

After-Hours Pharmacy Service Models in U.S. Hospitals

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Practicing pharmacists, pharmacy educators and national pharmacy organizations have performed principal roles for many years in evaluating, designing, implementing, staffing and monitoring the medication use systems employed in the U.S. to fulfill patients' medication-related needs. The sustained rise in the use of emergency rooms and hospital admissions during the evenings and nights in many acute care community, tertiary, psychiatric, rehabilitation, critical-access and long-term acute care hospitals in various regions of the country reveals the growing importance after-hours healthcare plays in medication utilization and patient safety.¹ Many patients are willing to make allowances for special circumstances after-hours – e.g., delaying the start of their intravenous chemotherapy until morning when the oncology nurse and pharmacist are on duty. However, patients do not expect variations in the level or quality of services after-hours to reach the point where their chances of injury due to medication errors, adverse drug events or poor treatment outcomes are increased.

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24/7 HEALTH CARE: THE AFTER-HOURS PHARMACY GAP

Although it is widely acknowledged that the presence of pharmacists is imperative for patient safety in hospitals, national surveys continue to reveal that a majority of hospital pharmacies operate less than 24 hours a day, seven days a week.² More than 3,000 hospitals nationwide; including acute care, rehabilitation and psychiatric facilities; close their pharmacy departments in the evenings, at night and/or occasionally on weekends and holidays. Thus, in many hospitals, drug distribution and medication review during the nighttime is carried out primarily by nursing supervisors, as well as nursing and allied health staff. The traditional on-call pharmacist service allows medical and nursing staff to contact a pharmacist in emergencies to provide pharmaceutical support by telephone or in person. Intensive efforts are now being directed towards reducing medical errors and improving patient safety within the healthcare system. The Institute of Medicine (IOM), the American Hospital Association (AHA), the Institute for Safe Medication Practices (ISMP), the American Society of Health-System Pharmacists (ASHP), The Joint Commission (TJC), the United States Pharmacopeia (USP) and many other groups and individuals have spoken forcefully on the need for greater patient safety.^{3, 13} More than 50% of medication errors are due to prescribing errors; followed by administration errors, transcription errors, and dispensing errors.⁴⁻⁵ Strategies for systematically reducing medication errors have been described and prospective review of orders by pharmacists and preventing non-pharmacy personnel from accessing pharmacies after-hours have been recognized as two important measures.⁶⁻⁸

MEDICATION USE TRENDS

All medications (including biologicals and contrast agents) used for therapeutic, prophylactic or diagnostic purposes can be associated with serious errors and adverse events in patients. Several of these medications and medication classes routinely utilized in hospitals are associated with sufficient medication errors and adverse events as to have been classified by organizations as high-risk drugs. These high-risk medications principally possess a narrow therapeutic index, are inherently toxic, and require extraordinary knowledge and precautions to minimize errors and harm to the patient. Our most effective safety system and practices are

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employed to properly manage these agents and mitigate patient injury, as well as prevent drug misuse and diversion. Examples of high risk drugs include morphine and other opioids, concentrated injectable electrolytes (e.g. potassium chloride), neuromuscular blocking agents and antineoplastic drugs, as well as anticoagulants including heparin and warfarin. Most high-risk drugs are mainstays of therapy and must be utilized 24/7 in hospitals.

Polypharmacy is a consequence of many factors in modern therapeutics. It is seen in common chronic and acute conditions afflicting hospitalized patients such as congestive heart failure, diabetes, hypertension, seizures, mood disorders, HIV/AIDS, asthma, pain, renal disease, autoimmune disorders and transplantations. Polypharmacy, defined in part as patients taking 5 or more medications per day, occurs frequently in hospitalized adult patients and is seen more often in populations 65 years and older.⁹ For these patients, proper care requires the support of pharmacists who are trained and equipped to appropriately dispense as well as perform complete review of each medication order for drug allergies, contraindications, dosing and administration issues, serious drug-drug interactions and other precautions as well as compliance with institutional protocols and restrictions.

The outpatient medications that hospitalized patients list on admission histories must be reviewed against admission, transfer and discharge medication orders. This complex cognitive procedure, performed by the prescriber and heavily supported by the nurse and pharmacist, is known as medication reconciliation. Designated a national patient safety goal by TJC in 2006, it is an essential part of efforts in hospitals and other healthcare systems to avoid medication errors and subsequent adverse events. Lack of information, knowledge and/or adequate time by physicians, nursing and hospital staff can frequently cause errors of omission and commission on the medication admission list of patients. Over 10,000 medications exist in practice with the average hospital pharmacy stocking about 1,500 medications, some of which are various dosage forms and strengths of the same product. The number of FDA-approved medications continues to expand. Alternative appropriate therapies must often be established based on existing formulary policies. Today, non-formulary interventions are the most common pharmacist-directed intervention in many hospitals. After-hours non-formulary drug management must continue throughout the night, especially for the newly admitted and unstable patients who present the greatest likelihood of delays or missed doses or errors from non-formulary drug orders.

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Special populations of patients are often recognized for their unique drug therapy needs and/or risk of harm from medications. Pregnant, pediatric-neonatal, obese and elderly (especially the frail elderly) patients and those with renal or hepatic disease are increasingly included in patient safety practices and systems designed to provide additional safeguards and monitoring. New FDA-approved drug labeling information often addresses proper use and monitoring for many of these special populations. The consequences of caring for special populations in practice are significant and present challenges in the best daytime systems, where emphasis is placed on clinical competency of staff, vigilance (e.g. policies and protocols) and, sometimes, restrictions on the use of medications. The loss of a pharmacist's services after-hours in some hospitals creates the potential for increased patient and institutional liability by not delivering a single standard of care to these special populations.

AFTER-HOURS PHARMACY SERVICE MODELS

The dispensing of new and refill prescriptions in the community setting, by law requires the services of a licensed pharmacist operating during hours when the pharmacy is open. Of course, exceptions exist for the issuing of emergency supplies or samples of medications by the prescriber in the doctor's office, a clinic or emergency department. There is no substitute for access to a 24-hour retail pharmacy when it comes to patients obtaining the medications prescribed by their physician, nurse practitioner, dentist, podiatrist or other authorized prescriber in the community. Consistent with trends in other service sectors, the retail pharmacy community has recognized the growing need for 24/7 access to care and responded by markedly expanding the number of pharmacies and personnel available after-hours in the U.S.¹⁰

Inpatient or institutional pharmacy practice which provide dispensing and related clinical pharmacy functions for hospitalized and other institutionalized patients have, in fact, operated differently from retail pharmacies, in many cases for decades. These inpatient practices are consistent with state laws that were created to regulate hospital pharmacies despite the concern that it may not be in the patient's best interest. As described earlier, most hospital pharmacies close at night and institutions are permitted to establish alternative after-hours models for servicing the needs of patients for new and re-ordered medications. Four primary service models for after-hours pharmacy services have been utilized in the U.S. for drug distribution and related medication use processes (depending on the organization and its pharmacy service, as well as state laws and regulations). The models, along with some associated strengths, weaknesses and budget considerations, are described in Table I. There is a growing emphasis on 24/7 access to care, avoidance of medical errors, optimizing nursing support and adoption of information technology and automation. These and other factors have driven some, but not most, private and governmental hospitals (without 24-hour pharmacy services) to embrace advanced after-hours pharmacy models or established 24/7 (onsite) pharmacies.

Table I.
Service Models for After-Hours Pharmacy and Medication Use in Hospitals

Features	Models			
	RN Managed without on-call R.Ph.	RN Managed with on-call R.Ph.	Telepharmacy with on-call R.Ph.	Pharmacy open 24/7
Prevalence in the U.S.	Historical and declining; estimate less than 500 hospitals	Over 3,500 hospitals (approximately 60% of hospitals)	Newer model; number of hospitals not known but estimated about 1000 hospitals use this model including daytime and/or after-hours services	Approximately 2,000 hospitals (approximately 30%)
Staffing Requirements	Lowest after-hours workload; opening pharmacy workload often heavy; inconvenient and more liability for RN	Low R.Ph. work load; opening pharmacy workload often heavy; inconvenient and more liability for RN	Higher R.Ph. workload; improved use of R.Ph. staff via shared service between hospitals or outsourced companies; more convenient and less liability for RN	Highest R.Ph. workload but may be under utilizing staff for slower facilities; most difficult to staff with R.Ph.; most convenient for RN including dispensing support
Technology Requirements	Low technology use usual; more manual processes and limited support for nurse for review of orders and drug information	Usually limited to phone consults; may have emergency remote access to pharmacy profile/labs/ automated dispensing technology and computerized MD order entry	Routine access to computerized pharmacy/hospital records; work through phone, fax and internet; can interface routinely with automated dispensing machines and CPOE; more drug information and clinical support	Maintains major technology support for pharmaceutical services 24/7; often some or all decentralized (unit) services and major clinical activities are limited based on hospital's choice after-hours
Fulfills "Best Practice" and accreditation	Not designed and unlikely to meet best practices and standards	Not designed to meet best practices and standards: no routine R.Ph. order review until pharmacy reopens; inconsistent support for drug information/ clinical consults; supports emergencies when requested by RN	Designed to meet best practices and standards. Routine R.Ph. order review before medication given; consistency for drug information/clinical consults; supports RN in proper preparation/ dispensing procedures	Recognized as the original design to meet best practices and standards. Routine R.Ph. order review before medication given; consistency for many clinical as well as distributive pharmacy services
Estimated Annual Cost* per 8 hour shift for 7 days/week	Usually lowest cost (e.g. \$0)	Usually low cost (e.g. \$0-30K/yr)	Moderate cost (e.g. \$40-100K/yr)	Highest cost (e.g. \$150-200K/yr)

RN = Registered Nurse; R.Ph. = Registered Pharmacist, CPOE = Computerized Physician Order Entry

* Cost estimates include only R.Ph. staff hours or outsourced service cost. No cost included for pharmacy technician(s) which are often staffed after-hours in hospitals.

NIGHTTIME MEDICATION ERRORS

It is difficult, if not nearly impossible, to provide an adequate description of the nature of medication errors and adverse drug events encountered by patients after-hours in U.S. hospitals. Very few specific studies on this topic have appeared in the published, peer reviewed, biomedical English literature. The landmark report by the IOM, "To Err Is Human," did not address nighttime medical or medication errors.³ The Physician Insurance Association of America (PIAA), which has maintained surveillance for many years on the nature and scope of medical injuries resulting in malpractice claims, does not offer specific data on nighttime or after-hours medical errors. However, multiple investigations on the epidemiology of medication errors in hospitals have incorporated these events regardless of the time of day or night of their occurrence. It may be assumed these reports provide some perspective on after-hours medication risk.³⁻⁵

My colleagues and I provided original observational data from a single hospital on nighttime medication use and prescribing errors from an after-hours telepharmacy practice in 2002.¹¹ Most notable were findings that (1) 1,039 orders were written at night in a 3-month period, (2) high risk targeted medications (see Table II) accounted for 29% of all orders reviewed at night by the pharmacist and (3) clarification of the physician's orders, many due to prescribing errors, was performed by the pharmacist in 21.7% of the 1039 medication orders.

Table II. Classification of High Risk and Targeted Medications:

1. Antiinfective (antibiotics and antifungals)
2. Anticoagulants
3. Antiplatelet agents
4. Hematopoietic agents (e.g. epoetin alfa)
5. Hemostatic agents
6. Miscellaneous blood agents
7. Drugs for newly admitted patients
8. Drugs for patients transferred to or from critical care areas
9. Drugs with many potential interactions or contraindications
10. Drugs with a narrow therapeutic index
11. Drugs for which a test dose is required (e.g. iron dextran)
12. Drugs indicated for treating adverse drug events (e.g. naloxone)
13. Drugs identified by TJC as being associated with sentinel events, such as opiate agonists and I.V. potassium and other concentrated electrolyte solutions
14. Restricted-use drugs and agents specified in hospital-approved protocols

The innovations associated with the use of after-hours telepharmacy services and remote order entry services have generated new standards.

Since the original publication, the practice has received over 1.3 million after-hours prescriptions from over 35 hospitals in 12 different states and the District of Columbia. Potential prescribing errors and other order clarifications addressed by the after-hours pharmacist are referred to as the pharmacist's intervention rate. Across all these hospitals, pharmacy documentation revealed an annual mean after-hours intervention rate of 3%. The facilities possessing the full electronic medical record and computerized physician order entry generated a lower mean intervention rate of about 1.5%. A few community hospitals, operating entirely with handwritten physician orders and experiencing frequent after-hours admissions, have run intervention rates of 8% up to 10%. These mean rates are likely an underestimation due to the nature of reporting during peak order processing times.

In 2006, TJC announced that all non pharmacy personnel were banned from entering pharmacies in accredited hospitals in the U.S. Although the trend towards enforcing this restriction was already evidenced in some practices, the heightened awareness and accountability precipitated by this declaration revealed the inherent seriousness of dispensing errors and availability of viable alternate models for providing medication to patients when the pharmacy was closed. Some state regulations had already moved to ban nurses and other non pharmacists from entering and removing medications from pharmacies after-hours in order to reduce medication errors and control drug access.

A detailed accounting of prescribing, dispensing and other medication errors observed in our after-hours telepharmacy practice is beyond the scope of this review. Actual medication errors encountered in our practice typically fall into the category of near misses that did not reach the patient. In most cases, the errors were averted at the phase of the pharmacist's order review and required resolution via communication with the patient's nurse and/or physician.

MEDICATION USE AND INTERDISCIPLINARY ROLES

Medication use in the hospital is a multistep, integrated, time-sensitive process. It engages the patient and many members of the healthcare team in the selection, procurement, storage, prescribing, preparation/dispensing, transcription/administration and monitoring of drugs and biologicals, as well as some nutrients and nutraceuticals. Health professionals employ these medicines in varied clinical settings such as surgical, critical care, labor and delivery, etc. for prophylactic, therapeutic and/or diagnostic purposes. Core knowledge – e.g., medical terminology – is shared by the team; however, major roles are established for distinct health professionals. Licensed clinicians are responsible for prescribing, preparing/dispensing, administering and monitoring (including patient education) medication use in patients.

The team provides medication use around the clock for patients as care is continually being initiated, modified and monitored. No single or uniform description of changes in the roles of the team is established in the after-hours. However, several frequent adjustments occur, especially in non-critical care settings and even, for some hospitals, in their intensive care units. These after-hours adjustments in roles may include a shift from private attending physicians to hospital-based physicians, on-call physicians or house staff models. There is also reduced staffing and complement of specialists in nursing and other clinical personnel, assignment of senior clinical task to a night (nursing) supervisor, closing of some units (e.g., outpatient surgery and critical care satellite pharmacy) and services (e.g., pharmacy department, MRI studies and infusion center), as

well as limiting or eliminating new patients or the types of new patients admitted until the next day. More subtle role changes compared with daytime operations may also occur, including (1) change in the method by which new medication orders are processed due to closure of pharmacy or computer downtimes associated with maintenance requirements, (2) modified drug distribution systems to provide nurse supervisors access to additional and more complex medication supplies for patients, (3) altered or underuse of standard order sets (to prescribe) and medication protocols (to dose and/or convert patients to formulary equivalent products), and (4) reduced or inconsistent support for education and training. Unlike the daytime when the healthcare team is most likely to conduct interdisciplinary patient care rounds, the after-hours staff more heavily relies on one-on-one communication between each team member to manage patients' medications. This dialogue, more than in the daytime, involves discussions between covering or on-call physicians and staff who may have less firsthand familiarity with the medication-related issues of the patient. Consequently, the proper hand-off between professionals (the practice of providing necessary clinical information regarding patients to the next covering shift/staff member) and maintenance of adequate staffing, resources and systems are needed to deliver continuous quality in medication use and patient care among an array of team members after-hours.

STANDARDS SETTING AND AFTER-HOURS SERVICE

Certainly in large part to assure patient safety, the practice of pharmacy and the requirements for medication use in hospitalized patients is heavily standardized, regulated and monitored. Variations in standards, regulations and laws have in limited areas been modified at the state and local levels in order to navigate specific needs and challenges of hospitals to care for patients after-hours. Some major leading regulatory, professional and accreditation groups address practice and medication-use requirements after-hours in U.S. hospitals. These include, but are not limited to, the state boards of pharmacy, the departments of health, ASHP and TJC.

The innovations associated with the use of after-hours telepharmacy services and remote order entry services have generated new standards. In the spring of 2010, guidelines on remote medication-order processing were made available by the ASHP based on work completed by the Council on Pharmacy Management in collaboration with an expert panel.¹² Because remote medication-order review is an increasingly adopted model for assuring 24-hour access by hospitals to the skill and services of qualified pharmacists and telepharmacy providers, these guidelines can be reviewed for guidance by both service providers and health care facilities.

The ISMP, a certified Patient Safety Organization (PSO), offers the Medication Safety Self Assessment tool for hospitals.⁸ This tool; endorsed by multiple major pharmacy, medical, quality and health provider organizations; identifies key safety areas for after-hours medication use based on best practices. Included in these best practices are (1) drug standardization, (2) storage and distribution recommendations, (3) onsite or remote pharmacist access 24/7 to review medication orders and answer drug information questions, and (4) prohibition of non-pharmacy personnel from entering the pharmacy when it is closed.

Pragmatic alternatives to these after-hours best practices have been proposed and permitted by TJC and other organizations. Examples of alternative approaches include double-checking the patient's order and medications by two trained on-site nurses, as well as deferring non-urgent treatment until the pharmacist is available in the daytime. However, evidence to support the effectiveness of these alternatives to prevent medication errors and optimize medication outcomes

in the practice setting is needed. The American Organization of Nurse Executives, the nursing leadership group of the American Hospital Association, has not specifically established a position regarding the role of nursing in the care of hospitalized patients after-hours when the pharmacy is closed.

The need to effectively fulfill the medication needs of hospitalized patients at night and during other after-hour periods is increasingly recognized and supported by regulatory standards setting bodies and professional associations. A greater understanding by health professionals, administrators, academics, legislators, regulators and the general public should serve to strengthen and expand the practices, resources, laws and regulations, as well as training regarding after-hours pharmacy services and medication use.

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