Wireless Refrigerator Temperature Monitoring Systems

Peggy Bickham, PharmD

No conflicts of interest.

How Many Have Had Any of the Following Experiences?

• Discovered the next morning that a med refrigerator door was left open all night.
• Discovered on Monday morning that a med refrigerator door was left open all weekend.
• Thrown away meds (and money) following an extended period of out-of-range storage (see above).
• Scrambled to “fill in the blanks” on those refrigerator monitoring documentation logs when the Joint Commission walks in the door for an unannounced survey.

More “Have You Ever’s”…..

• Recreated an entire month’s documentation sheet that went missing prior to a JC survey (a truly prodigious feat of memory).
• Received an RFI for a refrigerator temperature monitoring issue during a JC survey.
• Found refrigerator log forms on which out-of-range temperatures were faithfully documented but no action taken (“Is that what that grey zone meant?”)
• Investigational Drug Service needed to provide an adequate level of temperature monitoring to meet requirements of study monitor.
Wireless Temperature Monitoring Systems
- Consist of hardware, monitoring software, and PC or server
- Refrigerator probe wired to RF transmitter
- Repeater to boost signal to receiver
- Receiver connected to hospital computer system
- Computer system stores data, triggers alerts, provides reports

Hardware
- Air probes versus glycol probes (simulates product)
- Transmitter attached to each probe
- Signal repeaters (RF range extenders) required in multi-floor, extended range, or other areas of interference
- Receivers (base stations)
- Server / PC

Software
- Remote support capability
- Adequate data storage
- Memory buffering
- Alert or notification of hardware malfunction such as lost transmission, low battery charge
- Adequate report capability
- Accessible from one PC or through hospital network
Temperature Excursion Alerts

- Alert capability with customizable escalation options
- Alert notification options: alpha-pages, email, cell phone text, computer pop-ups
- Intervention documentation capability
- Report capability for quality assurance purposes

Shopping For a System

- Multiple vendors
  - Broad price range
  - Variability in features
  - Technical support and training
  - Service contracts
- Include your IT department, facilities, and biomedical engineering in evaluating systems

Policy and Procedure Issues

- Description of process – screen shots help!
- Assign responsibility for response to alerts
  - Normal business hours
  - After hours
- Stepwise directions for responding to alerts and troubleshooting causes
- Escalation of alerts if response does not occur
- Clearing of alerts and documentation of action taken
Other Considerations

- Variable refrigerator quality
- Remote access to system versus in-house access only
- Modes of alert notification
- Training and education process
- Monitor alert responses and trouble-shoot the troubleshooting process
Troubleshooting Tips

• Actually read the alert message and tweak the correct refrigerator
• Be careful when restocking room temp items to a small refrigerator
• Do not overstock refrigerator and block airflow to probe
• Probe must be positioned properly so that it is immersed in glycol
• Do not over-correct temperature settings

References


1. What policy issues did you find most difficult to address when implementing wireless temperature monitoring?

2. What features were most important to you when selecting a wireless monitoring system?

3. What difficulties did you encounter when implementing the wireless temperature monitoring system?
Refrigerator Alarms – Post test questions
09-039
Peggy Bickham

1. Which of the following are advantages of implementing wireless temperature monitoring of medication refrigerators?
   a. Wireless monitoring ensures that refrigerators will consistently remain within the desired temperature range.
   b. Wireless monitoring combined with a defined process for timely response to alerts can eliminate wastage of medications and bring your hospital into compliance with TJC standards on monitoring of medication refrigerators.
   c. Wireless monitoring provides the capability to detect substandard refrigerators that are inadequate for medication storage.
   d. b and c
   e. All of the above

2. Some important features to consider when purchasing a wireless monitoring system are:
   a. Alert options and reporting capability
   b. Probe type
   c. The system’s ability to quickly cool down an out-of-range refrigerator
   d. a and b
   e. All of the above.
Vendor Tracking Services

Dave Hicks, RPh, MBA
Vice-President and Chief Pharmacy Officer
University of Chicago Medical Center

Neither I or my spouse have any actual or potential conflict of interest in relation to this presentation.

Pharmaceutical Rep Check-in Audience Poll

• Who has pharmaceutical reps check-in at pharmacy?
• Who has pharmaceutical reps check-in elsewhere?
• Which institutions use a vendor tracking service?

Why Vendor Tracking is Needed

<table>
<thead>
<tr>
<th>Compliance Reasons</th>
<th>Why Vendor Tracking is Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health &amp; Human Services (HHS) Office of Inspector General (OIG)</td>
<td>Check against &quot;List of Excluded Individuals &amp; Entities&quot; with Medicare/Medicaid Fraud sanctions</td>
</tr>
<tr>
<td>U.S. Treasury - Office of Foreign Assets Control (OFAC)</td>
<td>Mandate to continuously monitor that no vendors representatives are on the Terrorist watch list</td>
</tr>
<tr>
<td>Deficit Reduction Act</td>
<td>Federal regulation of policy and training presentation</td>
</tr>
<tr>
<td>Stark Law / Anti-kickback Federal Statute</td>
<td>Must have an auditable record of all disclosures of conflicts of interest</td>
</tr>
<tr>
<td>Health Insurance Portability and Accountability Act (HIPAA)</td>
<td>Ensure patient information is protected and have complete records of all who are granted access</td>
</tr>
<tr>
<td>Homeland Security</td>
<td>Disaster readiness: Know which vendor representatives are onsite, current company and individual contact information</td>
</tr>
<tr>
<td>Joint Commission (JCAHO) Audits</td>
<td>Demonstrate ability to: control facility access, maintain immunizations and product/service competency</td>
</tr>
<tr>
<td>CDC/Association of Preoperative Registered Nurses/American College of Surgeons Guidelines</td>
<td>Validate immunizations and multiple training certificates for any healthcare vendor representative with access to procedural areas</td>
</tr>
</tbody>
</table>
Why Vendor Tracking is Needed

<table>
<thead>
<tr>
<th>Supply Chain Reasons</th>
<th>Cost Control Reasons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Security</td>
<td>Scheduling</td>
</tr>
<tr>
<td>Identify vendor representatives in the facility, who are they, where are they going and who are they meeting.</td>
<td>Manage “end-run” sales calls directly to physicians.</td>
</tr>
<tr>
<td>Central Contact Information</td>
<td>Productivity</td>
</tr>
<tr>
<td>Access to valid self-reported contact information by all the vendor representatives.</td>
<td>Limit drop-in interruptions.</td>
</tr>
<tr>
<td>Contractual Product</td>
<td>Efficiency</td>
</tr>
<tr>
<td>Avoid purchases of products or services already under contract.</td>
<td>Reduce cost of administering vendor management programs.</td>
</tr>
<tr>
<td>Capturing Vendor Policy Obedience</td>
<td></td>
</tr>
<tr>
<td>Document a vendor representatives exceptional or unwanted behavior.</td>
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<tr>
<td>Merger and Acquisitions</td>
<td></td>
</tr>
<tr>
<td>Attain additional information on vendors for merger and acquisitions.</td>
<td></td>
</tr>
</tbody>
</table>

Vendor Information Turnstile

- 20% of all addresses change every year
- 18% of all phone numbers change or are disconnected annually
- Every hour, 33 new businesses open
- Every hour, 36 C-Level changes occur
- Every hour 251 business will have a suit, lien, or judgment filed against them.

Source: Experian

- 42,000+ individuals and entities are on the HHS/OIG Exclusion List
  - 50 reinstatements/month
  - 400 new exclusions/month
- State level Medicaid/Medicare exclusion lists are not consistently reported to the Feds
- 14,000 bankruptcy filings Q1 2009

Vendor Tracking Benefits for Pharmacy

- Lower vendor management administrative costs
- Expanded vendor and rep information
- Better vendor compliance and activity monitoring
- Integrated compliance, scheduling, and photo badges
- Ease of mass communication: moves, H1N1 alerts
- Activity reports:
  - Staff and vendor compliance with policies
  - Volumes, frequencies, and time on site for reps
  - Vendor scorecard, complaint, and discipline logs
- Little IT support required – web hosted
- No cost to your organization
Vendor Tracking Systems Audience Poll

- Who has Reptrax at their hospital?
- Who has Vendormate?
- Who has VendorClear?
- Who has Status Blue?
- Who has Vendor Credentialing Service?
- Any others?

Hospital Vendor Risk Profiles

<table>
<thead>
<tr>
<th>HIGH $250</th>
<th>MEDIUM $100</th>
<th>LOW $25</th>
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<tbody>
<tr>
<td>• Representatives access procedural areas &amp; require a badge</td>
<td></td>
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<tr>
<td>• Representatives have access to patients or patient data</td>
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<tr>
<td>• Greater than $10,000 in annual spend</td>
<td></td>
<td></td>
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<tr>
<td>• Annual Business Verification, Financial Health Assessment &amp; Legal Review</td>
<td></td>
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<tr>
<td>• Monthly Sancion Checks – Entity, Principals, Reps</td>
<td></td>
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<tr>
<td>• Historical Sancion Checks</td>
<td></td>
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<tr>
<td>• Verified Document Storage &amp; Management – Immunizations &amp; etc.</td>
<td></td>
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</tr>
<tr>
<td>• Representatives do not access procedural areas but visit your facility requiring a badge</td>
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<tr>
<td>• Representatives do not have access to patients or patient data</td>
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<td></td>
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<tr>
<td>• Between $10,000 and $1,000 in annual spend</td>
<td></td>
<td></td>
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<tr>
<td>• Annual Business Verification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Monthly Sancion Checks – Entity, Representatives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Verified Document Storage &amp; Management – Insuranc certifications &amp; Diversity documentation</td>
<td></td>
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</tr>
<tr>
<td>• Do not have a current business relationship – financial, contractual, or otherwise</td>
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<tr>
<td>• Representatives do not visit your facility</td>
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</tr>
<tr>
<td>• Less than $1,000 in annual spend</td>
<td></td>
<td></td>
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<tr>
<td>• Annual Sanction Check – Entity</td>
<td></td>
<td></td>
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<tr>
<td>• Unverified Document Storage</td>
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Vendor Program Information Flow

Vendor/Supplier Representatives of Products or Services
- Initial Registration
- Continuous Access
- Sign-In & Print Badge

Hospital Staff/Employees
- Continuous Access of Credentialed & Monitored Information
- Scheduling & Badge Authorization

VENDOR CREDENTIALING SERVICE

150+ Fields of Information
- Company Information
- Representative Information
- Policy Acknowledgments
- Document Uploads

100+ Background Checks
- Business Verification
- Financial & Legal Checks
- Federal Government Sanction List Check
- OFAC, GSA, OIG & 5 other lists
- Document Verification

Continuous Review
- Financial & Legal
- Sanction List
- Score Card
- Sign-In & Print Badge
Integrated Daily Photo ID Badges

– All vendors on your premises are clearly identified
– Electronic sign-in and out report of all vendor representatives
– Badge displays name, date, appointment location, photo, vendor status, and individual status
– Appointment scheduling integrated to Outlook Calendars

Vendor Tracking Service Reports

Vendor Pushback

Fear a change in business: “We’ve always had easy access. Everyone knows me. Why am I being questioned now?” It’s not an issue of trust. It’s an issue of consistency and efficiency.

Believe this is only about controlling access
Don’t understand that business operations, compliance guidelines, and access control are converging to drive this change.

Believe this is unduly burdensome
This change shifts the responsibility (and cost) of proof from the buyer to the seller. Not surprisingly, the sellers resist.

See no benefit to them
Corollary benefits include: Leveling the playing field across all vendors. Some standardization as only a few vendor systems vs. unique paper forms at each hospital.
Questions?

Roundtable Discussion

• Give a quick summary of how your current vendor management program monitors vendor visits, meets vendor compliance issues, and limits vendor access.
• Estimate how many vendors your department sees or schedules per month and how much administrative time that requires
• Describe challenges and successes your department or organization has had with your vendor management program.
1. Give a quick summary of how your current vendor management program monitors vendor visits, meets vendor compliance issues, and limits vendor access.

2. Estimate how many vendors your department sees or schedules per month and how much administrative time that requires.

3. Describe challenges and successes your department or organization has had with your vendor management program.
**Post-test Questions**

1. Which of the following are valid reasons hospitals implement vendor credentialing systems?
   a. To reduce administrative cost of vendor management.
   b. To improve hospital compliance with TJC infection control and access control requirements.
   c. To meet federal mandates against doing business with individuals on terrorist watch list or with Medicare/Medicaid sanctions.
   d. To facilitate increased vendor charity donations to hospital foundations.
   e. All of the above

2. Which of the following are common features of vendor credentialing systems?
   a. Multiple financial, legal, and sanction list background checks of vendors and representatives.
   b. Multiple reports of vendor representative activities, document compliance, credentialing status, and any staff complaints.
   c. Integrated daily vendor ID badges.
   d. All of the above
Repackaging for a Reason:
Implementation of a Repackaging Process to Support BCMA

Dan Makowsky, CPhT
Pharmacy Barcode Coordinator
NorthShore University HealthSystem

Objectives
• List the various reasons for repackaging medications
• Explain the rules and regulations related to repackaged medications
• Discuss the features of a repackaging system

NorthShore University HealthSystem

Corporate Services
• NorthShore University HealthSystem (NorthShore) is located in the northern suburbs of Chicago
• Academically affiliated with the University of Chicago Pritzker School of Medicine.
• Four Hospitals: Evanston Hospital, Glenbrook Hospital, Highland Park Hospital, and Skokie Hospital.
• 885 licensed beds.

NorthShore University HealthSystem

Pharmacy Services
• 24 hour per day pharmacy services in all four hospitals.
• Decentralized pharmacist staffing model
• Sterile product preparation
• Operating room pharmacy satellite
• Repackaging operations
• Decentralized pharmacy technicians

NorthShore University HealthSystem

Technology
• Electronic medical record (EMR)
• Integrated Pharmacy Software
• Computer physician order entry (CPOE),
• Automated dispensing cabinets (ADC)
• Barcode medication administration (BCMA)
• TPN Compounder
• Repacking machine

Conflict of Interest Declaration
I have no actual or potential conflict of interest in relation to this activity.
Roles of Barcode Coordinator

- Day to Day operations
  - Identify and resolve barcode issues
  - Assist pharmacy buyer
  - Analyze barcode reports
  - Maintain repackaging machine
- Corporate Responsibilities
  - Planning and implementation of BCMA
  - Pharmacy compliance with BCMA
  - Monitor end user compliance with BCMA
  - Assist and maintain quality improvement measures

Rules & Regulations

Labeling (1)

- Drug Name
- Strength
- Form
- Repackaging Facility
- Lot Number
- Expiration date
- Manufacturer
- Controlled Substance Symbol

Beyond-Use Date (2)

- One year from date packaged, or
- Original expiration date, whichever is earliest

Repackaging at NorthShore

Before BCMA

- Repackaging was done as needed
- Different between sites
  - Evanston used Medical Packaging, Inc. repackaging system
  - Glenbrook & Highland Park a manual process
- Lack of strict library maintenance procedures
- All users could save changes

Repackaging at NorthShore

BCMA required changes

- Standardization of each hospital’s repackaging systems
- All formulary medications must be available in Unit-Dose with a barcode
- Creation of repackaging technician position

Repackaging at NorthShore Cont.

- Tighten access on repackaging system
  - All users assigned unique login & password
  - Standard user unable to change library
  - “Super User” to maintain library
- Repackaging system training
  - All technicians trained
  - Overnight pharmacists
  - Operations managers

MPI Repackaging System (3)

- Auto-Print™ UD Packaging System
- Pharmacy Accessory Label Printer (PALP)
- Computer with WinPakUD™ & WinPak Labels™ software
Repackaging System Maintenance

Medication library management
- User maintained library
- Barcode scan/check ensures correct product (UD)

Security
- User ID's with password
- Customizable user access
- Control over library

Repackaging System Maintenance Cont.

- Label customization
  - Adjustable font size
  - On screen label preview
  - Tallman lettering available (UD)

Barcoding
- Supports all popular healthcare barcode symbologies

Available Repackaging Reports

- Reports
  - Daily Log
  - Custom report generator

NorthShore System

Daily Operations
- Staffed repackager M-F
- Ensure all medications are barcoded
- Repackage medications as appropriate
- Pharmacist check of repackaged/relabeled medications

Repackaging Process (Receiving)

- All medications sequestered upon delivery
- Technician scans all medications
  - Meds with working barcodes go to the shelves
  - Meds without working barcodes at Unit-of-Use quarantined
    - Bulk oral solids get repackaged
    - Meds without barcodes get relabeled
    - Meds with invalid barcodes are Rejected

Reasons to Repackage

- Unit-dose product not available
- Cost
- Inventory management
- Adding barcodes to medications
- Packaging partial doses (e.g. half tablets)
Repackaging Process
(Packaging)

Repackaging tech
1. Selects product from library
2. Enters manufacturer’s lot number and expiration date
3. Assigns hospital lot number and expiration date
4. Verifies all information is correct
5. Starts printing
   • UD bulk bottle fully repackaged
   • Flag labels printed & affixed to product

Repackaging Process
(Pharmacist Check)

• Repackaging tech prints repackaging log and groups the medications
• Pharmacist verifies information is correct on packaging/labels
  A. Correct
     – Signs off product on log sheet
     – Med placed in stock by technician
  B. Incorrect
     – Indicates error on log sheet
     – Returned to repackaging queue

Lessons learned

• Buying Unit Dose vs. bulk bottle
  – Philosophy: get as much as possible in unit-dose
  – Reasons not to purchase unit dose: LASA, cost, manufacture backorders, or BCMA reasons
• Waste
  – 1yr expiration date, others that normally have short exp date (levothyroxine)
  – Inventory control is important

References

Post Presentation Questions
Daniel Makowsky - 09-039

Repackaging for a Reason

1. Which of the following is not required by the FDA to be on the label of a repackaged medication?
   a. Name of the facility where the medication was repackaged.
   b. NDC of the medication.
   c. Unique control/lot number for the repackaged medication.
   d. Manufacturer of the medication.
   e. The medication name.

2. What are some of the reasons that institutions choose to repackage medications into Unit-of-Use packaging on site?
   a. Adding a barcode to the medication at the Unit-of-Use packaging.
   b. Medication may not be available in Unit-Dose packaging from the manufacturer.
   c. Cost to repack a medication on site is lower than purchasing a Unit-Dose option from the manufacturer.
   d. All of the above.

3. What should the beyond-use date of a repackaged medication be?
   a. 12 months from the date repackaged.
   b. The manufacturer’s expiration date.
   c. Six months less than manufacturer’s expiration date.
   d. A or B, whichever is shorter.
Clinical Decision Support

Michael Postelnick, RPh BCPS AQ Infectious Diseases
Senior Infectious Diseases Pharmacist
Clinical Coordinator
Northwestern Memorial Hospital
Chicago, IL
The speaker has no conflict to disclose.

Clinical Decision Support (CDSS)
- Interactive computer program to assist clinicians with decision making tasks
- Medication management
- Rules-based system
- Real time alerts
- Ongoing monitoring after initial order entry

Why The Need?
- Initial review in order entry process
- Pharmacists rushed, multiple duties
- Alert fatigue – pharmacist misses
- Incomplete patient info on admission
- Initial drug profile review inconsistent
Pharmacy CDSS Benefits

- Consistent identification of potential opportunities to improve patient care
- Reduce tasks that involve manual pharmacist review
- Improve clinical workflow
- Improve outcomes

CDSS benefits cont.

- Increased scope of surveillance
- FTE impact
- Improved staff pharmacist utilization
- Improved staff retention
- Reduced cost of drug therapy
- Improved medication safety

Pharmacy CDSS – what we want

- Real-time alerts
- Intelligent rules
- Competent responders to alerts: Pharmacist, Nurse, Physician
- No false positive alerts
- Track users, documentation
CDSS role in medication management
Medication Safety Program
- ADR detection
- ADR prevention
- Reduce pharmacist misses
- ADE documentation
- ADR cost savings analysis and reporting

CDSS – role cont.
Pharmacist Clinical Interventions
- Document, track and report data
- Pharmacist productivity
- Drilldown on intervention types
- Track pharmacist actions

CDSS – role cont.
Regulatory TJC, CMS, CDPH
- NPSG Anticoagulation management
- DVT prophylaxis
- Black Box Warnings
- ADR tracer drug tracking
CDSS – role cont.
Drug utilization
• Criteria for use
• Length of therapy
• Physician specific
• Location specific
• Track savings

CDSS – role cont.
• Antibiotic stewardship
• Antibiotic utilization
• Microbiology data tracking
• Cost savings tracking
• Antibiogram

Northwestern Memorial Hospital
• 3 Million square feet covering one city block
• High Tech – “Most Wired”
• Level I trauma networks and
  Level III neonatal intensive care unit
  ~ 9000+ deliveries

<table>
<thead>
<tr>
<th>Total Beds:</th>
<th>897</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Admissions:</td>
<td>43,312</td>
</tr>
<tr>
<td>Total Outpatient Visits:</td>
<td>436,979</td>
</tr>
<tr>
<td>Total Outpatient Clinics:</td>
<td>72</td>
</tr>
<tr>
<td>ED Visits:</td>
<td>73,681</td>
</tr>
<tr>
<td>Average Daily Census:</td>
<td>598</td>
</tr>
</tbody>
</table>
Pharmacy Practice at NMH

- 6 satellite pharmacies over 3 buildings
- Integrated practice model
- Diverse specialty practice areas
  - Critical care
  - Medicine
  - Neonatal ICU
  - Hematology/oncology
  - Transplantation
  - Nutritional Support
  - Antimicrobial Stewardship
  - Anticoagulation Service

Continuity of Care

- Shift to Shift
- Day to Day
- Critical Issue Follow-up Identification
Rounding Documentation

General Documentation

Non-rounding Documentation
Critical Alerts

<table>
<thead>
<tr>
<th>Alert Time</th>
<th>Start</th>
<th>End</th>
<th>Impact</th>
<th>Full Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/01/2023</td>
<td></td>
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</tbody>
</table>

Assessment of Impact
Monthly Intervention Report

Thomson Healthcare Action OI

- Solucient clinical workload reporting
- Provides standard times and values for interventions
- Provides for cross-institutional comparison

Tracking and Reporting
Tracking and Reporting

Summary and Conclusions
• CDS increases clinical pharmacist efficiency and impact
• CDS contributes to enhanced medication safety
• Documentation tool provides consistent method to document pharmacist impact

Acknowledgement
• John Russillo, RPh
Clinicai Decision Support
09-039
Michael Postelnick

Post Test Questions

