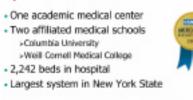
NewYork-Presbyterian The University Hospital of Columbia and Cornell



# FAILURE MODE AND EFFECTS ANALYSIS OF INTRAOPERATIVE DISPENSING PRACTICES FOR STERILE FIELD MEDICATIONS Orsini MJ, Dawson A, Wollenburg K, Cooper MR

#### **OBJECTIVE**

#### The use of medications on the sterile field is unique from other settings and its complexity makes it more susceptible to error. Infection control procedures require that medications and solutions be labeled and delivered aseptically. The use of multiple medications and non-standard concentrations, the lack of a defined labeling system, the common practice of verbal orders, the absence of patient unit-dosing, and the infrequent review by pharmacy of individual orders increases error risk. Published reports of serious patient injuries and deaths from medication errors on the sterile field from other hospitals lead us to conduct a proactive, comprehensive safety analysis of this medication use process in our institution. An area of concern identified was the dispensing practices in the operating rooms (OR). A sub-analysis of a comprehensive failure mode and effects analysis (FMEA) of the medication use process in the operating room was conducted that focused on dispensing practices for getting medications on the sterile field. The goal of this initiative was to identify potential failure modes in the dispensing system that could lead to an error.

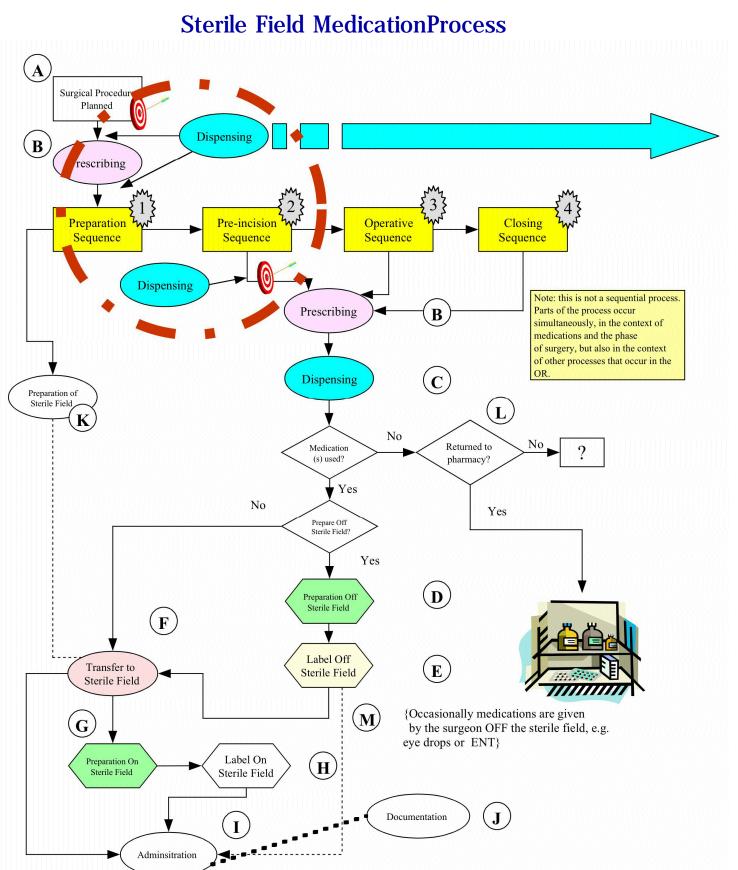
#### METHODS

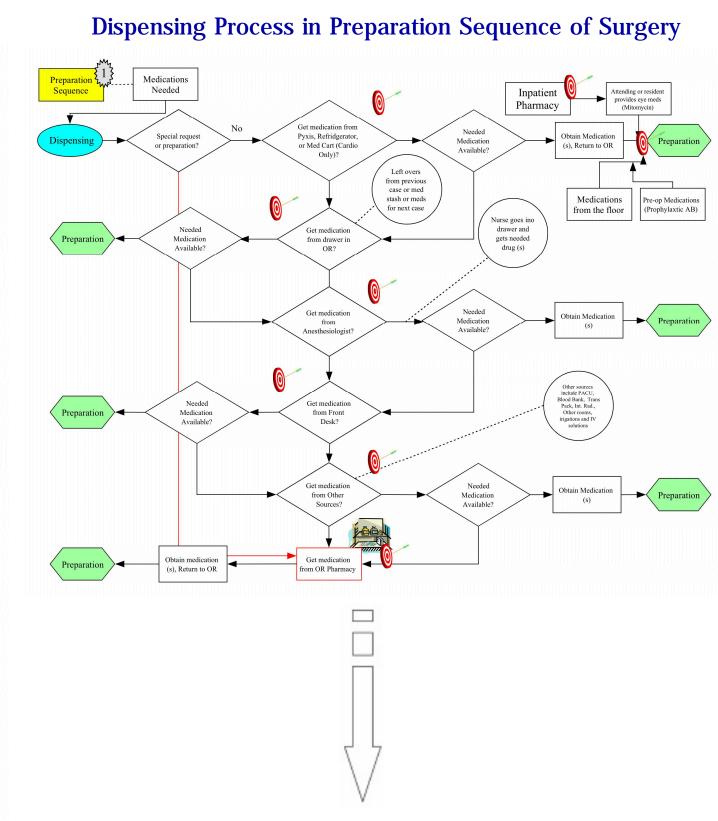
An interdisciplinary team of surgical nurses, operating room technicians, and pharmacists was assembled to conduct an FMEA. Flow-charts for the dispensing process for medications brought into the OR for use on the sterile field were created. The panel was asked to provide expertise on the medication use process, help identify system issues that may increase medication error risk, and assign criticality scores to identified failure modes. A research pharmacist coordinating the project served as the FMEA facilitator.

# **FMEA Steps**

- Form an interdisciplinary team
- Flow chart the process
- Determine failure modes

# RESULTS





# **Dispensing Process: REDESIGN**

- (what can go wrong)List cause (s) of failure
- List effect (s) of failure
- Investigate actions to reduce the criticality index
- Implement actions
- Follow up and assess

# **Criticality Scores**

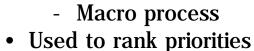
#### Criticality = Severity x Frequency x Discoverability

Score	10	1
Severity	10 - death	1 minor injury
Frequency	10 - often	1 not often
Discoverability	10 – not caught	1 almost always discovered

	S/I5/2004 1. Flow chart the selected process as it is routinely conducted (the actual process)     ispensing 2. List each step and each link between steps of the intended process in Column 5 below     3. Enter discrepancies between the flow chars (steps 18. 3. 2) in Column 5 below									
6.	7.	8.	9.	10.	11.	12.	13.			
List all potential Failure Modes	Potential effect	Severity of effect	Frequency of failure	Discover ability	Criticality (8:9x10)	Possible cause(s) (from RCA)	Recommended redesign			
	Waste of inventory	28	5	4.3	60.2					
Needed medication not available	Delay in giving medication, may delay surgery	5.8	5.8	4.5	151.4					
Expired medications	Expired medication given to patient	7.3	3.3	53	127.7					
Medications not stored in	× .		4.8	4						
			5.5	48						
Brand of product purchased changes, nurse may not be familiar		5.8	4.5	5.3	138.3					
Anyone can go and get medshard to keep frack of inventory. bitained from front Medication obtained from	Drug misadventure	7.5	7	3.5	183.8					
	Average Total	5.8	5.1	4.8	142.0					
	Failure Modes Overstocked medications variable Expired medication not available Expired medications Medications not stored in an orderly manner No requisition stip Brand of product purchased changes, modes in the store and the medication store and product purchased changes, modes, market to keep medication obtained from Medication obtained from	Failure Modes         effect           Cveredocked medication         Waste of investory           Delay no purp         Delay no purp           Needed medication not         medication, not           medications not         medication           available         Expired medication           Expired medication         grave and purp           delay argry         delay argry           Expired medication         grave and purp           Modications not stored in an orderly memory         Drug misadventure           No requisition slip         Mead charges           Deard of product parcharge and thus cannot find medication         Drug 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Medications not stored in an otderly manner         Drug misadventure         6         4.8         4         115.2           No requisition slip         Missed changes         4         5.5         4.8         105.6           David of priodu change, ranked changes         4         5.5         4.8         105.6           David of priodu change, ranked changes         4.5         5.3         138.3         138.3           prich set change, ranked for medication         Drug misadventure         5.8         4.5         5.3         138.3           prich set change, ranked for medication         Drug misadventure         7.5         7         3.5         183.8	Failuré Modes         effect         offent         offent <thoffent< th=""> <thof< td=""></thof<></thoffent<>			

# Where Do Sterile Field Medications Come From?

- Anesthesia
- Blood Bank
- Drawers in OR
- Eye Box (Ophth.)
- From the FloorFront Desk
- Intervent. Radiology
- Materials Mgt.
- Med cart (OR12A)
- PACU
- Pharmacy
- Pre-op areas
- "Private stash"
- Pyxis
- Refrigerator
- Residents
- Surgeons



- Target step

- Failure mode

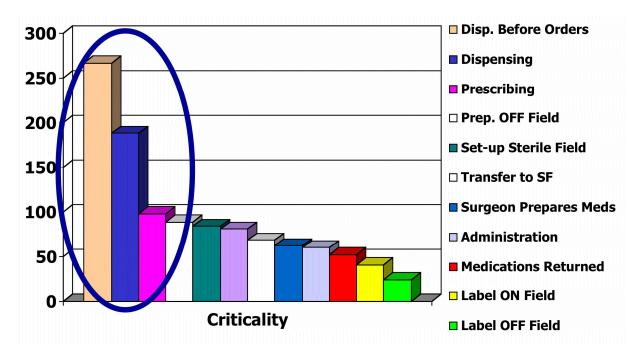
**Average Criticalities** 

• 3 scores



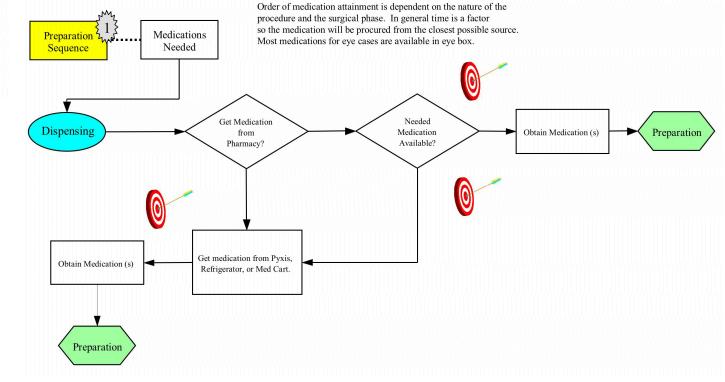
Targets represent steps in the process where the FMEA team felt the risk for a medication error is greatest.

# **Criticality Averages Total Process**



#### CONCLUSIONS

How a medication makes it into the OR is independent of other steps in the medication use process (for example the prescribing method (written or verbal order)) and was more controlled by non-medication related factors, such as an OR's location in relation to a Pyxis® machine or time constraints, i.e. the need to get medications into the OR quickly. These and other factors contribute to a perceived need to circumvent the usual distribution channels. Results from this analysis revealed system issues that could lead to a medication error. While an OR Pharmacy exists it was not always the first source for medication distribution. System improvements, whether inside or outside the medication process, that make it less attractive to go outside the customary supply route, will simplify a rather complex system of steps by removing the need for multiple medications sources.



### **Statistics**

72 Steps – 16 recognized for significant error poten	itial					
<ul> <li>Top 5 based on criticality</li> </ul>						
<ul> <li>Medications obtained from Pyxis <sup>®</sup></li> <li>Medications obtained from other sources</li> <li>All steps in dispensing process together</li> <li>Medications obtained fro OR Pharmacy</li> <li>Medications obtained from drawers (Stash)</li> </ul>	244 207 177 161 145					
45 Failure modes identified						
<ul> <li>Top 5 based on criticality</li> </ul>						
(Result-Medications obtained from unauthorized areas)						
<ul> <li>Needed drug not in stock</li> <li>Pyxis <sup>®</sup> to far from OR rooms</li> <li>Long line at Pyxis <sup>®</sup></li> <li>No pharmacy on ambulatory surgery floor</li> <li>Not enough time to get medications (late orders)</li> </ul>	349 328 316 297 293					