Impact of Workflow Management Systems and Technology Interoperability on Optimizing Medication Safety

APRIL 24, 2022

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Disclosure Statement

None of the planners for this activity have relevant financial relationships to disclose with ineligible companies.

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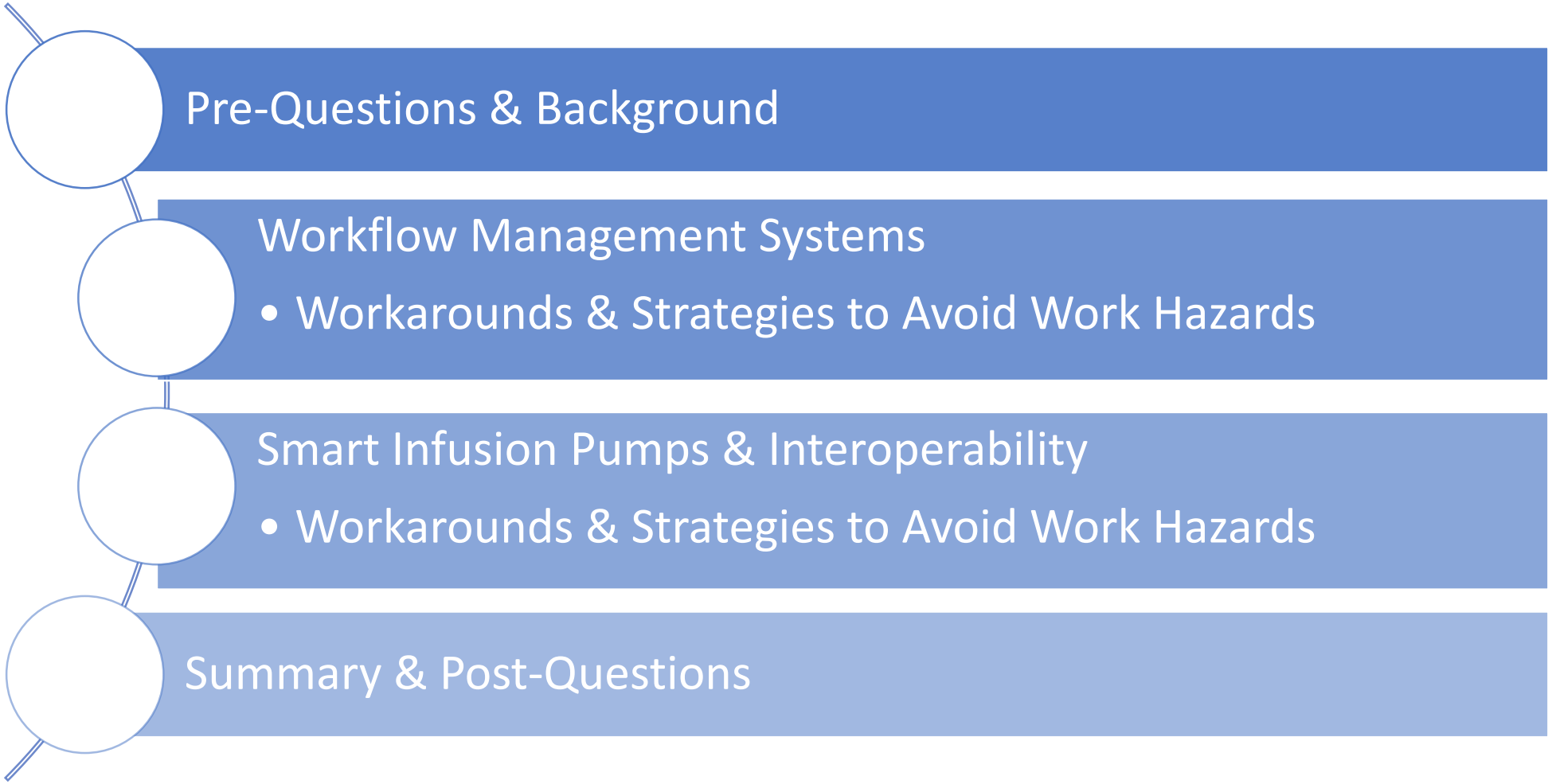
Objectives

1. Analyze the utility of technology in reducing medication errors with a focus on workflow management systems and Smart pump interoperability

2. Identify the pitfalls of implementing new technology and potential for novel/unexpected errors to occur as a result

3. Evaluate strategies to combat workaround errors that arise for technology-related implementations

Overview



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Pre-Questions

1. All of the following statements describe the benefits of implementing a workflow management system, EXCEPT:

A. Can prevent volume and overfill error by detecting density/weight variations

B. Allows for image capture to see real-time product preparation

C. Will always allow for a quicker compounding process due to automation steps

D. With appropriate use of BCMA, can reduce product/concentration errors

BCMA Bar code medication administration

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2. Which of the following statements accurately describes the limitations of Smart Pump interoperability?

A. With interoperability, the wrong concentration and rate would auto-populate into the Smart Pump

B. Interoperability does not prevent users from manually changing initial dosing parameters

C. Reliable wireless connection is required to ensure appropriate flow of information

D. BCMA compliance is unnecessary with interoperability as all information is transmitted wirelessly

E. B & C

BCMA Bar code medication administration

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3. Which of the following strategies could be applied to remove hazardous work-arounds during implementation of a new workflow management system?

A. Educate compounding colleagues about the new process and error reporting

B. Collaborate with front-line staff to determine barriers causing skipped steps

C. Apply "in-line verification" or examine real-time digital images of the compounding process

D. Perform regular safety audits

E. All of the above

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Background

Human errors

- Manual verification of IV products oftentimes insufficient to avoid medication error

2017 ASHP survey

- 26.9% : used barcode scanning for CSP prep/verification
- 64%: omitted automation technology for CSP preparation
- 12.8% : used drug workflow software for CSP prep/verification/dispensing

CSPs of particular interest

High alert medications

- Peds/neonatal products
- Epidural/intrathecal
- Pharmacy-sourced bulk containers

ASHP Policy Positions 1982–2021. ASHP.org; 2022.
ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017

CSP Compounded sterile products

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Risk vs. Safety Barriers – A Current Disproportion

Oral medications

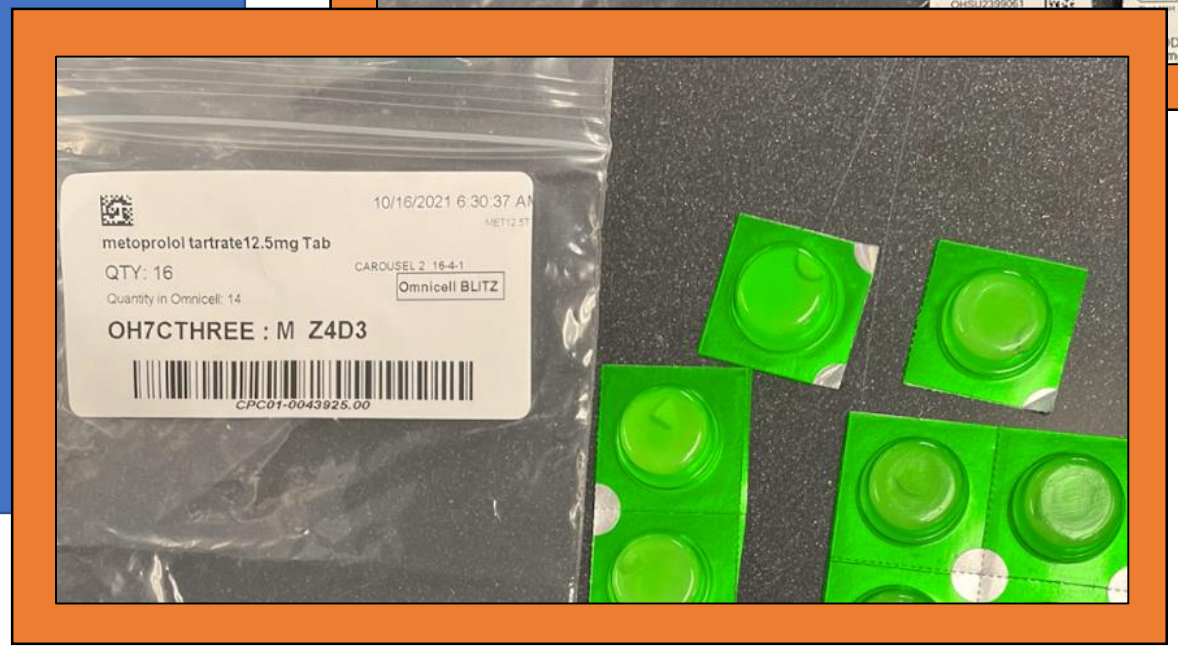
- Liquids, tablets, buccal systems

Risk

- Proportionately **low**
  - Enteral tract defenses
  - Poison control measures
  - Visual inspection of physical drug
  - Unit-Dose packaging

Safety Barriers in Place

- Barcode scanning



ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations. ISMP.org; 2016.

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Risk vs. Safety Barriers – A Current Disproportion

Intravenous-type medications

- IV, IM, intrathecal, subdural solutions

Risk

- Proportionately **high**
  - Direct to bloodstream/other sterile area
  - Limited poison control interventions
  - Little/no visual cues for inspection
  - Exponential onset (esp. higher risk meds)

Safety Barriers in Place

- ???

ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations. ISMP.org; 2016.

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Risk vs. Safety Barriers – A Current Disproportion

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- ???

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Med Safety Goal: Removing Human Error through Technology Interventions

Workflow Management Systems (WFMS)

Smart Pumps & Interoperability

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Workflow Management Systems

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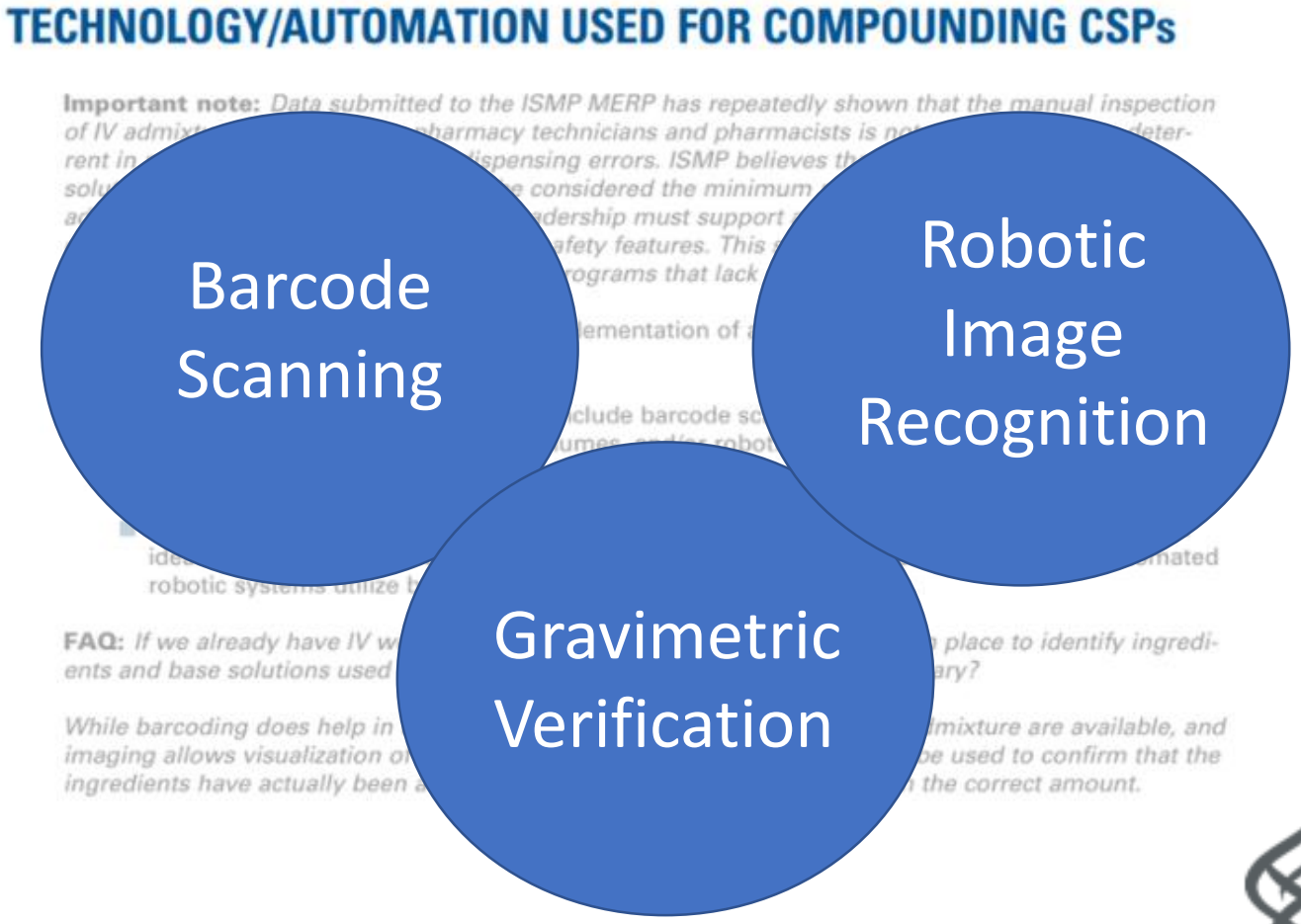
ISMP Guidance – Minimum Requirements

- Manual inspection not completely effective
- IV Admixture Minimum
  - Barcode Scanning Base Solutions & Ingredients
- Chemotherapy & Pediatric CSPs (ideal)
  - Barcode Scanning
  - Gravimetrics

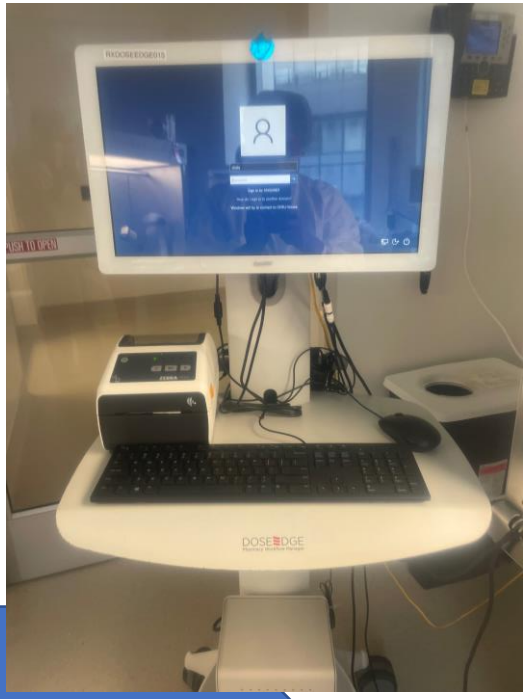


ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations. ISMP.org; 2016.

High alert medications: + independent double-checks

Workflow Management Systems

- Process Automation & Standardization
  - CSPs: Preparing >> Verifying >> Tracking >> Documenting



Pre-Compounding
- Barcode Scanning

Compounding Process
- Standard steps
- Labels auto-generated with appropriate BUD
- Auto-calculations
- Real-time image capture of products
- Gravimetric Analysis

Post-Compounding
- Dose tracking
- Reduced waste

Electronic data capture throughout

ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017

BUD By-Use-Date

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Pre-Compounding

Barcode Scanning

- Barcode-assisted medication preparation (BCMP)
- Minimum requirement by ISMP
- Barcode scanning each drug, diluent, and base fluid
  - Done before any removal or manipulation of ingredients
  - Reduce product/concentration errors
- Safety benefits dependent on appropriate, consistent use

Am J Health Syst Pharm. 2013;70(23):2076-2080.

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Compounding

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Standardized Workflow

- Standardized steps
  - Standard Operating Procedures (SOPs)
  - Institutional Policies
- Labels auto-generated with appropriate BUD
  - Applied immediately after preparation
  - Follow USP 797, USP 800 (Hazardous)
- Auto-calculations

ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017

Real-Time Image Capture

- Image recognition
  - Sequential photo imaging at each step of the compounding process
  - Allowing for prospective verification of each product
    - Retrospective review non-optimal from potential waste viewpoint

Am J Health Syst Pharm. 2009;66(13):1211-1217.
ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017

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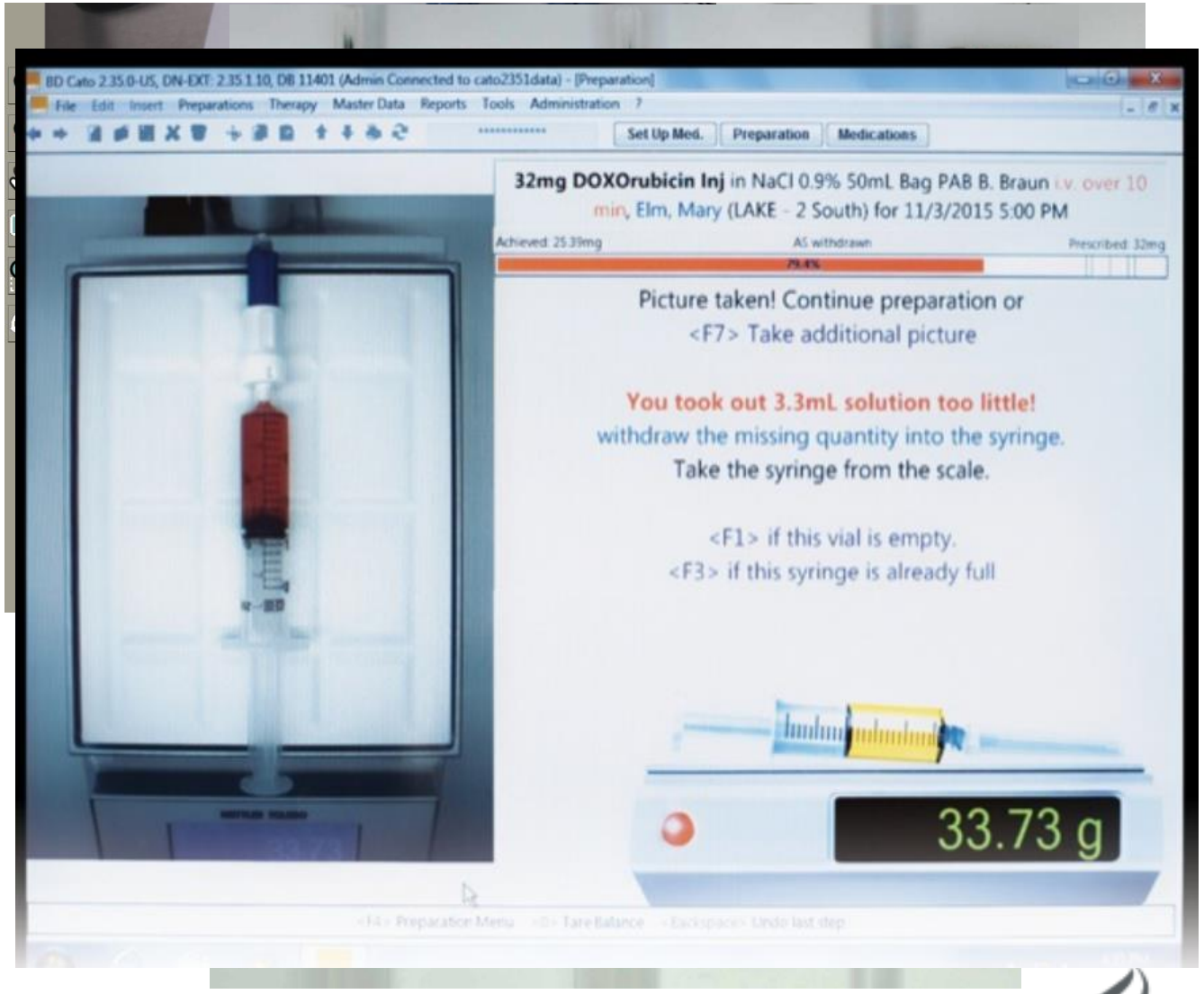
Barcode Scanning & Real-time Image Capture – Effect on Errors

- Speth et al. 2013
  - Barcode-intercepted errors: 75%
    - Wrong Drug – 60%
    - Wrong Diluent/Fluid – 28%
    - Wrong Concentration – 12%
  - Pharmacist-rejected errors: 25%
    - Incorrect Drug/Diluent Amount 75%
    - Unclear images or improper technique 25%
  - 2 year BCMP Project
    - 12-week implementation
    - Error rate reduction from 29 to 23 errors/week

Am J Health Syst Pharm. 2013;70(23):2076-2080.

Gravimetric Analysis

- Using an electronic balance to weigh solutions, step by step
- Accuracy determined by comparison to verified weight
  - Specific gravity and volume calculations
  - Margin of error limits
  - Prevents volume/overfill errors
- First recommended in ISMP's 2016-2017 Targeted Medication Safety Best Practices for Hospitals



Making the Switch to IV Workflow: Automated systems yield benefits, present challenges. PharmacyPracticeNews.com; 2016.
ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017.

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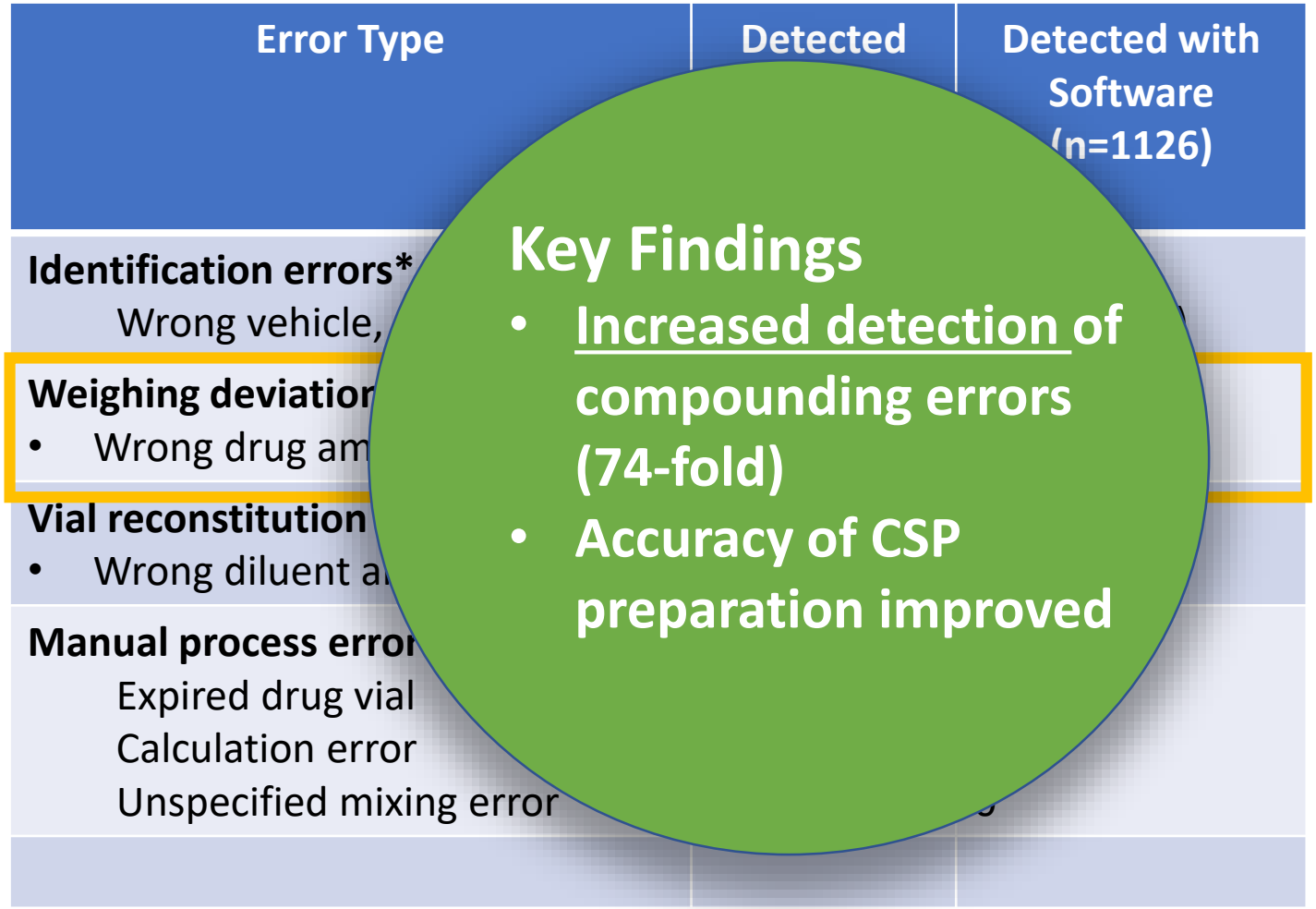
Gravimetric Analysis Effect on Detecting Errors

Reece et al. (2016)

- Ambulatory Pharmacies
- 15,843 doses
- 1,126 errors (7%) detected
  - All **during** compounding
- 12 month study period
  - ⇩ 34% Production time
    - Charts/References in software
    - Auto-printing dose/vial labels
  - ⇩ 37% Pharmacist check time



*via barcode scanning

Am J Health Syst Pharm. 2016;73(3):165-173.

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Caveats to WFMS

"Human factors experts have long warned that each innovation, whether in practice, procedure, drugs, or equipment, carries its own particular set of hazards and, thus, new potential for inducing errors."

Crit Care Med. 2005;33(3):679-680.

Caveats to WFMS

- Barcode Scanning Errors
  - Recalibration of scanners
  - Training new products (shortages/new drugs)
    - Presence of multiple barcode types per product
    - Visual verification of product / overrides
- Scanning Omitted due to Time trade-off
  - Perceived obstruction to typical workflow
    - Comfortability with visual inspection of products
  - Time constraints at certain times of day (e.g. batches, post-rounds)
- Time/Resource Additions
  - Up to 1.0 FTE to just maintain database (Gravimetrics)
  - Adding FTE hours/resources to maintain efficiency with added safety layer

ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017.

FTE full-time equivalent

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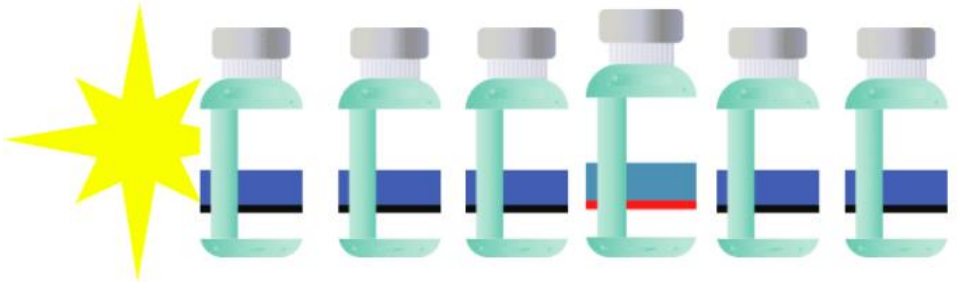
Caveats to WFMS

Safety Risks During Batching

- Singular Vial Scans
  - Scanning first vial repeatedly
    - Potentially missing erroneous vials



- Decoy products for scanning
  - Bag, vial, syringe specifically for scanning
  - Efficient but risky

ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017.

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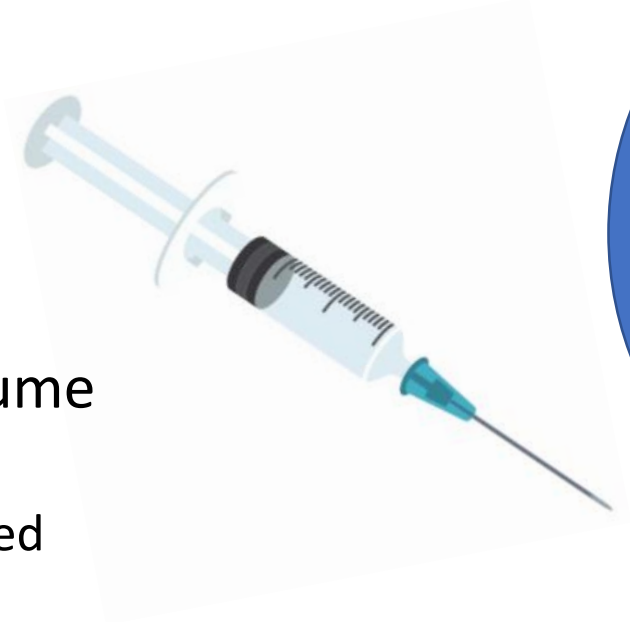
Caveats to WFMS

- Pull-back method for syringes
  - Bag injected with drug first
  - Empty syringe filled with air to volume injected
    - Unable to verify actual volume injected



Minnesota BOP prohibits retroactively certifying drug amounts for high alert medications

ASHP Policy #1903: COMPOUNDED STERILE PREPARATION VERIFICATION

"To advocate that health systems adopt automation and information technology to facilitate in-process and final verification of … CSPs… [and to] oppose the use of the syringe pull-back method or other proxy methods of CSP verification"

ASHP Policy Positions 1982–2021. ASHP.org; 2022.
ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017.
Revisor of Statutes, State of Minnesota. www.revisor.mn.gov; 2012.

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Caveats to WFMS

- New product integration issues
  - Cross scanning of products during drug shortages
- Calculation error due EHR or Compounding Software record errors
  - Ingredient error in → Calculation error out
- Poor image capture quality
  - Similar appearance of full and empty syringes to untrained (and trained) eye
  - Extra time to re-take images / arrange syringes

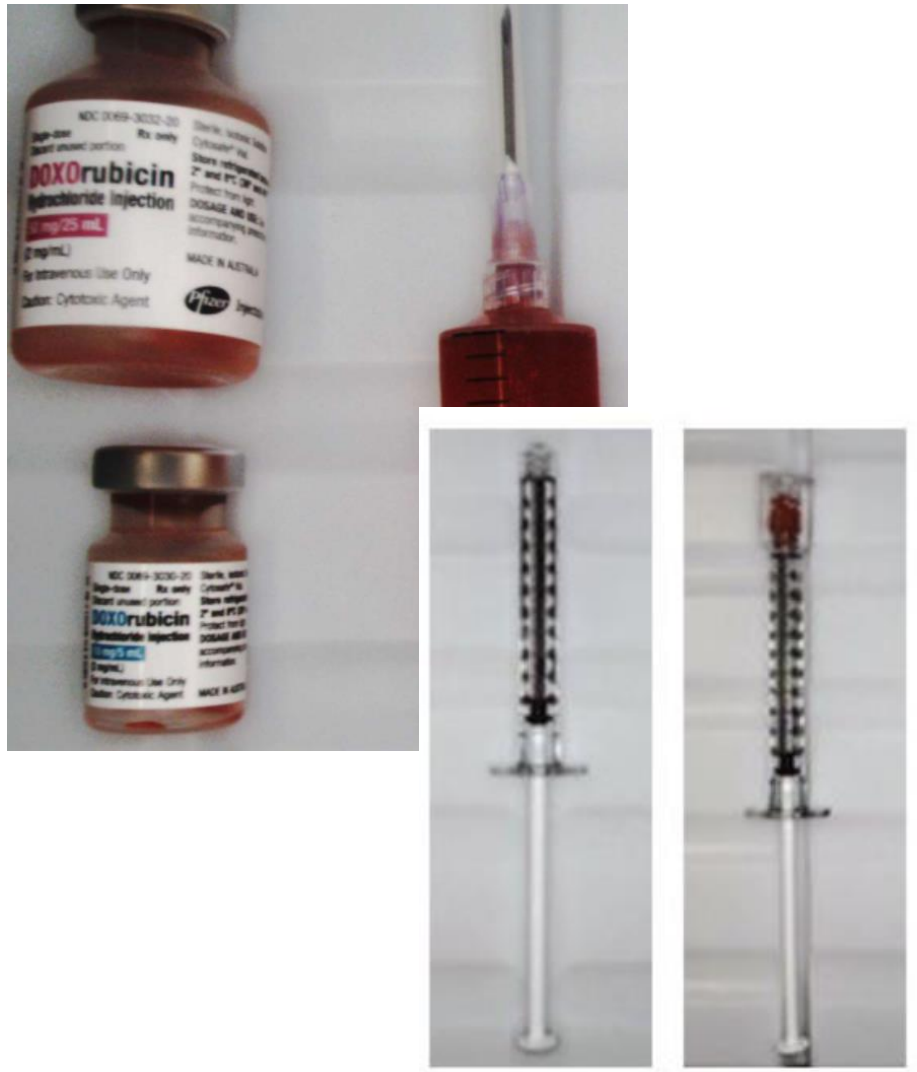

Figure 1. Volume in syringe may not be easily visualized. The syringe on the right is filled, while the syringe on the left is empty.

ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017.

EHR electronic health record

Caveats to WFMS

- Gravimetric weighing scale error/failure
  - Laminar flow hood interference and/or vibrations
    - Low volume products most problematic

- Human Error
  - Labeling/Transcription Error
    - Lot number and expiration
  - Confirmation Bias
  - Label swapping post-production

ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017.

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Considerations to Resolve WFMS Work-Arounds/Caveats

- Prioritize highest severity / probability risks with an FMEA
  - Failure mode and effects analysis

Table 2. Failure Modes Identified in IV Workflow Technology[a]

Failure Mode	Process Step	Cause	Effect	Severity		Frequency	Detectability	RPN	RHI
				Clinical	Production				
Label does not print or printer malfunction	Product label printed	Software or equipment failure	Troubleshoot printer, redirect label printing, or use Epic label	1	2	2	1	4	4
Incorrect label affixed	Final container removed from scale; final label attached to container	User error	Label will not match product ingredients and/or dose	3	1	1	1	3	3
Error not detected visually[a]	Pharmacist verifies preparation by checking patient information, drug, diluent, photo, and video	User error	Incorrect product dispensed	3	1	3	1	9	9
Pharmacist does not select "DUE"	After confirmation, pharmacist selects "DUE" on system manager and bags final container	User error	No issue with compounding preparation, as preparation would already be completed at this point; pharmacist would not have checked preparation details before releasing to patient	1	2	3	1	6	6

Abbreviations: DUE, drug use evaluation; EMR, electronic medical record; IV, intravenous; RHI, Risk Hazard Index; RPN, Risk Priority Number. Epic refers to EMR system (Epic Systems Corporation, Verona, WI).
[a]Highest-risk mode, as determined by RPN and RHI scores of 9.

ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017.
Am J Health Syst Pharm. 2021;78(14):1323-1329.

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Considerations to Resolve WFMS Work-Arounds/Caveats

Human error (wrong volume, dose, product, etc.)	Barcode scanning & gravimetric analysis
Barcode Scanning Errors	Recalibrate barcode scanners and test barcodes prior to use, EHR reports
Image Capture Issues	Select supply design (e.g. syringes) with legible markings, test prior to use
Retrospective syringe checking	Avoid syringe pull-back method, optimize in-step image capture (esp. high alert)

ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017.

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Considerations to Resolve WFMS Work-Arounds/Caveats

Unfamiliarity with Workflow	Hands on training & didactic learning for staff; emphasize risks of workarounds
Omission of WFMS Steps	Internal reporting and pharmacist training to recognize skipped steps
Technique deviation into unsafe practice	Visual auditing and re-certification processes; offer re-training sessions
Equipment issues or interference	Work with third-party vendors to optimize

ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017.

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Considerations to Resolve WFMS Work Arounds /Caveats

When in doubt, throw it out!

Missing documentation

Reason
Rejected: Other (no pictures taken of the syringes/volume for paclitaxel)

Unclear or omitted digital images

Questionable compounding technique

Reason
Rejected: Other (remake w/light protected process)

- Impact of pharmacist final inspection

25% of errors revealed during this stage of the WFMS workflow

ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017.

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Post-Compounding

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Dose Tracking & Reduced Waste

Dose Tracking

- Medications tracked through WFMS compounding process & at dispensing

Waste Reduction

- Gravimetric software allows partial vials to be weighed & labeled
- Label with BUD and barcode

ISMP Maximize Benefits of IV Workflow Management Systems by Addressing Workarounds and Errors. ISMP.org; 2017.
Am J Health Syst Pharm. 2016;73(3):165-173.

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Med Safety Goal: Removing Human Error through Technology Interventions

Workflow Management Systems (WFMS)

Smart Pumps & Interoperability

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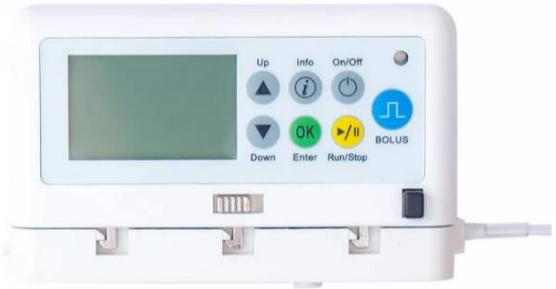
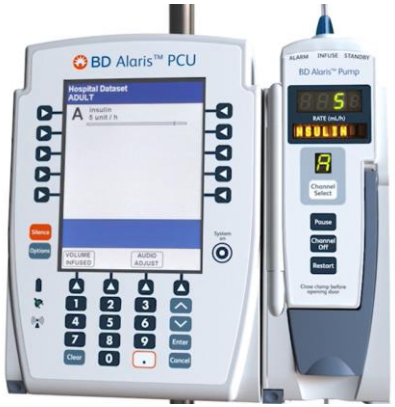


boundtree.com



BD.com

BBraunusa.com

Smart Pumps & Interoperability

Moogmedical.com

CenturionService.com

Baxter.com

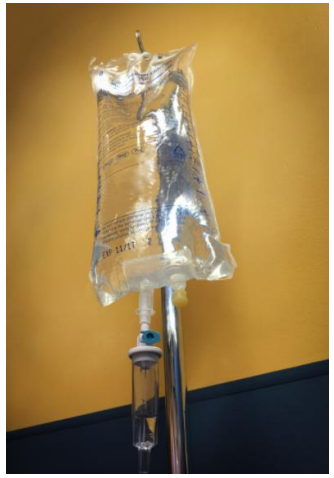
IV Medication Infusion Timeline

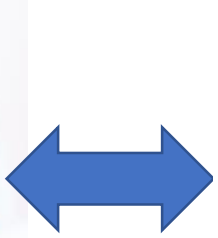
IV Bags manually hung and administered via gravity

Smart Pumps introduced
- Medication orders manually entered

Interoperability between Smart Pumps and EHR

1950s **2001** **2016**

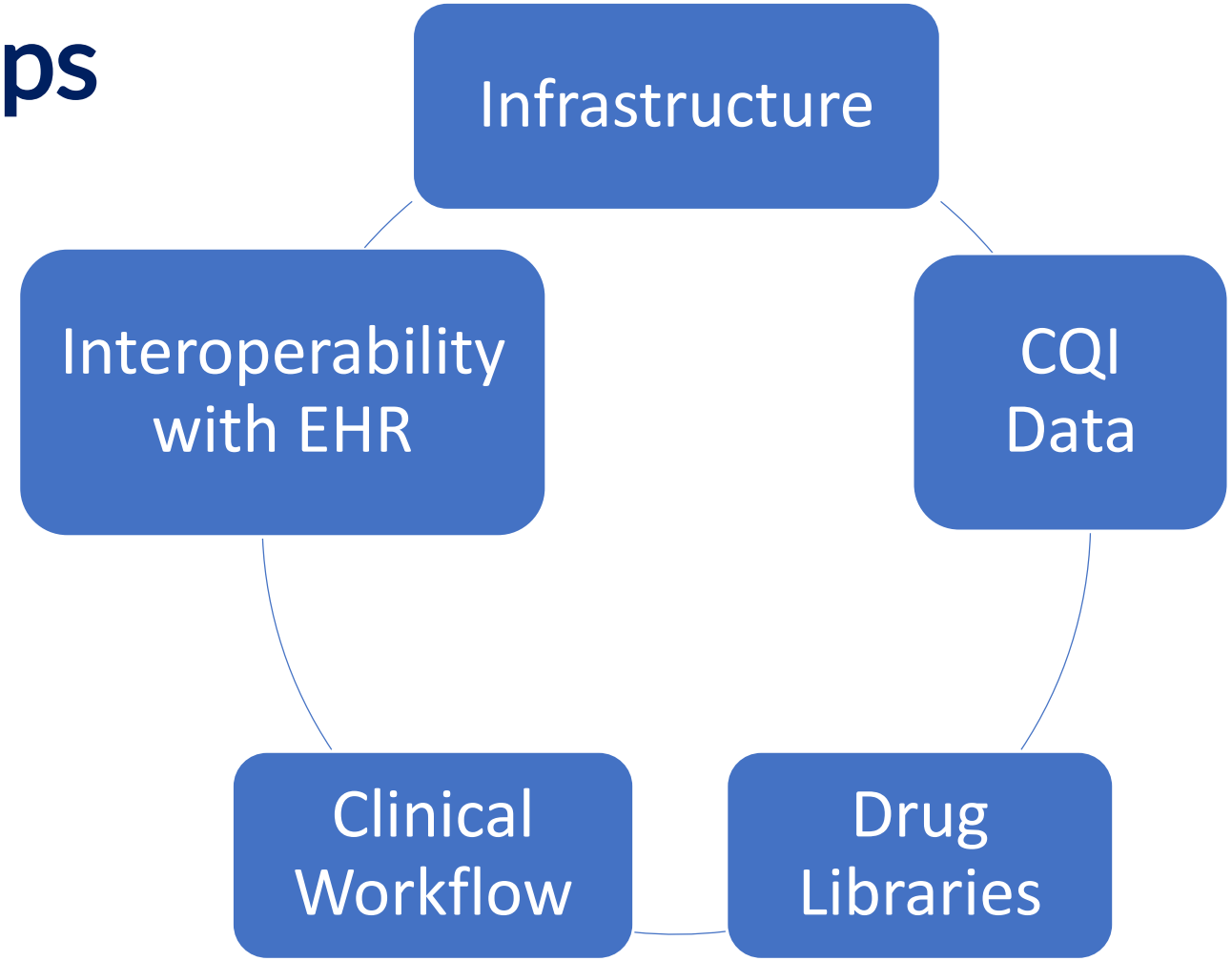




Am J Health Syst Pharm. 2021.
Smart Pumps: Advanced Capabilities and Continuous Quality Improvement. PSQH.com; 2007.
Interoperability Preparedness: What Hospitals Can Do to Be Ready for Smart Pump-EMR Interoperability. PSQH.com; 2016.

Smart Infusion Pumps

- Coined by ISMP in 2002
- ISMP Guidelines for Optimizing Safe Implement and Use of Smart Infusion Pumps (2018)
- Dose Error Reduction Software (DERS)
- Pre-set parameters – drug type, strength, dosing, etc.



ISMP "Smart'' infusion pumps join CPOE and bar coding as important ways to prevent medication errors. ISMP.org; 2022.
J Pharm Pract Res. 2011;41(3):192–5.

CQI Continuous Quality Improvement

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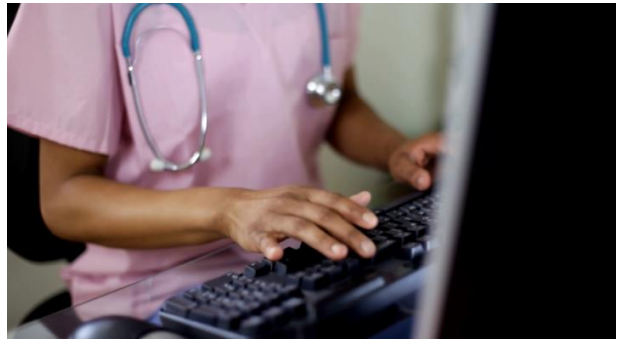
Smart Infusion Pumps – Traditional Workflow

Nurse receives order on the electronic health record (EHR)

Nurse manually enters order information into the Smart Pump

Nurse documents medication start time and order details into the MAR on the EHR

- Medication
- Duration
- Volume
- Rate



MAR medication administration record

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Smart Infusion Pumps

- 80% of US hospitals
- Improves dosing compliance
    - Drug library
    - Alert types, frequency of alerts
    - Response to alerts (action)
        - # Overrides
    - Investigation of pump errors
    - Wireless connectivity
        - Updates / data download

Standardize Infusion Practices

Dosing Limits
- Soft Limits
- Hard Limits

ISMP Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps. ISMP.org; 2020.

Smart Infusion Pumps

Study	Population	Key Findings (Pre- vs. Post-implementation)
Rothschild et al. (2005) – Controlled Trial	Cardiac surgical intensive care and step-down units	• Bypassing of the drug library (25%) • Overriding alerts including the use of inappropriate boluses **Serious medication error rates***: 2.03 and 2.41 (*p* = .124) **Rates of preventable ADEs (corrected)*:** 0.28 to 0.18 (***p*** = .27) **Rates of non-intercepted potential ADEs (corrected)*:** 2.12 to 0.36 (***p*** < .0001)
Ohashi (2014) – Systematic Review	21 studies✦ • Descriptive observational (10) • RCT (1) • Before–after comparisons (7)	• Medication errors intercepted/recorded (n=12) • Wrong rate, wrong dose, pump setting errors • Errors observed (n=10) • ADEs or error reports (n=9) • Smart Pump Compliance Rates: Ranging 62 % to 98 % • Challenge of combining rate of errors caught vs. reduced errors due to technology intervention

*Per 100 patient-pump-days

✦ Quantitative analysis not feasible (RCT =1)

Crit Care Med. 2005;33(3):533-540.
Drug Saf. 2014;37(12):1011-1020.

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Caveats - Smart Infusion Pumps

- Human Error
  - Mis-programming/miscalculation of doses or rates
    - Label admixture / administration instruction confusion
    - Multiple standard concentrations available
    - Custom concentrations (manual entry)
      - Can lack minimum concentration limits

Falsely “low” concentration programmed → Increase in amount of drug delivered by the pump → Patient Overdose

ISMP Smart Pump Custom Concentrations Without Hard “Low Concentration” Alerts. ISMP.org; 2012.

Smart Pumps & Human Factors Engineering

*"Humans can always defeat technology if it is perceived as a barrier. A cardinal human factors design principle is to **make every device user friendly**. The device should save time, not add to it."*

Crit Care Med. 2005;33(3):679-680.

Smart Infusion Pumps – Interoperability Workflow

Nurse receives order on the electronic health record (EHR)

Interface message between EHR and Smart Pump transmits Order information

Nurse infuses medication with auto-populated information; administration documentation transmitted in interface message back to EHR

- Medication
- Duration
- Volume
- Rate

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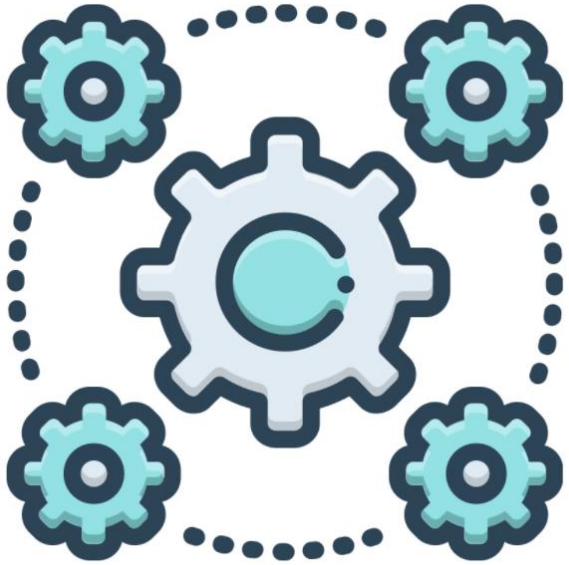
Am J Health Syst Pharm. 2021;zxab287.

Interoperability – Effect on Errors



- Skog et al. 2022
- Observational study - community healthcare system
- ***Per 100 infusions (pre- vs. post-implementation)***:
  - Total errors: 114.6 vs. 96.5 (p = 0.02*)
  - Administration errors: 41.1 vs. 32.4 (p = 0.12)
  - Expired medication errors: 3.1 vs. 0.5 (p = 0.02*)
  - High risk medication errors: 12.8 vs. 6.8 (p = 0.01*)
  - Continuous infusion errors: 12.6 vs. 6.0 (p = 0.005*)

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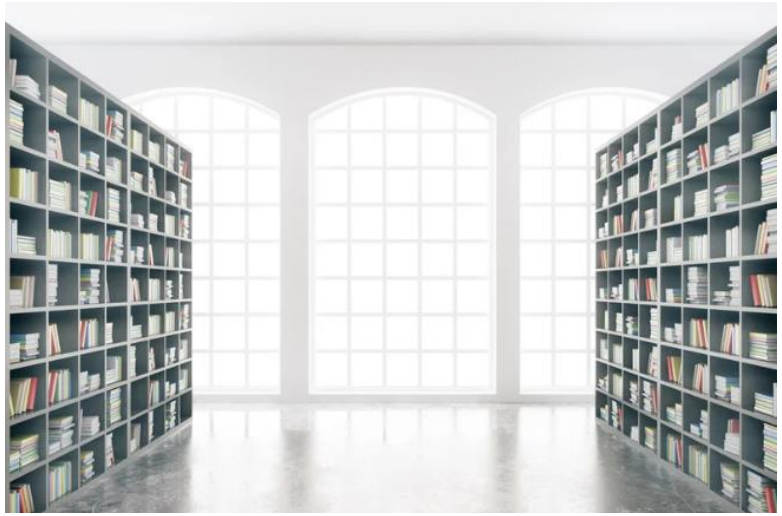
J Patient Saf. 2022;18(3):e666-e671.

Smart Infusion Pump Limitations

- **Users able to:**
  - Bypass use of the pump or the drug library
  - Override Smart Pump alerts (soft-stops)

- **Smart Pumps rely on medications/limits set in drug library**
  - Maintenance-heavy – customization dependent



- **Important Interoperability Limitations**
  - Dependent on wireless connectivity
  - Re-programmability after initial interface message
  - Still requires BCMA to verify medication used

ISMP Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps. ISMP.org; 2020.
Optimizing smart infusion pump safety with DERS - Sentinel Event Alert. www.jointcommission.org; 2021.

BCMA Bar code medication administration

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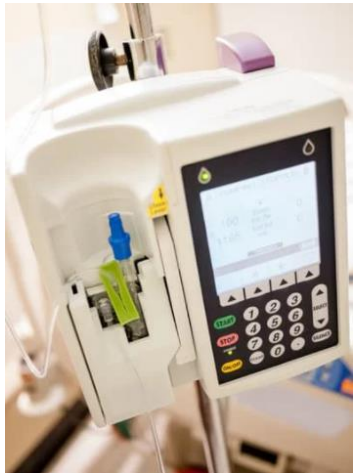
Managing Smart Infusion Pump Risks

- **Limit orderable concentrations with doses in metric weight/time (vs. mL/hr)**
  - mg/hour, mcg/kg/hour
  - MAR and label match-up



- **Policies & education**
  - Final infusion verification (e.g. low concentrations -> high infusion rates)
  - Smart Pump double checks (e.g. high alert meds)
  - Colleague education

- **Maintenance of drug libraries with limited, standardized concentrations**
  - Remove residual “custom” concentrations
  - Avoid “factor of 10” concentrations

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ISMP “Smart’’ infusion pumps join CPOE and bar coding as important ways to prevent medication errors. ISMP.org; 2022.

Managing Smart Infusion Pump Risks

- **Focusing on high-impact warnings only**
- **Remove extraneous label information (e.g. prep instructions)**
- **Converting frequently-overridden soft-warnings to hard-warnings**
  - Set hard minimum concentrations
- **Barcode scanning and interoperability**
- **Continuous data analysis**
  - Identifying overridden alerts and barriers

ISMP "Smart'' infusion pumps join CPOE and bar coding as important ways to prevent medication errors. ISMP.org; 2022.

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Summary

- **Workflow Management Systems (WFMS)** and **Smart Pumps** (+/- Interoperability) can improve medication safety in the **preparation** and **administration** stages, respectively

- **Appropriate use of technology** drives safety benefits; workarounds lead to unintended risks/errors

- Forming mitigation strategies for to counteract work-arounds is key to maximizing technological benefits

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Post-Question

1. All of the following statements describe the benefits of implementing a workflow management system, EXCEPT:

A. Can prevent volume and overfill error by detecting density/weight variations

B. Allows for image capture to see real-time product preparation

C. Will always allow for a quicker compounding process due to automation steps

D. With appropriate use of BCMA, can reduce product/concentration errors

2. Which of the following statements accurately describes the limitations of Smart Pump interoperability?

A. With interoperability, the wrong concentration and rate would auto-populate into the Smart Pump

B. Interoperability does not prevent users from manually changing initial dosing parameters

C. Reliable wireless connection is required to ensure appropriate flow of information

D. BCMA compliance is unnecessary with interoperability as all information is transmitted wirelessly

E. B & C

3. Which of the following strategies could be applied to remove hazardous work-arounds during implementation of a new workflow management system?

A. Educate compounding colleagues about the new process and error reporting

B. Collaborate with front-line staff to determine barriers causing skipped steps

C. Apply "in-line verification" or examine real-time digital images of the compounding process

D. Perform regular safety audits

E. All of the above

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Questions?

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Thank You