

ASHP Guidelines on the Safe Use of Automated Dispensing Cabinets

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Automated dispensing cabinet (ADC) technology is used to improve patient care, enhance the efficiency and accuracy of medication dispensing in the medication-use system, support medication storage and security, and provide evaluation of ADC-user interactions. ADC use has become widespread in healthcare institutions, with 93% of hospitals using ADCs in their medication-use systems,¹ and 70.2% using ADCs as a primary method of maintenance dose distribution.²

Implementation steps and objectives to support an ADC system include the following:

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- Software and hardware technology for optimal operations are available and supported by knowledgeable staff;
- ADC maintenance is supported with adequate personnel, minimum downtime, and analytical reporting for ordering and restocking;
- Staff education and competency on ADC operation are supported at a high level;
- Interfaces to other technologies supporting medication use (e.g., intravenous [IV] infusion systems) are created to enable efficient workflows and enhanced medication diversion detection;
- Interoperability is established with the electronic health record (EHR) and related systems;
- Safe and secure operation is ensured with real-time reporting functionality of medication diversion;
- Mechanical operation and inventory management capabilities exist to allow efficient, accurate, and optimized availability of medication;
- Employment of other technology is used, e.g., barcode scanning, biometric identification, special storage and alerting features; and
- ADCs in procedural and non-acute extended patient care areas (e.g., long-term care, ambulatory clinics) have the same standard of medication control as traditional patient care areas.

These guidelines address components of ADC technology implementation and important detailed steps to meet and maintain basic ADC requirements.

Background

Appropriate, accurate, and timely distribution of medications to patients is a well-established responsibility of pharmacists. Use of ADCs has become the standard of care for the medication-use process in healthcare systems.² ASHP supports use of ADCs, because they are essential to provide quality patient care, secure storage of medications, and ensure viability of the medication-use process in healthcare organizations.

These ASHP guidelines reflect the evolving and increased use of ADCs to improve patient safety and allow secure access to a broad selection of medications. Consideration of the use of ADCs 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 ADCs.³

Requirements

ADCs must provide accurate and controlled storage, dispensing, and monitoring of medications, while providing medications in an efficient and safe manner. The ability of ADCs to accomplish these requirements has improved since their introduction in the late 1980s, leading to the technology becoming the primary means of medication distribution.^{1,2} To be successful at implementing and sustaining ADC benefits, an organization must ensure that the ADC will help optimize the medication-use process and meet financial, operational, and clinical goals of the organization.

Information technology infrastructure

Technical infrastructure that will best support the system and allow for smooth operation and future growth is of utmost importance. Infrastructure requirements include servers, interfaces, upgrades, integration with other systems, and security. It is essential to ensure that both physical and personnel infrastructure necessary to maintain the system are in place.

Servers. Servers are typically client-hosted but are becoming increasingly cloud-based as health systems move away from owning and maintaining their own servers.⁴ Regardless of the hosting approach, servers should be readily available and highly reliable to minimize workflow interruptions. Servers must be adequately sized to store both formulary and user information, as well as transactional information for analytics and reporting, and should be scalable to allow for future growth. Consideration should also be given to minimizing the amount of redundant software maintenance (e.g., formulary maintenance). Depending on an organization's size, an ADC server might be a single standalone server. Larger organizations and integrated delivery networks (IDNs) may employ integrated servers that work together, but physically separate different data components into separate servers. Options for server redundancy to offer protection and limit interruptions in the event of unplanned downtime must also be considered. A range of options are available, from data refreshes every few hours to more frequent data refreshes that support minimal losses in the event of unplanned downtime.

Partnering with the information technology (IT) department is essential for proper server maintenance, such as operating system patches, security software to protect against viruses and malware, as well as integrity of frequent data backups. Maintenance may be supplied internally by the system for virtual machines or by the vendor (more commonly for

standalone servers). In either case, IT should be engaged to assist and help coordinate proper server security. Finally, an organizational downtime and recovery policy and procedure should be developed and implemented to minimize disruptions in patient care.

Interfaces. With the growth of large healthcare IDNs and proliferation of multiple electronic clinical applications used within healthcare systems, ADC vendors have moved toward integrated platforms that simplify and standardize system maintenance. The ADC system must work seamlessly with other clinical systems, which include at a minimum EHRs, pharmacy information systems (PIS), and admission/discharge/transfer systems. Each of these other systems serve as the source of primary data for the formulary, barcodes, patient information, medication profile, and medication orders. The ADC provides source information for other clinical systems through interfaces based on Health Level Seven International (HL7) standards. Affected clinical systems include inventory information for the PIS, dispense information for billing systems (for organizations that charge on dispense), usage information for inventory management systems, and user information for a domain management system. Finally, many systems also use interface engines to streamline system connectivity, especially when multiple systems come from the same vendor.

During the build phase of ADC system implementation, all interfaces must be thoroughly tested to ensure that both accurate and current information is transmitted into the ADC system. In addition to the ADC vendor, the organization and EHR vendor play important roles in successful implementation and maintenance of the ADC system. Both the ADC and EHR vendors have test plans for the implementation process, which should be used in conjunction with the organization's testing plan, and all will be incorporated to create successful interfaces. If there

is a change in EHR or ADC vendor, new interfaces and a retrievable archive of dispense data for reference purposes needs to be created.

System integration. In addition to foundational clinical systems described above, integration of several optional systems with the ADC system must be completed if they are used. Other dispensing devices, such as central pharmacy robotics, or ADC replenishment may require connectivity. Pharmacy inventory management systems used to manage a perpetual inventory based on all pick and restock transactions within the pharmacy must also be considered. These systems may utilize dispensing robotics and can also be used for both central fill within a hospital or across a healthcare system. Finally, many healthcare organizations also use a controlled substance (CS) system that provides secure storage for CS and integrates with the ADC system to provide secure CS dispensing.

Database management within the ADC system involves maintenance of information integral to ADC workflow, including ADC formularies, barcodes, users, user roles, rules, and alerts. In multihospital IDNs, these databases are typically shared between all sites to streamline support processes and allow for sharing of ADC formulary, barcodes, and user role information. There are scenarios in which IDNs are required to maintain separate databases at each facility (e.g., separate PIS and/or different ADC version), but typically the goal is to get all facilities on a single database.

Upgrades. ADC upgrades involve updating hardware and/or software. While hardware upgrades are not uncommon, timely software upgrades may coincide to prolong the life of cabinets. These efforts may allow for core hardware to remain in place (sometimes with an option of swapping drawer types or configurations within the drawers), while any major

updates occur with the software. There may also be the option of keeping the cabinet intact while changing the computer system that drives the cabinets. This model allows for new functionality and changes to the user interface while minimizing costs by allowing the healthcare organization to continue using existing hardware. Upgrades will also involve updates to the operating system, which can include security patches and necessary hardware changes.

Safe and secure operation

Topics to be considered to ensure safe and secure operation of ADCs include but are not limited to access control, medication stocking and dispensing, the override function, return and waste of medications, emergency access, ADC placement, and alerts.

Access control. Safe and secure operation of ADCs starts with well-defined processes for granting and maintaining user access. Current technology allows for centralized user management through the IT or pharmacy departments. A domain management system allows for centralized control of access to multiple applications, while the user can utilize the same credentials for each application. For ADC systems, the domain management system must allow for immediate suspension of access if an employee is suspended, terminated, or under investigation.

The ADC should also have a mechanism to lock accounts of inactive users who have not been successfully authenticated within a facility-defined time period. The organization's ADC access policy should address privileges of all clinical team members who administer or manage medications, including learners. A single ADC system often supports multiple facilities within an

IDN and should use the same user templates and policy to create standardization throughout the organization.

Biometric identification may be available for an ADC system. Staff should be required to use biometrics, and if a particular individual's biometrics are unable to be consistently recognized, the use of user ID and password or an alternative workflow recognized by regulatory bodies and organizational policy should be followed. Use of biometric ID data must meet individual state requirements for security and user consent.

Medication stocking and dispensing. Organizations should establish processes for loading and withdrawal of medications from the ADC by the pharmacy, including how and when medications are supplied to the ADC and authorized personnel. The layout and type of storage areas within the ADC can ensure the correct medication, dose, and dosage form are being refilled or withdrawn. When medications are refilled, barcode technology should be consistently used to ensure medication is placed in the correct storage area. ADCs can be configured so that personnel refilling an ADC are required to scan both the medication and the storage area to minimize the number of ADC fill errors.

The barcode database is a critical component to ensure safe ADC use when stocking, removing, and returning medications to the ADC. The pharmacy department should establish procedures for addition and maintenance of barcodes in the database. Only appropriately trained and credentialed staff members should add barcodes to the drug dictionary. Typically, one credentialed pharmacy staff member adds the barcode and a pharmacist verifies the barcode, or as allowed by state regulations.

All medications dispensed from the pharmacy should have a barcode. Although most medications have a barcode incorporated by the manufacturer, pharmacy is responsible for adding barcodes for compounded or repackaged items and those items with unusable barcodes. Supplemental barcode labeling may be provided by special equipment or under contract with a wholesaler or other specialty company.

Barcode technology should be used when a practitioner removes medication from an ADC for administration. Risk avoidance should be weighed carefully against the time requirement for a practitioner to scan on removal. Organizations utilizing barcode-assisted medication administration (BCMA) technology reduce risk of error. If the ADC is configured with drawers that limit access to a medication and barcode scanning is required for adding medications to the device, the risk of a wrong medication being dispensed is greatly reduced. When a practitioner is returning a medication to the ADC, barcode scanning should be used to verify the medication and storage location.

ADC systems may allow remote queuing of medication withdrawals. The process allows a practitioner to select patient medications for withdrawal while away from the ADC by completing the process through EHR integration or a web-based portal. When medications are in the queue, the practitioner can access them at the ADC. Remote access to the ADC should be considered a tool to decrease wait times and allow optimization of workflow. Nurses may also witness and document waste of medications via the EHR or web portal, rather than at the ADC. Organizations should evaluate processes for workflow benefits and compliance with laws and regulations.

ADCs can be configured as either open-access or restricted devices. Restricted machines only allow access to medications via a verified medication order or defined automatic override list. In open-access devices, individuals administering medications have unrestricted access to all medications in the machine. The Institute for Safe Medication Practices (ISMP) does not recommend the use of open-access devices.⁵ Open-access devices should be limited to areas where pharmacists are unable to review medication orders (e.g., ambulatory, radiology, and operative areas), due to standards and regulations that require prospective review of medication orders by pharmacists. Restricted devices have been successfully deployed in the emergency department (ED), where historically open-access devices have been used. As more pharmacists begin to review ED orders, ADCs should be converted to restricted status to limit opportunity for error. Successful conversion of an ED to restricted access can be accomplished by partnering with ED personnel to develop appropriate turnaround times, override lists, and auto-verification algorithms.⁶

Override function. If a medication stored in a restricted ADC is needed, but there is not an active order on the patient profile, permission to override may be allowed, although this practice is discouraged. Medications can have access grouped by practitioner type, specialty, or location to ensure they are unit-specific and available only for emergency needs or approved protocols.⁵ A list of override medications should be defined by the organization's pharmacy oversight committee, typically the pharmacy and therapeutics committee. Guidance for developing this list is available both from ASHP⁷ and ISMP.⁸ A policy should be developed that defines the criteria by which a medication can be added to the override list and the frequency with which the list shall be reviewed. Development of this list requires weighing risk versus

benefit (i.e., potentially delayed patient care against the reduced risk achieved by pharmacist review of the medication order).

The reason for an override must be documented when withdrawing a medication so that data can be standardized for later analysis. A second individual should be required to verify the correct patient, medication, dosage form, dose, strength, route, frequency, duration of therapy, and indication upon override removal of medications included in a list of high-alert medications or from certain ADCs.⁷ ADCs should be configured to require entering a minimum number of letter characters (ISMP⁸ recommends using at least 5 letters) during a medication search to decrease likelihood of similar medication names appearing on the screen. The number and types of overrides should be regularly reviewed for process improvement and identification of safety issues.

Return and waste of medications. Organizations must develop policies and standard procedures that follow federal and state laws for medications returned or wasted using an ADC. The ADC can be configured to require documentation of the reason for wasting a medication. Standardized responses for medication waste documentation should be developed to support data analysis and process improvement. When returning unopened medication, the ADC can be configured to return it only to the original storage area or to a separate returned medication space, and barcode scanning should be employed to ensure the medication is returned to the proper location.

Emergency access. ADCs rely on electrical power and are typically equipped with a battery backup. However, procedures are necessary to outline processes for dispensing medications in the event of an extended power loss.

ADC placement. The number of devices to deploy and placement are important decisions. Several factors impact the number of ADCs in patient care areas, including number of beds, patient acuity, floor plan, budget, medication distribution model, and other institution-specific issues. Pharmacy and nursing distribution experiences and vendor recommendations will drive an appropriate ADC ratio for each care area. ADCs should be located in areas that are well illuminated and ventilated, central to patient care areas, connected to the hospital network and systems, supplied with emergency power, and have efficient caregiver workspace with a quiet zone designation.

ADC size is also a factor in determining placement. Time-motion studies may be done to determine ideal locations. State laws and regulations may require ADCs to be placed in a secured and/or locked area.

Alerts. ADC systems allow for passive or active messaging and alerts to guide clinical decision-making. Alerts should be standardized and approved across an IDN using a governing body and developed with consideration for alert fatigue. The process for developing new alerts should include stakeholders from those who will receive the alert and consideration of other safety measures already in place for a particular medication. For example, alerting should only provide information that is relevant at time of administration if the alert appears on withdrawal of a medication from the ADC. Metrics on alert overrides should be consistently and periodically evaluated, including metrics per individual and rationales, and the governing body should consider effectiveness of each alert.⁹ Consider the Five Rights of Clinical Decision Support¹⁰ when developing and maintaining alerts.

Configuration and inventory selection

Configuration of ADCs can be highly customized, depending on device design and organizational preference. Cabinets may be configured with drawers, towers, or a combination of both, in various sizes. Options may include return bins, integrated locks on refrigeration units, or other customizations. Frame selection and configuration are driven by several factors, including the organization's distribution model, space available for equipment, number and type of medications to be stored, control level requirements, and the care role of the user. Within each device, the number of storage locations may vary and include open or lidded pockets with features that guide users to specific medications or allow ease of reconfiguration.

Safe configuration considerations. Safety is the primary concern when determining medication configuration within the ADC. Restricting access to medications through appropriate configuration reduces potential for inadvertently selecting the wrong medication. ADCs should be configured to prevent clinically inappropriate medications from being loaded into specific cabinets without prior approval (e.g., enabling ADC features to prevent adult-sized medications from being loaded in ADCs for pediatric and neonatal use). Storage of high-alert medications, reversal agents, medications with common look-alike/sound-alike (LASA) names and packaging, and agents prone to diversion within a matrix drawer or tower is inappropriate.⁵ Each medication and strength should be loaded in an individual, locked ADC compartment that opens only when the specific medication is requested. If neuromuscular blocking agents (NMBAs) must be stored in ADCs (in a critical care, ED, or perioperative setting), organizations should standardize storage practices by keeping NMBAs in lock-lidded pockets with a prominently displayed auxiliary label on the pocket that states: "WARNING: CAUSES

RESPIRATORY ARREST – PATIENT MUST BE VENTILATED.”^{5,11-13} Organizations should also consider using an interactive alert that requires users to enter or select clinically relevant information for removal of the NMBA (e.g., purpose for removal, patient ventilation status).^{11,13} Interactive alerts can also be used to warn staff when removing other high-alert medications and are customizable. LASA or high-alert medications, and medications with multiple strengths, should be positioned throughout the ADC, rather than near one another, to minimize incorrect restocking or retrieval.

Access to refrigerated medications should be monitored through the ADC system whenever possible and may be accomplished via an integrated refrigerator or ADC-connected lock that provides simple access to information and temperature monitoring. Secure refrigeration bins should be utilized for types of medications that require refrigerated storage. Items with a limited beyond-use date (BUD) outside of refrigeration should be labeled with the appropriate BUD and stored in a drawer away from the computer/monitor or any warm or heated sections of the cabinet.

To address staff safety, frequently dispensed medications should be positioned in an area of the ADC that is ergonomically friendly for both pharmacy and nursing staff. For example, placement of frequently used medications toward the bottom of the ADC should be avoided to reduce the need for bending or stooping to retrieve or restock.

Inventory selection considerations. The pharmacy department, as part of an interdisciplinary committee that provides medication safety oversight,⁵ should develop criteria for determining medications and quantities that will be stored under different levels of access control in specific configurations of drawers, bins, pockets, or other compartments. Criteria

should be determined based on the organization's medication distribution model, needs, and acuity of patients, and should address all elements listed in Table 1. Medication storage practices should be routinely reviewed and adjusted based on prescribing patterns, utilization, and specific unit needs. When possible, a small number of ADC pockets should be kept unassigned in the event they are needed for a patient-supplied medication or other unique situation.

Monitoring, reporting, and surveillance

Topics to be addressed regarding monitoring, reporting, and surveillance include but are not limited to inventory counts; discrepancy management; diversion surveillance, monitoring, and detection; and medication dispense transaction reconciliation.

Inventory counts. Because ADCs have become a common source of diversion, CS should only be stored in secured pockets (individually locked-lidded), and strict attention should be paid to ADC CS inventory counts. Par levels should be kept to quantities that facilitate ease of counting to increase inventory accuracy. Pocket settings should include blind counts, which require the user to count the remaining number of items in the pocket and enter this information into the ADC to complete the transaction.^{14,15} Blind counts alone will not guarantee that inventories stay accurate; regular cycle counts of pockets must be included in written policies and documented accordingly when completed. Based on a case study by Blackmere et al.¹⁶ it may be most productive for nursing to perform a weekly count only of CS accessed since the last inventory 3 weeks out of every month, and then complete a full inventory of CS once a month. Cycle counts should be intermittently observed to prevent blind count work-arounds.

Removal or unloading of CS that are not frequently used will decrease CS inventory time, decrease risk of delays in detecting diversion of low- or no-use CS, and make a valuable internal footprint available.

CS waste creates a significant opportunity for diversion. Witness or second nurse electronic identification via biometric signatures should be required for items wasted and items returned to the ADC return bin (direct return to a pocket should not be allowed). Organizational policy should require that the second authorized user either witness the waste or return the CS to the ADC return bin prior to signing as a witness.^{4,14} In the event waste is returned to the pharmacy for testing, procedures should be in place to maintain proper chain of custody during the return process. Implementation of a mechanical or chemical CS waste disposal system that deactivates and renders CS irretrievable may help standardize the waste disposal practice.¹⁷ Policies and procedures should include how waste is managed outside of the ADC to minimize the potential for diversion.

Discrepancy management. Discrepancies between actual inventory count and recorded count occur frequently enough that constant vigilance to notification and swift reconciliation are required to minimize loss, identify process improvements, and adhere to state and federal regulations with respect to CS losses. ISMP⁵ and the California Hospital Association Medication Safety Committee (CHAMSC)¹⁵ recommend discrepancies be resolved upon discovery, no later than end of shift. Further, CHAMSC advises that discrepancies not resolved by end of shift be jointly reviewed by pharmacy and patient care leadership with resolution within 24 hours.¹⁵ The ASHP Guidelines on Preventing Diversion of Controlled Substances provide additional recommendations on discrepancy management.¹⁴

Diversion surveillance, monitoring, and detection. Every facility or institution that manages CS is at risk for diversion. Those reporting little or no drug diversion are likely not providing adequate oversight and surveillance.¹⁸ As part of a CS diversion prevention plan, institutions should form a diversion response team and establish routine diversion surveillance processes that will proactively monitor staff involved in CS ordering, inventory, dispensing, administration, and documentation activities.¹⁴ Staff members involved in diversion surveillance should receive training to understand ADC user patterns that may indicate diversion.

Because manual data and report review are tedious and time consuming, diversion detection software options should be evaluated and employed to facilitate the review process.¹⁷ Installing security cameras in medication rooms that provide a bird's-eye view of ADC activity has also become a common practice in many institutions. It is important to work closely with the organization's security and human resources departments to review state laws and labor contracts that might constrain the use of such surveillance, as well as determine the organization's policies and procedures regarding security footage review.

Medication dispense transaction reconciliation. Medications dispensed from ADCs consist of many individual transactions, which may include order, dispense, administration, waste, return, and cancel transactions. ADC reports as described by New and Overmire¹⁸ should be reviewed at least monthly by the diversion surveillance team or as defined by the organization. Diversion monitoring and surveillance procedures should include a comparison of ADC dispense transactions with the medication administration record to identify unusual or unreconciled activity to determine whether there are gaps in practice competencies or

potential diversion. Dispense transactions can be considered reconciled when matched to a prescriber's order and the dose dispensed is equal to the dose charted as administered plus any amount of drug documented as wasted or returned. These transactions should be reconciled in a timely manner during the normal course of a clinician's work shift.

Dispense event review can be a tedious and resource-intensive process. Organizations should support CS administration practices that minimize the risk of diversion, such as the following:

- Time lapse between CS retrieval from storage area and the time of administration and documentation, waste, and return is appropriate.
- Dose dispensed is package-size equivalent to, or closest available to, the dose to be administered.¹⁴
- Only healthcare providers operating within the scope of their practice may dispense and administer CS.
- CS is removed from the ADC for one patient at a time.
- The person dispensing CS from the ADC is also the person who administers and documents the medication outside of acceptable emergency situations.
- CS drawn into a syringe is labeled per institutional policy.¹⁵

Maintenance and monitoring

ADCs require ongoing maintenance and monitoring to ensure operational safety and efficiency. Additionally, policies and procedures related to access, proper use, daily tasks, and ongoing

maintenance are necessary to ensure the system is being used appropriately and maintained for optimal performance and inventory savings.

Access monitoring. The process of credentialing ADC users ensures correct access levels and privileges for end-users, which allows complete tracking of any user transactions related to system security. Pharmacy and nursing employees perform many basic tasks as they interact with the ADC. In addition to keeping the system running efficiently, certain tasks must be performed on daily, weekly, monthly, 90-day/quarterly, semi-annually, or annual schedules, depending on the organization's goals, time, and availability of resources. Some organizations choose to use basic reports for task management, while others invest in comprehensive analytical platforms to streamline the task management process and to provide additional insight into ADC use. Regardless of the approach, a list of basic pharmacy and nursing tasks can be found in Table 2.

Maintenance and optimization. ADCs require hardware maintenance, as well as software updates, upgrades, and optimization. In some cases, vendors may be contractually obligated to provide preventive maintenance to manage ADC issues (full hard drive files, equipment failures, operating system patches, and anti-virus software updates). It is important to install the latest operating system, software, and malware updates. Upgrades should be completed in a timely manner and remain a top priority for the health system IT department to ensure efficient use of the ADCs.

It is important to have a maintenance checklist that includes the following:

- determination of optimization processes and frequencies,
- volume and type of inventory in each device,

- optimal par levels based on usage,
- stock out analysis,
- barcode and alert maintenance,
- override list monitoring and associated reconciliation policies,
- test system maintenance,
- cleaning and infection control measures,¹⁹
- spare parts inventory, and
- software and hardware updates.

Monitoring the existing fleet of ADCs in relation to changing patient care needs and medication-use process demands will facilitate future equipment planning. Existing nursing units may require additional ADCs, new nursing units may need new ADCs, and older cabinets may need to be replaced. Enhancements and new products are released periodically. Keeping up-to-date with existing systems and competitive systems will help users make informed decisions on what is needed for a particular facility or institution.

Education and training

Education and training are important and necessary with any automated system implementation or upgrade and standard components of a robust and complete project plan. Adequate lead time must be planned for development of educational materials and scheduling of training sessions prior to system go-live dates. Attention should be given to development of training materials and sessions that meet the needs of varying user types and roles, as well as

workflow differences between patient care areas. Education should include not only technical skills, but also the theory and policies supporting proper use (e.g., reasoning behind not overriding).

Vendors should provide standard training support for new implementations and significant upgrades. Health systems should designate personnel that can train new and existing employees on an ongoing basis. Training strategies should include scheduled classroom training sessions as well as self-guided online training courses, either through a vendor website or the organization's intranet. Hands-on classroom sessions should be highly encouraged, if not mandatory. Because there will always be exceptions, flexibility to accommodate ad hoc training sessions and online courses should be used to fill training gaps to ensure 100% education coverage. For example, online access to full training manuals might be preferable to printing a copy for each individual trainee. Pocket-sized guides or similar education aids may be helpful for users to reference until familiar with normal daily usage. The project manager or designated hospital resource should assemble the training plan to determine which roles need training and at what level, and to ensure accurate training documentation of all staff members.

An adequate number of certified trainers should be available to cover the various roles and staff members who need training. Certain staff members may be identified as super-users who need to be properly trained and/or certified to provide education to any end user, regardless of role. Super-users can also provide support to certified trainers when there are large numbers of staff to be trained. Super-users should be familiar with the environment and staff they will train, and may also serve as added support staff during implementations. Night and weekend shift staff might need extra training and support.

Once initial ADC implementation and training is completed, it is important to plan for ongoing training for new and existing team members. Succession planning and cross-training for key members (such as administrators and super users) of the ADC team as they move to new roles or leave the organization should also be anticipated. Live or self-guided training courses, manuals, best practices, quick guides, on-screen help, and posted 1-800 help desk numbers are important tools to provide immediate support and keep users' skills up to date. It is helpful to provide the centralized help desk with a decision tree to triage calls and determine what can be quickly resolved by the help desk and where to direct other issues.

Competency of users should be assessed annually or as defined by the organization's policies and procedures, especially when ADC software upgrades include new features. Sites may consider permanently installing a training ADC for testing and training.

Health systems may change ADC vendors, and the above recommendations can be used to guide education and training. User experience will change with a new vendor, including computer screens, medication compartments and drawers, and procedures. Workflows between vendors can vary greatly, and an additional step of mapping workflow changes from vendor to vendor will be needed to ensure staff understands current state and future state.

Perioperative ADC use

Use of ADCs in perioperative areas is expanding due to the need for health systems to obtain better inventory control, improve efficiency, and improve accountability for non-controlled and controlled drugs specifically stored and administered in the perioperative area.²⁰ There are typically two ADC choices to consider for these specialized areas: standard ADCs that are

adapted to perioperative use, or anesthesia ADCs, which take the form of an automated cart and are typically used in surgical suites and procedural rooms.

A key point to consider when expanding an ADC medication distribution system into the perioperative area is determining which users will be using the ADC. A user's role will determine their ADC access and privileges in the perioperative area. Frequently, standard ADCs are in core operative areas near operating room (OR) suites for use by nurses or surgeons. In the perioperative area, diverse levels of staff may need access (e.g., anesthesiologists, anesthesia techs, nurses, and nurse anesthetists). A licensed healthcare provider will be independently ordering, removing, and administering medications. Perioperative nurses are most likely removing medications from the ADC based on surgery-specific preference documents. Standard ADCs used in the perioperative area are generally open access machines that store many medications needed for surgeries taking place in OR suites. These can be used as added storage for anesthesia-specific medications that are either too large to fit in anesthesia-specific machines or are critical and could be quickly accessed if out of stock in anesthesia machines.

Anesthesia ADCs specifically for use by anesthesia, surgical, and procedural staff vary in functionality when compared to standard ADCs. These specialized ADCs have improvements in workflow, CS accountability, and access to critical medications as primary features and are visually quite different from their standard ADC counterparts. Commonly, anesthesia ADCs contain high-alert medications, and care needs to be taken in how these medications are stored in ADCs, including proximity to other LASA medications, use of alerts, use of locked compartments, and creation of surgery-specific virtual kits to help ensure appropriate selection

of medications.^{4,5,12} High-alert medications such as NMBA require special attention to selection requirements.^{4,5,11,13}

Advantages to implementing more specialized anesthesia ADCs in the perioperative area include increased medication security, added inventory visibility (particularly useful during medication shortage situations), and speeding up provider access to medications during surgical procedures. Operational challenges include ensuring provider buy-in with the correct process of removal to ensure accurate administration documentation, inventory counts, and standardizing medication and supply layout between anesthesia ADCs. Anesthesia ADCs also have the capability to interface with external or embedded products that allow providers to comply more easily with The Joint Commission and American Society of Anesthesiologists syringe labeling requirements.^{21,22} Anesthesia ADCs may assist in providing accurate medication administration charging if the appropriate ADC and EHR interfaces have been developed and integrated. Some limitations to implementing anesthesia ADCs include challenges with restock based on availability of the OR suite, and discrepancies between physical and electronic inventory levels.

Many anesthesia ADCs are equipped with features to allow flexibility around use. Helpful mobility features include wireless access, wheels, and backup uninterrupted power source in cases of power loss. These features allow for repositioning based on case-type for rooms where space is tight and bed orientation is critical. With increased mobility, the security of the anesthesia ADC needs to be considered to ensure no devices are taken out of an OR suite inappropriately.

ADC settings and configurations. Perioperative ADCs have different configuration requirements unique to the areas they serve. An appropriate timeout interval is important in all locations of perioperative ADCs to ensure users have prompt access when needed but that limits are in place to prevent unrestricted access, while keeping accurate user documentation. Configuration of the timeout interval in the OR suite could be longer than the interval on the nursing floors due to the need for ongoing access throughout an OR case. Review of settings to limit access to CS without re-verification of user identity is important to ensure ongoing accountability and security. Patient lists in perioperative areas need to be configured to ensure prompt access to patients and limit creation of temporary patients. Some considerations when setting patient lists include configuration of patient location in the EHR, access to patients in the perioperative ADC following discharge for case reconciliation, and the need to have access to all patients admitted. Broader access creates greater need for safeguards to ensure quicker detection of inappropriate access. Like use of system-level kits for a standardized patient treatment protocol in non-OR areas, access to appropriate medications for specific treatment protocols and surgery cases can similarly be facilitated through creation and management of medication kits in perioperative care areas. Prompt access to emergency medications must also be granted. Due to the fast pace of perioperative areas, secure storage and dispensing of CS may best be accomplished by placing CS into single-use pockets. Then, if a provider requests one vial of a CS, they get access to only one vial. This limitation helps ensure CS counts remain correct, prevents discrepancies, and enables quick access to CS for anesthesia providers. There may also be requests to stock items other than medications in the ADC. Ordering, stocking, and replenishment of such items should be discussed with end-users to ensure adequate systems

are in place to replenish supplies promptly and clearly designate who is responsible for ongoing management.

Processes for medication returns to the ADC must be discussed with the perioperative department to ensure that processes match workflow and prevent restocking issues. One option for returning medications recommended by ISMP⁵ includes returning unused medications to a one-way return bin. When making determinations on preferred workflow, the size of the return bin, expected volume of medications returned to the bin, and processes needed to clear the bin need to be determined. The return bin can securely store CS waste after the provider has electronically wasted leftover medications at the ADC if the decision is made to have pharmacy manage all physical waste. Safeguards also need to be in place to ensure chain of custody for all CS and CS waste placed in return bins is trackable and secure throughout the reconciliation process. Depending on the EHR and anesthesia ADC vendors, there may be some available interfacing capabilities that allow transaction information to flow from the ADC to the EHR, including removals, returns, and waste transactions. Select EHRs also have the capability for a CS reconciliation report at the end of an OR case that alerts the provider to any CS discrepancies. This capability also helps keep accurate CS accountability. When implementing anesthesia ADCs, the organization will need to make a policy decision on how to handle partially administered CS (e.g., return all partially administered doses to pharmacy for reconciliation versus allowing providers to waste with a witness).

ADC use outside the hospital

Use of ADCs is expanding from hospital to off-site, non-acute areas, such as long-term care facilities, hospice, skilled nursing homes, ambulatory care clinics, rehabilitation facilities, standalone surgery centers, freestanding emergency rooms, and veterinary hospitals. Inclusion of ADCs in non-acute areas has been facilitated by the ability to collect, control, and maintain all transaction information, and accurately track the medication movement in and out of the system for the enhanced security, accuracy, and accountability of medications. In addition to “starter doses” of medications, ADCs can store emergency kits and supply continuous dosing of CS when appropriately registered.²³ Sites may be miles from the pharmacy that monitors them. The implementation of an ADC in a non-acute setting is impacted by the same considerations given to implementation in acute care locations, but further considerations include those outlined in Table 3 below.²⁴

Switching ADC systems

Hospital systems may replace ADC systems entirely. Regardless of whether upgrades occurred over time, new versions of ADCs may be available that provide options previously unused or unavailable. Processes should be mapped to minimize potential for error and test for accuracy as if it were a new system. The swap of an ADC system should be treated like a new installation with appropriate training to ensure safety, accuracy, and efficiency in the medication-use process.

Mechanisms should be in place to determine quality of installation (done completely and correctly), operation of the system (as installed it fits the needs of the organization and

contractual specifications), and processes (good fit for workflows within the organization and supported by laws, regulations, policies and procedures).

Regulations

Pharmacy personnel must be familiar with state and federal laws concerning ADC use, report diversion where required, and stay up-to-date with changes. At present, most ADCs are not regulated as medical devices, so organizations are responsible for ensuring that vendors are responsive to patient safety or diversion issues, as they are not required to be reported to the Food and Drug Administration (FDA). However, some anesthesia ADCs are regulated by the FDA and do require safety reporting. ADC use is part of an integrated approach in the medication-use process and rarely operates in isolation. With technological advancements, interoperability with other systems such as smart pumps, EHRs, and the hacking potential with any connected device, these systems may be considered medical devices by the FDA in the future. Until then, it is imperative that organizations take appropriate steps to report issues that may impact diversion or patient safety to vendors and appropriate agencies to ensure appropriate evaluation and timely resolution.

Future considerations

Organizations should communicate suggestions that would improve the interoperability, safety, and efficiency of ADCs and enhance the medication-use process to ADC vendors. In addition, vendors should have a method of documenting and deploying best ideas and practices, as well

as innovating with safe and efficient methods of medication distribution that align with customer objectives and state and federal laws.

ADCs are abundant in hospitals, store and distribute medications as a primary tool in the medication-use cycle, and are becoming progressively more interoperable with other hospital systems and devices. As a result, ADCs need to continually evolve with technology improvements, workflow enhancements, and proactive monitoring, which can help organizations keep medication distribution systems safe for patients, efficient for providers, and in compliance with state, federal, and Drug Enforcement Administration requirements.

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Disclosures

The authors have declared no potential conflicts of interest.

Additional information

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References

1. Halvorson RM. State of pharmacy automation 2019. *Pharmacy Purchasing and Products*. 2019; 16:50, 52-53.
2. Schneider PJ, Pedersen CA, Scheckelhoff DJ. ASHP national survey of pharmacy practice in hospital settings: Dispensing and administration-2017. *Am J Health-System Pharm*. 2018; 75:1203-26.
3. ASHP statement on the pharmacist's responsibility for distribution and control of drug products. In: *ASHP Best Practices 2020–21*. Hawkins BH, ed. Bethesda, MD: American Society of Health-System Pharmacists; 2021. Available at: <https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/pharmacists-responsibility-distribution-control-drug-products.ashx> (accessed 2021 May 1).
4. Cloud Standards Customer Council 2017. Impact of cloud computing on healthcare version 2.0. <https://www.omg.org/cloud/deliverables/CSCC-Impact-of-Cloud-Computing-on-Healthcare.pdf> (accessed 2021 May 6).
5. Institute for Safe Medication Practices. Guidelines for safe use of automated dispensing cabinets (2019). <https://www.ismp.org/resources/guidelines-safe-use-automated-dispensing-cabinets> (accessed 2021 May 6).
6. Ortman MJ, Johnson EG, Jarrell DH et al. ASHP Guidelines on Emergency Medicine Pharmacist Services. *Am J Health-Syst Pharm*. 2021; 78:261–75. doi.org/10.1093/ajhp/zxaa378
7. ASHP Section of Inpatient Care Practitioners. Practice resource for automated dispensing cabinet overrides. www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/patient-safety/patient-safety-practice-resource-for-automated-dispensing-cabinet-overrides.ashx (accessed 2021 May 2).
8. Institute for Safe Medication Practices [ISMP]. ISMP guidelines for safe electronic communication of medication information (2019). <https://www.ismp.org/node/1322> (accessed 2021 May 6).
9. Partnership for Health IT Patient Safety. Safe Practices to Reduce CPOE Alert Fatigue through Monitoring, Analysis, and Optimization (2021). https://d84vr99712pyz.cloudfront.net/p/pdf/hit-partnership/partnership_whitepaper_alertfatigue_final.pdf (accessed 2021 May 1).
10. Osheroff JA, Teich JM, Levick D et al. *Improving Outcomes with Clinical Decision Support: An Implementer's Guide*, 2nd ed. Boca Raton, FL: Taylor & Francis; 2012.
11. Institute for Safe Medication Practices. Paralyzed by mistakes - reassess the safety of neuromuscular blockers in your facility (2016). <https://www.ismp.org/resources/paralyzed-mistakes-reassess-safety-neuromuscular-blockers-your-facility> (accessed 2021 May 6).

12. Institute for Safe Medication Practices [ISMP]. ISMP targeted medication safety best practices for hospitals: 2020. <https://www.ismp.org/guidelines/best-practices-hospitals> (accessed 2021 May 6).
13. Institute for Safe Medication Practices. Safety enhancements every hospital must consider in wake of another tragic neuromuscular blocker event (2019). <https://www.ismp.org/resources/safety-enhancements-every-hospital-must-consider-wake-another-tragic-neuromuscular> (accessed 2021 May 6).
14. Brummond PW, Chen DF, Churchill WW et al. ASHP guidelines on preventing diversion of controlled substances. *Am J Health-System Pharm.* 2017; 74:325-48.
15. California Hospital Association Medication Safety Committee 2013. Reducing controlled substances diversion in hospitals. https://www.chpso.org/sites/main/files/file-attachments/controlled_substance_diversion.pdf (accessed 2021 May 6).
16. Blackmere J, Crowson K, Danley B et al. Determining the most efficient controlled substance inventory practice that minimizes discrepancies and maximizes security. https://www.bd.com/documents/case-studies/medication-supply-management/DI_Managing-Controlled-Substances_CS_EN.pdf (accessed 2021 May 6).
17. Belisle C. Establishing a controlled substance compliance program. *Pharmacy Purchasing and Products.* 2017; 14:2-5.
18. New K, Overmire L. Utilize adc transaction data to detect diversion. *Pharmacy Purchasing and Products.* 2017; 14:10-17.
19. Institute for Safe Medication Practices. Considerations for Automated Dispensing Cabinets (ADC) usage during COVID-19 (2020). www.ismp.org/resources/considerations-automated-dispensing-cabinets-adc-usage-during-covid-19 (accessed 2021 May 1).
20. Bickham P, Golembiewski J, Meyer T et al. ASHP guidelines on perioperative pharmacy services. *Am J Health-Syst Pharm.* 2019; 76:903-20.
21. The Joint Commission 2019. National patient safety goals effective January 2019. https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/historical/npsg_chapter_hap_jan2019.pdf (accessed 2021 May 6).
22. American Society of Anesthesiologists. Statement on labeling of pharmaceuticals for use in anesthesiology (2020). <https://www.asahq.org/standards-and-guidelines/statement-on-labeling-of-pharmaceuticals-for-use-in-anesthesiology> (accessed 2021 May 6).
23. United States Department of Justice, Drug Enforcement Administration. Preventing the accumulation of surplus controlled substances at long term care facilities (Final Rule). 70 Fed. Reg. 25462 (May 13, 2005). <https://www.govinfo.gov/content/pkg/FR-2005-05-13/pdf/05-9538.pdf> (accessed 2021 May 6).
24. White L. Key success factors in the implementation of an automated dispensing system in a community pharmacy. *Int J Healthcare Tech Mgmt.* 2009; 10(6):393-407.

Table 1. Inventory selection criteria

Frequency and appropriateness of individual medication use
Identification of medications considered to be inappropriate for inclusion in ADCs, such as products with short expiration dates, special preparation or storage requirements, those that present cross-contamination risks, or are hazardous
Party responsible for medication safety oversight and administrative control of medication availability in the ADC, such as the pharmacy and therapeutics committee ⁵
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 with other devices or applications
Tall-man lettering, standardized concentration displays, and form designations as examples of many items that improve safety in use
Procedures to prevent and minimize the incorrect return of medications directly to the ADC by nursing staff to decrease the potential for error
Procedures for keeping policies, procedures, and education current
<p>Policies addressing medication integrity, including:</p> <ul style="list-style-type: none"> ● the importance of accuracy and integrity of product labels ● how to handle medications that are removed from an ADC but not used ● how to account for medication waste ● checking products for expiration and BUDs ● identification and follow-up on tampered products ● product storage ● procedures for delivering medications to patient care units and individual patients
<p>Controls that ensure accurate restocking of ADCs, such as:</p> <ul style="list-style-type: none"> ● Ensure the ADC system permits use of barcoding to restock correct medication in correct drawer, bin, or pocket

- 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
- Standardization of restocking procedures to limit process variation

ADC, automated dispensing cabinet; BUD, beyond-use date.

Table 2. Employee ADC interaction tasks

Pharmacy	Nursing and Other Clinicians
Restocking/stock outs	
Patient-specific medication stock and removal	Removing, returning, and/or wasting medications
Expired medication removal	
Returned medication maintenance	
Recalled medications status	
Discrepancy resolution	Discrepancy resolution
Waste reconciliation procedure	
CS monitoring	CS monitoring (e.g., counting)
Patient-specific medication maintenance	
System integrity (e.g., are any cabinets malfunctioning?)	
Inventory optimization	Inventory optimization

CS, controlled substances.

Table 3. ADC Implementation and Considerations for Off-Site Use

<p>Cost justification</p> <ul style="list-style-type: none"> ● Ability to decrease inventory through better management ● Cost of monthly lease and service agreement ● Regulatory/licensing requirements ● Ownership of the device ● DEA licensure requirements (i.e., how medications are transferred and tracked from pharmacy to the non-acute area) ● Creation and management of override lists for access to medications prior to order verification ● Adherence to regulations around use of ADCs in non-acute areas
<p>Operations</p> <ul style="list-style-type: none"> ● Requesting restocking of medications ● Servicing and maintenance of the ADC ● Refilling the ADC, pharmacy vs. non-pharmacy staff ● User access and management <ul style="list-style-type: none"> ○ may require new roles that did not have access historically ○ new or updated privileges may be required ● Type of access to ADC, restricted or open <ul style="list-style-type: none"> ○ If restricted, will medications require pharmacy verification prior to removal ○ If open access, what is process for order review including steps to take in the event of a delay or an error ● Policy and procedures for access to medications during system malfunction or electrical outage
<p>Security</p> <ul style="list-style-type: none"> ● Securing medications during transport to be tamper evident? ● Safety of staff during transport ● Physically security of the ADC ● Video surveillance
<p>Accountability</p> <ul style="list-style-type: none"> ● Responsibility for reconciliation ● Responsibility for electronic surveillance of activity at the ADC <ul style="list-style-type: none"> ○ Monitoring activity on the ADC if located in care areas that are closed nights or weekends, or temporarily have no patients ● Responsibility for temperature monitoring and response to alerts
<p>System design and interoperability</p> <ul style="list-style-type: none"> ● Address differences in EMR vendors between organizations and non-acute areas ● Reconcile differences in formularies among organizations' off-site area(s) and hospital ● Access to system software to make changes to settings and build

DEA, Drug Enforcement Administration; ADC, automated dispensing cabinet.