Top RHC Deficiencies in 2022

Presented by:
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Objectives

Participants will:

• Review common deficiencies reported from recent surveys

• Discover mitigation strategies to avoid deficiencies within the facility
J-0043

• The clinic has a preventive maintenance program to ensure that drugs and biologicals are appropriately stored
Mitigation Strategy

- Review outdates on medications
- Ensure proper use of MDV/SDV medications
- Review temperature and other environmental conditions
- Secure medications
  - Lock vs. line of sight
Surveyor Guidance

- Determine who has access to medications
  - If medications are kept in private office or other area where patients/visitors are not allowed, they are considered secure
  - If medications are kept in cabinets located in areas where patients, visitors or other unauthorized personnel have ready access when clinic personnel are not also present, the cabinets must be locked
- Verify drugs are stored according to mfr. instructions
- Verify drugs are not accessible to unauthorized individuals/personnel
Top Deficiencies 2022

J-0125

• Patient Care Policies – Policies include the storage, handling, and administration of drugs and biologicals
Mitigation Strategy

- Review drugs/biologicals policy to discover if the following items are covered:
  - Storage of drugs
  - Proper environmental conditions
  - Security
  - Record keeping for scheduled drugs
  - Handling drugs/biologicals
  - Expiration and beyond use dates
  - Basic safe practices for administration (5 Rs)
Surveyor Guidance

- Determine if drugs are stored in a secure manner
- Determine who has access
- Spot check expirations and beyond use
- Controlled medication handling and distribution process
- Determine who can administer
- Observe medication administration to verify proper process and compliance with policy
- Review policy to determine if it covers storage, handling, disposal and all other required components
# SDV/MDV Information

<table>
<thead>
<tr>
<th>Single-Dose Vials</th>
<th>Multi-Dose Vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved for use on single patient for single procedure or injection</td>
<td>Can be used for more than one patient when aseptic technique is followed</td>
</tr>
<tr>
<td>Does not have antimicrobial preservative</td>
<td>Contains an antimicrobial preservative to limit growth of bacteria</td>
</tr>
<tr>
<td>Harmful bacteria can grow and infect a patient</td>
<td>Preservatives have no effect on bloodborne viruses</td>
</tr>
<tr>
<td>Do not assume a vial is SDV or MDV based on size or volume of medication. ALWAYS CHECK THE LABEL</td>
<td>Discard MDVs when the expiration date has been reached or beyond use date has been reached (28 days)</td>
</tr>
<tr>
<td><strong>DISCARD AFTER EVERY USE</strong></td>
<td>Discard if sterility of the vial is in question</td>
</tr>
</tbody>
</table>
SDV Decision Tree

- **Single Dose Vial**
  - **Closed**
    - Not Expired: Keep
    - Expired: Discard
  - **Open**: Discard
MDV Decision Tree

1. **Closed**
   - Not Expired: Keep
   - Expired: Discard

2. **Open**
   - Open Date
     - Beyond Use: Discard
     - Not Beyond Use: Keep
   - No Open date: Discard
Cautions:

• Common causes of deficiency:
  • Suppliers change the type of vial they send
  • Stored in areas that are not used/reviewed on a regular basis
    • Personal caddy
    • Travel medication bag
  • New staff members
  • Staff keep vial as reminder to chart/order
  • Surplus of supplies
  • Volume/size of vial
Cautions:

• Common causes of deficiency:
  • Multi-dose vials placed back in packaging and forgotten
  • Everyone is responsible which means NO ONE is responsible
    • Who owns the medication cabinet/room?
  • Training kits
  • 28 day discard date on multi-use vials might be before monthly rounding
  • Implication of date on a single dose vial
Mitigation Strategies

• Educate, Educate, Educate
  • Ensure staff that handle medications understand the difference between a multi-dose and single-dose vial
  • Multi-dose vials must have an open date and be discarded within 28 days
  • Single-dose vials are one and done
  • Review all incoming stock to ensure full compliance
  • Size of vial does not determine number of doses
  • Free educational resource: [CDC and the One and Only Campaign](https://www.cdc.gov/vaccines/schedules/downloads/hcp/peds-one-only.pdf)
Mitigation Strategies

• Utilize visual reminders:
  • Get stickers that say “SINGLE USE ONLY” for single-dose vials
  • Get stickers that say “Open date/Discard by date” for your multi-dose vials
  • Make a grid that outlines the 28 days from open date for the entire year and keep it with your medications
  • Keep the open multi-dose vials in a separate bin to highlight additional need for review
Mitigation Strategies

• Environmental Rounding:
  • Designate who is responsible for maintaining and monitoring your medication area
  • If this is a struggle area for your clinic, have them review weekly until full compliance is achieved and then review monthly
• Some facilities opt to treat all vials as single dose vials
Top Deficiencies 2022

E-0037

• Training Program. The facility must do all of the following:
  • Initial training to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles
  • Provide training at least every 2 years
  • Maintain documentation
  • Demonstrate staff knowledge
  • Conduct training on updated policies and procedures
Mitigation Strategy

• Create a PowerPoint to lead staff through the plan
  • Discuss risks, meeting points, roles/responsibilities, communication plan, testing and training requirements and review hazard policies
• Have an acknowledgement form in personnel file
• Assign training to staff at least every two years
Surveyor Guidance

- Determine if clinic has disclosed training process in emergency plan
- Confirm training program complements risk assessment
- At a minimum, training covers policies
- Review documentation that clearly identifies staff training
  - Sign-in roster
  - On-line training module available for review with report of participants
  - Individual training certificates
- Surveyor may ask for a list of employees to verify training on emergency plan
Top Deficiencies 2022

J-0161

• The clinic carries out, or arranges for, a biennial evaluation of its total program.

• The evaluation includes review of:
  • The utilization of clinic services, including at least the number of patients served and volume of services;
  • A representative sample of both active and closed records; and
  • The clinic’s health care policies.

• The purpose of the review is to determine whether:
  • Utilization of services was appropriate
  • Established policies were followed
  • Any changes needed
Mitigation Strategy

• Define in policy what information will be covered and who will participate in review

• Ensure you have formal report available at least every 2 years

• Update policy to reflect biennial instead of annual
Surveyor Guidance

- Evaluation findings must be documented in a summary report and include recommendations
- Corrective actions must be defined
- Review evidence that the evaluation is completed biennially and includes review of number of patients served and volume of services provided
- Report must include a sample of open/closed records
- Determine who participates in review and qualification to do so
- Review evidence of findings and recommendations from review and if they address each required component
Top Deficiencies 2022

J-0101

- Physician responsibilities. The physician performs the following: Periodically reviews the clinic’s patient records
- PA/NP members of the clinic’s staff: Participate with a physician in a periodic review of the patients’ health records.
Mitigation Strategy

• Review policy to determine number/frequency for review
• Review collaborative agreements to ensure this is defined
• Confirm you have documented proof of the ongoing review
  • Proof of collaboration
  • Meets number/frequency in policy
  • Available for surveyor review
Surveyor Guidance

- Ask staff what the clinic’s policy is for the interval for record review, when it last took place and documentation of review
- If State law requires co-signature, request evidence
- If RHC has more than one physician, ask whether policy permits sharing of responsibility
Top Deficiencies 2022

J-0136

• Direct services: Emergency, The clinic provides emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.
Mitigation Strategy

• Confirm the clinic has an emergency kit available WITHIN the four walls of the certified facility
• Disclose who determined contents and where it is located in the facility
• Recommend taping content list to outside of unit with expiration dating for easy review
• Secured yet accessible
Surveyor Guidance

• Review clinic policy to determine the types and quantities of drugs/biologicals it stores for medical emergency purposes
• Ask how contents were determined
  • Based on community history, medical history of patients, standards of practice
• Review contents and compare to clinic policy and confirm they are not outdated/beyond use
• Ask how staff monitor supply to ensure policy is being followed
Top Deficiencies 2022

J-0042

- Maintenance: The clinic has a preventive maintenance program to ensure that:
  - All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition
Definitions

• Biomedical equipment means devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the clinic
  • Blood pressure monitors
  • Reusable diagnostic scopes
  • EKG machines
  • Scales
  • Laboratory equipment, etc.
Mitigation Strategy

• Review previous inspection log to ensure all equipment has been reviewed

• Inspect all equipment before initial use, after major repairs or upgrades and according to mfr. Guidelines
Surveyor Guidance

- Request documentation that mechanical or electrical equipment is regularly inspected, tested, and maintained in accordance with mfr. Guidelines
- If documentation is missing, ask to see clinic’s policies for equipment maintenance to determine if problem is with content of policy or failure to follow policy
- Ask staff to provide a copy of or access to copies of mfr. Guidelines for mechanical/electrical equipment
- Ask staff whether there have been any problems with equipment breakdowns or malfunctions
  - If so – request documentation from maintenance on equipment in question
Top Deficiencies 2022

• J-0135

• Basic requirements: The laboratory requirements of this section apply to RHCs

• The RHC provides laboratory services essential to the immediate diagnosis and treatment of the patient, including:
  • Chemical examinations of urine by stick or tablet method or both (including urine ketones);
  • Hemoglobin or hematocrit;
  • Blood glucose;
  • Examination of stool specimens for occult blood;
  • Pregnancy tests; and
  • Primary culturing for transmittal to a certified laboratory
Mitigation Strategy

- Review lab area to confirm the clinic has the equipment and supplies to run each required test
- The 6 required tests are considered the minimum requirement
- Review CLIA certificate
Surveyor Guidance

- Verify that the RHC offers the 6 required laboratory services on site
  - If not, is there a State law that prevents the RHC from doing so?
- Verify that all laboratory services are operating under a current, appropriate CLIA certificate, including for additional services provided in the RHC beyond the minimum required 6 basic laboratory services.
Questions

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