

ACCREDITATION AGENCIES INFLUENCE ON DRUG USE AND PHARMACY QUALITY



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Learning Objectives

1. Distinguish between the voluntary accreditation agencies in terms of their scope of hospital and managed care accreditation services.
2. Assess the impact of accreditation changes and key initiatives (in the late 1980s and early 1990s) on the evolution of continuous quality improvement and outcomes management.
3. Assess how the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards and accreditation process has impacted pharmacy and drug use quality initiatives.
4. Design a quality improvement initiative based on JCAHO standards and other performance improvement initiatives.
5. Assess the impact that National Committee for Quality Assurance (NCQA) accreditation has on the quality of health care and pharmacy services.
6. Construct a project that addresses an NCQA standard or a Health Plan Employer Data and Information Set indicator.
7. Evaluate the impact that standards of accreditation agencies and other organizations have on the pharmacist's evolving role in quality improvement.

Overview

Escalating emphasis on health care quality has prompted evolution in accreditation programs and increased scrutiny of a program's effect on quality and safety. During the past several decades, health care organizations have enhanced their focus on accountability, outcomes, and safety.

Governmental and nongovernmental agencies have taken responsibilities to set guidelines or define standards, assess compliance with standards, and continue to improve health care performance. As these standards changed to include more focus on quality performance measures related to drug use, pharmacist involvement in the quality movement continues to expand. This chapter provides an overview of accreditation agencies and quality improvement development. Focus is placed on the major accreditation agencies that influence the quality of pharmacy services and the role of pharmacy in health care improvement. The new imperatives of quality assessment and accountability set the stage for an expanding pharmacist role in the drug use system.

Accreditation

As defined in Webster's Dictionary, to accredit is "to certify as meeting a prescribed standard." Accreditation agencies often developed as voluntary organizations, setting standards to assist in self-assessment, development, training, or self-regulation. Accreditation agencies can be governmental agencies but often are businesses or services that perform the standard-setting and review process for organizations or components of an institution or system. Cost-containment also was an impetus for the initiation of many programs, such as health plan and provider performance measurement systems. In general, the accreditation agency uses experts in a particular field, as well as a highly structured process, to define and review prescribed standards of performance. The agency has a review process that measures compliance with the standards and accredits organizations that meet the standard. Accreditation often is conducted on a national scale, but there are local and state accreditation agencies as well.

Hanam MS. The Fundamentals of Accreditation. Washington, D.C.: American Society of Association Executives, 1997.

Abbreviations in this Chapter

CMS	Centers for Medicare and Medicaid Services	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
CQI	Continuous quality improvement	NCQA	National Committee for Quality Assurance
HEDIS	Health Plan Employer Data and Information Set	NPSG	National Patient Safety Goals
HMO	Health maintenance organization	SE	Sentinel event
IOM	Institute of Medicine		

Value of Accreditation

Individual health plans, health maintenance organizations (HMOs), hospitals, and other facilities choose to undergo accreditation to achieve a variety of benefits. In some instances, an organization voluntarily chooses to pursue accreditation to demonstrate achievement of performance or quality. Accreditation standards often are developed by experts and undergo peer review. These standards provide an organization with a self-assessment tool for identifying performance. Organizations can use the standards in setting performance improvement goals. The survey accreditation process often is educational for the organization and individuals, prompting improvement ideas. Some accreditation agencies offer educational seminars, publications, and consulting services about performance improvement and compliance with standards. Outside consultants often are available to assist in preparation for the accreditation surveys. An accredited organization may have a reduced cost of liability insurance coverage and may use the accreditation to assist in litigation defense. Accreditation can assist in an organization's public relations efforts. In addition, the community and referring health professionals often look at accreditation as a commitment to or benchmark of quality. Some professional organizations or other groups have developed an accreditation process to assist with self-regulation of a program or organization.

Rising health care costs and increasing focus on the financial benefits of improving quality have driven the development and adoption of accreditation standards. Many early health plan accreditation programs were developed by employer and consumer groups to assist in cost-containment. Most of these programs have expanded to enhance focus on patient outcomes. Demonstrating achievement of satisfaction and quality standards can assist in improving the health plans' membership recruitment and retention, resulting in improved financial benefits.

The enhanced focus on health care accountability, outcomes, and safety has prompted accreditation to be mandatory for some organizations to provide and obtain reimbursement for certain services. Insurance providers and financing agencies often require accreditation as a condition of participation. Accreditation can be a requirement to be eligible for insurance reimbursement, to receive financing, to participate in a managed care plan, or to bid on contracts. Accreditation by a nongovernmental agency can sometimes fulfill licensure requirements or

replace governmental surveys. Some health care organizations use their accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association to qualify for a Medicare and Medicaid certification, in lieu of undergoing scheduled Centers for Medicare and Medicaid Services (CMS) survey. Several states recognize accreditation by the JCAHO as fulfilling state licensure requirements.

There has been increased scrutiny of accreditation agencies and challenges regarding the value of their accreditation process. Criticisms revolve around the level of the standards and the review process. The standards can be complex and broad in scope, especially in mature accreditation agencies. In some cases, a whole business of training programs, publications, and consultants have developed to assist in meeting the standards and preparing for the review process. Some agencies have been criticized for setting standards at such a high level that compliance would require huge financial resources or functioning at an "ivory tower" performance level. Lack of flexibility in the standard-setting and review process also is a frequent criticism. Some government-endorsed accreditation programs are accused of having moved from a voluntary activity to another form of regulation.

Organizations that choose to or are required to be accredited are measured by the accreditation agency standards and the subscribed level of performance. Key to the value of an accreditation program is whether the established standards and the accreditation process are successful in "raising the bar"—identifying and improving the quality of services provided to patients in the accredited organizations.

Quality

Webster's Dictionary defines quality as, "peculiar in essence or nature, an inherent feature, superior in kind, degree of excellence, and a distinguishing attribute." Assessing the quality of an organization includes determining whether the organization's services are superior in kind or achieve a degree of excellence. One approach to the assessment of quality uses the structure-process-outcome conceptual framework. Using this framework, quality measures can be classified under three categories: structure, process, and outcome. Structure denotes the attributes or the physical and organizational properties of the setting in which care is provided.

Donabedian A. The quality of care: how can it be assessed. JAMA 1988;60(12):1743-8.

Assessment of the characteristics of buildings, equipment, human resources, or organizational structures (e.g., Pharmacy & Therapeutics Committee member composition) are structure measures. Process denotes the activities in giving and receiving care or what is done for patients. Process measures include treatment decisions made by practitioners delivering care. Outcome denotes the effects of care on the health status of patients and populations or what is accomplished for patients. Outcome measures include the changes to the patient's health (i.e., quality of life and functional status) and the patient's satisfaction with the provided care. The structure, process, and outcome model is based on the principles that good structure increases the likelihood of good processes, and good processes increase the likelihood of good outcomes. It is necessary to have established such a relationship before any particular component of structure, process, or outcome can be used to assess quality. Identifying outcome measures can be difficult in health care. Sometimes the effort required is not feasible or the marker to assess the final patient outcome is not reasonable. In the case of measuring chronic disease outcome, the patient is not in an acute care organization long enough to measure the effect on the disease. In addition, having a quality structure or process may not guarantee a quality outcome. For example, an organization may have a quality structure (Pharmacy & Therapeutics Committee) and process (physician selection of a formulary drug) for approving formulary drug additions. However, the patient may experience an adverse drug reaction, which may not lead to a quality outcome.

Figure 1-1 provides an example of structure, process, and outcome measures. Quality laboratory equipment (structure) increases the likelihood that a test is performed accurately. Correct procedures followed in performing the laboratory test (process) increase the likelihood of an accurate test. Correct interpretation of the test results (process) would allow for more accurate diagnosis of the patient. Accurate diagnosis and selection of a treatment option increase the likelihood of an improvement in a patient's health (outcome). Dispensing the correct drug for a patient could be a drug example. In this example, a central pharmacy with proper lighting, adequate space requirements, and appropriate font size on the label generated for the pharmacy are examples of quality structure. Quality process to verify the drug include checking the drug, dose, route, frequency, correct patient, and expiration date of the drug. The quality outcome would then be that the correct drug is dispensed for the right patient.

After a decision is made to use a structure, process, or outcome measure, four basic questions can be used in designing the measure. These questions are "Who is being assessed?" "What are the activities that are being assessed?" "How are these activities supposed to be conducted?" and "What are the activities meant to accomplish?" An example of this process could be the evaluation of pharmacist interventions regarding prophylactic antibiotic use. First,

the "Who" and "What" should be answered. A decision is made to assess whether pharmacists intervene when inappropriate prophylactic antibiotics are prescribed. How this is done is the next step. The criteria for intervention can be based on a hospital policy, guideline, or best practice. Current scientific knowledge published in the literature or currently identified best practices are the basis for assessing the appropriateness of treatment decisions. The fourth question addresses identifying what is to be accomplished. The goal is for the pharmacist to intervene when necessary to promote appropriate use. Using these four questions can assist in designing a measurement to assess the quality of a process. In this example, the measurement may be the frequency of pharmacist intervention when patients received prescriptions for prophylactic antibiotics not consistent with therapy recommended in selected published guidelines.

Once a measure is selected, a standard of acceptable performance is associated with each measure. The framework and model of measuring and improving compliance with standards has evolved throughout the past 2 decades from one of quality assurance to one of continuous quality improvement (CQI). Quality assurance is a process of setting a standard and measuring performance against that standard. Quality assurance measures a department or discipline's compliance to its individual standards. If the measurement shows that the standard is not being met, a change in the structure or process would be necessary. Quality assurance efforts were often largely driven by external requirements, such as those set by the JCAHO and National Committee for Quality Assurance (NCQA).

In the late 1980s, the model of quality improvement evolved from quality assurance to CQI. Continuous quality improvement is a process of measuring objective data, initiating change, and measuring the effect of change on performance. The goal of CQI is to improve the process or outcome and document the improved performance. The CQI model includes an emphasis on identifying and evaluating processes. Processes are mapped as flow charts, graphic representation of the sequence of steps that are performed to produce the end results. Then a cause-and-effect diagram (i.e., fishbone diagram) is created that identifies and categorizes potential causes to assist in identifying root causes and solutions to process breakdowns. The model includes a focus on measuring baselines and documenting progress. Statistical process control methods (e.g., trend lines, and upper and lower statistical control limits) are used to track progress on initiatives. Organizations strive continually to improve the care processes. The CQI process enhanced the focus on working across professional disciplines and involving all members of the organization in improving processes to meet the needs and expectation of the customer. In addition, sustained commitments from leadership to identify priorities and keep projects moving are all important to achieve improvement. Along with the evolution to CQI, the focus of performance efforts changed. Historically, the performance

Buss HE. Continuous quality improvement: adaptation of the 10-step model with post anesthesia care unit application. *J Post Anesth Nurs* 1993;8(4):238-48.

Decker MD. Continuous quality improvement. *Infect Control Hosp Epidemiol* 1992;13:165-9.

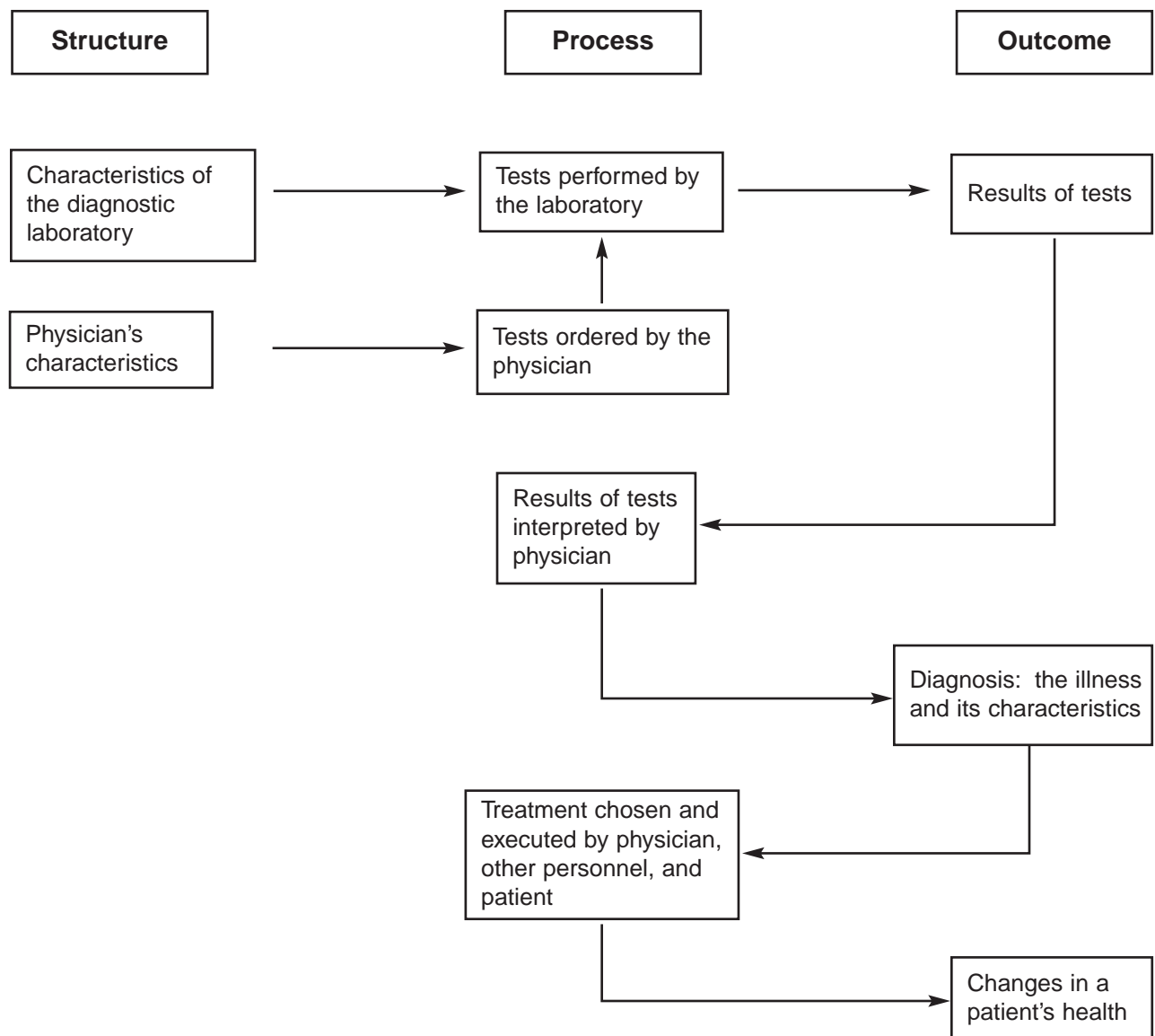


Figure 1-1. Conceptual model of structure, process, and outcome. Reprinted with permission from the Joint Commission on Accreditation of Healthcare Organizations. Donabedian A. The role of outcomes in quality assessment and assurance. QRB Qual Rev Bull 1992;18(11):356-60.

of individuals often was the focus of change efforts. With increased understanding that process problems often are the cause of the undesirable results, the focus has changed to analyzing processes for steps that are missing, redundant, or unnecessary. The evolution of these assessment models and quality improvement processes can be seen throughout the development and evolution of accreditation.

History of Health Care Organization Accreditation and Quality Efforts

Numerous standard-setting and accreditation organizations have emerged during the past century. With a lack of early public policy, private initiatives developed and voluntary accreditation organizations emerged. Governmental agencies directly operate some accreditation programs. In other cases, the governmental agency recognizes the accreditation granted by other agencies to

qualify an organization to perform designated services for governmental patients. The growth of the accreditation agencies, together with other quality movements in health care during the 20th century, increased the focus on measuring and improving the quality of health care in the United States. The rest of this section discusses selected highlights in this development.

American College of Surgeons

Several of the early health care accreditation initiatives began around the early 1900s. The American Medical Association and the Association of American Medical Colleges launched a joint effort for a national accreditation for medical schools after a 1910 American Medical Association report. During the same year, Ernest Codman, a surgeon at Massachusetts General Hospital, proposed his “end results thesis.” His dissertation discussed the benefits

of surgeons evaluating the results of surgical procedures and of making these results public. This discussion of the accountability of health care providers and the focus on the end result of care can be considered one of the first discussions of the concept of outcomes management. Medical school standardization and increased focus on medical accountability guided the way for hospital standard development. Codman led the effort in the American College of Surgeons to develop the initial Hospital Standardisation Programme in 1918. The Programme used a standards-based approach, in which compliance with standards was used to indicate the likelihood of outcomes. Hospitals quickly adopted the initial standards.

Joint Commission on Accreditation of Healthcare Organizations

In 1951, the American College of Surgeons joined several other organizations to form the Joint Commission on Accreditation of Hospitals to provide voluntary accreditation. The hospital accreditation process evolved throughout the next several decades. The name was changed in 1987 to the JCAHO. The JCAHO expanded its role to include accreditation of health care networks (including HMOs, integrated delivery networks, and preferred provider organizations) in 1994. The activities of JCAHO also extend to nonacute settings, such as long-term care facilities, clinical laboratories, ambulatory care settings, home care, and behavioral and substance abuse facilities. The JCAHO standards apply to all patients in a JCAHO-accredited organization compared to CMS standards that focus only on Medicare and Medicaid beneficiaries.

Key JCAHO initiatives impacting the quality and outcome movement include the 1987 JCAHO Agenda for Change, the 1997 ORYX initiative, and the changing focus on drug use and safety. The Agenda for Change was a JCAHO initiative to update its standards. This initiative included revision of the indicators (i.e., measures of performance) to place a greater emphasis on patient outcomes, CQI, and key functions crossing departmental lines. The JCAHO drug use indicators, developed in 1989–90, describe four major components of the drug use process (i.e., prescribing, dispensing, administering, and monitoring) and increased the focus on the drug use process as a key component of patient outcomes. There was a move from a quality assurance to a CQI focus during the 1980s and 1990s. More emphasis was placed on the use of statistical process control methods in tracking continuing performance improvement. The JCAHO began requiring performance data for accreditation of hospitals and networks. Patient safety also received increased JCAHO focus during this time. The JCAHO identified standardized National Patient Safety Goals (NPSG) for institutions to implement beginning in 2003.

The JCAHO standards are published in a series of comprehensive manuals that are specific to the type of institution being surveyed, but many of the standards are consistent across practice settings. The JCAHO Web site (<http://www.jcaho.org>) includes additional resources and answers to frequently asked questions related to JCAHO standards. Standardized core performance measures, part of

the ORYX initiative in 2002, permit comparison of the results of care across hospitals. Home Care Core Measure identification focuses on adopting the Outcome and Assessment Information Set-derived measures for home health agencies. Long-term Care Core Measure identification focuses on the adoption of the Minimum Data Set-derived measures.

American Osteopathic Association

The American Osteopathic Association implemented a voluntary hospital accreditation program in 1945. This program initially focused on the quality of patient care in institutions that provided osteopathic student training. The American Osteopathic Association also has accreditation programs for ambulatory care, substance abuse, mental health, and rehabilitation facilities.

Centers for Medicare and Medicaid Services

Another key development impacting health care organization accreditation was the establishment of Medicare and Medicaid programs in 1965. The Health Care Financing Administration was the federal agency within the Department of Health and Human Services established to administer these programs. Now named the CMS, this agency provides health insurance to elderly and disabled, and supports the joint federal-state Medicaid program. To receive Medicare funds, hospitals need to be accredited according to the Medicare Conditions of Participation for Hospitals. The CMS has established the quality improvement organizations program to monitor and improve use and quality of care for Medicare beneficiaries. Formerly known as peer review organizations, the quality improvement organizations have a performance-based contract with CMS and operate in their respective state(s) to monitor and improve patient outcomes. The quality improvement organizations are charged with ensuring Medicare beneficiary care meets standards and that Medicare funds are used effectively (e.g., only reasonable and medically necessary services are paid). The quality improvement organizations initially were charged to identify quality problems and take corrective action. Their work evolved toward a more proactive and evidence-based approach. Close collaboration of the quality improvement organization with providers and health professionals providing care is critical for improving patient care. The quality improvement organizations also monitor the hospital's patient safety initiatives, including quality assessment and improvement programs across the organization. Although CMS focuses on Medicare and Medicaid patients, the CMS requirements influence the care processes for all patients in institutions that receive Medicare funds.

Commission on Accreditation of Rehabilitation Facilities

Several other agencies developed accreditation programs about the same time that the Medicare program evolved. The Commission on Accreditation of Rehabilitation Facilities is a voluntary organization, founded in 1966, that establishes and maintains standards and performs

accreditation surveys of medical rehabilitation, behavioral health, assisted-living centers, and other ambulatory centers.

Accreditation Association for Ambulatory Health Care

The Accreditation Association for Ambulatory Health Care, formed in 1979, sets standards and accredits ambulatory health care organizations, including clinics, HMOs, surgery centers, medical groups, and other community facilities. The CMS has granted authority to the Accreditation Association for Ambulatory Health Care to certify ambulatory surgical centers for Medicare reimbursement.

National Committee for Quality Assurance

The NCQA was established in 1979 by several managed care organizations and the Group Health Association of America, and began to accredit health plans in 1991. The NCQA accredits HMOs, evaluates performance against measures, and conducts member satisfaction surveys. The NCQA Health Plan Employer Data and Information Set (HEDIS) is a list of clinical performance measures (e.g., β -blocker treatment after acute myocardial infarction) developed in 1993. These measures enable employers to compare and assess value in health plans by determining how well the plan provides care in key clinical and service areas. The HEDIS measures were used by NCQA as part of the managed care organization accreditation process starting in 1999. The NCQA assesses numerous domains of health plan performance, including effectiveness of care, access and availability to care, member satisfaction, stability of the health plan, and cost of care. In addition to increasing focus on health outcomes, the NCQA 2000 standards more specifically addressed procedures for pharmaceutical management (e.g., formulary management, exception requests, and recalls). The HEDIS measures and the NCQA accreditation results are compiled in a national database, The Quality Compass, and can be purchased from NCQA.

Key Articles

Two key articles, published in the late 1980s, focused on the outcomes of care. The term “outcomes management” was introduced in a 1988 Shattuck lecture describing the critical link between the health care services provided and patient health outcomes as measured by quality of life and health status. The benefits of having aggregate patient experience data in medical decision-making were described. In a 1988 article, “the third revolution in medical care” was defined as “the era of assessment and accountability”. The article affirmed the need to measure the results of health care services provided. These articles exemplified contemporary discussions regarding assessing the outcomes of care provided by health care providers that were incorporated into accreditation standards during the next decade. Additional patient outcome projects were started about the time of these publications.

Agency for Healthcare Research and Quality

The federal Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality) is the health services research arm of the United States Department of Health and Human Services. The Agency for Healthcare Research and Quality created the Center for Outcomes Effectiveness Research in 1989 and subsequently funded Patient Outcome Research Team projects to look at clinical treatments and patient perspectives for some common conditions in which drug use often played a major role. These federally funded projects exemplified the government’s interest in supporting research on the effect of drug use on quality of life and patient outcomes. The center has supported a Pharmaceutical Outcomes Research Program and continues to promote research in clinical economics and health outcomes measurement. The Agency for Healthcare Research and Quality developed the standardized Consumer Assessment of Health Plans Survey in 1995 to measure health plan member satisfaction. This tool has been used in NCQA assessments. The Consumer Assessment of Health Plans program now includes surveys to assess nursing homes and providers. The Agency for Healthcare Research and Quality is working with CMS to develop a standard hospital patient experience instrument. In addition, Agency for Healthcare Research and Quality has the National Guideline Clearinghouse, which is a Web-based listing of selected clinical practice guidelines.

The URAC

The URAC (formerly known as the Utilization Review Accreditation Commission also known as the American Accreditation Healthcare Commission) founded in 1990 to establish standards for managed health care. The URAC’s membership includes employers, consumers, regulators, industry, providers, and managed care entities. The URAC’s focuses on preferred provider organizations, use management organizations, and workers’ compensation programs. Numerous states have incorporated URAC accreditation into their regulatory process.

Foundation for Accountability

The Foundation for Accountability is an organization that was formed in 1995 by health care purchasers. This organization provides a clearinghouse for consumer-centered educational materials and performs research to identify the aspects of health care performance most important to consumers. The Foundation for Accountability created the Consumer Information Framework, a tool for collecting consumer-relevant measures of health care quality (e.g., access, satisfaction, and health status). The framework was adopted by NCQA, and Foundation for Accountability surveys have been integrated into health plan scorecards. Although it is not an accrediting organization, the Foundation for Accountability standards and measures are used in health plan comparisons.

Ellwood PM. Shattuck lecture—outcomes management: a technology of patient experience. *N Engl J Med* 1988;318(23):1549–56.

Relman AS. Assessment and accountability: the third revolution in medical care. *N Engl J Med* 1988;319(18):1221–2.

Collaboratives

In addition to the work of the individual agencies and organizations to develop their respective surveys and tools, the accreditation and standard-setting organizations are collaborating on developing and using quality indicators and measures. One example is the collaborative formed by the American Medical Association, JCAHO, and NCQA to create integrated performance measurement sets across health plans, provider organizations, and practitioners. Several of the accreditation agencies are adopting the tools and measures developed by other quality committees and agencies.

Hospital Accreditation

Hospitals that care for Medicare and Medicaid beneficiaries must be accredited according to the CMS Conditions of Participation to receive payments for services. The CMS recognizes accreditation by JCAHO and American Osteopathic Association as alternatives in conducting its own accreditation surveys of acute care hospitals. Other insurers frequently require hospitals to have similar accreditation. Currently, most hospitals and health systems choose JCAHO as their accreditation agency. Although accreditation by these voluntary agencies may take the place of CMS accreditation for Medicare participation, the hospitals are still subject to CMS authority and may be subject to surveys by CMS. In some states, the state health department acts as the agent of CMS for licensing and survey. In other states, the accreditation process involves several agencies. For example, in the California Consolidated Accreditation and Licensure Survey, the JCAHO, the Department of Health Services, and the Institute for Medical Quality (a subsidiary of the California Medical Association) jointly survey acute care hospitals for licensing and accreditation.

In addition to accrediting hospitals or health systems, agencies accredit departments within the hospital setting. Clinical laboratories are one such example. The CMS administers the Clinical Laboratory Improvement Amendment's laboratory certification program, and laboratories must be certified or obtain a waiver. An organization can choose to have the certification completed by one of the many accrediting organizations approved under the Clinical Laboratory Improvement Amendments to certify laboratories. The JCAHO and American Osteopathic Association are included in the approved organization list.

Hospitals associated with academic institutions for training of professionals (e.g., physicians, nurses, and pharmacists) also participate in academic and residency accreditation programs. Specific to pharmacy, the Accreditation Council for Pharmacy Education accredits colleges of pharmacy, and the American Society of Health-System Pharmacists is a national association that conducts a pharmacy residency accreditation program.

Managed Care Accreditation

As enrollment in managed care plans increased, employers and government payers began to look for

measures of quality for these plans. Although health plan accreditation is voluntary, large employers often look for accreditation as a sign of compliance with standards and as an indicator of quality. The NCQA is the primary accreditation organization chosen by managed care plans. About half of the HMOs participate in NCQA accreditation and certification; however, the majority of HMOs measure their performance using the HEDIS indicators. The URAC and JCAHO also accredit a smaller number of managed care plans.

The NCQA and the JCAHO joined with the American Medical Accreditation Program to establish the Performance Measurement Coordinating Council. The goal of the council is to establish integrated performance measurement sets across health plans, provider organizations, and practitioners. The council plans to align standard measures and data requirements to help ensure efficient collection of comprehensive performance information across all levels of the health care system.

Each of the accrediting organizations has its own scope, mission, process, and standards, yet each plays a role in identifying, assessing, and improving health care quality within its scope. There has been a dramatic change in the focus of accreditation agency standards from structure and process to outcomes during the past 15 years. The remainder of this chapter focuses primarily on the effect of JCAHO and NCQA on the quality of pharmacy services and drug use, and the role of pharmacists in quality initiatives. Other organizations impacting standards and guidelines around drug use and quality also are discussed.

Influence of JCAHO on the Quality of Pharmacy Services

The JCAHO Accreditation Program

The JCAHO accreditation program was established with the intent of improving the quality of care in health care organizations. Improving the quality of care is accomplished by setting standards and surveying the performance of organizations based on those standards. The survey consists of interviews, observation, and a review of an organization's documents.

Historically, the JCAHO accreditation survey process was prescriptive in defining the standards and the methods for an organization to achieve compliance with the standards. For example, a pharmacy department might have been asked during a survey to provide the list of departments represented on the Pharmacy & Therapeutics Committee, an indicator that there was a multidisciplinary committee managing the drug formulary. In the late 1970s, the JCAHO incorporated the concept of quality assurance into the survey process and introduced performance measures to assess the hospital's capacity to provide quality health care to patients. The JCAHO also increased its focus on processes. Pharmacists were asked to perform drug use

evaluations to evaluate if pharmaceuticals were being used appropriately. The evaluation later expanded to include all parts of the drug use process (i.e., prescribing, dispensing, administering, and monitoring). The concept of quality improvement appeared in the standards in the 1990s. Hospitals used quality improvement techniques to document improved performance over time, demonstrating actual performance rather than only their capacity to perform. The JCAHO encouraged departments of pharmacy not only to conduct drug use evaluation to assess compliance with set criteria, but also to improve continually and document the progress.

The JCAHO actively encourages health care organizations to develop CQI as part of their effort to improve the quality, and ultimately, the outcome of patient care. Examples of this effort by the JCAHO include:

- modifying standards to encourage organizations to use the concepts of quality improvement.
- using quality improvement goals, such as the Core Measures of ORYX.
- publishing NPSG to encourage reduced structure and process errors in health care organizations.
- developing tools, such as the root cause analysis for analyzing sentinel events (SEs), and the failure mode effect and critical analysis for identifying weaknesses in structure and processes.

The JCAHO Standards

The JCAHO publishes a Comprehensive Accreditation Manual for Hospitals. As of 2004, drug standards are contained in a separate chapter, the Medication Management Standards. Drug-related issues also are addressed in JCAHO safety goals, drug error process guidelines, and drug use indicators. The JCAHO significantly increased the focus on drug safety and performance improvement in the 2004 standards.

The JCAHO Medication Management Standards require a well-planned and implemented drug management system that supports patient safety and improves the quality of care. This is accomplished through:

- reducing process variation, errors, and misuse.
- monitoring drug management processes regarding efficiency, quality, and safety.
- standardizing equipment and processes across the organization to improve the drug management system.
- using evidence-based practices to develop drug management processes.
- managing critical processes associated with drug management to promote safe practices throughout the organization.
- handling all drugs in the same manner, including sample drugs.

The Medication Management Standards is divided into the six critical drug use processes (selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration, and monitoring) and two essential components (patient-specific information and

high-risk drugs). Within each standard, the JCAHO provides the standard's intention and element of performance. The JCAHO sought input from various expert panels, focus groups, and other external guideline-establishing organizations to ensure the validity of the 2004 Medication Management Standards. The Medication Management Standards and the NPSG are two of the four performance areas that are to be evaluated by JCAHO during each site survey. Therefore, pharmacists have an expanding role in establishing processes, participating in multidisciplinary teams, and improving performance to assist in achieving compliance with standards and NPSG. For example, pharmacists could lead a multidisciplinary team working to improve the safety of the patient-controlled analgesia process. This effort crosses multiple disciplines in the drug use process. Prescribing could be improved with physician use of preprinted orders. Stocking, storing, and dispensing processes could be improved through standardization of drug concentrations and volumes. Establishing a check of intravenous pump setting by a second nurse could improve drug administration safety. Pharmacist-led teams to evaluate and improve processes assist the organization in improving performance and complying with Medication Management Standards and NPSG.

The JCAHO has enhanced the focus on drug use and safety in the standards. However, in some cases, the JCAHO initially sets a standard at a minimum or basic level, or only includes a standard once the process is common in practice. For example, there were frequent publications in the 1990s that addressed the prevention of drug errors, including the 1999 Institute of Medicine (IOM) report. However, the expanded safety standards were not incorporated until the 2003 NPSG, and then were integrated into the 2004 standards. The JCAHO started with only six of the many goals that were documented in the literature. Any organization that did not address these six specific safety initiatives based on published reports in the 1990s will need to make changes to comply with the accreditation standards. Organizations should be moving forward on many other patient safety areas documented in the literature and by safety organizations. For example, implementing a computerized physician order entry system is not a requirement in the accreditation standards. However, computerized physician order entry can assist in increasing compliance with evidence-based medicine and in improving order legibility.

The presence of safety initiatives in the JCAHO standards provides impetus for organizational emphasis on safety. The Medication Management Standards assist pharmacists in justifying changes in the drug use. For example, one of the 2004 Medication Management Standards states that the organization should develop processes for managing high-risk or high-alert drugs. The element of performance states that an organization identifies high-risk and high-alert drugs and develops processes for procuring, storing, ordering, transcribing, preparing,

Joint Commission on Accreditation of Healthcare Organizations. 2003 Comprehensive Accreditation Manual for Hospitals. Oakbrook Terrace, IL: Joint Commission Resources, 2003.

dispensing, administering, and/or monitoring these drugs. Organizations have the autonomy to designate the high-risk or high-alert drugs, evaluate processes, and implement initiatives for managing these drugs. This autonomy allows organizations to review the literature and gather information at their organization on adverse drug events to determine which drugs to classify as high risk and high alert. For example, heparin procedures and control, including allowing multiple intravenous infusion concentrations to be available or having the product stocked on the floor, have varied in hospitals. With the publication of heparin errors in the literature and information gathered at its own specific site, an organization could elect to classify heparin as a high-risk drug. The organization could then focus on increasing processes to manage heparin (e.g., standardizing to one concentration of a continuous infusion bag, decreasing the number of vial concentrations stocked, and requiring double-checking of intravenous infusion pump settings before administration).

The JCAHO encourages the involvement of multidisciplinary teams in developing and implementing processes and conducting CQI. The JCAHO standards have historically included a focus on pharmacist involvement, such as in the food-drug interaction and the formulary processes. Continued multidisciplinary involvement will be needed to achieve the new standards. For example, multiple disciplines need to be involved in achieving the standard that requires drug orders to be written clearly and/or transcribed accurately. The JCAHO rationale for this standard is that many drug errors occur during the communication of orders. The elements of performance for this standard are: required elements of a drug order and whether an indication is required for identified orders; a list of abbreviations, symbols, acronyms, and dose designations; precautions or procedures for soundalike and look-alike drugs; and actions to take when an order is incomplete, illegible, or unclear. Involving a multidisciplinary team is key to developing policies and implementing practices to achieve this standard because the changes affect a large number of disciplines in each part of the drug use process. A good example of a pharmacist-led initiative that focused on inpatient order legibility was described in a study conducted to improve the quality of written orders. The pharmacist worked with the medical executive committee on an improvement plan. The organization achieved a decrease in illegible handwriting on orders from 10.9% to zero, and saw a decrease in the use of felt tip pens on orders from 13.03% to 1.37%.

The JCAHO has continued to improve the drug use standards, to increase the emphasis on processes that drive efficacy and safety, and to continue the emphasis on CQI. The 2004 Medication Management Standards continues to raise the efficacy and safety of pharmacy services in JCAHO-accredited organizations. However, in many cases, the JCAHO sets this level of performance at a minimum level for hospitals and departments of pharmacy, rather than challenging pharmacy departments to strive for greater levels of efficacy and safety. Much of the quality

improvement focuses on improving process changes that are assumed to have a positive patient outcome. The JCAHO, in collaboration with the pharmacy profession, can continue to set standards that stretch pharmacy practice and continue to improve the quality of patient care provided.

The JCAHO ORYX and Core Measures

As part of the 1987 Agenda for Change initiative, the JCAHO integrated the collection of performance measurement data into the accreditation process. Organizations can use these measures to assess their performance and compare their results to those of other organizations. This initiative was named ORYX. In the initial phase of ORYX, the JCAHO provided organizations with a large choice of ORYX measures, allowing organizations great flexibility in determining the performance measures that best fit their strategic goals. However, this large measure set did not allow valid comparison among health care organizations because organizations did not select the same measures or design, and collect the same data, even if similar measures were chosen. To address concerns regarding the need for a valid comparison among health care organizations, the JCAHO selected a small number of the ORYX measures and standardized reporting for sets of valid, reliable, and evidence-based measures, called Core Measures. The initial four Core Measures were acute myocardial infarction, heart failure, community-acquired pneumonia, and pregnancy and related conditions.

The Acute Myocardial Infarction Core Measure has nine set measures, six of which are related to drugs as illustrated in Table 1-1. Data for the Core Measure can be abstracted from data sources, such as a data warehouse, which is a storage file of health care claims. The pharmacists can help develop and implement programs to improve the acute myocardial infarction drug-related measures. The pharmacist should be a member of the multidisciplinary team designed to address this Core Measure. The pharmacist can identify opportunities in the drug use system (e.g., prescribing, dispensing, administering, and monitoring). The development of treatment protocols and guidelines can prompt the prescribing of necessary drugs, both initially and at discharge. Pharmacists can assist in developing procedures for timely dispensing and drug availability, and for communicating drug availability to the nurse to assist in timely administration. Drug administration guidelines could be developed so that drugs are administered at the right time and appropriate rate. Finally, pharmacists can assist in assessing data to ensure that processes are working efficiently and patients are receiving the appropriate drugs at discharge.

The Heart Failure and Community-acquired Pneumonia Care Measures also have drug-related components. The Heart Failure Core Measure contains an identical Core Measure to the JCAHO acute myocardial infarction measure set No. 3—to ensure patients with left ventricular systolic dysfunction receive an angiotensin-converting enzyme inhibitor before discharge. The Community-acquired

Meyer TA. Improving the quality of the order-writing process for inpatient order and outpatient prescriptions. *Am J Health-Syst Pharm* 2000;57(24):S18–22.

Table 1-1. Acute Myocardial Infarction Core Measure Set

Set Measure ID Number	Measure Short Name
AMI-1	Aspirin at arrival
AMI-2	Aspirin prescribed at discharge
AMI-3	Angiotensin-converting enzyme inhibitors for left ventricular systolic dysfunction
AMI-4	Adult smoking cessation advice/counseling
AMI-5	β -Blocker prescribed at discharge
AMI-6	β -Blocker at arrival
AMI-7	Time to thrombolysis
AMI-8	Time to percutaneous transluminal coronary angioplasty
AMI-9	Inpatient mortality

AMI = acute myocardial infarction; ID = identification.

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Pneumonia Core Measure set includes a measure that specifies that antibiotics are administered within 4 hours of admission.

The four JCAHO Core Measures were developed from evidence-based medicine and are considered best practice. Most of the measures are process measures, and following the evidence-based process will improve the likelihood of a better patient outcome. There is one measure in the Acute Myocardial Infarction Core Measure focused on outcome (i.e., inpatient mortality rate). Having both process and outcome measures is valuable as a change in outcomes is not always directly related to process improvements. Although mortality is an extremely important outcome measure, there could be many confounding factors resulting in inpatient mortality. A delay in treatment because of a delay by the patient to seek medical assistance for the acute myocardial infarction could result in increased mortality, despite the organization's processes of care. Although organizations strive to prove that their patient outcomes are superior, directly measuring patient outcomes is a challenge. The outcomes of treating a patient's chronic disease often are more long term, so acute care organizations rely on process measures of managing acute episodes of chronic disease.

National Patient Safety Goals

In 2004, the JCAHO lists seven NPSG. The JCAHO initiated seven NPSG for hospitals in 2003. Accredited hospitals are required to develop and implement strategies around each goal to reduce adverse events, including adverse drug events. The seven goals and recommendations are listed in Table 1-2. Each goal has one or two succinct evidence-based or expert-developed recommendations. The JCAHO may introduce new goals annually based on emerging priorities and is incorporating the language into the standards and scoring process.

In the first of the NPSG, the JCAHO defined three critical processes for verifying patient identification. Practitioners are expected to use two patient identifiers when drawing blood, administering drugs, or performing procedures to ensure the correct patient is selected. The patient's name, birth date, social security number, or a picture containing his or her name (e.g., driver's license) are examples of identifiers that could be verified before a procedure is conducted or a drug is administered. Another potential

solution to verifying the correct patient and drug could be through the use of bar code or machine-readable technology. The technology works by the practitioner scanning the machine-readable code on the patient wristband, on the practitioner name badge, and on the drug. Through interfacing with the drug profile, the device alerts the practitioner for any discrepancy in the patient, drug, dose, dosage form, or administration time. Pharmacists could lead this technology implementation that not only would assist in meeting the standard, but also would improve drug system safety.

The intention of the second of the NPSG is to reduce the number of errors associated with incorrect order communication. The first part of this goal is that a readback system must be part of the process of taking verbal or telephone orders for drugs or critical test results. Pharmacists should be actively involved in developing these policies and educating practitioners on the errors that result from miscommunication of verbal orders. The second part of this NPSG is a focus on standardizing abbreviations, acronyms, and symbols. Written abbreviations have been identified as the root cause for significant adverse drug events. In 2004, the JCAHO published a minimum list of abbreviations that accredited organizations need to eliminate in orders and the medical chart. In addition, the JCAHO requires accredited organizations to identify and list three additional abbreviations if the organization did not already have abbreviations beyond those required not to be used. Unsafe drug or drug-related abbreviation lists also are available from organizations, such as the Institute for Safe Medication Practices. Pharmacists should be familiar with unsafe abbreviations listed in the literature and found in the organization's drug error reports and be involved in identifying and routinely updating the organization's list of drug abbreviations, acronyms, and symbols that are unacceptable for use in the medical record.

The third of the NPSG involving drugs is to improve the safety of using high-alert drugs. This goal includes removing concentrated electrolytes from patient care units and standardizing and limiting the number of drug concentrations the organization has available. Pharmacists could lead a multidisciplinary team in identifying the high-risk drugs used in their organizations and developing strategies for error reduction in the drug use process. The team can identify high-risk drugs by investigating the

Table 1-2. 2004 National Patient Safety Goals

2004 National Patient Safety Goals	Evidence- or Expert-based Recommendations
Improve the accuracy of patient identification	Use at least two patient identifiers (neither to be patient's room) whenever taking blood samples or administering drugs or blood products Before the start of any surgical or invasive procedure, conduct a final verification process, such as a "time out", to confirm the correct patient, procedure and site, using active not passive communication techniques
Improve the effectiveness of communication among caregivers	Implement a process for taking verbal or telephone orders or critical test results that require a verification "readback" of the complete order or test result by the person receiving the order or test result Standardize the abbreviations, acronyms, and symbols used throughout the organization, including a list of abbreviations, acronyms, and symbols <u>not</u> to use
Improve the safety of using high-alert drugs	Remove concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, and sodium chloride > 0.9%) from patient care units Standardize and limit the number of drug concentrations available in the organization
Eliminate wrong-site, wrong-patient, wrong-procedure surgery	Create and use a preoperative verification process, such as a checklist, to confirm that appropriate documents (e.g., medical records and imaging studies) are available Implement a process to mark the surgical site and involve the patient in the marking process
Improve the safety of using infusion pumps	Ensure free-flow protection on all general use and patient-controlled analgesia intravenous infusion pumps used in the organization
Improve the effectiveness of clinical alarm systems	Implement regular preventive maintenance and testing of alarm systems Ensure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit
Reduce the risk of health infections	Comply with current Centers for Disease Control and Prevention hand care/hygiene acquired guidelines Manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with a health care-acquired infection

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organization's error reports, reading published literature, or networking with colleagues. The team should then develop strategies to reduce the potential of adverse drug events occurring with these drugs. For example, fatalities resulting from the direct intravenous administration of concentrated potassium chloride were reported for many years, and some hospitals removed concentrated potassium chloride from patient care units based on those data. Based on this goal, in addition to concentrated potassium chloride, pharmacists should remove other concentrated electrolytes from the patient care units. Pharmacists also could improve drug safety through standardizing concentrations of high-alert drugs used in the organization. For example, heparin is available in a large number of concentrations and vial sizes, with many of the products having similar packaging. Selecting to stock only a few necessary concentrations or vial sizes will reduce the likelihood that the incorrect amount of heparin is administered.

The fourth of the drug-related NPSG is to improve the safety of infusion pumps. Pumps with free-flow administration should be eliminated. Pharmacists should participate in the team evaluating and selecting infusion pumps for the organization. Pump technology is evolving to

allow programming of standardized concentrations and to use machine-readable coding printed on drug labels. These advances, in addition to interfaces with drug profiles, will improve the safety of high-risk drug administration.

The publication of the NPSG and the JCAHO requirement for hospitals to establish safe drug use processes should positively affect the pharmacist's ability to influence other practitioners to make improvements in the drug use system. Pharmacist activities to promote safe drug use have moved to the forefront of practice, and practitioners and health care administrators are beginning to take a stronger stand to support these activities. Pharmacists and organizations will need to continue to review systems, identify unsafe practices, and improve the drug processes. Because all JCAHO-accredited hospitals are working on these safety areas, sharing ideas and publishing results of improvement efforts can assist in improving care on a broader scope. Pharmacists also should provide feedback to JCAHO on improving the existing NPSG and ideas for future goals.

Sentinel Event and Root Cause Analysis

Sentinel events represent the most serious reported adverse events that occur in health care organizations. The JCAHO defines an SE in its SE policy as “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.” Serious injury specifically includes loss of limb or function. The phrase, “or the risk thereof”, includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. The purpose of the JCAHO SE policy is stated as:

- to have a positive impact in improving patient care and preventing SEs.
- to focus the attention of an organization that has experienced an SE on understanding the causes that underlie the event, and on making changes in the organization’s systems and processes to reduce the probability of such an event in the future.
- to increase the general knowledge about SEs, their causes, and strategies for prevention.
- to maintain the confidence of the public and accredited organizations in the accreditation process.

The policy states that when an SE has occurred, the organization is required to perform a root cause analysis of the event. A root cause analysis is a process for identifying the underlying causes for a performance variation or a process breakdown. Typically, a team is convened that consists of individuals directly involved in the error and individuals from other disciplines involved in the process surrounding the SE. When conducting a root cause analysis, a flow diagram and a fishbone diagram often are used to assist in analyzing the process and identifying potential solutions. A root cause analysis is intended to focus on system processes, not individuals. Once the process breakdowns are identified, solutions are identified and implemented to prevent future occurrences.

Sentinel events involving unanticipated deaths; serious injury; or other selected events, such as suicide, infant abduction, and wrong site surgery, must be reported to JCAHO. Drug errors are listed as one of the top five SE types reported to the JCAHO. Organizations have 45 days from the date of the event or from the time of becoming aware of the event to prepare and submit a root cause analysis and action plan. If the root cause analysis is not acceptable, the JCAHO may place the organization on accreditation watch.

Since January 1995, the JCAHO has tracked data on SEs. Figure 1-2 shows the root causes for SEs from 1995 to 2002. Through accumulation of SE reports, the JCAHO has been able to communicate to hospital organizations about the seriousness of events and has used these data in developing the NPSG. The JCAHO began publishing the Sentinel Event Alert newsletter in 1998. The newsletter reports specific SEs and includes underlying causes and recommended steps to prevent the SE from occurring. Drug-related alert newsletter topics have included concentrated potassium chloride, potentially dangerous abbreviations, look-alike drug names, and high-risk drugs. The JCAHO noted a decline from 11 SEs reported in the 2 years before the release of the concentrated potassium

chloride alert in 1998 to two SEs reported in the next 4 years. However, not all hospitals changed their practices as a result of the alert, and patient deaths continued to be reported from concentrated potassium chloride and other electrolytes, prompting inclusion of this item in the NPSG. Pharmacists should regularly review the newsletter for SEs identified in other organizations, assess their organization’s risk for the specific SEs, and implement strategies to reduce the risk of the SE occurring.

Failure Mode Effect and Critical Analysis

A Failure Mode Effect and Critical Analysis is a structured process to identify, prioritize, and resolve process variations that may be vulnerable to errors. This process can be initiated before or after a negative outcome has occurred. An organization may determine that a drug use process has a high potential for error (e.g., chemotherapy process) and put together a team to conduct a Failure Mode Effect and Critical Analysis of the process. This team would identify areas where an organization may be vulnerable to errors and make improvements in the process to avoid errors. Beginning in 2002, the JCAHO requires organizations to conduct at least one process review annually using the Failure Mode Effect and Critical Analysis methodology. Figure 1-3 is an example of a Failure Mode Effect and Critical Analysis.

When conducting a Failure Mode Effect and Critical Analysis, weaknesses are identified in the drug use process and listed as potential failure modes. After all potential failure modes are identified, each of the failure modes is scored in three categories: potential effect on patient, frequency of failure mode, and likelihood of failure reaching the patient. Each category is given a numerical score of 1–10, with 10 being very high for that category. For each failure mode, the scores of the three categories are multiplied, resulting in an overall point total for that failure mode—called the criticality of the failure mode. The modes with the highest criticality points are identified as being the highest risk, and are prioritized first for action. Action plan, people responsible for completion of the action plan, and targeted completion dates should be identified. When actions are completed, it is important to determine if improvement has occurred in the process, specifically whether there has been an improvement in quality, a decrease in practice variation, or a reduction in errors. Pharmacists should identify drug-related processes for analysis and lead these Failure Mode Effect and Critical Analysis teams.

Networks and Preferred Provider Organizations

Although JCAHO primarily is known for accreditation of hospitals and associated facilities, it has accredited health plans, preferred provider organizations, and networks for almost 10 years. The JCAHO has a set of standards for accreditation of managed care plans and integrated delivery networks, and a separate set for preferred provider organizations. In general, the standards are quite broad and do not specifically refer to pharmaceutical management or pharmacy services. The accredited organizations can choose their performance measures and are not

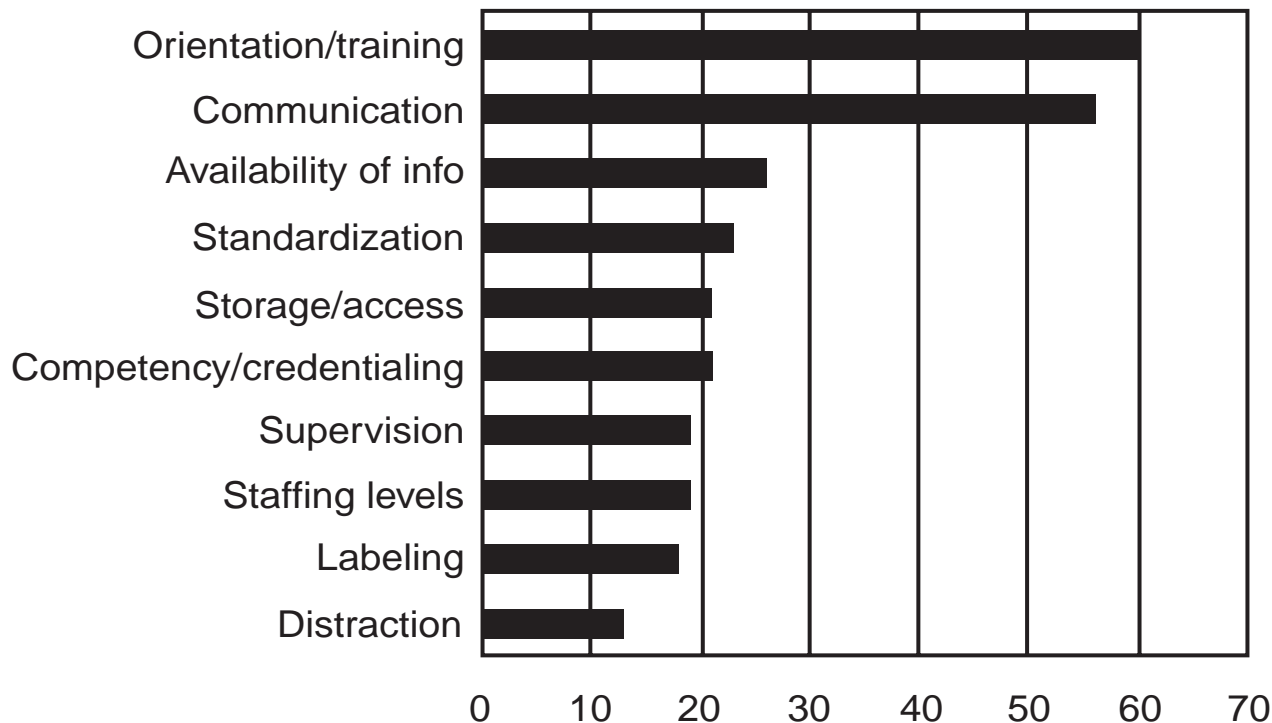


Figure 1-2. Identified root causes of medication errors 1995–2002 (percentage). Reprinted with permission from the Joint Commission on Accreditation of Healthcare Organizations, 2003. <http://www.jcaho.org/accredited+organization/ambulatory+care/sentinel+events/rc+of+medication+errors.htm>.

required to submit specific population data sets as of the 2003–04 standards.

The JCAHO has influenced the quality of health care by setting a minimum level of performance for all accredited organizations and encouraging these organizations to focus on the processes of delivering care to patients. Process improvements are the major focus of the Medication Management Standards, the ORYX initiative, the NPSG, Sentinel Event Alerts, and Failure Mode Effect and Critical Analysis. Through these initiatives, the JCAHO prompts organizations to analyze or measure processes in their organization to identify opportunities that may not have been identified otherwise. The focus on performance improvement promotes continual process improvement. Although improving processes of care may lead to improving patient outcomes, the JCAHO and organizations should not rely solely on process improvement measures. The JCAHO should place more emphasis on measuring patient outcomes. In addition, the JCAHO should be setting and raising standards to a higher level to prompt organizations to perform at optimal levels. Through these mechanisms, the JCAHO accreditation process will spur organizations continually to improve the quality of pharmacy services provided and the quality of patient care delivered.

The NCQA Influence on the Quality of Pharmacy Services

The NCQA Accreditation

In the early years of NCQA, the managed care organizations were slow voluntarily to seek accreditation from this committee. The large fee-for-service base and the low number of people enrolled in managed care plans at the time contributed to the lack of demand for accreditation. Accreditation by NCQA became more popular in the late 1980s. Employer and consumer groups developed benchmarks to assist in cost-containment and enhanced the focus on the quality of health care provided by health plans. Managed care competition and cost pressures also were growing. Employers and consumers feared that managed care organizations would reduce the level of service and the quality of services provided because of the increased competition to drive costs down. Therefore, managed care plans had more incentives to pursue accreditation and develop measures to benchmark and demonstrate quality. The NCQA has evolved to become the primary accreditation agency for managed care organizations. The NCQA assesses, measures, and reports information to consumers and purchasers about a health plan’s performance.

The NCQA accreditation is voluntary and is available to all types of managed care organizations (e.g., preferred

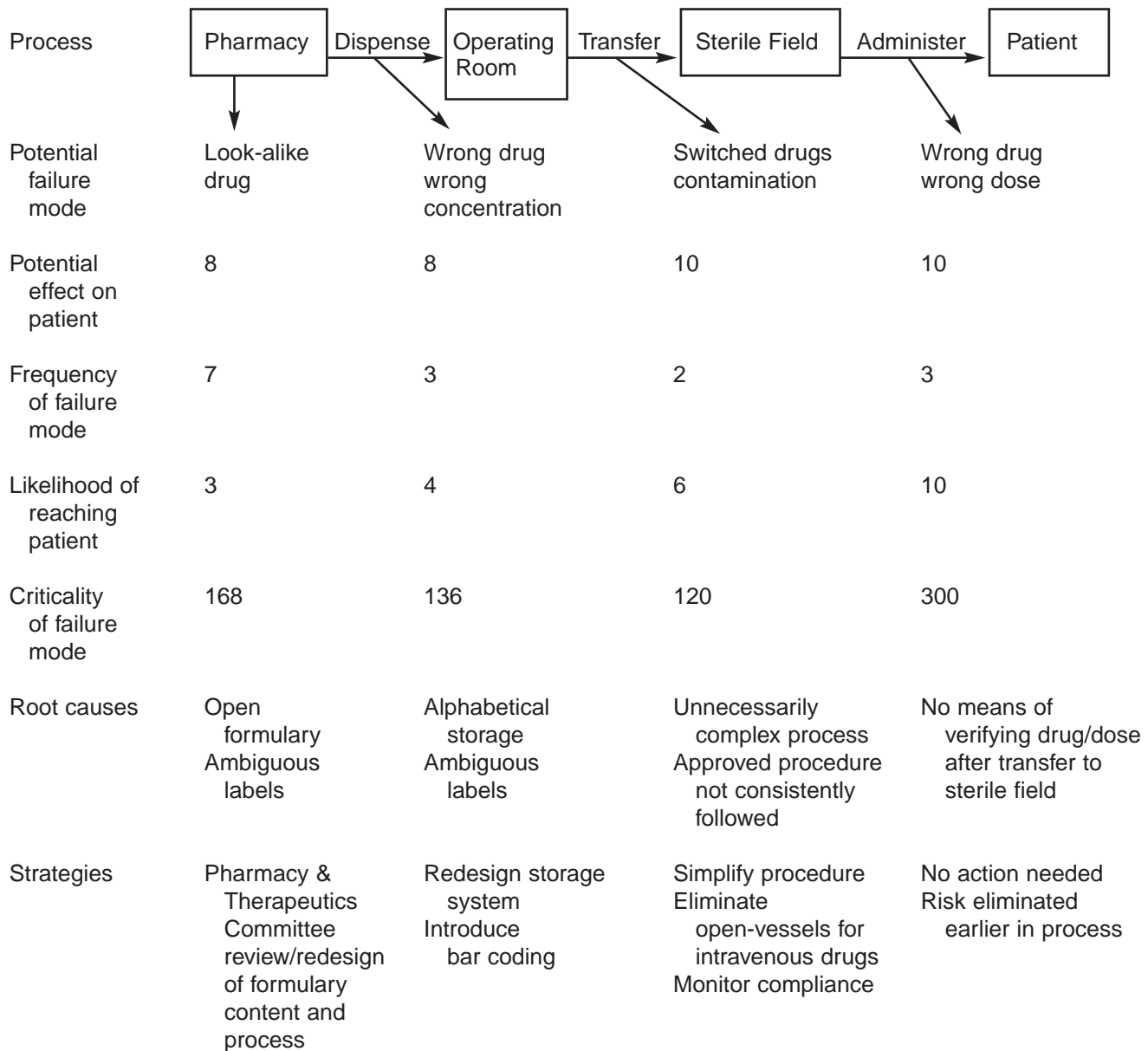


Figure 1-3. Example of a Failure Mode Effect and Critical Analysis (FMECA) for a hypothetical medication use process in the operating room. Reprinted with permission from the Joint Commission on Accreditation of Healthcare Organizations, 2003. http://www.JCAHO.org/accredited+organizations/patient+safety/fmecca/fmecca_chart.pdf.

provider organizations and HMOs). The process of accreditation evaluates six areas: quality management, physician credentialing, member rights and responsibilities, preventive health services, utilization management, and medical records. Each of the six areas has standards that are scored during the accreditation survey. Within the six areas scored for accreditation, the utilization management and quality management sections particularly relate to pharmaceutical services.

Utilization Management Standards

The Utilization Management 13 standard, Procedures for Pharmaceutical Management, states that the organization ensures that its procedures for pharmaceutical management, if any, promote the clinically appropriate use of pharmaceuticals. There are seven elements within the standard that describe the requirements:

- pharmaceutical management policies and procedures
- pharmaceutical restrictions and preferences
- pharmaceutical patient safety issues

National Committee for Quality Assurance. 2003 Standards and Guidelines for Certification in Utilization Management. Washington, D.C.: NCQA, 2003.

- review and updates of procedures
- involvement of pharmacists and appropriate practitioners
- availability of pharmaceutical management procedures
- considering exceptions

The first element, pharmaceutical management policies and procedures, states that organizations must have criteria for the use of pharmaceuticals and a process based on clinical evidence. This standard includes the development of a process for approving drugs to the formulary (e.g., Pharmacy & Therapeutics Committee) and reviewing drugs within classes to identify criteria for prior authorization or substitutions.

The second element states there must be a policy that addresses restrictions and preferences for pharmaceuticals. This standard includes policies on limits or quota on refills; a policy for practitioners to provide information on exception requests (e.g., nonformulary pharmaceuticals); and processes for generic substitution, therapeutic interchange, and established protocols.

The third element of the Utilization Management 13 NCQA standard refers to the need for a system to identify and classify the initiative to improve patient safety. Drug-drug interactions and specific managed care-defined alerts are communicated at the point of dispensing to the dispensing provider (e.g., pharmacist). Provision of the Food and Drug Administration's actions on recalls to clinicals also is part of this element. Administration's actions on recalls are part of this element. The managed care organization may adopt an external source to identify drug-drug interactions and specific interactions, or develop their own. In addition, the managed care organization must provide information on recalled products to pharmacists, patients, and providers.

The fourth element requires the review and updating of pharmaceutical management procedures annually or as new pharmaceutical information becomes available. This requirement attempts to ensure that the selection of pharmaceuticals for formulary status is based on the most up-to-date scientific information or publication of best practices. In addition, although a time frame or methodology for review of a new pharmaceutical is not specified, the review must not be a barrier to member access to the pharmaceutical.

The fifth element requires that pharmacists and appropriate practitioners be involved in the development and periodic update of policies and procedures. This includes an annual review of established policies, such as preferred pharmaceuticals and the Pharmacy & Therapeutics Committee.

The sixth element, availability of pharmaceutical management procedures, requires the managed care organization to communicate updated pharmaceutical management procedures to individual practitioners annually or when changes occur. Information that must be available includes copayment requirements; list of preferred pharmaceuticals; prior authorization criteria; procedures for

generic substitution; and any requirements, restrictions, and limitations or incentives that apply to the use of certain pharmaceuticals. This information can be mailed or published on the Internet. Written information, pertaining to the publication of pharmaceutical management procedures on the Internet, must be mailed to practitioners.

The final element of the standard states that a managed care organization has an exception policy and procedures for noncovered pharmaceuticals. These procedures include making exceptions based on medical necessity, obtaining the medical necessity information from providers, using appropriate pharmacists and practitioners to consider exception requests, handling the request in a timely manner, and if exceptions are denied, communicating reason for denial and explaining the appeal process.

Managed care organizations use pharmacists or can contract with pharmacy benefit management organizations to assist in meeting these standards. When developing or revising the formulary, pharmacists or the pharmacy benefit management organization should use evidence-based information or best practices in approving drugs to the formulary and reviewing drugs within classes to identify criteria for prior authorization and substitutions. Formulary decisions include selecting whether a formulary is open (i.e., list of recommended pharmaceuticals), closed (i.e., covering only approved pharmaceuticals), or tiered (i.e., applying a lower copayment to preferred pharmaceuticals). Once decisions are made about the formulary, the pharmacy benefit management organization can manage the services through online claim adjudication.

Many of the Utilization Management 13 standards focus on structure (e.g., establishment of a Pharmacy & Therapeutics Committee, policy on restrictions, or prior authorization.) Several standards focus on the pharmaceutical management processes (e.g., development of the formulary system based on clinical evidence and drug-drug interaction intervention). Similar to the JCAHO standards, the structure and process standards in Utilization Management 13 have a positive influence on drug use and pharmacy services. The managed formulary process incorporates a safety and efficacy review for drugs used in the ambulatory setting. The standards also focus on the safe use of pharmaceuticals. Pharmacists in the community are responsible to contact the prescriber when a drug-drug interaction or other safety message programmed by the pharmacy benefit management organization appears on the computer, warning the pharmacists about dispensing the drug. Although pharmacists in the community often are not involved in the managed care organization HEDIS improvement efforts, these pharmacists certainly could be involved in ensuring that patients are taking appropriate drugs for their diagnosis (e.g., lipid-lowering agents for hypercholesterolemia) or in assessing drug outcomes or noncompliance.

Quality Management Standards

This section of the NCQA accreditation standards contains four quality improvement standards that offer an opportunity for pharmacist involvement. These four standards and associated questions are:

- **Clinical Practice Guidelines**—Does the plan establish practice guidelines for its practitioners to follow? Are practitioners involved in the creation of the guidelines? Are the guidelines reviewed at least every 2 years? Does the plan measure its performance against guidelines annually?
- **Assistance for People with Chronic Health Conditions**—Does the plan offer programs and services to members with chronic health conditions? Are practitioners made aware of and educated about these programs?
- **Clinical Measurement Activity**—Does the quality improvement program focus on meaningful clinical activities? Is the plan using data collection, measurement, and analysis to assess its performance on three nonpreventive acute or chronic care clinical issues, including one behavioral health issue? Does the plan identify and prioritize improvement opportunities?
- **Intervention and Follow up for Clinical Issues**—Does the plan follow up on opportunities for improvement identified through measurement and analysis of clinical performance? Does the plan assess the effectiveness of its interventions?

Health plan or pharmacy benefit management organization pharmacists could assist the health plan in the creation of drug-related clinical guidelines or disease management standards. Published best practices and pharmacoeconomic studies can be used to develop the practice guidelines or disease management standards. The American Society of Clinical Oncology guidelines provide examples of best practice guidelines that can be useful in assessing quality of care. A recent study reported that one-third of respondent HMOs reported use of the American Society of Clinical Oncology guidelines, with higher rates of usage by larger HMOs and by those with higher NCQA ratings. Respondent HMOs valued guidelines and used several methods of guideline identification and implementation.

The HEDIS

The NCQA, in developing performance and outcome measures, produced the data set known as HEDIS. The HEDIS is designed to provide information on health plan performance and to assist consumers and purchasers in making informed health plan selections. The NCQA released its first version, HEDIS 2.0, in 1993. It has undergone several revisions since its inception, and the current version is HEDIS 2004. Within HEDIS 2004, the performance measurements are listed in six categories: effectiveness of care, access and availability, satisfaction

with experience of care, health plan stability, use of services, and health plan descriptive services. Under each category is a measurement and product line.

The HEDIS 2004 drug-related measurements are childhood and adolescent immunization status, appropriate treatment for children with upper respiratory infection, controlling high blood pressure, β -blocker treatment after a heart attack, cholesterol management after acute cardiovascular events, use of appropriate drugs for people with asthma, antidepressant drug management, flu shots for adults 50–64 years of age, and pneumonia vaccination status for older adults. Managed care organizations measure and report their compliance with the HEDIS measures.

Health plan, pharmacy benefit management organizations, or community pharmacists can work with the health plan to retrieve combined claims data (i.e., medical, laboratory, and pharmacy data) for use in selecting a HEDIS measure for improvement, targeting changes, and tracking progress. Education and intervention programs can be designed to improve compliance with best practices. In one study, community pharmacists were able to identify patients with left ventricular systolic dysfunction who were not receiving an angiotensin-converting enzyme inhibitor. The pharmacists contacted physicians and were able to increase the use of angiotensin-converting enzyme inhibitors by 23%. In the same study, these pharmacists were able to identify patient outcome projects to assist health plans improve their HEDIS scores. The pharmacists conducted a pediatric callback program to ensure patients were being treated with the correct antibiotic and were remaining compliant with the regimen. The pharmacists were able to improve care through proper dosage selection, discontinuation of inappropriate therapy, and identification of adverse drug events. The authors noted that a key to success was the selection of projects not solely based on HEDIS measures, but services that the community desired. This is an example of how pharmacists practicing in the community setting can work with a health plan to increase compliance with HEDIS measures and have a positive affect on the overall health of the community they serve.

A study that compared accredited health plans to plans that were nonaccredited and to those health plans denied accreditation demonstrated that NCQA accreditation was positively associated with some measures of quality. The study found accredited health plans performed significantly ($p < 0.05$) better in one of the nine HEDIS measures (e.g., follow up after hospitalization for mental illness) compared to health plans denied accreditation. Accredited health plans performed significantly ($p < 0.05$) better in five of the nine measurements compared to nonaccredited health plans. These five measures were childhood immunization, breast cancer screening, cervical cancer screening, prenatal care, and diabetic eye examination. Although accredited health plans performed significantly better in the five measurements, the authors noted that the magnitude of the difference was modest. In addition, accredited plans were in

National Committee for Quality Assurance. Standards and Guidelines for the Accreditation of Managed Care Organizations. Washington, D.C.: NCQA, 2002.
Bennett CL, Somerfield MR, Pfister DG, Tomori C, Yakren S, Bach PB. Perspectives on the value of American Society of Clinical Oncology clinical guidelines as reported by oncologists and health maintenance organizations. *J Clin Oncol* 2003;21(5):937–41.

the bottom 10% of scores for some of the HEDIS measures. Accreditation did not necessarily ensure higher HEDIS measure scores or improve patient treatment or quality of care.

In addition to meeting the HEDIS scores for accreditation, an organization also should review the literature in setting programs and goals. Similar to the measures used by other accreditation agencies, the HEDIS measures may lag behind evidence-based literature or current guidelines. The timing of the publication or review of the measure, or the agency's choice to set standards at a minimum level of performance, can be contributing factors. For example, the HEDIS 2004 measure for comprehensive diabetes care identifies several indicators, including glycosylated hemoglobin. Patients in a health plan with an glycosylated hemoglobin result of less than 9% are considered compliant with the measure. A study published in 2003 states that treatment regimens that reduced average glycosylated hemoglobin to 7% (1% above the upper limits of normal) were associated with fewer long-term microvascular complications. Therefore, in addition to reporting compliance with the HEDIS standard, the plan should use the more current glycosylated hemoglobin target for this population as a measure of performance improvement. Thus, HEDIS versions should be updated continually. Another example is the measure used to evaluate if patients are taking long-term control drugs as part of their treatment for persistent asthma. Current literature states that inhaled corticosteroids are preferred because they are the most effective anti-inflammatory drugs available for treating the underlying inflammation characteristic of persistent asthma. For patients with mild persistent asthma, other long-term drugs (e.g., cromolyn, leukotriene modifiers, nedocromil, and theophylline) could be used, but these drugs have not been as effective as inhaled corticosteroids. The HEDIS measure should be revised to state that patients with persistent asthma receive inhaled corticosteroids. These two examples illustrate the need for regular updating of the measures to reflect current literature and for organizations to use current literature recommendations in setting performance improvement targets.

In addition to focusing on the underuse of drugs, the HEDIS measures could be expanded to include more focus on overuse and misuse of drugs to promote appropriate and cost-effective care. For example, the HEDIS measures could focus on the misuse or overuse of montelukast for mild persistent asthma. Montelukast has not been as effective as inhaled corticosteroids; therefore, the evidence-based approach supports prescribing inhaled corticosteroids for most patients. Pharmacists should advocate for more aggressive NCQA measures to improve drug use. This advocacy includes working with state and local pharmacist organizations as well as health coalitions to encourage the NCQA to set higher measures. Pharmacists

also can work directly with employers to set and achieve the higher standards of care that are published in the literature. Regardless of the approach, pharmacists should continue to encourage the NCQA and other accreditation agencies to set measures at a level to achieve optimal patient outcomes rather than at a minimum level that achieves less than optimal outcomes.

Quality Compass, Health Plan Report Cards, and Quality Profiles

The NCQA Quality Compass is a database that includes HEDIS scores and accreditation status of managed care organizations. Consumers or purchasers can review the NCQA Quality Compass report to evaluate a health plan's performance.

The NCQA Health Plan Report Cards also provide information on the quality of health plans. The report cards rate health plans in five areas (access and service, qualified providers, staying healthy, getting better, and living with illness) and list health plans' accreditation outcomes. The report cards, published on the NCQA Web site (<http://www.ncqa.org>), are designed to provide an evaluation of clinical quality, member satisfaction, and a comprehensive assessment of key systems and processes. Consumers or purchasers of care can use the report cards to evaluate the performance of various health plans when determining which plan is best suited for them.

The NCQA produces the publication, *Quality Profiles*, which provides details of how NCQA-accredited health plans have implemented various quality improvement activities. This publication provides practitioners with useful tools and recommendations for program implementation.

Comparison with JCAHO

The previous sections discussed the JCAHO and NCQA accreditation standards. These agencies overlap in that both provide managed care accreditation. However, the majority of managed care organizations that choose to be accredited are accredited by NCQA. The JCAHO managed care accreditation was developed after NCQA and has a small share of this market. One paper presented the results of a survey that assessed purchaser perceptions of accrediting bodies that lend some insight into NCQA's market dominance. The survey results indicated that respondents considered themselves less knowledgeable about JCAHO. Fifty-nine percent of the purchasers stated that they exclusively used NCQA accreditation in the plan selection process, compared to only 6% who said they exclusively used JCAHO accreditation. Twenty-four percent of the respondents indicated that they used both for plan contracting. Twelve percent indicated that they used NCQA, JCAHO, and the URAC accreditation decisions for contracting. The flexibility and adaptability of the survey

American Diabetes Association. Standards of medical care for patients with diabetes mellitus. *Diabetes Care* 2003;6:S33–50.

Williams SG, Schmidt DK, Redd SC, et al. Key clinical activities for quality asthma care: recommendations of the national asthma education and prevention program. *MMWR Recomm Rep* 2003;52(RR-6):1–8.

Scanlon DP, Hendrix TJ. Health plan accreditation: NCQA, JCAHO, or both? *Manag Care Q* 1998;6(4):52–61.

process was one of the perceived advantages of JCAHO accreditation. Respondents also indicated that survey team visits to the care sites and greater incorporation of “best practices” were advantages of JCAHO. Respondents believed that one of the principle advantages of the NCQA accreditation process was its use of a standardized data set for measuring plan performance, likely because of an association of the HEDIS measures as part of the NCQA process. Survey respondents indicated that NCQA was the most qualified, had the best survey process, and emphasized and valued plan quality improvement to a greater degree.

The NCQA currently is the primary accreditation agency for managed care plans; however, the JCAHO process may be appealing to some organizations that have contractual partners (e.g., hospitals and long-term care facilities) already accredited by the JCAHO under separate programs. With the current low profile of JCAHO in the managed care accreditation arena, it is difficult to predict whether JCAHO can become a significant player. Although having competition usually is beneficial to drive improved quality, the presence of multiple standards for organizations can be confusing.

Similar to JCAHO, the NCQA accreditation survey has many measures of quality that focus on the processes of care rather than on patient outcome. Effectively implementing HEDIS measures (e.g., the hypertension measure to reduce the population’s risk for heart disease and stroke) provides an opportunity for managed care organizations to demonstrate to the public their commitment to health maintenance, which is one of the foundations of managed care. Because the HEDIS measures are evidence-based, improvement in HEDIS scores should improve drug therapy and, thus, improve patient outcomes. There is little published literature on the impact of NCQA accreditation or the inclusion of the HEDIS measures in the accreditation process on improving quality outcomes. The previously discussed study indicated that NCQA accreditation was positively associated with improved quality, but did not necessarily ensure quality.

Influence of Other Standard-setting Organizations

In addition to the major accreditation agencies, there are numerous other organizations that are developing standards to drive health care quality improvement and drug safety activities.

Consumer-oriented Organizations

With the increased focus on safety and quality of health care services provided, consumers have become more aware and involved in health care choices. Consumer-oriented organizations have developed to assist consumers in accessing information about health care quality, in assessing

managed care plans, and in advocating consumer interests with agencies developing standards and policies. The Foundation for Accountability has conducted research on consumer expectations of health plans and providers, and developed the Consumer Information Framework to collect consumer-relevant quality measures. The Foundation for Accountability provides consumer-oriented educational materials and provides advocacy for consumer protection and managed care standards. The Consumer Coalition, formed in 1993, is another organization focused on quality and consumer protection. The coalition developed *The Quality Imperative: Model State Legislation for Managed Care*, a document to assist consumers in advocating health plan quality standards and consumer participation in health care policy at the state and national level.

Employer Groups and Coalitions

Employers and other purchasers of health care have formed coalitions to use their purchasing power to enhance the return on their health care expenditures. Employer coalitions encourage providers to enhance the quality of care provided to employees, and thereby reduce the employer cost of providing the employee benefit. In addition to establishing standards and performance measures, many coalitions are developing provider incentives for achieving set levels of performance and safety. Many state coalitions combine employers, labor groups, governmental agencies, health care providers, consumer or community organizations, professional societies, and/or voluntary agencies to form statewide partnerships to improve health care. Examples of these organizations include the Massachusetts Health Council, Greater Detroit Area Health Council, and the Michigan Health and Safety Coalition.

One well-known coalition is The Leapfrog Group, founded by the Business Roundtable, a national association of Fortune 500 CEOs. Leapfrog is a coalition of large employers, health plans, physicians, and other health care groups. As of 2003, The Leapfrog Group was composed of more than 130 public and private organizations that provide health care benefits, representing 33 million Americans and more than \$56 billion in health care expenditures. The Leapfrog Group identified three practices, documented in the scientific literature, that could reduce preventable mistakes in hospitals, and whose presence could be easily ascertained. Leapfrog began to collect data and report hospitals’ progress toward the implementation of these three patient safety practices: computerized physician order entry, evidence-based hospital referral, and intensive care unit physician staffing. Two major goals of computerized physician order entry are to decrease mistakes from illegible handwriting and to allow ordered drugs to be automatically checked against patient information. Implementation of computerized physician order entry should reduce drug mistakes and provide for improved drug use. Pharmacists need to take a leadership role in planning and implementing computerized physician order entry to optimize the drug process and patient outcomes. Because of the large and

The Leapfrog Group. Available at <http://leapfroggroup.org>. Accessed December 20, 2002.

increasing membership and purchasing power of The Leapfrog Group, and the plan to attach the results of the three safety practices to provider incentives, providers are actively working to implement these safety practices. The Leapfrog Group released Bridges to Excellence Initiative, in 2003 to provide physician incentive payments for performance, starting with three areas: diabetes care, cardiovascular care, and patient care management. Some HMOs and physician groups are employing pharmacists to assist in managing these chronic patient populations. Refer to the Medication Safety chapter for a full discussion of The Leapfrog Group measures. In addition, a full discussion of employer and local health purchasing coalitions can be found in Employer Influence on Benefit Design chapter.

National Quality Forum

The National Quality Forum was created in 1999 to develop and implement a national strategy for health care quality measurement. The National Quality Forum has private and public membership, representing all sectors of the health care industry and stakeholders. Endorsement of quality measures for national use and promotion of those measures are two National Quality Forum goals. The National Quality Forum released a list of 31 measures in 2002 and eight more in 2003 to assess the quality of hospital care. These 39 measures comprise the National Quality Forum's initial set of national voluntary consensus standards to allow comparison of the quality of care in acute care hospitals across the nation. The 39 measures are in the areas of acute coronary syndrome, heart failure, pneumonia, patient safety, pregnancy/childbirth/neonatal conditions, surgical complications, pediatric conditions, and smoking cessation. Examples of drug-related measures include aspirin and β -blocker treatment for patients who have had an acute myocardial infarction, timing of prophylactic antibiotic administration, and screening for influenza or pneumococcal vaccinations for patients with pneumonia. The National Quality Forum also released a framework for implementing, reporting, and maintaining the measures. Standardized measures should allow benchmarking and sharing of best practices.

Funding for this work included CMS, Agency for Healthcare Research and Quality, the Department of Veterans Affairs, several foundations, and other organizations. These organizations developed these voluntary national consensus standards to begin the work of establishing consistent quality measures for hospital care. With about half of the 39 measures relating to drug use or timing, these measures provide significant opportunity for pharmacist leadership in developing programs to improve performance and improve patient outcomes.

Institute of Medicine

The IOM has stimulated debate on the quality of health care and rate of medical errors, both in the health care industry and public domains. The IOM was established in 1970 as a private organization under the National Academy of Sciences charter to identify concerns and advise the government on public health, medical care, and research issues. The IOM uses volunteer experts and committees to conduct studies and make recommendations, with a focus on

evidence-based research and expert opinions. The IOM embarked on a Quality of Health Care in America project to develop a strategy to improve the quality of health care. The first IOM report from this project in 1999, *To Err is Human: Building a Safer Health System*, focused on the high rate of medical errors. The report made recommendations to improve systems and quality in these areas. The authors proposed a Center for Patient Safety and called for dramatic system changes in the delivery of health care, citing problems in safety and quality. In 2001, the IOM released the report, *Crossing the Quality Chasm: A New Health System for the 21st Century*. This report analyzed the patient safety problem, described the gaps, and provided a framework for change and improvement. The report highlighted technology and a paperless system of measuring quality. These reports stimulated the interest of health care professionals and patients on the topic of medical error. Pharmacists can use the findings to assist in getting multidisciplinary support for drug use improvement projects. The third IOM report, *Leadership by Example: Coordinating Government Roles in Improving Health Care Quality*, was released in 2002. This third report called for standardized performance measures, electronic information availability, and rewarding high-quality plans and providers with higher rates of payment. The IOM report calls for focus on 20 key health care areas to improve quality and the provision of adequate funding and support to improve the health care system. The 20 areas of focus are:

- asthma
- care coordination
- children with special health care needs
- diabetes
- end-of-life care for advanced organ system failure
- evidence-based cancer screening
- frailty associated with old age
- hypertension
- immunization
- ischemic heart disease
- major depression
- medication management (error prevention focus)
- nosocomial infections
- obesity
- pain control in advanced cancer
- pregnancy and childbirth
- self-management/health literacy
- severe and persistent mental illness
- stroke
- tobacco-dependence treatment for adults

The IOM reports have stimulated local, regional, state, and national initiatives to improve patient safety and develop performance measures. A Quality Interagency Coordination Task Force was developed by the government to facilitate collaboration across federal agencies and to coordinate with public and private sectors to establish and implement national goals. As a result of the IOM reports, significant funding has been allocated to Agency for Healthcare Research and Quality to fund patient safety-related projects. Private foundations increasingly are dedicating funds to patient safety initiatives. Funding is

available to assist pharmacists and other professionals in pharmaco-economic and patient safety research projects.

Other Organizations

Several other organizations have been involved in developing patient safety guidelines and drug best practices in the past several decades. The Institute for Healthcare Improvement is an organization that sponsors conferences and collaboratives to share information and implement changes to drive improvement in the quality of health care. Several of the collaboratives have been focused on medical errors and drug-related topics (e.g., adverse drug events, diabetes, and asthma care). The Institute for Healthcare Improvement model emphasizes accelerated (i.e., small changes or rapid cycle) improvements to hasten change. The Institute for Safe Medication Practices, the National Coordinating Council for Medication Error Reporting and Prevention, and American Society of Health-System Pharmacists have developed standards and provided guidance on best practices for the drug use process. The organizations provide data for accreditation agencies to use in setting drug use and safety standards.

The government, private foundations, consumer organizations, health care providers, purchasing groups, health plans, and health systems all have begun initiatives designed to improve patient safety and enhance performance measurement. Numerous collaborative efforts and joint ventures are being established to work on these issues. Increasing numbers of contracts between health plans and providers have connected quality improvement to reimbursement.

Conclusion

There has been nationwide emphasis placed on greater accountability for health care quality assessment and improvement. Although demands for improved patient care quality are increasing, resources to provide the care continue to be scarcer each year. Employers and the public are looking for assurance that the care delivered represents high value and quality. National accrediting organizations, such as JCAHO and NCQA, increasingly are incorporating quality performance measures related to drug use. In addition, the National Quality Forum and IOM focus on key areas, many associated with drug use. Implementation of drug best practices and guidelines is key to compliance with JCAHO Core Measures and NCQA HEDIS measures. Pharmacists in ambulatory, hospital, and managed care have an opportunity to lead efforts to optimize drug use. Drug safety performance is emphasized, particularly by JCAHO, IOM, Institute for Safe Medication Practices, and American Society of Health-System Pharmacists. This focus on drug safety will challenge pharmacists to lead safety improvement efforts. Pharmacists can use root cause analysis, Failure Mode Effect and Critical Analysis, and other CQI methods in assessing and improving quality in the drug use process.

Increased use of electronic and Web-based data and information exchange, as well as other paperless systems, continue to enhance the ability to measure performance

improvement and to reward financially higher quality organizations. Accreditation agencies, standard-setting organizations, and health professional organizations are working together to improve quality for patients and consumers. These collaborative efforts will help to establish national standards of drug-related quality measures and reporting in health care. With the increase in drug-related measures and safety focus, pharmacists in all settings have an opportunity to enhance their roles in improving patient drug-related outcomes.

Annotated Bibliography

1. Dean Beaulieu N, Epstein AM. National Committee for Quality Assurance health-plan accreditation: predictors, correlates of performance, and market impact. *Med Care* 2002;40(4):325–37.

This article compares National Committee for Quality Assurance (NCQA) accreditation status to health plan characteristics, Health Plan Employer Data and Information Set (HEDIS) scores, and health plan enrollment. The analysis was based on data from NCQA, information on health plan characteristics and enrollment from InterStudy, data on health plan quality of care measured by HEDIS scores from the quality compass database, and patient-reported quality and satisfaction data from a survey of federal employees. Accredited plans, compared to nonaccredited plans, were more likely to have existed longer, have greater enrollment, be federally qualified, be affiliated with a national managed care firm, and offer point-of-service and Medicare managed care ($p < 0.05$). Fully accredited plans performed significantly better than plans denied accreditation on one of the nine HEDIS measurements ($p < 0.05$). Accredited plans performed better than nonaccredited plans on five of the nine HEDIS measurements ($p < 0.05$). Accredited health plans also were represented in the bottom decile of performance on some HEDIS measures, leading to the conclusion that accreditation does not protect health plan members from poor quality. Regarding patient-reported quality and satisfaction, fully accredited health plans performed statistically better in two of the eight measurements compared to denied plans ($p < 0.05$). Accredited health plans performed statistically better in two of eight measurements ($p < 0.05$) compared to nonaccredited health plans. Although accredited health plans performed modestly better than nonaccredited plans in HEDIS measures and member satisfaction, this study did not show a clear correlation that accreditation ensures quality of care or satisfaction. This article provides pharmacists with knowledge regarding the impact of accreditation on the quality of health care services provided by managed care plans.

2. O'Leary DS, O'Leary MR. From quality assurance to quality improvement. The Joint Commission on Accreditation of Healthcare Organizations and Emergency Care. *Emerg Med Clin North Am* 1992;10(3):477–92.

Pharmacists reading this article will gain a basic understanding of the comparison between quality assurance and continuous quality improvement (CQI) methodologies. The authors discuss the Joint Commission on Accreditation of Healthcare Organization (JCAHO) standards transition from a focus on quality assurance to CQI. The standards revision was intended to better determine if the hospital actually performed well versus if the hospital had the capacity to

perform well. The authors stated that quality assurance often was driven from outside agencies. Accreditation agencies such as the JCAHO require an organization to perform certain functions to ensure quality within the organization. Often, CQI is driven internally. Organizational leaders understand the need and will strive above the expectations of outside agencies for improved performance. In contrast to quality assurance, CQI focuses more on improving systems and less on individuals as the solution for improved performance. Continuous quality improvement recognizes that error-free systems cannot be attained, but looks to continuously improve performance from baseline measurements. This article provides a good summary of the differences between the concepts of CQI and quality assurance and describes the evolution of the JCAHO quality improvement standards.

3. Seidman JJ, Weiss KB. Health plans' use of asthma quality improvement projects to meet NCQA accreditation standards. *Am J Manag Care* 2001;7:567–72.

This article guides pharmacists in developing quality improvement initiatives to comply with the NCQA standards. The study objective was to determine how managed care health plans in the United States addressed the quality of asthma care through disease-specific quality improvement programs. The study involved a cross sectional review of reports from NCQA accreditation surveys conducted between 1996 and 1997. The NCQA accreditation standards required health plans to demonstrate quality improvement and quality management activities but left the specific area of focus up to the health plan. The results indicated that 89.7% of managed care health plans had an asthma-related quality improvement program. Sixty-two percent of health plans used published asthma guidelines as a basis for their quality improvement programs. The three categories of approaches used most frequently by health plans included: education to patients about therapy, education to health professionals, and an asthma disease management program that involved more than education. This article offers insights on how managed care health plans have approached quality improvement efforts, but it does not address whether the quality improvement efforts resulted in documented outcome improvements. Therefore, the reader cannot determine which approach resulted in the most improvements. Although the article does not demonstrate the patient care outcome, it does provide pharmacists with guidance on conducting quality improvement efforts.

4. Donabedian A. The role of outcomes in quality assessment and assurance. *QRB Qual Rev Bull* 1992;18(11):356–60.

This article provides pharmacists with guidance on assessing quality in an organization or a department and describes a conceptual model for assessing quality and the role of outcomes in assessing and ensuring quality in health care. The author identifies four questions that must be identified by the person or group assessing quality: “Who is being assessed?” “What is being assessed?” “How are the activities to be conducted?” and “What activities are to be accomplished?” These questions assist in developing the measures to assess quality. The author describes a structure-process-outcome conceptual framework. Structure refers to physical structure or organizational structure. Process refers to how care is delivered. Outcome refers to what is accomplished. A casual linkage, at the very least, must exist between the structure and process and the process and outcome components to expect that changing the structure or process will result in the desired outcome. A

strong relationship improves the degree of certainty that a structure or process change leads to quality outcome. The author also notes that outcomes only permit an inference about the quality of the process or structure of care (i.e., good outcomes can occur without high-quality care being provided). However, poor outcomes can lead an investigator to assess whether there are flaws in the structure or process. This article presents a model for pharmacists to use in developing quality assessment measures. It provides an understanding of the difficulty of measuring and assessing outcomes.

5. Capo KM, Rutledge DR. Applying managed care performance measures in community pharmacy-based outcomes research. *J Am Pharm Assoc* 1999;39:388–94.

This article discusses examples of community pharmacist projects designed to improve patient care and concomitantly assist a health plan in improving HEDIS scores. The projects included angiotensin-converting enzyme inhibitor use in patients with heart failure, a pediatric callback program, and a cardiovascular telemetry project. The community pharmacists identified patients with heart failure and increased angiotensin-converting enzyme inhibitor use by 23%. The callback program involved pharmacists making phone calls to parents whose children had received antibiotics from the pharmacy. The purpose of this follow-up call was designed to assess the efficacy of, tolerability of, and compliance with the antibiotic regimen. The pharmacists were able to impact therapy through proper dosage selection, discontinuation of inappropriate therapy, and identification of adverse drug events. The cardiovascular telemetry project involved pharmacist phone calls to patients placed on cholesterol-lowering agents. The pharmacists used the Medical Outcomes Study, short form, 36 items, questionnaire to assess patient quality of life. Results of the cardiovascular project were inconclusive because patients expressed resistance to follow-up phone calls to reassess the Medical Outcomes Study, short form, 36 items, questionnaire because of the length of time required. Although the initiatives set an excellent example of the role community pharmacists can have, the number of patients who choose to participate was small and did not allow for statistical analysis of improvement in patient care. The likelihood that one pharmacy would have a significant impact on the overall HEDIS score of a large health plan is small. However, this article provides an excellent example of targeted initiatives that, if implemented by a large network of pharmacies, could improve patient care and assist in improving HEDIS scores.

SELF-ASSESSMENT QUESTIONS

- Which one of the following organizations provides the broadest scope of evaluation and accreditation for a large integrated health system that includes hospitals, outpatient facilities, and a network?
 - Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
 - American Osteopathic Association.
 - National Committee for Quality Assurance (NCQA).
 - The URAC (formerly known as the Utilization Review Accreditation Commission also known as the American Accreditation Healthcare Commission).
- An employer is committed to maintaining the health of the company's employees. Standards that best address health maintenance are associated with which one of the following accreditation agencies?
 - The JCAHO.
 - The NCQA.
 - American Osteopathic Association.
 - Agency for Healthcare Research and Quality.
- Between 1988 and 1993, there were several key movements to enhance focus on continuous quality improvement (CQI) and outcomes measurement. Which one of the following had the most influence in targeting the pharmacist's role in the drug use process?
 - The Shattuck lecture on outcomes management.
 - The JCAHO Agenda for Change initiative.
 - Agency for Health Care Policy and Research Patient Outcome Research Team initiatives.
 - The NCQA Health Plan Employer Data and Information Set (HEDIS) indicators.
- Measuring quality in health care has received attention by many accreditation and standard-setting organizations. Which one of the following best describes the difficulty in using quality indicators to measure outcomes?
 - There often is an unclear relationship between the specific intervention or process and the desired effect.
 - The efforts of governmental agencies, health care plans, and employers are disjointed, impeding the development of uniform measurement tools.
 - The NCQA accreditation has not ensured quality performance.
 - Consumer coalitions often focus on outcomes different from employers.
- In the late 1990s, the JCAHO announced the Agenda for Change initiative. One major component of this initiative was the integration of performance measurement data into the accreditation process. Which one of the following best describes another major component of the Agenda for Change?
 - Introducing a tool for collecting key consumer-related measures of quality.
 - Revising indicators, placing more emphasis on CQI and patient outcomes.
 - Rewarding high-quality providers with financial incentives.
 - Revising indicators to require the use of clinical practice guidelines.
- A clinical pharmacist at the university hospital is developing a drug use evaluation on aminoglycosides. The pharmacist wants to focus on patient outcomes compared to a traditional drug use evaluation that focuses on process steps. Which one of the following measurements will accomplish this objective?
 - Evaluating the appropriate use for gram-negative bacterial infection.

- B. Determining how often gentamicin prophylactic doses are prescribed at 1 mg/kg.
 - C. Assessing the number of patients who experience renal impairment.
 - D. Identifying physicians who prescribe tobramycin as first-line treatment for *Pseudomonas* infection.
7. For this chemotherapy failure mode effect and critical analysis, which one of the following items would have the highest criticality of failure mode?

Failure Mode	Potential Effect on Patient	Frequency of Failure Reaching Patient	Likelihood of Failure
Missing body surface area on orders	9	6	8
Missing infusion rate on the label	6	9	7
No pharmacist double-check process	10	5	7
Missing height and weight	8	8	6

- A. Missing body surface area on orders.
 - B. Missing infusion rate on the label.
 - C. No pharmacist double-check process.
 - D. Missing height and weight.
8. Which one of the following is most helpful in establishing projects to reduce the number of adverse drug events in a hospital?
- A. The NCQA Quality Improvement standards.
 - B. The ORYX Core Measures.
 - C. The HEDIS measures.
 - D. The JCAHO standards.
9. The director of pharmacy at the university hospital is charged with ensuring that the hospital is measuring a JCAHO Core Measure as part of the ORYX initiative. Which one of the following measurements best meets the criteria?
- A. Comparing patient arrival time with the time of aspirin administration.
 - B. Auditing that a β -blocker was given to the correct patient admitted with an acute myocardial infarction.
 - C. Ensuring patients diagnosed with an acute myocardial infarction leave the hospital with a prescription for a cholesterol-lowering drug.
 - D. Ensuring that patients with a cerebral vascular accident diagnosis have controlled blood pressure.

Questions 10–12 pertain to the following case.

As the pharmacy director, you have chosen to evaluate key areas of the drug use process. You have chosen to focus on the prescribing phase of the drug use process and will conduct a drug use evaluation on the correct choice of antiemetics for chemotherapy-induced nausea and vomiting, based on the American Society of Clinical Oncology guidelines.

10. Which one of the following is the next step in trying to assess the quality of care provided for this patient population?
- A. Determine how your team will collect the data to ensure consistency among the individuals collecting the information.
 - B. Determine whether the goal is to assess the compliance of physician prescribing or of pharmacist intervention.
 - C. Determine whether the appropriate number of pharmacists are available to have influence on the prescribing of antiemetics.
 - D. Develop a collection tool to assess whether pharmacists are complying with the American Society of Clinical Oncology guidelines.
11. Which one of the following indicators is an example of a process quality indicator as defined in the structure-process-outcome conceptual framework?
- A. Number of pharmacists rounding with physicians.
 - B. Reduction in nausea and vomiting episodes.
 - C. Compliance of therapy with American Society of Clinical Oncology guidelines on ordering and after pharmacist intervention.
 - D. Presence of an oncology physician on the Pharmacy & Therapeutics Committee to assist in drug use evaluation development.
12. From the results of your assessment, pharmacists were 67% compliant on intervening with a physician when the antiemetic prescribed did not meet the American Society of Clinical Oncology guidelines. Which one of the following actions is more characteristic of quality assurance (compared to quality improvement)?
- A. Conducting a drug therapeutic interchange based on the American Society of Clinical Oncology guidelines.
 - B. Identifying pharmacists less likely to intervene and developing a pharmacist competency module.
 - C. Identifying a computer flag to assist pharmacists in targeting antiemetic orders.
 - D. Sharing the drug use evaluation results at a medical staff meeting to identify activities to improve adherence to the American Society of Clinical Oncology guidelines.
13. The president of World Health, an NCQA-accredited managed care organization, would like to contract services with General Motors. The president of General Motors asks why World Health's plan is superior in quality compared to plans that were denied accreditation. World Health could respond that accredited health plans performed better in which one of the following areas?
- A. Formulary decisions.
 - B. Patient care decisions.
 - C. Protecting patients from poor quality.
 - D. Ensuring maternal check ups after deliveries.

14. Which one of the following reports is most useful to a consumer with diabetes, rheumatoid arthritis, and hypertension to identify a health plan that will meet his or her health care needs?
- A comparative report of health plan accreditation status.
 - A report listing the NCQA standards.
 - A summary report of quality improvement examples.
 - A comparative report of health plan services, access to services, and member satisfaction.
15. You have been contracted by the NCQA to draft an updated version of the Utilization Management 13 standards. Your objective is to write the standards such that they will challenge health plans to provide a higher level of quality care for their patients using pharmaceuticals (as opposed to setting only minimum standards). Which one of the following creations or revisions of the standards would best accomplish this?
- Create a standard requiring health plan physicians to use hand-held devices for prescribing pharmaceuticals to eliminate poor handwriting.
 - Revise the second element of the standards to include restrictions on physician prescribing (e.g., only pulmonologists could prescribe epoprostenol).
 - Revise the third element of the standards to include more patient safety issues (e.g., readback for verbal orders communicated to community pharmacies).
 - Create a standard requiring health plans to show the impact of care decisions on patients based on the use of identified pharmaceuticals.

Question 16 pertains to the following table.

Health Plan	Access and Service	Qualified Providers	Staying Healthy	Getting Better	Living with Illness
Mercy Health	***	**	****	****	***
Unity Health	****	****	***	***	****
United Health	**	***	****	***	****

Each category is scored on a 1 to 4 scale (ratings denoted by asterisks [*]), with 4 asterisks indicating the highest level of performance.

16. As the benefits director for a hospital, your objective is to identify a health plan that will provide your employees the best health services to maintain good health and recover from illness. Based on the NCQA health plan report card above, which one of the following health plans will you choose and why?
- Mercy Health because of the four stars in both the staying healthy and getting better categories.
 - Unity Health because of the four stars in both the qualified providers and access and service categories.
 - United Health because of the four stars in the living with illness category.
 - Unity Health because overall it has the highest cumulative rating for the five categories (total of 17 stars).

Questions 17 and 18 pertain to the HEDIS indicator scores for Trinity Health Plan below.

17. You are the president of Trinity Health Plan negotiating with the president of Super Fast Automotive. You want to demonstrate the performance of your health plan using HEDIS measurement scores. Which one of the following reasons best describes why your health plan

HEDIS Indicator	Trinity Health Plan Year and performance				All NCQA Accredited Plans	
	1998	1999	2000	2001	2001 10th percentile	2001 90th percentile
β-Blocker treatment after heart attack ^a	68.2%	74.6%	82.9%	89.4%	71.5%	89.2%
Cholesterol management ^b	57.1%	58.2%	65.8%	72.4%	61.3%	84.3%
Controlling high blood pressure ^c	N/A	36.8%	54.6%	76.5%	48.6%	77.9%
Appropriate drugs for asthma ^d	N/A	54.8%	56.7%	58.9%	59.8%	68.5%

^aPercent of members, 35 years and older, hospitalized and discharged after surviving a heart attack, who received a prescription for a β-blocker at discharge.

^bHealth plan members, 18–75 years of age, who had evidence of acute cardiovascular event and whose low-density lipoprotein cholesterol was screened and controlled to less than 130 mg/dl in the following year.

^cBlood pressure was controlled, 45–85 years of age, diagnosed with hypertension. Adequate control was less than 141 mm Hg systolic and 91 mm Hg diastolic.

^dHealth plan members suffering from persistent asthma are receiving drugs deemed acceptable by the National Heart, Lung, and Blood Institute.

HEDIS = Health Plan Employer Data and Information Set.

- is superior in quality to the top 10% of NCQA-accredited health plans?
- The health plan's score for treating patients with a β -blocker after a heart attack is above the 90th percentile.
 - The score for controlling high blood pressure has doubled in the past 2 years for your health plan.
 - The health plan scored below the 10th percentile for appropriate asthma management in accordance with the National Heart, Lung, and Blood Institute.
 - The improved score of the health plan in all four HEDIS measurements.
- As the president of Trinity Health Plan, you decide to contract with a pharmacy benefit management organization. Your goal is to improve the HEDIS indicator scores, thus improving the quality of care for your enrolled members. You are evaluating the quality improvement approach of potential pharmacy benefit management organizations. After the pharmacy benefit management organization manager has analyzed Trinity's HEDIS scores, which one of the following is the best conclusion of the pharmacy benefit management organization manager?
 - The score of 76.5% for controlling high blood pressure is near the 90th percentile (77.9%); therefore, improvement initiatives should be focused so Trinity reaches a HEDIS score above the 90th percentile.
 - Programs should all be focused on the correct use of asthma drugs because Trinity still scores below the 10th percentile.
 - Efforts should be initiated to improve the scores of each indicator.
 - There is little opportunity for improvement in the β -blocker treatment after heart attack initiative because Trinity scores higher than the 90th percentile.
 - You are leading a project in which eight local community pharmacies will document pharmacists' ability to improve HEDIS scores for the largest health plan in the area and improve the overall health of the community they serve. Which one of the following pieces of information, along with the HEDIS measures, would be valuable to the success of the project?
 - The most common patient diagnosis using the eight pharmacy databases.
 - The clinical areas of expertise of the pharmacists.
 - The time commitment required to counsel the patients.
 - The interest of the community in having disease state programs, using a survey based on disease states included in HEDIS measures.
 - As a community pharmacist, you are trying to contract with a local managed care organization to provide services. You want to provide an example of your ability to assist the managed care organization in improving HEDIS scores. Which one of the following projects would accomplish this goal?
 - Measuring the use of angiotensin-converting enzyme inhibitors in patients with left ventricular systolic dysfunction.
 - Providing flu shots for patients 50–64 years of age.
 - Developing guidelines for treating acute coronary syndrome.
 - Developing guidelines for treating pneumonia.
 - You are the pharmacy manager for a chain of community pharmacies looking to contract services with a managed care organization. The managed care organization is seeking to gain accreditation from the NCQA and plans to use the HEDIS standards. Which one of the following is how you would identify opportunities to provide pharmaceutical services for the managed care organization?
 - Perform a literature search on the value and contribution of pharmacist services.
 - Identify antibiotic use best practices to assist the managed care plan in assessing the quality of antimicrobial therapy.
 - Survey the managed care organization's patients to identify their needs.
 - Evaluate the NCQA standards and HEDIS measures to identify potential quality improvement projects.
 - As the director of a pharmacy benefit management organization, you have been hired by a managed care organization to develop a formulary. Which one of the following examples complies with the Utilization Management 13 standard regarding formularies?
 - Establishing therapeutic interchange policies as a cost-reduction strategy.
 - Establishing an open formulary where only certain pharmaceuticals are covered.
 - Creating a drug use committee to review pharmaceuticals for formulary status.
 - Distributing recommended asthma therapy guidelines to members.
 - Patient safety, specifically drug safety, is a huge focus of regulatory, accreditation, and other standards-developing groups. To continue to evolve their role as drug use experts, pharmacists must be familiar with quality improvement and outcomes literature and techniques. Knowledge of which one of the following is most useful when trying to identify trends in drug errors?
 - Institute for Healthcare Improvement rapid cycle methodology.
 - Quality of life measurement tools.
 - Practice guideline development tools.
 - Statistical process control methodology.
 - As a board member of a professional pharmacy organization, you have been asked to speak on the pharmacist's role in drug use system improvements.

Which one of the following has most directly prompted drug use system improvements in accredited hospitals?

- A. Increased use of CQI techniques.
- B. Release of the Institute of Medicine report, *To Err is Human: Building a Safer Health System*.
- C. Release of The Leapfrog Group standards for computerized physician order entry.
- D. Incorporation of drug performance measures into accreditation agency standards.

25. A clinic pharmacist is looking to expand the pharmacist role in disease state management. Which one of the following organizations best provides suggested chronic disease states to target for improvement?

- A. Foundation for Accountability.
- B. Institute for Safe Medication Practices.
- C. National Coordinating Council for Medication Error Reporting and Prevention.
- D. National Quality Forum.

