Overview of Safety Recommendations for Medication Management Technology

Originally presented on Sunday, December 3, 2006 by Michael R. Cohen, RPh, MS, ScD
Institute for Safe Medication Practices

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Our long journey towards a safety-minded Just Culture

Part II: Where we’re going

The culture in healthcare is evolving into one that is neither wholly punitive nor wholly blame-free when errors happen. As noted in Part I (Where we’ve been [September 7, 2006]), the pendulum has swung from a “name, shame and blame” philosophy to an “amnesty for all” policy, and is now settling at a midpoint—a Just Culture—that is both fair to workers who make errors and effective in reducing safety risks.

In a Just Culture, all workers know that safety is valued in the organization, and they continually look for risks that pose a threat. They are thoughtful about their behavioral choices and always thinking about the most reliable ways to get the job done right. Managers are constantly looking for system design features that would give the workforce the best opportunity to perform well. While it is recognized that every endeavor carries the risk of human error, workers are held accountable for the things that are under their control: system design, particularly for the management and administrative team, and behavioral choices for the entire workforce.

Three types of behavior can be involved in error: human error, at-risk behavior, and reckless behavior. Each type of behavior has a different cause, so a different response is required.

Human error. Human error involves unintentional and unpredictable behavior that causes or could have caused an undesirable outcome, either because a planned action is not completed as intended or the wrong plan is used to achieve an aim. Since most human errors arise from weaknesses in the system, they must be managed through process, system, or environmental changes. Discipline is not warranted or productive, because the worker did not intend the action or the risk or harm that resulted. The only just option is to console the worker and shore up the systems to prevent further errors. As Reason notes, we cannot change the human condition, but we can change the conditions under which humans work.

At-risk behavior. Everyone knows that “to err is human,” but we tend to forget that “to drift is human, too.” Behavioral research shows that we are programmed to drift into unsafe habits, to lose perception of the risk attached to everyday behavior, or mistakenly believe the risk to be justified. In general, workers are most concerned with the immediate and certain consequences of their behavior—harm, for example—and undervalue delayed or uncertain consequences, such as patient harm. Their decisions about what is important on a daily list of tasks are based on the immediate desired outcomes. Over time, as perceptions of risk fade away and workers try to do more with less, they take shortcuts and drift away from behaviors they know are safest.

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St. Mary's nurse is charged with neglect
Medication error led to teen's death
By Steven Elbow
A former St. Mary's Hospital nurse was charged today with neglect in the death of 16-year-old Jasmine Gant, who died in July of a medication error while giving birth.

Julie Thao, 41, of Belleville, faces a count of neglect of a patient causing great bodily harm, which carries a maximum prison sentence of six years in prison.

Gant died after an epidural anesthetic that Thao allegedly removed from a locker was mistaken for a prescribed dose of penicillin. She injected the epidural into Gant intravenously, despite a hot pink label reading "FOR EPIDURAL ADMINISTRATION ONLY."

Epidurals are inserted via a catheter to ease pain. Instead the medication entered Gant's bloodstream and she was dead within the hour.

Her son, Gregory, was delivered successfully by Caesarian section.
Medication Management Process
with specific technologies to adverse drug events
Adapted from Classen – VHA 2001

History-Taking
- Obtain Medication-related History
- Document Medication History
- Wireless devices for medication history capture, etc.

Ordering
- Diagnostic/Therapeutic Decisions Made
- Physician Order Entry
- Medication Ordered
- Order verified and submitted

Surveillance
- Incident/adverse event surveillance and reporting
- Automated Surveillance

Medication Inventory Management
- Formulary, purchasing decisions
- Inventory management

Pharmacy Management
- Evaluate order
- Select medication
- Prepare medication
- Dispense/distribute medication
- Pharmacy Information Systems
- Robotic dispensing systems

Administration Management

Monitor/Evaluate Response
- Intervene as indicated for adverse reaction/interaction
- Assess and document patient response to medication according to defined parameters
- Barcoding administration

Document
- Document administration and associated information

Administer Medication
- Administer according to order and standards for drug
- Select the correct drug for the correct patient
- Smart Pumps

Education
- Educate patient regarding medication
- Educate staff regarding medications
Errors in the Medication Use Process

Errors: 39%

12%

11%

38%

Prescribing

Transcribing

Dispensing

Administering

Source: JAMA 1995;274:35-43

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Sources of Harm

Prescribing 28% 11% 10% 51%
Errors 39% Transcribing 12% Dispensing 11% Administering 38%

Source: JAMA 1995;274:35-43
Rank Order of Error Reduction Strategies

Forcing functions

\[ \downarrow \]

*Automation and computerization*

\[ \downarrow \]

Standardization and protocols

\[ \downarrow \]

Checklists and double check systems

\[ \downarrow \]

Rules and policies

\[ \downarrow \]

Education / Information

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Traditional Benefits Associated with ADCs

- Organizes medication storage
- Automates drug accounting/charging
- Automates inventory control
- Enhances controlled substances security processes
- Speeds drug availability process
Evolution of ADCs

- Profile systems
  - Pharmacist check
- Replaces cart exchange system
- Expanded software
  - Alerts, clinical questions, reminders, usage reports, bar coding
## Use of Automated Dispensing Cabinets: October 2006, ISMP Web-site Survey

**n = 508**

<table>
<thead>
<tr>
<th>Medication Choices</th>
<th>Percent</th>
<th>Number</th>
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<tbody>
<tr>
<td>Narcotics only</td>
<td>2%</td>
<td>9</td>
</tr>
<tr>
<td>Narcotics and stock/prn medications</td>
<td>15%</td>
<td>78</td>
</tr>
<tr>
<td>Narcotics, stock/prn and 1st dose medications</td>
<td>17%</td>
<td>85</td>
</tr>
<tr>
<td>ADCs are primary medication distribution system</td>
<td>47%</td>
<td>237</td>
</tr>
<tr>
<td>We don’t use ADCs</td>
<td>19%</td>
<td>99</td>
</tr>
</tbody>
</table>
PA-PSRS

Nearly 15% of all medication error reports indicate ADCs as the source of the medication

23% of these reports involve "high-alert" medications. Many of these reports describe cases in which the design and/or use of ADCs contributed to the errors

The types of errors include wrong drug errors, stocking/storage errors, and medications being administered to patients with a documented allergy

Types of Errors Reported with ADCs

- Stocking errors
  - Wrong drug, wrong location (drawer/bin)
  - Wrong drug selected from screen, wrong dose

- Overrides
Stocking Error
Look-alike Packaging

A dopamine infusion was ordered in the ED to maintain the patient’s blood pressure.

The nurse removed a bag of dopamine from an ADC and began the infusion, believing it contained the usual concentration of 1,600 mcg/mL.

Instead, the bag contained 800 mcg/mL (400 mg/500 mL), which had been accidentally stocked in the ADC in an area where 250 mL bags of dopamine 400 mg/250 mL were usually stored.

ISMP Medication Safety Alert! October 19, 2006 Volume 11 Issue 21
Best Practices Using High-Leverage Strategies

Standardization/Simplification

- Provide unit-dose products, commercially prepared solutions, and patient-specific doses when necessary (half tablets, pediatric doses)
- Manage drug formulations/concentrations
- Build drug interface (how drug names appear to the user)
- Avoid dangerous abbreviations and dose expressions
Best Practices Using High-Leverage Strategies

Limited access and use
- Only profiled system
- Formulary management
  - only certain drugs in specific units
- Strategic decisions around delivery model
- Medications that should never be in the cabinet
  - warfarin, high-dose narcotics
    (e.g. hydromorphone 10 mg/mL, morphine 20 mg/mL)
Best Practices Using High-Leverage Strategies

- Limited access and use
  - Segregate pediatric from adult medications
  - Do not allow nurses to return medications directly to the drawer
    - Use return bin
  - Separate look-alike drug names and packaging
  - Limit/reduce the storage of multi-dose vials
Best Practices Using High-Leverage Strategies

"High-alert" medications

- Limit the quantity and number of concentrations
- Place in individual cells rather than matrix drawers
- Add screen prompts as appropriate to assure correct use
- Mark inside of drawer to denote neuromuscular blockers if stored in the cabinet
Best Practices Using High-Leverage Strategies

- Fail safes and forcing functions
  - Use bar code for:
    - Selection of inventory in the pharmacy
    - Validating cabinet fill
    - Drug removal

- Have windows lockouts for safe delivery times
Monitoring the Safety of ADC Use

- Variety of reports available
  - “Filling” errors
  - Utilization reports to determine inventory changes
  - Override
  - Override time of day/day of week/associated with unit/unit staffing
  - Errors that occur when drug is taken from the ADC
    - Certain drug classes/drug formulations most commonly involved - wrong doses, wrong amounts
    - Did error happen on override
    - Was a double check performed
    - Time of day/staffing considerations
Institute of Medicine (IOM)

- Committee on Drug Safety (Study of the Drug Safety System)
- Committee on Identifying and Preventing Medication Errors
Preventing Medication Errors

Institute of Medicine
Committee on Quality of Health Care in America
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The main impact of CPOE is on ordering and transcription errors; the technique has relatively little impact on administration errors. For reducing the frequency of the latter errors, machine identification techniques such as bar coding – especially when linked to an electronic medication administration record – hold substantial promise, although the evidence for their efficacy is less strong than in the case for CPOE.
IOM “Preventing Medication Errors”

“Bar coding and smart pumps are widely recommended interventions for which more rigorous testing appears warranted.”

Should focus on: “How to implement individual approaches, such as CPOE, bar coding, and smart pumps.”
IOM “Preventing Medication Errors”

“A key feature of pharmacy database systems, infusion pumps, and bar-code and decision-support applications, is the alert function that warns clinicians of potential medication safety problems.”
Cumulative Intercepted ADE’s With and Without FDA Bar Code Rule

Estimated ADE’s from drug errors that could be averted if you have the rule (mandatory bar coding of meds and hospital use of bar coding) vs. no rule over a period of years.

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Medication Dispensing Errors and Potential Adverse Drug Events before and after Implementing Bar Code Technology in the Pharmacy

Eric G. Poon, MD, MPH; Jennifer L. Cina, PharmD; William Churchill, MS; Nirali Patel, PharmD; Erica Featherstone, BS; Jeffrey M. Rothschild, MD, MPH; Carol A. Keohane, BSN, RN; Anthony D. Whittemore, MD; David W. Bates, MD, MSc; and Tejal K. Gandhi, MD, MPH

Background: Many dispensing errors made in hospital pharmacies can harm patients. Some hospitals are investing in bar code technology to reduce these errors, but data about its efficacy are limited.

Objective: To evaluate whether implementation of bar code technology reduced dispensing errors and potential adverse drug events (ADEs).

Design: Before-and-after study using direct observations.

Setting: Hospital pharmacy at a 735-bed tertiary care academic medical center.

Intervention: A bar code-assisted dispensing system was implemented in 3 configurations. In 2 configurations, all doses were scanned once during the dispensing process. In the third configuration, only 1 dose was scanned if several doses of the same medication were being dispensed.

Measurements: Target dispensing errors, defined as dispensing errors that bar code technology was designed to address, and target potential ADEs, defined as target dispensing errors that can harm patients.

Results: In the pre- and post-bar code implementation periods, the authors observed 115,164 and 253,984 dispensed medication doses, respectively. Overall, the rates of target potential ADEs and all potential ADEs decreased by 74% and 63%, respectively. Of the 3 configurations of bar code technology studied, the 2 configurations that required staff to scan all doses had a 93% to 96% relative reduction in the incidence of target dispensing errors ($P < 0.001$) and 86% to 97% relative reduction in the incidence of potential ADEs ($P < 0.001$). However, the configuration that did not require scanning of every dose had only a 60% relative reduction in the incidence of target dispensing errors ($P < 0.001$) and an increased (by 2.4-fold) incidence of target potential ADEs ($P = 0.014$). There were several potentially life-threatening ADEs involving intravenous dopamine and intravenous heparin in that configuration.

Limitations: The authors used surrogate outcomes; did not mask assessors to the purpose of study; and excluded the controlled substance fill process (a process with low error rates at baseline) from the study, which may bias the combined decrease in error rates toward a larger magnitude.

Conclusions: The overall rates of dispensing errors and potential ADEs substantially decreased after implementing bar code technology. However, the technology should be configured to scan every dose during the dispensing process.


For author affiliations, see end of text.
Dispensing Errors and Potential ADEs: Before and After Barcode Technology Implementation

Dispensing Error Rate
- Before Period: 0.88%
- After Period: 0.61%

Potential ADE Rate
- Before Period: 0.19%
- After Period: 0.07%

31% reduction in dispensing errors
63% reduction in potential ADEs

Projections for errors prevented per year at study hospital:
- >13,500 medication dispensing errors
- >6,000 potential ADEs

* p<0.0001 (Chi-squared test)

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Effect of Barcode Technology on Target Potential ADEs

- 58% reduction*
- 53% reduction*
- 100% reduction*

Before Period (115164 doses observed)
After Period (253984 doses observed)

*p<0.001 (Chi squared test)  © 2006 Institute for Safe Medication Practices
<table>
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<tr>
<th></th>
<th>CPOE</th>
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<tr>
<td>Expense</td>
<td>High</td>
<td>High</td>
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<tr>
<td>Difficulty with</td>
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<tr>
<td>implementation</td>
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<tr>
<td>System complexity</td>
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<tr>
<td>Effectiveness in</td>
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</tr>
<tr>
<td>reducing error</td>
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<td>Main group impacted</td>
<td>Physician</td>
<td>Nurse/Pharmacist</td>
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<tr>
<td>Ownership / Impact</td>
<td>Physician</td>
<td>Nurse/Pharmacist</td>
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Bar Coding
Total doses administered in 300 bed hospital = 166,728

- Wrong medication in hand = 1,914 (1.15%)
- Wrong patient scanned = 453 (0.27%)
- Order expired = 94
- Drug package expired = 17
- PRN given too soon = 116
- Received maximum dose exceeded or minimum dose warning = 547
### ASHP National Survey of Pharmacy Practice in Hospital Settings: Dispensing and Administration

#### 2002 and 2005

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<th>Characteristic</th>
<th>n</th>
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<td></td>
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<td>2005</td>
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<tr>
<td>All hospitals</td>
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<tr>
<td>Staffed beds</td>
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<td>&lt;50</td>
<td>72</td>
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<td>≥400</td>
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### ISMP Medication Safety Self Assessment 2000 and 2004

**Bedside Bar Coding for Medications - National**

<table>
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<td><strong>2000</strong></td>
<td>97%</td>
<td>2%</td>
<td>1%</td>
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<tr>
<td><strong>2004</strong></td>
<td>87%</td>
<td>7%</td>
<td>6%</td>
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Are you ready?

- Poor planning **will** compromise success
- Readiness assessment = FMEA
  - Gain commitment, create enthusiasm
  - Understand challenges and plan accordingly
  - Remedy process problems before implementation
Tylenol packaging returns to yellow.

Last week, McNeil Consumer and Specialty Pharmaceuticals let us know that pouches of 500 mg Extra Strength TYLENOL (acetaminophen) will be returning to the familiar yellow color within the next 6 to 8 weeks. In the fall, ISMP began to receive reports from concerned practitioners after the drug was repackaged in a white pouch to accommodate a bar code and maximize scanning capability. This made the 325 mg and the 500 mg Yellow Tylenol packet returns.
Morphine Sulfate
Immediate-Release Concentrated Oral Solution

20 mg/1 mL

Each InveAmp™ ampoule contains 20 mg of Morphine Sulfate. 

INVEAmp/PATIENT: To administer, tear foil pouch at notch, remove ampoule from pouch and squeeze at raised square to break inner seal. Squeeze middle of ampoule to administer product to patient. Do not open pouch until product is to be used. See package insert for full prescribing information. Store at 25°C (77°F); excursions permitted to 15°–30°C (59°–86°F). Do not freeze.

LOT 69147A
EXP 09/2007

Mfd. for ETHEX, St. Louis, MO 63044

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DURAGESIC® 12 mcg/h
(FENTANYL TRANSDERMAL SYSTEM)
In vivo delivery of 12 mcg/h fentanyl for 72 hours
NOT FOR ACUTE OR POSTOPERATIVE USE
Each transdermal system contains:
1.25 mg fentanyl and 0.05 ml alcohol USP
KEEP OUT OF REACH OF CHILDREN
Rx only

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135 items
Clinical systems
Communication
Feedback mechanisms
Culture and leadership
Hospital formulary
Labeling and packaging
Technology
Education

Useful even if this technology is years in the future!