

The Journey of electronic messages— Patient safety catalyst or information overload

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MEDICINE *of*
THE HIGHEST ORDER



UNIVERSITY *of*
ROCHESTER
MEDICAL CENTER

Objectives

- Review of ePrescribing process and national standards in the medication information sharing process
- Demonstrate the patient safety advantages of electronic information exchange with discontinuation messages and medication history exchanges
- Examples of innovative programs with medication information exchange

Wouldn't it be great if:

We were able to send accurate patient medication information electronically from the provider to the pharmacy and have pharmacists electronically communicate back information to providers about medication therapy management and compliance risk and have it incorporated into patient care on a consistent basis

Examples of hardcopy prescriptions

GENERAL DENTISTRY

NAME: [REDACTED] DATE 7.2.05

ADDRESS [REDACTED] CITY [REDACTED] CALIF.

Rx

Bixin 24 x 500mg tabs

1. B.I.D.

Tylenol II 12 tabs q4h

PRN pain.

REP. _____ TIMES

NE. FEP. [REDACTED]

BNDD No. [REDACTED] _____, D.D.S.

Prescription Sample

TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE
One Finesand Street
Boston, MA 02111
555-969-9996

Name: Jane Doe
Age: 28
Address: 10 Kinsland Street
Boston, MA 02111
Date: 12/03/06

Drug: Amoxicillin 500 mg / capsule
Directions: 500 mg qid x 5 days
Quantity: 20
Refills: 0 (zero)

DEA #: XX55372

Signature:
Print Name:

INTERCHANGE is mandated unless the practitioner
Writes the words "NO SUBSTITUTION" in this space

(c) 2006, Kanchan Ganda, M.D.

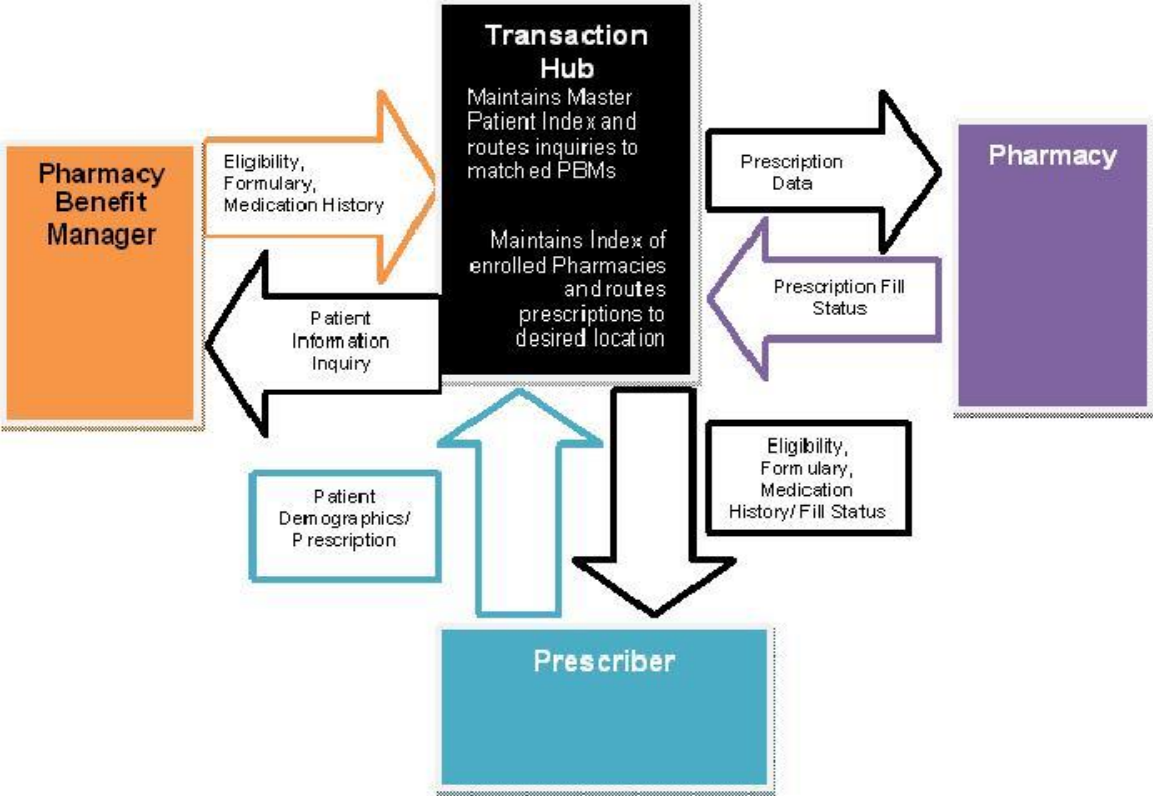
Background

- In 2000 the Institute of medicine reported that medication errors were the most common medical error estimating causing several thousand deaths per year
- Legibility of orders and prescriptions was a leading cause of medication errors and implementation of CPOE and ePrescribing has greatly reduced the legibility issues
- Change Management and training is a huge factor in transitioning from paper to electronic
- Starting in early 2000's, EHR technology incorporated printed prescriptions as a precursor to ePrescribing
- NY state mandated that all prescriptions be ePrescribed including controlled substances by March 2016

Standards

- ePrescribing standards are set through NCPDP- National Council for Prescription Drug Programs
- Requirements on what needs to be in the software requirements on each side (EHR and Pharmacy systems) as well as the bi-directional interfaces specifications
- Effort to streamline and standardize what EHR and Pharmacy software packages will accept and force standardization
- Recommendations but not regulations – no enforcement arm

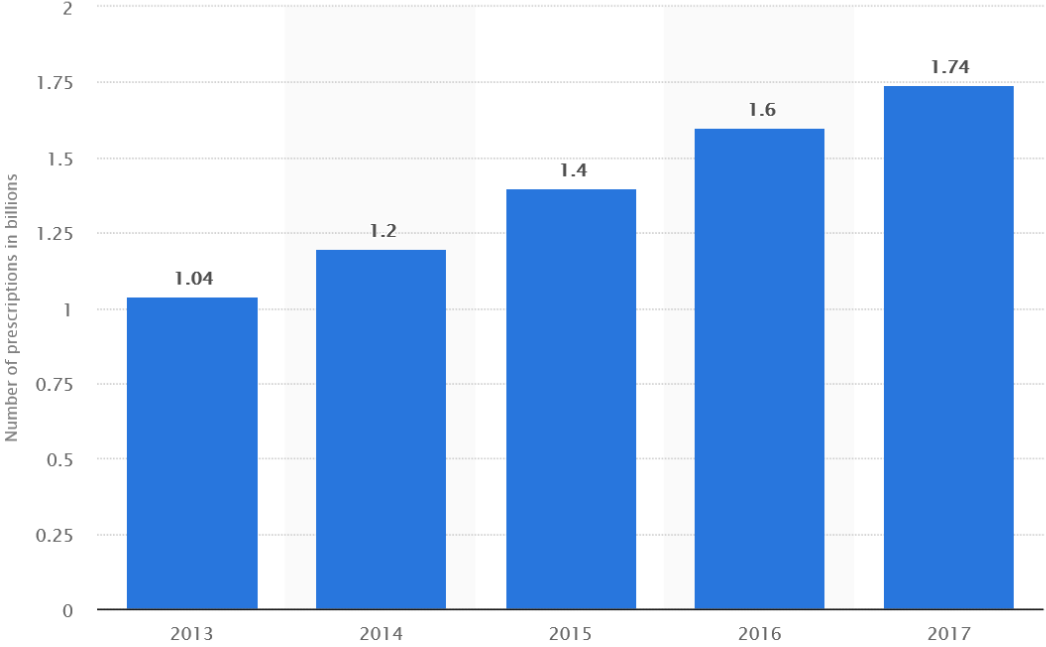
Electronic Prescription Workflow



Benefits of ePrescribing

- Instant notifications of allergies, drug-drug interactions and duplicate therapy while prescribing
- Prevention of medication errors
- Monitor controlled substances prescribing
- Medication Reconciliation ease
- More easily track prescription fulfillment- dispensing data
- Insurance coverage of prescribed is visual
- Improved medication adherence – 10% increase with eRX

Number of e-Prescriptions in the United States from 2013 to 2017 (in billions)



Electronic Prescribing of Controlled Substances

- Mandated by NYS I-Stop Law
in March 2016



JANUARY 2011



MARCH 2016

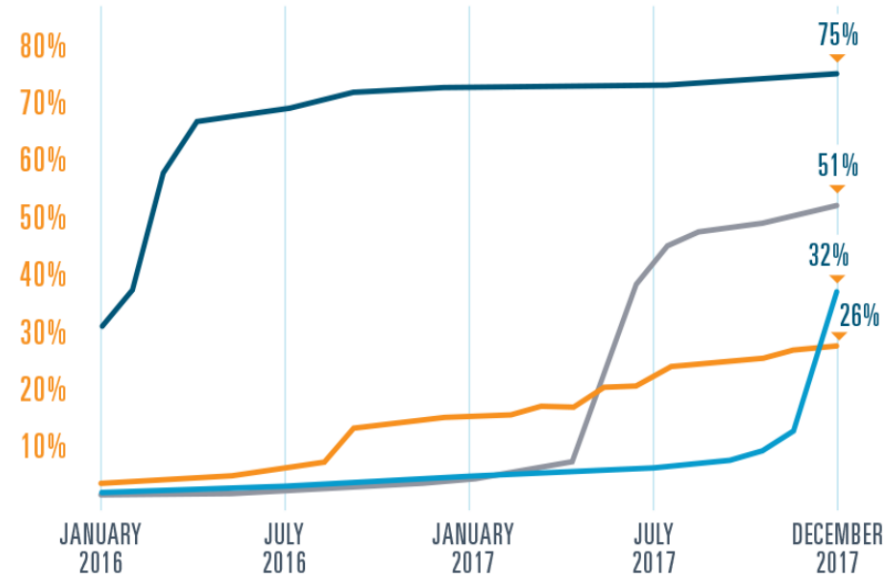


JULY 2017



JANUARY 2018

PRESCRIBER ENABLEMENT IN STATES WITH EPCS MANDATES



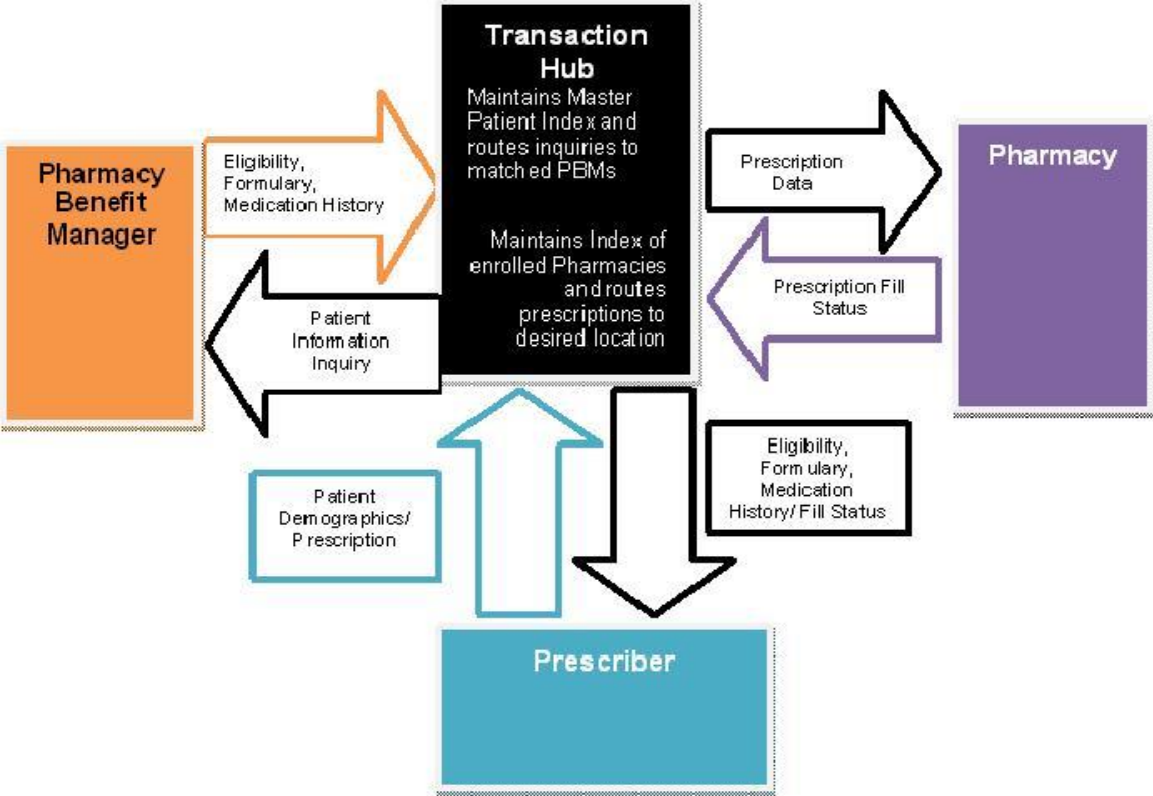
Nuances with ePrescribing messages (NewRX):

- Medications messages must contain an NDC code-
 - Without it there were mis-matches of products- Patient safety
 - Challenges with compounded medications- Need to use the NDC of an ingredient
 - Challenges with DME
- A frequency is not a frequency is not a frequency
 - Translation tables
 - Discrete Sigs

Challenges with ePrescribing correctly

- April 2016 JAMA published study Dhavle and colleagues¹
 - 14.9 % of electronic Rx with free text notes
 - 66.1% contained inappropriate content from which structured data exists in the new standard
 - Almost 20% of these inappropriate notes contained conflicting medication directions (SIGs) from the structured fields intended for this purpose
 - 9.6% were prescription cancellation requests for which separate ePrescribing message exists but is not widely supported on the community pharmacy software side

Electronic Prescription Workflow



Discontinuation of Medication messages

- Improves clinical outcomes and patient safety.
- Simplifies pharmacy and prescriber workflows by eliminating manual processes.
- Saves the time and money of manual processing.
- Strengthens collaboration between pharmacists and prescribers.
- Enhances the patient experience.
- Enables a fully electronic workflow.
- Helps reduce inadvertent duplicate prescriptions.
- Enables electronic changes to treatment course.
- Improves patient safety by ensuring patients pick up only the prescriptions their prescribers intend for them.

Literature review

- Yang et al, Aug 2018 *Journal of the American Medical Informatics Association* looked at 1.4 Million messages and how many New RX messages were really discontinuation messages
- 9735 (0.7% of the total) NewRx messages containing prescription cancellation instructions with 78.5% observed in the Notes field; 35.3% of identified NewRxs were associated with high-alert or LASA medications.
- The most prevalent cancellation instruction types were medication strength or dosage changes (39.3%) and alternative therapy replacement orders (39.0%).
- These findings reveal the need for wider industry adoption of the CancelRx message by electronic health record (EHR) and pharmacy systems, along with clearer guidance and improved end-user training, particularly as states increasingly mandate electronic prescribing of controlled substances

Discontinue messages volume

From January to June 2018,
Surescripts processed

4.4 MILLION

CancelRx transactions

trending towards

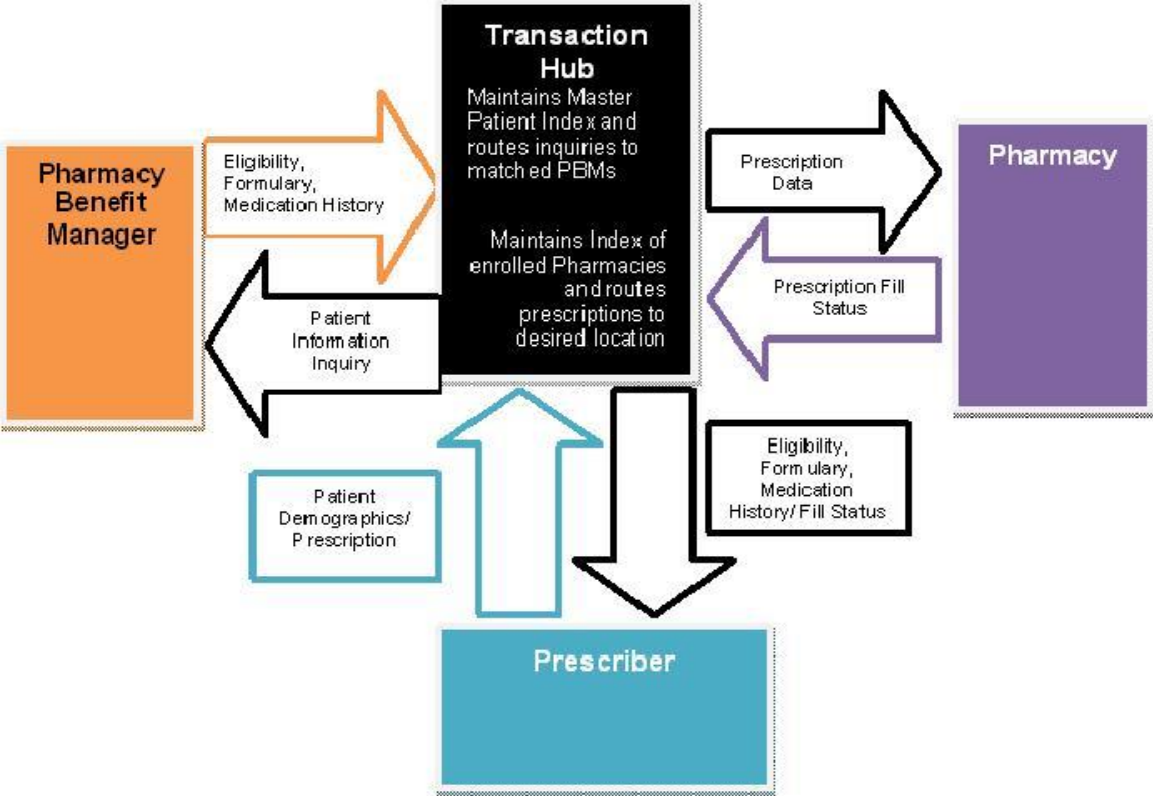
9 MILLION FOR 2018

(A PROJECTED INCREASE OF 137%)

Rochester and Monroe County- DC message project

- Request from providers for years- when can I stop calling the pharmacy on discontinued medications
 - Patient safety
 - Work around and extra work
 - Patient adherence
- Epic (electronic health record)- EHR is now enabled for sending discontinuation messages
- More community pharmacy systems have the ability to accept the messages in a place where pharmacists can use the data
- Working with MCMS and community pharmacies on a communication plan
- As of Sept 1 > 50% of pharmacies can support these messages and are acting on them

Electronic Prescription Workflow



Medication History Information

- Poor communication of information when patients transition levels of care
- Accuracy of medication information is an important piece of patient safety
- Good medication history information from PBM claims and pharmacy dispense data and can result in a decrease in inpatient medication order errors when available and used in the current provider workflow
- Using medication history tools can improve medication adherence

Dataflow for Medication History

How hospitals get electronic medication history using Surescripts



Hospital

- Admit patient and request medication history (MH)

EMR Vendor

- Request/receive MH for specified patients from Surescripts

Surescripts

- Request, receive, and aggregate MH for specified patients from PBMs and pharmacies

PBMs & Pharmacies

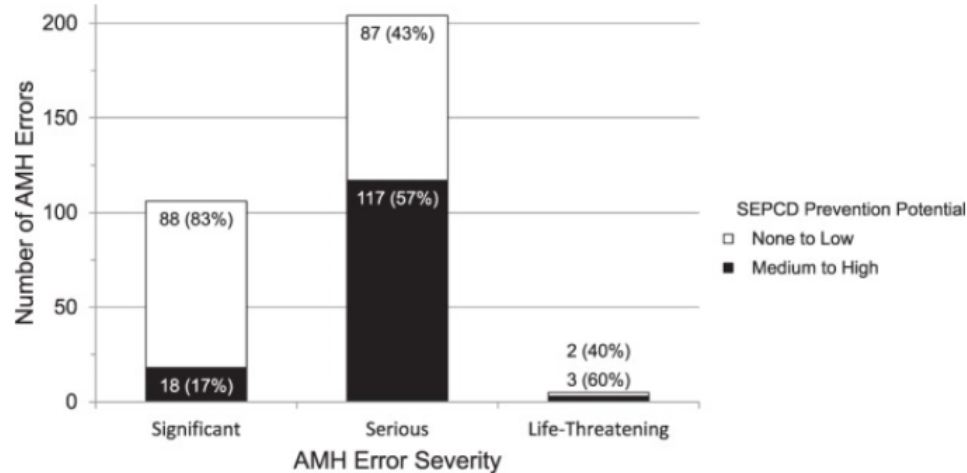
- Pharmacy data latency of 36 to 48 hours
- PBM data is real-time

Medication History Information and Medication error potential

PMC full text: [J Am Med Inform Assoc. 2016 Sep; 23\(5\): 942–950.](#)
Published online 2016 Jan 17. doi: [\[10.1093/jamia/ocv171\]](#)
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<< Prev Fi

Figure 2



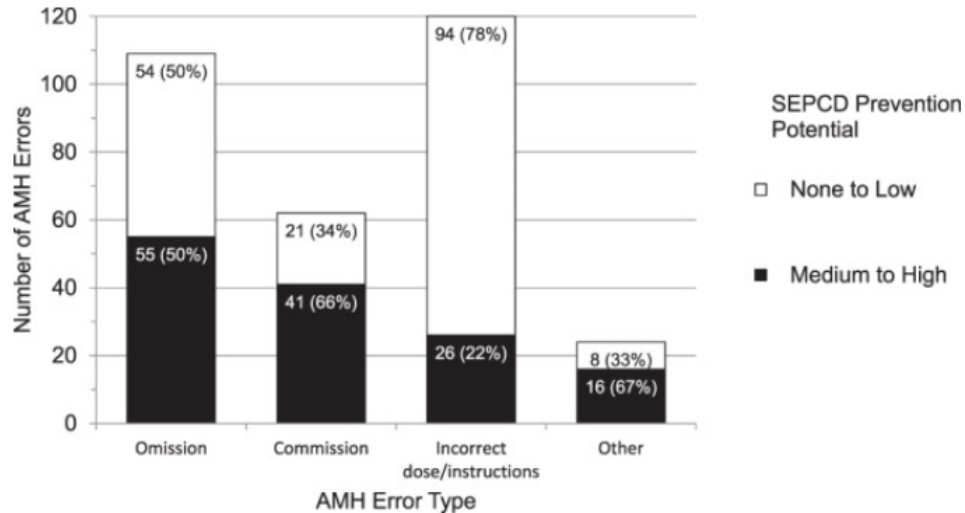
SEPCD potential to prevent admission medication history (AMH) errors by severity.

Medication History Information and Medication error potential

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Figure 4



SEPCD prevention potential of admission medication history (AMH) errors by type.

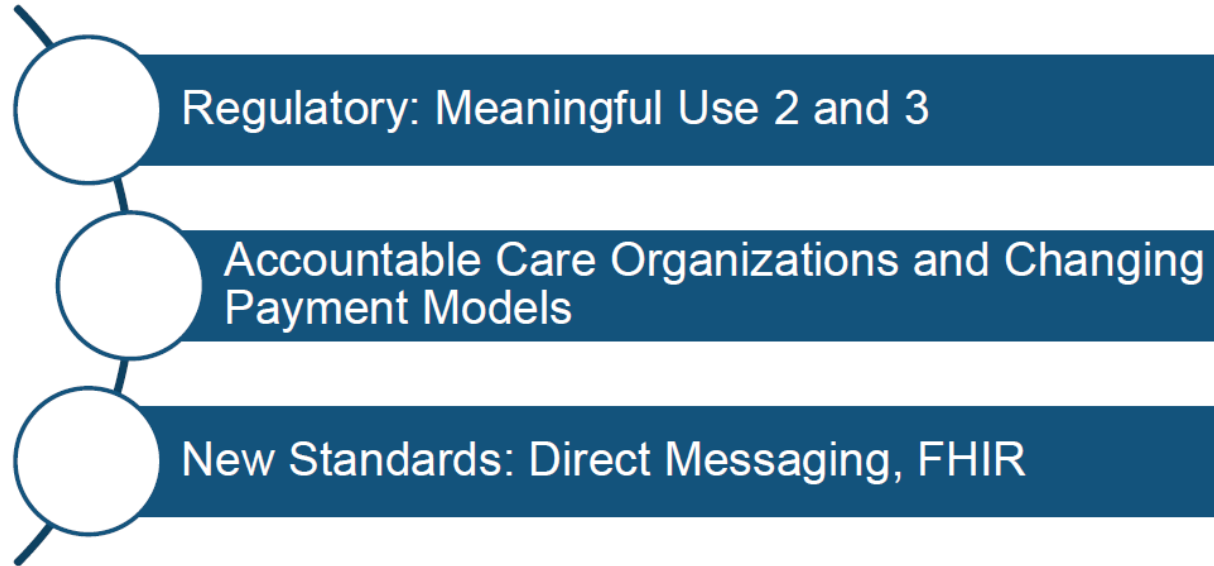
Challenges with Medication History

- Inconsistent Medication History Information
- Pharmacy benefits management (PBM) does not equal pharmacy dispense data
- Change management with workflow with medication history information
 - Accepting information into the record
 - Duplicate information
 - Patient mismatches – no Master Patient index (MPI)

Wouldn't it be great if:

Interoperable drug knowledge (including cross references to RxNorm) is of vital importance to EHR adoption and effective EHR use as it supports the portability of patient medication, immunization, and allergy history among disparate healthcare information systems. Use of interoperable drug knowledge enables clinical information exchange, electronic prescribing, the calculation of clinical quality measures, immunization and medication allergen decision support, and streamlines clinical information reconciliation.

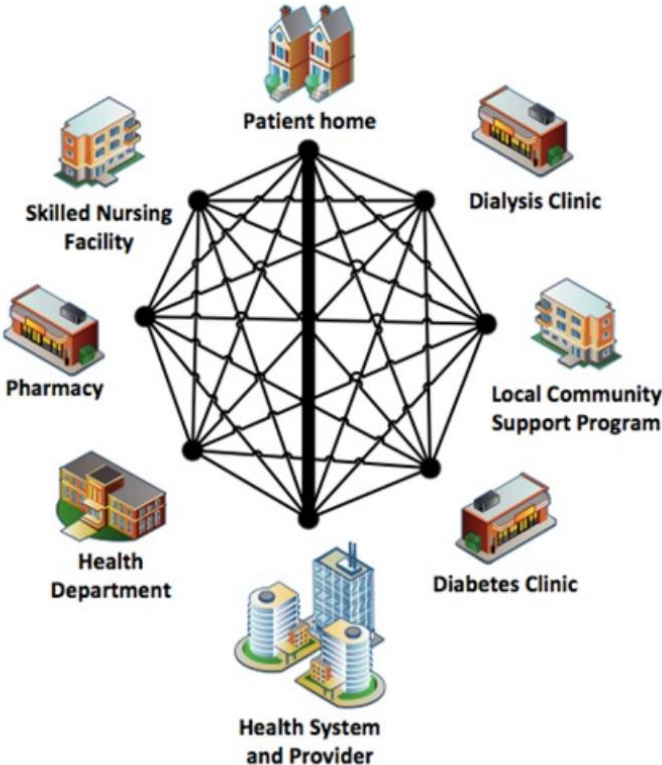
Key Drivers of Interoperability



Medication Adherence and Technology

- In some studies up to 50% of patients with chronic conditions are not compliant with their medication regimen
- Continual patient engagement can enhance medication adherence
- Medication non-adherence is an important public health consideration, affecting health outcomes and overall health care costs
- In addition to traditional methods of patient recall and questionnaires, using patient reminders, social media, patient portal options and patient centered medical home

Interoperability



Innovation with Interoperability

- Telemedicine with pharmacists under medication therapy management protocols engaging with patients and their families
- Heart failure patients with integrated scales that will promote clinical decision support for daily weights changes
- Blood pressure integration through a patient portal and intranet
- Patient refill reminders based on medication history data and notification from data coordinators

Improvement with Text messages

- Prayaga et al looked at non-adherent and partially adherent Medicare patients with chronic disease at Kaiser Permanente Southern California
- 13,000 patients received text messages compared to 76,000 patients who did NOT received TEXT messages from December 2016 to February 2017
- There was a significant difference in medication refill rates between the 2 groups, with a 14.07 percentage points higher refill rate in the text messaging group ($P<.001$)
- Both groups were exposed to refill and adherence reach out including phone calls, secure emails and robo calls

Improvement with Text messages

- Medication refill rates went up 14% among text message users
- It is estimated that 77% of Americans own a smartphone, up from 35% in 2011
- Next study will look at social determinants such as income level, The researchers plan to incorporate interventions that would account for rural dwellers, income and financial issues, or language and cultural barriers
- The team likewise plans on altering the text messaging system for non-English-speakers and those with lower levels of health literacy

New Technology

- Apps can emit a sound when it's time to take a medication, reminding patients when to do so. Oftentimes, patients may not remember if they took a dose or not, but smartphone app alerts eliminate this uncertainty by having tracking functions
- Smart pills are tablets containing tiny ingestible sensors that can detect when a person has swallowed the medication. Built-in Bluetooth technology relays the data to a smartphone app, which can be shared with family, caregivers, and the patient's doctor
- Eye drops in particular have a lower adherence rate, a small sensor installed in an eye drop medication container can detect when the bottle is opened and closed, when drops leave the container, and how many are administered. The sensor integrates with an analytics platform and offers various ways for patients and clinicians to act upon the data.

New technology

- In 2013 the FDA, began regulating apps but even 5 years later there are very few that are fully approved and endorsed HIPPA requirements and sharing patient data is still a major challenge
- Point of service education tools and patient portals are the most common apps that are in the market place
- A combination of inpatient interaction plus technological reminders can lead to both increased medication adherence and an improvement in clinical outcomes at a decreased cost

Questions



References:

1. Dhavle et al. **Analysis of Prescribers' Notes in Electronic Prescriptions in Ambulatory Practice** [JAMA Intern Med.](#) 2016 Apr;176(4):463-70. doi: 10.1001/jamainternmed.2015.7786.
2. Pernik JM et al. **Potential benefit of electronic pharmacy claims data to prevent medication history errors and resultant inpatient order errors.** [J Am Med Inform Assoc.](#) 2016 Sep;23(5):942-50. doi: 10.1093/jamia/ocv171. Epub 2016 Jan 17
3. Surescripts.com
4. Bosworth et al. **Health Information Technology: Meaningful Use and Next Steps to Improving Electronic Facilitation of Medication Adherence** [JMIR Med Inform.](#) 2016 Mar 15;4(1):e9. doi: 10.2196/medinform.4326
5. [Aurel O Iuga](#) and [Maura J McGuire](#) **Adherence and health care costs.** [Risk Manag Healthc Policy.](#) 2014; 7: 35–44.
6. Prayaga et al. **Improving Refill Adherence in Medicare Patients With Tailored and Interactive Mobile Text Messaging: Pilot Study** [JMIR Mhealth Uhealth](#) 2018;6(1):e30



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Improving Medication Safety- The Pharmacy Now and in the Future

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Associate Director of Operations*

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Objectives

1. Introduction to medication error
2. Role of the Pharmacist as part of the solution
3. Role of technology as part of the solution
4. Controlled substances and patient safety
5. The highest risk and the Pharmacy of the future





the healthcare community
medication practices

Acute Care

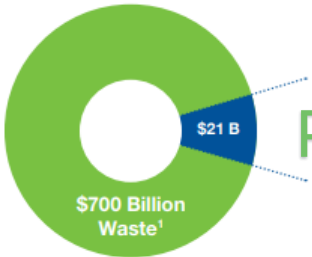
SafetyAlert!



voluntary manslaughter. The pharmacist
faces up to 5 years in prison.

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Prevention of Medication Error Waste

Healthcare Waste ¹



missions and 3.3 million outpatient preventable medication error

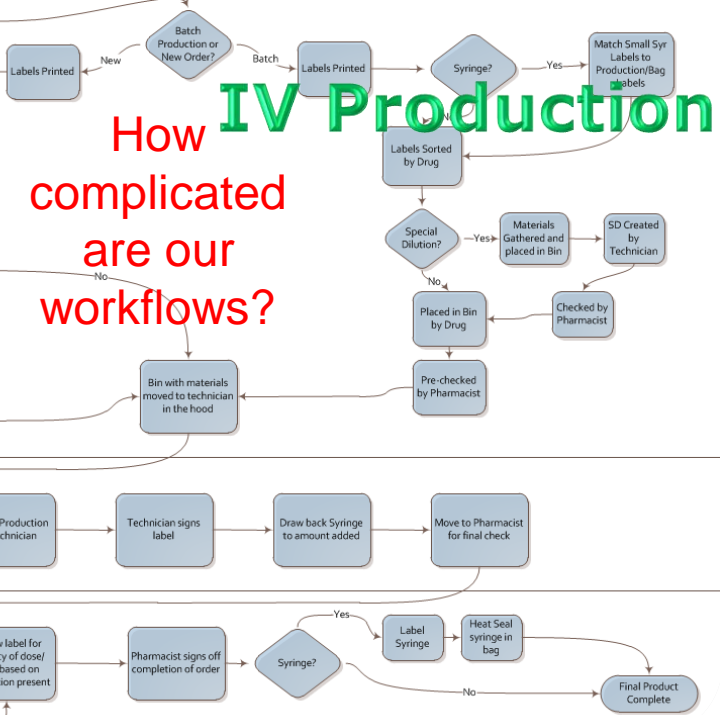
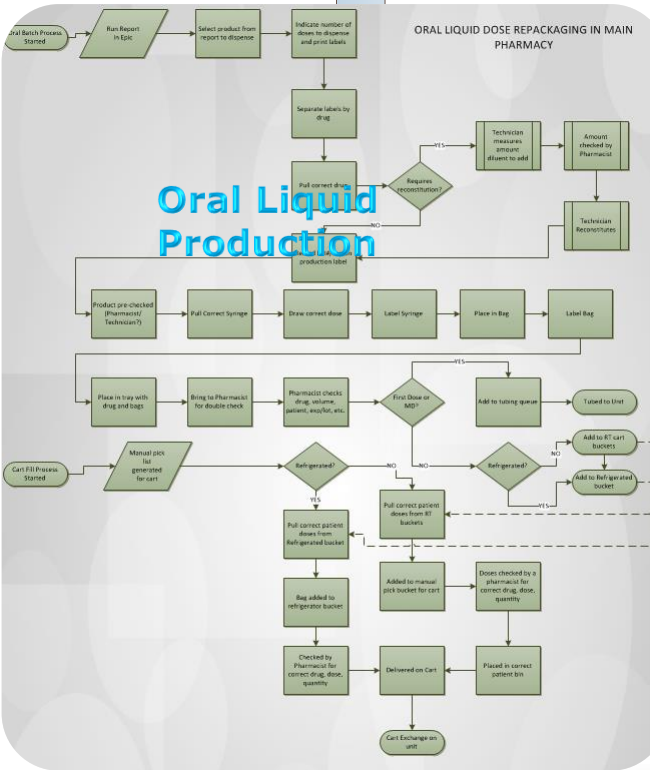
patient and \$4.2 billion outpatient cost of medication errors ³

¹ NEHI. (2008). How Many More Studies Will It Take? A Collection of Evidence That Our Health Care System Can Do Better.

² Massachusetts Technology Collaborative and NEHI. (2008). Saving Lives, Saving Money: The Imperative for CPOE in Massachusetts.

³ Burton, M.M., Hope, C., Murray, M.D., et al. (2007). The cost of adverse drug events in ambulatory care. AMIA Annu Symp Proc, 90-93

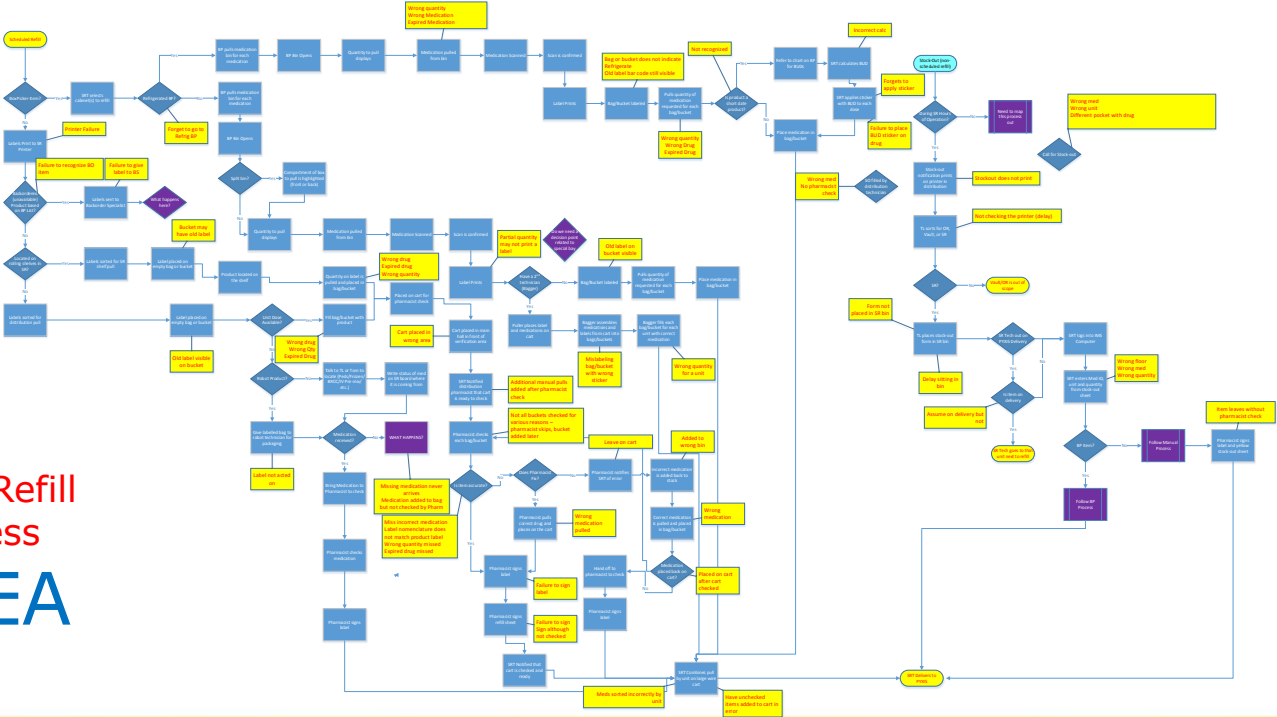
Room Workflow
New Order Received in IV Room (Assume order is accurate and ready to be acted on)



How IV Production are our workflows?



PYXIS Refill Process FMEA





ISMP Medication Safety Alert!® Acute Care ⚡

November 29, 2012 ■ Volume 17 Issue 24

Sterile compounding safety guidelines
ISMP has finalized the **Proceedings from the**

Side tracks on the safety express
Interruptions lead to errors and unfinished... Wait, what was I doing?

PROBLEM: If you're a health professional, and the nurse—who often had a cup of

- Clinical Staff are interrupted once every 2-5 minutes
- Nurses – error risk increases by 12.7% with each interruption
- Errors doubled when interrupted 4 times during drug administration; tripled when interrupted 6 times

ISMP Medication Safety Alert!, January 24th, 2013; Volume 18 Issue 2

response to frequent sterile compounding adverse events reported to the ISMP National Medication Errors Reporting Program and other reporting programs. The ISMP National Medication Errors Reporting Program is a voluntary, confidential, and secure reporting system for healthcare professionals to report medication errors. The program was established in 1995 and is the largest and most active medication error reporting program in the world.

minutes!^{1,2} Physicians are interrupted, too—about once every 5 minutes in an academic emergency department (ED) and once every 2 minutes in an ED. Interruptions are most frequent in the ED, where they occur as often as once every 2 minutes. Interruptions are also common in the hospital ward, where they occur as often as once every 2 minutes.

deferred.¹ When a person forms an intention, their memory establishes a specific cue to remind them to act. If the task is not completed, the person's memory will remind them to act. If the task is not completed, the person's memory will remind them to act. If the task is not completed, the person's memory will remind them to act.



Proprietary Name	Generic Name	Available Strengths	Labeled Dosing Frequency	Labeled Meaning of Suffix ^a	Product Characteristic ^b	Manufacturer
Tegretol XR	carbamazepine extended release	100 mg 200 mg 400 mg	twice daily	Extended release	Modified-dosage formulation	Novartis Pharmaceuticals Corp.
Tenoretic 50	atenolol and chlorthalidone	50 mg/25 mg	Please refer to full prescribing information	Atenolol 50 mg and chlorthalidone 25 mg	Strength of an active ingredient	Astrazenca LP
Tenoretic 100	atenolol and chlorthalidone	100 mg/25 mg	Please refer to full prescribing information	Atenolol 100 mg and chlorthalidone 25 mg	Strength of an active ingredient	Astrazenca LP
Tenzol 3	terconazole	0.8% cream 80 mg suppository	Once daily	3 day treatment	Therapy duration	Ortho-McNeil Pharmaceuticals
Tenzol 7	terconazole	0.8% cream	Once daily	7 day treatment	Therapy duration	Ortho-McNeil Pharmaceuticals
Tevent HCT	epinephrine and hydrochlorothiazide	600 mg/12.5 mg 600 mg/25 mg	Once daily	Hydrochlorothiazide	Other (Inclusion of active ingredient)	Abbott Laboratories
Timetin (ADD)	ticarcillin sodium and clavulanic potassium	3 g/0.1 g Add-Injectage vial	Varies	Unknown	Packaging configuration	GlaxoSmithKline
Toprol-XL	metoprolol succinate	25 mg 50 mg 100 mg 200 mg	Please refer to full prescribing information	Extended release	Modified-dosage formulation	Astrazenca LP
Transderm scop	scopolamine	1.5 mg	One transdermal disc every 3 days	Scopolamine		
Trelzor Depot	triptorelin pamoate	3.75 mg	Once per month	Depot life		
Trelzor LA	triptorelin pamoate	11.25 mg	Once every 84 days	Long act		
Triaminic AM	pseudoephedrine and dextromethorphan	15 mg/75 mg	Every 6 hours	Non-dose		
Tums EX	calcium carbonate	750 mg	As needed	Extra strength		
Ultram ER	tramadol	100 mg 200 mg 300 mg	Once daily	Extended release		
Uro-Mag	magnesium	140 mg	Varies	Magnesium		

Proprietary Name	Generic Name	Available Strengths	Labeled Dosing Frequency	Labeled Meaning of Suffix ^a	Product Characteristic ^b	Manufacturer
Zithromax IV	azithromycin	500 mg per 10 mL vial	Once daily for 2 days	Intravenous infusion	Route of administration	Pfizer US Pharmaceutical Group
Zofran ODT	ondansetron	4 mg 8 mg	As needed	Orally disintegrating tablets	Delivery mechanism	GlaxoSmithKline
Zomig-ZMT	zalmidriptan	2.5 mg 5 mg	Please refer to full prescribing information	N/A	Other	Astrazenca LP
Zyprexa Zydis	olanzapine orally disintegrating tablets	5 mg 10 mg 15 mg 20 mg	Once daily	Orally disintegrating tablets	Delivery mechanism	Eli Lilly and Company
Zyprexa IM	olanzapine for injection	10 mg vial	Once daily	Intramuscular	Route of administration	Eli Lilly and Company

Proprietary Name	Generic Name	Available Strengths	Labeled Dosing Frequency	Labeled Meaning of Suffix ^a	Product Characteristic ^b	Manufacturer	
Once daily	Extended release	Modified-dosage formulation	Novartis Pharmaceuticals Corp.	Once daily	7 tablets in each phase	Therapy duration	Ortho-McNeil Pharmaceuticals
8 hours	Sustained Release	Modified-dosage formulation	Novartis Pharmaceuticals Corp.	Once daily	Low dose	Strength of an active ingredient	Ortho-McNeil Pharmaceuticals
needed	Cold Formula	Other (Formulation)	Wyeth*	needed	Dexamethorphan	Other (Inclusion of active ingredient)	Wyeth*

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Proprietary Name	Generic Name	Available Strengths	Labeled Dosing Frequency	Labeled Meaning of Suffix ^a	Product Characteristic ^b	Manufacturer
Vardenin HFA	sildenafil sulfate	108 mcg per actuation	Every 4 to 6 hours as needed	Hydrofluoroaluminum propellant	Essential	Abbott Laboratories
Vicodin ES	hydrocodone bitartrate and acetaminophen	75 mg/750 mg	As needed	Extra strength	Strength of an active ingredient	Abbott Laboratories
Vicodin HP	hydrocodone bitartrate and acetaminophen	10 mg/650 mg	As needed	High potency	Strength of an active ingredient	Abbott Laboratories
Videx EC	didanosine	125 mg 200 mg 250 mg 400 mg	Once daily	Delayed-release capsules Enteric coated beads	Modified-dosage formulation	Bristol-Myers Squibb
Vielle-dat	estradiol	0.1 mg 0.05 mg 0.025 mg 0.075 mg 0.0375 mg	Twice weekly	Smaller than original Vielle	Other	Novartis Pharmaceuticals Corp.
Vitamin XR	diclofenac sodium extended release	100 mg	Once daily	Extended release	Modified-dosage formulation	Novartis Pharmaceuticals Corp.
Wellbutrin SR	bupropion hydrochloride extended release	50 mg 100 mg 150 mg 200 mg	twice daily	Sustained release	Modified-dosage formulation	GlaxoSmithKline
Wellbutrin XL	bupropion hydrochloride extended release	150 mg 200 mg	Once daily	Extended release	Modified-dosage formulation	GlaxoSmithKline
Xanax XR	alprazolam	0.5 mg 1 mg 2 mg 3 mg	Once daily	Extended release	Modified-dosage formulation	Pfizer US Pharmaceutical Group

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ISMP Medication SafetyAlert!® Acute Care

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December 18, 2008 ■ Volume 13 Issue 25

SafetyBriefs

ISMP will provide expert analysis for MEDMARX. ISMP has entered into a collaborative agreement with Quantros to provide ongoing analysis of MEDMARX data to identify opportunities to guide medication-centric interventions and best practices. Under this agreement, Quantros and ISMP will work together to disseminate key findings. MEDMARX, operated by Quantros, is a national, commercial, Internet-accessible database that hospitals and healthcare systems use to track and trend adverse drug reactions and medication errors. The program was formerly operated by USP; however, the standards setting organization made a decision recently to focus full attention and resources on its core standards setting activities. USP has also transferred the Medication Errors Reporting Program (MERP) to ISMP (formerly known as the USP-ISMP Medication Errors Reporting Program). We are pleased to accept these new responsibilities and remain fully committed to working closely with FDA, USP, the medical products industry, healthcare providers, and consumers to affect changes in



Color-coded syringes for anesthesia drugs: use with care

Chances are you have seen ads, or may even be using, color-coded syringes containing anesthesia drugs that are available from major repackaging companies such as PharMEDium, Ameridose, CAPS, and others (Figure 1). The companies have been marketing them for about a year, and they're now in demand by anesthesia providers who previously had to prepare and label all drug syringes themselves. But



Figure 1. Color-coded syringes (Ameridose ad).

a word of caution: we are concerned about risks associated with using these color-coded syringes unless certain actions are taken to prevent syringe mix-ups that could prove harmful to patients.

For many years, rolls of color-coded labels have been available to anesthesia providers. The colors are based upon an American Society for Testing and Materials (ASTM) standard for user-applied labels in the operating room (OR) (ASTM D4774-06

Standard Specification for User Applied Drug Labels in Anesthesiology). The colors aren't used just to differentiate products; they are used to specify a particular drug class. Labels are blue for all opiate 2 on page 2), fluorescent red for nitrular blockers, yellow for in agents, orange for tran violet for vasc green for ant gics, and so

We have p this color-codin for user-appliea among anes the

divers. But the color-coding system was not designed for commercial product labels. ISMP, ASHP, and pharmaceutical company scientists have opposed color-coding of commercial pharmaceutical products. The American Medical Association (AMA) is also opposed to it, testifying before the FDA in 2005 that scientific research is needed to determine whether such a system is safe (www.fda.gov/CDER/meeting/part15_3_2005/Transcript.pdf).

continued on page 2 ▶

Educating the healthcare community about safe medication practices

A federally certified Patient Safety Organization

©2013 Institute for Safe Medication Practices

ISMP Medication SafetyAlert!® Acute Care

June 13, 2013 ■ Volume 18 Issue 12

NANALERT

ISMP and the American Society of Health-

Independent double checks: undervalued and misused
Selective use of this strategy can play an important role in medication safety

Proven Practice:

- Including pharmacist on routine rounds reduced errors by 78%¹
- Adding a pharmacist to ICU rounds decreased costs by \$270,000 annually²
- Pharmacist follow up call with patients resulted in 88% fewer preventable medication errors leading to ED visit or hospitalization³

¹ Kucukarslan, S.N., Peters, M., Mlynarek, M., et al. (2003). *Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medicine units.* *Arch Intern Med*, 163(17), 2014-2018.

² Leape, L.L., Cullen, D.J., Clapp, M.D., et al. (1999). *Pharmacist participation on physician rounds and adverse drug events in the intensive care unit.* *JAMA*, 282(3), 267-270

³ Schnipper, J.L., Kirwin, J.L., Cotugno, M.C., et al. (2006). *Role of pharmacist counseling in preventing adverse drug events after hospitalization.* *Arch Intern Med*, 166(5), 565-571.

Nicole M. Acquisto, Pharm.D.

Emergency Medicine Clinical Pharmacy Specialist
University of Rochester Medical Center
Rochester, NY

The Outcomes of Emergency Pharmacist Participation
during Acute Myocardial Infarction

The Pharmacist

	Median Door-to- balloon time (IQR, min)	Median Adjusted door/ECG-to- balloon time (IQR min)	Median Adjusted door/ECG-to- CCL time (IQR min)	p-value*
EPh present (n=68)	59 (48-82)	59 (48-71)	22 (15-36)	<0.001
EPh not present (n=52)	87 (62-116)	77 (59-93)	40 (30-56)	
CCL present (n=52)	58 (45-82)	55 (44-70)	20 (13-35)	<0.001
CCL on-call (n=68)	86 (65-112)	76 (62-92)	38 (32-54)	
Arrival by EMS (n=87)	64 (50-84)	61 (50-78)	29 (16-40)	<0.001
Arrival by self (n=33)	107 (94-134)	89 (71-98)	45 (34-58)	

* Mann Whitney Rank Sum

	EPh (n=53)	No EPh (n=67)	p-value*
All events	11 events (9 patients)	37 events (30 patients)	P=0.002
ADEs	2 events (2 patients)	5 events (2 patients)	P=0.6
PADEs	5 events (4 patients)	21 events (18 patients)	P=0.01
Total med errors (inc PADEs)	6 events (1 patient)	23 events (20 patients)	P=0.01
Problem drug orders	3 events (3 patients)	6 events (6 patients)	P=0.6

*Chi-squared analysis

Technology



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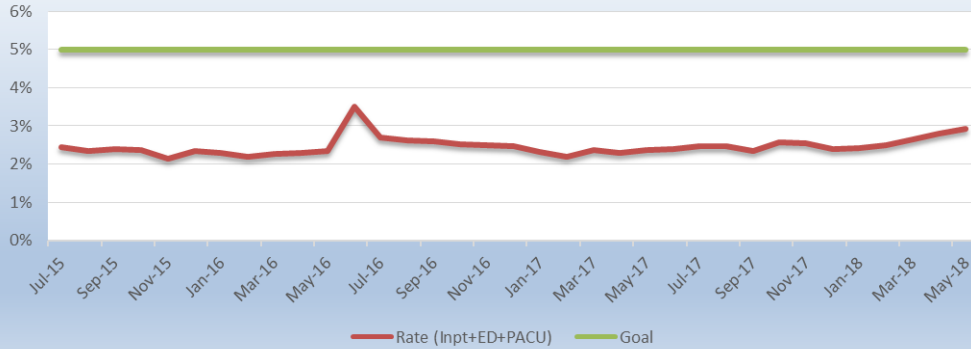




ADCs



Override Rates



Current technology at SMH includes robotic unit dose packaging and product selection directly from eRecord interface



As of May, 2018

20,470,271

Doses dispensed to patients with 0 incorrect selections

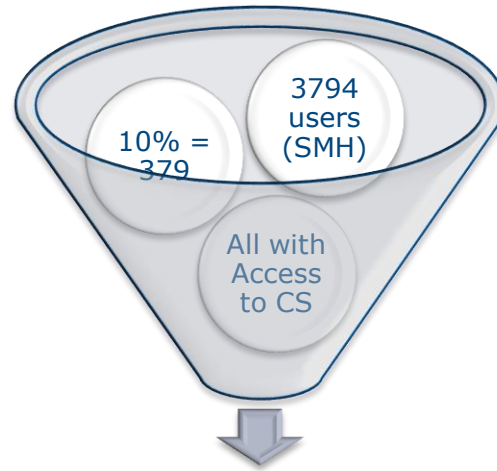
Perfect?



Controlled Substances

Incidence of drug/alcohol abuse

- Health care professionals – 10%-15%* depending on source



Diverters?

Diversion occurs in health care facilities every day

Statistics on Health Care worker diversion unknown (undetected and under-reported)

*2014 National Survey on Drug Use and Health by the Substance Abuse and Mental Health Services Administration

Consequences of Diversion – Who does it affect?

Patient

- Safety
- Infection risk
- Under-medicated

Individual Diverter

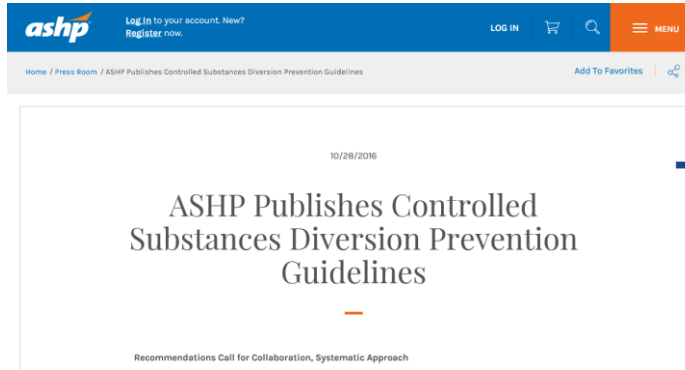
- Health
- Personal life
- Legal implications
- Professional/job implications

Co-Workers

- Take on additional burdens
- Peer pressure of reporting friends

Society

- Proliferation of addiction
- Proliferation of criminal activity



Controlled Substances

Taking Action

1 – Establish Oversight Structure

2 – Establish Best Practices

3 – Implement Modern Tools

**Controlled Substance Surveillance and Prevention Team
(CSSPT)**

Controlled Substance Surveillance and Prevention Team (CSSPT)

CSSPT Committee

CSSPT Team

- Program Leader (e.g. Pharmacy Compliance Officer)
- Analysts
 - Pharmacy, Nursing, other?

Support

- SP/Pharmacy Managers
- Nursing/Program Managers
- Compliance/Legal
- Others prn (e.g. IC, PR, etc.)



Best Practice Strategies

Focus on high-risk areas

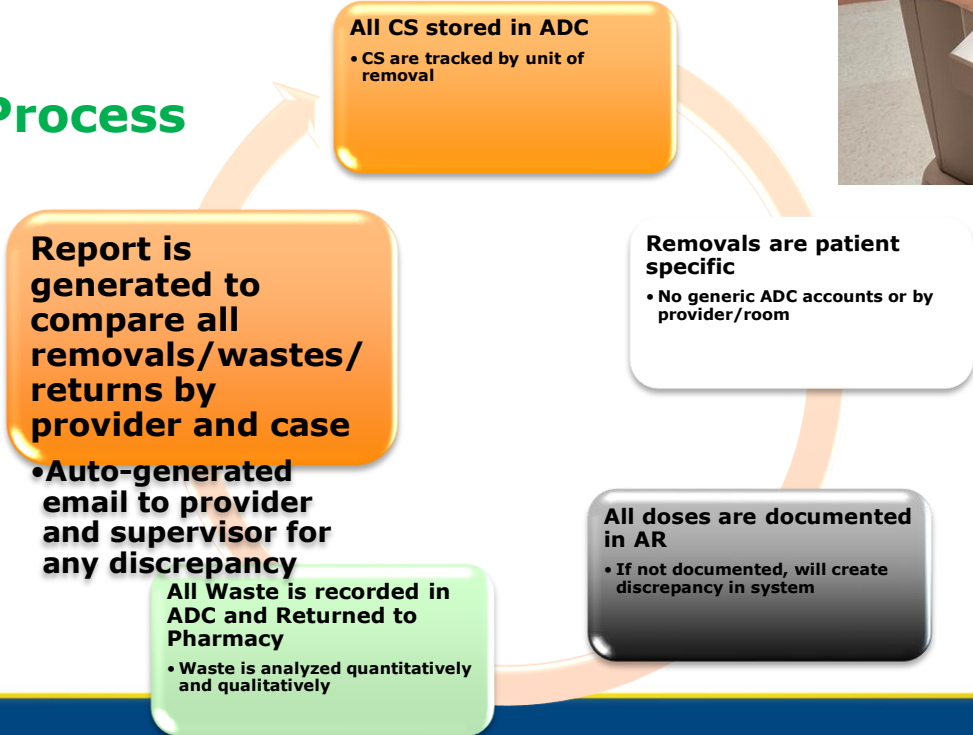
- ED
- OR

Focus on high-risk processes

- Compounding
- Waste
- Re-packaging

Best Practice Strategies

OR/Anesthesia Process



Controlled Substances



Strategies - Monitoring and Auditing

Evidence based indicators with detailed reports

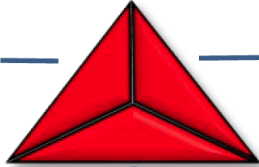
Prioritize potential diversion investigations

Strategies - Monitoring and Auditing

Controlled Substances

Drug Audit (Station Level)

- ✓ Specific user comparison
- ✓ Station groups are important
- ✓ Group stations / users / medications



Drug Audit (Hospital Wide)

- ✓ All user comparison
- ✓ Group stations / users / medications
- ✓ Risk associated with floaters

Daily Average Drug Audit (Station Level)

- ✓ Specific user comparison
- ✓ Group stations / users / medications
- ✓ Shifts 7:00AM – 7:00PM / 7:00PM – 7:00AM

High Risk



Moderate Risk



Low Risk



RxDiversion Index: Total Count

February 2017



Statistical Outliers By Station

5.0 or Greater Units of Standard Deviation Above Mean

Station	Med Group	User Name	Count	Mean	Assurance Metrics					
					UAM	% TDC	TriageRx	TrendRx	ProjectRx	
	Morphine		40.26	3.887	8.691	4.245%	▲	—	8.69	—
	Morphine		31	3.905	7.119	3.138%	▲	—	7.12	—
	Benzodiazepine		26	2.630	6.922	10.744%	▲	—	6.92	—
	Fentanyl		29	2.235	6.636	25.439%	▲	—	6.64	—
	Hydromorphone		77	11.701	6.170	1.970%	▲	—	6.17	—

4.0 - 4.9 Units of Standard Deviation Above Mean

Station	Med Group	User Name	Count	Mean	Assurance Metrics					
					UAM	% TDC	TriageRx	TrendRx	ProjectRx	
	Oxycodone		103	17.561	4.993	1.531%	▲	—	4.38	4.99
	Methadone		38	5.129	4.908	7.336%	▲	—	—	4.91
	Morphine		24.33	3.887	4.885	2.565%	▲	—	—	4.88
	Morphine		24.27	3.887	4.870	2.559%	▲	—	3.54	4.87
	Morphine		25	3.318	4.844	17.123%	▲	—	—	4.84
	Oxycodone		100	17.561	4.818	1.487%	▲	3.47	—	4.82
	Morphine		22	3.905	4.754	2.227%	▲	—	—	4.75
	Hydromorphone		39	7.658	4.689	1.726%	▲	—	—	4.69
	Hydrocodone		75	4.130	4.677	8.380%	▲	—	—	4.68



Diversion Detection Process



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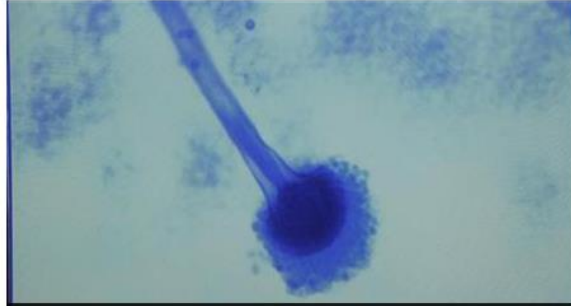
Strategies - Prevention

- Education
- Transparency
- Learn and adapt

What is the highest risk process in hospital pharmacy?

Insight: Red flags ignored for years at firm in meningitis crisis

Recommend 108 people recommend this.



A sample of *Aspergillus fumigatus*, the first fungus diagnosed in the fungal meningitis outbreak sweeping the United States, in Nashville, Tennessee on October 19, 2012. Credit: Reuters/Harrison McClary

By Toni Clarke and Sharon Begley
BOSTON | Fri Oct 26, 2012 3:41pm EDT

(Reuters) - A cracked vial here, a missing label there. The complaints coming into New England Compounding Center, the firm at the heart of the deadly U.S. meningitis outbreak, were piling up.

The complaints coming into New England

Compounding Center, the firm at the heart of the

The complaints coming into New England

(Reuters) - A cracked vial here, a missing label there:

The complaints coming into New England

(Reuters) - A cracked vial here, a missing label there:

The complaints coming into New England

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Pharmacy linked to meningitis shipped drugs before sterilization

Sterile Compounding Risks

Acute Care

ISMP Medication Safety Alert®

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20

Also, please use this tragedy as an opportunity to thoroughly examine the entire pharmacy IV admixture process. Although details of the pharmacy-related incident haven't been made public, there is little doubt that IV workflow technologies would have prevented this type of medication error. Now is the time for hospital leadership to support the acquisition of IV workflow technologies that utilize barcode scanning of products during pharmacy IV admixture preparation. Systems like DoseEdge, ScriptPro, BD Cato, and others that utilize barcode scanning support can assure proper drug selection, but only if the systems are fully integrated with the pharmacy and hospital information systems. Without full integration between the IV workflow technology and the order entry system, errors can still be introduced into the process. Although some hospitals have chosen to limit use of these systems for focused areas like admixture of chemotherapy or high-alert drugs, there's no telling when someone might accidentally introduce a high-alert drug when preparing other drug classes that wouldn't ordinarily be scanned. Therefore, to be maximally effective, the system must be utilized for all compounded admixtures.

ISMP Medication Safety Alert, December 18th, 2014; Volume 19 Issue 25

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UR
MEDICINE

Sterile Compounding Risks

January 15, 2015 ■ Volume 20 Issue 1

Acute Care

ISMP Medication *Safety Alert!*[®]

Educating the Healthcare Community About Safe Medication Practices

Technology and error-prevention strategies: Why are we still overlooking the IV room?

Harmful or fatal errors that have occurred when compounding sterile intravenous (IV) preparations in the pharmacy—including simple IV admixtures—have been fodder for headline news during the past decade.¹The 2012 meningitis outbreak that led to the death of 64 people from contaminated epidural solutions prepared by the New England Compounding Center (NECC) will long be remembered. There has been no shortage of sterile compounding errors in hospital pharmacies, either—from the accidental chemotherapy compounding error 9 years ago that claimed the life of 2-year-old Emily Jerry and eventually sent pharmacist Eric Cropp to jail, to the recent December 2014 compounding error in which a rocuronium infusion was prepared and dispensed instead of a fosphenytoin infusion, leading to the death of a 65-year-old woman.



Current State of Sterile Compounding

which put patients at risk. For example, our investigators observed that your operators processed sterile drug products wearing non-sterile gowns and gloves, with exposed wrists and nose, and using poor aseptic technique, such as **picking items up from the floor and continuing to process without changing gloves or sanitizing their hands**. In addition, your firm failed to use a sporicidal cleaning agent to disinfect the clean

Also, **multiple bacterial and fungal species were found in several locations within one of your firm's ISO Class 5 laminar flow hoods** and the ISO Class 7 clean room where you compound sterile drugs. These products are

serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, our inspection found your **facility was not physically designed and environmentally controlled to minimize airborne contamination, and the ISO 5 hood was located in an unclassified area. This area had no HEPA filters, no air pressure differentials**, and the "sterile product compounding room" and the "ante room"

2013 2014 2015 2016 2017 Partial

products, which put patients at risk. For example, during the inspection, we found personnel engaged in aseptic operations with exposed skin and hair, jewelry, **holes in gowns, and in-ear headphones hanging outside of the gown**. We also observed that supplies and equipment were not routinely disinfected prior to their placement within the ISO-5 areas, and staff did not routinely disinfect gloved hands after handling non-sterile items and prior to resuming sterile production. In addition, our inspection found multiple complaints of

The Risks of IV Compounding

Sterile compounding: Pharmacy profession should take back control

The recent USA Today article on hospital IV outsourcing and the ongoing patient safety problems it creates for hospitals and the communities they serve is one more call to action for our profession. The concern is that we have not been engaged enough in demanding safety measures or proposing counter measures to outsourced IV compounding.

It has been 2 years since the New England Compounding Center disaster, and yet patients continue to be harmed by contaminated sterile products produced by an industry that exists in the gray zone of regulatory oversight and control.

The USA Today report highlighted the latest in a continuing succession of quality problems—this time at Specialty Compounding in Texas, which resulted in two deaths and numerous patients sickened due to contaminated products. More importantly, the report reinforced that legislative attempts at control aren't the only solution. FDA had inspected Specialty Compounding about 5 months before the patients received the contaminated products and identified numerous and significant quality problems that were detailed in a formal FDA "483" report. Obviously, follow-up was insufficient at best. Furthermore, during inspections of 150 compounding centers, the FDA found 80% of them had safety and sanitary problems that warranted corrective action. Just in the past year, 28 warning letters have been issued.

We can't accept these conditions. It is time for the pharmacy profession to stand together and take back control of sterile compounding.

We all know that sterile compounding is challenging. It is one of the highest risk areas of pharmacy practice, and yet it has little technology to support safe compounding. Bar code medication preparation is used in less than 10% of hospital clean rooms, and



only about one-third of hospital pharmacy directors report that they are truly USP <97>-compliant. Since most hospitals and health systems have been unable to meet increasing IV output demands without significant investments in facilities and personnel, it's understandable how outsourcing would seem to be a viable option. The American Society of Health-System Pharmacists has developed comprehensive standards for outsourcing, but these are challenging to adopt, and unfortunately it comes at great cost.

Pharmacy needs to continue to build a safer medication system for our patients and staff. Fortunately, technology is catching up with our needs in the IV room. Workflow technologies are available that incorporate bar code scanning of the medications and diluents entering the IV compounding process. Bar code-enabled IV compounding should be the standard rather than the exception, and gravimetric dose verification must be integrated into our admixture processes to ensure accuracy of the end product.

With the recent advances in total robotic IV compounding technology, it is time to evaluate compound-

ing robots. Peer-reviewed studies have shown that robotics-based IV automation solutions can support in-house compounding by helping pharmacists and technicians to more safely and efficiently produce IV medications, while reducing errors, increasing throughput, and lowering costs associated with IV compounding and dispensing through risk reduction. Robotics and supportive technology provide a new standard in aseptic compounding as well.

For the first time in decades, there are now tools that can help us automate our IV rooms, along with other areas of our pharmacy, and provide the level of safety and productivity we need to take back control of our IV compounding.

It is our responsibility to rise to the challenge. Accountability is something we cannot outsource.

MORE ONLINE

■ USA Today article: www.usatoday.com/story/news/nation/2014/10/07/compounding-pharmacy-realizes-implications-contamination/76472741/

David Webster, BSPharm, MSBA, Associate Director of Pharmacy Operations, University of Rochester Medical Center, Rochester, NY (dave_webster@umc.rochester.edu)

The Letters column of *Pharmacy Today* provides a forum for APiA members and other readers to discuss current events in pharmacy and health care and comment on articles and columns published in the magazine. Letters should be limited to 250 words in length and are edited and published at the editor's discretion. Send letters to mpose@aphanet.org.

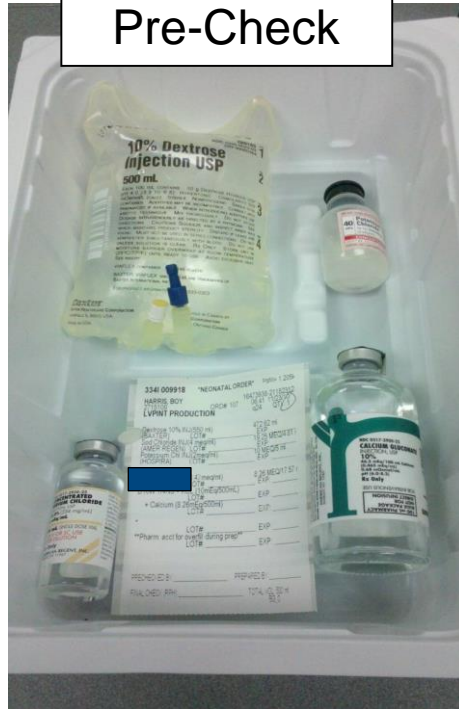
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MARCH 2015 • Pharmacy Today 7

It is our responsibility to rise to the challenge. Accountability is something we cannot outsource.

The Highest Risk

Pre-Check



Post-Check



The Future...Now



Common option
in pharmacy
information
systems or 3rd
party workflow
systems



Common for 3rd
party workflow
systems



Not common in
systems as an
integrated
feature

Decision path at URMC to IV Room Technology

- System needs to deliver **core needs, automated or manual**
 - All sterile compounded products **must incorporate bar code scan** verification of correct ingredients
 - Digital image capture should be available to enhance check processes
 - All sterile compounded products **must incorporate gravimetric checks** for accuracy (where possible)
 - Workflow must be managed through a central hub for distributing tasks
 - Must have integration to eRecord (Epic)
- Space constraints and expandability
- Diverse product line including incorporation of high-hazard production

The Future...Now



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The Future...Now

i.v.SOFT®

The Workflow Engine for the
I.V. Room of the Future



i.v.STATION®

The 2nd Generation Robot for Compounding
Non-Hazardous IV Preparations

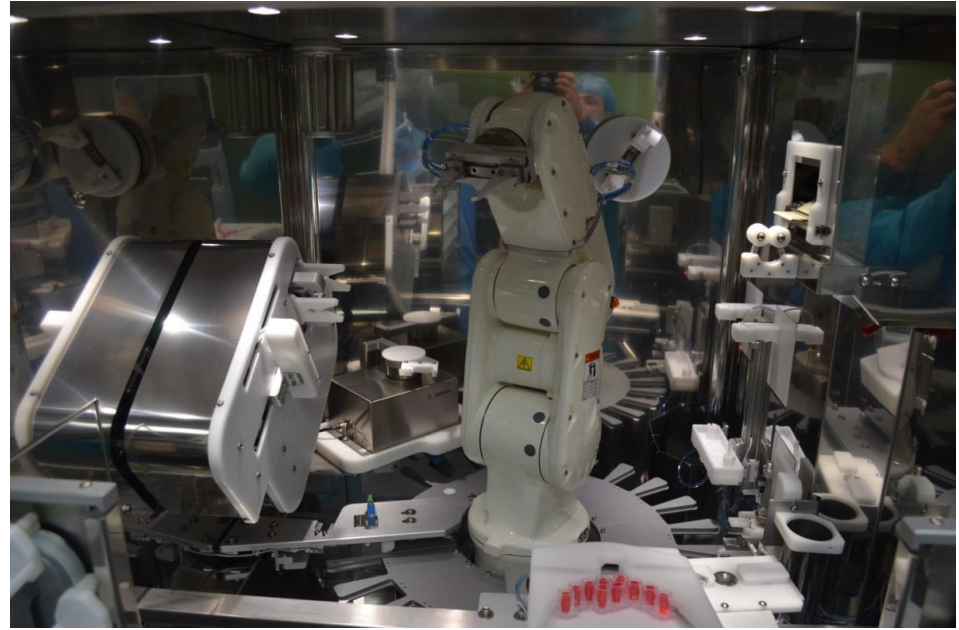


i.v.STATION® ONCO

The 2nd Generation Robot for Compounding
Oncology Sterile Preparations



The Future...Now



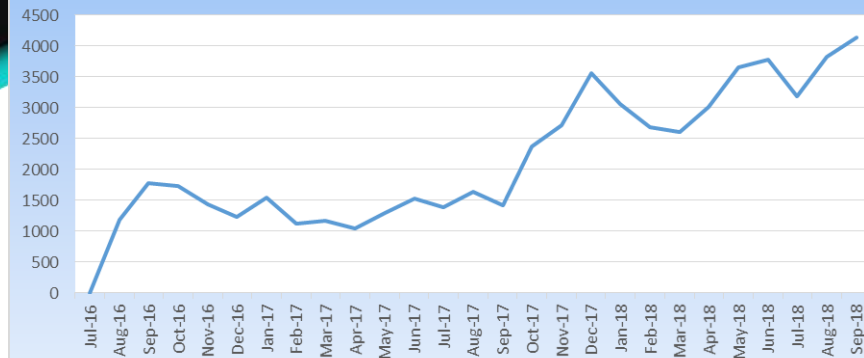
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iv Soft Assist Total Preps ALL



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Counts



Devices: 42

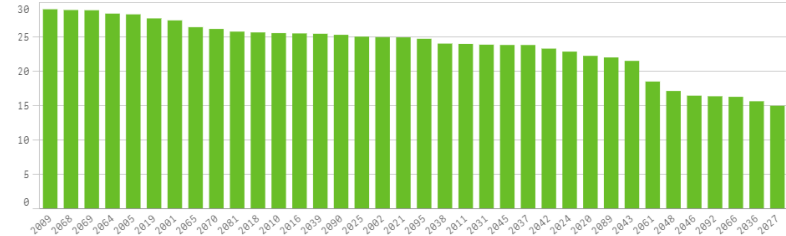
Drugs: 76

Preps: 1.63M

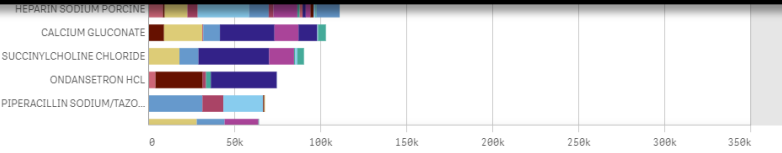
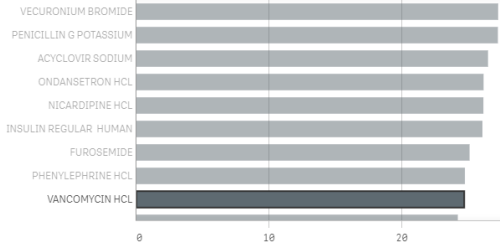
1 | Preps by Drug *



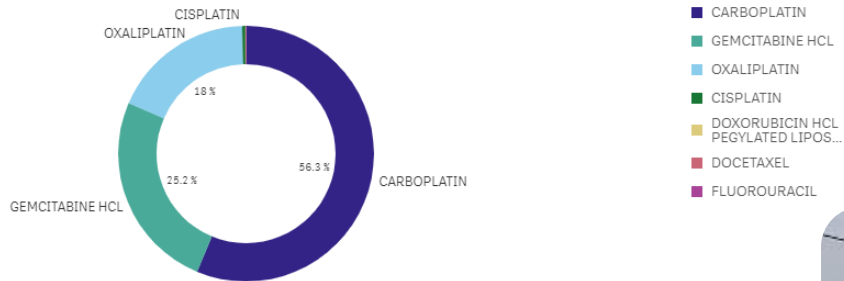
15 | Average Preps per Hour by Device



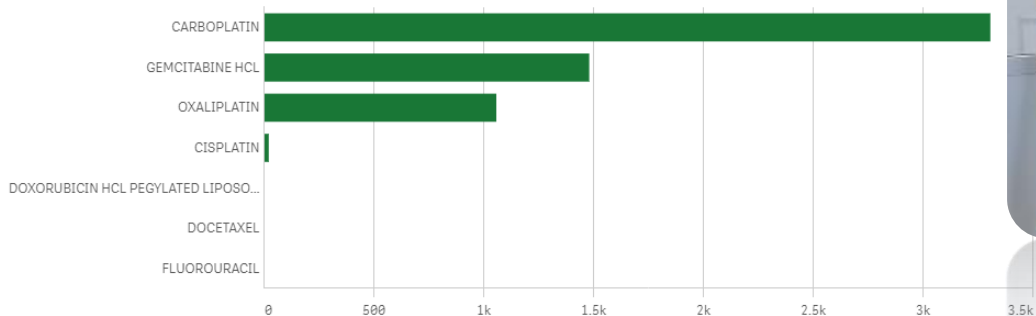
16 | Average Preps per Hour by Drug



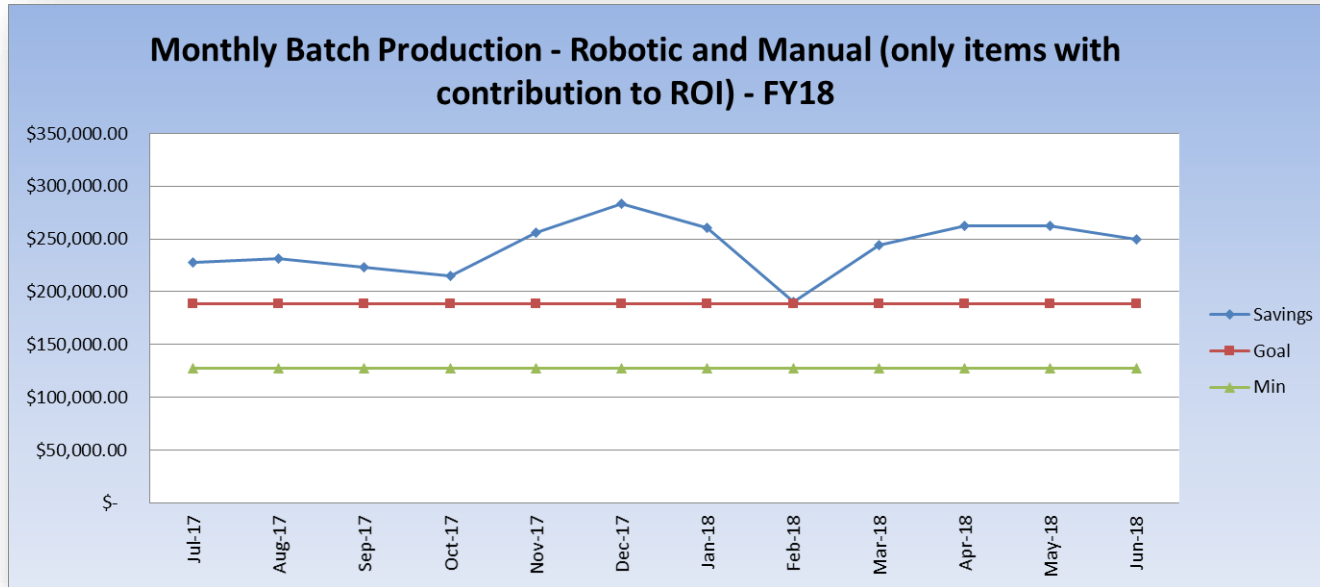
1 | Preps by Drug



3 | Preps by Drug by Device



Can we afford the future?



Questions and Comments

Thank you!

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