

Practice Administration and Development: Protocol Development and Quality Assurance

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**New Hanover Regional Medical Center
Wilmington, North Carolina**

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Learning Objectives

1. Develop and promote critical care pharmacy services.
2. Evaluate strategies to justify and document critical care pharmacy services.
3. Develop critical care pathways and formulary proposals.
4. Differentiate quality improvement opportunities in the critically ill patient to optimize outcomes.
5. Identify the resources needed to care for the critically ill patient.
6. Determine the metrics associated with quantifying critical care pharmacist activities.

Abbreviations in This Chapter

ADE	Adverse drug event
ASHP	American Society of Health-System Pharmacists
CMS	Centers for Medicare & Medicaid Services
EBM	Evidence-based medicine
ICU	Intensive care unit
LOS	Length of stay
PPMI	Pharmacy Practice Model Initiative
QI	Quality improvement
UTI	Urinary tract infection

Self-Assessment Questions

Answers and explanations to these questions may be found at the end of this chapter.

1. Which best represents a direct medical cost?
 - A. Delirium.
 - B. Morbidity.
 - C. Medical professional time.
 - D. Adverse drug events (ADEs).
2. From the patient's perspective, which best describes indirect costs?
 - A. Care for visit to the health care provider's clinic.
 - B. Cost of treatment for hypertension based on hypertension management goals.
 - C. Loss of income based on admission days in the hospital.
 - D. Drug effects on activities of daily living.
3. A critical care pharmacist's services constitute three major facets: fundamental, desirable, and optimal. Which best reflects a service provided by the critical care pharmacist that is considered a fundamental service?
 - A. Clinical.
 - B. Order entry/order verification.
 - C. Administrative.
 - D. Scholarly.
4. When quantifying the value of a critical care clinical pharmacist's services, which economic evaluation method is best to use?
 - A. Cost-utility analysis.
 - B. Cost-benefit analysis.
 - C. Cost-minimization analysis.
 - D. Cost-effectiveness analysis.
5. You are the critical care pharmacist implementing a delirium screening in critically ill patients. After reviewing the current literature on delirium, you believe that delirium is an important aspect in screening your patients. Which best reflects what would be considered a barrier to implementing delirium screening in a practice environment?
 - A. Standards of practice.
 - B. Organizational constraints.
 - C. Medical training.
 - D. Sense of competence.
6. You have been asked to develop a quality improvement (QI) strategy for your intensive care unit (ICU) regarding when to institute hypothermia in patients after cardiac arrest. You identify key stakeholders in this patient population to collaborate with you in this process improvement. Which is the next best step in developing the QI program?
 - A. Determine how the patient is involved.
 - B. Evaluate the physician/prescriber's practice.
 - C. Determine the current process.
 - D. Evaluate the data.

7. As the critical care pharmacist, you decide to perform a research study with the primary objective of determining the quality of life after admission to the ICU. Which best describes the type of research outcomes this study will determine?
 - A. Clinical.
 - B. Humanistic.
 - C. Economic.
 - D. Operational.

8. Using the plan-do-check-act cycle, which is optimized in the “do” phase?
 - A. Details are described.
 - B. Data are collected.
 - C. Change is made.
 - D. Details are described.

I. CRITICAL CARE PHARMACY SERVICES

- A. Goals of a Critical Care Pharmacist: “The recommendations are focused on delivering direct and proactive patient care services at the desirable and optimal levels with the ultimate goal of enhancing the level of pharmacy services provided to the care of critically ill patients” (Pharmacotherapy 2011;31:135e-175e).
- B. Practice Statements from the American College of Clinical Pharmacy (ACCP): “The practice of clinical pharmacy embraces the philosophy of pharmaceutical care, blending a caring orientation with specialized therapeutic knowledge, experience and judgment for the purpose of ensuring optimal patient outcomes” (Crit Care Med 2006;34:S46-51).
- C. Critical Care Pharmacist – Strong knowledge base and diverse skill sets, including effective communication, advanced problem solving/critical thinking, judgment, leadership, and time management for critically ill patients with dynamic issues and multisystem pathologies
- D. Critical Care Pharmacist Characteristics
 - 1. Typical critical care pharmacist
 - a. Those with a B.S. degree in pharmacy, those with a Pharm.D. degree
 - b. Ideally, 1–2 years of postdoctoral residency training
 - c. Board certification (BCPS, BCNSP, BCCC; other specialties complementary of their practice setting [e.g., BCOP, pediatrics])
 - 2. Working on a multiprofessional critical care team (just as the first multi-specialty practices developed in the late 1890s with the Mayo brothers)
 - 3. Apply to all ICU practice sites and populations (medical, surgical, neurosurgical, trauma, burn, pediatrics, neonatal, etc.) or any site encountering an ICU patient (operating room, emergency department, transplant or coronary unit) across all types of institutions (community, private, academic, government).
 - 4. In-depth knowledge of medications integrated with understanding of biomedical, pharmaceutical, social behavior, and clinical sciences
 - a. Core therapeutic topics
 - b. Maintain knowledge base, which includes current medical practice.
 - c. Commitment to lifelong learning
 - 5. Skill development: Resource development
 - 6. To achieve desired therapeutic goals, the critical care pharmacist applies the following:
 - a. Evidence-based medicine (EBM) therapeutic guidelines
 - b. Evolving science
 - c. Emerging technology
 - d. Relevant legal, ethical, social, cultural, economic, and professional principles
 - 7. Services
 - a. Fundamental services
 - i. Distributive
 - ii. Order entry/verification duties
 - iii. Policy change – Tech-check-tech
 - b. Desirable services – Advanced clinical functions beyond fundamental services for the specialized care of critically ill patients
 - i. Clinical
 - (a) Provide formal nutrition consultation.
 - (b) Respond to resuscitation events.

- ii. Educational
 - (a) Provide didactic lectures to health care professionals, students, residents, and fellows in critical care pharmacology and therapeutics.
 - (b) Train pharmacy residents, students, and fellows through experiential critical care rotations.
 - iii. Administrative
 - (a) Develop and implement ICU policies and protocols.
 - (b) Evaluate the economic impact on services provided in the ICU.
 - iv. Scholarly
 - (a) Perform research – Collect data, establish study design, perform data analysis
 - (b) Manuscript preparation
 - (c) Present case reports and data to affect practice.
 - c. Optimal services – Integrated, specialized, and dedicated model of direct patient care functions aimed to optimize outcomes
 - i. Clinical: Assist physicians or providers with pharmacy and therapeutics to aid in decision-making regarding treatment options.
 - ii. Educational
 - (a) Coordinate or direct residency or fellowship programs.
 - (b) Teach advanced cardiac life support.
 - (c) Implement training programs for personnel working in the ICU.
 - iii. Administrative: Design new pharmacy programs for the ICU.
 - iv. Scholarly
 - (a) Perform clinical research.
 - (b) Disseminate the results of clinical research, outcomes data
 - (c) Perform laboratory analysis.
- E. Daily Activities
1. Prospective evaluation of all drug therapy
 2. Evaluation of appropriateness of therapy
 3. Define goals and monitoring for efficacy and toxicity.
 4. Documentation of services
 5. Reporting of adverse events
 6. Provision of drug information
 7. Participation in educational and institutional activities, medication use evaluation (MUE), multi-disciplinary committees, development of protocols, and collaboration with medical and nursing staff in practice and research
 8. Make contributions to Pharmacy and Therapeutics (P&T) Committee, implementing protocols for critically ill patients.
 9. Activities on cost-containment
 10. Drug-dosing adjustments for renal, hepatic dysfunction or alterations in pharmacokinetics in the critically ill patient.
 11. Monitoring and preventing drug interactions and ADEs
 12. Nutritional assessment and metabolic management in critically ill patients
 13. Checking the compatibilities of a patient's extensive list of intravenous medications
 14. Prevention and treatment of life-threatening infections
 15. Safe and optimal use of technologies for the critically ill

16. Promoting critical care pharmacy services – Which pharmacy services have been shown to improve health care outcomes in the following:
 - a. Adverse drug reaction management
 - b. Drug information
 - c. Protocol/guideline management
 - d. Admission medication history and medication reconciliation
 - e. Disease state management
 - f. Participation in patient care rounds
 - g. Cardiopulmonary resuscitation
 - h. Safe transitions to next care level (transfer/dismissal medication reconciliation; handoffs)

- F. Evidence-Based Literature Supporting the Value of Critical Care Pharmacy
Position papers supporting clinical pharmacy services for critically ill patients
 1. The Institute of Medicine’s “To Err Is Human” (JAMA 1999;282:267-70) – Call to pharmacy to improve safety and outcomes
 2. ACCP white paper on the future of pharmacy practice: “A Vision of Pharmacy’s Future Roles, Responsibilities, and Manpower Needs in the United States” (Pharmacotherapy 2000;20:991-1020)
 3. Society of Critical Care Medicine (SCCM) – Describes the delivery of critical care services, defines clinical roles and a best practice model (Crit Care Med 2001;29:2007). Specifically, the article describes retrospective order evaluation without participation on rounds, availability of a critical care satellite pharmacy, and individual pharmacist deployment to round with the critical care team.
 4. SCCM – Position paper on critical care pharmacy services (Crit Care Med 2000;28:3746-50)
 5. Pharmacist contributions as members of the multidisciplinary ICU team (Chest 2013;144:1687-95)
 6. Articles discussing the economic benefits of critical care pharmacist services – See references.

- G. Justify/Document Critical Care Pharmacy Services
Pharmacist involvement has a direct effect on decreased drug-related costs, prevents adverse effects and improves quality and efficacy of care, reduces mortality, shortens length of stay (LOS), and lowers overall patient care costs.
 1. Justification
 - a. Assessment and recognition of need
 - b. Identification of stakeholders
 - c. Describes services or programs
 - d. Funding assessment or rationale
 - e. Presentation of justification plan
 - f. Evaluation
 - g. Business plan – SCCM supports an ICU pharmacist as an essential component of an ICU team.
 2. Evidence to support the critical care pharmacist:
 - a. Reduced ADEs in the critically ill
 - b. Reduced order-prescribing errors
 - c. Optimization of the correct drug for the correct disease process
 - d. Promotes the safe and effective use of medication
 - e. Decreases medication use
 - f. Decreases LOS
 - g. Reduces medication costs
 - h. Reduces medication administration errors
 - i. Reduces inappropriate use of antibiotics
 - j. Protocol development

3. Documentation of clinical activities
 - a. Electronic (or other) reporting system – Capture clinical interventions.
 - b. Weighted metric for each variable to quantify measured activities
 - c. Pharmacotherapy improvement
 - d. Cost savings
 - e. Antibiotic stewardship
 - f. Provider education
 - g. Quality/safety improvement (value-based purchasing, SCIP [Surgical Care Improvement Project], HCAPS [Hospital Consumer Assessment of Healthcare Providers and Systems])
 - h. Emergency cardiac arrest, stroke, sepsis
 - i. Chart review
 - j. Rounding with health care providers
 - k. Formal pharmacy consults
 4. Documentation of services should show diversity, effectiveness, cost, and outcomes of activities
 - a. Policy development
 - b. Education
 - c. Research
 - d. Resource use
 - e. Management
 - f. Leadership
 5. Outcomes of documentation
 - a. Establish additional clinical services.
 - b. Expand roles of existing services.
 - c. Assess new processes or practices (prescriber privileges or provider reimbursement).
 - d. Provide data for quality assurance or research initiatives.
 - e. Accreditation purposes
 - f. Promotional reasons
 - g. Financial impact can be analyzed and used to justify time spent in that area.
 6. Reports
 - a. Statistical interpretations of services
 - b. Satisfaction surveys of their services
 - c. Risk reduction
 - d. Peer review
 - e. Publication
 - f. Return on investment data
 - g. Future initiatives
 7. Education
 - a. Pharmacy students
 - b. Pharmacy residents (PGY1, PGY2)
 - c. Pharmacy personnel
 - d. Multiprofessional team members
- H. Establish and sustain collaborative professional relationships with other members of the interdisciplinary critical care team. Goals: Provide opportunity to establish rapport with other personnel, promoting the rational and safe use of medications, educating other health care professionals, and learning and applying the policies that affect practice in the ICU
1. Pharmacy department policies
 2. P&T committee

3. ICU-specific practice team/committees
 - a. Multidisciplinary – ICU medical director, nursing management/leadership, pharmacy, respiratory, epidemiology, palliative care, PT/OT (physical therapist/occupational therapist, registered dietitians)
 - b. ICU multidisciplinary team, which meets on a regular basis
 - c. Discussion of ICU projects, clinical pathways, policies or procedures, QI initiatives, medication safety, implementation of new or revised systems, infections identified in the respective ICU
4. Weekly/daily rounds with the collaborative team
5. Collaborate with research – Multidisciplinary
6. Hospital committees – Multidisciplinary, multispecialty (emergency medicine, ICU, anesthesia, operating room)
 - a. Involvement in committees that have the ability to optimize care of the critically ill patient
 - b. Identify QI opportunities.
 - c. Identify process issues.
 - d. Prioritize hospital-wide initiatives.
7. Critical care committees
8. Investigational review board
9. Education-related committees
10. Specific quality and/or safety committees

POLICIES AND GUIDELINES

Objective: To advance critical care pharmacy, pharmacists should participate in the development, implementation, and data collection of protocols and medication use evaluations. The ICU pharmacist should participate in developing ICU or institutional policies, procedures, clinical pathways, and education of others.

- I. Policy and Procedures
 1. Policy – A course or plan of action; the existence of written policies and procedures establishes standards of practice or quality/compliance measures and protects against error. Statement that clearly and unambiguously describes the organization’s guiding principles and views about a particular matter
 - a. Benefits
 - i. Keeps the institution running efficiently
 - ii. Training tool during a new employee’s orientation
 - iii. Reference material for consistent practice
 - b. Development and implementation should involve all team members so that the process works smoothly.
 - c. Reduces the organizational risk through mandating compliance
 2. Procedure – A simple course of action intended to achieve a result; describes in detail a logical sequence of a processes to be followed to complete the task in a consistent manner
 - a. Aids in doing business as a team
 - b. Identifies each team member’s responsibility to the respective task of the procedure
 - c. Team members work more effectively together because the expected outcome is identified.
 - d. Procedures can be described in the form of the following:
 - i. Written steps of the process
 - ii. Flowcharts
 - iii. Checklists
 - e. Can be used as a QI tool or a source of measures

J. Clinical Protocol/Guidelines

1. Supports clinical decision-making by defining best practice
2. Employs evidence-based and standardized treatment options
3. Developed through examining the evidence and gaining consensus among practitioners
4. Physician champion
5. Protocol can be an extension of a clinical policy or practice standard.
6. Clinical protocols are often kept separate from institutional policies and procedures.
7. Disease and drug therapy protocols
8. Critical care pathways
9. Formulary proposals
10. Medication reconciliation – Important component of the Institute for Healthcare Improvement 100,000 Lives Campaign

K. Framework of a Policy and Procedure

Critical care pharmacists should lead the assessment of guidelines, protocols, practice changes, or performance improvement initiatives in the ICU.

1. Purpose – What audience is the policy intended to address and why is the policy and procedure being written
2. Definitions – Any definitions needed to provide the reader with an understanding of the language
 - a. Policy – Intent of the policy
 - b. Provisions
 - c. Procedure
 - d. Resources/references
 - e. Owner
3. How to write policies
 - a. Policy (or planning/evaluation) day
 - i. Identify key stakeholders in the organization.
 - ii. Appoint a facilitator, especially if there are known differences between participants.
 - iii. Keep track of the content of the day.
 - iv. Define aims, objectives, strategies
 - v. Determine priorities for policy development.
 - b. Consultative process for developing a particular policy
 - i. Obtain other perspectives and viewpoints, which will include identifying organizational or external issues.
 - ii. Promote good relations between sites and service providers.
 - iii. Encourages participation and feeling of ownership in the process
 - iv. Provides new ideas and expertise
 - v. Alternative viewpoint provides identification of inconsistency, ambiguity, and/or duplication.
 - c. Policy review process
 - d. Formal process may or may not be required within the institution (i.e., standing Policy and Procedures Committee, which develops and reviews the policy and provides recommendations and decisions).
 - e. Involvement and approval from the P&T and Critical Care committees or other oversight committees.
 - f. General steps in drafting
 - i. Write a first draft.
 - ii. Distribute the draft, and consult across the same organization/stakeholders/experts for comments.

- iii. Review feedback, both written and verbal, and amend/revise the draft.
 - iv. Redistribute the draft for final feedback.
 - v. Write the final draft.
 - g. Document the date the policy was ratified on the policy and the review the date.
 - h. Incorporate the new policy into the policy and procedures.
 - i. Communicate the new policy to all relevant people.
4. Review existing policies.
- Continuous QI is the newest arena requiring documentation and training for pharmacists and staff. Many state boards of pharmacy are requiring reportable events to be identified and documented. Policies and procedures can also be developed for analyzing the data collected to assess causes and contributing factors so that findings can be used to improve outcomes.
- a. Every policy should regularly be reviewed for relevance and appropriateness (e.g., every 1–3 years), depending on organizational structure/standards.
 - b. Monitor and evaluate compliance with, and effect on, policies and guidelines.
 - c. Planning and evaluating
 - i. Evaluation policy and plan
 - ii. Evaluation strategies
 - iii. Ongoing monitoring
 - iv. Presentation of data
 - v. Consumer feedback
 - vi. Stakeholder feedback
 - vii. Planning day agenda
 - viii. Forms: Data collection sheets, data reporting format
 - ix. Client/consumer questionnaires, community group questionnaires
 - d. Medication Use Evaluations
 - i. Also known as drug use evaluation and drug use review
 - ii. Refers to the systematic evaluation of medication use using standard, observational QI methods
 - iii. Establishes evidence-based criteria for medication use
 - iv. Applies the criteria retrospectively
 - v. Determines the degree of medication use according to established criteria
 - vi. Determines interventions to improve prescribing practices according to the data obtained
 - vii. Individual medications or the entire disease state process of care evaluation
 - viii. Affects economic, clinical, and humanistic outcomes
 - ix. Collects data to guide decision-making or uses data to measure the effect of interventions (implementation of a protocol)
 - x. MUE activities – Range of focus from medication acquisition to patient monitoring
 - xi. High-risk, high-cost medications; complex process that may be problematic at the institution
 - xii. MUE is part of the organization’s overall QI program.
 - xiii. Use MUE to evaluate processes/medications added to formulary when evidence is lacking.
 - xiv. P&T committee should be involved in MUE.
 - xv. Observational evaluation is preferred to retrospective evaluation – Relevant outcomes can be collected versus obtaining information in the medical record.
 - xvi. Medications added to the formulary should be reviewed 6–12 months after their addition (especially if there is inappropriate use or concern about ADEs).
 - xvii. Incorporation of patient safety data

- e. Evaluation examples:
 - i. Smart pump technology – Implement pump library for selected areas (e.g., critical care library, oncology, cardiothoracic surgery) – Evaluate whether pump libraries are being used— or are practitioners going outside the assigned framework of the library
 - ii. Evaluate the financial impact of policy compliance or noncompliance.
 - iii. Evaluate susceptibilities – If antibiotic criteria are not followed, evaluate if there is a change in susceptibility patterns
 - iv. Centers for Medicare & Medicaid Services (CMS) – Pay for performance
 - (a) Bloodstream infections – Developed in the hospital
 - (b) Urinary tract infections (UTIs) – Developed in the hospital
- f. Evidence-based critical care literature and clinical practice guidelines in designing a patient-specific plan of care
 - i. Definition: “The conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.”
 - ii. Pros and cons of EBM
 - (a) Advantages
 - (1) Critical appraisal skills of the literature improve with the review EBM.
 - (2) Questions asked; be more skeptical of the answers
 - (3) Wasteful practices can be abandoned.
 - (4) Presupposes that we keep up-to-date; ideally, a systematic process of incorporating new EBM is included
 - (5) Makes the decision-making process transparent to colleagues and patients
 - (6) Leads to greater appreciation of the evidence for our practice as well as the inherent uncertainties
 - (b) Disadvantages of EBM
 - (1) Time-consumingExpensive
 - (2) Sometimes impossible (when there is no published literature on a question)
 - (3) Useful papers may be disregarded because of minor blemishes (“rescue bias”).
 - (4) No science to tell us how robust the evidence must be for its use to be incorporated into clinical practice
 - (5) External validity is subjective, and evidence can be misapplied.
 - (6) Easy-to-prove techniques more favored in literature
 - (7) It is never “up-to-date.”
 - (8) Tends to emphasize the priority of randomized controlled trials (which have inherent flaws) to the exclusion of other study designs (which may be appropriate in certain settings)
 - (9) May underemphasize patient values and interests
- g. Barriers to implementation of evidence
- h. Practice environment (organizational context)
 - i. Financial disincentives – Lack of reimbursement
 - ii. Organizational constraints – Lack of time
 - iii. Perception of liability – Risk of formal complaint
 - iv. The patient’s expectations – Expressed wishes related to care
- i. Prevailing opinion (social context)
 - i. Standards of practice – Usual routine
 - ii. Opinion leaders – Key individuals not in agreement with evidence

- iii. Medical training – Obsolete knowledge
- iv. Advocacy – By pharmaceutical companies
- j. Knowledge and attitudes (professional context)
 - i. Clinical uncertainty – Necessary test for vague symptoms
 - ii. Sense of competence – Self-confidence in skills
 - iii. Compulsion to act – Need to do something
 - iv. Information overload – Inability to appraise evidence

II. QUALITY IMPROVEMENT

A. Overview

1. QI consists of systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups.
2. Organization's quality is based on the current system, e.g., how things are currently done.
3. Health care performance is defined by an organization's efficiency, outcome of care, and level of patient satisfaction. Using benchmarks may help with measurements/goals/outcomes.
4. To achieve a different level of performance i.e., results, and improve quality, an organization's current system needs to change.
5. Key components of a successful QI program:
 - a. QI works as systems and processes.
 - b. Focuses on patients
 - c. Focuses on being part of the team
 - d. Focuses on use of the data
6. Improvement strategies:
 - a. Understand the delivery system and key processes.
 - b. Recognize that both resources (inputs) and activities carried out (processes) are addressed together to ensure or improve the quality of care (outputs/outcomes).
7. Quality management departments within a health care institution often share data with the risk assessment department.
8. QI programs within an institution
 - a. Executive steering committee
 - b. Many departments
 - c. Pharmacy department
 - d. Quality department
 - e. Medical ethics committee
 - f. P&T committee
 - g. Data reporting

B. Critical Care Pharmacist's Role in QI – Metrics for evaluating the quality of critical care pharmacy services

1. ICU LOS
2. Hospital LOS
3. Impact on mortality
4. Impact on disease identification
5. Evaluation of infectious diseases within the ICU
6. Cost-effectiveness
7. Duration of mechanical ventilation

8. Medication management procedures need to be continuously monitored and improved because of their complexity.
 9. Medication safety
 10. Direct costs (medication costs, technological upgrades, and software)
 11. Indirect costs (salaries, power for building)
 12. Data collection, analysis
 13. Identify opportunities to reduce waste within a system – Could result in reduced patient care and medication costs
- C. National Quality Initiatives
1. The Institute of Medicine – Chartered in 1970. Published reports titled “The Urgent Need to Improve Health Care Quality,” “Crossing the Quality Chasm,” “To Err Is Human”
 2. The Institute for Healthcare Improvement – Founded in 1991
 - a. 100,000 Lives Campaign, 5 Million Lives Campaign
 - b. No needless list
 - i. No needless deaths
 - ii. No needless pain or suffering
 - iii. No helplessness in those served or serving
 - iv. No unwanted waiting
 - v. No waste
 - vi. No one left out
 - c. Initiatives promoted are focused in ICU.
 - i. Acute myocardial infarction (AMI)
 - ii. Catheter-associated UTI
 - iii. Central line–associated bloodstream infections
 - iv. Health care–associated infections
 - v. Severe sepsis bundles
 - vi. Medication reconciliation to prevent ADEs
 - vii. Sedation, delirium, and mobility
 - viii. Surgical site infections
 - ix. Ventilator-associated pneumonia
 - x. Rapid response teams
 - xi. High-alert medication safety
 - xii. Pressure ulcer care
 3. National Quality Forum – Created in 1999
 - a. More than 300 measures, indicators, events, practices, and other products to help assess quality. Has been endorsed to become the gold standard of measuring health care quality
 - b. Associated measures notable for ICU care
 - i. ADEs
 - ii. Catheter-associated UTIs
 - iii. Central line bloodstream infections
 - iv. Surgical site infections
 - v. Ventilator-associated pneumonia
 - vi. Stroke
 - vii. AMI
 4. The Leapfrog Groups – Launched in 2000
 - a. Hospital quality and safety survey – Voluntary survey of hospitals rating themselves on quality and safety practices

- b. Reported at www.leapfroggroup.org
- c. ICU related
 - i. Catheter-associated UTIs
 - ii. Catheter-associated bloodstream infections
- 5. The Joint Commission founded in 1951
 - a. An independent, not-for-profit organization that sets the standards for accreditation in health care
 - b. Tracer methodology – Method of evaluation done during an on-site survey that traces the health care experiences of a patient while in the hospital
 - c. Identifies, tests, and specifies standardized performance measures
 - d. 2014 National Patient Safety Goals
 - i. Preventing infection
 - ii. Uses the hand-cleaning guidelines from the Centers for Disease Control and Prevention or the WHO. Set goals for improving hand cleaning. Use the goals to improve hand cleaning.
 - iii. Uses proven guidelines to prevent infections that are difficult to treat
 - iv. Uses proven guidelines to prevent infection of the blood from central lines
 - v. Uses proven guidelines to prevent infection after surgery
 - vi. Uses proven guidelines to prevent UTIs caused by catheters
 - vii. Core performance measure sets for hospitals
 - (a) AMI
 - (b) Heart failure
 - (c) Pneumonia
 - e. ICU measure – Not in production
 - i. Set of performance measures applicable to the ICU setting – Solicitation from key stakeholders in 2002
 - ii. Six measures contained in the Specifications Manual for National Hospital Quality Measures – ICU underwent two phases of rigorous testing, and the results were reviewed by the technical advisory panel.
 - iii. November 2004 – Four measures recommended for potential national implementation; two measures were to be implemented as test measures not to be publicly reported or included in the Joint Commission accreditation process until additional information on training needs, reliability, and the impact on reliability of the predicted outcomes could be ascertained
 - iv. July 1, 2005 – Measure set implementation halted – The Joint Commission suspended implementation of data collection for the ICU measure set. The suspension was implemented to enable the Joint Commission to align its ORYX performance measure requirements with respect to the ICU measures, with the decision of the Hospital Quality Alliance priority of next adding measures related to surgical care to the nationally reported measure set portrayed on the CMS Hospital Compare Web site.
- 6. Agency for Healthcare Research and Quality (AHRQ) – The health services research arm of the U.S. Department of Health and Human Services. Sponsors the National Quality Measures Clearinghouse – A “public repository for evidence-based quality measures and measure sets”
- 7. Hospital Quality Alliance – Created in 2002
 - a. 2004 – Hospitals could voluntarily report data on 10 “starter-set” quality performance and receive incentive payment.
 - b. 2005 – Quality-of-care data expanded to 21 measures
 - c. 2006 – HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems)
 - d. Reporting initiatives sharpens the focus on QI.

8. CMS

- a. Mission – To “ensure effective up-to-date health care coverage and to promote quality care for beneficiaries”
- b. Quality initiative (established 2001) empowers consumers with quality-of-care information and encourages providers to improve the quality of care.
- c. Hospital quality initiative (est. 2003) – Hospitals must submit data measures or accept a reduction in payment.
 - i. Pay-for-performance measures on quality measures
 - ii. Heart attack
 - iii. Heart failure
 - iv. Pneumonia
 - v. Cardiopulmonary bypass
 - vi. Hip and knee replacements

D. The Pharmacy Practice Model Initiative (PPMI) of the American Society of Health-System Pharmacists (ASHP) aspires to transform how pharmacists care for patients by empowering the pharmacy team to take responsibility for medication use outcomes (from ASHP’s Web site www.ashpmedia.org/ppmi/docs/ppmi_national_dashboard.pdf).

1. Goal 1 – Pharmacist roles, practices, and activities will improve medication use and optimize medication-related outcomes.

Select goals

- a. 1.1. Percentage of hospitals/health systems that have pharmacist-review of all medication orders before the first dose is administered (either onsite or via telepharmacy except for procedure areas and emergency situations)
 - b. 1.2. Percentage of hospitals/health systems that require that pharmacists document their recommendations* and follow-up notes in the patients’ permanent medical records. *Level and type of recommendation as determined by hospital protocol
 - c. 1.3. Percentage of hospitals/health systems where pharmacists have privileges to write medication orders (modify or initiate therapy) in the health care setting
 - d. 1.4. Percentage of hospitals/health systems where pharmacists have the authority to order serum medication concentrations and other clinically important laboratory tests
 - e. 1.5. Percentage of hospitals/health systems that have pharmacists routinely assigned to patient care units/specialty services to provide drug therapy management at least 8 hours per day, 5 days a week for a majority of patients.
 - f. 1.7. Percentage of hospitals/health systems where pharmacists provide drug therapy management to all inpatients who exceed the threshold value on the patient medication complexity index
2. Goal 4 – Pharmacy departments use available automation and technology to improve patient safety and improve efficiency.
- a. 4.1. Percentage of hospitals/health systems using a computerized prescriber order entry (CPOE) system with clinical decision support for inpatient medication orders (e.g., rules that integrate order information, patient information, and clinical practice guidelines into computer system logic that provide feedback to prescribers).
 - b. 4.3. Percentage of hospitals/health systems that use automated dispensing technologies (e.g., automated dispensing cabinets, robotics)
 - c. 4.4. Percentage of hospitals/health systems who have smart infusion pumps that are integrated into a closed-loop medication-use process (i.e., where CPOE/pharmacy information system is integrated with pumps, and administration is documented on eMAR)

- d. 4.5. Percentage of hospitals/health systems that use machine-readable coding (e.g., Bar-Code Medication Administration system) to verify the identity of the patient and the accuracy of medication administration at the point-of-care
3. Goal 5 – Pharmacists will demonstrate leadership in exercising their responsibilities for medication use systems and will be accountable for medication related patient outcomes
 - a. 5.1. Percentage of hospitals/health systems whose pharmacists with drug therapy management responsibilities are held accountable through formal evaluation for the clinical outcomes of patients under their care
 - b. 5.3. Percentage of hospitals/health systems that regularly* conduct strategic planning to determine their optimal scope and level of pharmacy services, use of automation and technology, assignment of technicians, and readiness of staff to serve their patient population (*Strategic planning has been conducted in the past 24 months.)
 - c. 5.4. Percentage of hospitals/health systems that have used the PPMI Hospital Self-Assessment Tool at least annually (self assessment survey of 106 questions)
 - d. 5.5. Percentage of hospitals/health systems that conduct proactive and ongoing assessments and mitigate risk of medication-use systems (e.g., ISMP Medication Safety Self Assessment)
 - e. 5.6. Percentage of hospitals/health systems that routinely provide training to pharmacy students and/or residents (from ASHP’s Web site: www.ashpmedia.org/ppmi/docs/ppmi_national_dashboard.pdf)
- E. Local Quality Initiatives (from ASHP: The pharmacist’s role in quality improvement)
 1. Every accredited hospital must participate in quality improvement initiatives.
 2. Overall goals of the performance improvement programs is to maintain and support the delivery of safe, quality care.
 3. Each program should include the following:
 - a. Adherence to standards of care
 - b. Opportunities for improvement, with action plans to implement change strategies
 - c. Strategies for the effectiveness of change strategies
 - d. Involvement of multidisciplinary teams in process improvement
 4. Performance improvement plans should:
 - a. Articulate commitment to performance improvements
 - b. Delineate the goals of the performance improvement process
 - c. Specify the authority and responsibilities for performance improvement
 - d. Describe the organizational structure and process related to the performance improvement program
 - e. Describe the method for improving organizational performance
 - f. Describe the communication and recognition of performance improvement activities
- F. QI Tools:
 1. Apply the LEAN Healthcare production process (https://www.ashp.org/DocLibrary/Policy/QII/ApplyingLEAN_Flyer.pdf).
 - a. Define the problem.
 - b. Map current processes.
 - c. Identify operation barriers.
 - d. Develop future state process.
 - e. Process control strategy

2. Plan-do-check-act cycle: Means of identifying ideas for change
 - a. What are we trying to accomplish? – An aim or project goal must be developed.
 - i. Needs to describe the process to be improved
 - ii. Set a target for improvement that extends beyond current performance.
 - iii. Secure necessary resources in the process.
 - b. How will we know that a change is an improvement?
 - i. Establish baseline measurement – Select and gather data.
 - ii. Baseline data compared with the target and key causes and sources of variation
 - c. What changes can we make that will result in improvement?
 - i. Broad, general ideas and thoughts about change (“change concepts”)
 - ii. Change is tested
 - d. Plan-do-check-act cycle
 - i. Plan
 - (a) Questions are asked and predictions are made.
 - (b) Details described
 - (c) Who will make the test?
 - (d) What exactly will they do?
 - (e) When will they do it?
 - (f) Where will they do it?
 - (g) How long will they do it?
 - ii. Do
 - (a) Change is made following the “plan.”
 - (b) Data collect the single change.
 - (c) Unexpected problems and observations are documented.
 - iii. Check
 - (a) Study the effect of the test change on the single measure.
 - (b) Compare data with predictions.
 - (c) Summarize what was learned.
 - iv. Act
 - (a) Select which change(s) to implement.
 - (b) Develop implementation plan.
 - (c) Determine additional improvements.
 - (d) Determine which actions will hold the gains.

G. Tools Used to Summarize Data

1. Benchmarking – Compares your performance with that of another health care system
2. Describe a process.
3. Identify problem areas.
4. Suggest solutions.
5. Assess the effects of change.
6. Identify customers and their needs.
7. Show process or output variation.
8. Consensus decision-making tools (multiple voting, rank ordering, structured discussion)
9. Ground rules
10. Idea-generating tools (brainstorming, affinity diagramming, storyboards, role-playing, etc.)
11. Opportunity statements
12. Patient concerns or comments: Reports from third-party payers and regulatory agencies
13. Incident reporting

14. Root-cause analysis reports
15. Accident reports
16. Patient care conferences
17. Patient care evaluation studies
18. Patient satisfaction survey results

H. Analysis

1. Affinity diagrams
2. Cause-and-effect diagrams
3. Decision matrixes
4. Root-cause analysis
5. Error or failure models
6. Effects analysis
7. Flowcharts
8. Force-field analysis
9. Histograms, scatterplots
10. Relationship diagrams

III. EDUCATION

A. Educate Health Care Professionals and Other Stakeholders Concerning Issues Related to the Care of Critically Ill Patients

1. Provides informal instruction to pharmacists and other ICU health care professionals
2. Participates in the training of pharmacy students, residents, fellows through experiential critical care rotations
3. Provides didactic lectures to health care professionals, students, residents, fellows in critical care pharmacology and therapeutics
4. Implements pharmacist and pharmacy technician training programs for ICU personnel
5. Provides accredited continuing education sessions
6. Educates lay group community medical personal about the role of the ICU pharmacist
7. Coordinates or directs internships; experiential training; traineeships, residency, or fellowship programs
8. Teaches advanced cardiac life support

B. Communication Strategies

1. Seven percent of the things you say are the words themselves, 38% are tone of voice and inflection, and 55% are body language.
2. Evaluate the Audience
 - a. Patient/general public
 - b. Health care providers
 - c. Legislators
 - d. The media
3. Communication:
 - a. Credibility – Is your messenger credible? Is the messenger a trusted and respected source of information with your audience?
 - b. Context – Is your message in context with reality and the environment in which your audience is located?
 - c. Content – Is your message relevant to your audience? Is the audience interested in the information?

- d. Clarity – Is your message straightforward? How far will it travel and how long will it last? Do not use abbreviations.
 - e. Continuity and consistency – Repeat your message for audience penetration.
 - f. Channels – What channels/tools of communication are you using? What value are they bringing to your audience?
 - g. Customer benefits – What is in it for me?
 - h. Caring, compassion, and concern – Does your audience know that you care?
 - i. Capability of audience – Is your audience capable of understanding the message? Will the audience take the time to read, watch, or listen to it?
 - j. Call to action – What is your audience supposed to do now?
4. Sharing the message/tools to communicate
- a. Pharmacy departmental newsletter
 - b. Hospital newsletter
 - c. Electronic screensavers providing information
 - d. Best practice advisory methods
 - e. Local/regional communique
 - f. Electronic message

IV. PHARMACOECONOMICS

A. Overview

1. Economic studies can convey different results, depending on the following:
 - a. Disease and therapy under evaluation
 - b. Other therapies available to treat the condition
 - c. Interest of regulatory bodies, providers, payers, and patients
2. Primary economic message: The therapy is good value for the cost.
3. Cost-effectiveness – Economical with respect to the tangible benefits produced by the money spent (*Webster's*); estimates costs and outcomes of intervention, but the two are measured in different units
4. Cost minimization
 - a. Estimates the costs, but not the benefits, of an intervention
 - b. Appropriate when two therapies of equal efficacy are compared
5. Types of costs
 - a. Depend on what is affected by illness and its treatment and what is of interest to decision-makers
 - b. Direct medical or nonmedical
 - c. Time costs – Lost because of illness or treatment
 - d. Intangible costs

B. Needs Assessment Techniques

1. Gap analysis compares actual performance with potential performance. Goals of a gap analysis – Provide project team with an understanding of the differences between current practices and best practices. An assessment must be made of the barriers that need to be addressed before best practice can successfully be implemented.
 - a. Review systems.
 - b. Develop requirements.
 - c. Comparisons
 - d. Implications
 - e. Recommendations

2. Gap analysis - Can also be used to analyze gaps in processes and between the existing outcome and the desired outcome. This step process can be summarized as follows.
 - a. Identify the existing process.
 - b. Identify the existing outcome.
 - c. Identify the desired outcome.
 - d. Identify the process for achieving the desired outcome.
 - e. Identify and document the gap.
 - f. Develop the means to fill the gap.
 - g. Develop and prioritize requirements to bridge the gap.
 - h. Examples of ICU gaps
 - i. Staffing model – Not enough ICU pharmacists to see all ICU patients, based on workload, documentation requirements
 - ii. Delirium assessment – Practice needs
 - iii. Wake-up assessment
 - iv. Antibiotic streamlining
 - v. Criteria-based antimicrobials and non-antimicrobials for high-cost/misused drugs
3. Medication use evaluation – See previous section.
4. Best practice survey
 - a. Survey provides feedback from practitioners (e.g., ICU pharmacists, nurses, physicians)
 - b. Benchmarking
 - c. Survey strategies
 - i. Have a single well-defined objective.
 - ii. Keep the survey short.
 - iii. Design the survey for easily measureable results.
 - iv. Ask one thing per question.
 - v. Avoid biasing the response.
 - vi. Limit the number of required questions.
 - vii. Question order matters – The first question or two should be easy and interesting.
 - viii. Create a logical flow to the questions.
 - ix. Test the survey.
 - x. Spell out time expectations in your invitation and on the greeting page.
 - xi. Survey the appropriate people.
 - xii. Share the results and actions with the respondents.

C. Resources Necessary to Care for Critically Ill Patients

1. Financial
 - a. Medications – High in cost, specialized, and routine
 - b. ICU bed use
2. Technology
 - a. CPOE
 - b. Integrated profiles (one system instead of several) providing laboratory, medications, microbiology, progress notes, operative interventions, imaging
 - c. Automated distribution (Cardinal, McKesson, etc., products)
 - d. Bar coding and scanning
 - e. Mechanical ventilator
 - f. Electronic drug information
 - i. Lexi-Comp, Inc
 - ii. Micromedex

- g. Library access – Preferably electronic, to retrieve literature supporting real-time practice
 - h. Robotic sterile product preparation
 - i. Parenteral nutrition admixing compounders
 - j. Smart intravenous pumps, library management, and integration into electronic medical records
3. Human
- a. Physician and midlevel providers have advanced training in managing the critically ill.
 - b. Critical care pharmacist
 - c. Respiratory therapist
 - d. Critical care nurses
 - e. Specialty services – Cardiology, surgery, pulmonary, neurosurgery, burn, pediatrics
 - f. Social work

V. RESEARCH

Outcomes Research Evaluated the Effects of Medical Care on Individuals and Society in Three Areas:

- A. Clinical – Measures the consequences of treatment and disease on the patient using discrete indicators (i.e., mortality rates, readmission rates, LOS, morbidity, quality of care, achieving therapeutic levels, fluid management, nutrition support, duration of mechanical ventilation with sedation, medication errors, infection rates)
- 1. Pharmacotherapeutic management guidelines – Sedation, stress ulcer prophylaxis
 - 2. Preventing ADEs (i.e., monitoring medications with a narrow therapeutic index, high alert medications, and critical care medications with known ADEs)
- B. Economic – Cost and resources used are higher in a critically ill patient.
- 1. ICU costs account for 5% of hospital admission, 15%–20% of hospital budget (around 15% of pharmacy budget).
 - 2. Cost savings versus cost avoidance – In the literature, these terms are sometimes interchanged.
 - 3. Cost savings – Acquisition cost of original therapy prescribed without intervention minus cost of therapy after the pharmacist’s intervention
 - 4. Cost avoidance – Cost of the therapy that would have been incurred before an intervention minus cost of the actual therapy with interventions
 - 5. Cost of providing clinical pharmacy services should be included in the accounting.
 - 6. Direct/indirect costs – More precise studies involving direct/indirect cost, cost savings, and cost of providing clinical pharmacy services are needed.
- C. Humanistic – Measure the function and overall well-being of patients using quality-of-life assessment tools, such as those used in the ICU:
- 1. Nottingham Health Profile
 - 2. Sickness Impact Profile
 - 3. Post-traumatic stress disorder questionnaire
 - 4. EuroQol questionnaire
 - 5. Medical Outcome Study Short Form 36 (SF-36)
 - 6. Example: Pharmacist-managed sedation in the critically ill; the effect of sedation medications on the critically ill. The evaluation could measure quality of sedation provided based on the perception of the patient.

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ANSWERS AND EXPLANATIONS TO SELF-ASSESSMENT QUESTIONS

1. Answer: C.

Answer C, medical professional's time, is correct. Direct medical costs are associated with the medical products and services used in the identification, prevention, detection, and treatment of a disease. Examples of direct medical costs include medications, supplies, and hospitalizations. Delirium is an example of intangible costs (Answer A). Morbidity is an example of indirect cost (Answer B). Adverse drug events are a direct non-medical cost (Answer D).

2. Answer: C.

Indirect costs are occur because of work loss, and decreased productivity occurs because of illness. Drug effects on patient functioning are an indirect cost from the employer's perspective (Answer D). Costs involved in the care of the patient's health occur because of clinic visits (Answer A), and costs of hypertension treatment (Answer B) are direct costs.

3. Answer: B.

Three major components of a critical care pharmacist service have been described. Fundamental characteristics include distribution, order entry and/or order verification. Desirable characteristics include limited clinical activities (Answer A) of a specialized patient population. Optimal characteristics include clinical activities, educational lectures to various health care professionals, administrative functions (Answer C) such as policy development and guideline creation, and scholarly activities (Answer D) such as research and writing. Answer B is correct because order entry/order verification is a fundamental characteristic.

4. Answer: B.

Cost-benefit analysis is the best economic tool to evaluate the value of a critical care pharmacist service. For example, the financial value can be determined in dollars by comparing the cost of implementing a critical care pharmacist's service (pharmacist salary and benefits) with the benefits gained through the critical care pharmacist's activities such as reduced LOS and decreased drug cost. Answer B is correct.

5. Answer: B.

Practice environment constraints include financial disincentives, organizational constraints, perception of liability, and patient's expectations. Other barriers (non-practice environment) to implementation of the delirium screen include standards of practice (Answer A), opinion of leaders, medical training (Answer C), and advocacy. The final barrier is knowledge and attitudes with includes clinical uncertainty, sense of competence (Answer D), compulsion to act, and information overload.

6. Answer: C.

The next best step is determining the patients involved in the process, followed by evaluating the prescriber's practice. Finally, data will be collected on the current process, which will be evaluated to determine the areas for improvement in the outcome desired.

7. Answer: B.

Quality-of-life assessment instruments are within the humanistic outcomes research category because they measure the function and overall well-being of the patient. Economic outcomes focus on financial impact (Answer C). Clinical outcomes focus on specific clinical aspects of patient care (Answer A). Operational is not a type of outcomes research (Answer D).

8. Answer: C.

Changes are made during the "do" part of the cycle. The planning phase involves describing the practice (Answer A), collecting data (Answer B), outlining the details (Answer D), and describing who, what, when, and where the process will be done.