ADC Guidelines: Core Safety Processes

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Core Process # 1
Provide Ideal Environmental Conditions for the Use of ADCs

The physical environment for ADC use can have a direct effect on the safety and efficiency of medication distribution and administration. Specifically, the work environment, interruptions, and a busy, chaotic clinical area were cited as contributing factors for medication errors.(Westbrook, Woods, Rob, Dunsmuir, and Day 2010; Grissinger, 2012; ISMP 2012 [MSA 11/29]) *Reports submitted to the ISMP National Medication Errors Reporting Program (ISMP MERP) suggest that poor environmental conditions (e.g., unnecessary noise, dim lighting, interruptions, remote medication storage locations) can contribute to errors.*(Raban 2014, Mandrack,2012)

Organizational decisions regarding the intended use of ADCs; whether designed for full decentralized drug distribution, or alternatively for the management of a limited amount of medications (e.g., controlled substances, as needed medications [prns], and first doses only) are a factor in determining the size and space required for ADC placement. The availability of multiple ADCs in a clinical location or the placement of ADCs in strategic locations, can be key to an enhanced workflow for staff and aid in the prevention of risky practices and unsafe workarounds that may result from inadequate environmental conditions. Not having sufficient ADCs for the volume of patients and staff, or having them located far from patient rooms, leads to workflow inefficiencies, user frustration and fosters at-risk behaviors such as taking medications for more than one patient at a time or taking medications for a patient for more than one scheduled administration time. (Tina Hull; Linda Czirr; Marian Wilson, 2010)

Guidelines:

1.1 Provide a sufficient quantity of adequately-sized ADCs, with consideration of intended use.

a. Consider whether the ADCs will be used for first doses, prn medications, and/or controlled substances; or for decentralized distribution.

b. Select the size and quantity of ADCs based on the selected distribution model, considering the variety of medications and formulations necessary including those that require significant space (e.g., prefilled syringes, large and small volume IV infusions, patient-controlled analgesia [PCA] syringes, and medication-containing boxes, kits, and trays).

1.2 Locate ADCs and associated refrigerated storage in a secure location, with limited foot traffic (e.g., within a medication room or alcove), to limit distractions.

a. Select an area that is easily accessible to authorized staff and near patients to support safe and efficient workflow, reducing the distance and time needed for practitioners to reach ADC locations and potential workarounds by staff (e.g., removing medications for more than one patient at a time).

1.3 Ensure sufficient space around ADCs and associated refrigerated storage to allow for the complete opening of the ADC drawers and doors, and unimpeded access to refrigerated medications. If ADCs are located within a medication or supply room, or adjacent to an access door, ensure that when the entry doors are fully open that there is no risk of injury to the staff when using the ADC.

1.4 Provide sufficient lighting in the area around the ADC to allow for easy reading of the ADC screen, the medication label, and the medication administration record (MAR) as necessary.

1.5 Provide readily accessible horizontal workspaces (i.e., countertops) for medication preparation and labeling. The surface of the ADC should not substitute for horizontal countertops for medication preparation.

1.6 Ensure the MAR is readily accessible and used during medication selection and removal. Allow for sufficient space if mobile carts are utilized to access the MAR.

1.7 Store oral and parenteral syringes, medication measurement devices, auxiliary labels, IV tubing, and other medication administration supplies near ADCs and associated refrigerated storage.

Core Process # 2
Ensure ADC System Security

Security processes must be established and regularly reviewed to ensure appropriate access, transfer, and adequate control of medications as part of an effort to reduce the potential for medication diversion from automated systems. Dedicated measures such as limiting access, inventory management, and the adoption of advanced technologies should be used to prevent unauthorized access and ensure secure filling and withdrawal procedures. *(ISMP 2016, 21[5])*

Guidelines:

2.1 Use biometric identification for ADC access whenever possible. If not possible, establish alternative secure procedures to access ADC systems (e.g., identification badge access; password).

2.2 Limit access and define user privileges for specific practitioner types (e.g., respiratory therapists, anesthesia providers), based on the need to access specific medications and/or patient care areas.

2.3 Limit the number of individuals who can assign usernames and passwords to ADC users.

a. Restrict the use of temporary usernames/passwords.

b. Prohibit staff from sharing usernames/passwords.

c. Define a secure procedure to address forgotten usernames and passwords.

d. Update user access upon change in employee status.

e. Establish a process for user access to be removed immediately upon employee separation from the organization.

2.4 Periodically monitor appropriate user access based on organizational workflow requirements and scope of practice.

2.5 Develop a procedure to limit ADC access when a clinical unit is closed.

2.6 Use security cameras in key locations as a deterrent for diversion and for monitoring current ADC refilling processes.

2.7 Provide a locking mechanism for refrigerated storage associated with the ADC, if not in limited access room.

2.8 Establish a limited time frame for the ADC device to time out with user inactivity.

2.9 Minimize the use of temporary patients. If an organization allows users to enter temporary patients, restrict the type and number of individuals who can perform this function and establish a process to monitor all transactions performed under this function.

2.10 Implement procedures on a pre-determined interval for two individuals to perform a manual count of controlled substance ADC inventory, in all clinical areas including pharmacy.

2.11 Use “blind counts” for controlled substance inventory management.

2.12 Stock the smallest-sized container necessary to provide the typical ordered dose of a controlled substance to minimize the need for drug waste and limit the potential for drug diversion.

2.13 Implement procedures for addressing ADC discrepancies.

a. Immediately address all controlled substances discrepancies as soon as they are identified.

b. Require two individuals to perform all discrepancy resolutions.

c. Define a process for escalation of any discrepancies if unable to resolve by the end of the shift.

2.14 Conduct routine audits to verify that issued controlled substances were administered, wasted, or returned as documented, and discrepancy resolution reasons are appropriate.

2.15 Implement an automated surveillance system to proactively monitor controlled substance usage patterns associated with the ADC system. (Consider using similar tracking for other non-controlled substances with a high rate of diversion.)

Core Process # 3
Profiled ADCs and System Overrides

The use of an ADC in a "profiled mode" is considered by the industry a safety feature as it directs practitioners to a patient-specific medication profile and limits access to medications which have been reviewed and verified by a pharmacist as appropriate for the patient. Use of non-profiled ADCs allows practitioner access to all medications contained within, typically bypassing the pharmacist's review of the order prior to medication selection. *(CMS 2015 pg. 34, TJC 2015, Traynor, 2018)*

The use of ADC overrides should be situation dependent, and not based merely on a medication or a list of medications. While there may be a list of drugs with the potential to be obtained emergently, there may be other situations when there is sufficient time for the pharmacist to review these medications prior to retrieving the dose.

Guidelines:

3.1 Optimize the use of ADCs in a profiled mode which allows medication selection after orders have been reviewed and verified by a pharmacist. In addition to inpatient areas, use the profiled mode in outpatient areas (e.g., the emergency department [ED]; preoperative care areas; post anesthesia care unit [PACU]; procedural and ambulatory locations).

3.2 Require a medication order prior to any ADC override.

3.3 Establish a policy which limits ADC system overrides to the following situations:

a. When a licensed independent practitioner controls ordering, preparation, and administration of the medication.

b. When medications are required in emergent circumstances and waiting for a pharmacist to review the order could adversely impact the patient's condition, such as the need for:

- Antidotes, rescue, and reversal agents.

- Life-sustaining medications.
- Urgent comfort measure medications (e.g., to manage acute pain or intractable nausea and vomiting).

3.4 Implement strategies that reduce the risk of error when an override is used:

a. Avoid the use of multi-dose containers**.**

b. Limit the quantity and number of drug concentrations available on override.

c. Use a process where the drug and dose are checked against the patient's allergies and weight, if applicable, to determine if the drug and dose are appropriate**.**

d. Require documentation of override rationale**.**

e. Consider an independent double-check with another licensed healthcare provider when removing organization-identified high-alert medications on override.

3.5 Review and approve all override medications, clinical locations, practitioner types, and associated policies through the Pharmacy and Therapeutics (P&T) Committee, Medication Safety Committee, or their equivalent interdisciplinary group. Update the list of medications approved for access via override as appropriate.

3.6 Use an interdisciplinary group to routinely analyze override reports to identify if an order was obtained and whether the rationale for each overridden medication was appropriate. Trend override reports by medications, users and areas, and address barriers to the pharmacist's review of the medication order prior to drug administration. Discuss results regularly with nursing, anesthesia, and other disciplines with ADC access.

Core Process # 4
Select and Maintain Optimal ADC Inventory

The ADC inventory should be determined based on the needs of the patients served and replenished on a regular basis. Medication stock should be regularly reviewed and adjusted based on medication prescribing patterns, utilization, and unit-specific needs (considering typical patient ages and diagnoses). *(Grissinger 2012, Helmons 2012, Findlay 2015)*
Standard stock medications should be identified, and approved, for each patient care area, with an effort to limit excess volume and quantities that can lead to serious medication errors. *(O'Neil 2016,ASHP, 2010, ISMP)*

Guidelines:

4.1 Limit the overall quantity of medications and variety of medication concentrations to a number/selection sufficient to care for patients yet reduce the potential for a multi-fold overdose.

a. Specifically restrict the variety and quantities of medications stored in "non-profiled" ADCs.

4.2 Have an interdisciplinary committee provide medication safety oversight of drug availability in the ADC by establishing criteria for including or excluding medications with special attention to high-alert medications using the following guidance:

Exclude from ADC Inventory:

a. Medications that require multiple dilutions or calculations.

b. U-500 insulin vials and pens.

c. Medications that have been restricted from ADC storage based on organizational USP 800 Assessment of Risk.

d. Vials/ampules of concentrated electrolytes (i.e., potassium chloride; hypertonic sodium chloride for injection [greater than 0.9% concentration]; potassium phosphate; sodium phosphate; and potassium acetate). Exception: Vials in a cardiac surgery kit or a cardiac surgery locked storage area.

Include in Inventory

a. Medications, including oral solutions, in ready-to-use, unit-dose, or unit-of-use containers.

b. Emergency medications, rescue agents, and antidotes should be included in ADC inventory.

c. If neuromuscular blocking agents are stocked in an ADC, ADC pockets or drawers containing neuromuscular blocking agents should include an auxiliary label to clearly communicate that respiratory paralysis will occur and ventilation is required (e.g., WARNING: PARALYZING AGENT—CAUSES RESPIRATORY ARREST; WARNING: CAUSES RESPIRATORY PARALYSIS—PATIENT MUST BE VENTILATED).

d. Patient-specific doses (if they are not available in the ADC) ideally should be provided by the pharmacy.

e. Patient's own medications, can be stored in an ADC; however, locations should be individualized and secured per patient.

4.3 Ensure unit-dose products most closely match the usual doses administered in that patient care area (e.g., prepare/package commonly-used half tablets and/or oral syringes with oral liquid medications in the pharmacy to stock in the ADC).

4.4 Regularly analyze ADC activity reports to determine the appropriate quantity and variety of medications based on patient unit needs to ensure safety while balancing operational efficiency. (O'Neil 2016)

a. Assign appropriate maximum par levels designed to prevent multi-fold overdosing.

b. Establish an active notification process to alert pharmacy when inventory reaches critically low par levels.

c. Establish a process for prompt replenishment between routine deliveries when inventory reaches critically low levels.

d. Investigate repetitive critical low par levels and adjust par levels as appropriate.

4.5 Plan for monitoring, communicating, and maintaining sufficient inventory levels during downtime.

4.6 Designate emergency medications, rescue agents, and antidotes as permanent stock in the ADC system to avoid accidental elimination from inventory.

Core Process # 5
Select and Maintain Appropriate ADC Configuration and Functionality

Restricting access to medications limits the potential for inadvertently selecting the wrong medication and dose. Medications stocked in ADCs may be high-alert drugs, and it is important to ensure that only the right drug is selected. For these reasons, it is important that each drug has its own unique and segregated location within the ADC, so only the specific drug or vaccine needed is accessible. *(Grissinger 2012, Pazour 2012)*

Guidelines:

5.1 Maximize the use of high security storage configurations (e.g., individually locked and lidded, secure compartments).

a. Do not use matrix drawers, including open storage in refrigerated units, to store high-alert medications (e.g., neuromuscular blocking agents), controlled substances, reversal agents, drugs with common look-alike drug name and packaging confusion, and drugs prone to diversion.

b. If matrix drawers (open access compartments) must be utilized, limit them to non-prescription medications, (e.g., non-opioid analgesics [i.e., acetaminophen, ibuprofen], antacids, and 0.9% sodium chloride flush syringes).

5.2 Couple the removal of items that are always used together (linking the items using ADC functionality or placing together in a kit), such as medications that use specific diluents for reconstitution (e.g., vaccines, neuromuscular blocking agents).

5.3 Restrict users from removing medications ahead of an organization-defined administration window. At a minimum, provide an alert to the user if an attempt is made to remove a medication ahead of an administration window.

5.4 Ensure that there are well-designed procedures for ADC system downtime (planned and unplanned), as well as ADC hardware and software failures, and that staff are trained on alternative procedures.

5.5 Display a visible warning on the ADC screen when the ADC is operating in critical override mode.

Core Process # 6
Implement Safe ADC Stocking and Return Processes

The restocking process encompasses many sub-processes that may involve both pharmacy as well as frontline practitioners. A safe replenishment process contains redundancies to ensure that the correct medication, concentration, and formulation is selected for distribution to the unit and is placed in the correct location within the ADC. In the past, mistakes in drug selection resulting from incorrectly stocked items have resulted in serious medication errors. *(Cohen 2016, ISMP 2013 18[7], and ISMP 2013 1[19]).*

One source of incorrectly stocked items is allowing practitioners to return a medication directly to the ADC matrix drawer, pocket or auxiliary storage, or to return an item to a specific location without the use of technology. Errors in drug product returns can occur either because of user distraction, mis-selection of look-alike medication names on an ADC screen, look-alike packages in a matrix bin, or a slip in procedure. Limiting the return of ADC medications to a designated secure drawer or storage location in the ADC for replenishment by pharmacy, or returning to a single designated bin only with the use of barcoding technology will help to eliminate this source of error. It is also important that the process be defined and organized so staff involved can only follow the correct pathway and the potential for process variation is limited.

Guidelines:

Recommended processes within the pharmacy:

6.1 Facilitate accurate selection of medications during the refill process by standardizing drug name nomenclature in the ADC system, on pharmacy bin labels, and in the pharmacy inventory system.

6.2 Use barcode scanning upon selection to confirm that the medication chosen for distribution to the ADC matches the medication listed on the ADC fill report.

6.3 Develop a check process prior to dispensing.

a. Designate an area with appropriate space that avoids comingling of medications and minimizes interruptions or distractions for ADC stock management.

b. Provide a final independent check of all medications selected for ADC distribution to ensure the right drug, strength, dosage form, correct amount, and expiration dates are verified. Even if technology is used in the selection process, a manual independent double check should be done prior to distribution. (If available, barcode verification could be used to supplement the manual independent double check; however, be aware these verification systems typically only provide scanning of a single package even when multiple packages are being dispensed.)

6.4 Require medication expiration date tracking on all medications stocked in the ADC.

6.5 Adopt recommended processes for the secure delivery of medications to the ADC.

a. Segregate and secure all medications designated for an individual ADC during transport.

b. Plan delivery times in conjunction with the workflow in the patient care area, avoiding general restocking procedures during scheduled medication administration times.

c. Use barcode scanning to promote accurate placement of medications in the correct ADC drawer or pocket location.

d. Restock one individual medication and strength at a time.

e. Avoid multitasking, interruptions, and distractions during the drug restocking process (e.g., the use of phones, electronic pagers, and other devices).

f. Implement use of an audit tool to evaluate the distribution/restocking process and communicate results as appropriate.

6.6 Establish policies and procedures for returning medications after removal from the ADC.

a. Require staff to return all non-refrigerated medications with intact packaging to a common secure one-way return bin in the ADC that is maintained by pharmacy or to the original secure locked-lidded pocket, only if able to use a barcode scan verification.

b. Refrigerated medications selected and not used should be returned to the designated ADC refrigerated return bin.

Core Process # 7
Display Important Patient and Drug Information

Having sufficient patient information and drug information when dispensing and administering medications is key to the safety of the medication use process. (Cohen 2007) *Because there is limited space available for patient information on ADC screens, it is important to present information that is of the greatest safety value to practitioners when selecting and administering medications. Systems should provide the ability for unique identification of individual patients, review of their active medication orders, and full integration with the electronic health record to provide a closed loop process.* (ASHP, 2010)

Guidelines:

7.1 Provide the ability for users to create an assigned patient list in the ADC system to minimize the opportunity to select the wrong patient.

7.2 Display the following patient demographics on all patient-specific screens:

a. Complete patient name, ensuring that there is a sufficient number of characters in the field to avoid truncation.

b. Second organization-defined patient identifier.

c. Patient allergies.

d. Patient location.

Consider displaying medication information in accordance with ISMP's Draft Guidelines for the Safe Electronic Communication of Medication Information available at: https://www.ismp.org/guidelines/safe-communication-electronic-medication-information-draft.

7.3 Ideally, medication information should be displayed in the following fashion:

a. Ensure the name and strength of the medication on the ADC display screen matches the medication label, the MAR, and the IV smart infusion pump drug library as appropriate. (ISMP, 2008)
b. After the medication name, prominently display the medication strength making sure it matches the primary strength printed on the medication container label. (Note: For injectable medications other than insulin, the concentration should be displayed as total strength per total volume. Display of a mg/mL or mcg/mL dose expression alone has led to significant misunderstanding about the total amount of drug in the container and subsequent overdoses.) (USP<7>, ISMP)
c. Include any instructions for selecting the ordered dose.
d. Identify the location of the medication as appropriate.
e. Display the medication name differently in the onscreen profile when the medication is not available in the ADC, and ideally inform the user where the drug can be located.
f. Include additional instructions or alerts as appropriate (e.g., prompt for use of a filter for appropriate medications, dilution information, medications that should not be crushed). Use active alerts (compared to flat text) judiciously to prevent high harm events (e.g., validation of ventilatory support with override removal of a neuromuscular blocker). Balance these alerts with the understanding of alert fatigue and the ability to have many of these alerts directly on the MAR.
g. Allow the user to sort medications by time of administration or frequency such as: PRN, STAT, and SCHEDULED.

Core Process # 8
Develop Procedures for Accurate ADC Withdrawal and Transfer to the Bedside

Processes must be developed to reduce the risk or mitigate the harm associated with accessing a medication without an order, or the mis-selection and administration of the wrong medication, dose, route, or frequency due to medication retrieval errors from the ADC. The contents (variety, concentrations, and volume), configuration, and functionality of the ADC play a large role in the practitioner's ability to safely select and remove medications. (ASHP 2010)

A process should be developed that reduces the risk of medications being administered to the wrong patient at the wrong time that may occur during the transportation of medications from the ADC to the patient's bedside. (Mandrack 2012) *Safety is optimized when practitioners clearly identify the patient's medications at the time of administration using bedside barcode point-of-care systems.* (ASHP 2009, Seibert, 2014) *Alternatives, such as final visual checks of the medications while at the bedside, the use of an independent double-check for selected high-alert medications and doses, as well as appropriate patient education have also been known to assist in identification of an error in drug selection. The safety of this process is also impacted by the organization's ability to secure medications during transport between the ADC and the patient's bedside.* (Mandrack, 2012)

Guidelines:

8.1 To limit the risk of wrong drug/dose/formulation selections from ADCs:

a. Prohibit the removal of medications using an inventory function.

b. Confirm accurate selection by comparing the product to the order or the MAR.

8.2 Encourage practitioners to remotely preselect medications via the MAR to reduce the amount of time needed for medication selection and removal at the ADC.

8.3 Require that practitioners remove medications from the ADC one patient at a time.

8.4 Avoid multitasking, interruptions, and distractions (e.g., the use of phones, electronic pagers, and other devices) during the drug selection and removal process.

8.5 When medications are removed from a non-profiled ADC, and additional safety support such as bedside barcode medication administration is not available, configure the ADC to require users to barcode scan medications upon removal to ensure the correct drug has been selected.

8.6 Label all clinician-prepared syringes of IV push medications or solutions, unless the medication or solution is prepared at the patient's bedside and is immediately administered to the patient without any break in the process.

8.8. Transport medications, removed from the ADC to the bedside in their original unit-dose or unit-of-use package. Open packages immediately prior to use at the patient's bedside. The only exception may be for medications that need to be crushed, measured, or wasted.

8.9. Hand-carry a single patient's medications for one administration time directly to the patient's bedside. Alternatively, establish standard work to allow practitioners to sequentially remove two patient's medications while at the ADC provided that each patient's medications are bagged separately and appropriately labeled at the time of removal.

Core Process # 9
Provide Staff Education and Competency Validation

All users of the ADCs (pharmacists, technicians, nurses, respiratory therapists, designated physicians, and others) must be educated and have regular competency validation in the use of the device to meet expectations for safe use. Most often this education occurs during the practitioner's orientation period, or upon ADC installation and software upgrades, but an annual update may be required to ensure ongoing appropriate use. Users who are not properly oriented to the device may develop practice habits and device work-arounds that are considered unsafe. *(PSRS, 2005, Mandrack, 2012)*

Guidelines:

9.1 Following initial orientation to the ADC model of drug distribution, employ a formal competency assessment for all ADC users upon hire based on the practitioner type.

9.2 Share with staff lessons learned from the regular review and discussion of ADC-related medication events and close call reports. In addition, use external sources of error information to promote safe practice.