Draft ASHP Guidelines on the Safe Use of Automated Dispensing Cabinets

Purpose

Automated dispensing cabinet (ADC) technology is used to improve efficiency and accuracy of medication dispensing in the medication-use system, improve patient care, support medication storage and security, and provide evaluation of ADC-user interactions. ADC use has become widespread in healthcare institutions, with 97% of hospitals using ADCs in their medication-use systems.[1]

Objectives to support the ADC system reaching dispensing efficiency and accuracy goals would include the following:

- Software and hardware technology for optimal operations available and supported by knowledgeable staff.
- Interfaces to other technologies supporting medication-use systems created to enable efficient workflows.
- Interoperability with the electronic health record (EHR) and other healthcare information technology systems sought whenever possible.
- Included in any systemwide integration of medication use or standardization.
- ADCs operate in a safe and secure way, optimizing high levels of security, operation documentation, and alerting functionality to medication diversion.
- ADC mechanical operation and inventory management capabilities allow efficient, accurate, and optimized availability of medication for patient care needs.

- ADC employs other technology such as barcode scanning, biometric identification, and special storage and alerting features.
- Controlled substance (CS) management and diversion prevention focus of the ADC.
- Mandatory ADC features include real-time alerting and reporting capabilities to support CS management.
- ADC maintenance is well supported with adequate personnel, minimum downtime, and analytical reporting for optimal ordering and restocking.
- Staff education and training on ADC operation and use are supported at a high level to continually maintain competency.
- Use of ADC in procedural, nontraditional, and nonacute (e.g., long-term care, clinics) patient care areas established to enable same standard of patient care and medication control as in more traditional patient care areas.

Requirements

ADCs must provide accurate and controlled storage, dispensing, and monitoring of medications, while providing medications in an efficient and safe manner in patient care. The ability of ADCs to accomplish these requirements have improved since their introduction in the late 1980s, leading to the technology becoming the primary means of medication distribution across facilities of many sizes.[2] For an organization to be successful at implementing and sustaining the benefits of ADCs, it must assure that the ADC will help optimize the medication-use process and meet the financial, operational, and clinical goals of the organization. These guidelines will

address the components of ADC technology implementation listed in Table 1, which provide important detailed steps an organization should follow to meet basic ADC requirements.

Architectural and infrastructure considerations

When evaluating ADCs, careful consideration must be given to infrastructure that will best support the system and allow for smooth operation and future growth. Infrastructure requirements include servers, interfaces, upgrades, integration with other systems, and security. Each organization will need to ensure that both physical and personnel infrastructure necessary to maintain the system are in place.

Servers. Servers are typically client hosted and must be adequately sized to store both formulary and user information, as well as transactional information for analytics and reporting. Typical infrastructure requirements include power and data jacks within a medication room or in the area where the ADCs will be located. Physical hardware should be scalable to allow for future growth, and current systems should utilize a unified server approach. 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. Vendors provide a range of options, from data refreshes every few hours to more frequent data refreshes that support minimal losses in the event of unplanned downtime.

Interfaces. With the growth of large healthcare IDNs, as well as the proliferation of multiple electronic clinical applications used within healthcare systems, ADC vendors have moved toward integrated platforms that simplify and standardize system maintenance through interfaces. The ADC system must work seamlessly with other clinical systems, including EHRs, pharmacy information systems (PIS), admission/discharge/transfer (ADT) systems, and billing systems. Each of these other systems serve as the source of truth for formulary and barcode information, patient information, medication profile information, and medication order data. Thus, bidirectional interfaces are required to reliably pull this information into the ADCs system. Health Level Seven International (HL7) standards are also employed for these interfaces. Finally, many systems also utilize interface engines to streamline system connectivity, especially when multiple systems come from the same vendor.

During the build phase of ADC system implementation, all bidirectional interfaces must be thoroughly tested to ensure that both the most accurate and current information is flowing into the ADC system. In addition to having information flow into the ADC system, some EHRs are able to pull in dispense transaction information from the ADC system as well. This information provides the clinician with a more complete picture of the medication management process within the EHR, thus allowing the EHR to provide a more complete picture in patient care. In addition to the ADC vendor, the EHR vendor will also play an important role in successful implementation and maintenance of the ADC system. Both the ADC vendor and the EHR vendor will have test plans to be used during the implementation process, and both will work together to create an interface between their respective systems. If there is

a change in EHR vendor, new interfaces and an archival of dispense data for reference purposes will need to be created.

System integration. In addition to the foundational clinical systems described above, integration of several additional optional systems with the ADC system must be completed if they are in use. Other dispensing devices, such as a central pharmacy robotics system used for cart fill 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 carousels and can be used for both central fill within a hospital or across a healthcare system. Finally, many healthcare organizations also use a CS system that provides secure storage for CS and integrates with the ADC system to provide secure dispensing for CS.

Database management within the ADC system involves maintenance of several key pieces of information integral to ADC workflow. These include formularies, scan codes, users, user roles, and rules and alerts. In multihospital IDNs, these databases are typically shared between all sites to streamline support processes and allow for sharing of information (e.g., formulary, scan codes, user roles). There are scenarios in which IDNs may be 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 have historically involved updated hardware and software. This strategy has changed with ADC vendors; now the core hardware remains in place (sometimes with an option of swapping drawer types or configurations within the drawers), while any major updates occur with the software. This model allows for new functionality as

well as changes to the user interface but minimizes costs by allowing the healthcare organization to continue using existing hardware and drawers.

Safe and secure operation

Access control. Safe and secure operation of ADCs starts with well-defined processes for granting and maintaining user access. Current technology in ADC systems allows for centralized user management through the information technology (IT) or pharmacy departments. Organizations should use Active Directory to administer access to the ADC. Active Directory allows for centralized control of access to multiple applications, while the user can utilize the same credentials for each application. For ADC systems, the Active Directory system allows for immediate suspension of access if an employee is suspended or terminated. Password maintenance is no longer the responsibility of the pharmacy department and can shift to IT, which most likely manages access for all other enterprise-wide software.

Each organization should have defined policies on which personnel shall have access to the ADC. Because the pharmacy department is organizationally responsible for controlling access to all medications, including through ADCs, pharmacy departments should have a process in place to remove employee access upon termination, suspension, or investigation for CS diversion. Given the risks involved with medication theft, the pharmacy director should ensure a process is in place so that employee access can be removed at any time. The policy should address other clinical team members, including nurses who administer or manage medications, in addition to what access students should have. User templates that define what a user can perform on the ADC system should be developed based on the access policy, and the

total number of user templates should remain manageable. Creating a user template for a single individual is often inappropriate and should be handled by grouping the needs of that user with other like users. A single ADC system often supports multiple facilities within an IDN. ADCs within an IDN should use the same user templates and policy to create standardization throughout the organization.

Finally, all ADC systems include biometric identification hardware. Today's biometric hardware has advanced to become much more sensitive than prior iterations. All staff should be required to utilize the biometric hardware. If failure to utilize biometric identification hardware is observed, accommodations should be made to allow the use of user ID and password to access the ADC.

Medication dispensing. Organizations should establish processes for the addition and withdrawal of medications from the ADC. Processes should ensure every patient receives the right medication every time. The layout and type of storage areas within the ADC can prevent the wrong medication from being refilled or withdrawn. Guidelines for ADC configuration are provided elsewhere in these guidelines. When medications are refilled at the ADC itself, barcode technology should be utilized to ensure the correct 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 in order to complete the refill. This important safety feature can reduce the number of ADC misfills for an organization.

Barcode technology may be utilized when stocking, removing, and returning medications to the ADC. Therefore, the barcode dictionary is a critical component to ensure safe ADC use. The pharmacy department should establish procedures for addition and

maintenance of barcodes to the dictionary. Two people should be required to add a barcode to the dictionary; one person to add the barcode and one person to verify the barcode. Final verification should be completed by a pharmacist. All medications dispensed from the pharmacy should have a barcode. Although the majority of medications will have a barcode incorporated by the manufacturer, the pharmacy is responsible for adding barcodes for items compounded or repackaged by the pharmacy. ADC vendors and other specialty companies provide niche equipment to produce supplemental barcodes. Supplemental barcode labeling may also be provided under contract with a wholesaler or other specialty company.

Barcode technology may also be utilized when a caregiver removes medication from an ADC. Requiring barcode verification for removal of medication requires careful consideration and should not be considered a standard practice. 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 drug being dispensed is greatly reduced. Risk avoidance should be weighed carefully against the time requirement for a caregiver to scan on removal. When a caregiver is returning a medication to the ADC, barcode scanning should be used to verify the medication and storage location. In addition, ADC manufacturers offer label printers that can automatically print a corresponding patient-specific label for proper identification, which is required if time lapses between dispensing and administration, or whenever a label is needed or required.

Most ADC systems allow for remote queuing of medication withdrawals. The process allows a caregiver to select medications for withdrawal for a particular patient away from the ADC. Remote queuing is completed through a web-based portal or integrated into the EHR.

Once medications are in the queue, the caregiver can access them at the ADC. Remote queuing reduces the amount of time nurses need to spend at the ADC. Remote access to the ADC should be considered as a tool to decrease wait times at the ADC and allow nurses to spend less time in the medication room. In addition to remote queuing, ADCs also allow for remote wasting of CS. Nurses can witness and document the waste of medications via the EHR or web portal, instead of at the ADC. Organizations should evaluate whether this process would be beneficial for nursing workflow.

ADCs can be configured as either profile or nonprofile devices. Nonprofile devices allow access to all medications in the machine. Profile machines only allow access to those medications for which a pharmacist has verified the medication order. Nonprofile devices should be limited to areas where a physician is present during medication administration. Typical areas for nonprofile devices are radiology and operative areas. Profile devices should be used for all inpatient areas, and may also be successfully deployed in the emergency department (ED). Historically, these areas have been classified as nonprofile, but as more pharmacists have begun to review ED orders, ADCs should be considered for profile status. Successful conversion of an ED from nonprofile to profile can be accomplished by partnering with ED nurses and physicians to develop appropriate turnaround time standards, override lists, and autoverification algorithms.

If a medication stored in a profile ADC is needed, but there is not an active order on the profile, the provision to override the medication may be allowed. A list of override medications should be defined by the organization's pharmacy oversight committee, typically the pharmacy and therapeutics committee. A policy should be developed that defines the criteria by which a

193 medication can be added to the override list, and medications can be grouped by nurse type or
194 location. Development of this list will require careful consideration of timely patient care
195 against the reduced risk achieved by pharmacist review of the medication order. Organizations
196 should require nurses to document the override reason when withdrawing a medication so that
197 override reasons can be standardized for later data analysis. A second individual should also be
198 required to verify the correct patient, medication, strength, route, and indication upon override
199 removal of a list of high-risk medications or from certain ADCs.[3] The number and types of
200 overrides should be regularly reviewed for process improvement.

201 **Return and waste of medications.** Organizations should develop policies and standard
202 procedures that follow federal and state laws related to the return and waste of medications.
203 The ADC may require documentation of the reason for wasting a medication. Standardized
204 responses for medication waste should be developed because these allow for easier querying
205 than free text responses and can also allow for process improvement. When a nurse is
206 returning unopened medication to the ADC, the system can be set up to return the medication
207 to the original storage area within the ADC or to a separate returned medication space.
208 Pharmacy regulations may define where returned medications should go. Barcode scanning
209 should be utilized for medications returned to their original storage area within the ADC to
210 ensure medications are placed back in their assigned space.

211 **Implementation of new ADCs.** Implementing a new ADC system will require careful
212 thought regarding the number of ADC devices to deploy and their placement, based on patient
213 acuity and physical layout of the care unit. A rule of thumb for the number of general care beds
214 per ADC is 12:1. For critical care areas, a ratio of 8:1 should be considered. A higher ratio may

be considered if ADCs are only used for PRN and first doses. ADCs should be located in areas that are well illuminated and central to patient beds, but ADC size should also be a factor in determining placement. More devices may be needed for efficient care if ADCs are placed far from patient beds. Time-motion studies may be done to determine the ideal location for the device. State laws may also require ADCs to be placed in a secured and/or locked area.

Optimization of the ADC system. Optimizing the use of an ADC system requires the evaluation of performance metrics and goals. When goals are not met, evaluations should be performed to improve the ADC system. Some metrics to consider include percentage of total doses from the ADC, override rate, discrepancy resolution rate, nurse wait time, steps between patient rooms and ADC, and ADC expired medication cost. ADC systems also allow for passive or active messaging and alerts to users to help guide practice. Alerts should be standardized and approved across an IDN using a governing body and developed with a consideration for alert fatigue. Development of 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 or if the alert appears on withdrawal of a medication from the ADC. Metrics on alert overrides should be evaluated, and the governing body should consider the effectiveness of each alert.

Configuration and inventory selection

The configuration of ADCs can be highly variable, depending on device design and organizational preference. Primary frame options include a main cabinet, an auxiliary cabinet,

and towers. Frame selection and configuration are driven by several factors, primarily the organization's distribution model, space available for equipment, and number of drugs to be stored within the ADC. Within each frame, the drawer, bin, and pocket configurations may also vary, depending on device design and organization preference. Open matrix drawers, lidded pockets that open or light up for a specific medication, and multiple open bins within a cabinet tower door are among the different configurations available from vendors.

Safe configuration considerations. Safety should be the primary concern when determining medication configuration within the ADC. Restricting access to medications through appropriate configuration will limit the potential for inadvertently selecting the wrong medication. The use of matrix drawers should be limited as much as possible due to the potential for errors when restocking or dispensing. In particular, storage of high-alert medications, reversal agents, and agents prone to diversion within a matrix drawer is inappropriate. Each medication and strength should be loaded in an individual, lock-lidded ADC pocket that opens only when the specific medication is needed. If neuromuscular blocking agents (NMBAs) must be stored in ADCs (e.g., in a critical care, ED, or perioperative setting), organizations should standardize storage practices by keeping them in lock-lidded pockets with an auxiliary label on the pocket that states: "WARNING: CAUSES RESPIRATORY ARREST – PATIENT MUST BE VENTILATED." 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).[4,5] Look-alike/sound-alike (LASA) or high-alert medications, and medications with multiple strengths, should be positioned throughout the ADC, rather than side-by-side in the same drawer, to minimize incorrect restocking.

When considering 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 over to retrieve or restock. Access to refrigerated medications should be monitored through the ADC system whenever possible; such monitoring can be accomplished via an ADC-connected lock that provides simple access information to secure integrated refrigeration systems with locking compartments and sophisticated temperature monitoring.

Inventory selection considerations. The pharmacy department should develop criteria for determining drug products and quantities that will be stored under different levels of access control in specific configurations of drawers, bins, or pockets. These criteria should be determined based on the organization's medication distribution model and the needs of patients served and should address all elements listed in Table 2. Medication storage practices should be routinely reviewed and adjusted based on prescribing patterns, utilization, and specific unit needs. Items other than medications (e.g., patient-controlled analgesia keys, patient belongings) should not be stored in the ADC at the expense of additional medications.

CS management and diversion prevention. ADCs are relied upon to provide the primary means of medication distribution across both small and large facilities, having reached 62% (400+ beds) to 77% (100-200 beds) usage.[7] Thus, ADCs have established an important role in CS diversion prevention plans (CSDPPs), and all healthcare institutions should establish a CSDPP that includes ADCs.[8]

ADCs serve several roles in a CSDPP, from secure storage and dispensing that are accurately and continuously monitored, to providing additional surveillance capabilities such as biometric authorization for access and camera or video monitoring capabilities. ADCs can also perform many medication-use process functions. ADCs can provide both system-level and provider-level controls, such as user documentation, controlled medication dispensing, accurate inventory management, auditing, surveillance, multiple witness for returns and waste, and inventory discrepancy alerting. These characteristics enable the ADC to be an important tool in medication distribution as well as in the CSDPP. The ADC commonly becomes a primary purveyor of medication-use information when an institution is trying to optimize the operational use of the ADC, but it is also important when beginning an investigation of possible medication diversion. Regardless of ADC location in an institution, ADC operation and information contributions to a CSDPP should be part of the optimization review. Optimization of the ADC can also help manage drug distribution inefficiencies, decrease the opportunity for diversion by storing only CS required for patient care, and decrease medication discrepancies.

CS inventory management processes. ADC CS management requires policies and procedures that support accurate inventory management, delineate well-defined user processes, and meet legal and regulatory requirements. ADC automation technology must also support the highest possible level of access control and monitoring and dispensing accuracy. The support of accurate ADC inventory management begins with storage configurations, stocking processes, and physical security of CS in the ADC equipment. Policies and procedures maximizing accurate dispensing and security of CS through all phases of the medication distribution process are required to support best practices.

The total number CS and how they are physically stored in an ADC must be established to enable efficient inventory counting and minimize count discrepancies. Keeping only those medications needed for patient care and destocking those that are not routinely used can have a positive effect on the amount of time spent on inventory counting.[9] Stocking only one medication in each secured storage location (drawer bin or pocket) can allow increased accuracy in counting, thus decreasing count discrepancies and the potential for diversion.

The variety of services a pharmacy department may be required to support in an institution will impact the level of staff resources dedicated to ADC management on a daily basis. Inventory management and software optimization will be needed to assure appropriate supplies of CS are available at the right time. Establishing par level evaluation and restocking at correct times to support varying levels and intensity of CS use are required to ensure the pharmacy department is efficient and responsive to changing patient care needs. Access to ADC CS by only adequately trained, pharmacy-authorized staff can minimize recordkeeping and dispensing mistakes. In addition, storage security must meet all federal and state regulatory requirements until time of distribution to an ADC.

Software programs to analyze user medication dispensing and other transactions from an ADC to patients can identify suspicious activity and potentially detect medication diversion. With reported rates of 1.12 diverters per 100 beds per year,[10] pharmacy departments must take advantage of analytical tools to address the profusion of data that ADCs can capture.

User management. Careful attention should be given to the creation of roles and authorization for access to devices and system functions, which should balance security against the user's job requirements. The specific roles of personnel involved in operating or using the

automated pharmacy system should be identified and standardized across the health system with consideration for a clear separation of duties when possible (e.g., staff nurse with dispense-only access vs. nurse manager with access to resolve discrepancies but not dispense). Each role should have responsibilities and privileges clearly defined with authorizations assigned accordingly and should be set forth in written policies and procedures.[8, 11] The policies and procedures should also clearly specify the processes for creation and use of temporary users and temporary patients (e.g., who can create them and under which circumstances) and should state that their use should be minimized. Processes should be established to routinely monitor temporary users and patients and resolve discrepancies in a timely manner to minimize their potential use in diversion.

User accounts should be maintained by a limited number of staff utilizing user management best practices, which may include central management by an IT security team. Utilization of the health system's Active Directory electronic files to add, change, and delete user accounts and to synchronize system passwords is another best practice. Use of Active Directory minimizes the need for manual user account maintenance when changes occur, especially with respect to account deletion upon termination or separation from the organization. Biometric devices such as fingerprint readers should be used as primary device authentication to minimize unauthorized access through stolen passwords.[8, 11] Special procedures to assure immediate removal or inactivation of ADC access and privileges should be used when individuals suspected of diversion are involuntarily separated from the organization.

Monitoring, reporting, and surveillance

Inventory counts. As ADCs have become a common source of CS diversion, CS should only be stored in secured pockets and strict attention should be paid to ADC CS inventory counts. 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 in order to complete the transaction.[8, 12] Blind counts alone will not guarantee that inventories stay accurate; thus, regular cycle counts of pockets should be included in written policies and documented accordingly when completed. It may be most productive to perform a weekly count only of CS accessed since the last inventory three weeks out of every month, and then complete a full inventory of CS once a month.[9] Removal or unloading of CS that are not frequently used will free up valuable pocket space and decrease CS inventory time.

CS waste creates a significant opportunity for drug diversion. Witness and second nurse electronic signatures should be required for items wasted and items returned to the ADC or return bin. Organizational policy should require that the second nurse either witness the waste or return the CS to the ADC prior to signing as a witness.[8,11] 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.[13]

Discrepancy management. CS count discrepancies between actual inventory count and recorded count occur frequently enough that constant vigilance to notification and swift reconciliation are required in order to minimize loss, identify process improvements, and

adhere to state and federal regulations with respect to CS losses. Policies should require and enforce that CS discrepancies be reviewed and resolved within 24 hours. The ASHP Guidelines on Preventing Diversion of Controlled Substances provide additional recommendations on discrepancy management.[8]

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.[14] As part of a CSDPP, institutions should create a diversion response team and establish a routine diversion surveillance process that will proactively monitor staff involved in CS ordering, inventory, dispensing, administration, and documentation activities.[8] Staff members involved in diversion surveillance should receive training to understand staff and clinician work patterns that may indicate potential diversion. Work patterns that could indicate diversion include but are not limited to:

- Volunteers for overtime or stays late frequently.
- Volunteers to administer narcotics to other patients frequently.
- Records high number of waste transactions.
- Takes frequent breaks or trips to bathroom.
- Shows discrepancies between patient reports of pain relief and charted medications.
- Uses more drugs for similar or same patients as colleagues consistently.
- Carries drugs and syringes in pockets frequently.[15, 16]

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.[13] 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 determine 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 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:

- Defining the time between CS retrieval from storage area and the time of administration and documentation.
- Dose dispensed from ADC is package-size equivalent to, or closest available to, dose to be administered.

- 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 emergent situations.
- CS drawn up into a syringe is labeled per institutional policy.[12]

Leadership should evaluate and respond to gaps in practice competencies as process improvement opportunities (rather than punitive measures) that can in turn allow more time to be spent reviewing and reconciling problematic dispense transaction(s).

Maintenance and monitoring

Pharmacist responsibilities include the safeguarding of medications throughout the organization. ADCs are one method of medication storage that requires ongoing attention to ensure safety and security of the drug supply. Maintenance and monitoring of these systems are imperative to ensure the ADCs continue to operate safely and efficiently within the healthcare facility. Additionally, policies and procedures related to access, proper use, daily tasks, and ongoing maintenance are necessary to ensure the system is being used correctly and maintained for optimal performance and inventory savings.

Access

The process of credentialing ADC users assures correct access level and privileges for end-users, which in turn allows for complete tracking of any user transactions for the security of the system. Components of credentialing include the following:

- Who is in charge of the system?
- How do various staff members interact with the system? Examples include but are not limited to pharmacy manager or director, informatics pharmacists, ADC system administrators, pharmacists, super-users, pharmacy technicians, nurses and nursing supervisors, and other ancillary staff (e.g., respiratory therapy, ambulance personnel).
- How do users access the system? Are biometrics/single sign on or dual identification used?
- What type of access is available by user's role?
- By what process are users privileged and credentialed?
- Are users passed into the database using Active Directory or entered manually?
- How is a user's access revoked upon separation from the organization?
- How often are passwords changed?
- What method is used to grant access to vendors for software updates and system repairs, including onsite visits and remote access? Best practices include chaperones for onsite repair visits or a written agreement for remote vendor access to system.

Proper use and consideration of user tasks. Nursing and pharmacy employees access the ADC for different reasons, and it is important to clarify the general extent of those interactions. Pharmacy responsibilities may include system set up, system maintenance, and ADC use in accordance with the hospital's policies and procedures. Nursing responsibilities may include accessing the ADC in accordance with the hospital's policies and procedures or to remove, return, or document the waste of medication for a patient.

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 annually, depending on the organization's goals, time, and personnel. Some organizations choose to use their vendor's 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, basic pharmacy and nursing tasks may include, but are not limited to, ADC interactions listed in Table 3.

Ongoing maintenance. ADCs will require maintenance as well as software updates and upgrades over time. Maintenance will require determination of optimization processes and frequencies, volume and type of inventory in each device, optimal par levels based on usage, stockout analysis, barcode and alert maintenance, override list monitoring and associated reconciliation policies, test system maintenance, cleaning per vendor guidelines, spare parts inventory, and software and hardware updates. Preventive maintenance (check-ups by the vendor) is sometimes included in contracts regarding management of ADC issues (e.g., health checkup, full hard drive messages, older equipment failures, servers, and office suite and anti-virus software updates not delivered). It is important to install the latest operating system, software, and malware updates, which can be scheduled at times when the system is used least to minimize employee disruption. A healthcare facility's medication needs will also change over time, so awareness of medication needs on nursing units and optimization of either existing ADC cabinets or expansion of current cabinets with additional equipment or drawers should be considered.

Future planning. Monitoring the existing fleet of ADCs in relation to changing patient care needs and medication-use process demands will allow plans for the future to be developed. Existing nursing units may require additional ADCs, new nursing units may need ADCs, and older cabinets may need to be replaced. ADC vendors release new products each year to enhance their product lines. Keeping up to date with existing systems will help users make informed decisions on what is needed for the future from the current vendor or what is available from other vendors.

Education and training

Education and training are important milestones with any automated system project implementation or upgrade and should be standard components of a robust and complete project plan. Adequate lead time should be planned to allow 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. For example, training will be slightly different between ADC profile and nonprofile patient care areas as well as anesthesia or procedural areas. Similarly, training for end-users will vary for those responsible for ADC inventory and stocking. Various training methods should also accommodate different user learning styles, as well as the nature of 24-hour schedules in acute care settings.

Vendors should provide standard training support for new implementations and significant upgrades. 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. 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 assure 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.

A train-the-trainer approach is a practical method used to provide a broader base of trainers where there are large numbers of staff to be trained, such as nursing staff or other direct patient care providers in patient care areas. Super-users should be familiar with the environment and staff they will train, and may also serve as additional support staff during implementations. Night and weekend shifts might require extra training and support due to limited availability of super-users. Specific roles that should be considered for individualized training include nursing staff, pharmacists, pharmacy technicians, anesthesia providers, respiratory care, EMT/Lifeline, and system administrators (IT/informaticists). Specialized training for nursing leadership to reauthorize privileges for infrequent users should also be considered.

Once initial ADC implementation and training is completed, it is important to plan for ongoing training for new and existing team members and succession planning and cross-training should key members (such as administrators) of the ADC team move on to new roles or leave the organization. Ongoing training material should include material for existing users as well as new hires. Live or self-guided training courses, manuals, best practices, quick guides,

onscreen help, and posted 1-800 help desk numbers are some important tools to keep users' skills up to date. It is helpful to provide the centralized help desk with a decision tree to help triage calls and determine what can be quickly resolved versus what needs to be forwarded to pharmacy (e.g., Active Directory issues). Vendors may also provide online e-learning portals for staff to access for basic or advanced certified training. ADC user competency should be assessed annually, especially when ADC software upgrades include new features. Sites may consider permanently installing a training ADC to allow users to practice first-time training or adoption of changes due to significant software or hardware upgrades.

Specialty use ADCs

Use in anesthesia/operating room areas. The use of ADCs in perioperative areas is expanding due to the need for health systems to obtain better control, increase access, and improve accountability for CS stored and administered in the perioperative area. The primary users of ADC devices are anesthesia practitioners (physicians, nurse anesthetists, and perioperative nurses). Many of the vendors in the ADC market are marketing ADCs specifically for use by anesthesia providers with improvement in workflow, CS accountability, and access to critical medicines as the main features. ADCs marketed for anesthesia use vary in functionality when compared to other ADCs. Several features increase access to medications to meet the needs of the anesthesia provider and have administrative settings that need to be tailored to health-system practice. Perioperative area ADCs will likely vary from the settings of the other ADCs used in traditional patient care areas.

Some primary advantages to implementing anesthesia ADCs in the perioperative area include increased medication security, added inventory visibility (particularly useful during drug shortage situations), and expediting provider access to medications during surgical procedures. ADCs may also have the ability to provide real time alerts at time of dispensing, adding a safety layer for high-alert medications. Some of the biggest challenges are ensuring provider buy-in with the correct process of removal to ensure accurate administration documentation, inventory counts, and standardizing medication and supply layout between ADCs in a perioperative area. Anesthesia machines also have the capability to interface with external products that allow providers to more easily comply with The Joint Commission and American Society of Anesthesiologists syringe labeling requirements.[6]

Institutions may utilize ADCs in the perioperative area in different ways. Frequently, standard ADCs are located in core operative areas near operating room (OR) suites for use by nurses or surgeons. Anesthesia providers practicing outside of standard perioperative areas may also use standard ADCs to access medications needed for a procedure. These are generally nonprofile machines that store the majority of medications required for the surgeries taking place in OR suites. These can also be utilized as additional 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. Many times these ADCs contain high-alert medications, so care needs to be taken in how high-alert medications are stored in ADCs, including proximity to other LASA medications, use of alerts, and creation of surgery-specific virtual kits to help ensure appropriate selection of medications.[3, 11] High-alert medications such as NMBAs require special attention to selection requirements.[3-5] Some

limitations to adding anesthesia ADCs include limited timeframes to restock based on availability of OR suite and discrepancies between physical and electronic inventory levels. The capital expense of adding to all procedural suites should also be considered.

Key differences of anesthesia ADCs. Key points to consider when evaluating and designing an ADC medication distribution system in perioperative areas begin with determining how and which users will be using the ADC. In the perioperative area, different levels of staff may need access (e.g., anesthesia techs, nurses, nurse anesthetists, and physicians). A licensed healthcare provider will be independently ordering, removing, and administering medications. Perioperative nurses most likely are removing medications from the ADC based on surgery-specific preference cards. Access and privileges to various ADCs in the perioperative area can be limited based on user role in the ADC system. Access and privileges should be discussed with perioperative leadership to ensure that access is granted to all users who need it based on current workflow but that access is limited or restricted for users with no clinical requirements.

Other key differences that must be considered are the settings and configuration of the ADCs. For ADCs in the OR suite, the appropriate timeout interval should be discussed with anesthesia teams to ensure they have timely access when needed but that limits are in place to prevent ADCs from being left logged in for longer than required. In most cases, the timeout interval in the OR suite will be considerably longer than what is configured on nursing floors due to the need for ongoing access throughout a case. Review of settings to limit access to CS without re-verification of user identity is important to ensure ongoing accountability. Patient lists in perioperative areas need to be configured to ensure timely access to patients and limit creation of temporary patients. Some considerations when setting patient lists include

585 configuration of patient location in the EHR, access to patients in the ADC following discharge
586 for case reconciliation, and the need to have access to all patients admitted to ADCs. Broader
587 access creates greater need for safeguards to ensure that inappropriate access is detected
588 quickly. The creation and management of system-level kits can be very beneficial for end-users
589 to ensure that appropriate medications are removed each time for specific cases. Quick access
590 to emergency medications must also be granted in timely manner.

591 Many ADCs configured for use in the perioperative area can also provide added features
592 to allow flexibility around use. Helpful mobility features include wireless access, mobile wheels,
593 and backup uninterrupted power source in case the ADC needs to be moved during a case or if
594 power is lost. This allows for ADC repositioning based on case type for rooms where space is
595 tight and bed orientation is critical. With increased mobility, the security of the ADC needs to be
596 considered to ensure no devices are taken out of an OR suite inappropriately.

597 **Medication supply storage and design.** When designing storage solutions for
598 medications in the perioperative areas, attention must be given to end-user needs, case type
599 and volumes, medication safety concerns, and available space, since many medications stocked
600 in perioperative ADCs are not stocked in any other locations. When designing ADCs for use by
601 anesthesia providers, the drawer configurations need to be planned and reviewed with end-
602 users to ensure optimal layout based on drug class, frequency of use, high-alert status, and
603 LASA medication concerns.[11] NMBAs continue to cause significant harm and death due to
604 medication errors,[4,5] and are subject of a targeted best practice by ISMP.[3] Particular attention
605 should be given to placement to ensure segregation and easy identification of these high-risk

medications. Using a labeling system with barcode scanning can add an additional layer of safety during preparation, labeling, and administration of NMBAs.

Due to the fast pace of the perioperative area, storage and dispensing of CS should be considered with preference toward limiting required medication inventory by placing CS into single-use pockets so 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 or supplies 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 in a timely manner and clearly designate who is responsible for ongoing management.

Processes for medication returns to the ADC should be discussed with the perioperative department to ensure that processes match workflow and prevent restocking issues. Options for returning unused items include returning to the drawer with or without scanning the item and pocket, or returning to an external or internal return bin. When making determinations on preferred workflow, the size of the return bin, expected volume of medications returned to bin, and workflow required to clear the bin need to be addressed. The return bin can also be used to securely store CS if the decision is made to have pharmacy manage all physical waste after the provider has electronically wasted leftover medications at the ADC. Safeguards also need to be in place to ensure all CS and CS waste placed in return bins are trackable and secure throughout the reconciliation process when physical and electronic inventories are not aligned.

Tracking and inventory. As mentioned previously, anesthesia ADCs offer improved inventory visibility in the perioperative setting, a particular advantage during drug shortages.

However, provider education is paramount during implementation to ensure that the providers are accurately documenting what is being removed from the ADCs. If medication removal is not being documented properly, it will hinder the accuracy of physical counts and make the restocking process more difficult. When designing the layout of the inventory inside the ADC, care should be taken to avoid placing LASA medications in close proximity. For facilities that are using a color-coded labeling system for anesthesia medications, the potential for error still exists and should also be considered during the design phase. Machine replenishment should also be considered to ensure that the appropriate staffing is in place, since the ADCs will not be available for replenishment at all times due to active OR cases.

Depending on the EHR and anesthesia machine vendors, there may be some available interfacing capabilities that allow a selection of transactions to flow from the machine 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 of any CS discrepancies. This capability also assists in maintaining 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).

Emergency access. Anesthesia ADCs rely on electrical power and are typically equipped with a battery backup. However, the organization should develop procedures for dispensing perioperative medications in the event of an extended power loss. These procedures may include increased dispensing from a perioperative pharmacy satellite (if available) or maintaining an emergency cache of perioperative medication kits.

Use in nonacute areas. ADC use has also expanded to nonacute areas, such as long-term care facilities, hospice, skilled nursing homes, clinics, rehabilitation facilities, standalone surgery centers, freestanding emergency rooms, and veterinary hospitals. The shift to nonacute areas has been driven by the necessity to collect, control, and maintain all transaction information with accurate tracking of drug movement. ADCs are therefore critical to the security, accuracy, and accountability of medication movement within a system. Before ADCs were used in ambulatory care areas, many locations used tackle box style storage solutions to ensure timely access to critical medications. In addition, sites may be one to hundreds of miles from the pharmacy that monitors them. When considering placing an ADC in a nonacute area, key considerations should include the following:

Cost justification

- Ability to decrease inventory through better management.
- Cost of monthly lease and service agreement.

Regulatory/licensing

- Who owns and operates the device?
- If the nonacute area has its own Drug Enforcement Administration (DEA) license, how will medications be transferred from pharmacy to the nonacute area (e.g., use of a DEA Form 222)?
- If the ADC requires pharmacy verification prior to allowing access to an ordered medication, who creates and manages the override list for emergency access to medications prior to order being verified?

- What are the specific state board of pharmacy regulations for use of the ADC in nonacute areas?

Operations

- Who orders medications for the device?
- How and who will service the device?
- Who will fill the device (pharmacy or nonpharmacy staff)?
- User access to the device and user management:
    - May require new roles that have not previously had access.
    - New or updated privileges may be required.
- Will the device be profile or nonprofile?
- Storage of patient-supplied medications:
    - Managed in the ADC or with an alternative storage solution?
    - Infection control considerations.
- Do medications require pharmacy verification prior to removal, or can verification be done retroactively?
- Do medications require special storage considerations (e.g., hazardous, refrigeration or freezer, light sensitive)?
- If the ADC is being used in remote areas with limited access to alternative supplies of medications, does the nonacute area have policies and procedures in place for manual access to medications during system malfunction?

Security

- How will medications be secured during transport to be tamper evident?

- How will the safety of staff during transport be assured?
- How will the ADC be physically secured to floor or wall?
- Is there video surveillance in the area?

Accountability

- Who will be responsible for CS reconciliation?
- Who will be responsible for electronic surveillance of activity at the device?
- How will activity on the ADC be monitored if it is in areas that are closed at nights or on weekends?
- Who will be responsible for temperature monitoring and response to excursions?

System design and interoperability

- How will differences in EHR vendors between organizations and nonacute areas be addressed?
- How will differences in formularies among organizations' nonacute areas and hospital be reconciled?
- Who has access to system software to make changes to settings and build?

Switching ADC systems

Hospital systems on rare occasion may switch ADC systems entirely. Such switches may occur when an IDN acquires a hospital that uses a different ADC vendor and wishes to standardize due to the increasing age of equipment, opening up a bidding process, or when the end of a contract opens up bidding and a new vendor is selected. Organizations should remain current on what is available from all vendors and the innovations that have taken place since legacy

systems were installed. Regardless of whether upgrades occurred over time, new versions of ADCs may be available that provide options previously unused or unavailable. When changing ADC systems, care should be taken to map processes to minimize the potential for error. Systems vary between vendors, and unexpected challenges can and do occur. The swap of an ADC system should be treated like a new installation, and support needed to ensure safety, accuracy, and efficiency in the medication-use process should be provided.

Regulations

Most states have rules and regulations concerning deployment and use of ADCs. ADCs contain CS and legend drugs and are not impervious to diversion. Pharmacy personnel must be familiar with state and federal laws concerning ADC use and stay up to date with any changes that may occur. At present, 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). ADC use is part of an integrated approach in the medication-use process and rarely operates in isolation. With technological advancements, the opioid crisis, and interoperability with other systems such as smart pumps, EHRs, and the hacking potential with any connected device, it is unclear whether these systems will be considered medical devices by the FDA in the future. It is therefore imperative that organizations take appropriate steps to secure ADC systems and report issues that may impact diversion or patient safety to vendors to ensure problems are resolved quickly outside of regularly scheduled system updates.

Future considerations

Organizations should communicate suggestions to ADC vendors that would improve the interoperability, safety, and efficiency of ADCs and enhance the medication-use process. In addition, ADC vendors should have a method of documenting and deploying the 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. Blockchain, radio frequency identification (RFID), predictive analytics, and facial recognition are just some of many technologies that could be part of ADC systems in the near future. ADCs house some of the most dangerous and addictive medications using electronic databases and communication between systems. As these systems become more sophisticated, failures in any part could cause devastating events and result in large fines if not monitored closely. Technology improvements, proactive monitoring, and inclusion of emerging proven technologies can help organizations keep medication distribution systems safe for patients, efficient for providers, and in compliance with state, federal and DEA requirements.

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Table 1. ADC implementation review steps.

Architectural and infrastructure considerations
Safe and secure operation
Configuration and inventory selection
Controlled substance management and diversion prevention
Monitoring/reporting/surveillance
Maintenance and monitoring
Education and training
Use in anesthesia and operating room areas
Use in nonacute areas

Table 2. Inventory selection criteria.

Frequency and appropriateness of individual medication use
Identification of drug products 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 drug availability in the ADC, such as the pharmacy and therapeutics committee[6]
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 drugs directly to the ADC by nursing staff to decrease the potential for error
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 ADC but not used • how to account for medication waste • checking products for expiration and beyond-use dates (BUDs) • identification and follow-up on tampered products • product storage • procedures for delivering medications to patient care units and individual patients
Controls that ensure accurate restocking of ADCs, such as: • 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[6] • Standardization of restocking procedures to limit process variation[6]

Table 3. Employee ADC interaction tasks.

Pharmacy	**Nursing**
Restocking/stockouts	Removing medications
Patient-specific medication stock and removal	Returning medications
Expired medication removal	Wasting medications
Returned medication maintenance	Narcotic counting
Recalled drugs status	Discrepancy resolution

Discrepancy resolution	
Waste reconciliation procedure	
Controlled substance monitoring	
Patient-specific medication maintenance	
System integrity (e.g., are any cabinets malfunctioning?)	
Inventory optimization	