

ASHP Guidelines on the Safe Use of Automated Medication Storage and Distribution Devices

Purpose

Automated medication storage and distribution devices are an increasingly prevalent component of the medication-use process in health care organizations. The pharmacy profession's transition to pharmaceutical care, changes in health care systems, and pressures to reduce costs have created interest in availability of and use of automated devices. ASHP supports the use of automated devices when it frees pharmacists from labor-intensive distributive functions, helps pharmacists provide pharmaceutical care, and improves the accuracy and timeliness of distributive functions. Experience with automated devices suggests that when they are used appropriately these benefits can be realized.¹⁻⁴ When automated devices are not used appropriately, their complexity, design and function variations, maintenance requirements, staff-training requirements, and other factors can have undesirable effects and compromise patient safety.^{5,6} The National Association of Boards of Pharmacy (NABP) has adopted language on automation for incorporation into the NABP Model State Pharmacy Act and Model Rules. The Model Act uses the term "automated pharmacy systems" and defines them as "including, but not limited to, mechanical systems that perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information."⁷ Data-processing and bar-code technologies, although incorporated as integral components of some of these systems, are not considered in the Model Act definition of automated drug distribution technology. The Model Rules suggest specific requirements and options for helping individual states determine which are appropriate.⁸ These ASHP guidelines reflect and expand upon the requirements of the Model Rules.

Automated pharmacy systems are designed for centralized filling of individual patient prescriptions and unit dose medication orders, for decentralized dispensing cabinets, and for other purposes. This document addresses primarily computer-controlled decentralized medication-dispensing cabinets, which ASHP prefers to call automated medication storage and distribution devices. Since many of the concepts may be applicable to related technologies, the term "automated system" will be used generally and the term "automated device" will be used specifically. Automated pharmacy devices are located in hospital patient care units, surgical suites, emergency rooms, long-term-care facilities, physicians' offices, and other settings. Several manufacturers produce automated devices with a variety of configurations and software capabilities that may interface with the pharmacy's and the health care organization's information systems.^{9,10}

The purposes of these guidelines are to (1) propose goals and objectives for the safe use of automated medication storage and distribution devices in the medication-use process, (2) provide guidance on the safe use of automated devices to pharmacists and others involved in the medication-use process, and (3) advise vendors of automated devices about the safety needs of those in health care who use their systems.

Background

The appropriate, accurate, and timely distribution of medications to patients is a well-established responsibility of pharmacists. In acute care settings in particular, distribution systems have been developed that enable pharmacists to review medication orders and to oversee the preparation and packaging or selection of medication doses, as well as the delivery of doses to patient care units. Automation has evolved to ease fulfillment of pharmacists' distributive responsibilities, expand distribution-system capabilities, and improve efficiencies.

The use of automated medication storage and distribution devices continues to evolve. Some health care organizations deploy one or several devices in selected areas, such as emergency rooms, that are floor-stock intensive and where lost charges can be substantial; or for selected categories of medications, such as controlled substances, that have time-consuming tracking and documentation requirements. Some organizations deploy devices throughout patient care areas to cover nearly all medications used.

The rapid development of technology applications in health care, including automated devices, and pressures to expand their use have raised concerns about patient safety, access to medications, and possible legislative and regulatory barriers. Several pharmacy organizations, in cooperation with NABP, launched the Automation in Pharmacy Initiative, which produced draft language for inclusion in the NABP Model State Pharmacy Act and Model Rules and a white paper on automation in pharmacy.^{11,12} The white paper noted that there were no national standards for automated pharmacy systems and reminded pharmacists that they have professional responsibility for ensuring that appropriate policies and procedures and quality assurance programs are in place to ensure safety, accuracy, security, and patient confidentiality.

Goals and Objectives

Goals for the use of automated devices in the medication-use process should focus on improving patient care and resource use. Specific objectives related to these goals may include the following:

1. Information necessary for appropriate medication management and patient care is accurate, accessible, and timely.
2. Appropriate medications are readily available and accessible to meet patient needs within safety and security controls.
3. Vulnerabilities to medication errors are minimized, and those that remain are identified, documented, and modified.
4. Staff members involved in the medication-use process are safety conscious, accurate, and productive.
5. Patients are satisfied with the quality and delivery of care.
6. Medication distribution services are facilitated across the continuum of practice settings in health care systems.

7. Resource management is improved by linking supply-reordering channels to the medication distribution system.

Requirements

Automated medication storage and distribution devices should be thought of by users as tools for improving the medication-use process, rather than as inherent solutions to problems in that process. Consideration should be given to how the technology can be adapted to meet the goals and objectives of the user rather than to how the user's systems should be redesigned to fit the automated device.

Before deciding to deploy automated devices in the medication-use process, an organization should assess its circumstances; the safety, patient care, and resource benefits it hopes to gain; and how the benefits would be observed and measured. It should also determine if the automated devices being considered are capable of producing the desired benefits. Specific consideration should be given to

1. Incorporating the use of automated devices into the organization's strategic planning (i.e., ensuring that automation is compatible with the vision and mission of the organization).
2. Assessing the use of automation from a complete systems standpoint. Automated devices should integrate well with other systems and processes, both manual and automated. Interfaces with overall patient-care computer systems especially must be considered.
3. Establishing performance standards for safety, accuracy (including medication error rates), timeliness, and costs.
4. Determining the responsibilities of the automated device vendor and the organization for installation, maintenance, training, operations, and troubleshooting.
5. Ensuring effective training for the organization's employees who have automated device involvement and user responsibilities.

Since the medication-use process involves multiple health care disciplines, selection of automated devices and establishment of rules for their use will require decisions that meet the needs of the disciplines involved. However, since pharmacists have professional and legal responsibility for the safety and integrity of the entire medication-use process, they should provide leadership in the development and maintenance of policies and procedures for the safe use of automated systems. Any system or device adopted for drug distribution and control should meet the intent of established professional standards and guidelines regarding patient safety. The automated system or device should

1. Provide the following inherent safety features of unit dose drug distribution systems
 - Medications are contained in, and administered from, single unit or unit dose packages,
 - Medications are dispensed in ready-to-administer form to the extent possible,
 - Medication is available for administration to the patient only at the time at which it is to be administered, and
 - A patient medication profile is concurrently maintained in the pharmacy for each patient.

2. Provide for prospective, timely review of medication orders by a pharmacist at all appropriate decision points in the medication-use process, especially before administration of the first dose; and provide for the independent interpretation of the medication order by a pharmacist and a nurse.
3. Ensure safe medication storage, distribution, access, and use wherever the devices are deployed in the organization's practice settings. Safety includes meeting required environmental conditions for the storage and handling of medications.
4. Comply with applicable federal and state consumer protection laws and regulations. State boards of pharmacy may have different requirements for the use of automated devices in various practice settings and for obtaining approval for their use.

Access to Medications through Automated Systems

All medication distribution systems, both automated and nonautomated, have features that give nurses and other caregivers access to some medications before order review and approval by a pharmacist, especially in patient emergencies. Clearly stated organizational policies should be developed that limit access to medications before orders have been reviewed and approved by a pharmacist. Access to medications should be limited to the following cases:

1. The order has been reviewed and approved by a pharmacist.
2. The drug product has been approved by a multidisciplinary committee of physicians, pharmacists, and nurses who agree that it has minimal risk for misadventures.
3. There is a clinically urgent need for the medication that outweighs the potential risk.
4. Medication retrieval and administration are supervised by an identifiable, responsible physician (in the emergency department, catheterization laboratory, etc.).

Provision should be made for the retrospective review and reconciliation by a pharmacist of orders that were initiated without a pharmacist's review and approval.

Safety Checks

The pharmacy is responsible for ensuring that the automated system operates as designed and is well maintained to prevent errors and system interruptions. All elements of the automated system require periodic checking, including, as applicable, patient information and medication profiles, computer controls for access, operations of drawers and bins, and transaction records.

1. Each organization that uses an automated system should have a written plan for safe and effective use of the system. The plan should be developed by the pharmacy in that organization, with input from nursing, medicine, and other disciplines that may be affected by the system. The plan should address
 - Potential sources of medication errors and the procedures to be followed to avoid such errors,
 - Limits on access to medications,
 - How medications will be packaged and labeled,

- Procedures for ensuring the security of controlled substances,
 - Procedures for auditing all system transactions,
 - Procedures for avoiding drug product cross-contamination, and
 - Procedures for ensuring operator safety.
2. Each organization should have a written plan for ensuring the accuracy of (a) medications stored and accessed through an automated system and (b) machine-readable identification on medications. This plan should provide
 - A thorough review of the automated system to identify potential sources of error that may be introduced in operating that system,
 - Policies and procedures designed to preclude errors, and
 - A quality assurance program for reviewing medication error data and identifying opportunities for improvement.
 3. Any organization that allows external suppliers to replenish medications in automated systems should have a written plan for ensuring medication accuracy.¹³ When appropriate, the plan should address medications tagged with machine-readable identification.
 4. Each organization should have a written contingency plan for maintaining timely medication distribution, security, and documentation when system interruptions occur.
3. Compliance with the plan should be monitored through the organization's quality assurance program.

Storage and Inventory

The drawer and bin configurations of automated devices vary from multidrug and multidose matrix drawers to individual patient drawers and single drug and unit dose bins within drawers. Controls may vary from allowing access to multiple medications and multiple doses to allowing access to only a single medication and single dose for a specific patient. Matrix drawers and similar configurations may allow access to medications other than those approved by a pharmacist for a specific patient. Location lights, bin lids, and locking bin lids are available on some matrix drawers to reduce vulnerability to errors.

The pharmacy should develop criteria for determining the drug products and quantities that will be stored under different levels of access control in specific configurations of drawers and bins. Patient safety should be the primary concern in establishing criteria. These criteria should address

1. The frequency and appropriateness of individual medication use.
2. The effective use of reports available through the automated system related to safe, accurate, and timely withdrawal of medications.
3. The identification of drug products that are considered inappropriate for inclusion in automated devices (e.g., products with short expiration dates, those that require special storage conditions, those with special preparation requirements, those that present cross-contamination problems, and those that pose high risks to patients and employees).
4. The need for ongoing monitoring by a pharmacist of the contents of the automated device, considering such points as evolving therapeutic trends, the differing needs of individual patient care areas, and the capabilities and safety features of the automated system.
5. Policies addressing drug product integrity, including
 - The importance of accuracy and integrity of product labels,
 - How medications removed from an automated device, but not used, should be handled,
 - How medication waste is accounted for,
 - Checking of products for expiration and beyond-use dates,
 - Identification of and follow-up on tampered products,
 - Storage of products, and
 - Procedures for delivering medications to patient care units and individual patients.
6. Controls that ensure accurate restocking of devices, such as access controls on drawers and bins, including location lights and bin lids that support safe access.

Monitoring and Surveillance

Pharmacists are responsible legally and organizationally for ensuring that drug supplies are adequately controlled and that medication use is documented within the health care organization. Automated systems usually provide options for tracking and accounting for medication use. These options often include freestanding computer-controlled access and record keeping for each device, computer-controlled access and record keeping linked to the pharmacy information system, and computer linkages among the pharmacy, patient record, or billing information systems. Appropriate interfaces with pharmacy and overall patient-care computer systems are critical. Each of these options may require a different level of oversight.

1. The organization should have a written plan for the monitoring and surveillance of medications accessed through automated systems. The plan should be developed by the pharmacy with input from nursing and communicated to staff members responsible for its implementation.
2. The plan should include
 - Identification of the data to be captured and the reports generated that are used to monitor medication use (data and reports may vary by drug categories and requirements for control and accountability),
 - Assignment of responsibility for reviewing the reports, for scheduling the frequency of report reviews, and for reporting discrepancies,
 - Assignment of responsibility for resolving discrepancies, scheduling the resolution of discrepancies, following up on unresolved discrepancies, and taking action if the discrepancy is not resolved on schedule, and
 - A description of the process for investigating trends in discrepancies and assigning responsibility for this.

Security and Responsibility

Among pharmacy's responsibilities for the medication-use process is preventing threats to patient and employee safety and economic loss through medication misuse, pilferage, and diversion.

1. Each organization that uses an automated medication distribution system should have a written plan that assigns responsibility and addresses issues of security. The plan should be developed by the pharmacy in that organization, with input from nursing, medicine, and other disciplines that may be affected by the system. The plan should clearly identify that the pharmacist in charge has general responsibility for the automated system. The plan should specify who in the pharmacy and elsewhere in the organization has responsibility for computer-interface issues; operational problems; the accuracy of medications contained in the system; maintenance of access codes, magnetic cards, and other more positive identification methods; and training and retraining of users and what skills those individuals must have.
2. The specific responsibilities of all personnel involved in operating or using the automated system should be set forth in written policies and procedures.

Education and Training

Automated systems bring together information systems, machines, and humans in highly complex, interdependent relationships. Involved individuals must possess the knowledge and skills required by their responsibilities.

1. The organization using automated systems should have procedures for ensuring that all staff members involved receive adequate education and training, both initially and on an ongoing basis.
 2. The organization should ensure that there are adequate resources for providing effective education and training.
 3. The organization should ensure that the content of education and training programs is continually updated.
 4. The organization should evaluate staff members to ensure competency in the use of the automated system; the evaluations should be documented.
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