



## IV Safety: Preventing Death and Harm from IV Medication Errors

*Quality Standards in Clinical Practice Series*



Monday, June 15, 2:00 p.m. – 5:00 p.m.

### FACULTY BIOS

#### **Bona E. Benjamin, BS Pharm**

Ms. Benjamin received a B.S. in Biology in 1970 and B.S. in Pharmacy in 1972 at the University of Louisiana, Monroe. In 2003, she completed an Executive Fellowship in Patient Safety at Virginia Commonwealth University, Medical College of Virginia. She has practiced hospital pharmacy for over 25 years, focusing on sterile product preparation, education and training, accreditation and regulatory compliance, performance improvement, and management. From 1997 to 2007, she was the Quality Officer for the Pharmacy Department at the Mark O. Hatfield Clinical Research Center at the National Institutes of Health, where she coordinated medication-related performance improvement, Joint Commission readiness, and policy development activities for the hospital-wide quality team as well as the NIH Pharmacy Department. While at NIH, she participated in the Medication-Use Safety Strategy Project conducted by ASHP and served as an instructor for a medication safety class for pharmacy and nursing students at the University of Maryland. In 2007, she joined the American Society of Health-System Pharmacists as the Director of Medication-Use Quality Improvement. In that role she serves as staff liaison and member advocate with such groups as the FDA, AHRQ, USP, IHI, NPSF, NQF, IOM, CMS, and others. She represents ASHP on the National Coordinating Council on Medication Error Reporting and Prevention, the Joint Commission Professional and Technical Advisory Committee for Hospitals, the Pharmacy Quality Alliance, and the National Consumer's League SOS Rx initiative. She assists with review, testimony, and ASHP official written commentary on medication-related regulatory and accreditation initiatives.

#### **Frank A. Federico, BS**

Frank Federico, R.Ph. is Executive Director for Strategic Partners at the Institute for Healthcare Improvement in Cambridge, MA. His primary areas of focus include patient safety, application of reliability principles in health care, preventing surgical complications and the Idealized Design of Perinatal Care. He is also faculty for the Patient Safety Officer Training Program. Mr. Federico has worked with the Institute for Healthcare Improvement since 1996 as a faculty member and Co-Chair of a number of Patient Safety Collaboratives. Prior to joining IHI, Mr.

Federico was the Program Director of the Office Practice Evaluation Program and a Loss Prevention/Patient Safety Specialist at Risk Management Foundation (RMF) of the Harvard Affiliated Institutions in Cambridge, MA. He, along with a team of nurse surveyors, developed a compendium of effective practices to reduce risk and harm in the office setting. Mr. Federico is one of the Executive Producers of First, Do No Harm, Part 2: Taking the Lead. He served as Director of Pharmacy at Children's Hospital, Boston. While in that position, he was co-chair of a quality improvement team charged with revamping the medication system and chaired the Adverse Drug Event Committee. He is co-author of a chapter in Achieving Safe and Reliable Health Care, Strategies and Solutions. Frank Federico coaches teams and lectures extensively, nationally and internationally, on patient safety.

#### **Allen J. Vaida, BSc, PharmD, FASHP**

Allen J. Vaida is the Executive Vice President for the Institute for Safe Medication Practices (ISMP) in Horsham, PA. He previously served as Vice President of Clinical Operations (Chief Operating Officer) at Mercy Suburban Hospital in Norristown, PA. Prior to his appointment as Vice President in 1995, Vaida served on the United States Pharmacopeias Safe Medication Use Expert Committee from 2000 through 2005 and is Clinical Assistant Professor at the University of the Sciences in Philadelphia, Assistant Adjunct Professor at Temple University School of Pharmacy, Adjunct Associate for the Centers for Health Policy and Primary Care and Outcomes Research at Stanford University and Stanford University School of Medicine, and adjunct faculty for the Executive Patient Safety Fellowship offered through Virginia Commonwealth University, Richmond, VA. Dr. Vaida is a past president of the Pennsylvania Society of Health-System Pharmacists and a recipient of the Pharmacist of the Year Award in Pennsylvania and the Jonathan Roberts Award from the Delaware Valley Society of Health-System Pharmacists. He was elected as a Fellow of the American Society of Health-System Pharmacists in 1995. Vaida received a Bachelor of Science in Biology from the University of Scranton, a Bachelor of Science in Pharmacy from the Philadelphia College of Pharmacy and Science, and a Doctor of Pharmacy degree from the University of Minnesota.

### ABSTRACTS

#### **ASHP'S IV SAFETY SUMMIT: PREVENTING HARM AND DEATH FROM INTRAVENOUS MEDICATION ERRORS**

Benjamin, B.E.

American Society of Health-System Pharmacists, 7272 Wisconsin Avenue, Bethesda, MD, USA Email: bbenjamin@ashp.org

The findings of a multidisciplinary consensus conference on intravenous medication use safety are described. Data on the

frequency and severity of intravenous medication error reports are reviewed, with discussion of implications. Recommendations for best practices, those that are fundamental and essential to safety, as well as the barriers to adoption of the practices and potential solutions are presented. An ambitious action agenda is described, which will require commitments by engaged stakeholders in medicine, nursing, pharmacy, safety and quality, regulatory and accreditation, and advocacy groups is needed



**Program Number: 204-000-09-109-L05P (3.0 Contact Hours)**

The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Attendees must complete an online CE Request form or a paper form to earn CE credit. A CE Session Code is required to obtain CE. CE Session Codes are announced in the sessions. CE statements can be printed immediately for online requests or will be mailed 8-10 weeks after the meeting if you use the paper form.

to achieve real and sustained improvement in intravenous medication use safety.

**Learning Objectives:**

1. Describe the primary goal of ASHP's IV Safety Summit.
2. List the medications that most commonly cause harm according to data in one proprietary error reporting database.
3. Identify at least one major theme common to the IV Safety Summit IV safety practices.

**Self-Assessment Questions:**

1. (True or False) Intravenous medication errors occur frequently.
2. (True or False) The causes of intravenous medication errors are well-known.
3. Which of the following is not a recommended safety practice from the IV Safety Summit (choose 1).
  - a. Standardize intravenous medication infusion concentrations
  - b. Engage patients and family members in safe administration of intravenous medications
  - c. Encourage nursing staff to prepare their own infusions if it saves time for them
  - d. Use intelligent pumps with drug libraries and rate-limiting software and other safety features enabled

**Answers:** 1. False; 2. False; 3. c

**ESSENTIAL CONCEPTS AND PRACTICAL RECOMMENDATIONS FOR IMPROVING IV SAFETY**

Federico, F.

American Society of Health-System Pharmacists, 7272 Wisconsin Avenue, Bethesda, MD, USA Email: ffederico@ihi.org

Performance improvement change concepts are demonstrated using a common hospital-wide IV safety problem as an interactive case study. Attendees use their individual institutions as test hospitals for the case, apply change concepts, and report conclusions for feedback and comment.

**Learning Objectives:**

1. Summarize essential concepts for improving safety.
2. Describe an improvement model that is applicable to IV medication safety.
3. List at least two components required for successful and sustained change.

**Self-Assessment Questions:**

1. (True or False) Data for judgment is essential for performance improvement projects.

2. (True or False) The performance of a reliable system depends most heavily on education and training.
3. Which of the following is not an essential element of a successful improvement strategy?
  - a. Ideas
  - b. Financial resources
  - c. Execution
  - d. Will

**Answers:** 1. False; 2. False; 3. b

**PERFORMING AN ORGANIZATION-WIDE IV SAFETY SELF-ASSESSMENT**

Vaida, A.

Institute for Safe Medication Practices, 200 Lakeside Drive, Horsham, PA, USA. Email: avaida@ismp.org

Practical techniques for conducting a self-assessment of organizational safety status associated with the intravenous medication-use system are presented. Core processes and information that influence IV medication safety are identified as well as a strategy for recruiting an interdisciplinary team to perform the assessment. Medications and examples of processes that should receive priority focus are highlighted.


**Learning Objectives:**

1. Explain the elements of a comprehensive IV safety self-assessment.
2. Identify three organizational departments that should be represented on a safety self-assessment team.
3. Describe processes requiring heightened attention in the prescribing, preparation, and administration of IV medications.


**Self-Assessment Questions:**

1. (True or False) Standardization of IV medication concentrations is a higher level strategy than instituting checklists.
2. (True or False) Appearance of drug information on the label of IV medications is a frequent cause of IV medication errors?
3. Which of the following individuals are often neglected when choosing a group to review IV medication safety?
  - a. Pharmacists
  - b. IT personnel
  - c. Biomedical engineering personnel
  - d. Nurses
  - e. b & c
  - f. All of the above

**Answers:** 1. True; 2. True; 3. e

  
June 14-17, 2009  
ASHP 2009 Summer Meeting & Exhibition  
Donald E. Stephens Convention Center  
Village of Rosemont • Chicago Metro Area



## IV Safety: Preventing Death and Harm from IV Medication Errors



○○○ **Disclosures**



The following presenters have no relevant financial relationships:

- Bona E. Benjamin
- Frank A. Federico
- Allen J. Vaida

○○○ **Objectives**

- Summarize key findings on intravenous medication safety from ASHP's IV Safety Summit.
- Explain how to plan and conduct an organizational assessment for intravenous medication-use safety.
- Develop a strategy for organization-wide improvement of the safety of intravenous medication use.

  
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## The IV Safety Summit



Best Practices for  
Intravenous Medication-  
Use Safety



○○○ **ASHP's IV Safety Summit**  
July 14-15, 2008

**"Preventable accidents like the tragic deaths of these babies should never happen,"**  
Henri R. Manasse, Jr., ASHP executive VP and CEO.  
[ASHP Urges Hospitals to Take Key Steps to Improve Safety.](#)



**"Nothing can erase the grief and loss experienced in ... Indiana that led to the death of three infants. But it should be of some comfort that some positive actions are occurring as a result of the tragedy."**  
[November 2, 2006 ISMP Medication Safety Alert](#)

○○○ **ASHP's IV Safety Summit**

Summit goal:  
Initiate actions that prevent harm from misuse of intravenous medications



No more harm –  
no more death –  
from intravenous medication use.

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○○○ **Summit Participants**

**Steering Committee**

<u>Regulatory, Standards-setting</u>	<u>Practitioners</u>
<ul style="list-style-type: none"> <li>○ AHRQ</li> <li>○ FDA</li> <li>○ CMS</li> <li>○ HRSA</li> <li>○ NQF</li> <li>○ The Joint Commission</li> </ul>	<ul style="list-style-type: none"> <li>○ Physicians: ACEP, ASA, SHM, AAP, APSP</li> <li>○ Pharmacists: HOPA, ASHP, ASHP REF</li> <li>○ Nurses: ONS, ACCN, AORN, ANN, NANN, Infusion Nurses Society</li> </ul>
<u>Patient Safety and Quality</u>	<u>Other</u>
<ul style="list-style-type: none"> <li>○ Institute for Safe Medication Practices</li> <li>○ US Pharmacopeia</li> <li>○ IHI</li> <li>○ National Patient Safety Foundation</li> <li>○ ECRI</li> <li>○ Brigham Centers of Excellence</li> </ul>	<ul style="list-style-type: none"> <li>○ Industry: Baxter, Hospira, B Braun, McKesson, Cardinal</li> <li>○ Advocacy groups: CHCA, NHIA, ASPEN, PPAG</li> </ul>



○○○ **Summit ground rules**

- All stakeholders contribute equally
- Share common goal
- Candid, open exchange
- Not a marketing opportunity
- Focus on problem-solving and action








○○○ **Summit Objectives**

1. Best Practices
  - Consensus by Expert Panel
2. Barriers to adoption and solutions
  - Recommendations from work groups
3. Recommendations for adoption of Best Practices
  - What actions are needed to make the necessary changes?






○○○ **Heparin: Lessons learned?**


The Indiana Infants

			
D'myia Nelson	Emmery Miller	Dawn Jeffers	The Quaid twins



**17 Babies Nearly Killed by Blood Thinner Overdose at Texas Hospital**  
Natural News.com, AZ - Nov 30, 2008  
The children received a major overdose of the blood thinner **heparin** in the neonatal intensive care unit of **Christus Spohn Hospital** South in Corpus Christi, ...

○○○ **Intravenous medication error data**





- Voluntary reporting
- 800 hospitals (out of ~5700)
- 1,073,467 events (2002-2006)
- 126,596 parenteral errors

○○○ **How frequent and serious are IV errors?** N = 1,073,467



- Of all medication error reports, % involving parenteral drugs?
  - 4%
  - 12.5%
  - 24%
- Of parenteral error reports, % that cause harm
  - 0.3%
  - 3%
  - 13%

○○○ **How frequent and serious are IV errors?**



3. IV errors are reported to occur most frequently at what point in the med use process?

A. Administering	57.7%
B. Prescribing	12.8%
C. Dispensing	11.9%

○○○ **IV Medication errors: other findings**



- Parenteral errors almost 3 times as likely to cause harm 3% vs 1.2%
- 3873 events caused harm = 0.35% (n = 126,696)
- Top 3 drugs
  - morphine
  - heparin
  - hydromorphone

○○○ **IV Medication errors: other findings**


- Top 3 drug classes
 

18%	Opiates
16%	Heparin (s)
9%	Insulin
- 25 fatalities (\*n = 126,696)






○○○ **Numbers ≠ people**

Arginine: not on the high alert drug list





Sebastian Ferrero

○○○ **Most common error scenarios\***  
(\*n = 3873 error reports involving harm)

- Incorrect pump rate programming
- Policies/protocols not followed
- Incomplete documentation
- Inadequate communication
- Mix-up with another IV
- Order entry error

### Why do IV errors occur?

IV "harm" reports n=3873

Error Cause	n	%
Performance Deficit	2,106	54.5
Procedure/Protocol not followed	1,368	35.3
Knowledge deficit	809	20.9
Communication	734	18.9
Monitoring inadequate/lacking	407	10.5
Transcription inaccurate/omitted	360	9.3
Documentation	358	9.2
Pump, improper use	286	7.4
Calculation error	263	6.8
Computer entry	254	6.5

### What is "performance deficit"? What is "policy not followed"?



Emily Jerry  
NaCl 23.4%



Jasmine Gant  
Bupivacaine  
IV



Alyssa Shinn  
Zinc

- ### Conclusions?
- IV errors not frequent, but are more likely to cause harm
  - Insulins, opiates, and heparins most frequently associated with harmful errors
  - The causes of IV errors are not well defined



- ### Best Practices for IV Safety
1. Standardize infusion concentrations
  2. Implement standardized comprehensive IV medication use policies
  3. Use commercially available ready-to-administer intravenous medications
  4. Incorporate special precautions in medication-use processes for high-alert medications  
<http://www.ismp.org/Tools/highalertmedications.pdf>

- ### Best Practices for IV Safety
5. Standardize procedures for managing medication errors and other adverse events.
  6. Control availability of concentrated injectables
  7. Limit available concentrations; one or two strengths if possible
  8. Standardize ordering and ordering forms (paper or electronic)

- ### Best Practices for IV Safety
9. Standardize dosing protocols for emergency/high alert drugs
  10. Standardize label format, display administration information prominently  
[www.ismp.org/Tools/guidelines/labelFormats/default.asp](http://www.ismp.org/Tools/guidelines/labelFormats/default.asp)
  11. Differentiate look-alike medications, including separating storage locations  
[www.ismp.org/Tools/confuseddrugnames.pdf](http://www.ismp.org/Tools/confuseddrugnames.pdf)  
[www.ismp.org/Newsletters/acute/articles/20020612\\_2.asp?ptr=v](http://www.ismp.org/Newsletters/acute/articles/20020612_2.asp?ptr=v)
  12. Limit preparation of admixtures by nursing staff

○○○ | **Best Practices for IV Safety**



13. Adopt ISMP Guidelines: Safe Use of Automated Dispensing Cabinets  
[www.ismp.org/Tools/guidelines/ADC\\_Guidelines\\_Final.pdf](http://www.ismp.org/Tools/guidelines/ADC_Guidelines_Final.pdf)
14. Use smart infusion devices with safety features fully enabled
15. Standardize IV administration processes; minimize interruptions and distractions
16. Include the patient and family members in the medication administration process



○○○ | **Best Practices for IV Safety**



**Monitoring**

16. Standardize communications during handoff
17. Continuously improve IV medication use with data from smart infusion devices and information systems




○○○ | **Next steps**

- Compile comprehensive IV reference with standardized concentrations
- Initiate discussion with FDA re: faster approval of RTU infusions
- Build consensus for interoperability among safety technologies



○○○ | **Next steps**

- Provide guidance for safe use of “intelligent” pumps  
<http://www.ismp.org/Tools/guidelines/smartpumps/comments/default.asp>
- Provide resources, tools, comprehensive IV reference
- Build the “business case” for safety




○○○ | **ASHP’s IV Safety Summit**

**Preventing harm and death from intravenous medication errors**

<http://www.ashp.org/iv-summit>





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## Performing an Organization Wide IV Safety Self - Assessment

Allen J. Vaida, Pharm.D., FASHP  
Institute for Safe Medication Practices

### Where do We Stand? Beginning the Process

- How many have performed the ISMP Medication Safety Self Assessment® for Hospitals?
- How many have read the findings of the ASHP IV Safety Summit?
- How many have performed a review of IV practices in your organization?
- What medication safety projects are you working on?

### Beginning the Process

- Select an assessment tool
- Make your own – or select a process that is error-prone
- Gather a team
- Provide background information

### Manual Redundancies – ISMP Medication Safety Self Assessment®

	None	Partial	Full
High-alert floor stock (183)	45%	38%	17%
mg/m <sup>2</sup> ; mg/kg (179)	23%	39%	39%
Chemotherapy/pediatric drugs – nurses (180)	45%	41%	15%
Chemotherapy/pediatric IV – pharmacist (181)	30%	35%	35%
Filling from order copy and label (188a) – 90%	35%	25%	40%

### Who Should be Involved in the Assessment?

- Pharmacy
- Nursing
- Medical Staff
- Administration
- IT Personnel
- Biomedical Personnel
- Risk Management
- Others ...

### What to Assess

- Order sets
- Standardized and **limited** number of concentrations of medications available – heparin, opioids, infusions
- Labeling – pharmacy compared to MAR
- Distribution and storage of IV medications on the patient care unit – distribution model
- Nurse preparation or manipulation of IV medications



### ○○○ Nurse Preparation of IVs

- Amiodarone
- Epinephrine infusions
- Fosphenytoin infusions
- Insulin infusions
- Nitroprusside infusions
- Norepinephrine infusions
- Antibiotics



### ○○○ Commercially Available Pre-Mixed Solutions

	<u>None</u>	<u>Partial</u>	<u>Full</u>
○ Premixed IV solutions used whenever available (68)	4%	43%	53%
○ Prefilled syringes for 90% of injectable products (69)	30%	55%	16%



### ○○○ “Simplify” Adding Complexity to Systems

<u>No. Elements</u>	<u>Success of Each Element</u>		
	0.98	0.99	0.999
1	0.98	0.99	0.999
15	0.74	0.86	0.99
20	0.67	0.82	0.98
30	0.55	0.74	0.97
40	0.45	0.67	0.96



### ○○○ Eliminate Steps Pre-Mixed IV’s

- Drug preparation – obtain correct medication, choose correct diluents, add correct amount (if from powder)
- Withdraw correct amount of drug, choose correct final diluents and container
- Labeling – ingredients, expiration
- Additional checks along the process



### ○○○ Outsourcing

- Parenteral Nutrition
- Cardioplegic
- Dialysis
- Epidurals – Oxytocin
- Others





### ○○○ What to Assess

- Use of IV pumps – sequencing of set up compared to labeling – drug libraries – units used
- Handoffs of patients receiving IV therapy to other departments (radiology, cardiac, GI)
- Capture and sharing of internal hazardous conditions – near misses – errors
- Use of external information
- Plans for the use of technology





○○○ **What do You do with the Information?**

- Improve simple processes identified without much ‘fanfare’
- Identify a project to ‘drill down’ on
- Use an improvement model – PDSA – Six Sigma – Lean Six Sigma...
- Get key players involved



○○○ **Rank Order of Error Reduction Strategies**

**Forcing functions and constraints**  
 ↓  
**Automation and computerization with Redundancies**  
 ↓  
**Standardization and protocols**  
 ↓  
**Checklists and double check systems**  
 ↓  
**Rules and policies**  
 ↓  
**Education / Information**  
 ↓  
**Be more careful**



○○○ **Areas of Focus**

- High Alert Medications
- Pediatrics/Neonatal
- Chemotherapy
- Other
- **Checking process for IV order entry – calculations – preparation**







○○○ **Area of Focus – IV Order Entry and Preparation Process**

- Environment
- *Check* of the original order
- *Calculation Check*
- *Check* of medications before preparation
- *Check* after preparation (“pull back method”)
- Automation – other technology

DATE/TIME	PATIENT STATUS: <input type="checkbox"/> Admit to Inpatient Bed <input type="checkbox"/> Place in Observation Bed <input type="checkbox"/> Outpatient
7/1/11	D.C. - Randy June
	Transfer to Inpatient Bed
	Jolly

**How to Improve**  
Every system is designed to produce the results it produces

Frank Federico  
Institute for Healthcare Improvement

○○○ **Outline**

- Introduction to how to improve
- Introduction to an improvement model
- Necessary components to be successful (leadership support, etc).
- Adopting a model for improvement rather than policy, education and training alone
- Case example

○○○ **Principles of a Safe System**

- Prevent
  - Simplify and standardize
- Detect
  - Processes to identify when the system has failed
- Mitigate
  - Take action to rectify

○○○ **How to Improve**

- Will
  - Status quo not acceptable; want new way
- Ideas
  - Those interventions that have been demonstrated as effective
- Execution
  - Implementing the desired changes

○○○ **Will**

- Desire to be better
- Desire to improve the system
- Status quo not acceptable
- Use data
- Use stories

○○○ **Ideas**

- Recommendations from IV Medication Safety Summit ASHP.org
- ISMP.org
- IHI.org
- Colleague next to you

○○○ | **Execution**

- Examine what exists
- Find willing participants
- Must have clinical 'buy-in' or cannot develop reliable process
- Simulation
- Test in one area
- Look for unintended consequences



○○○ | **Who should be involved?**

- Multidisciplinary effort: medications involve many disciplines
- Must have leadership support
  - Clinical and administrative
- Consider who else affected
- The patient is your key customer

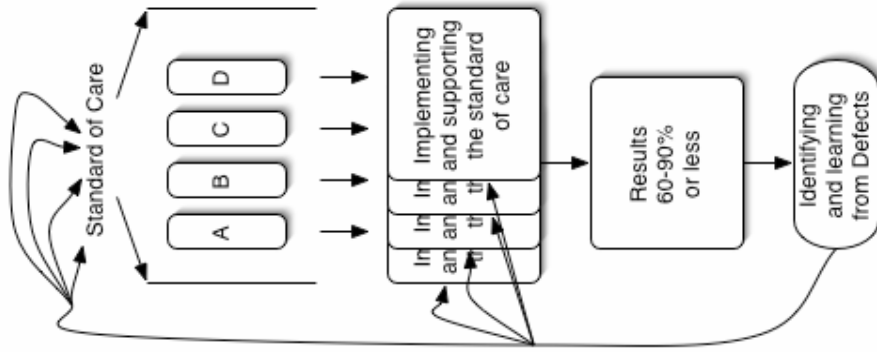


**Why is Standardization Important?**

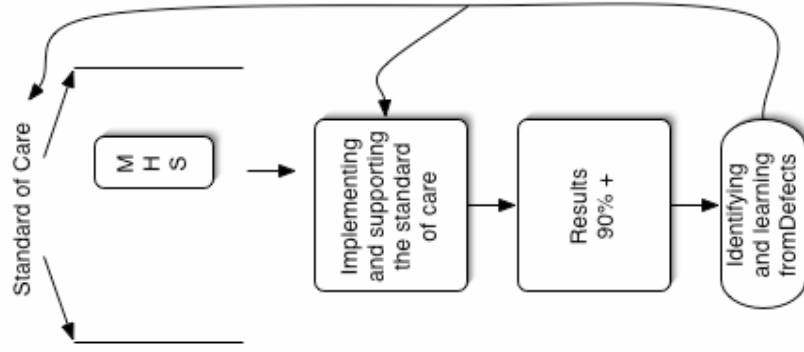


# Health Care Processes

**Current -**  
Variable, lots of  
autonomy  
not owned,  
poor if any  
feedback for  
improvement,  
constantly altered  
by individual  
changes,  
performance stable  
at low levels



**Desired -** variation  
based on clinical  
criteria, no individual  
autonomy to change  
the process,  
process owned from  
start to finish,  
can learn from  
defects before harm  
occurs, constantly  
improved by  
collective wisdom -  
variation





Terry Borman, MD Mayo Health System



○○○ | **Addressing Human Factors**



Human Factors and Reliability Science: 95% Performance  
(Designing sophisticated failure prevention, failure identification and mitigation)

- Decision aids and reminders built into the system
- Desired action the default (based on evidence)
- Redundant processes
- Use fixed current scheduling in design
- Take advantage of habits and patterns



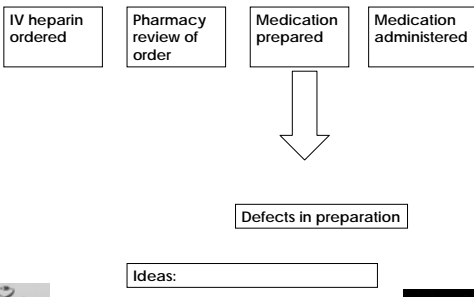


○○○ | **Getting Started**



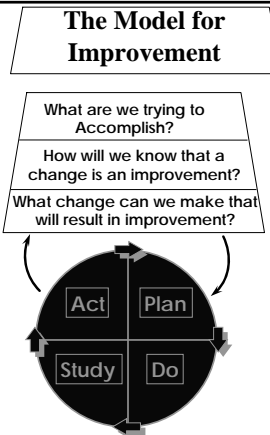
- Select what it is you want to improve
- Determine a segment where you can test the changes
- Develop a high-level flow diagram
- Determine where the greatest number of defects occur
- Design a process to address those defects



○○○ | **Example**





○○○ | **The Model for Improvement**





○○○ | **Getting Started**

- Who should be involved?
- Agree on what you are trying to achieve
- Identify best practices
- Select a smaller area/segment
- Use small scale tests
- Ask those at the front line for ideas



○○○ | **Remember**

- Training and education are necessary but not sufficient
- Policies are needed but not enough
- Procedures are developed to support policies
- A process owner is essential
- Develop measures for your system



○○○ | **Exercise**

- Pick a medication or group of medications
- Develop a high-level flow diagram
- Where do you find challenges/defects?
- How will you approach these challenges/defects?



○○○ | **Exercise**

- Describe who will be involved
- Describe your first step
- How will you know if your change is an improvement?

