ASHP Guidelines on the Safe Use of Automated Dispensing Devices

Purpose

The purposes of these guidelines are to (1) propose goals and objectives for the safe use of automated dispensing devices in the medication-use process, (2) provide guidance on the safe use of automated dispensing devices to pharmacists and others involved in the medication-use process, (3) advise vendors of automated dispensing devices about the safety needs of health care professionals who use their systems, and (4) recommend standardization for Health Level 7 (HL7) interfaces between pharmacy information systems and automated dispensing devices. The recommendations presented in these guidelines should be used in conjunction with other literature on the topic and information from prospective or selected automated dispensing device or system vendors, established guidelines, and state and federal regulations. Pharmacists should exercise professional judgment in assessing their health system's needs regarding automated dispensing devices and systems and in adapting these guidelines to meet those needs.

Automated pharmacy systems are designed for centralized filling of individual patient prescriptions and unit-dose medication orders, decentralized dispensing, and other purposes. These guidelines address primarily computer-controlled decentralized medication-dispensing cabinets, which will be referred to as "automated dispensing devices." Since many of the concepts discussed here may be applicable to related technologies, the term "automated pharmacy system" will be used generally and the term "automated dispensing device" will be used specifically. Automated dispensing 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 dispensing devices with a variety of configurations and software capabilities that may interface with the pharmacy or health care organization's information systems.[1,2]

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 patient-specific medication orders and oversee the preparation and packaging or selection of these medication doses, as well as the delivery of these medication doses to patient care units. Automation has evolved to ease fulfillment of pharmacists' distributive responsibilities, expand distribution system capabilities, and improve efficiency in distribution.

Automated dispensing devices are an increasingly prevalent component of the medication-use process in health care organizations today. The pharmacy profession's transition to an emphasis on direct patient care, changes in health care systems, and pressures to reduce costs have all created interest in the availability and use of automated dispensing devices. ASHP supports the use of automated dispensing devices when it frees pharmacists from labor-intensive distributive functions, helps improve patient care by both pharmacists and nurses, improves accountability and storage of medications, and improves the accuracy and timeliness of medication product availability. Experience with automated dispensing devices suggests that, when used appropriately, these benefits can be realized.[3–11] When automated dispensing devices are not used appropriately, their complexity, design and function variations, maintenance and education requirements, and other factors can have undesirable effects and compromise patient safety.[12,13] The National Association of Boards of Pharmacy (NABP) includes language on automation in the NABP Model State Pharmacy Act and Model Rules.[14,15] The NABP Model Act uses the term "automated pharmacy systems" and defines them to include, but not be 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."[14] Data processing and bar code technologies, although incorporated as integral components of some of these systems, are not considered in the NABP Model Act definition as automated drug distribution technology. The NABP Model Rules suggest specific requirements and options for helping individual states determine which automated pharmacy systems are appropriate for use.[15] These ASHP guidelines reflect and expand on the requirements of the NABP Model Rules.

The use of automated dispensing devices continues to evolve. Some health care organizations deploy one or several devices in selected areas, such as emergency departments, that are floor-stock intensive and where lost charges can be substantial. Some devices are used 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 dispensing devices, and pressures to expand their use have raised concerns about patient safety, access to medications, and possible legislative and regulatory barriers. While technologies can be designed to minimize opportunities for medication errors, that same design can create other, often unanticipated, opportunities for medication errors. Consideration of the use of automated dispensing devices, like consideration of any other technology, must include serious evaluation of existing and potential opportunities for error and the implementation of mitigating strategies to minimize or prevent such errors. Pharmacists have a professional responsibility to ensure that appropriate policies, procedures, and quality-assurance programs are in place to address the safety, accuracy, security, and patient confidentiality of automated pharmacy systems, including automated dispensing devices.

Goals and Objectives

Goals for the use of automated dispensing 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:

- Information necessary for appropriate medication management and patient care is accurate, accessible, and timely.
- Appropriate medications are readily available and accessible to meet patient needs within safety and security controls.
- Vulnerabilities to medication errors are minimized, and those that remain are identified, documented, and mediated.
- Staff members involved in the medication-use process are safety conscious, accurate, and productive.
- Patients are satisfied with the quality and delivery of care.
- Medication distribution services are facilitated across the continuum of practice settings in the health care system.
- Resource management is improved by linking supply ordering channels to the medication distribution system.
- Billing accuracy is improved by allowing charges and credits to post when medications are dispensed from or returned to the automated dispensing device.

Requirements

Automated dispensing devices should be regarded by users as tools for improving the medication-use process rather than 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 how the user's systems should be redesigned to fit the automated dispensing device. It is important to consider the recommended workflow for the automated dispensing device while simultaneously reviewing the facility's current workflow and practices to ultimately determine the best practices that will provide safe and efficient patient care while maximizing the safety and efficiency advantages offered by the automated dispensing device.

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

- Incorporating the use of automated dispensing devices into the organization's strategic planning (i.e., ensuring that automation is compatible with the vision and mission of the organization).
- Assessing the use of automation from a complete systems perspective. Automated dispensing devices should integrate smoothly with other systems and processes, both manual and automated. Interfaces with overall patient care computer systems especially must be considered.
- Establishing performance standards for safety, accuracy, timeliness, and costs.[16]
- Determining the responsibilities of the automated dispensing device vendor and the organization for installation, validation, maintenance, education, operations, and troubleshooting.
- Assessing the impact of automation on organizational culture. Automation has a significant impact on employees, particularly pharmacy technicians and nurses. Optimal preparation and support should be considered.
- Ensuring effective education for the organization's employees who use the automated dispensing device or whose responsibilities are affected by its use.
- Developing an ongoing support plan.

Since the medication-use process involves multiple health care disciplines, selection of automated dispensing devices and establishment of policies and procedures for their use will require decisions that meet the needs of all disciplines involved. However, since pharmacists have a 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 pharmacy systems. Any system or device adopted for drug distribution and control, including automated dispensing devices, should meet the intent of established professional standards and guidelines regarding patient safety. The automated system or device should 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.[17]
- Medications are available for administration to the patient only at the time at which they are to be administered, according to the institution's policy.
- An electronic patient medication profile is concurrently maintained in the pharmacy for each patient and made easily accessible to the pharmacist.
- Medications are accessible to different categories of health care professionals with the ability to limit access based on policy or law.

In addition, the automated systems or devices should ensure safe medication storage, distribution, access, and use wherever they are deployed, including meeting required environmental conditions for the storage and handling of medications. Plans for use of automated dispensing devices should include

- Sufficient quantity and appropriate location of devices to support intended use and efficient work processes,
- Selection of a location that minimizes distractions and interruptions during use,
- Consideration of surrounding work-space to allow efficient device operation and movement of staff,
- Ensuring appropriate ventilation and temperature control, including refrigeration for applicable medications,
- Ensuring adequate infection control policies and procedures are maintained when appropriate for the intended use and placement of the device,

- Ensuring appropriate and sufficient lighting to support the safe and accurate verification of medication orders, reading of medication labels, and administration documentation,
- Establishing proximity of the device to medication information and documentation systems,
- Selection of location or placement of the device that permits only the patient's caregivers access to protected health information, and
- Ensuring power and data connections essential to the operation of the device are included in the facility's emergency backup power and data management systems, so that support and information are provided in a reliable manner during power or data interruptions.

Finally, the automated system or device should comply with applicable federal and state consumer protection laws and regulations. State boards of pharmacy may have different requirements for the use of automated dispensing devices in various practice settings and for obtaining approval for their use.

Override Access to Medications Through Automated Dispensing Devices

All medication distribution systems have medication withdrawal functions that allow nurses and other caregivers limited access to certain medications before order review and approval by a pharmacist, especially in cases of patient emergencies. This function is typically referred to as an "override." Clearly stated organizational policies and criteria for system overrides should be developed that limit access to medications before orders have been reviewed and approved by a pharmacist.[16,18,19] Override access to medications should be limited to cases in which the drug product has been approved by a multidisciplinary committee of physicians, pharmacists, and nurses as having a clinically urgent need for the medication that outweighs the potential risk of medication error.

Subsequent order-based retrieval of the same medication should cause the user to be reminded that an override supply of medication was recently dispensed for the patient. 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. Override data (e.g., name of medication, quantity, location of the automated device, any associated adverse drug events) should be routinely reviewed to help evaluate and manage those medications approved for override access. Override data evaluation can aid an organization in improving the outcomes of automated dispensing device use by decreasing medication errors and potential adverse drug events[20] and should be considered part of the routine management process for automated dispensing devices.

Interfaces with Automated Pharmacy Systems

Proper planning should include the development of an interface strategy. Automated pharmacy systems interface with systems for pharmacy information, electronic medical records, admission/discharge/transfer, bar-coded medication administration (BCMA), and materials management for various purposes in support of the medication-use process, including the following:

- Commanding distribution of medications from a pharmacy location,
- Maintaining current data on patient population, including demographics and patient location, for the automated pharmacy system,
- Maintaining a current and accurate patient medication profile for each patient served by the automated pharmacy system,
- Maintaining current formulary information,
- Recording the addition, removal, or dispensing of medications from automated dispensing devices,
- Issuing charges for medications removed or dispensed from automated dispensing devices (if this is the charge method of choice), and
- Integrating with bedside point-of-care systems to assure accurate medication dispensing and patient administration.

Interfaces are effectively used to communicate patient demographic information, medication order information, formulary additions and updates, dispensing/charting information, and inventory management transactions between the automated dispensing device and the pharmacy information system (or pharmacy functionality in a hospital information system). Such interfaces may also pose challenges related to the complexity of their own deployment and maintenance. Their completeness and level of application may also impact the workflow associated with the use of automated dispensing devices. For these reasons, it is important to consider the impact that specific interfaces will have on the hospital and system users.

Interfaces between automated dispensing devices and pharmacy systems can be costly to create and maintain. Most vendors base these interfaces on HL7 standards[21] but do not necessarily interpret and apply the HL7 specifications in the same way. The result is that automated dispensing device interfaces should be easily customizable and thoroughly tested prior to implementation. Pharmacists should consult with other users of the same pharmacy system, automated dispensing device, and interface for advice on functionality and customization.

ASHP believes that the vendor community should work with the HL7 organization to identify one standard message set for communicating key transactions to and from automated dispensing devices to permit interfaces to be more easily implemented and supported. In addition, vendors should be prepared to support XML-based interfaces with the newer Web-based pharmacy applications.

Safety Checks

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

Any organization that uses an automated pharmacy system should have a written plan for the safe and effective

use of the system. The plan should be developed by the pharmacy and nursing staff, with input from respiratory therapy, medicine, and other disciplines that may be affected by the system.[22,23] The plan should address

- Conformance with industry and government standards as well as accepted practice standards,
- Potential sources of medication errors and the procedures to follow to avoid such errors,
- Limits on access to medications,[24]
- How medications will be packaged and labeled, including standardizing and limiting available concentrations,
- How medications will be safely and securely transported from the pharmacy to the automated dispensing device,
- The use of clinical alerts for high-risk medications,
- How medications will be transported from the automated dispensing device to the patient to reduce risk of administration to the wrong patient or at the wrong time,[16]
- How patient and medication information will be available and displayed while maintaining patient privacy,[16]
- How user privacy, security, and safety will be ensured,
- Procedures for ensuring the security of all stored medications, especially controlled substances, with a process in place to prevent and detect diversion,[25,26]
- Procedures for auditing all system transactions,
- Procedures for avoiding drug product cross-contamination (evident or trace amounts of a liquid or solid drug that may contaminate another drug or package),
- Procedures for identifying and removing medications prior to expiration, and
- Procedures for reporting malfunction or breakdown of the automated dispensing device.

The organization should have a written plan for ensuring the accuracy of (1) medications stored and accessed through an automated pharmacy system and (2) machine-readable identification on medication labels. This plan should provide

- A thorough review of the automated pharmacy system to identify potential sources of error that may be introduced by the system,
- Policies and procedures designed to preclude errors, and
- A quality-assurance program for reviewing override data and medication error data associated with the automated dispensing device and identifying opportunities for improvement, including a process for validating any medications that have been designated as high risk via machine-readable coding on removal.

Any organization that allows external suppliers to replenish medications in the automated pharmacy system should have a written plan for ensuring medication accuracy.[27] When possible, this plan should include the use of machine-readable identification to ensure placement of medications in the appropriate containers within automated dispensing devices, as well as recording that the proper filling was performed. To support this, processes must be in place to ensure that products do not reach the active inventory before confirmation that the product's bar code is accurately loaded into the appropriate cross-reference file. If possible, the machine-readable identification should also be used to ensure that medication supplies are not expired or in immediate danger of expiring.[28] If a hospital utilizes BCMA, all medications present in an automated dispensing device must be encoded with a bar code that will appropriately identify them in the BCMA system.

The organization should have a written contingency plan for maintaining timely medication distribution, security, and documentation when system interruptions occur.

A profile interface in which all medication order information is sent from the pharmacy information system to the automated dispensing device should be present whenever 24/7 pharmacy order entry is available. (For facilities that do not have 24/7 pharmacy order entry, a profile interface should be employed whenever feasible.) A profile interface is important for patient safety because it requires that a pharmacist review medication orders before the caregiver can access the medication from the automated dispensing device. Profiling functionality should include

- Transmission of all components of medication and i.v. orders, including drug, dose and/or infusion rate, route, frequency, dosing schedule, and order start/stop times,
- Ensuring that all patient care areas use the profiling functionality, including ambulatory and outpatient areas such as the emergency department, whenever possible,
- Limiting the variety and quantity of medications that are accessible without pharmacist review (override), and
- The option to require a double-check (witness) at the time of dispensing of an identified high-alert medication from automated devices, especially when pharmacist review and order entry have not occurred.[16]

The organization should include a process for comparing patient allergies with the current medication profile. Automated devices should receive coded allergy information from the pharmacy or hospital information system, which would allow an alert to be displayed when a medication to which a patient is allergic is dispensed.

Monitoring and Surveillance

Pharmacists are legally and organizationally responsible for ensuring that drug supplies are adequately controlled and that medication use is documented within the health care organization. Automated pharmacy systems usually provide options for tracking and accounting for medication use, which can be used to help monitor important data, such as the number of adverse drug events.[29,30] 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 linking among the pharmacy, patient record, and 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.

The organization should have a written plan for the monitoring and surveillance of medications accessed through automated pharmacy systems. The plan should be developed by the pharmacy, with input from nursing staff and other clinicians, and communicated to staff members responsible for its implementation. The plan should include[18,25,26,31]

- Identification of the data to be captured and the reports to be generated for monitoring medication use, waste reconciliation, and discrepancies (data and reports may vary by drug categories and requirements for control and accountability),
- Assignment of responsibility for reviewing reports, scheduling the frequency of report reviews, and 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,
- A description of the process for investigating trends in discrepancies and assigning responsibility for conducting the investigation,
- Appropriate access by personnel, including timely removal of access when no longer employed or credentialed by the facility,
- Determination of frequency of narcotic counts, who will perform them, and who is responsible for verifying that the narcotic counts were completed,
- Examination of charge and credit flow to ensure billing accuracy, and
- Assignment of reviewing overrides to ensure the function is being used appropriately.

Compliance with the plan should be monitored through the organization's quality-assurance program.

Storage and Inventory

The drawer, bin, and pocket configurations of automated dispensing devices vary depending on device design and hospital preferences. Open matrix drawers, pockets that open or light up for a specific drug, and multiple open bins within a cabinet door are just a few of many different configurations available from various vendors. 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, pockets, or bins. Patient safety should be the primary concern in establishing these criteria. The criteria should address

- The frequency and appropriateness of individual medication use,
- The effective use of reports related to the safe, accurate, and timely withdrawal of medications available through the automated pharmacy system,
- The party responsible for medication safety oversight and administrative control of drug availability in the automated pharmacy system (e.g., the pharmacy and therapeutics committee),[16]
- The identification of drug products that are considered inappropriate for inclusion in automated dispensing devices (e.g., products that have short expiration dates or special preparation or storage requirements, present cross-contamination risks, or are hazardous),
- The need for ongoing monitoring and optimization of the contents of the automated dispensing device by a pharmacist, taking into consideration such matters as evolving therapeutic trends, the differing needs of individual patient care areas, and the capabilities and safety features of the automated pharmacy system,[17]
- Oversight of the positioning of look-alike and sound-alike drugs, high-alert drugs, and drugs with multiple strengths throughout the automated dispensing device as well as procedures to minimize the incorrect restocking of these medications (e.g., keeping these items as far apart as possible),
- Procedures to prevent and/or minimize the return of drugs directly to the automated dispensing device by nursing staff to decrease the potential for error,
- Specification of the individual(s) responsible for adding, modifying, or reviewing formulary items on a regular and ongoing basis to ensure they correctly display and interface map. Tall-man lettering, standardized concentration displays, and form designations are just a few of the many items that need to be maintained for safety,
- Procedures for keeping policies, procedures, and education current,
- Policies addressing drug product integrity, including
  - The importance of accuracy and integrity of product labels,
  - How to handle medications that are removed from an automated dispensing device but not used,
  - How medication waste is accounted for,
  - Checking products for expiration and beyond-use dates,
  - Identifying and following up on tampered products,
  - Storing products, and
  - Procedures for delivering medications to patient care units and individual patients.
- Controls that ensure accurate restocking of automated dispensing devices, such as
  - Access controls on drawers, bins, and pockets, including software restrictions and use of location lights and/or locking bin or pocket systems that support safe access,
  - Process redundancies to ensure correct restocking,[16]
  - Standardization of restocking procedures to limit process variation,[16] and
  - When the system permits, use of bar coding to restock the correct medication in the correct drawer, bin, or pocket, and
- Controlling access to medications to limit the potential for inadvertent selection of the wrong medication, and assuring that each drug has a unique and segregated location within the automated dispensing device so only the specific drug needed is accessible.[16]

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.

Any organization that uses an automated pharmacy system should have a written plan that assigns responsibility for and addresses issues of security. The plan should be developed by the pharmacy, 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 pharmacy 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 positive identification methods; and education of users and the determination of skill levels those individuals must achieve.

The specific responsibilities and privileges of all personnel involved in operating or using the automated pharmacy system should be set forth in written policies and procedures. The policies and procedures should minimize the use of temporary user and patient identifications and should describe the circumstances in which these features may be used.

Downtime procedures in case of software or hardware malfunctions, power failures, or planned maintenance affecting normal operations should be developed to ensure medication security, accurate documentation of distribution and administration, and continued patient safety.[16]

Education

Automated pharmacy systems bring together information systems, machines, and humans in highly complex and interdependent relationships. Individuals involved in the use and operation of the system must possess the knowledge and skills required by their level of responsibility and understand the risks associated with the use and foreseeable misuse of automated pharmacy systems.[16] The organization should

- Have procedures in place for ensuring that all staff members who use the automated pharmacy system receive adequate education, both initially and on an ongoing basis,
- Ensure that adequate resources are provided for effective education,
- Ensure that the content of the education programs is continually updated,
- Evaluate staff members to ensure competency in the use of the automated pharmacy system and document the evaluations,
- Share with staff members the lessons learned from the evaluations and discuss medication errors related to the automated pharmacy system and near-miss reports,[16] and
- Include at least one higher-level user group capable of managing and supporting the system and its end users.

Support

When automated dispensing devices are utilized, alternative distribution systems need to be in place to deliver medications in case of failure. The organization must negotiate a service level agreement with the vendor that meets the organization's minimal acceptable downtime requirements. The organization should define the level of support that will be provided internally and ensure that staff are sufficiently educated to deliver the defined level of internal support. The organization will need to negotiate with the vendor the purchase of spare parts needed to optimally recover from mechanical failures.

Conclusion

Automated dispensing devices are increasingly being used in health systems for centralized filling of individual patient prescriptions and unit-dose medication orders, decentralized dispensing, and other purposes. When such devices and the systems that support them are not used appropriately, their complexity, design and function variations, maintenance and education requirements, and other factors can compromise patient safety and have other harmful effects. ASHP supports the appropriate use of automated dispensing devices and has developed these guidelines to provide recommendations to pharmacists and others involved in their use.

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Developed through the ASHP Section of Pharmacy Informatics and Technology and approved by the ASHP Board of Directors on July 21, 2009. These guidelines supersede the ASHP Guidelines on the Safe Use of Automated Medication Storage and Distribution Devices dated April 22, 1998.

A work group of the ASHP Section of Pharmacy Informatics and Technology 2008–2009 Section Advisory Group on Automation and Documentation (Leslie Brookins, M.S.; Ron Burnette, M.B.A.; Thomas W. Cooley, M.B.A.; Paul M. Seelinger, B.S.Pharm.; and Gwen Volpe, B.S.Pharm.) is gratefully acknowledged for revising these guidelines. Other members of the section advisory group included Christopher J. Urbanski, M.S., Chair; Arash T. Dabestani, Pharm.D., M.H.A., FABC, Vice Chair; Jim Besier, Ph.D., FASHP; Kimberly Dove, Pharm.D.; Craig P. Frost, M.B.A.; Rick K. Glabach, B.S.Pharm.; Gary L. Johnson, Jr., Pharm.D., M.H.A.; Denise Mckenzie; Brad Rognrud, M.S.; Charles De la Torre, M.S., M.I.S.; Rayburn Brian Vrabel, Pharm.D.; Matt Marshall, Pharm.D.; Marvin H. Choi (Student Member); Dennis A. Tribble, Pharm.D. (Executive Committee Liaison); and Karl Gumpper, Pharm.D., BCNSP, BCPS.

The bibliographic citation for this document is as follows: American Society of Health-System Pharmacists. ASHP guidelines on the safe use of automated dispensing devices. *Am J Health-Syst Pharm.* 2010; 67:483–90.