Clinical Surveillance: Clinical Decision-Support Systems in the Pharmacy Practice Model Initiative

Contributors

DAVID A. ZILZ, RPH, MS, FASHP
JOSEPH L. HIGH, RPH, PHARM D
JEROD NAGEL, PHARM D, BCPS (AQID)
CLINICAL SURVEILLANCE:
CLINICAL DECISION-SUPPORT SYSTEMS
IN THE PHARMACY PRACTICE MODEL INITIATIVE

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CLINICAL SURVEILLANCE: CLINICAL DECISION-SUPPORT SYSTEMS IN THE PHARMACY PRACTICE MODEL INITIATIVE

ACTIVITY DESCRIPTION
New technologies and a shifting health policy landscape are rapidly changing medication management. To achieve quality-improvement goals, health systems are called upon to apply knowledge consistently and systematically across interdisciplinary teams. Clinical decision-support systems (CDSS) are an effective means to these ends. At this pivotal time, the ASHP’s Pharmacy Practice Model Initiative (PPMI) is gaining recognition and momentum. PPMI aims to capitalize on pharmacists’ knowledge of the medication-use process and their acumen as patient-care providers. This monograph focuses on the capabilities of CDSS, its value in the PPMI, and its application in antibiotic stewardship efforts.

LEARNING OBJECTIVES
The target audience for this activity is pharmacists. Upon completion of this activity, the reader will be able to:
• Summarize the impact of U.S. health policy initiatives on hospital pharmacy technology
• Describe the available technologies and automation methods used in hospital pharmacy and their integration with hospital-wide systems
• Outline the potential impact of hospital pharmacy technologies on patient safety, clinical outcomes, operational efficiency, and institutional cost savings
• Discuss the Pharmacy Practice Model Initiative, its goals, and vision for pharmacy practice
• Explain the capabilities of clinical decision-support systems and how their use can guide pharmacy-specific and institutional practices
• Describe how implementation of CDSS can enhance an antimicrobial stewardship program by saving personnel time and costs while improving patient care

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DAVID A. ZILZ, RPh, MS, FASHP

David A. Zilz is Senior Consultant, Corporate Pharmacy Programs, at the University of Wisconsin Health System and Hospital & Clinics, and is Clinical Professor Emeritus at the UW School of Pharmacy in Madison, Wis., where he earned his B.S. and M.S. and completed his residency training. His professional career at UW Hospital and Clinics was devoted to identifying and implementing innovative pharmacy practices, training of pharmacy residents, and developing new hospital administrative services. In addition to serving as Director of Pharmacy Services for over 2 decades, he was involved in other hospital administrative responsibilities, including Central Services, Materials Management, and Respiratory Care/Pulmonary Function. He was instrumental in establishing a number of key hospital programs, including Home Care and Infusion Services, a UWHC Technology Identification and Assessment organization, and the Office of Clinical Research for the UW Medical School and Center for Health Sciences.

He is involved in numerous leadership roles in pharmacy and health-related entities, colleges of pharmacy, associations and foundations, as well as his church and local community organizations. His leadership roles have included two 3-year terms as Treasurer of ASHP. He is the Past President of ASHP, the ASHP Research and Education Foundation, and the Wisconsin Society of Hospital Pharmacists. His awards include the Harvey H.K. Whitney Lecture Award and the ASHP Award for Distinguished Leadership in Health-System Pharmacy Practice. He has an extensive list of publications related to pharmacy, hospital administrative, and other health-related topics. He continues to lecture on trends that impact the research, production, distribution, utilization, and management implications of pharmaceuticals in the United States.

JOSEPH L. HIGH, RPh, PHARMD

Joe High, PharmD, CAPT USPHS Retired, is Director of Pharmacy at Corpus Christi Medical Center, in Corpus Christi, Texas. He was previously Regional Director for Pharmacy Services for CHRISTUS Spohn Health System, a 6-hospital organization in South Texas. In 2014, he will complete 35 years of service as a pharmacist. As an early adopter of technology and initiator of services, High experienced emergency and critical care medicine in the late 1970s and early 1980s. As the pediatric clinical pharmacist, he learned about neonatal and childhood cancers, which expanded his knowledge of clinical research and pharmaceutical development. The unfortunate experience of seeing a fatality secondary to a medication misadventure fostered a passion to understand how variation in processes leads to disasters. High’s personal life is fulfilled through participation – together with his wife, Debbie – in Rotary International and as a volunteer with Boy Scouts of America.

JEROD NAGEL, PHARMD, BCPS (AQID)

Dr. Nagel is an Infectious Diseases specialist at the University of Michigan Hospital and Health Systems, and the PGY2 Infectious Diseases Residency Program Director. He graduated from Purdue University and completed PGY1 and PGY2 residencies at Meriter Hospital in Madison, Wis. As an Adjunct Clinical Assistant Instructor, Dr. Nagel lectures for the University of Michigan School of Public Health, Nursing School, and College of Pharmacy. He has also mentored numerous student and resident research projects. His research interests focus on improving patient outcomes through antimicrobial stewardship programs, management of multidrug-resistant pathogens, clinical microbiology, infections and complications in transplant patients, and pharmacokinetic/pharmacodynamics in morbid obesity. He is an active member of local and national organizations, including American Society of Health-System Pharmacists, Society of Infectious Diseases Pharmacists, and American College of Clinical Pharmacy.
THE EVOLVING HEALTHCARE ENVIRONMENT

During my career, spanning over 50 years, there has never been a time when so many different and impactful forces have converged on health-systems services and pharmacist’s activities. Just a few examples of some non-debatable trends validate this statement:

- Evolving demographics of American society and, thus, patients being served;
- National policy expectations;
- Organizational structures and arrangements for payment and delivery of care;
- Accelerating changes in automation and technological capabilities throughout society, and no less in health care;
- Higher level of expectations in professional practice performance.

All of these trends raise expectations for hospital pharmacists to increase their contributions to effective patient care and safety, improve the efficiency of their practice and health systems, and better engage fellow practitioners in the work place. In this article, I will review current issues in healthcare dynamics, the rising tide of health policy and technology changes and the resultant need for clinical surveillance, and (to that end) the use of clinical decision-support systems in the Pharmacy Practice Model Initiative.

VIEW FROM THE C-SUITE

Health-system leaders are learning to address changes that were historically slow moving (evolutionary), but are now very rapid and revolutionary. Six major changes are behind this revolution, and they require simultaneous management:

1. Understanding and managing health and wellness of total populations;
2. Assessing how health systems need to function in the transformed employer and insurer marketplace;
3. Realizing the “health care” has now become a retail transaction;
4. Moving for the first time from the traditional, ever-increasing use of resources to flat, and even declining, utilization;
5. Expanding formation of mega-systems (multi-hospital + multiple-service entities);
6. Acknowledging the emergence of new competitors from outside the existing entities.

RISING TIDE OF HEALTH POLICY AND TECHNOLOGY CHANGES

Over the past several years, national policy changes, such as financial incentives, and associated new technologies have been developed with the intention of increasing the quality of health care and decreasing costs. The American Recovery and Reinvestment Act of 2009 authorized at least $20 billion to promote the adoption and the use of electronic health records.
Financial incentives calling for the adoption of new, efficient, and effective technologies continued with the passage of the 2010 Patient Protection and Affordable Care Act. One specific initiative was the implementation of “Meaningful Use” of electronic health records to allow hospitals and physicians to qualify for additional Medicare and Medicaid payments. Over the course of its 3-stage rollout, Meaningful Use calls for significant integration of technology in hospital pharmacies.

**HEALTH POLICY LANDSCAPE: OVERVIEW**

The Patient Protection and Affordable Care Act accelerated the financial positioning of Accountable Care Organizations (ACOs) – groups of coordinated healthcare providers that are accountable for quality and cost for a defined patient population. Minimum requirements for an ACO include: at least 1 hospital; a minimum of 50 physicians; at least 5,000 patients; and a 3- to 5-year commitment. The essential functions of ACOs are depicted in Figure 1.

**FIGURE 1. ESSENTIAL FUNCTIONS OF ACCOUNTABLE CARE ORGANIZATIONS**

- **Provide or manage continuum of care as a real or virtual integrated delivery system**
  - Local accountability for cost, quality, and capacity

- **Measure longitudinal outcomes and costs**
  - Balance team and individual performance goals

- **Distribute cost savings to members of ACO**
  - Prospectively plan budgets and resource needs

The restructuring of payments by ACOs results in major changes within hospitals and health-systems – notably, a tactical trend toward fewer but larger integrated health-systems. The phases that lead to the formation of “mega-systems” are aggregation, federation, and integration (Figure 2). Many organizations are going through all 3 phases simultaneously.

**FIGURE 2. TACTICAL MOVEMENT TOWARD FEWER AND LARGER INTEGRATED “MEGA-SYSTEMS”**

- **Aggregation**
  - Merger and acquisitions

- **Federation**
  - Legal and financial

- **Integration**
  - Clinical and operational
During the **aggregation** phase, much of the effort is focused on merger, acquisition, affiliation, partnerships, and other relationships. During this phase, the C-Suite expertise in finance and legal is crucial to structure a successful organization.

Organizations then typically enter a **federation** relationship (think nation versus state), in which the structure includes the parent organization and all the constituents. As a federation, various disciplines such as legal, human resources, financial, and information technology decide on a strategy to optimize centralized decisions versus autonomous hospitals, clinics, or business units.

The next step – and most critical to the health professionals and pharmacy departments – is **integration.** This involves the blending of the operational and clinical entities – talent, expertise, experience, programs, and contractual arrangements – of multiple organizations.

Successful enterprises will be those that understand the trends affecting healthcare reimbursement, as well as how organizations are structured and how they function. Additionally, they will have the capabilities to develop a complement of sophisticated clinical decision-support systems (CDSS) for their financial, operational, and clinical information.

Hospitals and hospital pharmacies are rapidly adopting and integrating technological advances to minimize adverse events and maximize operational efficiency. A plethora of technologies are used in medication-related activities. These include electronic health record for documentation, barcode-assisted medication administration, computerized provider order entry, and CDSS.

**WHAT IS A CDSS?**

Intended to make medical knowledge readily available those who need and use it, CDSS is a tool born of information technology. It is a consistent, systematic, comprehensive application of health-related knowledge, intelligently filtered or presented at appropriate times. CDSS encompasses a variety of interventions, including computerized alerts and reminders, clinical guidelines, evidenced-based order sets, patient data reports and dashboards, documentation templates, diagnostic support, and clinical workflow tools.

Despite the tremendous impetus to expand technology, only 12% of hospitals report implementation of CDSS, and only 45% of hospitals are using some components of an electronic health record (although use is increasing). The use of bar coded medication administration is increasing in pharmacy departments, but only 52% of hospitals have bar-coding systems implemented throughout the hospital.

Pharmacists are using CDSS to recommend interventions and achieve significant cost savings. The use of data-mining software helps to optimize therapy and identify patients at risk of harm related to drug therapy. Examples include antibiotic stewardship, monitoring pharmacokinetics, converting intravenous to oral therapy, and avoiding adverse drug events. With the ongoing need to reduce wasteful expenditures, one of the key benefits of CDSS is the ability to tabulate financial data associated with pharmacist interventions.
THE PHARMACY PRACTICE MODEL INITIATIVE

The ASHP’s Pharmacy Practice Model Initiative (PPMI) conference took place in 2010, and was a major milestone in defining a new pharmacy practice model. The ASHP literature is replete with discussions and deliberations, as well as recommendations for health-systems pharmacists. An array of resources can be accessed on the PPMI webpage, PPMI - Pharmacy Practice Model Initiative (Figure 3).

In essence, the PPMI calls upon the pharmacy profession to focus on optimizing patients’ use of medication. Importantly, for the PPMI to succeed, the potential exists for dependency on CDSS.

The PPMI conference put forth 10 categories of focus (Table 1). Currently, 4 segments are already using CDSS technology to manage data; many, if not all, of these areas may eventually benefit from the ever-expanding reach of CDSS. Everyone in the profession should become familiar with the details of effective PPMI implementation to achieve the goal of a cohesive vision of the future influence of the profession. As health-systems consolidate and become ACOs, pharmacy departments can focus activities in which pharmacist’s expertise is unquestioned, and in which pharmacy services can be highly coordinated to bring value to payers, provider systems, and patients. Two activities that meet these criteria are medication reconciliation and transitions of care.

### Table 1. The 10 PPMI Categories of Focus and Dependence on CDSS

<table>
<thead>
<tr>
<th>Category</th>
<th>CDSS Dependent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient outcomes</td>
<td>X</td>
</tr>
<tr>
<td>Discharge education/transitions of care</td>
<td></td>
</tr>
<tr>
<td>Monitoring tools</td>
<td>X</td>
</tr>
<tr>
<td>Medication safety systems (e.g., smart pumps)</td>
<td>X</td>
</tr>
<tr>
<td>Technician advancement</td>
<td></td>
</tr>
<tr>
<td>Student education</td>
<td></td>
</tr>
<tr>
<td>Residency training</td>
<td></td>
</tr>
<tr>
<td>Hospital leadership</td>
<td></td>
</tr>
<tr>
<td>Medication reconciliation (EHR, CPOE)</td>
<td>X</td>
</tr>
<tr>
<td>Pharmacist provider status and effectiveness of an ACO</td>
<td></td>
</tr>
</tbody>
</table>
MEDICATION RECONCILIATION

With implementation of the electronic health record and physician order entry systems, accurate documentation of a patient’s medication history is critical, both for safety as well as efficiency. Pharmacy departments are increasingly assuming this responsibility – by telephone before elective hospital admissions, in the emergency department during a crisis episode, or at the bedside during the patient’s hospital stay. The expanded tools and access to information through electronic medical records also allow pharmacists to increase their accountability for the monitoring of laboratory and other data and to reconcile the tremendous number of medication order changes that occur every day.

Pharmacists are also playing an increasing role in discharge education; patients need a well-thought-out discharge plan to manage their medications when they return to their homes or other previous environment. If the discharge education is not done well and medications are not taken appropriately, the result may be costly readmissions and complications that could have been avoided.

TRANSITIONS OF CARE

Three key functions have to be integrated across the continuum of therapeutic care and coordinated during a patient’s transition from the hospital. Pharmacists are the most logical profession to fulfill these activities because they are all related to patient compliance with their medications:

- A comprehensive plan, which ideally should be created and initiated by the pharmacist.
- The prescription process, to ensure that the patient will have all needed medications on an ongoing basis. Providing the medications with the discharge education enhances patient comprehension and compliance, and avoids disruption in the therapeutic regimen.
- One of the common reasons for patient noncompliance is the inability to pay for the products. A comprehensive evaluation of the patient’s financial resources to afford ongoing treatment is therefore a desirable service. It is increasingly a service that is being provided by hospital pharmacy departments.

The PPMI recommends that all levels of the pharmacy profession – students, residents, pharmacists, and PharmD’s on advanced professional practice rotations – should expand their activities to provide an integrated model of service and learning. With all levels of pharmacy practitioners providing direct patient-care activities, such a model can make the profession considerably more visible and accountable than in the past. The service/learning model may include attending pharmacists, practitioner learners, or a layered teaching model, enabling participation on pharmacy teams.

DIRECT INTERACTION WITH PATIENTS: 3 PHASES OF EVOLUTION

The pharmacy profession has evolved through 3 phases of interaction with patients: being accessible, being accountable, and being constructively assertive.

- **Accessible pharmacy.** The number of pharmacy graduates has been increasing over time, providing a greater number of pharmacists to provide coverage for extended hours in hospitals and on patient-care units. At the risk of stating the obvious, patients have medication needs 24 hours a day, 7 days a week, 365 days a year; their needs are not limited to a pharmacist’s 40-hour week.
- **Accountable pharmacy.** The era of monitoring and advising is coming to a close as the pharmacy profession recognizes that these roles no longer meet the needs of patients or providers. Pharmacists must assume accountability through direct patient-care “actions” – not only talk.

- **Assertive pharmacy.** As uptake of the PPMI continues, pharmacy teams are being positioned to expertly manage the continuum of every patient’s medication process – not only discrete segments (e.g., clinical, distributive, or financial). Therefore, pharmacists are increasingly called upon to carry an assertive (not aggressive) attitude in the care of patients.

With the ever increasing technological enhancements and accompanying data accumulation, all of these evolving trends and forces can be optimized by use of sophisticated clinical surveillance and CDSS.

**USING CDSS TO OPTIMIZE PHARMACY’S CONSTRUCTIVE INFLUENCE**

As health-system providers – especially pharmacists – continue to change their practices during this era of major transformation, they will need technology, toolkits, and integrated systems. CDSS can assist pharmacists in their management of all of the following:

- Management of diversified patient populations, with an emphasis on improving outcomes
- Optimal use of all resources (human, medication and therapeutic products, and devices)
- High level of efficiency within the pharmacy enterprises of “mega-health-systems”
- Development of new metrics and informatics capabilities to ensure continuity of care and optimize patient outcomes in their care transitions
- Continual addition of new, sophisticated, and potentially dangerous therapeutics to the pool of existing products to achieve expected outcomes

As technological innovations and increasing quantities of data converge on health-systems and pharmacy departments, the potential information overload is daunting. Yet each added technology has the potential to improve the quality of care in more efficient manners. The PPMI has fueled the need for more automation and technology to accomplish the outcomes expected by patients and payers. There is a significant need to capture and use data that will demonstrate the successes and additive benefits of pharmacy’s efforts in medication management and direct patient care. To achieve this vision requires an investment and a more sophisticated approach than ever before. It is critical to implement CDSS to meet these requirements.
CLINICAL DECISION-SUPPORT EXPERIENCE IN A SIX-HOSPITAL SYSTEM

By Joseph L. High, RPh, PharmD

INTRODUCTION

Increasingly, pharmacy service customers request and expect the pharmacy department to provide clinical services. These requests must be balanced against the operational goals of increased productivity and improved financial performance. The ability of a pharmacy department to accommodate the increased clinical services without increases in personnel or related costs is a significant barrier for most community hospital pharmacy organizations. The CHRISTUS Spohn health system is no exception. Therefore, in 2009, our pharmacy service embarked on a process to re-invent and re-purpose ourselves through the implementation of various technologies, and through process standardization to facilitate the success of the pharmacists and pharmacy technicians of our organization. In this article, I will describe how the pharmacy service of the 6-hospital CHRISTUS Spohn system is using a clinical decision-support system (CDSS) to expand the clinical services provided by the pharmacy department. This document should be viewed as an interim, not final, report of the adoption of this technology.

RATIONALE FOR CDSS

Initially, our goals were to stabilize the operations of the pharmacy. But soon we identified some key objectives:

- Improve patient safety by:
  - Moving the pharmacists to clinical areas
  - Adapting technologies to improve the efficiency and effectiveness of medication delivery and administration
- Reduce or at least stabilize the spend for pharmaceuticals by:
  - Standardizing processes across the region
  - Implementing Medication Management processes
- Rebuild the image of the pharmacy and the hospital system within the community.

To achieve our goals, we recognized that the adoption of technology would play a major component. As an organization, we were positioned to implement several complementary technologies, not only in the pharmacy department but throughout the hospital and health-care system. Table 1 provides the timeline for the implementation of major technology systems. These technologies serve as the basis of our medication-safety tools, and they facilitate the efficiency and effectiveness of our pharmacy associates, nurses, and physicians. They were

<table>
<thead>
<tr>
<th>Year</th>
<th>Technology</th>
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<tbody>
<tr>
<td>2009</td>
<td>UBC &amp; Med Order Image</td>
</tr>
<tr>
<td>2010</td>
<td>HIS and eMAR</td>
</tr>
<tr>
<td>2010</td>
<td>Smart infusion pumps</td>
</tr>
<tr>
<td>2011</td>
<td>Barcode medication verification</td>
</tr>
<tr>
<td>2012</td>
<td>CDSS – HIS Data</td>
</tr>
<tr>
<td>2013</td>
<td>Computerized physician order entry</td>
</tr>
<tr>
<td>2014</td>
<td>Clean room quality and workflow</td>
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</table>
not implemented simply for the sake of having technology, but to serve as key components in the standardization of processes within our operations.

Why is standardization so important? The simple answer is, through standardization we reduce variations. Variation reduction also reduces the opportunity for medication misadventures and waste – not only pharmaceutical waste, but also waste as defined by Lean Six Sigma (LSS) – a management approach that emphasizes methodologies and tools to identify and remove waste and process variation, and increase process velocity and quality. In LSS terminology, waste is the gap between “True North” and one’s current process. True North is the “ideal methodology” of accomplishing what we need to do to serve our patients. Achievement of True North is implicitly impossible. However, elimination of waste moves an individual, processes, and organizations to more effective operation. We have defined our True North (ideal state) for our inpatient health-care environment as:

- The “ready to use” correct medication and dose appears the moment the nurse is ready to administer to the correct patient at exactly the correct time, without the nurse’s input or effort.
- This medication will have no side effects and will cure with one dose.
  – Zero waste of resources!

For most hospital pharmacy operations, multiple redundant activities can occur, resulting in a waste of resources; this becomes significantly more pronounced in a multiple-hospital situation. These redundancies may include:

- Packaging
- Labeling
- Inventory
- Barcode maintenance
- Procedure, policy development and implementation
- Reporting and interpretation of data, both clinical and operational

The last of these redundancies, related to data use, was thought to be a primary reason for the implementation of a CDSS tool that would support pharmacists in the conduct of their daily functions. Frequently, preparation for rounding with the patient care team required more than 2 hours and caused our clinical pharmacists to rely on faulty information. Multiple standard reports from the hospital’s information system would be required on a daily basis.

In the health system setting, the ability to identify and quantify the effectiveness of a clinical pharmacist is a major challenge for the pharmacy department, as it depends on the ability of the directors of pharmacy at each site to effectively monitor and report on the activities of the pharmacists on their teams. Indeed, it is a challenge for leadership to continuously demonstrate the value of clinical pharmacy programs. The legacy tool within the hospital’s previous information system had several limitations, particularly in terms of specificity, documentation of the intervention, and workflow of the pharmacy order entry system. By contrast, the CDSS integrates workflow with tracking and documentation for every intervention.
IMPLEMENTATION AND EXPECTATIONS

CDSS facilitates the collection of data from a variety of departments, such as pharmacy, laboratory, surgery, and radiology. Data from the hospital information system includes patient demographics and admission, transfer, and discharge information. The data received through the CDSS program is compiled and converted into useful information. We intended to use CDSS to help optimize drug therapy by alerting the pharmacy to changes in patients’ conditions and other potential risks. We also expected an overall increase in efficiency within the pharmacy team.

Additional benefits of CDSS include the ability to provide constant surveillance, real-time alerts, and well-timed analysis of infections that threaten patients. We found that we could customize alerts and reports to help identify the use of expensive drug therapies as well as those on our list of short-supply or out-of-stock medications. The real-time alerts facilitate the identification of drug-bug mismatch for antimicrobial stewardship and reduced attempts to treat patients who have resistant organisms with inappropriate drug therapy. Additionally, CDSS provided us the opportunity to identify patients who may require a pharmacy intervention secondary to changes in clinical conditions – for example, failing renal function or improved renal function.

In the first year of using CDSS, we identified and documented more than 11,000 pharmacy interventions (Table 2).

CURRENT STATUS OF CDSS

Implementation of CDSS at our facility was planned with the purpose of deriving objective, measurable outcomes data that could be used to justify the expansion of clinical pharmacy operations. A detailed implementation plan was developed and initiated. However, a major barrier to the success of this study was found in the interface used to pass information from the hospital information system; it was filtering out some relevant information. Specifically, compounded sterile products were failing to appear in the rounding reports. We are continuing to redevelop the interface to improve the data feed of our CDSS.

The successes realized during the first 18 months of using CDSS have been significant in terms of reinvention and repurposing our pharmacy associates. The CDSS is facilitating the decentralization of our clinical pharmacists to patient care areas.

<table>
<thead>
<tr>
<th>Table 2. Intervention data summary: September 2012 to August 2013</th>
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<tbody>
<tr>
<td>Number of Interventions</td>
</tr>
<tr>
<td>Total Intervention Savings</td>
</tr>
<tr>
<td>Average Intervention Savings</td>
</tr>
<tr>
<td>Total Provider Costs</td>
</tr>
<tr>
<td>Net Savings</td>
</tr>
<tr>
<td>Total Time Spent</td>
</tr>
<tr>
<td>Average Time / Intervention</td>
</tr>
<tr>
<td>Minimum Time / Intervention</td>
</tr>
<tr>
<td>Maximum Time / Intervention</td>
</tr>
<tr>
<td>Rejected</td>
</tr>
<tr>
<td>Accepted Modified</td>
</tr>
<tr>
<td>Accepted</td>
</tr>
<tr>
<td>Undetermined</td>
</tr>
<tr>
<td>Canceled</td>
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</table>
The CDSS alert tools have been leveraged to identify and quickly react to several clinical situations:

- **Patients at risk for sepsis.** Sepsis has a significant impact on the mortality and morbidity of our patient populations. A system-wide process-improvement program led us to the conclusion that earlier determination of lactic acid levels could dramatically improve patient outcomes. Identification of patients who are at risk for sepsis – whether entering or currently admitted at any of the hospitals of the region – became an objective. Multiple points to identify patients with questionable mental status or other conditions included triage of the Emergency and Critical Care departments, and throughout our nursing care units. We implemented an alert to identify patients whose initial and serial lactic acid levels were >2 mmol/L. These alerts are provided to the sepsis nurse managers responsible for the overall implementation and operation of the Sepsis Improvement Team.

- **CHF patients with potential for readmission.** The current U.S. health-policy landscape includes programs that penalize healthcare organizations for failing to treat patients across the continuum of care. Such policies provide incentives for organizations to improve the overall patient care. For example, hospitals may forfeit reimbursements based on excessive 30-day readmission rates. In our system, we aimed to improve our ability to identify patients who are at high risk for readmission to our hospitals. We started with a pilot program of readmission alerts in our smaller community hospitals. We analyzed trends in readmission data and implemented methodologies to identify patients within our organization who tend to recycle – notably, those with congestive heart failure (CHF). To help reduce the number of readmissions in CHF patients, action plans were created to include pharmacist involvement in discharge planning and in a teaching program. A unique component of this program was funding to purchase bathroom scales that helped CHF patients to monitor their weight at home. The program’s success is reflected in the decrease in readmission rates at two of our community hospitals. We now have the opportunity to expand this program throughout the regional system, and will leverage the capabilities of CDSS technology as clinical pharmacy services are more broadly implemented.

- **Drug-bug mismatches.** The implementation of an antimicrobial stewardship program in our community faces multiple barriers, including the relative lack of physicians who are infectious disease specialists. Additionally, the management of antimicrobial resistance has become critical, not only in our hospitals, but also other community hospitals and extended-care and skilled nursing facilities. It is nearly impossible for any single pharmacy or infection-control department to empirically select appropriate antimicrobial therapies through manual efforts at admission because of the sheer volume of patients and laboratory cultures. One of the primary justifications for the purchase and implementation of a CDSS in our organization was to help the Infection Control department manage this volume of work in a timely manner. We discovered that we could leverage the information generated from the CDSS in our multidisciplinary rounds, supporting our clinical pharmacists in their efforts to provide effective antimicrobial stewardship. Additionally, the ability to generate an almost real-time antibiogram is improving our ability to select appropriate antibiotics, thereby avoiding antimicrobial resistance during empiric initiation of therapy.

- **Alerts to new orders for snakebite antivenin.** The frequency of human encounters with rattlesnakes is probably higher in South Texas than in most other regions of the United States. In an effort to be “good stewards” of the region’s resources, we maintain a large quantity of antivenin at our central pharmacy distribution facility. The initial dose is delivered in the Emergency Departments of the rural
community hospitals. Afterward, the patient will either be transported to the main regional trauma facility or, if no critical care beds are available, additional doses of antivenin will be sent to the original site of care. Snakebite episodes tend to be cyclic – occurring not as isolated incidents but tending to come in a series, especially on weekends. These occurrences tend to stress our antivenin supply pipeline. Using CDSS, early notification of the pharmacy purchasing agents as well as the pharmacy leadership serves to ensure uninterrupted supplies of these critical medications.

**FUTURE RELIANCE ON CDSS**

Opportunities to continue to leverage and improve the use of the CDSS are many, and we have identified additional alerts.

- We have developed an alert to identify patients, early in their hospital stay, who may be candidates for outpatient antimicrobial therapies. We have organized a multidisciplinary committee that meets weekly to discuss potential patients for our outpatient infusion therapy center. However, it has been difficult to keep the attention of our clinicians, who fail to effectively move patients toward discharge and decrease their length of stay. Early identification of patients for outpatient therapy during their hospital stay enables our team to proactively case manage and intervene as needed.

- Our CDSS system captures and compiles intervention data as a component of the clinical pharmacy workflow. Coordinators of our physician affiliations use the pharmacy intervention information as a component of the annual review of the process for granting physician privileges. Traditionally, this information had been used to identify physicians who were not fully compliant with hospital formularies and other practices. The additional information available through our CDSS helps to identify the leaders among our providers – those who readily seek and accept the input of the clinical pharmacist, replacing a potentially negative outcome with a positive interaction.

- The development of a robust interface between the hospital information system and our CDSS will enable further expansion and acceptance of this system in the next year. As the pharmacy becomes adept at using reports, we will identify additional opportunities to implement alerts and to capitalize on enhanced communication and documentation.

**REFERENCES**


CDSS IN THE PHARMACY PRACTICE MODEL INITIATIVE: APPLICATIONS IN ANTIMICROBIAL STEWARDSHIP

By Jerod Nagel, PharmD, BCPS (AQID)

OVERVIEW

The U.S. healthcare system will likely undergo significant changes in the future, and the consistent theme among several leading organizations promotes more emphasis on accountability on providing optimal care and improving outcomes. The 5 goals of the Pharmacy Practice Model Initiative (PPMI) include a major emphasis on creating pharmacy roles that improve outcomes and creating pharmacists accountability (Table 1).1

<table>
<thead>
<tr>
<th>Table 1. Goals of the Pharmacy Practice Model Initiative1</th>
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<tbody>
<tr>
<td>• Pharmacist roles, practices, and activities will improve medication use and optimize medication related outcomes.</td>
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<tr>
<td>• Pharmacy technicians will prepare and distribute medications and perform other functions that do not require a pharmacist's professional judgment.</td>
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<tr>
<td>• Pharmacists and pharmacy technicians will have appropriate training and credentials for the activities performed within their scope of practice.</td>
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<tr>
<td>• Pharmacy departments utilize available automation and technology to improve patient safety and improve efficiency.</td>
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<tr>
<td>• Pharmacists will demonstrate leadership in exercising their responsibility for medication use systems and will be accountable for medication related patient outcomes.</td>
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The Centers for Medicare and Medicaid Services aim to improve the quality of patient care by linking payment to compliance with quality performance measures.2 The program started in 2004 with 10 quality and patient experience measures. This number increased to 25 in 2013 and 29 in 2014, and will likely continue to increase. Pharmacy can play a significant role in providing optimal patient care by adhering to quality performance measures, both those linked to value-based purchasing and those outlined in national guidelines. Additionally, pharmacists have traditionally played a major role in improving medication use processes and will likely continue to place emphasis on improving the way medications are prescribed and timely delivery of patient care. The PPMI strongly encourages the appropriate positioning of pharmacists to impact improvements in quality performance measures, medication use processes, and patient outcomes.

Clinical decision support software (CDSS), by definition, provides rules that integrate order information, patient information, and/or clinical practice guidelines into computer system logic that provides feedback to clinicians.3
There are multiple advantages of incorporating CDSS in the pharmacist’s workflow including:

- Improving efficiency in identifying patients for possible clinical intervention
- Providing a quick and standardized documentation process
- Improving intra- and inter-departmental communication
- Quickly compile and analyze reports

There are many situations in which CDSS can help improve quality performance measures and medication use processes aimed at improving outcomes. Numerous CDSS vendors are capable of providing these services (Table 2).

### Antimicrobial Stewardship and CDSS

Antimicrobial stewardship programs (ASPs) are gaining recognition for their ability to reduce inappropriate antibiotic utilization and costs. The Centers for Disease Control and Prevention (CDC) recommends antimicrobial stewardship as part of its Get Smart campaign, with roots dating back to 1995, and again in its 2013 Threat Report. Additionally, The California Antimicrobial Stewardship Program Initiative recommends implementation of ASPs in all California hospitals.

The Infectious Diseases Society of America (IDSA) published guidelines for developing an ASP in 2007. The guidelines state, “The primary goal of antimicrobial stewardship is to optimize clinical outcomes while minimizing unintended consequences of antimicrobial use, including toxicity, the selection of pathogenic organisms, and the emergence of resistance.” The guidelines also outline some basic suggested daily activities of ASPs (Table 3).

CDSS programs can help pharmacy departments to efficiently implement several of these suggested activities. CDSS can identify patients on specific antibiotics (or combinations), antibiotics that can potentially be switched from IV to PO, culture results (including those that require antibiotic escalation or de-escalation), and antibiotics that might require dose optimization. These CDSS features improve efficiency and allow pharmacists to perform prospective audit and feedback, document interventions, and run reports. Additionally, CDSS can be built into the ordering process and help guide physicians to select the appropriate antibiotic and dose based on patient-specific factors.

Several studies have demonstrated CDSS can decrease inappropriate antibiotic utilization, decrease costs, increase intervention documentation, and improve clinical outcomes. Malani and colleagues described the

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**Table 2. CDSS Vendors**

<table>
<thead>
<tr>
<th>Vendor</th>
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<tbody>
<tr>
<td>Asolta, Inc</td>
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<tr>
<td>Atlas Development Corporation</td>
</tr>
<tr>
<td>CareFusion MedMined</td>
</tr>
<tr>
<td>Epic Systems Corporation</td>
</tr>
<tr>
<td>ICNet</td>
</tr>
<tr>
<td>RL Solutions</td>
</tr>
<tr>
<td>Safety Surveillor by Premier</td>
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<tr>
<td>Sentri7 by Pharmacy One Source</td>
</tr>
<tr>
<td>TheraDoc by Hospira</td>
</tr>
<tr>
<td>Truven Health Analytics</td>
</tr>
<tr>
<td>Vecna Technologies</td>
</tr>
<tr>
<td>VigiLanz Corporation</td>
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<tr>
<td>WHONET</td>
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</tbody>
</table>

**Table 3. IDSA Recommended Activities in an Antimicrobial Stewardship Program**

- Prospective audit with intervention and feedback
- Formulary restriction and prior authorization
- Guideline and clinical pathway development
- Antimicrobial de-escalation
- Antimicrobial dose optimization
- IV-to-PO conversion
- Education

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impact of CDSS on antibiotic utilization and patient outcomes. Their study evaluated inappropriate antibiotic utilization, antibiotic expenditures, mortality, 30-day hospital readmission, and acquisition of \textit{Clostridium difficile} colitis before and after implementation of an ASP that utilized CDSS. The CDSS program allowed for convenient single-screen display of patient, target drug, and intervention documentation.

They evaluated 455 patients before the ASP (fiscal year 2009) and 440 patients during the stewardship intervention period (fiscal year 2010). The prospective audit and feedback process resulted in antibiotic discontinuation or change in antibiotic therapy in 30.4\% of all antibiotic orders. The antimicrobial budget decreased by 15.2\%, target antibiotic cost was reduced by 35.6\%, and antibiotic cost per patient day decreased by 13.3\% (Table 4). The mortality and hospital readmission rates were similar between the pre- and post-intervention groups; these findings demonstrate that ASPs can significantly decrease antibiotic utilization without adversely effecting patient outcomes. Moreover, the intervention group reduced their use of broad-spectrum target antibiotics, a finding associated with significant reductions in \textit{C. difficile} colitis (OR 0.46 [95\% CI 0.25-0.82]; P<0.01).

| Table 4. Economic outcomes from an antimicrobial stewardship program$^8$ |
|-----------------|-----------------|-----------------|
| **Antimicrobial Agents** | Fiscal Year 2009 | Fiscal Year 2010 | Percent Change |
| **Total Costs** | $1,503,748 | $1,274,837 | -15.2\%\ (-$228,911) |
| **Antimicrobial Cost per Patient Day** | $10.16 | $8.81 | -13.3\% |
| **Targeted Antimicrobial Agents** | $462,404 | $297,851 | -35.6\%\ (-$164,553) |

CDSS systems can also enhance ASPs when they are incorporated into the electronic health record. Doing so allows for complete integration of stewardship team alerts; electronic communication to prescribers; links to guidelines, reference materials and patient information; and documentation of intervention. Schulz and colleagues$^9$ described the process of utilizing CDSS – specifically, a best-practice alert tool – to efficiently perform and document interventions (Figure 1). They demonstrated that this was a novel and effective way to communicate with prescribers, and had an 81.6\% acceptance rate. A subgroup analysis showed that the system was effective for almost all types of interventions (escalation, de-escalation, IV-to-PO) and types of antibiotics (anti-pseudomonal agents, anti-MRSA agents, broad-spectrum agents, etc).

**FIGURE 1. INTEGRATED STEWARDSHIP COMPONENTS FOR THE ELECTRONIC HEALTH RECORD**

- **Notes:** Review ASP recommendations
- **Anti-infective Orders:** Discontinue, modify, or add orders
- **References:** Links to anti-infective references
- **Respond to Best-Practice Alert:** Thoughtful response to ASP leads to discontinuation of alert
- **Select Patient Data:** E.g., WBC, SCr, micro results
**USING CDSS TO IMPROVE PATIENT OUTCOMES**

National guidelines, review articles, and opinion papers call for an increased emphasis on positioning ASPs to optimize patient outcomes. The published literature overwhelmingly demonstrates the ability of stewardship interventions to decrease antimicrobial utilization and cost. An emergence of recent data also demonstrates that ASPs can improve compliance with quality performance measures, patient safety, and patient outcomes, as well as influence antibiotic resistance.

**REAL-TIME CULTURE REVIEW**

The single biggest factor associated with improved infection-related mortality is timely initiation of appropriate antibiotic therapy (Figure 2). Therapy is deemed “appropriate” if it tests sensitive against the isolated organism. In addition, appropriate empiric antimicrobial therapy should target the most likely pathogen, with cultures performed to definitively identify the causative organism.

![Figure 2. Mortality rates for patients with bacteremia started on inappropriate versus appropriate antibiotic therapy](image)

Despite our best efforts to prescribe appropriate empiric therapy, antibiotic resistance is still common. CDSS systems offer the ability to provide real-time alerts for positive cultures, including alerts following Gram stain, organism identification, and susceptibilities. Huang and colleagues evaluated the ability of an ASP to improve patient outcomes through a dual-process intervention, consisting of rapid organism identification plus real-time review of blood cultures.

Their method for rapid organism identification – matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) – can identify an organism 1.0 to 1.5 days earlier than conventional methods. By means of a CDSS, a member of the stewardship team received a real-time notification after every positive blood culture Gram stain, organism identification, and susceptibility result, and was then able to provide antibiotic recommendations to prescribers. The antimicrobial stewardship intervention reduced the time to
effective and optimal antibiotic therapy compared with the historical control group. Other outcomes included reduced mortality, decreased length of ICU stay, and decreased recurrent bacteremia (Table 5).

<table>
<thead>
<tr>
<th>Table 5. Clinical and treatment-related outcomes after combining CDSS real-time alerting for positive blood culture results13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Intervention (n=256)</td>
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<tr>
<td>---------------------------</td>
</tr>
<tr>
<td><strong>Clinical Outcomes</strong></td>
</tr>
<tr>
<td>30-day all-cause mortality (%)</td>
</tr>
<tr>
<td>Time to Microbiological clearance (days)*</td>
</tr>
<tr>
<td>Length of hospitalization (days)*£</td>
</tr>
<tr>
<td>Length of ICU stay (days)*£</td>
</tr>
<tr>
<td>Recurrence of same BSI (%)</td>
</tr>
<tr>
<td><strong>Treatment-Related Outcomes</strong></td>
</tr>
<tr>
<td>Time to Effective Therapy (hours)*</td>
</tr>
<tr>
<td>Time to Optimal Therapy (hours)*</td>
</tr>
</tbody>
</table>

* Mean ± Standard Deviation.
£ Length of hospitalization and ICU stay were defined as time from blood culture positivity to discharge.

Several other studies have demonstrated that combining rapid diagnostic testing and stewardship team intervention can reduce time to appropriate therapy and improve patient outcomes.14-20 Additionally, one study demonstrated decreased mortality from real-time stewardship team review and intervention without implementation of rapid diagnostic testing for patients with Gram-negative bacteremia (5.6% vs. 1.7%, p=0.19).21

**Compliance with Quality Performance Measures**

The Centers for Medicare and Medicaid Services is withholding reimbursements to hospitals until satisfactory compliance with quality performance measures is obtained.2 Pharmacists can play a major role in improving their hospitals’ quality performance measures linked to reimbursement, especially in the selection of antibiotics for pneumonia and surgical prophylaxis, and in the delivery of immunizations to high-risk populations. Pharmacists can also impact other quality performance measures that are not directly linked to reimbursement. The IDSA published treatment guidelines for most common diseases, including a section of suggested quality performance measures. For example, guidelines for the treatment of *Staphylococcus aureus* bacteremia recommend the following quality performance measures:22
- Identification and removal of source
- Repeat blood cultures every 2-4 days till documented clearance
- Target vancomycin troughs of 15-20 mcg/mL for adults
- Confirmation of antibiotic susceptibilities
- Beta-lactam therapy for methicillin-susceptible *S. aureus* bacteremia

Antworth and colleagues23 used CDSS to optimize the impact of an antibiotic stewardship team on quality indicators for patients with candidemia. They evaluated 78 patients with candidemia (41 in the stewardship intervention group and 37 controls). A CDSS system provided real-time alerting upon positive blood cultures
for yeast, and the stewardship team prospectively developed a 5-element candidemia care bundle to comply with the IDSA quality performance measures for the management of candidemia.24 Patients with stewardship review and intervention were more likely to achieve compliance with all 5 bundle endpoints (40.5% vs. 78%, p=.0016) (Table 6). There were improvements in all quality performance measures, including both medication-related and non-medication-related endpoints.

### Table 6. Impact of a comprehensive care bundle and ASP on compliance with IDSA performance measures for the management of candidemia

<table>
<thead>
<tr>
<th>Performance Measures</th>
<th>Control Group (n=37)</th>
<th>Stewardship Group (n=41)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Bundle Compliance</td>
<td>40.5%</td>
<td>78%</td>
<td>0.0016</td>
</tr>
<tr>
<td>Appropriate therapy</td>
<td>86.5%</td>
<td>100%</td>
<td>0.0488</td>
</tr>
<tr>
<td>IV catheter removal</td>
<td>86.5%</td>
<td>95.1%</td>
<td>0.3494</td>
</tr>
<tr>
<td>Microbiologic clearance</td>
<td>78.4%</td>
<td>85.4%</td>
<td>0.6118</td>
</tr>
<tr>
<td>Appropriate duration</td>
<td>67.6%</td>
<td>97.6%</td>
<td>0.0012</td>
</tr>
<tr>
<td>Ophthalmology exam</td>
<td>75.7%</td>
<td>97.6%</td>
<td>97.6%</td>
</tr>
</tbody>
</table>

This study was underpowered to detect a difference in clinical outcomes, but future studies evaluating the impact of antimicrobial stewardship on quality performance measures should also focus on demonstrating the clinical impact of guideline compliance.

### HIV Medication Errors

Alarmingly high rates of medication errors have been reported in hospitalized HIV-infected patients, with incidence ranging from 26% to 72%.25-27 It is difficult to promote appropriate use of HIV medications through traditional avenues of standardization, such as guidelines, dosing recommendations, and prescriber alerts. Significant inter-patient variability can occur in genotypic and phenotypic resistance, adverse effects, drug-drug interactions, compliance, and degree of immunosuppression. Therefore, it is reasonable for ASPs to use CDSS to identify HIV patients and determine whether appropriate therapy, dosing, drug-drug interactions, and prophylaxis have been prescribed. Additionally, CDSS can alert pharmacists to HIV medications that require dose adjustment due to renal or hepatic dysfunction, and it also allows for efficient documentation of review and intervention. In a report published by Kunapuli and colleagues,28 antibiotic stewardship team review resulted in identification and correction of HIV-related medication errors in 38% of hospitalized HIV patients (Figure 3).

**Figure 3. Medication errors identified in HIV-infected patients receiving antiretroviral therapy Corrected via CDSS recommendations**
SUMMARY

CDSS can help to improve the efficiency of pharmacy operations by: alerting pharmacists to high-risk patients that require intervention; allowing for standardized documentation of interventions; enhancing communication among fellow pharmacists or healthcare professionals; and improving the ability to gather and evaluate data. To achieve the goals of the PPMI, individual hospitals should evaluate their patient populations and workflow, and consider the impact pharmacists can have on patient outcomes. CDSS is an effective tool in the efforts to position pharmacists to have a positive impact on medication use and patient outcomes.

REFERENCES


CLINICAL SURVEILLANCE:
CLINICAL DECISION-SUPPORT SYSTEMS
IN THE PHARMACY PRACTICE MODEL INITIATIVE

POST-TEST

1. Which federal legislation accelerated the influence of accountable care organizations (ACOs)?
   a. United States Health Policy and Technology Advancement Act
   b. American Recovery and Reinvestment Act
   c. Patient Protection and Affordable Care Act
   d. Expansion of Patient Apps Act

2. Which of the following is not among the 6 major changes that healthcare administrators must manage simultaneously?
   a. Understanding and managing total population health and wellness
   b. Organizing to reduce regulations from governmental agencies
   c. Moving from increasing to decreasing or flat utilization of resources
   d. Expanding formation of “mega-systems”

3. To qualify as an accountable care organization, the group must include a minimum of 5 hospitals, 100 physicians, and 5,000 patients.
   a. True
   b. False

4. The essential functions of an accountable care organization include:
   a. Local accountability for cost, quality, and capacity
   b. Balancing team and individual performance goals
   c. Prospectively planning budgets and resource needs
   d. All of the above

5. Clinical decision-support systems are being used by hospital pharmacists for all of the following, except:
   a. Support antibiotic stewardship programs
   b. Schedule teams of pharmacists during peak work periods
   c. Convert intravenous to oral therapy
   d. Tabulate financial data associated with pharmacist interventions

6. Of the 10 categories of focus in the Pharmacy Practice Model Initiative, which of the following is not currently dependent on CDSS to manage data?
   a. Patient outcomes
   b. Transitions of care
   c. Medication safety systems
   d. Medication reconciliation
7. As hospitals and healthcare systems trend toward mega-systems, which of the following phases does not occur?
   a. Federation
   b. Centralization
   c. Integration
   d. Aggregation

8. Technology expansion, clinical surveillance through CDSS, and the PPMI recommendations are interdependent.
   a. True
   b. False

9. As defined by Lean Six Sigma, standardization of processes within a pharmacy organization is most important because:
   a. “True North” becomes a possibility
   b. Waste will be reduced to zero
   c. Through standardization we reduce variations
   d. Redundant data will be reported from multiple hospitals

10. With the implementation of a clinical decision-support system (CDSS), a hospital pharmacy system can expect all of the following to occur, except:
    a. Automated alerting features to identify opportunities for interventions by clinical pharmacists
    b. Documentation of activities of the clinical pharmacist
    c. Increased preparation time for interdisciplinary rounds
    d. Increased communication of interventions between pharmacists, nurses, and providers

11. CDSS offers a number of benefits to health-systems pharmacy, including:
    a. Poorly timed analysis of infections
    b. Fixed and inflexible alerts
    c. Near real-time clinical alerts
    d. Inability to identify patients with end organ (e.g., renal) changes

12. Implementation of CDSS in a multi-hospital system can be used to:
    a. Collect data from numerous departments
    b. Justify the expansion of clinical pharmacy operations
    c. Monitor the effectiveness of pharmacy teams
    d. All of the above

13. Quantification of pharmacists interventions through a CDSS may do all of the following, except:
    a. Assist pharmacy leadership to justify additional clinical services
    b. Establish value of clinical pharmacists and their activities in direct patient-care areas
    c. Identify opportunities to facilitate the success of medical providers who have chosen not to be cooperative in the past
    d. Provide the opportunity to justify pharmacists as members of the healthcare team
14. Early identification of bacterial susceptibility to a drug, facilitated through a CDSS drug- bug mismatch report:
   a. Streamlines empiric therapy
   b. Increases the likelihood of antimicrobial resistance
   c. Requires additional clinical pharmacy time to correlate data
   d. Eliminates the need for antibiograms

15. Which of the following is not a benefit of computerized decision-support software?
   a. Identify patients who may require pharmacist intervention
   b. Efficiently document interventions
   c. Improve electronic communication between health-care professionals
   d. Compound intravenous antibiotic in mass quantities

16. According to Infectious Diseases Society of America guidelines, the primary objective of an antibiotic stewardship program is:
   a. Optimize clinical outcomes while minimizing unintended consequences of antimicrobial use
   b. Reduce antibiotic utilization and cost
   c. Decrease antibiotic resistance
   d. Appropriately convert intravenous antibiotics to oral antibiotics

17. Studies have shown that real-time review of positive blood culture results in combination with rapid diagnostic techniques can improve mortality.
   a. True
   b. False

18. What is the incidence of medication errors in hospitalized HIV patients?
   a. Less than 10%
   b. 10% to 20%
   c. 20% to 80%
   d. Greater than 80%

19. Antimicrobial stewardship programs can improve compliance with national quality performance measures.
   a. True
   b. False

20. Which of the following is not a national quality performance measure for the management of candidemia?
   a. Timely initiation of appropriate antifungal therapy
   b. Ophthalmology consult when patient is not neutropenic
   c. Removal of the source of candidemia whenever possible, including any intravenous lines
   d. Weekly laboratory blood draws for sedimentation rate, until normalized

Complete Post-Test and Evaluation online at www.ProCE.com/ClinicalSurveillance