

## Quality Improvement Pearls

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## Reducing Hazardous Drug Exposure

Stephanie Beam, PharmD, BCOP  
 Rush Copley Medical Center

Speaker has no conflicts of interest to disclose



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### Learning Objective - Pharmacist and Technician

- Define Hazardous Drug and list consequences of exposure



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### Background

- 1970's: Chemotherapy agents were found to be linked to secondary cancers
- 1980's: OSHA recommended the use of Biological Safety Cabinets
- 1990: ASHP published a document on handling cytotoxic and hazardous drugs
- 1995: OSHA issues new guidelines on controlling occupational exposure to hazardous drugs
- 2004: NIOSH alert issued - Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings
- USP 800: Guidelines to protect healthcare workers from hazardous drug exposure – implementation in December 2019.



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## Why are things changing?

- According to CDC, approximately 8 million US health care workers are exposed to Hazardous Drug's (HD) each year
- HD's have been known to cause:
  - Teratogenicity
  - Reproductive toxicity
  - Organ toxicity
  - Carcinogenicity
- Purpose of USP 800 is to provide standardized guidelines when handling HD's that help reduce unnecessary exposure

NIOSH 2014. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2014. By Connor TH, Mackenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH US DHHS, CDC



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## Consequences of hazardous drug exposure

- Routes of Exposure:
  - Absorption: Skin contact / handling contaminated materials
  - Inhalation: Crushing pills, mixing liquids
  - Ingestion: Hand to mouth contact / handling food with contaminated hands
- Short-term effects of exposure:
  - Skin irritation / burning
  - Ocular irritation
  - Flu-like symptoms
  - GI toxicity
- Long-term effects of exposure:
  - Birth defects
  - Fertility impairment
  - Secondary cancers

ASHP. ASHP guidelines on handling hazardous drugs. Am J Health-Syst Pharm. 2006;63:1172-1193.

NIOSH 2014. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2014. By Connor TH, Mackenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH US DHHS, CDC



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## Are you currently using a Closed System transfer device (CSTD) at your institution?

- Yes – only for chemotherapy administration
- Yes – only for chemotherapy compounding
- Yes – for both chemotherapy administration and compounding
- No - currently not using a CSTD



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## USP 800 recommendations for CSTD use

- A CSTD must not be used as a substitute for a C-PEC when compounding
- CSTDs **should** be used when compounding HDs when the dosage form allows
- CSTDs **must** be used when administering antineoplastic HDs when the dosage form allows

C-PEC = containment primary engineering control = ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs  
US Pharmacopeial Convention. General Chapter <800> Hazardous drugs – handling in healthcare settings. 2016.



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## USP 800 recommendations - CSTD evaluation

- Until a published universal performance standard for evaluation of CSTD containment is available, users should carefully evaluate the performance claims associated with available CSTDs based on independent, peer-reviewed studies and demonstrated containment reduction

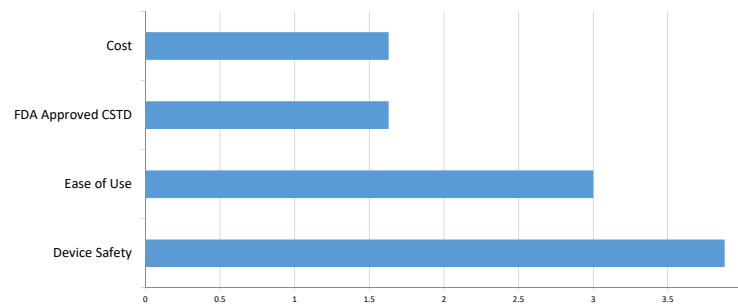
National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. A performance test protocol for closed system transfer devices used during pharmacy compounding and administration of hazardous drugs (draft). [www.cdc.gov/niosh/topics/hazdrugs/pdfs/performance-test-protocol-closed-system-transfer-devices.pdf](http://www.cdc.gov/niosh/topics/hazdrugs/pdfs/performance-test-protocol-closed-system-transfer-devices.pdf), 2017

US Pharmacopoeial Convention. General Chapter <800> Hazardous drugs – handling in healthcare settings. 2016:285.

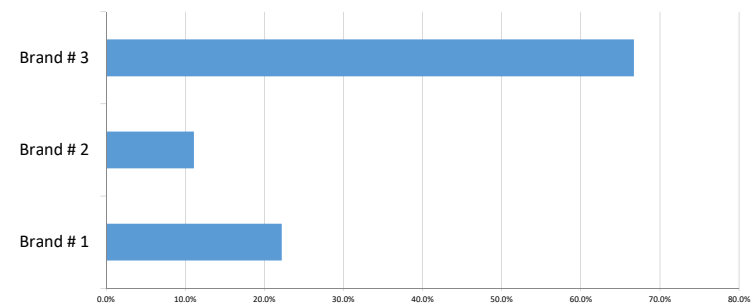
## CSTD Failure



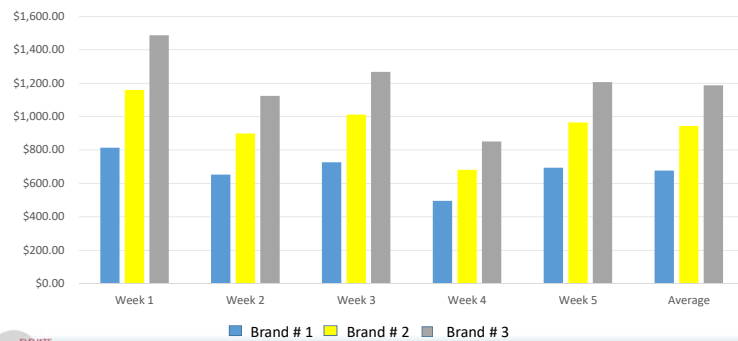
## CSTD Survey – Ranking By Level of Importance Pharmacy and Nursing



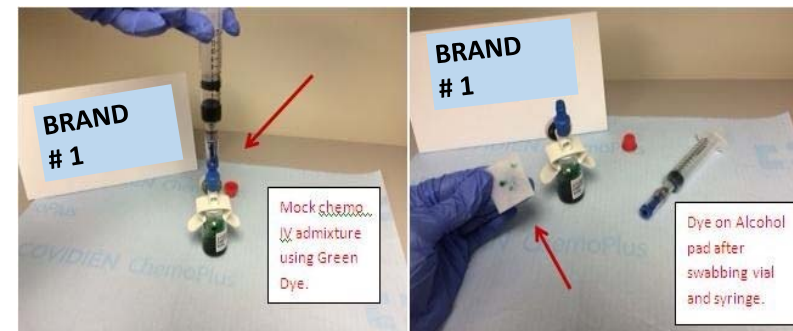
## CSTD Survey – Which CSTD would you prefer Pharmacy and Nursing



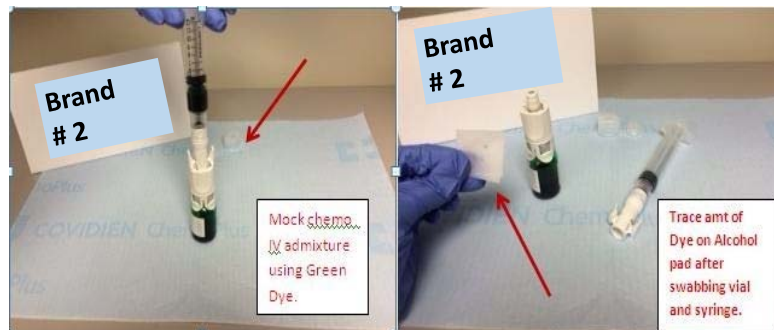
## Cost Comparison – weekly average



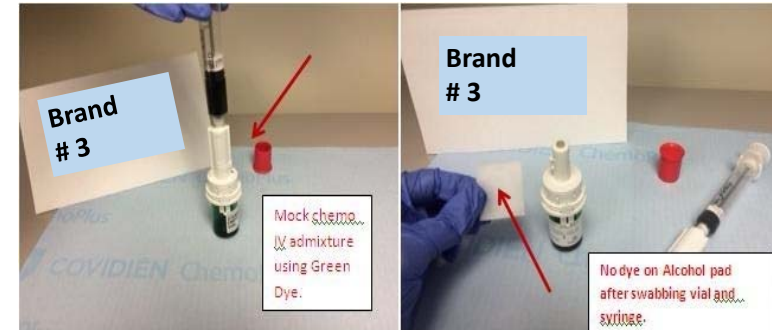
## CSTD evaluation



## CSTD evaluation



## CSTD evaluation



## Selecting a CSTD

- Does the CSTD meet the definition of a closed system - mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system
- Does the CSTD have FDA 510(k) clearance
- Is the CSTD compatible with other administration equipment
- Safety
- Ease of Use
- Cost



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## Conclusion

- Lack of a universal performance standard for evaluating CSTDs
- NIOSH is currently developing performance protocols that may be useful for evaluating CSTDs
- Pharmacists and other health care professionals should evaluate all available information to make decisions to protect the health of those individuals who prepare, handle and administer hazardous drugs

US Pharmacopeial Convention. General Chapter &lt;800&gt; Hazardous drugs – handling in healthcare settings. 2016.



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## References

- NIOSH 2014. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2014. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH US DHHS, CDC.
- ASHP. ASHP guidelines on handling hazardous drugs. Am J Health-Syst Pharm. 2006;63:1172-1193.
- US Pharmacopeial Convention. General Chapter <800> Hazardous drugs – handling in healthcare settings. 2016.
- National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. A performance test protocol for closed system transfer devices used during pharmacy compounding and administration of hazardous drugs (draft). [www.cdc.gov/niosh/topics/hazdrugs/pdfs/performanceprotocolclosedsystemtransferdevices.pdf](http://www.cdc.gov/niosh/topics/hazdrugs/pdfs/performanceprotocolclosedsystemtransferdevices.pdf). 2017.



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## Utilizing EHR Tools to Improve IV to PO Conversion

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## Disclosures

I have no financial relationships to disclose regarding the topic of this presentation



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## Learning Objective – Pharmacist and Technician

Describe strategies that can be implemented into the EHR to assist with IV to PO conversion.



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## Background

Conversion of intravenous (IV) medications to oral (PO):

- Reduces costs
- Reduces length of stays
- Improves patient comfort and ambulation
- Reduces risk of infusion related reactions
- Reduces risk for infections associated with IV catheters

Barlam TF, Cosgrove SE, Abbo LM. Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology. Clin Infect Dis. 2016;62(10):e151-e177.  
Kuper K. Intravenous to Oral Therapy Conversion. In: Mordough L. Competence Assessment Tools for Health-System Pharmacists. 4<sup>th</sup> ed. American Society of Health-System Pharmacists; 2008:347-360.



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## Memorial Medical Center

- 500 bed Magnet designated, teaching-community hospital
- Bariatric Center of Excellence
- Kidney-Pancreas Transplant Center
- Regional Cancer Center
- Level I Trauma Center
- Regional Burn Center
- Comprehensive Stroke Center



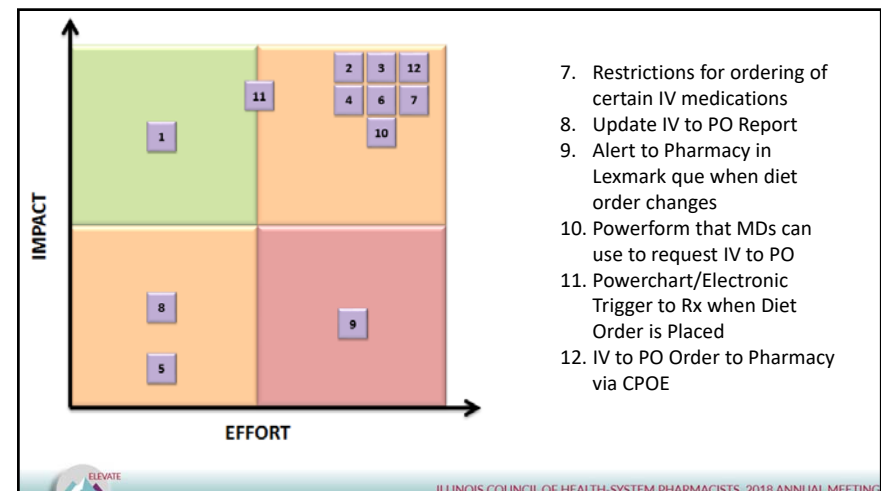
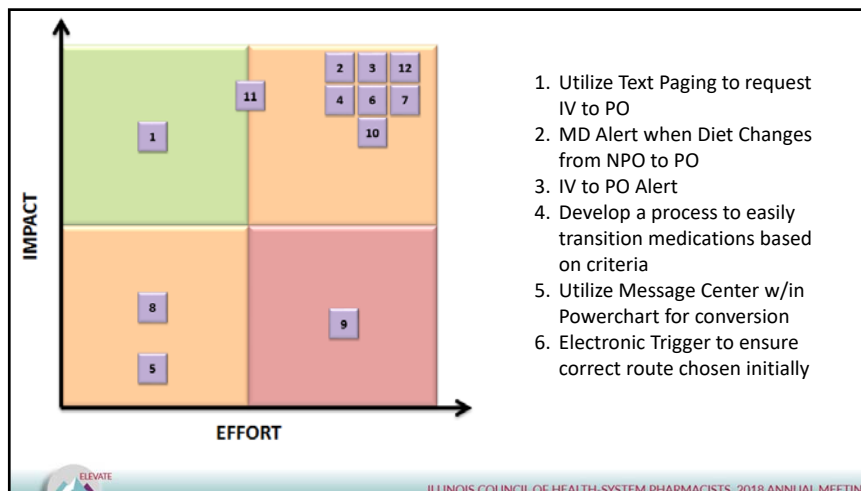
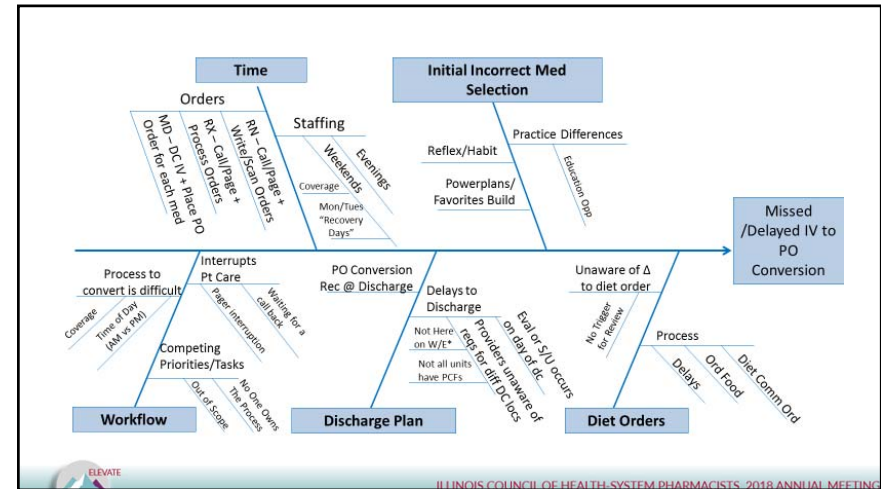
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## Background

- The IV to PO conversion rate was estimated at 73%
- The rate of missed opportunities was estimated at 39%

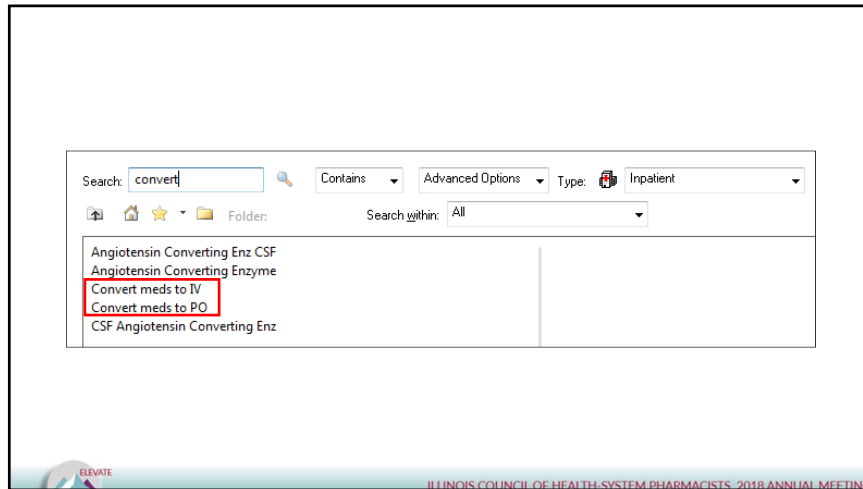
### Scope of the Project:

- Patients Age > 18 years old
- In-Patients
- Medications:
  - Antimicrobials
  - Anticonvulsants
  - Levothyroxine
  - H<sub>2</sub> Antagonists
  - Proton Pump Inhibitors

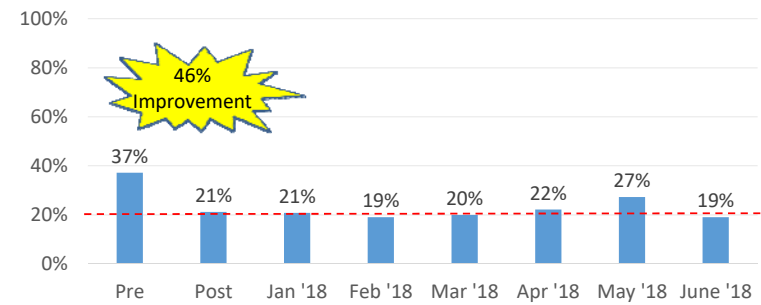




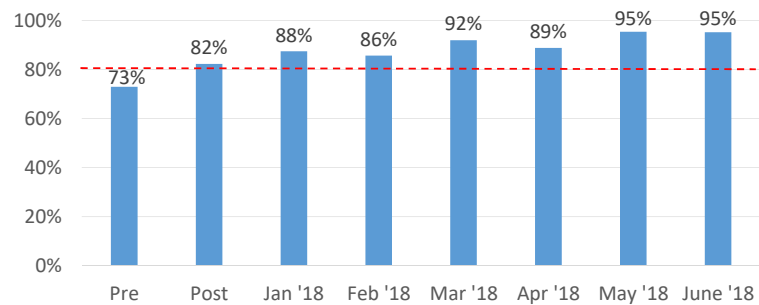




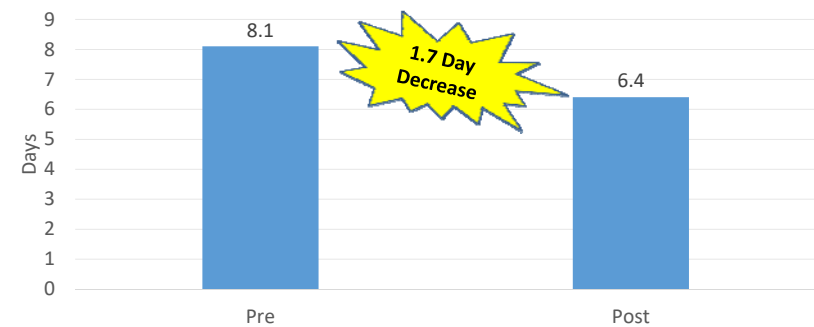
## Rate of Missed Opportunities



## IV to PO Conversion Rate



## Length of Stay



## Project Extensions

- Share Improvements with Pharmacy Departments at Affiliates
- Add more medications to the Automatic IV to PO Policy:
  - Ampicillin-Sulbactam
  - Digoxin
  - Folic Acid
  - Metoclopramide
  - Multivitamin
  - Ondansetron
  - Thiamine
  - Voriconazole



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## Conclusion

- Explore what your EHR offers
  - Engage your IT pharmacist/resources
- Key Elements to a report or worklist
  - Diet Order
  - Specified list of IV medications
  - Group all of the patient's eligible orders
- Multi-disciplinary approach



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Which of the following are improvements can be implemented into the EHR?

- i. Implement an IV to PO Policy for automatic conversion
  - ii. Clinical Pharmacy Worklist
  - iii. EMar Comments
- A. iii only  
 B. i and ii  
 C. i and iii  
 D. ii and iii



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## iMAS: The Solution to Patient Barriers with High Cost Medications

Jordan Johnson, Pharm.D.

Clinical Pharmacist

SwedishAmerican: A Division of UW Health

Disclosure: I do not have any actual or potential conflict of interest in regard to the content discussed in this presentation



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## Learning Objective – Pharmacist and Technician

- Describe the role and patient impact of an inpatient medication access specialist



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## Current Issues

- High cost medications can negatively impact patient's hospital experience
- Lack of education provided on new medications and potential barriers
  - Decreased compliance
  - Increased dissatisfaction
- Potential for readmission due to these factors



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## Current Issues

- Pharmacists do not perform discharge medication reconciliations
  - Performed by nurse or physician
- Lack of awareness of potential costs or dispensing issues with medication
- Lack of education provided to the patient
- Once identified, patient may have already left hospital or refused filling medication



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## Impact on Patient Compliance

- Eaddy, et al., literature review 2012<sup>1</sup>
  - 160 articles assessing cost-sharing, adherence, and outcomes
  - For each \$1 increase in copay, adherence decreased by 0.4% (24 studies)
  - Increased adherence improves clinical outcomes (57 studies)
  - Increased patient cost sharing adversely affects outcomes (19 studies)
- Overall, 85% of studies found negative effect on adherence with increasing cost



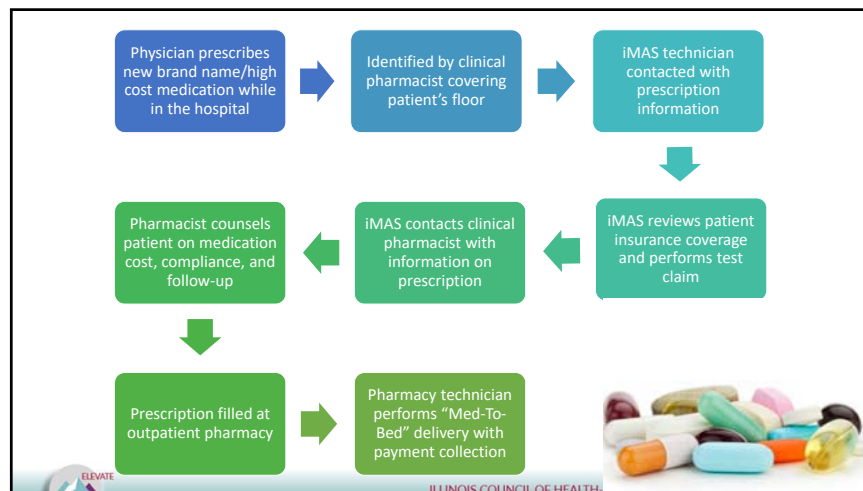
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## Impact on Patient Compliance

- CMS National Health Expenditures data
  - Historical and prospective spending patterns
- National health spending is projected to grow at an average 5.6% per year<sup>2</sup>
- Prescription drug spending growth project to grow an average 6.3% per year through 2025

## iMAS: Inpatient Medication Access Specialist

- Pharmacy technician trained in retail and inpatient setting
- Access to retail pharmacy software as well as inpatient records
- Available Monday through Friday 8:00 am to 5:00 pm
- Performs test claims with patient specific insurance and qualifying coupon cards to find best options for high cost medications prior to discharge



## Patient Impact

- Average patient savings= \$1875 per month
- Average claims ran per month = 92
  - Prior to April 2018, > 100 claims per month
- Average monthly outpatient pharmacy revenue = \$15,000
  - Recent outbreak of K2 poisonings
- 340B eligible health system

## Future Goals

- Expansion of iMAS program to cover multiple areas of hospital setting
- oMAS: Out-patient medication access specialist
  - Primary care clinics and ambulatory services
- Improved access to iMAS data collection and documentation
- Improvement in patient capture and follow-up



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## What impact does an iMAS technician have on patient care?

- A. Medication cost savings
- B. Disease state management
- C. Faster turnaround for medications
- D. Improved patient compliance
- E. All of the above
- F. A,C,D



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## What areas are iMAS technicians most applicable?

- A. Inpatient only
- B. Ambulatory care
- C. Cancer centers
- D. All of the above



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## Resources

1. Eaddy M, Cook C, et al. How patient cost-sharing trends affect adherence and outcomes: a literature review. Pharmacy and Therapeutics. 2012;37(1):45-55.
2. Centers for Medicare & Medicaid Services. National Health Expenditure Data. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData>. Accessed August 13,2018



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## Utilizing Lean Six Sigma Methodology to Prevent Medication Omissions at Discharge

Ashlie Kallal, Pharm.D., CLSSBB  
September 15, 2018



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## Conflict of Interest

The speaker has no actual or potential conflict of interest in relation to this presentation.



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## Learning Objective – Pharmacists and Technicians

Identify decision-making tools available to evaluate possible solutions within a quality improvement project.



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## Project Background

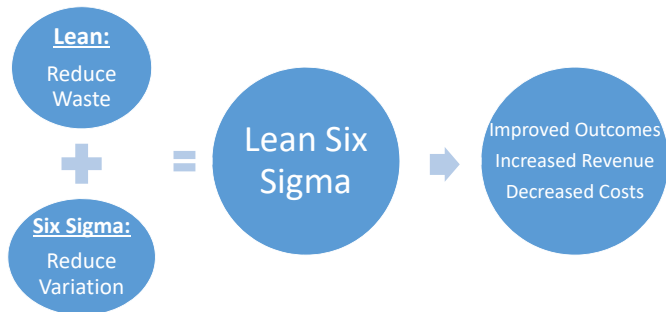
- Lean Six Sigma quality improvement project stemmed from a patient safety event
- Data collection revealed 1 patient/month discharged without warfarin
- Warfarin omissions are associated with:
  - Hospital readmissions
  - Increased medical costs
  - Patient harm, including mortality



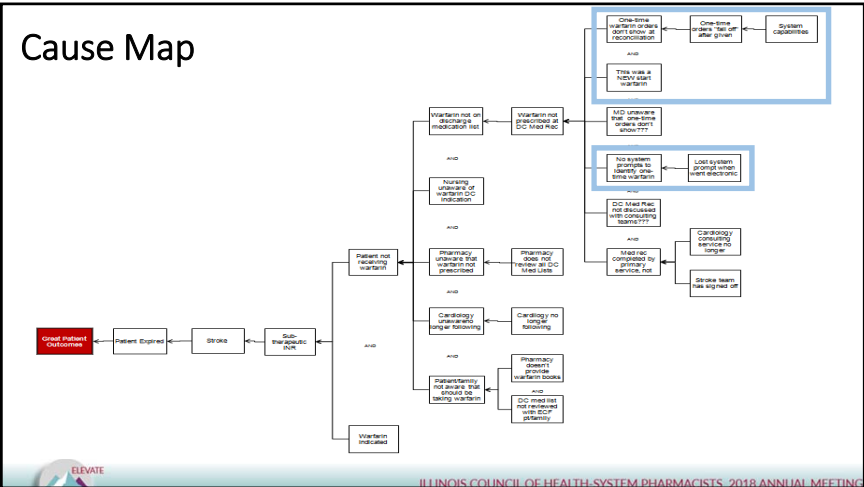
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## What is Lean Six Sigma?

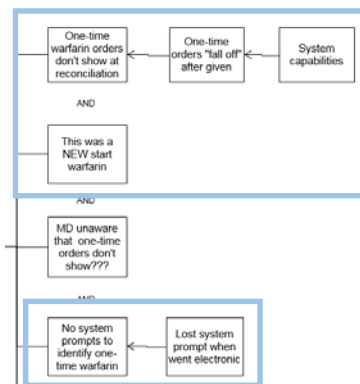
A fact based, data driven problem solving methodology



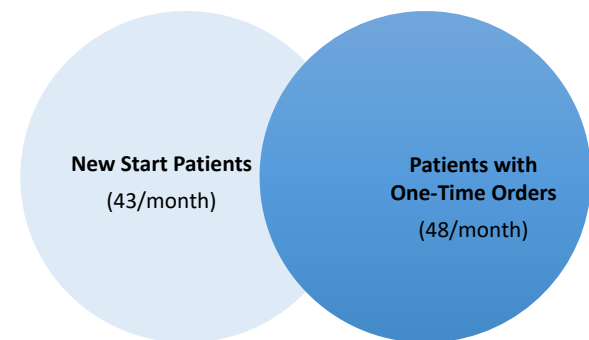
## Cause Map



## Cause Map - Root Causes

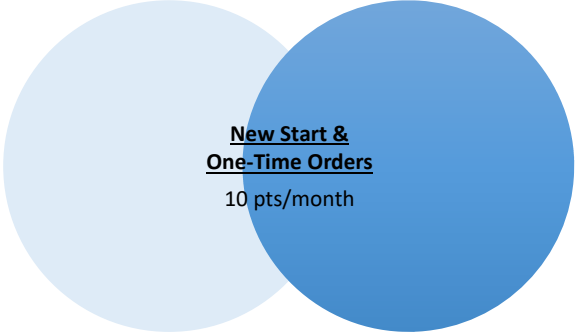


## Warfarin: New Start & One-Time



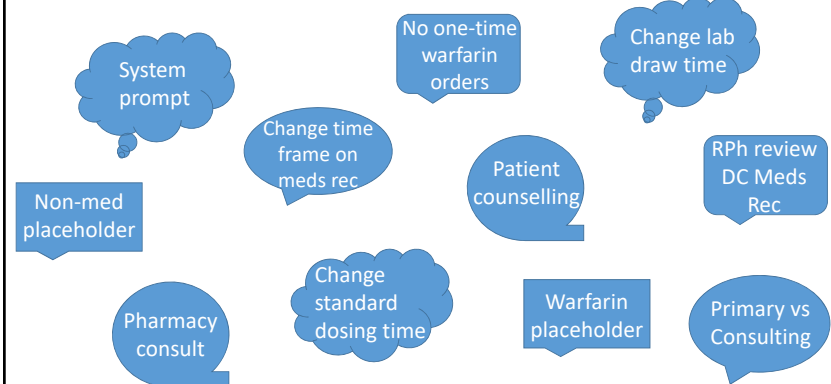
## Warfarin: New Start & One-Time

**New Start &  
One-Time Orders**  
10 pts/month




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## Warfarin Omission – Possible Solutions



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## Selecting a Solution - Which is best?

- Solution should address the root cause
- What is required to implement?
- What additional data/information is needed?
- Utilize decision-making tools
  - Quality Impact & Effort Matrix
  - Failure Modes and Effects Analysis (FMEA)
  - Stakeholder & Resistance Analysis Tool



Pyzdek T, Keller P. The Six Sigma Handbook. 4th ed. New York, NY: McGraw Hill Education; 2014.

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American Society for Quality. Impact Effort Matrix. Available at: <http://asq.org/healthcare-use/why-quality/impact-effort.html>. Accessed 8/18.



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## Warfarin Omission – Impact/Effort Matrix

### Major Effort

- A1 – System Prompt/Reminder
- A2 – Non-med Placeholder
- C1 – Do not allow one-time orders
- D1 – Warfarin (med) Placeholder

### Hard Sell

- B1 – Every warfarin patient to receive counseling
- E3 – RPh to review every DC Meds Rec
- E1 – Pharmacy consult to “oversee” (not manage)
- E2 – Primary team to discuss DC Meds with Consulting Team
- F1 – Change lab draw times
- F2 – Change Warfarin Standard Dosing Time
- G1 – DC Meds Rec to pull in 24 hrs of DC'd Meds

Image removed due to copyright



## Failure Modes and Effects Analysis

Process or Product Name: Process Owner:			Prepared by: FMEA Date (Yr):			Page: of Pages									
Key Process Step or Input	Potential Failure Modes	Potential Failure Effects	S E V	Potential Causes	O C C	Current Controls	D E T	R P N	Actions Recommended	Resp.	Actions Taken	S E V	O C C	D E T	R P N
What is the Process Step or Input?	In what ways can the Process Step or Input fail?	What is the impact on the Key Output Variables once it fails (customer or internal requirements)?	Severity of Effect	What causes the Key Input to go wrong?	How often does it occur?	What are the existing controls and procedures that either prevent or detect failure mode?	Can you detect it?	Risk Priority Number	What are the actions for reducing the occurrence of the cause, or improving detection?	Who is Responsible for the recommended action?	Note the actions taken include dates of completion	How often does it occur?	How often does it occur?	Can you detect it?	Risk Priority Number
1								0							0
2								0							0
3								0							0
4								0							0
5								0							0
6								0							0
7								0							0
8								0							0
9								0							0

Institute for Healthcare Improvement. Failure Modes and Effects Analysis Tool. Available at: <http://app.ihl.org/workspace/tools/fmea/>. Accessed 8/18.

## Warfarin Omission - FMEA



## Failure Modes and Effects Analysis

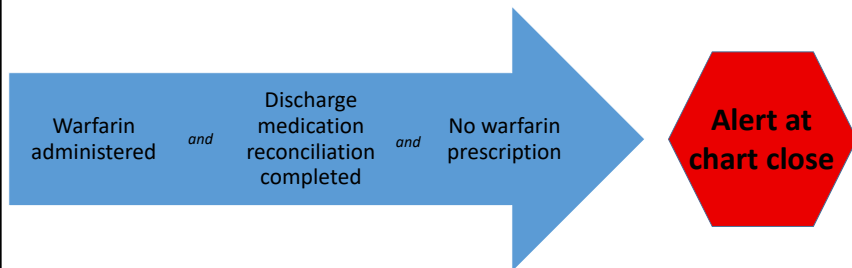
Process or Product Name:		Warfarin Omission at Discharge--Alert to MD					Prepared by: Achille Katal			
Process Owner:							FMEA Date (Orig): Sep-17			
Key Process Step or Input	Potential Failure Modes	Potential Failure Effects	Severity	Potential Causes	Occurrence	Current Controls	Detection	RPN	Actions Recommended	Resp.
What is the Process Step or Input?	In what ways can the Process Step or Input fail?	What is the impact on the Key Output Variables once it fails (customer or internal requirements)?	Severity of Effect	What causes the Key Input to go wrong?	How often does it occur?	What are the existing controls and procedures that either prevent or detect failure mode?	Can you detect it?	Risk Priority Number	What are the actions for reducing the occurrence of the cause, or improving detection?	Who is Responsible for the recommended action?
MD completes DC Meds Rec. 1	No warfarin to be reconciled and warfarin omitted from plan.							0		
2. System alert fires to MD	MD ignores alert	warfarin omission at DC	7		4	no detection	8	224	Require MD response at point of alert firing	ITU with MD on individual basis

## Stakeholder & Resistance Analysis Tool

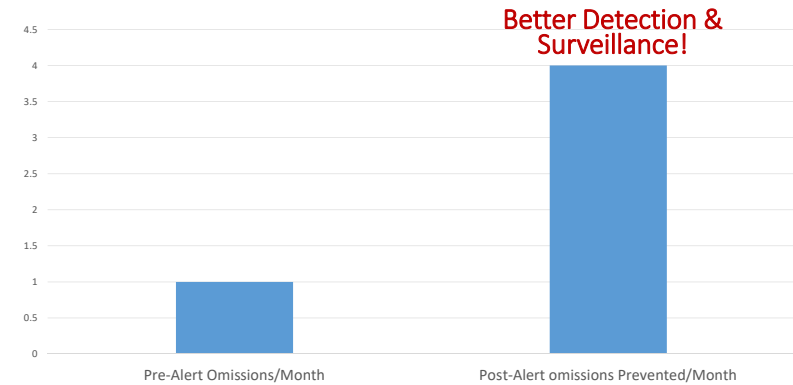
Key Stakeholder	Strongly Against	Moderately Against	Neutral	Moderately Supportive	Strongly Supportive

iSixSigma. Preventing Conflicts Through Stakeholder Management. Available at: <https://www.isixsigma.com/implementation/change-management-implementation/preventing-conflicts-through-stakeholder-management/>. Accessed 8/16/18.

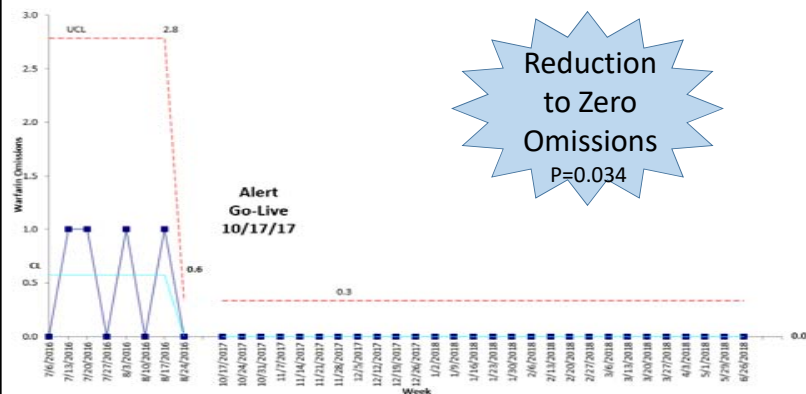
## Improvement: System Alert



## Results – Warfarin Omissions



## Results – Warfarin Omissions



## Applying to YOUR Practice

- Are you at risk for medication omissions at discharge?
- Examine your data
- Be open to new solutions
- Utilize decision-making tools when choosing which solution to implement

Tools that can be utilized to evaluate possible process improvement solutions include:

- A. Failure Modes and Effects Analysis
- B. Stakeholder & Resistance Analysis
- C. Impact & Effort Matrix
- D. All of the above



# Quality Improvement Pearls - Reducing Hazardous Drug Exposure

## Self-Assessment Questions

1. Hazardous Drug Exposure has been known to cause all of the following except?
  - A. Teratogenicity
  - B. Reproductive toxicity
  - C. Organ toxicity
  - D. Cardiotoxicity
  
2. USP 800 requires the use of a Closed System Transfer Device (CSTD) for \_\_\_\_\_?
  - A. chemotherapy administration only
  - B. chemotherapy compounding only
  - C. both chemotherapy administration and compounding
  - D. neither – CSTD use is optional