2016 26th Summer Institute in Nursing Informatics

Informatics at the Crossroads of Care Coordination

July 20-22, 2016

University of Maryland School of Nursing, Baltimore, Maryland





Intravenous medication errors related to smart infusion pumps: multi-hospital observational study

Kumiko O. Schnock, RN, Ph.D.
Research fellow at Harvard Medical School,
Brigham and Women's Hospital
kschnock@patners.org









Agenda

- Background
- Project overview
- Methods
- Interventions
- Results
- Barriers and solutions of Implementing intervention plans
- Next steps

Background

- Intravenous(IV) medication errors
 - Frequent, dangerous, harmful to patients
- Association for the Advancement of Medical Instrumentation(AAMI)/FDA Infusion Device Summit in 2010
 - 56,000 reported incidents related to IV infusions, and the FDA has increased scrutiny of infusion safety because of these reports
- Expectations for smart IV pumps
 - Computerized patient infusion devices that include features for administration error prevention and data collection

Background

Previous Study 1

- Evaluation of smart pumps by Rothschild et al*1
 - "Smart pumps did not reduce the rate of serious medication errors. The issues around usages of smart pumps including alert overrides and violation of safety procedures prevented realization of the potential medication safety benefits"
 - Lesson Learned
 - Culture of competence and safety among staff is needed
 - Reviewing current practice issues, common errors, and assessing the organization's readiness for adoption are key
 - Institutions must maintain continuous and ongoing relationships and a dialogue with vendors as the technology upgrades occur

^{*} Rothschild J, Keohane C, Cook E, Orav E, Burdick E. A controlled trial of smart infusion pumps to improve medication safety in critically ill patients. Crit Care Med. 2005;33(3):533Y540.

Background

Previous Study 2

- Study by Husch, et al*2 assessed the frequency of intravenous medication errors and impact of potential smart infusion pump technology on the frequency of intravenous medication errors in Northwestern Memorial Hospital
 - Observed errors associated with orders, documentation, labeling and patient identification
 - This study was conducted in one medical facility with one vendor, making the generalizability of these results uncertain

Overview of Study

- Duration: April 2012-March 2015
- Title: National Study of Intravenous Medication Errors, Understanding How to Improve Intravenous Safety with Smart Pumps
- Nationwide multi-institutional study (10 hospitals in the U.S)



Project Goal

- To conduct a national, 10-site study using the general methodology described by Husch et al*, which allows a rapid assessment of the frequency and types of medication errors
- To identify the key issues related to the use of smart pumps
- To develop broadly applicable strategies that will improve the prevention of intravenous errors
- To improve safety related to the use of smart pumps in hospitalized patients

^{*}Husch M, Sullivan C, Rooney D, Barnard C, Fotis M, Clarke J, Noskin G. Insights from the sharp end of intravenous medication errors: implications for infusion pump technology. Qual Saf Health Care. 2005 Apr;14(2):80-6.

Research Questions



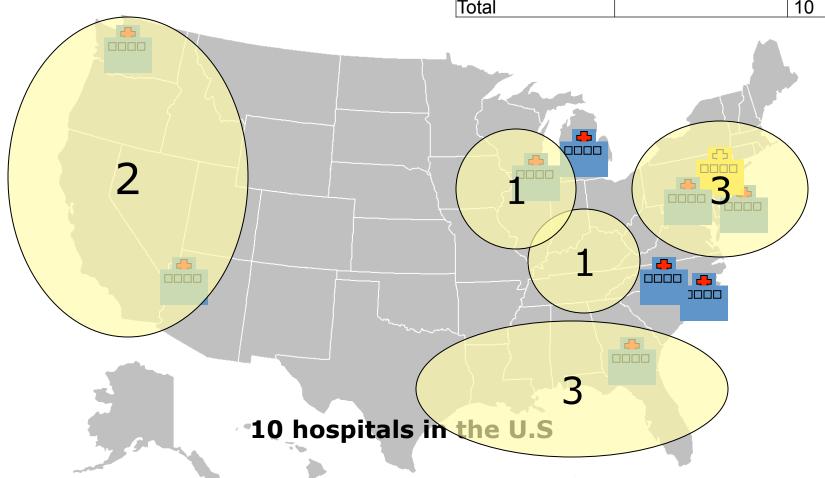
- 1. What are the frequency and types of IV medication errors?
- 2. How much variability is there by frequency and type among settings?
- 3. After review of the initial data, what strategies appear to have the greatest potential for reducing IV medication error frequency?
- 4. How effective is an intervention including a bundle of these strategies at multiple sites?

Participating Sites

		Smart pump Vendor	# Beds	Magnet Designation	Nursing Union	CPOE	eMAR
Co	mmunity Hospital						
1	St Joseph/Candler Hospital, Savannah, GA	Carefusion	331	Yes	No	Phase 1 No, Phase 2: yes(implemented since Feb 2012)	
-	Winchester Medical Center, Winchester, VA	Bbran	411	Yes	No	Yes	Yes
3	Central DuPage Hospital, Winfield, IL	Carefusion	350	Yes	No	Yes	Yes
Ac	ademic Medical Center(AMC)						
4	Vanderbilt University Medical Center, Nashville, TN	Carefusion	1000	Yes	No	Yes	Yes
5	Brigham and Women's Hospital, Boston, MA	Carefusion	793	No	Yes	Yes	Yes
6		General IV:Sygma PCA/Syringe:Smith medical	1057	Yes	No	Yes	Yes
7	UC San Diego Health System, San Diego CA	Carefusion	511	Yes	Yes	Yes	Yes
8	Johns Hopkins Hospital, Baltimore, MD	Carefusion	982	Yes	No	Yes	Yes
9	Maricopa Medical Center, Phoenix, AZ	Carefusion	449	No	No	Yes	Yes
10	Network/Danbury Hospital,	General IV:Sygma PCA/Syringe: Smith medical	371	No	Yes	Yes	Yes

Demographics

Hospital Type	Bed size Range	# of sites
AMC	371-1057	6
Community	331-411	4
Total		10



Study Plan

Timeline

Apr 2012 Apr 2013 Apr 2014 Mar 2015

Feb 2013 Aug 2013 Oct 2014 Dec 2014

Pre data collection Post data collection

Year 1

- 1. Development of data collection form
- 2. Observer training
- 3. Initial measurement of IV medication errors

Year 2

- 1. Observation data analysis
- 2. Face-to-face-meeting for developing recommendations
- Interventions to reduce IV medication errors

Year 3

- 1. Second measurement of IV medication errors
- 2. Data analysis
- 3.Face-to-face-meeting for developing final recommendations
- 4. Publication of final report

Methods

Study Procedure	
Study Design	A prospective point prevalence approach
Study Units	4 units (including medical and surgical wards, medical and surgical ICUs) in 10 hospitals
Inclusion Criteria	 Large IV (exclude TPN, blood products) Syringe PCA (exclude PCEA)
Types of Errors	 Wrong patient Wrong IV fluids/medications Wrong concentration Wrong dose Wrong rate Delay(between 2-4 hours) Omission of IV fluids/meds(after 4 hours) Wrong channel/wrong pump setting Wrong information on label Missing information Oversight allergy Smart pump/drug dictionary was not used Unauthorized medication

Development of Data Collection Form

- Develop electronic standardized data collection form
 - REDCap (Research Electronic Data Capture):
 a secure, web-based application designed to support data capture for research studies
- To classify the severity of each incident/error

National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index*

- (A) Capacity to cause error
- (B) Error occurred but did not reach the patient
- (C) Error reached the patient but did not cause harm
- (D) Error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm
- (E) Error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
- (F) Error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
- (G) Error occurred that may have contributed to or resulted in permanent patient harm
- (H) Error occurred that required intervention necessary to sustain life
- (I) Error occurred that may have contributed to or resulted in the patient's death

^{*}http://www.nccmerp.org/types-medication-errors

An iterative participatory development process

Final version of data collection tool

Step 5

Validate with incident cases
Test with observers at units

Updated web-based prototype

Step 4

Test with observers

Refine design based on feedback from experts and observers

Step1

Review literature and data collection form from Husch's study

Framework of an observation database

Step2

Define IV medication errors and identify Hospital policy/ drug library with expert consensus (MDs , RNs, RPh, bioengineers, patient safety specialists)

Standard content

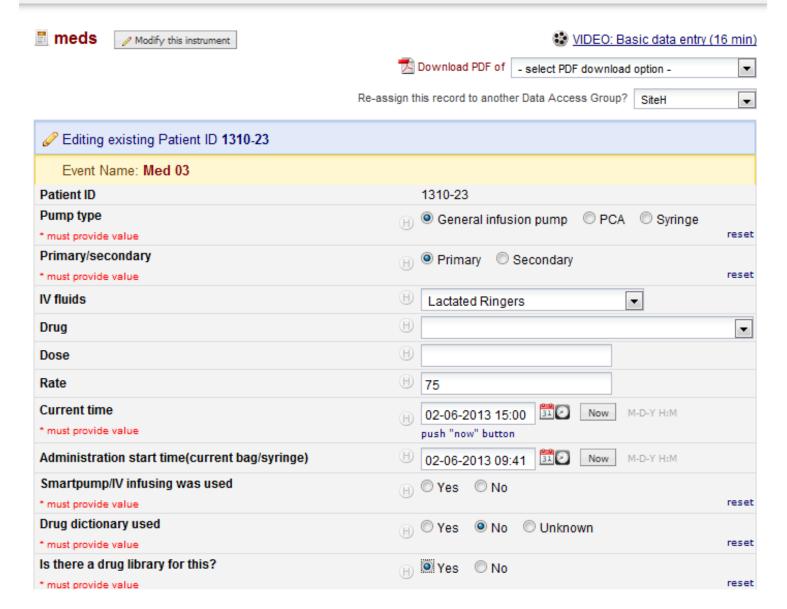
Step 3

Develop the tool into web-based database

Web-based prototype

Redcap Data Collection Form

2. Smart Pump Patients/Meds



Interventions

Smart Pump Safety Intervention Bundle

Labeling/Tubing

A-1: Implement standardized labeling toolkit

Implement Standardized labeling toolkit** that is compliant with the Joint commission standards (large IV, syringes, PCA)

A-2: Implement standardized IV tubing change labels

Implement standardized IV tubing change labels***

Unauthorized Medications

B-1: Implement standardized discontinuation policy

Implement standardized discontinuation policy statement related to: discontinuation of medications within X* min of time the order was discontinued (*each site defined)

Implement alert related to discontinued medications(time critical medications)

Sign off required when medications are discontinued (documentation)

B-2: Implement standardized KVO rates and KVO order sets

Implement standardized policy statement related to KVO rate

Implement standardized KVO rates and KVO order sets

<u>Example standardized KVO rates</u>: Specified in order: following to the ordered rate, Standard rate (Central or peripheral line):10mL/h, Patients with concern about fluid overload:5mL/hr, PICC(Peripherally inserted central catheter) or Mediport:20ml/hr

B-3: Implement standardized verbal orders practice recommendation

Investigate frequency of verbal order at each site Identify verbal order policy at each site

B-4: Implement medication barcode scanning compliance rate report

Implement monthly scanning compliance rate improvement report with individualized (or unit level) feedback

Smart Pump & Drug Library Use

C-1: Implement drug library use compliance report with individual feedback

Implement drug library use compliance report (use of basic infusion mode, override data, per medication/solution data) - Unit level, individual level

C-2: Implement standardized drug library list

Update drug library, minimize drug library list (ex. collapse fluids list, use "IV fluids" for KVO solutions,) or improve search functions

Standardized Labeling Toolkit*

*Compliance with The Joint Commission standard

	Immediate use medications A single medication immediately administers to that	Pa	Patient care Pharmacy prepared prepared		Procedural, Perioperative areas(ir procedure room) Labeling requirements include all medication containers	IV product removed from a medicine cabinets(no medication added on unit) IV solutions are in this category(check 24hr>expiration time medications)	
	patient without any break in the process				,	medications)	
Medication name		1		1	V		
medication strength/concentration		1		$\sqrt{}$	V		
Medication amount(if not apparent from container)	No labeling	1		$\sqrt{}$	V		
Expiration time(if expires< 24 hours)	required	7		√	V	√	
Expiration date		1		$\sqrt{}$	V	V	
Date prepared(if IV bag)		1		$\sqrt{}$			
Diluents(if IV bag and not apparent from container)		1		V	V		
Patient's name				V			
Location for medication delivery				$\sqrt{}$			
Directions for use				$\sqrt{}$			
Cautionary/Accessory instructions(if applicable)				V			

Standardized IV Labels

Medications Prepared on Units Pre-prepared IV solutions

Medication name					
Medication concentration					
Medication amount					
Date prepared**					
Expiration date/time*					
Diluents					

Expiration date_____ Expiration time*____

^{*} If expires<24 hours ** exclude procedural preoperative areas

Standardized IV Tubing Change Labels

	96 hours tubing change label	12 or 24 hours tubing change label
Start date	\checkmark	√
Discard date	√ (preprinted)	1
Time	√	√
RN initial	\bigvee	

Start Thursday on Discard
(Date) | Monday Time (Initial)

I.V. Set Change
Start Date_____ HR___
Discard Date____ HR___
Initial____

Implemented Interventions per Site

*Legend

✓ Implemented	▼ Already in place/implemented
---------------	--------------------------------

Site	В	С	D	E	F	G	Н	l	J
Bundle 1: Labeling/Tubing Implement Standardized labeling toolkit that is						•		•	
compliant with the Joint commission standards	~	▼	▼	~	▼	~	V	▼	V
Implement standardized IV tubing labels	▼		~	/	▼	~	▼	~	/
Bundle 2: Unauthorized Medication									
Implement standardized discontinuation policy statement related to: discontinuation time		V				V	V		V
Implement standardized KVO rates and KVO order sets		•	•	V	V	V		V	
Implement the best verbal order practice recommendation	~	•	•	•	•	V	•	V	V
Implement monthly scanning compliance rate improvement report with individualized (unit level) feedback	•	\		\	•	•	V	*	•
Bundle 3: Smart Pump & Drug Library Use						•			
Implement drug library use compliance report (basic infusion, override data, interview) – Unit level, individual level	•	v		V		V	v	~	
Minimization of drug library (ex. Collapse fluids list, use "IV fluids" for KVO solutions,)Improve search functions									

ResultsCounts and Frequency of Errors

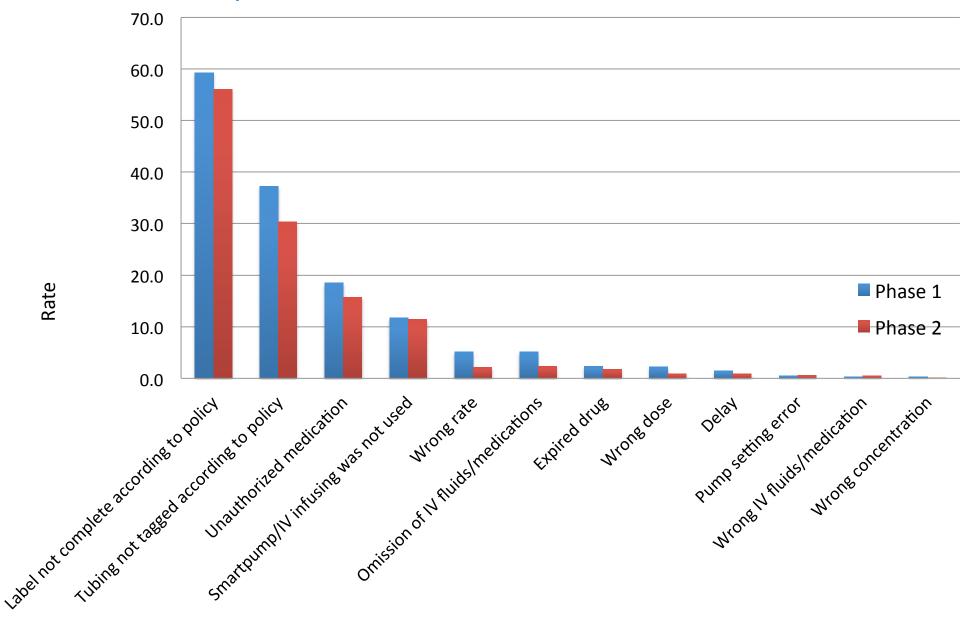
	Pha	se 1	Phas	se 2	р
	N	Rate per 100 meds	N	Rate per 100 meds	
		100 meas		100 meas	
Patients	ents 418		422		
Medications	972		1059		
Total errors	1402	144.2	1296	122.4	<.0001
Serious errors	359	36.9	307	29.0	0.001

Frequency and Type of Errors

Error categories*		Phase 1	Pha	se 2
	n	Rate per 100 meds	n	Rate per 100 meds
Labeling error	576	59.3	594	56.1
Tubing error	362	37.2	322	30.4
Unauthorized medication	180	18.5	167	15.8
Smart pump wasn't used	114	11.7	121	11.4
Wrong rate	50	5.1	23	2.2
Omission	50	5.1	25	2.4
Expired Drug	23	2.4	19	1.8
Wrong dose	22	2.3	9	0.9
Delay	14	1.4	9	0.9
Pump setting error	5	0.5	2	0.2
Wrong IV/medication	3	0.3	5	0.5
Wrong concentration	3	0.3	1	0.1
Total	1540		1296	

^{*}There were no wrong patient and oversight allergy errors

Comparison of the Distribution of Errors

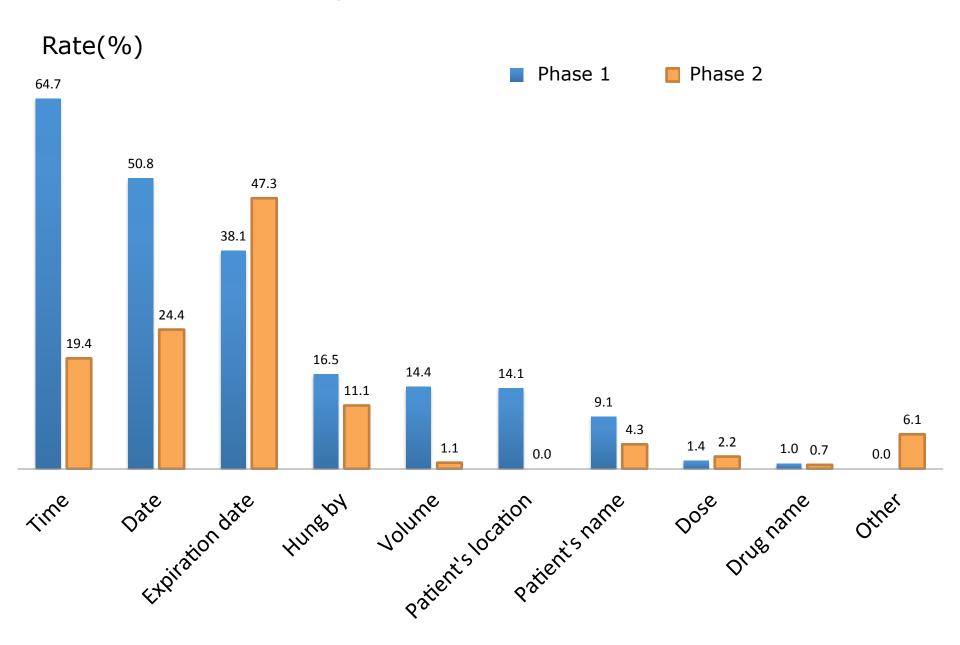


Potential Harm of Errors

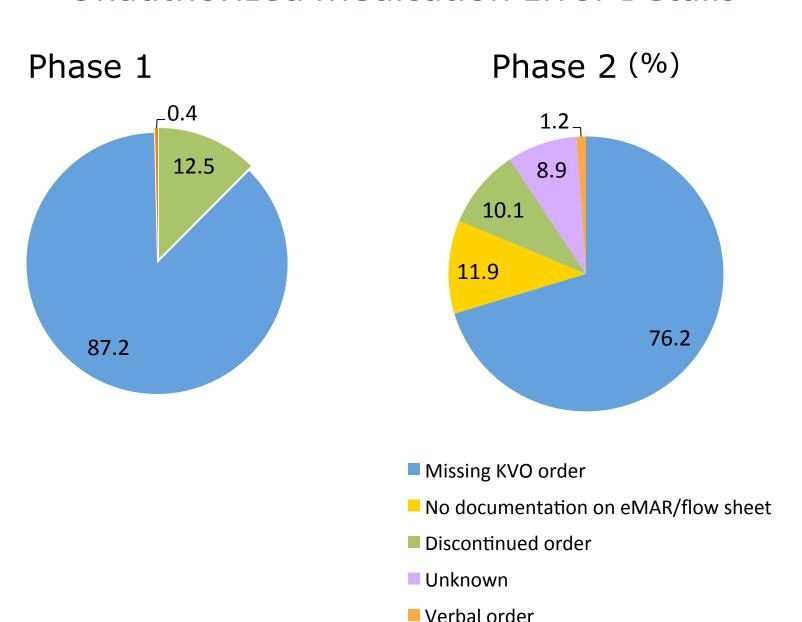
	Pha	se 1	Phase 2		Potential harm (Phase 1 Phase					se 2)	
	N	Rate	N	Rate	F	E		[)	(
Label not complete according to policy	576	59.3	594	56.1						486	466
Tubing not tagged according to policy	362	37.2	322	30.4						330	284
Unauthorized medication	180	18.5	167	15.8					4	129	121
Smart pump/IV infusing wasn't used	114	11.7	121	11.4			1		2	109	107
Wrong rate	50	5.1	23	2.2	1		2	2	1	45	18
Omission of IV fluids/medications	50	5.1	25	2.4			1	1	1	29	21
Expired drug	23	2.4	19	1.8				1	4	19	7
Wrong dose	22	2.3	9	0.8			1			19	8
Delay	14	1.4	9	0.8		1	1			13	8
Wrong IV fluids/medication	3	0.3	5	0.5				3			5
Wrong concentration	3	0.3	1	0.1			1	3			

^{*} No wrong patient or allergy errors were found

Missing Information on IV Labels

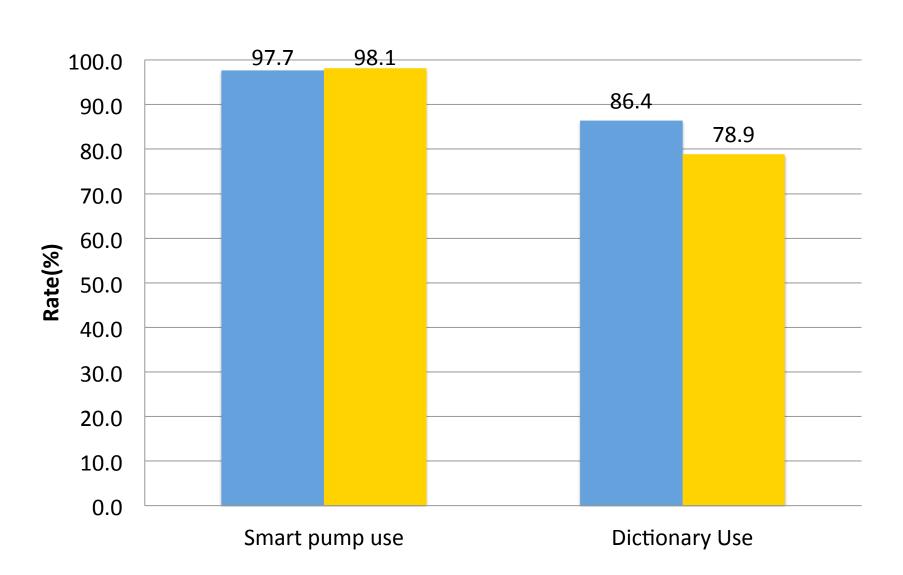


Unauthorized Medication Error Details



Smart Pump Use Compliance Rate

Phase 1/ Phase 2



Example of Unused Drug Library*

IV fluids	
NS	55
Lactated Ringers	9
D5W	4
D5+NS	3 2
D5+1/2Normal Saline	2
D5 1/2NS+KCL20mEq/L	4
D10W	1
1/2NS 100meq Bicarb	1
1/2NS	1
Total	80

IV medication	
DOXOrubicin	1
Piperacillin	1
Sodium phosphate	1
CefTRIAXone	1
Micafungin (Mycamine)	1
TOBRAmycin	1
Sodium phosphate	1
Cefepime (Maxipime)	1
Calcium Gluconate	1
Total	9

Evaluation of Labeling Interventions

		Phase 1		Phase 2	
	N	Rate per 100 meds	N	Rate per 100 meds	P value
Labeling intervention plan					
All errors	900	167.1	798	149.8	0.02
Serious errors	209	40.2	190	34.2	0.09
label not complete according to policy	382	71.6	354	65.8	0.18
Tubing intervention plan					
All errors	647	131.9	657	121.4	0.18
Serious errors	162	30.8	147	29.0	0.58
Tubing not tagged according to policy	214	43.8	209	38.5	0.11
Labeling/tubing bundle plan over all					
All errors	1129	145.6	1064	133.4	0.04
Serious errors	249	31.2	237	30.6	0.81

Evaluation of Unauthorized Medication Interventions

	Phase 1		Phase 2		
	N	Rate per 100 meds	Z	Rate per 100 meds	P value
Unauthorized medication	Unauthorized medication intervention plan				
All errors	1229	158.6	1100	130.2	<.0001
Serious errors	335	43.7	254	29.7	<.0001
Unauthorized medication errors	121	13.3	107	13.3	0.4

Evaluation of Smart Pump Use Interventions

	Phase 1		Phase 2		
	N	Rate per 100 meds	N	Rate per 100 meds	P value
Smart pump use intervention plan					
All errors	1134	168.3	1027	146.5	0.002
Serious errors	294	43.5	253	36.5	0.03
Smart pump/IV infusion					
device not used	104	15.7	107	15.0	0.65

Barriers of Implementing Intervention Plans

Labeling/Tubing	Barriers	Solutions
A-1: Implement standardized labeling toolkit	 Needed involvement of all stakeholders and their decisions (nursing, pharmacy, hospital leadership, etc) 	➤ Work with different department to obtain consensus
	•Needed to consider a process in different areas (prepared by pharmacy dept. vs. nurses)	
	•Some sites required medical label supplier changes	➤ Work with current medical label suppliers to change labels or look for other new suppliers
	Needed to consider comparability with existing medical cabinet systems	➤ Work with medical cabinet system vendors to see if they can auto-print the recommended labels
A-2: Implement standardized IV tubing change labels	 Some sites could not use any color labels due to other existing specific medication labels 	> Use one color or white label
	Require tubing change label supplier changes	➤Work with current medical label suppliers to change labels or look for other new suppliers

Barriers of Implementing Intervention Plans

Unauthorized Medications	Barriers	Solutions
B-1: Implement standardized discontinuation policy	 There was no standardized discontinuation recommendations available in literatures or guidelines 	➤ Each site discussed with stakeholders and picked up the discontinuation time (ranging from 30 min to 4 hours)
B-2: Implement standardized KVO rates and KVO order sets	 There were no standardized KVO rates available in literatures or guidelines. 	Compared all sites' recommended KVO order rates(or coming from nursing manual)
	 Adding KVO order set required a modification of CPOE systems and took a long time 	➤ Work with all stakeholders including system vendors
B-3: Implement standardized verbal orders practice recommendation	 There were no standardized policies or recommendations available even though most sites had their own verbal order practice policy (e.g. limiting verbal order except certain care areas or situations) 	➤ Limit verbal orders as a practice
	 Major reason for verbal order was due to missing/ delay of written orders in CPOE. 	➤ Need to improve an ordering process of medications
B-4: Implement medication barcode scanning compliance rate report	 This intervention was already implemented in most sites and the compliance rate was already high. However, the report data was only unit level, and not individual level. It was hard to use for quality improvement activities for individual level staff education. 	 If the compliance rate is low, should include this intervention It was helpful to work with nursing directors/educators to follow up with individual nurses who had a low compliance rate.

Barriers to Implementing Intervention Plans

Smart Pump & Drug Library Use	Barriers	Solutions
C-1: Implement drug library use compliance report with individual feedback	 The smart pump may not have the capacity to generate a report for this. It would help to see current status of using drug library. 	➤ If there is no capacity to generate a report from a pump, may need to investigate the pump data log or conduct observations to do spot check of drug library use
C-2: Implement standardized drug library list	 The group could not develop a standardized drug library due to different factors(different care setting, medication, available resources) 	
	 Some sites prefer to minimize the list to make it simple whereas others prefer to add more medication lists 	Either minimizing or adding to the drug library helps to avoid manual infusing

Intervention Summary

 Interventions were effective for reducing both error rate overall and serious error rate

1. Labeling Intervention

- Overall error reduction
- No significant reeducation for labeling/tubing compliance rate

2. Unauthorized medication intervention

Significant reduction for both overall and serious errors

3. Drug library intervention

- Overall and serious error reduction
- No significant improvement for use of drug library use

Next Steps

- 1. Develop additional intervention plans
 - Titration practice standard
 - Overfill practice
- 2. International site comparison study
 - UK
 - Canada
 - Finland
- 3. Other areas
 - Pediatrics
 - PCA/PCEA pumps
 - Interoperability smart pumps
- 4. Publish research papers and disseminate the smart pump intervention recommendation plans

Phase 1 study results: Schnock KO, Dykes PC, Albert J, et al. The frequency of intravenous medication administration errors related to smart infusion pumps: a multihospital observational study. BMJ Qual Saf. 2016 Feb 23.

Thank you!

Any Questions?

Definition of Error Type

Error Type	Definition
1. Wrong Dose	The same medication but the dose is different from the prescribed order.
2. Wrong Rate	A different rate is displayed on the pump from that prescribed in the medical record. Also refers to weight based doses calculated incorrectly including using a wrong weight.
3.Wrong Concentration	An amount of a medication in a unit of solution that is different from the prescribed order.
4.Wrong Medication	A different fluid/medication as documented on the IV bag label is being infused compared with the order in the medical record.
5. Delay of Rate or Medication/ Fluid Change	An order to change medication or rate not carried out within 4 hours of the written order per institution policy.
6. Omission of Medication	The medication ordered was not administered to a patient.
7. Unauthorized Medication	Fluids/medications are being administered but no order is present in medical record. This includes failure to document a verbal order.
8. Patient Identification Error	Patient either has no ID band on wrist or information on the ID band is incorrect.
9. Bypassing Smart pump/drug library	IV change label is not tagged per institution policy.
10. Oversight Allergy	Medication is prescribed/administered to a patient with a known allergy to the drug.
11. Smart pump programing/ setting error	Setting programmed into the pump is different from the prescribed order.
12. Wrong information on Label	Applies both to items sent from the pharmacy and floor stocked items per institution policy.
13. Label not complete according to policy	Documented information on the medication label is different from required information per institution policy.
14. Tubing not tagged according to policy	IV change label is not tagged per institution policy.