PRN Opinion Paper

An Opinion Paper Outlining Recommendations for Training, Credentialing, and Documenting and Justifying Critical Care Pharmacy Services

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In 2000, the Society of Critical Care Medicine (SCCM) and the American College of Clinical Pharmacy (ACCP) published a position paper that defined critical care pharmacy services as fundamental, desirable, and optimal. A task force was developed that included individuals who are members of the ACCP Critical Care Practice and Research Network, the SCCM clinical pharmacy and pharmacology section, and the American Society of Health-System Pharmacists to develop an opinion paper with three primary objectives: to provide recommendations for the level of preparation and training of pharmacists to practice in critical care, to develop recommendations for the credentialing of pharmacists providing critical care services, and to develop mechanisms for documenting and justifying intensive care unit (ICU) pharmacy services. Each objective was addressed to accommodate the levels of services defined as fundamental, desirable, or optimal, and are targeted at all pharmacists providing or wanting to provide pharmacy services to critically ill patients. The training and preparing of the pharmacist caring for critically ill patients is discussed in the context of the knowledge and skills required to provide pharmacy services in the ICU. Credentialing of the critical care pharmacist and the documentation of services take into account the various scopes of practice, and recommendations are based on current and idealistic mechanisms. A detailed outline is provided for the process of services justification. This paper provides a foundation that is focused on delivering direct and proactive patient care services, particularly 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. This commentary should be of interest to numerous stakeholders including pharmacists, other pharmacy department staff, other ICU health care professionals, hospital and academic administrators, accrediting agencies, government officials, and payers. The task force encourages the profession of pharmacy in general to incorporate key recommendations provided in this document with respect to specialized training, credentialing, and service justification.

Key Words: critical care, intensive care, pharmacy, pharmacotherapy, services, programs, training, education, credential, competency, documentation, justification.

(Pharmacotherapy 2011;31(8):135e–175e)

In 2000, the Society of Critical Care Medicine (SCCM) and the American College of Clinical Pharmacy (ACCP) published a position paper that defined the scope of critical care pharmacy services.[1] This report encompasses clinical and nonclinical pharmacy services and stratifies levels of service as fundamental, desirable, or optimal to patient care. *Fundamental* activities reflect services associated with order entry and distribution duties that are necessary for the safe provision of pharmaceutical care; *desirable* activities add some clinical functions necessary for the specialized care of critically ill patients; and *optimal* activities reflect an integrated, specialized, and dedicated model of direct patient care functions that aim to maximize outcomes. Various aspects of pharmacy practice are addressed in this report including clinical, educational, administrative, and scholarly activities. The results of a recent survey found that fundamental services are consistently provided to the intensive care unit (ICU) but desirable or optimal services are far less likely to occur across all types of practice activities.[2]

The provision of fundamental services to ICU patients is key to insure safe patient care. However, technological advances (e.g., provider-order entry, integrated profiles, automated distribution systems, bar coding, etc.) and policy changes (e.g., technician-check-technician) may shift responsibilities to possibly render the role or alter the manner in which pharmacists provide these services. Concurrently, competitive pressures and safety mandates are driving institutions to focus resources on specific services, including the care and outcomes of the critically ill.[3] Several initiatives (e.g., ability and practice-based outcomes of the Accreditation Council of Pharmacy Education (ACPE), medication therapy management services, Medicare amendments recognizing pharmacists as providers, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO; now termed "The Joint Commission" or "TJC") national patient safety goals)[3-5] are empowering pharmacists to practice higher level pharmacotherapy that necessitates direct patient care. The Joint Commission of Pharmacy Practitioners envisions that "pharmacists will have the authority and autonomy to manage medication therapy and will be accountable for patients' therapeutic outcomes."[6] To achieve an optimal model of patient care in the ICU, SCCM recommends a collaborative approach to ICU care with an emphasis on practitioner certification.[7, 8] Pharmacy organizations have collaboratively indicated that pharmacists will require credentials in the future to provide various levels of patient care services.[9]

In order to meet the growing demands of providing, documenting, and justifying pharmacy services in the ICU, a task force was convened to develop an opinion paper addressing these issues. The task force included individuals who are members of the ACCP critical care practice and research network (PRN), the SCCM clinical pharmacy and pharmacology (CPP) section, and American Society of Health-System Pharmacists (ASHP). The specific objectives of the task force were to: 1) provide recommendations for the level of preparation and training of pharmacists to practice in critical care, 2) develop recommendations for the credentialing of pharmacists providing critical care services, and

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Opinions expressed in this document are endorsed by the American College of Clinical Pharmacy critical care practice and research network, the Society of Critical Care Medicine clinical pharmacy and pharmacology section, and the American Society of Health-System Pharmacists.

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3) develop mechanisms for documenting and justifying ICU pharmacy services. This document was developed over a two year period with subcommittees assigned to each objective. The subcommittees communicated electronically and convened several times at various professional conferences. Integration and alignment of the three sections was completed by a steering / editing committee comprised of the chairs of each subcommittee and the chairs of the ACCP critical care PRN and the SCCM CPP.

Each objective was addressed to accommodate the levels of services defined as fundamental, desirable, or optimal and are targeted at all pharmacists providing or wanting to provide pharmacy services to critically ill patients. The recommendations, however, 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. Recommendations were developed according to realistic standards although idealistic or speculative expectations were also addressed. These recommendations apply to all ICU practice sites and populations (e.g., medical, surgical, neurosurgical, trauma, burn, pediatric, neonatal, etc.) or any site encountering ICU patients (e.g., transplant, operating room, emergency room, etc.) across all types of institutions (community, private, academic, government, etc.) of all sizes providing all levels of medical care (level I – III).[7] The recommendations are dynamic so that the individual pharmacist, the department of pharmacy, or hospital administration may develop, enhance, and maximize their services. Additionally, this document should be of great interest to the pharmacy department, other ICU healthcare professionals, hospital and academic administrators, accrediting agencies, government officials, payers, and patients or their families.

Requirements of the ICU Pharmacist

The genesis of the ICU pharmacist typically begins with an individual entering or desiring to expand their practice by developing skill sets that allow practice advancements or transitions to higher level activities relative to the care of critically ill patients. Including pharmacists in the care of critically ill patients can lead to superior care by utilizing their role as the "ICU pharmacotherapy knowledge manager."[7, 8, 10–13] To be successful in such a role, pharmacists need a strong knowledge base and diverse skill sets that include effective communication, advanced problem solving / critical thinking, judgment, leadership, and time management. These skills are optimized when pharmacy services are directly provided in a proactive and applied manner. Of note, ACCP recently published an opinion paper describing the competencies required by clinical pharmacists that independently recommended skill sets similar to those put forth in this paper.[14]

Pharmacotherapy manager

ICU pharmacists must integrate pharmacology, pharmacokinetics / pharmacodynamics / pharmacogenomics, pharmacoeconomics, and pharmacotherapeutics with pathophysiological changes in the management of critical illness.[10, 15–17] Table 1 summarizes examples of core therapeutic topics that pharmacists providing care to adult ICU patients with these diseases or disorders should be knowledgeable of to the extent that they are able to be the "ICU pharmacotherapy manager."[12] Additional core topics may apply to pharmacists providing services to specialized patient populations (e.g., pediatric, neonatal, burn, transplant, emergency medicine, etc.). All pharmacists should maintain a knowledge base that incorporates current medical advances reported in the literature including any associated controversies in a given situation.[1] Knowledge must be integrated with sound judgment and the skill of practical application. This requires clinical familiarity and experience. A commitment to life-long learning, skill development, and resource development is essential to continually delivering any level of pharmacy service.

ICU pharmacists must possess statistical knowledge to the extent that they are able to interpret and apply data to patient-specific scenarios. Pharmacists providing desirable or optimal levels of care must understand and integrate non drug interventions such as mechanical devices (e.g., ventilators, renal replacement therapies, vascular catheterization, point-of-care testing, etc.), procedural processes (e.g., paracentesis; thorocostomy; basic surgical interventions; interventional radiology; fiberoptic imaging such as bronchoscopy or endoscopy; radiographic imaging such as computerized tomography, magnetic resonance imaging, fluoroscopy, radiography, etc.), measured responses (e.g., bedside observations;

Table 1. Examples of Core Therapeutic Topics for Pharmacists Caring for Critically Ill Adults.

Therapeutic Area	Specific Disease State, Condition, or Device
Neurology and Psychiatry	Altered mental status, encephalopathy, coma
	Brain injury
	Cerebrovascular diseases (e.g., hemorrhage, ischemia, thromboembolic)
	Delirium
	Encephalopthy
	Intracranial perfusion
	Movement disorders (e.g. neuroleptic malignant syndrome, seratonin syndrome, malignant hyperthermia, dystonia / dyskinesia, botulism, tetanus, etc)
	Neuromuscular blockade
	Neuromuscular diseases (e.g., Guillain-Barre syndrome, myasthenia gravis, etc.)
	Neuropathies, myopathies
	Pain management
	Sedation management
	Seizure management and prophylaxis
	Substance abuse
	Spinal cord injury
	Withdrawal syndromes (e.g., alcohol, opiate, nicotine, etc.)
Cardiovascular	Acute coronary syndromes (unstable angina, myocardial infarction)
	Acute heart failure (right and left sided, diastolic and systolic)
	Anaphylactic shock
	Aortic aneurysm
	Aortic dissection
	Arrhythmias (atrial fibrillation and flutter, paroxysmal supraventricular tachycardia, ventricular tachycardia and fibrillation, QT prolongation, sinus bradycardia, atrioventricular bradycardia, pulseless electrical activity, asystole)
	Cardiac temponade
	Cardiac or vascular surgical procedures
	Cardiopulmonary resuscitation
	Cardiovascular shock
	Cardiac Arrhythmias
	Hypovolemic shock
	Hypertensive emergencies and urgencies
	Mechanical assist devices
	Myocardial contusion
	Pericarditis
	Peripheral arterial occlusion
	Valvular diseases
	Venous thromboembolism management and prophylaxis
Pulmonary	Acute respiratory distress syndrome
	Asthma
	Aspiration
	Chronic obstructive pulmonary diseases
	Cystic fibrosis
	Etiologies of hemoptysis
	Extracorporeal membrane oxygenation
	Inhalation injury
	Mechanical ventilation
	Near drowning
	Obesity hypoventilation syndrome
	Pleural effusions
	Pulmonary arterial hypertension
	Pneumothorax, hemothorax
	Pulmonary embolism and other embolic syndromes
	Surgical resections
Hepato-gastrointestinal	Acute abdomen and necrosis
	Ascites
	Cholycystitis
	Fulminant hepatic failure
	Hepato-renal syndrome
	Lower gastrointestinal hemorrhage
	Motility disorders (e.g., ileus, gastroparesis, etc.)
	Malabsorptive disorders (e.g., inflammatory bowel disease, short bowel syndrome, etc.)

Table 1. (continued)

Therapeutic Area	Specific Disease State, Condition, or Device
Hepato-gastrointestinal	Nonvariceal upper gastrointestinal hemorrhage Pancreatitis Mesenteric or splanchnic thrombosis Stress-related mucosal disease Variceal hemorrhage Viral hepatitis
Renal	Acute kidney injury (prerenal, intrinsic, postrenal) Fluid and electrolytes homeostasis, abnormalities, and replacement Prevention of renal dysfunction Quantification of renal function Renal replacement therapies Rhabdomyolysis
Hematology	Anemias Coagulopathy Hemorrhagic shock Hemolytic uremic syndrome Hematologic neoplasms Hypercoagulation disorders Neutropenia Sickle cell crisis Thrombocytopenia Thrombotic thrombocytopenic purpura Transfusion medicine
Endocrine	Adrenal insufficiency Alcoholic ketoacidosis Autoimmune disorders (e.g., lupus, sarcoides, rheumatic disease, vasculitis, etc.) Cushing's syndrome Diabetic ketoacidosis, hyperosmotic nonketoacidosis Glucose control Hypothyroidism, myxedema coma Pheochromocytoma Thyrotoxicosis Tumor lysis syndrome
Infectious Diseases	Bloodstream and line infections Bone and joint infections Central nervous system infections (meningitis, encephalitis, abscess, shunt infection) Endocarditis Gastrointestinal infections (e.g., *E. coli* hemorrhagic diarrhea, *C. difficile* diarrhea, "Traveler's diarrhea", Yersinia, viral diarrhea, etc) Institution-specific antimicrobial susceptibility patterns Intra-abdominal infections (e.g., abscess, peritonitis, cholycystitis, etc.) Opportunistic infections (fungal, viral, bacterial, parasitic, etc.) Oropharynx (Ludwig's angina, epiglottitis, pharyngeal space, peritonsillar or laryngeal abscess) Pneumonia (community-acquired, nosocomial, ventilator-associated, aspiration) Sepsis, severe sepsis, and septic shock Sinusitis Skin and soft tissue infections (e.g., cellulitis, necrotization, diabetic, etc.) Spontaneous bacterial peritonitis Surgical prophylaxis and wound infections Tuberculosis Urinary tract infections (e.g., pyelonephritis, catheter-related, etc.)
Other	Acid / base disorders Adverse drug events Biohazard exposure Bioterrorism exposure Dermatology (e.g., decubitus ulcer, toxic epidermal necrolysis, erythema multiforme, necrosis, etc.) Drug interactions Drug overdoses Emergency medicine Environmental exposures Graft vs. host Heat stroke

Table 1. (continued)

Therapeutic Area	Specific Disease State, Condition, or Device
Other	Hypothermia (inadvertent and therapeutic)
	Immunization
	Nutrition support (enteral and parenteral)
	Obstetrical crises
	Organ transplant and complications
	Orthopedic injury
	Pain management
	Pharmacoeconomics
	Pharmacokinetics, pharmacodynamics, pharmacogenomics
	Solid organ neoplasms
	Surgical procedures
	Thermal injuries
	Toxicology
	Trauma (blunt and penetrating)

hemodynamic and cardiac monitoring; neurologic monitoring including sedation, analgesia, delirium; laboratory values; etc.). In addition, these pharmacists should be familiar with pharmacoeconomic and outcome assessments, ethical and legal considerations, risk management and medication safety, ICU design, service delivery, and workforce issues. All pharmacists need to be familiar with the health-systems processes for the delivery of medications and institution-specific policies or procedures that affect the care of ICU patients (e.g., clinical pathways or protocols, medication reconciliation, medication safety, quality measures, pharmacy operational processes, etc.). The ICU pharmacist may represent a team of pharmacy personnel, each contributing unique expertise and skills. In order to maximize services, the pharmacist must be aware of the responsibilities and activities of each individual and may be required to integrate or lead the team.

Direct pharmacy services

While hospital-wide mortality rates decrease as the pharmacist-to-occupied bed ratio increases, the primary factor contributing to this beneficial association is the involvement of pharmacists in the direct care of patients with activities generally deemed fundamental or desirable.[18–20] Guidelines developed by SCCM determined that pharmacists are an essential component for providing quality care to critically ill patients and recommend the integration of a dedicated pharmacist into the ICU team.[7, 8] The provision of pharmacy services in a manner that is proactive and directed at patient care decreases drug-related costs, prevents adverse drug events, improves the quality and efficiency of care, and is associated with reduced mortality, shortened length of stay, and lower overall costs.[13, 15, 18–26] Pharmacy services associated with favorable healthcare outcomes include[18-21]:

- Adverse drug reaction management
- Drug information
- Protocol management
- Admission medication history
- Disease state management
- Participation in patient care rounds
- Cardiopulmonary resuscitation

Most of these services are fundamental activities. Unfortunately, recent survey results indicate that pharmacists are providing direct patient care services in only 62.2% ICUs, which is similar to the 64.8% reported nearly twenty years prior.[2, 27]

Skills for success

Communication

As the ICU pharmacotherapy specialist and leader, the pharmacist must effectively communicate and interact with other disciplines. The development and refinement of communication skills is an essential component for advancement of pharmacy services into and within ICU practice. Communication in the ICU is key to a collaborative multidisciplinary approach, comprehensive patient care, and optimizing outcomes through the provision of effective and safe pharmacotherapy.[28, 29] Effective communication is built on trust and credible clinicians are those who by their actions demonstrate and advocate the best interests of

their patients. Pharmacists must be aware of the relationships established between the pharmacy department and the ICU and its practitioners. Therefore, frequent pharmacist-to-pharmacist or pharmacist-to-technician communication is also essential.

Directly providing pharmacy services is associated with beneficial outcomes.[18–20] Ideally, all pharmacists should assess patient needs at the bedside whenever possible and those providing higher level services must be visible. A practical approach for the pharmacist to assess critically ill patients includes:

- Observe the patient in addition to the laboratory, pharmacy, medical records, and information from other healthcare providers.
- Create a problem list, starting from the top of the patient and working down (e.g., head, neck, chest, abdomen, etc.) or by systems as outlined in Appendix 1. Include all problems. Recognize that the primary pharmacy problem may not be the reason for admission.
- Evaluate the pre-ICU medical records. Look carefully at the events that occurred in the ambulance, prior hospital, emergency or operating room. Evaluate the past medical history and determine the need to continue therapy in the ICU. Request additional information as needed (e.g., laboratory value).
- After developing a complete problem list, begin to integrate (impact of one problem on the others) and prioritize problems.
- Collaborate with other members of the healthcare team, including respiratory therapists, nurses, dieticians, and physicians. Learn how their activities impact the pharmacotherapeutic plan for the patient. Examples include:
  - How do different ventilator settings impact the required level of sedation?
  - What type of intravascular access is available?
  - How does nutrition support impact pharmacotherapy?
  - How does renal replacement therapy impact drug metabolism / elimination?
- Formulate a comprehensive therapeutic management plan for each problem that includes:
  - Drug regimens and devices needed.
  - Specific monitoring regimen (what and when).
  - Communicate desired and unexpected (e.g., adverse events, lack of effect) outcomes, including the monitoring regimen and reasons for discontinuation.
  - Anticipate physiologic (e.g., acute kidney injury), pharmacologic (e.g., need for an interacting agent), or process changes (e.g., loss of intravenous access)
- Reassess daily the problem list and the therapeutic plan.

Relying on information gathered and acted upon at an independent setting (e.g., pharmacy or office) may not encompass all the patient-specific clinical concerns. The presence and increased visibility of being at the bedside creates the opportunity to exchange patient-specific information and automatically engages the pharmacist in direct patient care that is often proactive rather than retroactive.[1, 14, 15, 26, 30] Efficiently extracting patient-specific information by asking key questions to gain a rapid understanding of the situation, listening to input provided by others, engaging in an exchange of information, educating others about all pharmacotherapeutic options, and setting the expectation for the selected drug regimens are some of the many ways to communicate while integrating into the healthcare team and gaining confidence that a pharmacotherapeutic plan will result in expected outcomes.[11, 31] A common flaw of inexperienced ICU pharmacists is to consume their time in data collection, compiling or gathering vast amounts of available information at the expense of analyzing it, developing a treatment plan, and effectively communicating or implementing the plan. To provide higher level services and truly be the pharmacotherapy expert, the pharmacist must efficiently interpret data and link the data to therapeutic management plans.

Participating in patient care rounds is beneficial and expected according to SCCM.[7, 8] Efficient use of time and resources may limit attendance, but pharmacists should strive to attend rounds as frequently as possible. Ideally rounds occur at the bedside but they may occur elsewhere or via automated interactive systems. Some may choose to conduct independent pharmacy-driven rounds. The established ICU pharmacist may serve as much as a consultant as a clinician. Since many therapies used in the ICU are technologically demanding, highly complex, and costly, a desirable goal for critical care pharmacy services is to share clinical, pharmacoeconomic, and outcomes research with the ICU team.[1, 7, 8, 11, 15, 20, 21] Involvement in patient care rounds also provides educational opportunities for the pharmacist to learn from

other ICU professionals.

Written communication skills are equally important to the care of critically ill patients. When indicated, written communication or documentation of pharmaceutical care activities should include a concise explanation of the management plan. A focused pharmaceutical care plan should conclude with precise wording of a recommendation that may include a therapeutic regimen and monitoring plan. Written communication, however, should complement direct verbal interactions.

Actively participating on ICU committees or hospital committees that affect the ICU provides the pharmacist with several opportunities including establishing rapport with other personnel, promoting rational and safe use of medications, educating other healthcare professionals, and learning and applying the policies that affect practice in the ICU. Communication during committee meetings or involvement with committee actions (e.g., ICU projects, clinical pathways, policies or procedures, quality improvement initiatives, medication safety, implementing new or revised systems, etc.) provide the pharmacist with additional opportunities to exemplify their unique knowledge of pharmacotherapy of critically ill patients. Similarly, informal (e.g., inservices, pharmacy updates, project results, etc.) and formal education (e.g., lecture series, continuing education, etc.) of other healthcare professionals are opportunities to communicate professionally and demonstrate the pharmacist's role as the pharmacotherapy expert. Similarly, the attendance of educational events conducted by other disciplines expands the pharmacist's scope of knowledge.

Advanced problem solving / Critical thinking

Optimizing patient outcomes in the ICU is dependent upon an organized and efficient approach to understanding and managing medical problems or pharmacotherapy needs of the acutely ill. At the core of this skill is a detailed understanding of common ICU disease states (Table 1), patient-specific pathophysiology, drug action properties, evidence-based medicine, and patient-specific goals of therapy. Intertwined with didactic and experiential work is the ability to integrate multiple sources of medical information. Data assimilated from the patient or family interview, other healthcare professionals, medical profile, physical assessment, laboratory examination, and other diagnostic tests provide the pathophysiologic pieces of the puzzle needed to create an acute problem list with corresponding differential diagnoses. Once a problem list or specific issue is established, a comprehensive and realistic care plan can be devised and implemented. Continual reassessment and revisions of the treatment plan should be anticipated as new or adjusted information is common in the ICU. To ensure the pharmaceutical care provided to the patient is effective, safe, and appropriate given the potentially rapid changes in their clinical presentation, skill in intensive monitoring must be developed. Key to the mastery of problem solving in the ICU is the ability to establish management plans early with therapeutic goals and anticipated outcomes (see list above). The plan, goals, and outcomes need to be serially assessed and frequently revised. Therefore, efficiency and sound clinical judgment are fundamental to critical thinking. The pharmacist should preemptively prepare a management plan for unexpected outcomes, adverse events, or new developments (e.g., acute renal dysfunction). Unexpected outcomes or adverse events should be rationalized by the pharmacist in an attempt to avoid reoccurrence.

Another component of critical thinking is elucidating issues that indirectly affect patient care. These may include workflow parameters, pharmacy or ICU structure, policies or procedures, the actions of committees, technology, etc. Judgment and communication are keys to effectively dealing with issues that indirectly impact patient care. While the ICU pharmacist offers unique knowledge and skills that may guide interpretation or application of these issues, all interested parties should be consulted since the issue may affect others. Similar to the patient care approach, the ICU pharmacist should anticipate potential indirect patient care concerns and preemptively manage or communicate the issue.

Other skills

Judgment, leadership, organization, and time management are essential skills that are difficult to learn but should be developed over time through continual application and practice. Experienced practitioners may help the ICU pharmacist develop these skills. Because increased stress is associated with the care of critically ill patients, the pharmacist should be

prepared to accommodate the emotional responses that are common. These responses are often natural, and planned activities to help alleviate stress are sometimes needed (e.g., communication, exercise, relaxation, etc.).

Project Management / Scholarship

Project management and scholarship are considered desirable or optimal to critical care pharmacy practice.[1] Scholarship refers to the assimilation and dissemination of information in any format at any level. At the foundation of this skill is the creation and capture of outcome measurements and reporting systems that function in the context of each individual ICU setting. The goal of collecting, analyzing, reporting, and ultimately implementing systems based on project findings is to lessen variability in the delivery of care, thereby optimizing outcomes, reducing errors and enhancing safety, and improving resource utilization. Therefore, to advance the profession of critical care pharmacy, pharmacists practicing at the fundamental level of service should participate in the development, implementation, and data collection of protocols and medication utilization evaluations. At the desirable level of service, pharmacists are project managers and lead the assessment of guidelines, protocols, practice changes, or performance improvement initiatives in the ICU. Optimally, the ICU pharmacist is the project champion of hypothesis driven initiatives. Internal and external dissemination of case reports, project results, or pertinent review articles should be expected of all pharmacists practicing at all levels. In addition, all pharmacists should participate in developing ICU or institutional policies, procedures, clinical pathways, and the education of others. Pharmacists should attempt to present their findings at local and regional meetings of critical care professionals and strive to disseminate their results at national and international conferences. These initiatives should be supported by the institution and its constituents and affiliates.

Training and Preparing the ICU Pharmacist

Education

Conventional

The training and preparation of pharmacists providing care to critically ill patients is currently not standardized and may take several successful pathways. In the United States, all professional pharmacy programs lead to the doctor of pharmacy degree.[4] The ACPE outlines standards and guidelines that emphasize communication skills, curriculum content, educational assessment and outcomes, experiential education, interprofessional teamwork, patient safety, professional competency, professionalism, and scholarship amongst other key educational components.[4] Several white papers prepared by the ACCP further delineate the educational requirements for the didactic curriculum,[17] experiential education,[32] professionalism,[33, 34] interprofessional networking,[35] and exposure to research.[36] Therefore, the doctor of pharmacy degree provides the core skill sets and knowledge for graduates to function as competent clinicians. Curricula, however, should be flexible enough to accommodate students desiring additional training, either didactically or through experiential exposure, in particular domains including but not limited to research, teaching, administration or management, and specialty practices like critical care.

Individuals desiring to practice in an ICU environment enter residency training shortly after receiving their pharmacy degree.[15] The first year resident, or postgraduate year one (PGY1), should be exposed to a variety of experiences that include multiple clinical subspecialties, project management and scholarly activities, teaching opportunities, and administrative functions.[37] The individual may then choose to pursue a second year of specialty training, or postgraduate year two (PGY2). Critical care is recognized by ASHP as a specific area for PGY2 pharmacy residency training. ASHP is the organization that accredits all pharmacy residency programs (PGY1 and PGY2).[37] As of May 2011, 85 critical care residency programs are either available or in the ASHP accreditation process. Information on the outcomes, goals, objectives and standards of residency programs may be found online at the ASHP website.[37, 38] Individuals completing PGY1 residency programs should have the knowledge base and skill sets to provide desirable pharmacy services to ICU patients with the expectation that optimal services be easily incorporated into practice. The PGY2 residency is directed by an experienced critical care pharmacist and is designed to develop an independent practitioner with advanced knowledge and skill sets. Therefore, these pharmacists should be capable of providing optimal services. Only 11.1% and 5.9% of

pharmacists providing critical care pharmacy services have completed PGY1 and PGY2 residency training, respectively.[2] Pharmacy organizations have independently and jointly proposed that residency training for new pharmacists become mandatory before entering a patient-care practice by the year 2020.[9, 39, 40] While this would standardize the training, ensure consistent preparation of critical care pharmacists, and lead to higher levels of services being provided, pharmacy graduates substantially outnumber available residency program positions.[37, 38, 41] A key challenge for the pharmacy profession as a whole is to provide sufficient training programs to meet future demands and the growing needs of all the subspecialties.[42–44] This section of the article will focus on developing and preparing the working pharmacist wanting to transition to or achieve higher level pharmacy services in the ICU.

Unconventional

A common cause linked to medication errors and adverse drug events in ICUs is the limited knowledge related to pharmacotherapy by the prescriber.[45–54] Therefore, any pharmacist wanting to practice in the ICU must have comprehensive knowledge of key ICU topics that are representative of their population of critically ill patients (Table 1). Similarly, these pharmacists must possess or be willing to develop the skills required to provide pharmacotherapy management. These may be learned through didactic lectures, active problem solving activities, or experiential opportunities such as on-the-job training, mini-sabbaticals, mentorship programs, masters or nontraditional doctor of pharmacy programs. Recognizing key sources of information and identifying a mentor are key to acquiring the necessary knowledge, resources, and skills.

Literature

Recognizing sources of information that can assist pharmacists in keeping current on the latest developments in patient care or gain additional expertise out of their daily scope of practice is key to professional development. Examples include peer reviewed journal articles, tertiary texts, or electronic and on-line resources that are easily accessible. Table 2 provides examples of journals that frequently publish articles related to critical care pharmacotherapy.[55–58] Unique sources of comprehensive information are articles that compile and briefly summarize primary literature that are clinically relevant to a specific area of practice, including ICU pharmacotherapy.[55–58] Consensus guidelines and systematic reviews may provide general information but the pharmacist providing higher level services must critically evaluate and clinically interpret the primary studies. Preselected critical care abstracts from various

Table 2. Examples of Journals Frequently Publishing Critical Care Related Articles.[55–58]

Type of Critical Care Pharmacotherapy Articles	Journal
Common Publications	American Journal of Critical Care
	American Journal of Respiratory and Critical Care Medicine
	Anesthesia and Analgesia
	Anesthesiology
	Chest
	Critical Care
	Critical Care Clinics
	Critical Care Medicine
	Heart and Lung
	Intensive Care Medicine
	Journal of Critical Care
	Journal of Trauma Injury, Infection and Critical Care
	Surgery
Landmark Publications	Annals of Internal Medicine
	Archives of Internal Medicine
	British Medical Journal
	New England Journal of Medicine
	Journal of the American Medical Association
	Lancet
Subspecialty Publications	American Journal of Health-System Pharmacists
	Annals of Emergency Medicine
	Annals of Pharmacotherapy
	Annals of Surgery
	Burns
	Clinical Infectious Diseases
	Emergency Medicine Journal
	Gastroenterology
	Hepatology
	Journal of Emergency Medicine
	Journal of Parenteral and Enteral Nutrition
	Neurocritical care
	Neurosurgery
	Pediatrics
	Pediatric Critical Care Medicine
	Pharmacotherapy
	Transfusion
	Transplantation

journals may be purchased so the pharmacist does not need to regularly search each journal. Publishers may send free alerts of new issues with article titles and abstracts. Online search engines may offer filtered searches. A number of resources are available in an electronic version including texts, journals, and personal digital assistants (PDA) that allow access anywhere, including the bedside.[59] Over 135 additional web-based resources in a variety of e-learning formats are available for critical care education.[60] The pharmacist desiring to provide higher level services must apply the available literature in a manner that takes into account the ICU-specific patient population, practice patterns, and hospital processes and structure. In addition, several organizations such as the ACCP PRNs, SCCM CPP section, and ASHP critical care and emergency medicine network provide ICU-specific education and networking opportunities for practice, education, and scholarship. Journal clubs may be available through various institutional departments or the aforementioned organizational networks.

Mentors

Mentors play vital roles in developing and advancing the level of care provided by pharmacists.[61] Mentoring may occur in multiple ways including co-workers, experts in the field, other critical care practitioners, or nonICU personnel and may be formal or informal. Identifying and developing good mentors is important for facilitating the learning process. Mentors may be chosen or assigned, but in general, the strongest mentorship relationships develop over time. An individual ICU pharmacist may have several mentors at any one time or an individual mentor may lead a process that designates preceptors to develop specific educational components or skill sets.

Ideally, an inexperienced pharmacist should seek a mentor with insight into critical care practice so they may provide skill development or enhance the understanding of approaches to assessing and managing critically ill patients and their disease sates.[61] NonICU personnel (other clinicians or academicians) may serve as mentors as they may provide skill development or career guidance applicable to the ICU. An inexperienced pharmacist should pursue a mentor who is geographically close enough that regular meetings are easily arranged. When a nearby mentor is not available, communicating by e-mail or telephone may be feasible alternatives to face-to-face meetings.[62] A more experienced pharmacist may not require direct mentorship or may seek mentors with expertise in a specific skill set (e.g., project management / scholarship, administration, teaching, specialized setting, etc.). The trainee may observe various approaches used by practitioners to consider which settings to emulate as they develop their own approach to being the pharmacotherapy specialist providing direct care of critically ill patients. The time required to develop the trainee into an independent pharmacist providing higher level services will vary according to the practice site(s), the baseline knowledge and skill sets of the trainee, and the precepting responsibilities of the mentor.

In order for pharmacists to move toward providing higher level services, educational experiences must provide opportunities to learn and apply the core therapeutic topics (Table 1). A good mentoring relationship will assist to further gain knowledge and skills by directly involving the trainee in critical care pharmacotherapy.[61, 63] A mentor / preceptor should guide pharmacists in dealing with usual daily ICU challenges including patient care issues, skill development, problem solving and judgment, critical thinking, multidisciplinary team interactions and communication, and time management and task prioritization. The process of learning through experience and caring for actual patients needs to be active and continuous with subtle but consistent supervision. While trainees should feel independence to learn and practice as the pharmacist on the multidisciplinary team, it is equally important to provide a safety net such that the trainee can learn without worrying about potential detrimental outcomes. One major component of learning is continuous improvement. Mentors and preceptors need to provide trainees with opportunities to learn, make mistakes with appropriate oversight, and reflect on how to improve their skills while encouraging them and maintaining an excellent level of pharmaceutical care. A safe environment with a practice leader who provides guidance will assist the new ICU pharmacist to develop the skill sets and confidence necessary to function independently. The mentor should provide feedback on successful approaches and help mold the trainee's ability to represent themselves when discussing patients and providing recommendations for improving patient care. Collaboration in the ICU

is essential for maximizing outcomes. Therefore, it is imperative that trainees integrate themselves and be responsible to the multidisciplinary team for patient care and for the team to view the trainee as the pharmacotherapy specialist. An effective ICU team will engage in all types of interactions, including some that may involve incorrect information, disagreements, and other controversial topics (e.g., social issues, religious or cultural beliefs, etc.). Trainees need to be respectful of other members of the team and act professionally with ethical diligence and empathy.

The mentoring relationship may extend to issues such as guidance for policy and protocol development, administrative training, accreditation exposure, and assistance with scholarship.[63-67] Whenever possible, the mentor should involve the trainee in committees, hospital projects, and teaching opportunities that involve various audiences and formats. The preceptor must ensure the appropriate level of information is conveyed in a manner conducive to learning for the targeted audience. Written communication skills should be developed through practical application. In some cases, the mentor may assist with professional relationships, guide career development, and provide counseling for personal challenges. Eventually the pharmacist requiring mentorship should strive to develop into the role of the mentor.

Resources Available

An established network of non-ICU pharmacists who offer practical knowledge is a valuable resource to the critical care pharmacist. These individuals may serve as advisors, provide examples of pharmacy practice models, or offer unique knowledge of emerging or changing therapies that potentially affect critically ill patients (e.g., oncology, neurology, nutrition support, transplant, infectious diseases, etc.). Another resource available to all pharmacists is the educational offerings of critical care conferences (e.g., SCCM Annual Congress). These multidisciplinary meetings provide practice perspectives of challenging patient care issues, clinical application of emerging data, and the opportunity to create networks of critical care colleagues. Pharmacy specific conferences (e.g., ASHP Midyear Clinical Meeting, ACCP meetings) provide excellent opportunities to liaise with pharmacists practicing in critical care or other specialties, who may offer examples of innovative pharmacy practice models or skills and knowledge that may be applied to the care of critically ill patients. Involvement in critical care and/or pharmacy organizations offers opportunities to develop skills of effective communication, leadership, organization, and time management. The pharmacist must be committed to continual learning and professional development to maintain scope of knowledge and applicable skills.

The ASHP Research and Education Foundation Critical Care Traineeship offers participants practical experiences in designing patient-specific pharmacotherapy, solving drug therapy problems, and developing protocols / guidelines and policies related to the care of critically ill patients.[68] The SCCM CPP section provides a mentoring service for ICU pharmacists desiring assistance in various activities (practice, education, administration, or scholarship). Mini-sabbaticals may be available through various organizations and allow developing pharmacists to travel to sites where an established pharmacist can provide advanced training opportunities. Ideally these programs will be expanded and structured to provide coordinated opportunities for individuals to expand their skills and apply their knowledge. Few pharmacy schools and some organizations (e.g., ASHP, ACCP) have developed programs designed to advance particular skill sets (e.g., teaching, project management / scholarship, leadership, etc.).

Support for a training environment

Administrative support for the developing pharmacist on the critical care team should be proactive. Support should come from the department of pharmacy, ICU directors and managers, and hospital administrators but may be required from other interested parties, such as affiliated academic departments, government agencies, payers, patient advocacy groups, or other healthcare providers. In order to optimize patient care, pharmacists, their employers, and ICUs must advocate for their presence and demonstrate their importance in the ICU.

Support may involve creating and funding the position, advancing the professional growth of the individual pharmacist, allowing sufficient time to achieve successful outcomes, identifying mentors and preceptors, or process changes that continually progress pharmacy services. Networks of affiliated institutions, academic

centers, or organizations with established residency programs may create an "in-house" training program that is designed to address the needs of the trainee. Financial support and time allotment to foster and encourage the professional development of the pharmacist is essential. This may include formal mechanisms of training, mentoring, or mini-sabbaticals. Resources should be allocated that allow pharmacists to obtain the necessary training and credentials required to practice in the ICU, join professional organizations, and attend the conferences supported by those organizations. Pharmacists provided with these opportunities can network, advance their knowledge, and refine approaches to managing their patients. This allows the institution to keep current on approaches to patient care as the information is disseminated internally to other healthcare providers. The dissemination of institution-specific scholarship at professional conferences may provide recognition to the institution. Enhanced patient care associated with the provision of training and advanced pharmacy services must be of value to the institution, especially during times of fiscal constraint.[69] In some cases, having qualified pharmacy preceptors to create additional formal training opportunities for students, residents, and other trainees may generate revenue that may partly offset the training and support of the critical care pharmacist.[69] The opportunity for additional training enhances career satisfaction and may aid individual development and employee retention.[70] In order to maximize their return on investment, hospitals and/or academic institutions should consider the benefits of collaborating with experiences gained internally or from other institutions.

Credentialing Pharmacist for Critical Care

Pharmacist credentialing is a contentious issue. Credentials are desirable for professionals, but attempting to define or clarifying the required credentials for pharmacists providing various levels of service remain controversial. The focus of this section of the document is to project the credential requirements for pharmacists caring for critically ill patients. This serves as an opportunity to define the expectations of ICU pharmacists for all interested parties and is integral to the advancement of pharmacy practice in the ICU setting, since they may be used for institutional privileging, eligibility for reimbursement from governmental and private payers, accreditation of residency training programs, and numerous other internal and external evaluations. For the purpose of the following discussion, credentials, accreditation, certification, and related processes are those defined by the Council on Credentialing in Pharmacy (CCP).[9]

Credentialing history

Credentialing, defining credentials, and designing processes to verify and maintain credentials is not limited to the profession of pharmacy. The Accreditation Council for Graduate Medical Education (ACGME) is responsible for establishing general requirements for medical residencies and developing the process of accrediting programs.[71] The American Board of Medical Specialties (ABMS) is responsible for certifying specialists.[72] The pharmacy profession parallels medicine in that ASHP is responsible for establishing requirements and accrediting pharmacy residency programs while the Board of Pharmaceutical Specialties (BPS) is responsible for credentialing pharmacy specialists.[73, 74] Like medicine, recognition of pharmacy specialty areas requires the presence of a distinct body of scientific knowledge, appropriate number of candidates who concentrate their practice in the area, professional support, presence of training programs with appropriate depth and scope, and candidate requirements.[75]

Characteristics of successful certification programs have been defined and include widespread professional acceptance, market penetration beyond the profession (e.g., demand driven by payers or employers), identification as the major source of professional specialty recognition, associated beneficial outcomes and cost-effectiveness, and economically sustainable.[75]

Over the past two decades, there has been an explosion of interest in the credentialing of healthcare providers.[75–78] In 1989, JCAHO (now termed TJC) required acute care institutions seeking accreditation to confirm the credentials of the medical staff and upon review of the information determine privileging status within the organization. The metrics for evaluating healthcare provision has changed to include a greater emphasis from payers on the quality of care provided. In addition, the general public is much more informed of health care quality and standards of practice, due in part to the

widespread dissemination of information on quality and medical errors found in various reports including the Institute of Medicine. This increased attention to healthcare quality has spawned the creation of a number of public and political advocacy and research organizations focused on optimizing quality of care. While many organizations utilize credentials as surrogate markers of practitioner knowledge, skills, and attitudes; there are very little data correlating the attainment or maintenance of particular credentials with improved quality of care or cost-effective for any healthcare discipline. This is particularly absent in the profession of pharmacy.[75]

Current pharmacy credentials

The CCP was formed in 1999 and is a coalition of 13 pharmacy organizations committed to providing leadership, guidance, public information, and coordination for credentialing programs in or relevant to pharmacy.[9] Table 3 outlines current pharmacy credentials.[74, 75] As of June 2004, the education credential awarded to those students completing collegiate studies is the doctor of pharmacy degree.[4] Pharmacy licensure is regulated by each state's board of pharmacy. Upon the receipt of the doctor of pharmacy degree and the completion of a specified number of practice hours, the individual may complete the licensing examination. Additional requirements to practice may be determined by the state in which practice will occur. Pharmacists who wish to advance their knowledge or skills may also acquire additional credentials through postgraduate education, training, or credentialing (Table 3). Of note, the methods used by these organizations to approve these credentials vary from knowledge-based tests to experiential practice hours.

In pharmacy, credentialing requirements by institutions have focused on meeting TJC standards. Most acute care institutions meet these standards by performing a pre-employment review of the pharmacist's credentials. This predominately involves confirmation of the appropriate degree and licensure. Some institutions have expanded upon this by either incorporating specific credentials required or outlining a privileging process to match specific job descriptions. In the future, it is anticipated that additional credentialing will be necessary to provide higher levels of pharmacy services.

Table 3. Current Pharmacy Credentials/Certifications.[74, 75]

Credential / Certification	Program(s)
Education	Doctor of Pharmacy (Pharm.D.)
Postgraduate Education	Masters Doctor of Philosophy
Postgraduate Training	Postgraduate Year 1 Residency Postgraduate Year 2 (Specialty) Residency Fellowship
Credentials/Certifications	American Academy of Pain Management Credentialed Pain Practitioner American Council for Pharmacy Education certificate programs[a] Commission for Certification in Geriatric Pharmacy Diplomat of the American Board of Applied Toxicology National Institute for Standards in Pharmacist Credentialing[b] Board of Pharmaceutical Specialties Credentials in nuclear, nutrition support, oncology, pharmaco-therapy, psychiatry, and ambulatory care Added qualifications in cardiology and infectious diseases

[a]no longer offered
[b]program expired December 31, 2008.

These services and associated credentials will be expected by interested parties in order to meet expanding accreditation benchmarks, meet the needs of the evolving pharmacy educational system, and meet institutional and payer standards for provider status and reimbursement. Some of these changes have already started as the newest version of the ASHP residency accreditation standards for PGY2 residencies requires program directors to obtain BPS certification when certification is offered in that specific advanced practice area.[37]

Pharmacy statements

The mission statements of both ACCP and ASHP focus on support and advancement of pharmacists and pharmacy practice.[77, 78] Their visions suggest the practice of pharmacy shift its focus from managing products to patient care. A required element for the occurrence of this shift is to develop credible and coordinated certification and credentialing processes for pharmacy practitioners. Licensure alone will be insufficient if pharmacists are to be the experts in

optimizing the use of medications and the systems in which they are delivered. Recommendations related to pharmacy credentialing and to the knowledge, skills, and abilities they are meant to represent are evident throughout numerous pharmacy organizational documents. The Task Force on Changing Demographics encourages pharmacy practitioners to pursue a lifelong process of maintaining competency with respect to issues that have a bearing on patient outcomes and practitioner team effectiveness.[79] Other recommendations include a vision for entry-level pharmacists to complete PGY1 training and for those practicing in highly specialized areas to complete PGY2 training.[39, 40] Additionally, most clinical pharmacists will need to obtain an appropriate specialty certification, such as those currently offered through BPS.[74, 80] ASHP recommends that by the year 2020 all pharmacists providing direct patient care must complete residency training.[81] These recommendations of advancing credentialing and training requirements are based on the recognition that pharmacists will be involved in all patient care settings, that pharmacists will assume responsibility and accountability for managing drug therapy, and that pharmacists will be recognized by payers as health care providers.[74] It is anticipated that credentialing will be based on the application of knowledge and the demonstration of performance.

Critical care statements

In the position paper endorsed by ACCP and SCCM, levels of service, service providers, and scope of service were outlined.[1] Stratifying adult ICU services by level resulted from data and outcomes identified from the American College of Surgeons (ACS) applied to trauma centers. Level 1 critical care centers provide comprehensive care and treat a wide range of patient populations.[7] In addition to order fulfillment, this document states that "it is essential that the pharmacist have the qualification and competency necessary to provide pharmaceutical care in the ICU."[7] Qualifications have been described as advanced degree, post-graduate training, or other specialized practice experiences. Level 2 centers provide comprehensive care for select areas of expertise. The expectation for personnel and services are the same as in Level 1 for these patient populations. Level 3 designation differs primarily because institutions provide limited critical care services and focus on patient stabilization and coordination of patient transfer to an appropriate comprehensive care center. Pharmacy services for these centers focus on medication system processes. Recognizing that critical care encompasses several distinct patient populations, SCCM has since emphasized practitioner certification for optimal delivery of care for all critically ill patients.[7, 8] Unfortunately, the specific certification requirements for pharmacists were not delineated. The scope of certification, however, is expected to vary depending upon the level of service and the specific patient population.

Recommended credentials for critical care pharmacist

Recommendations for credentials of critical care pharmacists are based on currently available credentialing mechanisms.[74, 75] It should be noted that considerable disparate opinions existed amongst those formulating these recommendations. This likely reflects the general critical care pharmacy community.[75] Therefore, idealistic methods of optimizing these credentials are also presented in hopes that the profession will consider similar methods of verifying competencies in the future. Table 4 outlines the recommended credentials and provides a template for idealistic credentials.[74, 75, 82, 83] Purposefully absent in this document are potential implementation strategies, time lines for achieving change, and the identification of the agencies responsible for administrative oversight as these will be determined by independent governing, regulatory, and accreditation entities. Several professional organizations, however, have vision statements with targeted dates for their recommendations to be implemented.[77, 78] It is recognized that achieving these credentials will vary based upon institutional structure, practice models, the pharmacy department, and the pharmacist. Therefore, it is highly unlikely that a single path will achieve the requirements for all involved in the credentialing process.

It is recommended that the process of credentialing involve a graduated system that progressively develops the requirements across the level of pharmacy services.[82] Pharmacists providing fundamental services should posses the basic licensing credentials; whereas those providing desirable and optimal levels of service

Table 4. Credentialing Recommendations for Pharmacists Providing Critical Care Services.[74, 75, 82, 83]

Level of Pharmacy Service	Recommended Credentials	Ideal Credentials
Fundamental	Pharmacy Degree Active state licensure	Same as recommended credentials under desirable level of pharmacy service 1-2 weeks of mentored clinical exposure every 5-7 years and/or focused continuing education
Desirable	Pharmacy Degree Active state licensure Postgraduate training year 1 or similar traineeship or equivalent experience Board of Pharmaceutical Specialist certification in Pharmacotherapy Advanced Cardiac Life Support certification	Same as recommended credentials under desirable level of pharmacy service Portfolio review every 5-7 years
Optimal	Pharmacy Degree Active state licensure Postgraduate training year 1 or similar traineeship or equivalent experience Postgraduate training year 2 in critical care or related practice (e.g. emergency medicine, transplant, etc) or equivalent experience Board of Pharmaceutical Specialties certification in appropriate area Advanced Cardiac Life Support certification	Same as recommended credentials under optimal level of pharmacy service Portfolio review every 5-7 years Possible onsite competency assessment

should complete additional PGY1 and PGY2, respectively. Recommendations for experience equivalent to residency training have been proposed; however, currently there is not consensus on this issue. One approach described by a recent ACCP statement recommends that PGY1 training equivalency should be portfolio-based and incorporate a personal statement, academic credentials, valid license, feedback from colleagues, and documentation of at least five years of experience with activities involving direct patient care services, practice management, medication use management and medical informatics, project management, and educational services.[83] Pharmacists practicing in critical care for three years or who have completed a PGY1 residency are eligible to sit for the BPS Pharmacotherapy specialty examination. These requirements are advantageously perceived by new practitioners.[84] Ideally, a critical care credential should be available that would be obtained after successful completion of the PGY2 specialty residency or equivalent experience. At the time of writing, CCP is discussing the optimal credentialing framework for the pharmacy profession. In addition, BPS is exploring several new specialties areas, including critical care. The reader is encouraged to monitor for these developments.

Several limitations of these credentials exist. In both the medical and pharmacy literature, the lack of efficiency in the documentation and verification of credentialing is a frequently cited issue. Ideally, there would be a single repository for the creation and maintenance of this information, allowing individuals to make seamless workplace transitions in their careers. Such a system would also be beneficial for employers since all verified documents would exist in one databank and there would be potential to make the information available to the public. Another issue in the pharmacy profession is the lack of validation of the currently available credentials against the characteristics associated with successful programs.[75] Also, currently available credentialing avenues may not assess the competencies of those with established pharmacy practices or those practicing in subspecialties (e.g., neuroscience, burn, etc.). Furthermore, today's credentials may not reflect the necessity of other types of credentials in the future as it is anticipated that the pharmacists' clinical responsibilities and accountability will increase.

Consideration may need to be given to assessing practical skills and/or structuring credentialing exams differently that allow pharmacists to demonstrate higher order cognitive skills or specific skills applicable to a specialized practice. Finally, increasing utilization of competency assessments will likely become a focus of future pharmacists seeking to obtain and maintain high level practice credentials.

Ideal credentials

Credentials should advance the level of practice and signify designated competencies that reflect skills required for performance. The competencies must advance knowledge assessment to include other core skill sets. The following discussion focuses on ideal credentials that critical care pharmacists should posses to provide the various levels of services. The critical care pharmacy community endorses the following model as an example that the profession in general should pursue when establishing required credentials in the future (Table 4).[74, 75, 82, 83] The proposed model is a combination of currently available credentials and the frameworks used in the United Kingdom where pharmacists may be assessed at levels of "general pharmacy", "advanced", or "consultant" after submitting a portfolio that is evaluated based on demonstrated competencies by a collaboration of pharmacy reviewers termed the Competency Development and Evaluation Group (CoDEG).[85, 86]

The basic credentials for all levels of services are identical to those for recommended credentials except that PGY1 training (or similar experiences) and BPS certification may become mandatory for pharmacists providing fundamental services (Table 4).[74, 75, 82, 83] This is in accordance with the recommendations of various professional organizations and should ensure the basic knowledge level and skills required to provide pharmacy services to critically ill patients and other patient populations. It is anticipated that many pharmacists currently providing fundamental services would possess experiences similar to PGY1 training.[83] In order to maintain practical skills and competency, all pharmacists providing fundamental services may periodically spend a short period of time in a mentored direct patient care ICU environment. Because these pharmacists may provide fundamental pharmacy services to various hospital units, it is anticipated that they may have several mentored exposures of direct patient care across various patient populations. Alternatively or in addition, continuing education programs may be developed to maintain competencies for these pharmacists.

What also differs from the recommended credentials is a mechanism for peer review that includes competency assessments for pharmacists providing desirable and optimal levels of service. These pharmacists may submit a portfolio that is externally and independently assessed by pharmacy practice experts (both critical care and non critical care) through the development of a specialist board, comprising clinical experts, academicians, and managers. Solicited appraisal from other entities (e.g., peers, professional colleagues, other ICU healthcare employees, trainees, subordinates, state licensing body, etc.) is recommended. This peer review model is similar to the processes used for promotion of faculty in academia, the designation of fellow by critical care and pharmacy organizations, and the peer review process implemented by the Veterans Health Administration in 2008.[87] It is also similar in philosophy to the process of "added qualifications" currently offered through BPS in the areas of infectious diseases and cardiology but differs substantially in structure and rigor. A similar model using competency assessment and outcome documentation has been introduced in Alberta to facilitate pharmacist prescribing authority in their scope of practice.[88]

Portfolio requirements, competencies evaluated, and rating levels may differ according to the level of service. For example, competencies assessed under desirable levels of service may include safe and efficient drug distribution, patient care delivery, personal traits (e.g., communication, leadership), problem solving, management/organization, education, and project management. The portfolio requirements for optimal services may be expanded to also include expert professional practice, advanced problem solving, systems and organizational management, education/training development, research/evaluation, and public health initiatives. Different rating scales may exist for different levels of service; pharmacists providing desirable services may need to be competent at ratings of foundational to excellent but ratings of excellent to mastery may be required to provide higher level services. Similar to the systems used to accredit residencies by

ASHP,[37] pharmacy schools by ACPE,[4] and institutions by TJC,[3] onsite observations of skills could be integrated into the model as a method of assessment, especially for determining competencies of optimal service.

As mentioned, the proposed competency assessment model is conceptually similar to the framework currently being implemented in the United Kingdom.[85, 86] The framework in the United Kingdom was endorsed by regional hospital agencies and flowed to the pharmacy profession. A key to implementing a similar system in the US will be institutional and government support since it is the profession that's stimulating change. This will enhance national acceptance and market penetration of the proposed model. In the United Kingdom, the position dictates the level of competency needed to practice whereas the proposed framework would allow the individual pharmacist to transition through the levels of practice as they gain experience or develop their practice. The proposed model is also fundamentally similar to the credentialing framework recently recommended by the CPP that delineates credentials based on practice domain (e.g., system-wide vs. patient focused), practice focus (e.g., generalist vs. population specific), and the acquired levels of knowledge, skills, and experiences (e.g., entry level vs. advanced).[74] Both models are aligned with the ability and practice-based outcomes used by ACPE to assess educational curricula.[4] The CPP framework, however, incorporates only currently available credentials, most of which are knowledge based and limited to specific patient populations. Under the CPP model, credentials are not currently available for pharmacists wishing to provide advanced services to critically ill patients. By incorporating a portfolio review component, the proposed model provides and defines opportunities for the demonstration and assessment of skills and experiences.

The proposed model recognizes skill sets beyond knowledge (e.g., communication, leadership, management, education/training development, and research / evaluation mentoring, education, committee participation, project management / scholarship). The level of service at which a pharmacist is assessed will depend upon the training background and experience of the pharmacist as well as the practice setting and requirements of the institution. This method of credentialing would provide opportunities for the established pharmacist without advanced training to demonstrate competencies necessary to perform higher level services. It provides all pharmacists with the opportunity to progress to providing higher levels of services and credentials. This is especially pertinent because it maximizes professional acceptance of the credentialing process, expands the market demand for credentialing, and provides a means to limit professional fragmentation that occurs with various training and experiential backgrounds. It also provides systematic structure to the process of credentialing that is easily interpreted by administrators and other healthcare providers. This system would advance the concept of the critical care pharmacy mentor so these opportunities are available to trainees and promote continuous learning as pharmacists would be required to maintain or achieve various levels of credentials.

Limitations exist to this model. Practically, implementation would be difficult and costly. Many professional organizations, governmental agencies, pharmacy schools, residency programs, acute care institutions, and payers would need to partner. Descriptions of competencies, submission guidelines and timeframe, panels of experts and mentors, and an appeals process would need to be established. It is anticipated that some of the costs of administering the program would be supplemented by government or educational programs and possibly payers. However, the individual pharmacist or employer would likely pay an assessment fee. It is envisioned that achieving and maintaining desirable or optimal skills in accordance with this model may encompass prescribing privileges and/or establish a method for financial reimbursement for pharmacy services. Accordingly, a nominal fee for the purpose of acquiring these credentials may be offset by the potential to generate revenue. It is, therefore, incumbent on the pharmacy profession to demonstrate that pharmacy services are associated with positive outcomes and/or cost-effectiveness and that assessment of these services may be incorporated into a credentialing model.[75]

Documenting and Justifying Critical Care Pharmacy Services

The documentation of services provided by critical care pharmacy practitioners should demonstrate the diversity, effectiveness, cost, and outcomes of the activities performed. In

addition, documentation may demonstrate core skill sets required for competency assessments and/or credentialing. Nearly 93% of ICU pharmacists document their services but most of these services are fundamental.[2] About 75% of documentation programs track clinical significance but only 22% attach an economic impact. Most documentation programs are either paper-based or use a centralized computer while far fewer use a decentralized system (e.g., hand-held/laptop computer). It is anticipated that documentation may lead to justification and increased funding of additional and/or higher level activities, thereby expanding the pharmacy services provided, matching the growth of ICU beds, and meeting the demands of the critical care profession. This portion of the document will focus on the elements of documentation for the various levels of pharmacy services, develop templates for documentation, and provide recommendations for service justification. Information is presented in general terms using critical care pharmacy as an example that may serve as a template for the profession.

Elements of documentation

Opportunities to document and justify pharmacy services in the ICU are vast and include increased patient exposure to medications, complex therapeutic regimens, rapidly altering patient-specific variables (e.g., organ function, pharmacokinetic profiles, etc.), costly medication regimens, therapeutic regimens with specific use criteria, safety, constantly emerging data, and greater interactions with other healthcare providers. The method and services documented, however, will depend on the levels of services provided, ICU and pharmacy structures, and available hospital support systems (e.g., information technology). As the level of pharmacy services progress, the functions of the pharmacists evolve from identification and resolution to prevention and management of a particular issue. As a result, the interventional target, documented skills and outcomes, and reasons for justification will also expand as the level of services advance. Table 5 outlines how the process of documentation may differ according to the levels of pharmacy services.

Pharmacists providing fundamental services are involved in order processing more than direct patient care.[1, 14] As a result, they act to identify and resolve issues that are usually directed at a particular medication or patient. Their interventions usually occur at the time of order verification and tend to be retrospective relative to when the order was written. The process of identification may be prospective if these pharmacists perform patient profile reviews. These pharmacists usually resolve issues by communicating with other healthcare professionals or directing therapy under the guidance of ICU or hospital-wide protocols or policies (e.g., automatic substitution, IV to PO conversion, medication restrictions, pharmacokinetic service, etc.). Activities that occur frequently and require documentation by these pharmacists include avoidance or resolution of drug-related problems, clinical interventions, therapeutic monitoring, and medication or administration related information. The most common interventions documented are order verification and entry, drug distribution, and drug information. Appendix 1 provides a template of a paper-based documentation form that captures these requirements. Alternatively, some institutions and pharmacists may use computer-based documentation methods that may involve pop-up screens incorporated into the hospital information system or independent documentation systems. Systems that are aligned with the hospital information system have the benefit of synching with the pharmacy or laboratory databases and may be accessed by others to generate reports. Of note, users spend less time and tend to prefer computerized systems over paper-based manual methods. Staff pharmacists, however, document more interventions when using a manual method.[89, 90]

The physical location of these pharmacists also alters the activities documented. Pharmacists working in a centrally located area are more likely to provide information regarding product identification and availability whereas pharmacists practicing in an ICU-related ("satellite") location are more likely to provide services such as therapeutic monitoring and interventions, education inservices, CPR participation, project management and clinical research endeavors, and information regarding medication administration and compatibility.[89, 90] These pharmacists also receive more inquiries and tend to interact directly with other healthcare professionals. The use of clinical decision support software (e.g., computerized prescriber order entry) also changes the type of interventions as some order errors are reduced

Table 5. Elements of Documentation Relative to the Level of Pharmacy Services.

Level of Service	Documentation Method	Function	Target Focus	Required Skills to be Documented	Required Outcomes Attached	Audience / Justification
Fundamental (primarily order processing)	Paper-based or computer-based (pop-up screens, possible health system integration)	Identify Resolve	Patient Medication	Avoidance or resolution of drug-related problems Clinical interventions Therapeutic monitoring Medication or administration information Medication reconciliation Potentially include: Education of other professionals Patient profile reviews CPR response Committee participation Research involvement	Cost Number of interventions Intervention outcome Potentially include: Medication safety Medication appropriateness Clinical significance Time commitment Resource utilization	Self Pharmacy department Accrediting agencies
Desirable (mixed order processing/clinical or clinical but not ICU specialist)	Should be computer-based	Identify Resolve Solve Prevent	Patient Medication Disease state	Must include: Avoidance or resolution of drug-related problems Clinical interventions Therapeutic monitoring Medication or administration information Medication reconciliation Education of other professionals Education of patient or family Patient profile reviews CPR response Committee participation Research involvement	Must include: Cost Number of interventions Intervention outcome Medication safety Medication appropriateness Clinical significance Time commitment Resource utilization Potentially include: Therapy outcome (e.g. analgesia or sedation levels) Cost of outcome Patient outcome Length of stay	Self Pharmacy department ICU service or department Pharmacy and ICU peers Hospital administration Affiliated university Accrediting agencies

(e.g., incomplete orders, wrong dose or frequency) but other issues emerge (e.g., inconsistent orders, unnecessary orders, orders not aligned with ICU guidelines, etc.) necessitating intervention and documentation by the pharmacist.[90–93]

In order to maximize documentation, users should be provided an opportunity to give

Table 5. (continued)

Level of Service	Documentation Method	Function	Target Focus	Required Skills to be Documented	Required Outcomes Attached	Audience / Justification
Optimal (ICU clinical specialist or clinical administrator)	Computer-based or minimal documentation as service is recognized and justified	Identify Solve Prevent Manage Guide Educate Research	Patient Medication Disease state ICU patient care	If needed, must include: Avoidance or resolution of drug-related problems Clinical interventions Therapeutic monitoring Medication or administration information Medication reconciliation Education of other professionals Education of patient or family Patient profile reviews CPR response Committee participation Research involvement Potentially include: Process of care Verbal communication Written communication Leadership Management Self reflection	Must include: Cost Number of interventions Intervention outcome Medication safety Medication appropriateness Clinical significance Time commitment Resource utilization Therapy outcome (e.g. analgesia or sedation levels) Cost of outcome Patient outcome Patient disposition / length of stay Patient readmission Potentially include: Satisfaction assessments by patients, families, or other ICU professionals Peer review Mentoring Process assessments Risk reduction Publication Statistical interpretation Prescriber privileges Return on investment Service reimbursement	Self Pharmacy department ICU service or department Pharmacy and ICU peers Hospital administration Affiliated university Accrediting agencies Public Payer Government agency Licensing body Granting agency

CPR=cardiopulmonary resuscitation; ICU=intensive care unit

feedback about the various methods and systems prior to implementing a documentation system. The documentation program must mesh with the pharmacists' responsibilities without creating burdensome duties that contribute to additional workload. Pharmacists starting a documentation program should consider whether efficiency is maximized by implementing a comprehensive program (e.g., Appendix 1) or focusing the program so that it captures the sickest patients or certain medications such as those highlighted by TJC as patient safety initiatives[22] or those known to cause the most serious adverse events (e.g., vasoactive agents, sedatives/analgesics, electrolytes, anticoagulants, insulin).[45–54, 93, 94] Another consideration is the method that will be used to compile the documented information. Interventions may be classified by type, target medication, hospital unit / patient population, time of day (or shift-based), intervention outcome (solved vs. unresolved), patient outcome, clinical significance, cost of intervention, time commitment, or pharmacist.

Pharmacists providing desirable services should have substantial responsibilities for clinical services that involve direct patient care.[1, 7] Many of these pharmacists are responsible for servicing several patient care populations and/or have order processing duties incorporated as a function of their direct patient care

responsibilities in the ICU. In addition to targeting specific medications or patients, these pharmacists tend to be involved in managing disease states either at the bedside as part of the patient care team or through the development of protocols and guidelines. These pharmacists should strive to identify and resolve issues prospectively and progress toward solving and preventing problems. Like those providing fundamental services, documentation will focus on the most common interventions but should include educational services provided to other healthcare professionals, patients, and family members; patient profile reviews; CPR response; committee participation; quality improvement initiatives; and project management and scholarly activities. As a result, the outcomes attached to documentation will expand upon those documented for fundamental services to include assessments of therapy outcome, cost of outcomes, patient outcomes, and possibly length of stay in the ICU. A computer-based system is the preferred method of documentation. This system must be shared or generate reports of activities and outcomes since the audience may include ICU personnel, hospital administrators, affiliated university departments, or accrediting agencies. The ideal documentation system should be user friendly, inexpensive, efficient, adaptable or customizable, expandable, exportable to other platforms, integratable, penetrable from various ports, retrievable, and secure. Appendix 2 provides a Microsoft Access®-based documentation template that may be downloaded and modified for pharmacists providing desirable pharmacy services to critically ill patients. Appendix 3 provides a comparative summary of the commercially available documentation systems.[95–102]

Pharmacists providing optimal services must provide direct patient care and are involved with disease state management.[1, 7] These pharmacists guide pharmacotherapy and may be directly responsible for medication management through established rapport with prescribers, collaborative practices, or ICU/hospital protocols. They shape ICU practices through their involvement with policy development, education, research, resource utilization, management, and leadership. The skills and outcomes documented may involve those outlined for fundamental and desirable levels of services but may also include processes of assessment and care, communication skills, leadership, management, and self reflection demonstrated through satisfaction assessments, peer review, mentoring, and possibly prescriber privileges, service reimbursement, or public health initiatives. They likely do not need to document to record or justify their services as they are recognized members of the ICU team and their services are expected and valued. Documentation of their services likely occurs to establish additional clinical services, expand the roles of existing services, assess new processes or practices (e.g., prescriber privileges or provider reimbursement), provide data for quality assurance or research initiatives, accreditation purposes, or promotional reasons. Given the specialized functions of these pharmacists, it is implausible that a single, standardized documentation system can serve as a template. It is more likely that each institution or pharmacist will develop a system that meets their specific requirements. These systems most certainly will generate reports and may include statistical interpretation of their services, satisfaction surveys of their services, risk reduction, peer review, publication, return on investment data, or future initiatives.

Service justification

While clinical pharmacy services consistently prove cost-effective,[19, 20, 26, 103–106] justification serves the purpose of providing sufficient evidence to gain or maintain the political and financial resources for the maintenance of existing services or position(s) or the modification or creation of the same. This is of particular importance because less than a third of all clinical pharmacists have defined criteria for career advancement and only 16% of institutions have established career advancement pathways yet more than half of all clinical pharmacists intend to pursue career advancement opportunites.[106] Individual pharmacists providing fundamental services may need to document these services for their performance evaluations or promotion but these services will not require justification as these are needed to safely provide pharmaceutical care. Therefore, it is anticipated that justification will primarily involve the provision of desirable or optimal services. Table 6 describes several potential situations where justification of these services may be required. The target audience or stakeholder of these efforts may vary but obvious points of convergence for justification may occur. However, it is important that the needs and concerns of specific groups be considered and

Table 6. Situations Requiring Justification of Critical Care Pharmacy Services.[a]

Target of Justification	Targeted Beneficiary	Benefit
Pharmacy department, peer pharmacists	Pharmacy department, self	Quality improvement, safety / risk reduction, efficiency, cost effectiveness, return on investment, education, scholarship, staff satisfaction, ICU rapport, publicity, self promotion
Hospital administration	Hospital or health system	Quality improvement, safety / risk reduction, efficiency, cost effectiveness, return on investment, staff satisfaction, publicity
ICU staff and department	ICU healthcare providers	Quality improvement, safety / risk reduction, efficiency, cost effectiveness, return on investment, education, scholarship, staff satisfaction, ICU rapport, publicity, patient or family satisfaction
Payer	Insurer, patient, government	Quality improvement, safety / risk reduction, efficiency, cost effectiveness, return on investment, accreditation
Patients, family	Patient, family, ICU staff and department, payer	Quality improvement, safety / risk reduction, efficiency, cost effectiveness, return on investment, education, staff satisfaction, patient or family satisfaction
Affiliated academic departments	Affiliated academic departments, pharmacy department, ICU department	Quality improvement, safety / risk reduction, efficiency, cost effectiveness, return on investment, education, teaching site, scholarship, ICU or hospital rapport, publicity
Granting agency or accrediting body	Granting agency, accrediting body, pharmacy department, ICU department, affiliated academic departments	Quality improvement, safety / risk reduction, efficiency, cost effectiveness, return on investment, staff satisfaction

[a]Justification is for the purposes of creation, modification, or maintenance of service(s), program(s), or position(s). ICU, intensive care unit

addressed as they likely will differ between constituents.[107, 108] The perspectives of these stakeholders must be serially assessed prior to, during, and after a critical care pharmacy service is added or modified.[107–109] Therefore, justification is a continual process. In addition, current staffing structures in the pharmacy department and ICU must be considered and the potential impact of the pharmacy service evaluated both a priori and after implementation with the goal of maximizing efficiency.[110, 111]

The process of justification

Table 7 outlines the various steps required when justifying critical care pharmacy services, program(s), or position(s). Adherence to the process should result in identification of perceived needs and expectations of stakeholders which will facilitate development of an accurate description of the service(s), program(s), or position(s) with measurable outcomes that promote ongoing establishment of the service(s), program(s), or position(s). The resulting description must be individualized to the needs of each institution and should contain achievable responsibilities valued by the stakeholders.[108, 109] Implementing and justifying a single activity (e.g., pharmacokinetic service) that serves as a foundation for additional services (e.g., pharmacy consult service) is a common mode of establishing and expanding pharmacy programs.[107–109]

The process must begin with an objective assessment and demonstration of needs related to patient-care, the ICU and pharmacy departments, and the institution or organization.[109–111] Other targets or stakeholders should also be considered (Table 6). The assessment must include the current level and scope of pharmacy and institutional critical care services, and the recommended scope of pharmacy services coordinated with the level of care within the organization. Useful reference sources for classification of ICU type and scope of pharmacy activities are outlined by 1) the position paper published by SCCM that describes ICU level of care and recommendations for service[7, 8] and 2) the position paper published by SCCM and ACCP that defines the scope of critical care

Table 7. Recommended Steps to Justify Critical Care Pharmacy Services.

Steps	Actions
1) Assessment and recognition of need	Determine level of ICU care Assess pharmacy services and programs (quantity and quality) Perform literature review and/or assess services provided at peer institutions Appraise current resources Determine potential barriers and risks Develop service vision, goals, and objectives
2) Identification of stakeholder(s)	Assess perspectives of stakeholder(s) including their needs, level of support, and concerns Identify champions or partners to support service(s) or program(s) through political influence and/or funding
3) Describe service(s) or program(s)	Develop responsibilities of the service(s) or program(s) Determine measurable outcomes of service(s) or program(s) Relate responsibilities and outcomes to stakeholder(s) Develop implementation plan, including timeline Develop plans to address barriers and risks Communicate service description and implementation plan to stakeholder(s)
4) Funding assessment or rationale	Quality assurance/improvement Cost containment or cost-effective Resource utilization Process efficiency Safety, risk reduction, sentinel event DRG outlier Accreditation requirements (e.g., TJC) External expectations Co-funding availability Staff satisfaction Educational opportunities Projection of return on investment
5) Presentation of justification plan	Tailor presentation to stakeholder(s) Modify service(s) or program(s) according to feedback
6) Evaluation	Assess service(s) or program(s) according to measurable outcomes Report outcomes to stakeholder(s) Modify service(s) or program(s) Reassess service(s) or program(s) Develop expansion and exit strategies

DRG, diagnosis related grouping; ICU, intensive care unit; TJC, The Joint Commission.

pharmacy services.[1] Current critical care pharmacy services offered at the institution may be compared to published literature,[2] similarly structured institutions identified through hospital networks (e.g., health management organizations, the University HealthSystem Consortium, the Voluntary Hospital Association, the Department of Veterans Affairs, Institute of Medicine), or internal or external benchmark data (e.g., TJC, Current Procedural Terminology (CPT) codes, Institute for Healthcare Improvement (IHI), Center for Medicare and Medicaid Services (CMS), etc.). The baseline assessment should function as a platform to develop goals and objectives of the pharmacy service(s), program(s), or position(s) that will lead to a comprehensive strategy to provide higher level pharmaceutical care to critically ill patients that is aligned with the vision of the institution.

At all steps in the process, the pharmacist must assess potential barriers and risks of implementing the service(s) or program(s). A plan to address these barriers will be needed. A thorough risk analysis should limit possible

threats to the proposed plan. Specific risks to consider include lack of organizational support or changes in organizational structure, financial limitations, personnel or time constraints, legal or policy restrictions, and other needed resources. Potential competitors (e.g., other clinical staff competing for funding) need to be recognized. The likelihood of implementing service(s) is enhanced substantially when support is available from key individuals who serve as champions or partners in the process.[107, 108] These may be pharmacy personnel, ICU physicians, ICU directors and nurse managers, other ICU personnel, hospital administrators, or external entities such as academic departments, payers, or accrediting bodies. They may offer policy influence or funding opportunities.

A description of the service(s) or program(s) follows the development of the service platform. Targeted responsibilities and measurable outcomes should be detailed relative to the needs of the stakeholder(s). The goals being presented to a particular stakeholder may be dramatically different than the internal intent of the plan or the goals being presented to another stakeholder.[107, 108] It is not unusual to generate several slightly modified proposals for different stakeholder(s). An implementation plan should be developed and include a timeline, methods to overcome barriers and risks, assessment strategies, and methods of communication. The plan will need to justify the resources for the service(s) or position(s) being introduced. Most commonly, the metrics of justification involve improved quality and/or efficiency of care, cost containment or cost-effectiveness, improved resource utilization, risk reduction, or the expectations of external organizations such as accrediting bodies (TJC, IHI, CMS). Specific outcome metrics should be identified as indicating success. The plan should be presented in a manner tailored to each stakeholder. Typically, most stakeholder(s) prefer a short synopsis describing the service, implementation strategies including acknowledgment of potential barriers and risks, timeline, assessment approach, likely outcomes, and budget.[108–110] The budget should forecast various projections of potential return on investment based on different assumptions. Services or programs that are cost neutral or reduce overall costs to the institution are most likely to gain approval by the stakeholder(s). Therefore, plans that propose to hire additional pharmacists, shift staffing structure, or require additional training of current personnel must provide downstream effects that show cost containment (e.g., reduced drug usage, fewer adverse events, reduced need for other services, etc.).[107–111] Alternatively, costly plans may provide rationale by increasing safety, improving quality of care, enhancing patient or healthcare worker satisfaction, offering educational or training programs, or strengthening external perceptions of the institution. Ideally, additional revenue streams may be identified such as affiliated academic departments, cost sharing between departments, educational / training programs, grants, government agencies or service re-imbursement.

The plan must include methods to modify, reassess, expand, or discontinue the service(s) or program(s). It is imperative that services be serially evaluated even after beneficial outcomes are demonstrated and justification is established. The perceptions will vary among stakeholders. Moreover, the service may transform and the needs of the stakeholders may change over time. These variations require a robust justification plan which continually addresses the individual needs and concerns of all stakeholders. Failure to do this may result in unmet stakeholder expectations and lead to additional barriers for future projects. A strategy to expand services deemed successful should be tempered with exit strategy that may be required in worst case scenarios (e.g., lack of personnel to support extended pharmacy services).

Summary

This opinion paper, prepared by a task force of critical pharmacists who are members of the ACCP PRN, the SCCM CPP, and the ASHP, is designed to provide pharmacists, pharmacy departments, ICUs, healthcare systems, and regulatory agencies with recommendations to prepare, credential, document, and justify critical care pharmacy services. By utilizing the recommendations provided in this document, the pharmacist should be able to create and provide higher-level pharmacy services in the ICU that will benefit patients, the ICU care team, and the institution. Ideally the process of preparing, credentialing, and justifying services will be linked and integrated.

Acknowledgments

The following individuals were provided the opportunity to review the paper and/or offered additional insight to the content of the paper: Nina

Ayrapetova, Pharm.D. (Kingsbrook Jewish Medical Center, Brooklyn, NY); Farooq Bandali, Pharm.D. (Saint Peter's University Hospital / Rutgers University, Piscataway, NJ); Jeffrey Barletta, Pharm.D. (Spectrum Health, Grand Rapids, MI); Seth Bauer, Pharm.D. (Cleveland Clinic, Cleveland, OH); Sarah Bemis, Pharm.D. (Exempla Lutheran Medical Center, Wheat Ridge, CO); Ryan Bickel, Pharm.D. (Denver Veterans Affairs Medical Center, Denver, CO); Bradley Boucher, Pharm.D. (University of Tennessee, Memphis, TN); Scott Chapman, Pharm.D. (North Memorial Hospital / University of Minnesota, Minneapolis, MN); Brad Cooper, Pharm.D. (Hamot Medical Center, Erie, PA); Joseph Dasta, M.Sc. (University of Texas, Austin, TX); Catherine Duggan, Ph.D. (University of London, London, UK); Brian Erstad, Pharm.D. (University of Arizona, Tucson, AZ); John Flanigan, Pharm.D. (Exempla Good Samaritan Medical Center, Lafayette, CO); Jeremy Flynn, Pharm.D. (University of Kentucky, Lexington, KY); Gail Gesin, Pharm.D. (Carolinas Medical Center, Charlotte, NC); Curtis Haas, Pharm.D. (University of Rochester Medical Center, Rochester, NY); Brian Hodges, Pharm.D. (Charleston Area Medical Center, Charleston, WV); Tyree Kiser, Pharm.D. (University of Colorado, Aurora, CO); Judith Jacobi, Pharm.D. (Methodist Hospital / Clarian Health, Indianapolis, IN); Stacey Kwan, Pharm.D. (North Kansas City Hospital, Kansas City, MO); Norman Kwong, Pharm.D. (Exempla Saint Joseph Hospital, Denver, CO); Stephanie Mallow Corbett, Pharm.D. (University of Virginia Health System, Charlottesville, VA); Steven Martin, Pharm.D. (University of Toledo, Toledo, OH); Karen McAllen, Pharm.D. (Spectrum Health, Grand Rapids, MI); William Miller, Pharm.D. (University of Iowa, Iowa City, IA); Holly Monatt, Pharm.D. (HealthOne Swedish Medical Center, Englewood, CO); Eric Mueller, Pharm.D. (University Hospital, Cincinnati, OH); Scott Mueller, Pharm.D. (University of Colorado, Aurora, CO); Marilee Obritsch, Pharm.D. (Hillcrest Medical Center, Tulsa, OK); Lance Oyen, Pharm.D. (Mayo Clinic, Rochester, MN); John Papadopoulos, Pharm.D. (Arnold and Marie Schwartz College of Pharmacy and Health Sciences, Brooklyn, NY); Steve Pass, Pharm.D. (University of Houston, Houston, TX); Asad Patanwala, Pharm.D. (University of Arizona, Tucson, AZ); Claire Swartwood, Pharm.D. (Denver Health Medical Center, Denver, CO); Ann Thompson, B.Sc. (Alberta Regional Health Services, Edmonton, AB, Canada); Edwin Webb, Pharm.D. (American College of Clinical Pharmacy, Washington, DC); Eric Whittenburg, Pharm.D. (St. Anthony Central Hospital, Denver, CO); Peggy Yam, Pharm.D. (Methodist Health Center, Memphis, TN).

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Appendix 1. Paper-Based Template for Documentation of Fundamental Services.

Critical Care Intervention Report Date: / /

Medication(s) involved: Time: :

Pharmacist's Name:

Identifiable Problem	Cause(s)	Intervention(s)
Adverse Drug Reaction ☐ Side effect (non allergic) ☐ Side effect (allergic) ☐ Toxic effect **Dosing Problem** Drug dose too low or regimen not frequent enough Drug dose too high or regimen too frequent Duration of therapy too short Duration of therapy too long **Drug Choice Problem** *Inappropriate:* ☐ drug ☐ route ☐ form ☐ duplication of drug/ingredient ☐ duplication of therapy Conflicting orders No clear indication for drug No drug but clear indication Non-formulary drug ordered **Drug Use Problem** Wrong drug administered Drug not administered at all **Interaction** *Drug – drug / food / disease state / lab / environment / age / gender* ☐ Potential ☐ Manifest **Drug Monitoring** Monitoring: ☐ Not ordered ☐ Incorrect Unnecessary	**Drug / Dose Selection** ☐ Inappropriate drug selection ☐ Inappropriate dose selection ☐ More cost effective drug available Pharmaco-kinetic/dynamic problems Synergistic / prophylactic drug required Deterioration / improvement of disease state New symptom / indication revealed Manifest side effects, no other cause Additive toxicity with other medication **Nurse / Patient / Other** Nurse has concerns with drug Nurse suspects side effect Nurse unwilling to bother prescriber Patient takes food that interacts **Drug Use Process** ☐ Inappropriate timing of dose ☐ Drug underused / under administered ☐ Drug overdosed / over administered ☐ No therapeutic drug monitoring ☐ Drug abused ☐ Unable to use drug / form as directed **Information** ☐ Lack of awareness of prescriber ☐ Lack of communication between healthcare professionals **Logistics** Prescribed drug not available Prescribing error (slip of pen) Dispensing error (wrong drug or dose) Suspect wrong patient	**None** ☐ No intervention **Prescriber** ☐ Prescriber informed only ☐ Prescriber asked for information *Intervention proposed and:* ☐ prescriber accepted ☐ **not** approved by prescriber ☐ outcome unknown **Drug** *Change:* ☐ Drug Schedule ☐ Dose Route *to:* _____ Drug stopped ☐ Added another drug: _____ ☐ Duplicate drug discontinued ☐ Illegible drug order clarified ☐ Refused to dispense **Review** ☐ Profile ☐ Lab tests ☐ Drug information references ☐ Other: _____ **Communication with healthcare professional** Discussion with nurse / other healthcare professional ☐ Written info provided to prescriber ☐ Nurse referred to prescriber ☐ Spoken to family / caregiver

Outcome(s)

☐ Unknown
☐ Problem totally solved
☐ Problem partially solved
Lack of cooperation from: ☐ Patient ☐ Nurse ☐ Prescriber
☐ Intervention not effective
☐ No need or possibility to solve problem

Clinical Significance

☐ None – cost savings only
☐ Low – information only
☐ Moderate – benefit could affect QOL
☐ Significant – brings care to acceptable level/standard
☐ High – averted potential major trauma/dysfunction
☐ Extreme – potential lifesaving

Adverse drug event ☐ Minor ☐ Intercepted error ☐ Serious error (level 2-6)_____

Additional Services

Drug Information or Education
☐ < 5 minutes – oral
☐ ≥ 5 minutes - oral
☐ Literature presented
☐ Informal in-service
☐ Formal in-service
☐ Other:_____

Other Services
☐ Therapeutic drug monitoring (PK/PD)_____
☐ Nutrition recommendation(s)
☐ Medication reconciliation
☐ Patient or family education
☐ Committee participation:_____
☐ Other:_____
☐ Profile review
☐ Chart documentation
☐ CPR response

Resource Utilization

Time Commitment:_____minutes **Other staff involvement:**_____

Appendix 2. Computer-Based Template for Documentation of Desireable Services.

Guide to Critical Care Intervention Database
The objectives of this database are to 1) aid critical care pharmacists (and other pharmacists) in documenting their interventions and 2) provide an integrated mechanism to run reports that document these interventions and associated outcomes.

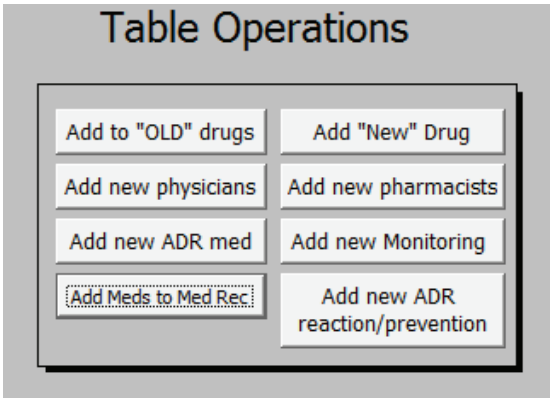
To begin:

a. Download the program. The icon ""Global Intervention 4" should appear. Click on this icon.
b. The password is "interventions" (all lower case).
c. Read the instructions below.
d. Play with the database with the sample patient profiles already provided in the database.
e. Create your won database by updating your intensive care unit (ICU) information under "Table Operations" on the Interface page. This includes physicians, pharmacists, formulary medications commonly used in the ICU, costs of medications, etc.
f. Practice entering your patients by using patients discharged prior to 2010 (otherwise patient-specific information WILL be counted in reports for this year).

I. The front page – The "Interface" page
A. The "Stop Sign" is to exit the database entirely.

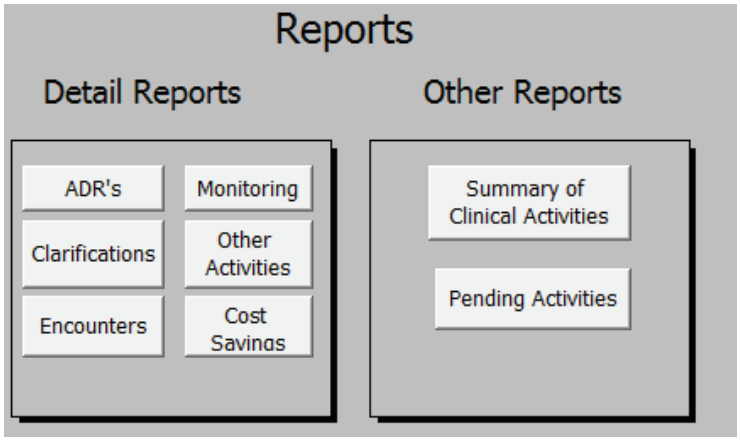
B. ANY time a form is closed, the program AUTOMATICALLY saves the information. You can either close forms by clicking the door icon, or close the form using the "X" in the top right corner of that form.

C. "Table Operations" box allows you to populate or amend variables in the lists/drop down boxes. These items include physicians, pharmacists, ADR reactions and cost of each type of ADR, drugs/classes of drugs that cause ADRs, drugs and prices (each drug needs to be added twice – once each to "OLD" drugs and "New" drugs), and items to monitor with costs of monitoring. YOU WILL NEED TO CHANGE ALL OF THE COSTS/SAVINGS TO MATCH YOUR INSTITUTION PRIOR TO ADDING PATIENT-SPECIFIC INTERVENTIONS.



Appendix 2. (Continued)

D. "Reports" box allows you to view and print detailed reports of each activity based intervention or a summary report of all activities.



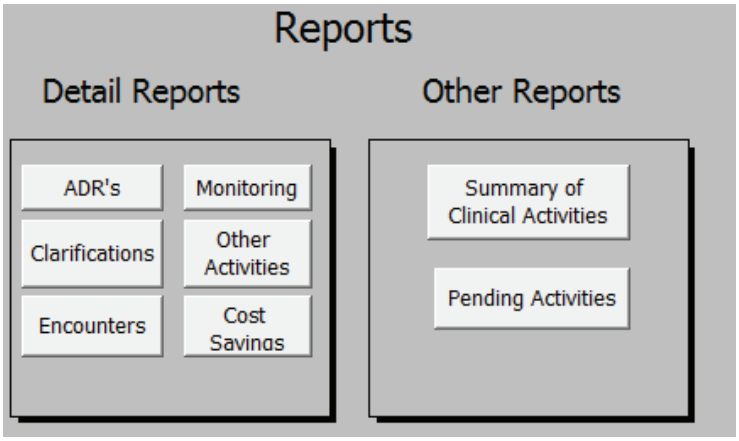
i. "Detail Reports" box allows you to view and print detailed reports for each of the following services or interventions: ADRs, Monitoring, Clarifications, Non-patient specific "Other Activities", Encounters, and Drug Recommendations ("Cost Savings").
ii. "Summary of Clinical Activities" box allows you to view and print the summary report for all above reports including overall costs for a specific time frame.
iii. "Pending Activities" box provides a report of activities awaiting completion of their documentation. On the bottom of each tab when entering patient specific information you can check the "pending" box. It will show up on this report as an activity that requires follow-up. In order to delete this report from the "pending" status, you must go back to that specific patient report and "uncheck" the pending box.
iv. To go back to the Interface page after previewing or printing a report, click the LOWER "x" in the upper right hand corner. The TOP "x" will close the database.

E. Add Date Range – This button allows you to run reports for specific date ranges.

F. "Other Activities" box allows you to enter and document activities not directly related to patient care, such as teaching, administration, scholarly activities, or drug information.

Appendix 2. (Continued)

D. "Reports" box allows you to view and print detailed reports of each activity based intervention or a summary report of all activities.



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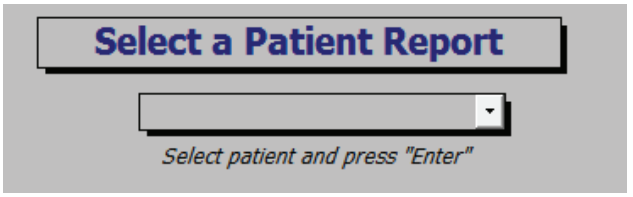
iv. To go back to the Interface page after previewing or printing a report, click the LOWER "x" in the upper right hand corner. The TOP "x" will close the database.

E. Add Date Range – This button allows you to run reports for specific date ranges.

F. "Other Activities" box allows you to enter and document activities not directly related to patient care, such as teaching, administration, scholarly activities, or drug information.

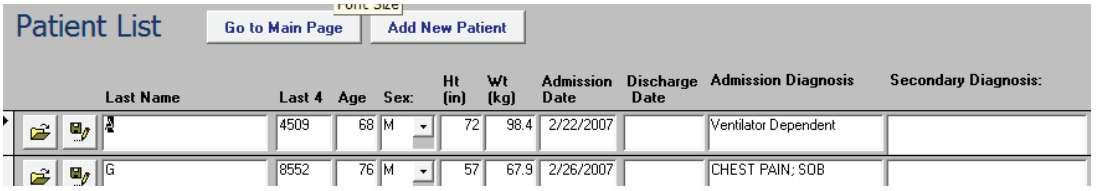
Appendix 2. (Continued)

G. "Select Patient Report" box allows you to view all interventions for one specific patient. Select the appropriate patient and press "Enter". This will bring up a report with detailed information for a specific patient.



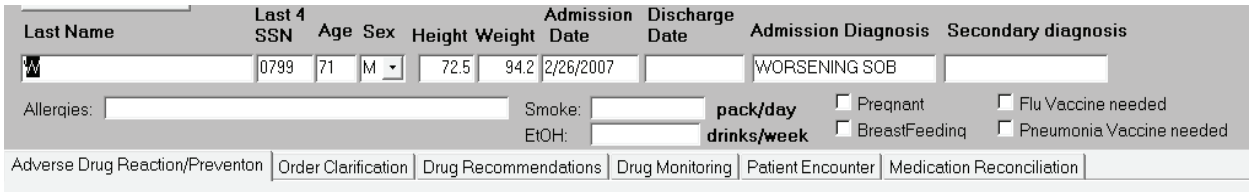
H. "Clinical Activities" box takes you to the "Patient List" - a form that provides information of all active patients.

II. "Patient List Screen" - When adding new patients, add them to this screen first using the "add new patient" icon which takes you to the bottom of the list so that you do not accidentally overwrite previously added information. Populate the required information. Notice that the discharge date is blank. Once this is filled in the patient disappears from this list. This allows you to only see active patients; however, the data of discharged patients is not removed from the database. Even if a patient is discharged, their information stills populates the detailed and summary reports (assuming that the date range includes the correct time frame.)



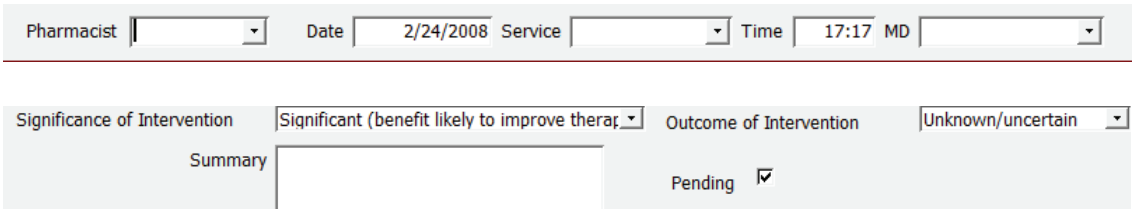
Select the icon next to the patient's name to save the information you added. When finished adding information, select the file icon that pops up as "open form" next to that patient's name. This will take you to the detailed interventions for this patient and allow you add patient specific information.

III. The "detailed intervention" screen allows you to add information about "ADRs", "order clarification", "drug recommendations", "drug monitoring", "other patient encounters" and "medication reconciliation". Notice also that more patient demographic information may be entered at the top of each screen - this is optional, but may help with certain types of interventions. Below this demographic information are six tabs that delineate different types of interventions as listed above. When selecting the tabs remember all interventions are for this specific patient. If you need a different patient you must return to the Patient list.



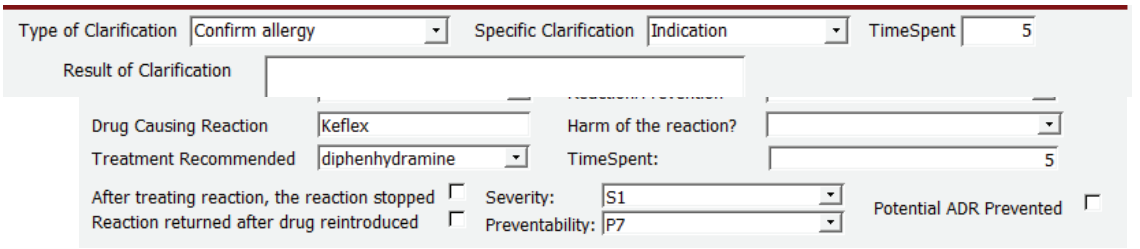
Appendix 2. (Continued)

A. For each of the specific tabs the first area of information population is the same. It records the pharmacist (add more under "Table Operations" on the Interface page if needed), date of intervention, service and time of the intervention and the physician involved (add more under "Table Operations" on the Interface page if needed). The bottom section is also the same for every tab and includes significance, known outcome, any notes/comments, and if there is anything pending for this specific record. The middle section is the portion that is different for each tab. The time spent box is to record the amount of time spent by you (or others) in minutes completing the intervention.



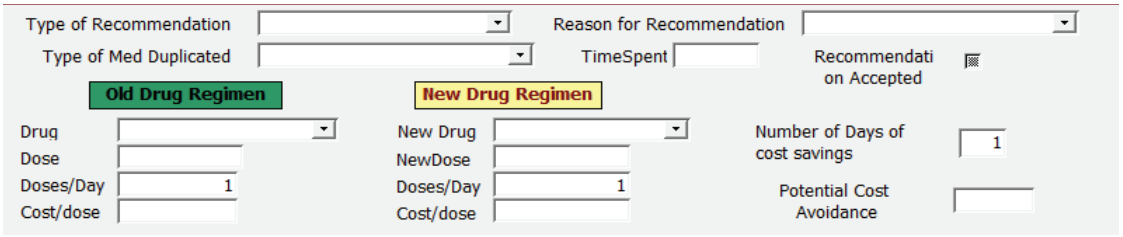
B. The "ADR/Prevention" tab is if for BOTH ADRs that occur and those that are prevented. The medication drop down list can be additionally populated using the box "Add new ADR meds" on the front page. This lists common medications or classes of medications that cause reactions. The Reaction/Prevention is a drop down list of reactions that can occur. Next to these are the costs of those reactions. This cost is taken into consideration on the summary report as well as the detailed ADR report. Make all of the costs in positive numbers. The reports assume that if an ADR was prevented that this would be a cost savings. The drug causing the reaction may be the same as the "Medication" however you may free text in this box. Check boxes if the answer is true.

C. The "Order clarifications" tab may be used frequently by some users and rarely by others. This tab is for clarification of physician handwriting, regimens, drug lists, etc.



Appendix 2. (Continued)

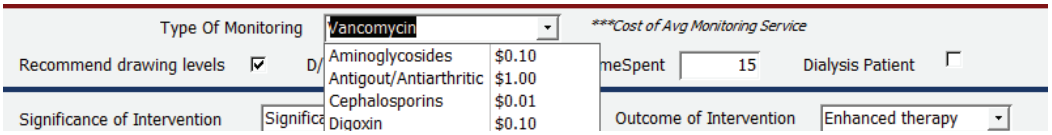
D. The "Drug Recommendations" tab allows you to document the addition, deletion or change of a drug regimen.



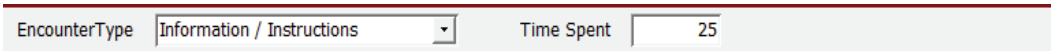
i. It takes into consideration the type of recommendation, and the reason for the recommendation.
ii. In order for the program to figure out potential cost avoidance, there MUST be a drug in both the "Old drug regimen" and the "New drug regimen". If the drugs are not listed you will need to add them on the Interface page under "Table Operations".
iii. If you are changing from IV to PO this is relatively simple, select the IV formulation in the "Old" drug drop down and the PO version in the "New" drop down. Fill in dose/day as needed.
iv. If you are adding a drug, the new drug goes in the "New" drug drop down. However you need to select "1" as the "Old" drug so that the program can complete the calculation. The opposite is true if you delete a drug. The drug being discontinued is under the "Old" drug drop down and "1" is in the "New" drop down.
v. If you need to add 1 ½ of a vial, use the "Dose/Day" to fix this. For example: Vancomycin 1.5 G IV Q12 hours - you would select the Vancomycin 1 gram vial and change Doses/Day to 3. This field can use decimals.
vi. The "Number of Days of cost saving" is estimated duration of additional therapy that may have occurred if you did not intervene. For example, if the old regimen was Gentamicin 120 mg IV Q8h for 10 days and you changed the regimen on day 3 to better match the patient's current CrCl you could assume the number of days of cost savings would be 7.

Appendix 2. (Continued)

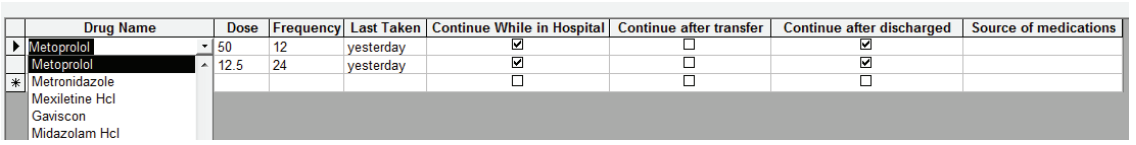
E. The "Drug Monitoring" tab is for monitoring levels. The cost associated should take into consideration the average time spent and cost of this type of monitoring. You can add more monitoring types on the Interface page under "Table Operations". The total for all patients is on the detailed monitoring report and is part of the Summary Intervention report.



F. The "Patient Encounters" tab is for all other patient related encounters (e.g. response to codes, patient counseling, etc).



G. The "Medication Reconciliation" tab allows you to document the maintenance or discontinuation of drug therapy while the patient is hospitalized. You can add more drugs the Interface page under "Table Operations".



Appendix 3. Characteristics of Commercially Available Documentation Systems.[95–102]

Unfortunately, selecting a documentation system is difficult because a comprehensive list of commercially available systems does not exist.[95] As a result, many pharmacists or pharmacy departments rely on the experiences of their colleagues when determining the appropriate documentation system to acquire. While this document provides templates of manual (appendix I) and computer-based documentation systems (appendix II), it is acknowledged that several commercial systems are available and in use. In an attempt to aid clinicians with obtaining information on documentation systems, a search of the internet and requested opinions of critical care pharmacists via the ACCP PRN about the various systems was conducted. The solicited comments were in response to the characteristics of the ideal documentation system. Product manufacturers were also contacted to provide information. Product demonstrations were requested when possible. The exclusion of a particular system was unintentional. In addition, documentation systems that are specific to one type of intervention such as pharmacokinetic monitoring were not included. In addition, several institutions have developed customized documentation systems, including in many cases their own proprietary software.

The features of the commercially available systems differ substantially. Some standardize the method of documentation with more advanced systems having several pull down menus for ease of use while others require consumers to modify lists or enter free-text information. While almost all systems are customizable, most systems do not provide a complete list of drugs or interventions and thus require personnel time to modify and continually maintain the system. A key difference among systems is the ability to integrate laboratory data with patient-specific data. This feature provides convenience and efficiency as information is linked and does not require additional input. The drawback of most linked systems is the inability to enter activities in bulk since they are usually patient-based. Some systems offer an alert feature that notifies the clinician of potential interventions or dangerous situations. In some cases, alert features may be customized but this option may cost extra and require technical support. Not all systems have the capacity to generate aggregate reports of documented activities.

Several documentation systems contain cost and time information to quantify the economic impact of pharmacy services. Cost data are typically based on either acquisition cost of the drug or information from the literature. Many institutions consider this feature useful; however, the cost interpretation is difficult. Using drug acquisition costs as the basis for the cost incurred or saved by an activity usually underestimates the overall cost. Moreover, the hospital may not visualize these cost savings since cost shifting between departments is possible. Most systems that attach costs to an outcome utilize the same cost for similar events (e.g., adverse drug events) despite potentially different outcomes (e.g., rash vs. nephrotoxicity). Some systems include the time required to provide a specific service. Usually the magnitude of time is standardized (e.g., pharmacokinetic consult equals 20 minutes). While this feature may be advantageous to clinicians, the standardized times may not adequately reflect the actual time needed to perform the activity. This may be particularly troublesome for systems that include personnel time as a component of cost. Therefore, it is imperative that the clinician understand the interpretation of cost values. Some systems are capable of modifying cost data.

Some systems have published data describing or supporting its clinical application which may be important, especially to clinicians wanting to use the system for research purposes.[96–102] All systems possess the ability to expand to different platforms. Handheld devices are convenient but need to be synced with the mainframe computer system before information can be accessed by others.

Lastly, the expense of existing systems varies considerably partly due to the available features. Most systems are not stand alone and require integrated software that contributes to the acquisition cost. All systems require maintenance which may be provided internally or from the company. The desired level of company support will contribute to the cost of the system. Purchase of a documentation system for multi-system institutions or several hospitals will result in lower pricing than if the system is being purchased for a single hospital. Another consideration is the company's policy regarding support in cases of computer down times or lost data and the efficiency of response for support staff to address questions or concerns.

Appendix 3. (Continued)

		Components of an Ideal Documentation System		
Commercially Available System	Manufacturer	Friendly Service	Inexpensive	Efficient
Clinical Measures (Clini-Doc) [a,b,c,d]	Gold Standard	Yes: focus on standardization of interventions making entries easy	Competitive	Some of the previous versions of Clini-Doc were slow with free-text entries; Clini-Doc is now in version 3 and this version is faster with pull down menus to make entry quick
CliniTrend[a,c,d]	American Society of Health-System Pharmacists	Yes	No longer commercially available	Clinicians can enter data differently so reports may not be standardized
RxRounds[a,b,c,d] Now called Rx Interventions	MedKeeper and exclusive reseller is Gold Standard	Yes	Competitive	Does not communicate with other informatic systems so patient identifiers need to be entered
Theradoc[a,b,c,d]	Theradoc, Inc.	Yes: allows patient data to be accessible during assessment and contains an advanced alert system	Costs are dependent on how many alert systems selected	Communicates with other informatic systems so patient information is available and contains multiple pull down menus for intervention and drug selection which minimizes free-text
Quantifi [a,b,c,d] Sentri7	PharmacyOneSource (Previously HealthProLink)	Yes: an integrated system allowing for patient data to be accessible during assessment and contains an advanced alert system	Cost is less expensive if Quantifi is purchased	Quantifi does not contain patient specific information but Sentri 7 does contain patient information; both contain multiple pull down menus for intervention and drug selection which minimizes free-text
Siemens Pharmacy [b,c,d]	Siemens	Yes: sometimes difficult to obtain information from the large company; integrated system allowing for patient data to be accessible during assessment	Competitive: cost is dependent on extent of Siemens system purchased	Yes
Pharmacy Care System[b,c,d]	Epic	Yes	Competitive: cost is dependent on extent of Epic system purchased	Yes
Patient Care System[a,c]	Meditech	Difficult to obtain answers to questions	Cost is dependent on the informatics system	Some duplication
Pharmacy Services Documentation System[b,c]	Healthkey Solutions	Difficult to find contact information	N/A	Publications supporting its use are available
PIDS® [c] PIDS®Enterprise PIDS®Desktop	RxInterventions	N/A	N/A	Creates SOAP notes; can assist with billing for services; provides alerts for patient follow up

Appendix 3. (Continued)

Adaptable or Customizable	Expandable	Exportable to other platforms	Integratable	Penetrable from other ports	Retrievable
Yes	Yes	Yes	Does not interphase with other systems but future versions should	Yes	Yes
Yes	Yes	Yes	N/A	Yes	Yes
Yes	Yes	Yes	Does not interphase with other systems	Yes	Yes
Yes: clinicians can develop their personal alert system	Yes	Yes	Interphases with many systems	Yes	Yes
Yes	Yes	Yes	Interphases with many systems	Yes	Yes
Yes	Yes	Yes	Interphases with products other than Siemens however Siemens is recommended	Yes	Yes
Yes	Yes	Yes	Interphases with products other than Epic however Epic is recommended	Yes	Yes
Yes	Yes	Yes	Interphases only with Meditech systems	Yes	Yes
Yes	Yes	N/A	Does not interphase with other systems	N/A	
Yes	Yes	Yes	Can be integrated with dispensing system	N/A	

Appendix 3. (Continued)

		Components of an Ideal Documentation System		
Commercially Available System	Manufacturer	Friendly Service	Inexpensive	Efficient
CareDoc Clinical Intervention Documentation manager[b,c]	MetaCare Pharmacy Management System	Yes	Cost is dependent on the informatics system	Laboratory results are viewed separately

[a] Information from demonstration
[b] Conversation with manufacturer representative
[c] Information from website
[d] Information from current user
N/A not available on internet

Appendix 3. (Continued)

Adaptable or Customizable	Expandable	Exportable to other platforms	Integratable	Penetrable from other ports	Retrievable
Yes	Yes	Yes	Interphase only with MetaCare system	Yes	Yes