With the recent publication of The Joint Commission standards and other guidelines related to antimicrobial stewardship (AMS), health care entities now have a renewed focus on their own programs, regulations, and policies. Facilities with existing programs are reevaluating their individual goals and policies with an eye on the new regulations and future direction of stewardship as well as cost savings and clinical outcomes. Many smaller facilities may not have a stewardship program in place and will need guidance and resources to start their own programs.

What Is the Importance of AMS?

In Alexander Fleming's acceptance of the Nobel Prize in 1945, he cautioned that exposing patients to subtherapeutic doses of penicillin would be an ideal situation to breed resistance.¹ He warned of the development of resistant strains and poor patient outcomes as a result.¹ This was likely the first reference to what we refer to as AMS.

Today, much progress has been made in regard to stewardship. Guidelines provide a framework for discussion and action with the goal to decrease unintended consequences of antimicrobials and optimize clinical outcomes.^{2,3} AMS programs have been shown to reduce emerging bacterial resistance to antimicrobials and improve patient care by de-escalating to the most appropriate antimicrobial agent(s).⁴⁻⁶ One of many examples of decreasing unintended consequences is after

implementation of an AMS program in a rural hospital, the nosocomial *Clostridium difficile* rate decreased to an average of 1.6 cases per 10 000 patient-days from an average of 5.5 cases per 10 000 patient-days.⁷

Pharmacists are on the front lines and play an important role in stewardship by collaborating with the providers to provide the patient with optimal therapy. Pharmacists may intervene during rounds to de-escalate therapy or recommend discontinuing the antibiotic based upon course completion. Participation in rounds is another way pharmacists may be an integral part of the patient care. No matter how big or small rounds are, opportunity for pharmacists exists not only with AMS but also with building relationships with providers. By improving the relationship between pharmacy and providers, a comradery will form. Through the relationship, providers may then lean on pharmacy and be more open to discussions related to antimicrobial therapy.

¹Medical City Arlington, TX, USA

²Parallon Supply Chain Services, Coppell, TX, USA

³HCA Clinical Services Group Nashville, TN, USA

⁴ID Partners, Mansfield, TX, USA

Corresponding Author:

Sondra Davis, Medical City Arlington, 3301 Matlock Road, Arlington, TX 76015, USA.

Email: sondra.davis@hcahealthcare.com

Figure 1. Timeline for antimicrobial stewardship and regulations. Note. CDC = Centers for Disease Control and Prevention; PCAST = President's Council of Advisors on Science and Technology.

What Are the New Regulations Surrounding AMS?

The benefits and urgency of these AMS programs are being recognized nationally (see Figure 1). In September 2014, the President's Council of Advisors on Science and Technology released a report titled "Combating Antibiotic Resistance." That report resulted in an Executive Order from President Obama directing federal departments and agencies to provide a 5-year plan to "prevent and contain outbreaks of antibiotic-resistant infections; maintain the efficacy of current and new antibiotics; and develop and deploy next-generation diagnostics, antibiotics, vaccines, and other therapeutics."⁸ To that end, President Obama established a task force and a presidential advisory council to develop action plans both nationally and in cooperation with international groups such as the World Health Organization. This directive created the National Action Plan for Combating Antibiotic-Resistant Bacteria.⁹ The plan includes 5 separate goals with targets at 1, 3, and 5 years (see Figure 2).⁹

Achieving the first goal, slowing and preventing the development of resistant bacteria, will require prudent utilization of antibiotics in both the agricultural and health care settings.⁹ Support will be needed from multiple sectors including pharmaceutical companies, health care personnel, patients, veterinarians, and the agricultural industry.⁹ In health care settings, there is a renewed emphasis on AMS programs. For organizations that already have an established AMS program, gap analysis and reviews for improvement opportunities are being conducted. These reviews and initiating of programs in hospitals may help achieve the first goal.

The other goals contained within the National Action Plan will have similar structures and metrics to be met over the coming years.⁹ One additional facet concerning hospital practice is the benefit of rapid diagnostics. Studies have shown that utilization of diagnostic technologies such as matrix-assisted laser desorption/ionization time-of-flight and polymerase chain reaction can shorten length of stay, reduce rates of recurrent infection, decrease antibiotic costs, and even reduce mortality.¹⁰⁻¹³

In addition to the National Action Plan for Combating Antibiotic-Resistant Bacteria, The Joint Commission has finalized AMS standards and the Centers for Disease Control and Prevention has released its Core Elements of Hospital Antibiotic Stewardship Programs. For an overview of the information included in each, see Figure 3.^{14,15}

Getting Started—Who Do We Need to Involve?

When implementing an AMS committee, a multidisciplinary approach is recommended.^{2,3,6} Core team members include an infectious disease physician, infectious disease trained pharmacist, clinical microbiologist, informatics specialist, infection control, an epidemiologist, and a representative from administration.^{2,3,6,16} Including physicians from different services (eg, surgery, medicine, hospitalist) will increase the recognition of the AMS program.¹⁷ The personnel may vary among facilities depending upon the resources available.¹⁶ However, physician and administration support is essential during the implementation of an AMS program.^{2,3,6}

A program is recommended to be led by an infectious disease physician or codirected with a clinical pharmacist who has been trained in infectious disease.^{2,3} In practice, there are many hospitals that may have the pharmacy department leading the AMS program. With the new regulations, facilities may need to review the accountability of their program. The Joint Commission recommends appointing one leader as the individual responsible for the outcomes of the program.¹⁵ Successful programs have shown that physician leaders are effective.¹⁵ With the program being led by an infectious disease trained personnel, the practicing providers within an institution may be more accepting of the program.¹⁷ For the drug expertise, appointing one pharmacist as a leader to improve antibiotic use of a hospital's AMS program would meet the core element of The Joint Commission Standard regarding AMS.¹⁵

How Can We Obtain Involvement From an Infectious Disease Physician and Obtain Leadership Support?

Facilities that have difficulty obtaining physician support may find a stipend can encourage involvement and reward the physician for participation and expertise. The stipend could be utilized to have the provider review order sets, complicated patients, and metrics. Even if your facility is only able to compensate a few hours a month, opportunities for improvement may be identified and reviewed one by one.

Leadership support is critical to the program.¹⁴ There are multiple ways your local leadership can show support of your ASP program. Someone from administration offers legitimacy to the program and can provide needed resources, for example, financial to ensure the advancement of stewardship practices.¹⁴ In addition, physicians not responding to committee requests may be more willing to follow approved policies

Figure 2. National action plan for combating antibiotic-resistant bacteria goals.

and procedures when the medical staff and administration are leading the conversation. Clinical reports of your program may be shared with leadership on either a monthly or quarterly basis. The report may highlight the program and the impact on improving patient care, clinical interventions, and antimicrobial drug spend. If your antimicrobial spend is trending down with the AMS program, a graph or trend line would highlight the change in prescribing.

What Topics Should Be Discussed at an AMS Committee Meeting?

When developing an AMS program, some questions may arise as to “What topics should we be discussing at our committee meetings?” and “How do we overcome all the obstacles?” The resources and time commitment personnel have to devote to the AMS program may play a role in what topics may be addressed and to what depth. Topics which may be discussed include but are not limited to developing algorithms, order sets, and antibiograms; providing education; reviewing antimicrobial data and outcome measures; evaluating microbiology panels; and completing antimicrobial audits.

Developing order sets to assist providers in empiric therapy based upon current guidelines is an excellent starting place for AMS programs.² In developing order sets, the committee could review current guidelines and then cross-reference empiric antibiotic therapy with their facilities’ current antibiogram. Order sets may be the first place where an AMS program may help guide antibiotic selection. Annual review of order sets is recommended to ensure recommendations are current and continue to be in line with local susceptibilities.

What Metrics Can Be Reviewed at an AMS Committee Meeting?

Antimicrobial utilization is another metric the committee should monitor to determine whether stewardship interventions are successful.¹⁶ Defined Daily Dose and Days of Therapy are recognized metrics of utilization that can generally be accessed with relative ease.¹⁶ In many facilities,

antibiotic purchase data are available and can be checked against utilization to create a full picture of stewardship interventions. Sharing your facilities’ clinical interventions and metrics with the clinical pharmacists and technicians may help improve support of the program. At my facility each month, the metrics along with a few good catches are distributed to the entire pharmacy staff and administration. Programs may also complete medication utilization evaluations (MUE). In completing an MUE, opportunities for improved patient care may be identified, developed, and implemented. For example, if an MUE identified a certain percentage of patients with Methicillin-Susceptible *Staphylococcus aureus* (MSSA) bacteremia which were not being treated with a beta-lactam, the AMS committee could educate providers, laboratory staff, pharmacists, and nursing on the mortality benefit associated with this intervention.^{18,19}

How Can I Review Selected Antimicrobials?

Regular reviews of selected antimicrobials by clinical personnel for appropriateness also reduce inappropriate utilization.^{2,6} There are multiple ways a facility may incorporate reviews of antimicrobials. If you currently participate in multidisciplinary rounds or have an AMS team, reviewing the appropriateness of antibiotics may be incorporated. For facilities that do not currently round, reviewing targeted antibiotics or specific patient populations for appropriateness of antibiotics may be accomplished via checklists. If an opportunity exists for possible de-escalation or discontinuation, providers may be contacted on an as-needed basis. Incorporating pharmacy students whenever feasible to review patients on broad-spectrum antibiotics or to review microbiology reports may help if there are staffing concerns.

How Can Education Be Provided?

Ongoing education is essential to any AMS program.^{2,6} Education for nursing, pharmacy, and providers improves antimicrobial utilization and may be incorporated into the

		CDC Core Elements	Joint Commission Standard
Leadership Support and Commitment		X	X
	Letter of Support	Example	
	Salary Support for dedicated time for antibiotic stewardship activities	Example	
	Inclusion of stewardship related duties in job descriptions and annual performance reviews	Example	
Drug Expertise and Accountability		X	X
	Stewardship program leader—Single leader usually physician	X	X
	Infectious Disease physician		If Available
	Clinicians or Practitioners	X	X
	Department heads	X	
	Pharmacy leader—Single pharmacy leader	X	X
	Quality improvement	X	
	Microbiology/Laboratory staff	X	
	Infection perfectionist(s) and hospital epidemiologist	X	X
	Nurses	X	
	IT	X	
Action: Implementing recommended actions		X	X
<ul style="list-style-type: none"> • Monitor for opportunities and then take action on data • Multiple options unless otherwise specified 			
Action: Implement Policies and Interventions to Improve Antibiotic Use	Policies that support optimal antibiotic use	X	X
Action: Broad Interventions	Document dose, duration and indication	Example	
	Antibiotic Time Outs --48 hour time out after antibiotics are started	Example	
	Antibiotic Restrictions --Prior authorization, Restricted antibiotics or criteria for use	Example	
	Prospective audit and feedback	Example	
Action: Pharmacy Driven Interventions	Automatic IV to PO	Example	
	Renal Dose adjustments	Example	
	Dose optimization	Example	
Action: Diagnosis and Infection Specific Interventions	Facility specific treatment recommendations that includes antibiotic selection and duration for common indications	Example	
Tracking and Reporting Antibiotic Use and Outcomes		X	X
Process Measures	Policy adherence to documenting indications are monitored	Example	
	Adherence to facility-specific treatment recommendations are monitored	Example	
	Are facility/unit or service specific reports shared with prescribers?	Example	
	Feedback to prescribers about how they can improve their antibiotic prescribing	Example	
Antibiotic consumption	Monitor antibiotic use at unit/service and/or facility wide?		
	One of the following specific consumptions metrics are measured: Days of therapy, Defined daily dose, Purchasing data, or AU data	X	
Outcomes	Antibiogram	Example	
	Tracking of infection rates: e.g. <i>C. difficile</i>	Example	
Education	Regular education	X	X
	Education upon hire or granting of initial privileges		X
	Education of patients, and their families as needed, regarding the appropriate use of antimicrobial medications		X

Figure 3. AMS Standards Crosswalk: CDC Core Elements and The Joint Commission Standard.

Note. AMS = antimicrobial stewardship; CDC = Centers for Disease Control and Prevention; IT = information technology; IV = intravenous; PO = oral.

credentialing process. A 1- to 2-page document or a couple of slides may be utilized for initial education. In addition to educating upon hiring, newsletters and/or bulletins may assist in education on an ongoing basis. At our facility, we send out a quarterly bulletin via fax and e-mail which contains a high-level overview of information the AMS committee has developed. Additionally, a monthly newsletter focused on antimicrobial stewardship is developed by the division infectious disease team and distributed.

Conclusion

AMS plays a key role in our hospital and community setting. There is no question of the importance of implementing strong AMS programs in the inpatient and outpatient setting, for both improvement in patient outcomes and compliance with newer regulations. Pharmacists are uniquely positioned to provide optimal patient care through rounding, review of patients' chart, and contribute to the improvement of AMS by working together with a multidisciplinary team. These efforts may allow for the antimicrobial agents we have to be effective now and into the future.

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