Needs and opportunities for achieving optimal outcomes from the use of medicines in hospitals and health systems

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For years, the patient safety literature has been replete with articles describing the scope and breadth of adverse drug events (ADEs) across the continuum of care. In 1991, Leape reported that drug complications constituted 19% of total adverse events in hospitalized patients. Bates et al. reported in 1995 that medication errors occurred in 5.3% of inpatient medication orders, with 7.5% resulting in an ADE. Later work in the primary care environment revealed 27 ADEs per 100 patients, with 13% identified as serious, 28% as ameliorable, and 11% as preventable. Transitions of care are often a source of ADEs as well. In one study, more than 12% of patients discharged from a general medicine service experienced an ADE, and a high rate of preventable events among community-dwelling elderly has been reported. The costs associated with ADEs are significant, with preventable ADEs resulting in $3.5 billion in hospital admissions and increased lengths of stay. Many preventable ADEs are the result of an increasingly complex medication-use system in hospitals and health systems. The components of these complexities are multiple and include increasing patient use of medications, especially high-risk, complex therapies; multiple handoffs and lack of standardization during the medication-use process; and an aging population with multiple chronic conditions.

Clarion call to improve the use of medications

Just over a decade ago, the Institute of Medicine (IOM) issued a clarion call for improving safety in the health system. To Err is Human: Building a Safer Health System provided a comprehensive strategy for government, health care providers, industry, and consumers to collaborate in reducing preventable medical errors. Around the same time, the Joint Commission of Pharmacy Practitioners, a consortium of national pharmacy practitioner associations, convened a conference to address the quality of the medication-use system, which resulted in a call for a major overhaul of the system. While progress has been made, the major gaps and opportunities in the medication-use system remain essentially the same as they were 10 years ago.

As physician Jerry Avorn describes in his book Powerful Medicines, every drug is a triangle of healing, hazards, and economic impact. Prescribers face the daily struggle of balancing the benefits and risks of a drug each time they write a medication order. Government regulation and policy have been trying to catch up to the complexity and potency of medications for the past 50 years. In 1962, the Kefauver–Harris Drug Amendments were passed, requiring...
that new drugs be proven effective (not just safe) before they could be sold in the United States, but it was not until 2007 that the Food and Drug Administration Amendments Act (FDAAA) gave the Food and Drug Administration (FDA) authority to take into account postmarketing safety information in its regulation of medications. 

While these efforts are important from public policy and safety perspectives, it is the daily management of complex medication regimens that continues to challenge health care providers. The number of Americans that have used five or more prescription drugs has increased by 70% over the past 10 years.

For the elderly, a particularly vulnerable population, the number of medicines used is quite high—almost 40% of older Americans have used five or more prescription drugs. An increase in evidence-based treatment guidelines for chronic medical conditions, improved access to medications for the elderly through Medicare Part D and patient assistance programs, increased availability of generic drugs, and longer life spans may all be contributors to increased medication use by the elderly. In addition, the elderly frequently use nonprescription medications and supplements, which increases the risk for drug–drug interactions.

For prescribers, it can be difficult to have the in-depth pharmacologic knowledge required to treat patients let alone identify and prevent the opportunities for drug–drug interactions, drug–disease incompatibilities, and allergies. Medical schools devote a very small part of the curriculum to pharmacology and the safe and effective use of medications. Physicians receive a large component of their education about drug products during their residency training and through exposure to pharmaceutical-industry-sponsored education.

In hospitals and health systems, the complexity of the medication-use process makes the process intrinsically hazardous in spite of intensive efforts to implement safety measures. Access to a complete and accurate medication list by all health care providers during hospitalization and transitions of care is a major challenge. While much effort is being made to implement electronic health information systems in hospitals, the cost and complexity of these systems have resulted in slow progress. Health care practitioners are challenged by immature and disparate electronic medical records and decision-support systems in which patient information is lacking or not up-to-date. Too often, care providers do not involve the patient when updating or clarifying his or her home medication list at admission and instead rely on old care notes or unreliable documentation from various sources.

Medications are commonly implicated in adverse events after discharge from the hospital; failure to adequately communicate the planned regimen and discuss potential adverse drug effects with the patient before discharge may be a contributing factor. In a study of elderly patients who had been recently discharged from the hospital, 14.1% experienced one or more discrepancies with their medication regimen. These patients were noted to have a higher rate of rehospitalization within 30 days of discharge. Patients should receive education regarding their medications at discharge, including a review of potential adverse effects, and be presented with a complete list of their medicines. As health systems struggle with incorporating medication reconciliation into daily practice, involving the patient at these critical transition points is essential.

A particular concern in hospitals for many years has been medication errors, which should be preventable "through effective systems controls involving pharmacists, physicians and other prescribers, nurses, risk management personnel, legal counsel, administrators, patients, and others in the organizational setting, as well as regulatory agencies and the pharmaceutical industry." The following excerpt from the “ASHP Guidelines on Preventing Medication Errors in Hospitals” offers an important perspective on this troubling issue:

Medication errors compromise patient confidence in the health care system and increase health care costs. The problems and sources of medication errors are multidisciplinary and multifactorial. Errors occur from lack of knowledge, substandard performance and mental lapses, or defects or failures in systems. Medication errors may be committed by both experienced and inexperienced staff. The incidence of medication errors is indeterminate; valid comparisons of different studies on medication errors are extremely difficult because of differences in variables, measurements, populations, and methods. Some medication errors result in serious patient morbidity or mortality. Thus, medication errors must not be taken lightly, and effective systems for ordering, dispensing, and administering medications should be established with safeguards to prevent the occurrence of errors.

The problems associated with the medication-use system in hospitals and health systems are vast. To reduce these problems, we must identify the barriers that need to be addressed and capitalize on opportunities that will drive constructive change and optimize patient care.

Major barriers to improving medication use in hospitals and health systems

Hennessy provided a useful overview of problems of medication use within health care at large that are potentially amenable to improvement.
These included

- The need for safer and more-effective drugs,
- Gaps in existing knowledge about drugs and their use,
- The need for better education and training for physicians, pharmacists, nurses, and patients,
- Reduced time spent on patient-related activities due to increased workload,
- Lack of access to patient-specific data,
- Professional practice roles unclear in nontraditional activities,
- Reliance on error-prone processes,
- The pervasiveness of commercial influences,
- Economic barriers that prevent patients from receiving needed medications,
- Multiple and changing formularies, and
- Nonadherence to therapy.

There are a number of key barriers to improving medication use in hospitals and health systems. In some cases, a potential “enabler” of constructive change can be a “barrier” when its implementation is not well planned or executed.

Information technology. Problems associated with health information technology (IT) that is immature and lacks interoperability are discussed thoroughly by Siska and Tribble later in the proceedings. As stated by these authors, health systems’ relatively low rate of adoption of IT that could help improve medication-use safety stems from financial barriers, work force issues, strategic problems, (lack of vision), cultural issues (siloed professional and departmental practices), data-structure problems, and privacy and security concerns.

Economic barriers. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provided first-time outpatient prescription insurance coverage to an estimated 7–15 million Americans. Nevertheless, there are still economic barriers to obtaining needed medicines among some ambulatory patients. The number of people without health insurance rose 9.4% to 50.7 million people in 2009, representing 16.7% of the U.S. population. When prescribing, physicians need to consider (1) what a patient is willing or able to pay and (2) the availability of manufacturer-sponsored patient assistance programs and other types of aid. The new health reform law, the Patient Protection and Affordable Care Act, should improve access to health care in the coming years, including subsidies for seniors who cannot afford their prescription medications.

In hospital inpatient care, third-party payment often does not adequately cover the cost of expensive drug treatments, which threatens the ability of the institution to provide optimal pharmaceutical care.

Limited financial and human resources. The economic pressures on hospitals and health systems, which translates to financial constraints on all facets of the medication-use system, have been well documented by the American Hospital Association. Work-force issues in health care, as identified in a recent study by the Association of Academic Health Centers, include worker dissatisfaction, occupational hazards, limited results of recruitment and retention strategies, overspecialization, and disincentives to entering health occupations. These factors contribute to a shortage of workers in health systems, which creates an immense challenge in designing and implementing safe medication-use systems.

Deficiencies in drug information. Keeping up with the most recent advances in medicine can be challenging for physicians who are already working long hours to care for their patients. Prescribers may lack knowledge about the comparative effectiveness and cost of medications. The pharmaceutical industry plays a significant role in educating prescribers, as approximately two thirds of continuing medical education is industry sponsored. Health systems have an obligation to ensure that their prescribers have objective information about the safe, effective, and cost-conscious use of medicines in their formularies. A systematic drug information program was shown to significantly reduce the rate of ADEs (p = 0.005) in a study of nearly 2 million hospitalized Medicare recipients.

Organizational and cultural issues within health systems. Perhaps the largest barrier to improved patient safety in health systems is organizational culture. When event reporting is used as a personnel-management tool rather than as a safety or quality-improvement tool, staff behavior is likely to reflect a culture of blame and error cover-up. When interdisciplinary teamwork is lacking, there is likely to be too little standardization of care, resulting in a more complex (and less safe) system. In some institutions, medication safety is not embraced as a systemic quality-improvement effort but as pharmacy quality-assurance work, which does not provide the broad buy in to safety that is needed for optimal results. Medication-use safety in some health systems is dependent on the vigilance of individuals; the tracking, reporting, and evaluation of ADEs, including near misses, are then inconsistent, and there is no adequate foundation for systematic improvement in medication-use safety.

Paper-based medication orders and oral orders are error prone, and paper-based medication administration records are typically incomplete and generally inaccessible, which increases the potential for error. A focus on short-term drug cost savings instead of therapeutic optimization feeds the perception that pharmacy “owns” all medication-related issues and reduces the commitment of pre-
siblers to honestly assess how their behavior contributes to the problem. Creating a safe culture takes hard work and requires a commitment from hospital leaders.

**Major enablers to improving medication use in hospitals and health systems**

Although the scope and breadth of ADEs is daunting, the problem is receiving immense attention, and there are many opportunities to improve the situation. In 2000, the Institute for Safe Medication Practices (ISMP) conducted the ISMP Medication Safety Self Assessment survey. More than 1400 hospitals responded, helping ISMP identify characteristics and best practices for improving medication safety. The activities enabling progress toward safe medication use included systematic redundancies, ready access to patient information, standardized and automated communication of drug orders, a nonpunitive system for error reduction and reporting, and patient education and involvement. In addition, multidisciplinary collaboration to develop a strategic plan for improving medication safety and then nurture and sustain the effort is critical for the organization’s success in implementing medication safety.

**ADE reporting and monitoring.** Monitoring and reporting ADEs and medication errors are key tools used to improve medication safety. At a national level, the Adverse Event Reporting System (AERS) is a computerized information database designed to support the FDA’s post-marketing safety surveillance program for all drugs and therapeutic biological products with approved labeling. FDA uses AERS to monitor for new adverse events and medication errors that might occur with these marketed products. However, reporting adverse events from the point of care is voluntary in the United States. FDA receives some adverse-event and medication-error reports directly from health care professionals and consumers. Health care professionals and consumers may also report these events to the products’ manufacturers, who are required to send the reports to the FDA.

At the health-system level, a nonpunitive culture of and framework for medication-error reporting are critical to ensure that such reporting occurs. The reporting of potential and actual events helps to identify error-prone systems that can be improved. Timely error analysis and recommendations for system changes encourage more reporting and supports a culture change. At the patient level, documenting an ADE to a specific medication should prevent a repeat episode. As part of the error-reporting safety strategy, errors with a high potential for patient harm should be analyzed. Two techniques available for this purpose: root cause analysis (RCA) and failure mode and effects analysis (FMEA).

RCA. The purpose of RCA is to trace a problem back to its root cause using a process that establishes a sequence of events or timeline to understand the relationships between contributory factors, the root cause, and the defined problem. There are various tools and techniques used by quality and safety teams for performing RCA. To be effective, RCA must be performed systematically as an investigation, with the conclusions and root cause supported by documented evidence.

FMEA. FMEA was first used in the manufacturing industry to examine product defects but has increasingly been used in health care to analyze service defects. Failure modes are any errors or defects in a process, design, or item, especially those that affect the customer, and can be potential or actual. Effects analysis refers to studying the consequences of the failures identified. FMEA is often employed when new systems are designed to provide a prospective analysis of high-risk processes.

**Laws and regulations.** Laws and regulations are used by the government to foster changes in health care that are meant to improve patient safety and quality. Many practitioners believe that some regulations add administrative burden without necessarily achieving the outcome envisioned by lawmakers.

The 2005 Patient Safety and Quality Improvement Act. This federal law encourages providers to submit voluntary and confidential reports of events that adversely affect patients. This information is submitted to the newly formed patient safety organizations (PSOs), which are tasked with conducting analyses regarding patient safety. The act established uniform privilege and confidentiality protections that apply nationally to all health care practitioners and institutional providers. The hope is that these protections will encourage providers to voluntarily report sensitive information to PSOs for examination and discussion under statutorily defined circumstances in order to improve patient safety.

Risk evaluation and mitigation strategy (REMS) program. In an overt public policy reaction to patient harm from high-risk medications, the FDAAA of 2007 gave FDA the authority to require that manufacturers conduct postmarketing studies and formulate a REMS program tailored to the risk–benefit profile of a specific product. This act implements recommendations from the IOM report The Future of Drug Safety: Promoting and Protecting the Health of the Public.

The Prescription Drug User Fee Act (PDUFA), which was reauthorized through fiscal year 2012, mandates that FDA staff have the additional resources needed to conduct the complex and comprehensive reviews necessary for new drugs. Title IX of the PDUFA reauthorization expands FDA’s authority and delin-
eates specific factors that should be considered by FDA when determining whether a medication should be required to have a REMS.

There are four potential components of a REMS including a medication guide, a communication plan, elements to ensure safe use, and an implementation system. For hospitals and health systems, meeting the elements of a REMS program (particularly the implementation system) is complex, expensive, lacks standardization and may disrupt continuity of care.44 Nevertheless, the REMS program provides opportunities to improve patient safety and may enhance communication with patients and health care providers. ASHP has a helpful Web resource center on REMS.35

Accreditation standards. Hospitals must meet Medicare’s conditions of participation in order to receive Medicare reimbursement.36 Hospitals accredited by any of the following bodies are deemed by the Centers for Medicare and Medicaid Services (CMS) to be in compliance with Medicare’s conditions of participation: the Joint Commission, the American Osteopathic Association (the Healthcare Facilities Accreditation Program) and Det Norske Veritas Healthcare, whose accrediting body is known as National Integrated Accreditation for Healthcare Organizations.

Accreditation standards drive various quality-improvement initiatives within hospitals and health systems. The standards are based on measurable best practices that have demonstrated improved patient outcomes. Within health-system pharmacy, ASHP administers a residency accreditation program based on the principles and philosophy of standards-based practice. The accreditation site visit is rigorous, and the surveyors evaluate the entire medication-use system, the educational integrity of the residency program, and the department’s relationship within the organization. Although the fundamental purpose of ASHP residency accreditation is to ensure the quality of the training program and to protect residents, it also ensures hospital administration that the pharmacy department is meeting national quality standards.37

Marketplace competition. As more quality and safety information become available through public and other sources of reporting, health care organizations are attempting to market these data to attract patients and third-party payers.

Public reporting. With hospitals publicly reporting quality measures, consumers can comparison shop for the hospital that best meets their needs. Many of these reportable metrics are medication related and draw public attention to the issue of medication-use improvement. The development of performance-based measurement systems used to compare elements of care across health care settings continues to evolve. The National Committee for Quality Assurance (NCQA) and the Joint Commission have been leaders in this arena. The Health Plan Employer Data and Information Set tool developed by the NCQA includes 75 measures that are updated annually.38 More than 90% of health plans today use this tool to measure a health system’s performance. The Joint Commission and CMS have been developing “core measures” of selected conditions including myocardial infarction, pneumonia, heart failure, pregnancy, and surgery-related infections. Medication therapy is involved in the majority of CMS’s core measures, providing opportunities and focus for pharmacist involvement in improving the quality of patient care.

Pay for performance. Employers, government agencies, and others are interested in rewarding hospitals, long-term-care facilities, and physicians for providing quality care. Pay-for-performance programs pay providers of health care based on the quality and efficiency of care provided and may penalize providers for not meeting expectations.

In 2006, President Bush signed an Executive Order to promote efficient and quality health care to U.S. citizens in health care programs sponsored by the federal government.39 This order commanded Medicare, Medicaid, and other government programs to share information with beneficiaries about the quality of care provided by hospitals, physicians, and others. Payers are turning to value-based purchasing, a payment mechanism that attempts to improve the quality of care received for the money spent. Included in the value calculation is the use of cost-effective, evidence-based medications for various conditions. Providers of health care are held accountable for both quality and cost.40

Patient education and engagement. Patients who are actively engaged in their health care experience help to reduce the rate of medication errors, ADEs, and treatment failures and have fewer hospital readmissions. Patients who receive counseling by a pharmacist at the time of hospital discharge had significantly fewer ADEs after discharge compared with patients who do not receive pharmacist counseling.41 Patients need to understand more about their medications, keep an up-to-date and accurate medication list, and feel comfortable communicating with their health care providers at any point in their care.

Interdisciplinary teams. A truly collaborative health care team (with the patient as an integral member) is the optimal model of care. The factors associated with high performance in quality and safety include a shared sense of purpose, a collaborative health care team with strong leadership, and an accountability system with a focus on results. The microculture of each health care team is
different, but a culture of continuous quality improvement pervades successful teams. The Joint Commission, through its Sentinel Event Program, found that communication issues were the most frequent contributors to serious medical errors. Strategies to improve teamwork in health care include staff introductions to the patient; team huddles before a procedure to verify the patient, procedure, and site; shift change reports; and event debriefings. To improve communication, many health systems are adopting a communication standard called SBAR (Situation, Background, Assessment, Recommendation), which provides a structure for providing the required information to get the appropriate action.

**Human factors engineering.** Human factors engineering (HFE) optimizes the relationship between humans and the systems in which they work. The three domains of HFE are physical, cognitive, and organizational, and they have the objectives of reducing errors, fatigue, stress, and injuries at work while improving productivity, ease of use, safety, comfort, acceptance, job satisfaction, and quality of life. In order to meet these objectives, leaders need to

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<th>Table 1. National Quality Organizations and Initiatives&lt;sup&gt;48&lt;/sup&gt;</th>
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<tr>
<td><strong>Organization (Website)</strong></td>
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<tr>
<td>Agency for Healthcare Research and Quality (AHRQ) (<a href="http://www.ahrq.gov">www.ahrq.gov</a>)</td>
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<td>ASHP Health-System Pharmacy 2015 Initiative (<a href="http://www.ashp.org/2015/index.cfm">www.ashp.org/2015/index.cfm</a>?)</td>
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<td>Centers for Medicare and Medicaid Services (CMS) (<a href="http://www.cms.hhs.gov">www.cms.hhs.gov</a>)</td>
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identify performance problems and solutions, analyze performance problems, and design systems to support performance and eliminate or reduce performance obstacles.

The Systems Engineering Initiative for Patient Safety (SEIPS) model is a framework for improving health care created by industrial engineers at the University of Wisconsin. SEIPS expands on the Donabedian continuous quality improvement framework of structure–process–outcome, integrating HFETs and systems engineering with health care disciplines. The model examines systems design, quality management, job design, and technology implementations (including medication administration technology, electronic health records, and computerized prescriber order entry) that affect safety-related patient, organizational, and staff outcomes in various health care settings.

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<th>Organization (Website)</th>
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<td>Hospital Quality Alliance (HQA) (<a href="www.cms.hhs.gov/HospitalQualityInits/5_HospitalQualityAlliance.asp">www.cms.hhs.gov/HospitalQualityInits/5_HospitalQualityAlliance.asp</a>)</td>
<td>Created in 2002 Public–private collaboration to improve quality of care by measuring and publicly reporting on that care; goal is to “identify a robust set of standardized and easy-to-understand hospital quality measures”</td>
<td>Beginning in 2004, hospitals could voluntarily report data on 10 “starter-set” quality performance measures to receive the incentive payment established by Medicare Prescription Drug, Improvement, and Modernization Act of 2003; in 2005, set was expanded to 21 measures. Hospital Compare is a website/Web tool to publicly report information about the quality of care in hospitals debuted 2005. Reports include process and outcome measures, use of medical imaging and patients’ hospital experience (<a href="www.hospitalcompare.hhs.gov">www.hospitalcompare.hhs.gov</a> and <a href="www.medicare.gov">www.medicare.gov</a>). Hospital CAHPS Survey, also known as the CAHPS Hospital Survey, provides a standardized instrument and data collection methodology for measuring patients’ perspectives on hospital care. Reporting is voluntary and began in late 2006.</td>
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<td>Institute for Healthcare Improvement (IHI) (<a href="www.ihi.org/IHI/Programs/Campaign/Campaign.htm?">www.ihi.org/IHI/Programs/Campaign/Campaign.htm?</a>)</td>
<td>Founded in 1991 as a not-for-profit organization with a goal of improving health care throughout the world Translated IOM aims into a “no needless list”: no needless deaths, no needless pain or suffering, no helplessness in those served or serving, no unwanted waiting, and no waste</td>
<td>100,000 Lives Campaign (12/2004–12/2006) aimed to introduce proven best practices with the goal of extending or saving as many as 100,000 lives 5 Million Lives Campaign (12/2006–12/2008) aimed to prevent 5 million incidents of medical harm over the next two years</td>
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<td>Institute of Medicine (IOM) ([<a href="http://www.iom.edu/CMS/About">www.iom.edu/CMS/About</a> IOM.aspx?](<a href="http://www.iom.edu/CMS/About">www.iom.edu/CMS/About</a> IOM.aspx?))</td>
<td>Chartered in 1970 as a component of the National Academy of Sciences with a mission to serve as adviser to the nation to improve health In 1996, IOM launched an effort focused on assessing and improving the nation’s quality of care and issued a series of quality reports. In 2004, Congress mandated CMS to sponsor IOM to study drug safety and quality issues.</td>
<td>Published reports such as <em>The Urgent Need to Improve Health Care Quality, Crossing the Quality Chasm, To Err is Human: Building a Safer Health System, and Preventing Medication Errors.</em> Publishes about 50 reports yearly</td>
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<td>Joint Commission (<a href="http://www.jointcommission.org/Performance">www.jointcommission.org/Performance</a> Measurement)</td>
<td>Founded in 1951, the original core measures were released in 2001. Joint Commission is a recognized leader with a long proven ability to identify, test and specify standardized performance measures. “It engages in cutting edge performance measurement research and development activities, and has established successful, ongoing, collaborative relationships with key performance measurement entities.”</td>
<td>Five core performance measure sets have been identified for hospitals: acute myocardial infarction, heart failure, pneumonia, pregnancy and related conditions, and surgical infection. Upcoming care measure sets include children’s asthma care, stroke, emergency department, and venous thromboembolism. All measures are submitted to NQF for review and endorsement.</td>
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<td>Leapfrog Group (<a href="http://www.leapfroggroup.org/about_us">www.leapfroggroup.org/about_us</a>)</td>
<td>Launched in 2000 in response to a 1998 discussion of large employers as to how they could influence the quality and affordability of the health care they purchase. The IOM report To Err is Human: Building a Safer Health System gave the group its initial focus—reducing preventable medical errors. “The Leapfrog Group is a voluntary program aimed at mobilizing employer purchasing power to alert America’s health industry that big leaps in health care safety, quality, and customer value will be recognized and rewarded”.</td>
<td>Hospital Quality and Safety Survey is a voluntary survey that asks hospitals to rate themselves on 4 “leaps” or quality and safety practices. Results are available online. Hospital Rewards Program measures performance in several areas for effectiveness and affordability and rewards hospitals that demonstrate excellence or show improvement. Bridges to Excellence is a rewards program focused on quality in doctors’ offices.</td>
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<td>National Committee for Quality Assurance (<a href="http://web.ncqa.org">http://web.ncqa.org</a>)</td>
<td>Founded in 1990 as a not-for-profit organization dedicated to improving health care quality.</td>
<td>Health Plan Employer Data and Information Set (HEDIS) is a tool designed to provide purchasers and consumers with the information they need to reliably compare the performance of health care plans. HEDIS measures include asthma medication use, persistence of β-blocker treatment after myocardial infarction, controlling hypertension, diabetes care, breast cancer screening, antidepressant use, immunization status, and smoking-cessation advice.</td>
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**Stakeholders and organizations involved with quality and safety initiatives**

There is support for hospitals and health systems that are developing a culture of safety. Numerous stakeholders are developing performance measurement methods that can be used to assess, on an ongoing basis, the quality of medication use in hospitals and health systems; these stakeholders include government agencies, accreditation organizations, private organizations, and public-private partnerships and alliances. Their initiatives are generally framed by IOM’s definition of quality: “The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”47 ASHP has developed a discussion guide entitled “The Pharmacist’s Role in Quality Improvement” that includes descriptions of the various national quality organizations, their...
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<td>National Quality Forum (NQF) (<a href="http://www.qualityforum.org">www.qualityforum.org</a>)</td>
<td>Created in 1999 in response to the 1998 report of the President’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry to develop and implement a national strategy for health care quality measurement and reporting.</td>
<td>Through 2006 NQF endorsed more than 300 measures, indicators, events, practices, and other products to help assess quality. NQF endorsement has become the “gold standard” for the measurement of health care quality.</td>
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Mission is to improve health care for Americans by endorsing consensus-based national standards for measurement and public reporting of health care performance data that provide meaningful information about whether care is safe, timely, beneficial, patient-centered, equitable, and efficient.

role in health care, the quality initiatives with which they are involved, and the websites of each organization (Table 1).48

Current methods of performance measurement

With so many stakeholders and organizations asking for measurements, it is critical for the pharmacy department to have a method to determine whether changes in its practice model are having the desired effect on the quality of medication use. Assessing improvement in the medication-use system is based on building and applying knowledge, which leads to a set of fundamental questions that help frame the approach: What are we trying to accomplish? How will we know that a change is an improvement? and What changes can we make that will result in improvement?

This model for improvement49 is used by many health care organizations and is widely taught by the Institute for Healthcare Improvement to accelerate change. The three questions are directly linked to action-oriented learning, an evidence-based method for testing change known as the plan–do–study–act (PDSA) cycle. Applying the model for improvement methodology to determine if changes in a pharmacy practice model are having the desired effect on quality improvement related to the use of medicines might follow these steps:

1. **Form an effective team.** The recommendations for effective teams vary but generally require a system leader or someone with enough organizational authority to allocate resources and implement the changes needed; a clinical technical expert who understands the technical and clinical process well; a day-to-day leader who drives the project and understands the details of the system and the impact of changes to the system. Other members should include those who have a vested interest in the change to be made.

2. **Set aims.** Set a clear aim that is time specific, measureable, and focused on a specific patient population.

3. **Establish measures.** Determine metrics for outcomes, process, and “balancing measures.” These balancing measures help the team scan for unintended consequences of the changes being made.

4. **Select changes.** Determine which changes are most likely to result in improvement.

5. **Test changes.** Once the team has created a list of potential changes, it will start running PDSA cycles of change to quickly determine if any of the changes are actually improvements in the medication-use system. IHI offers a PDSA work sheet that teams can use to track each cycle of change.50 Based on what the team learns from each PDSA cycle, adjustments can be made and tested on the next change cycle in an iterative process that promotes team learning. These tests of change help the team set aims and establish measures and are used to refine the improvement process.

Several tools are available to track and report various aspects of the improvement process. In many
NEW PHARMACY PRACTICE MODELS

Needs and opportunities

hospitals and health systems, the quality-improvement department has adopted an array of tools that work for their organization. Pharmacy departments should contact the quality improvement staff to learn more about the tools and techniques used in their organization. Tools may include brainstorming and constructing a flow chart, run chart, histogram, check sheet, Pareto chart, or affinity diagram.

Conclusion

Across the continuum of care, increased complexity creates an error-prone medication-use process at the expense of patient safety and quality. Despite the claims of various information technology solutions and well-intentioned quality-improvement initiatives, only limited progress has been made in improving medication-use outcomes. Many elements of the health care reform legislation are focused on improving quality and safety for patients and are tied to reimbursement. Measuring and publicly reporting quality and safety outcomes are not yet optional, which gives pharmacists a tremendous opportunity to take a leadership role in achieving optimal outcomes from the use of medicines. This leadership role must be owned by everyone in the hospital pharmacy department, with the goal of fully integrating the product and service lines of care. The covenant pharmacists have with their patients demands that we ensure the safe and effective use of medications. Our patients should expect nothing less from us.

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Health care imperative for practice model change

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We are living in a time when the hospitals in which we work are changing right under our feet. The patients we now see are more acutely ill than patients seen just 10 years ago, and when they arrive at the hospital for care, we must move them through the system quickly, as the beds on the medical floors and intensive care units are in high demand and the emergency department is overcrowded.

This is a summary of a speech at the Summit. An audio recording of the full speech, synchronized with slides, may be accessed at www.ashp.org/ppmi/watch-wellikson.

To manage a growing patient population efficiently and effectively, we need to better coordinate care. This will require better communication and transfer of patient information among shifts of professionals in a geographically dispersed facility, often without a unifying electronic health record.

This need for better coordination of care comes at a time of significant challenges to the executive leadership of hospitals. Some institutions are fighting for their fiscal survival because of cutbacks on payments and the growing burden of regulatory and accreditation requirements. Public trust in hospitals has eroded, partly due to the media attention given to medical errors. Turnover in nursing and other health professional staffs is substantial. There has been a marked realignment of many physicians’ hospital of choice, which has put some hospital’s future in jeopardy.

While hospitals are trying to provide round-the-clock medical services, many physicians (e.g., primary care doctors, neurologists) are leaving their hospital affiliations, and surgeons, subspecialists, and orthopedists are narrowing the scope of their practices. Some physicians are establishing their own procedure or surgical centers in direct competition with local hospitals.

Population demographics are having a major effect on hospital care. The fastest growing age patient population comprises individuals over age 100 years, and the Baby Boomers are just cresting their senior years. While per capita health expenditures in the United States are more than double that of the median health care costs for developed countries, we often misallocate these dollars, and the measurable outcomes our patients achieve are well below those of many other developed countries.

Recent national health insurance reform has set the stage for increased access to care with perhaps dubious promises of cost reductions and improved performance. There will be experiments with accountable care.