Complying with the FMEA Requirements of the New Patient Safety Standards

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New Patient Safety Standards

- It's a leadership thing!
  - Manage variation in performance
  - Integrated patient safety program implemented
  - Ongoing proactive program to identify risks to patient safety and reducing errors
  - Patient safety is a high priority

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LD.5.2

- Leaders ensure that an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented.

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Requirements of LD.5.2

- At least annually, select at least one high-risk process for proactive risk assessment
  - such selection to be based, in part, on information published periodically by the Joint Commission that identifies the most frequently occurring types of sentinel events and patient safety risk factors

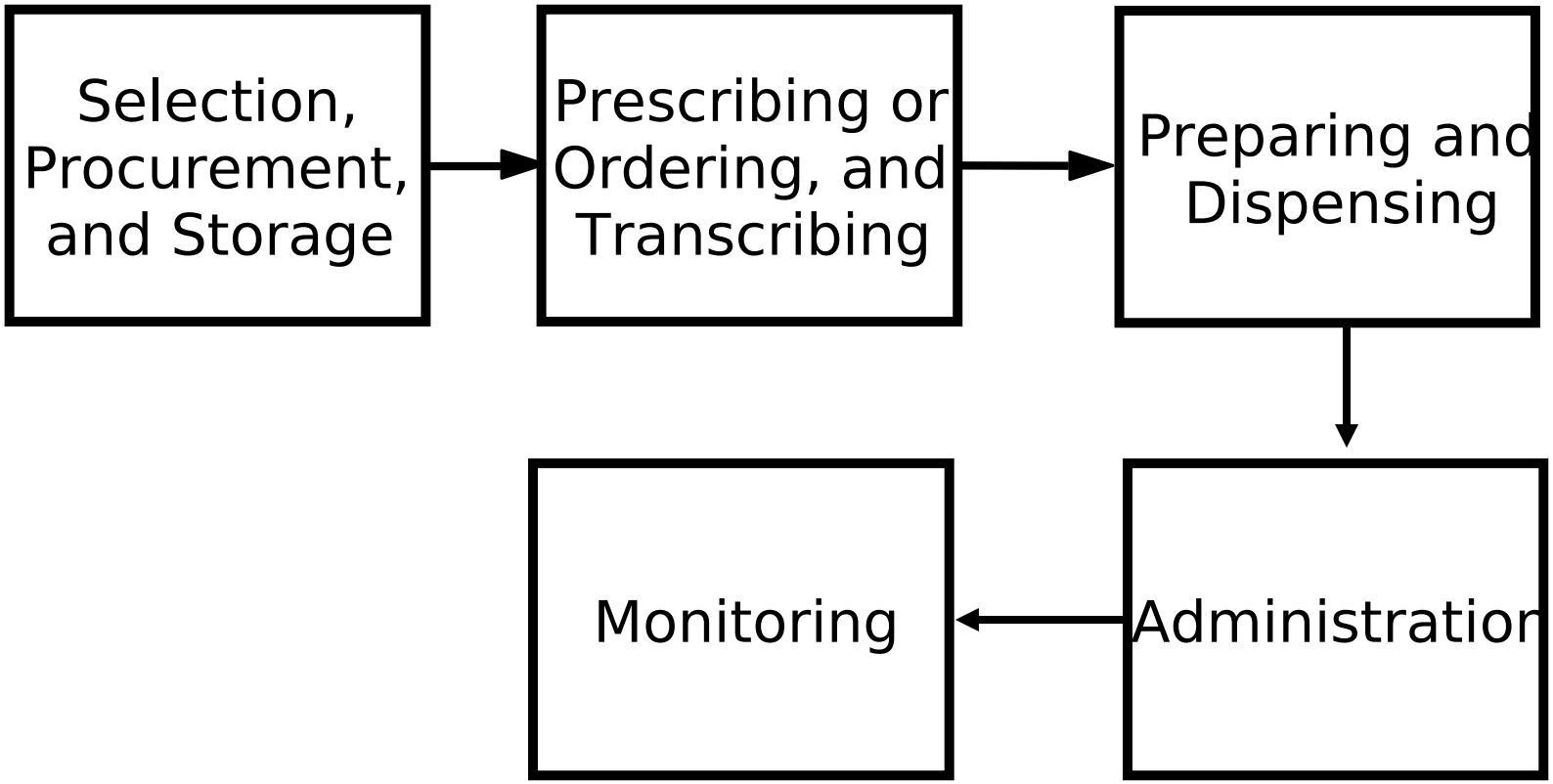
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High Risk Processes

- PI.4.2 – Processes that involve risks or may result in sentinel events
  - Medication Use
  - Operative and other procedures
  - Use of blood and blood components
  - Restraint use
  - Seclusion, when a part of care
  - Care/services provided to high-risk populations
  - Resuscitation

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The Medication Use Process



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Requirements of LD.5.2

- Conduct a Failure Mode and Effects Analysis (FMEA)
  - Assess the intended and actual implementation of the process to identify the steps in the process where there is, or may be, undesirable variation (i.e., what engineers call potential "failure modes")

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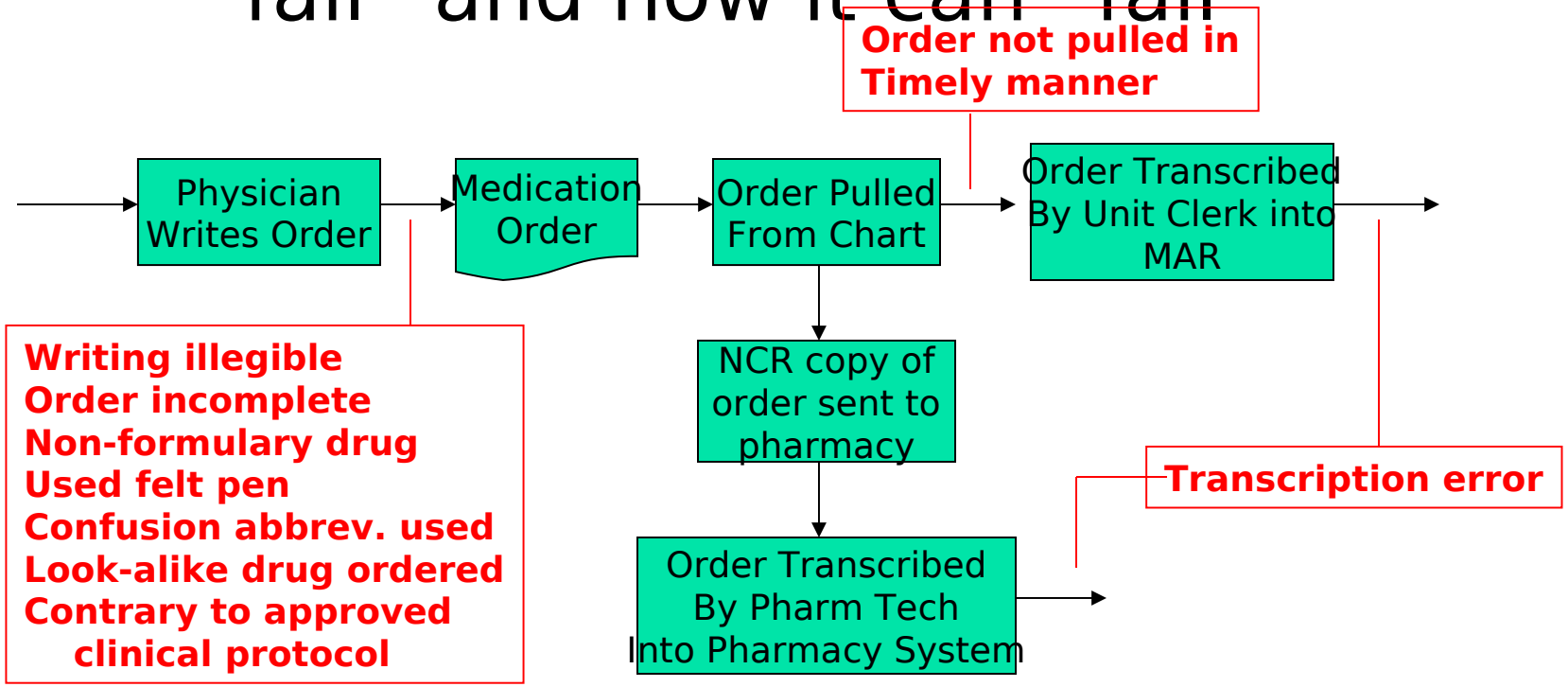
Step 1

- Construct a Detailed Flow Chart of the Process
  - Multi-disciplinary participation of all those involved in the process
  - Allocate plenty of time for this step
  - Be as detailed and complete as possible
  - Learn the flow chart process and symbols
    - Flow charting software can help

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Step 2

- Determine each step that can "fail" and how it can "fail"



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Requirements of LD.5.2

- For each identified "failure mode" identify the possible effects on patients (what engineers call the "effect"), and how serious the possible effect on the patient could be (what engineers call the "criticality" of the effect)

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Step 3

- Determine the “effect” of each possible “failure”

Illegible handwriting	**Wrong drug, dose, freq, route**
Incomplete order	**Wrong dose, freq, route**
Non-formulary drug	**More expensive therapy**
Used felt pen	**Cannot be read on NCR copy**
Confusing abbreviation used	**Wrong dose**
Look alike drug name used	**Wrong drug**
Doesn’t followed approved clinical protocol	**Wrong drug, dose, freq, route**

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Step 4

- Determining how serious the possible effect(s) can have on the patient – criticality
- For each effect:
  - Estimate likelihood of failure (occurrence scale rank)
  - Estimate severity of failure (severity scale rank)
  - Estimate probability that failure is detected (detection scale rank)
  - Then compute criticality index
    - is product of above three or CI=OSR x SSR x DSR

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Occurrence Scale

Likelihood		Probability
Remote	(1)	1 in 10,000
Low	(2, 3, 4)	1 in 5,000
Moderate	(5, 6)	1 in 200
High	(7, 8)	1 in 100
Very High	(9, 10)	1 in 20

- Remote
  - No known occurrence
- Low
  - Possible, but no known data
- Moderate
  - Documented but infrequent
- High
  - Documented and frequent
- Very High
  - Documented, Almost certain

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Severity Scale

Outcome possibilities

- Slight annoyance (1)
  - May affect the system
- Moderate System Problem (2, 3)
  - May affect the patient
- Major System Problem (4, 5)
  - May affect the patient
- Minor Injury (6)
- Major Injury (7)
- Terminal Injury or Death (8, 9)

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Detection Scale

Likelihood	Probability
Very High (1)	9 out of 10
High (2, 3)	7 out of 10
Moderate (4, 5, 6)	5 out of 10
Low (7, 8)	2 out of 10
Remote (9)	0 out of 10

- Very High (1) 9 out of 10
  - Error always detected
- High (2, 3) 7 out of 10
  - Error likely to be detected
- Moderate (4, 5, 6) 5 out of 10
  - Moderate likelihood of detection
- Low (7, 8) 2 out of 10
  - Low likelihood of detection
- Remote (9) 0 out of 10
  - Detection not possible at any point

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Step 4 (con't)

- Rank prioritize the failure modes based on their criticality index.

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Example: Top 5 criticality-indexed failure modes*

- Having lethal drugs available on floor stock
- Mistakes in math when calculating doses
- Doses or flow rates for IV's calculated incorrectly
- Not checking armbands before administration
- Excessive drugs on nursing floor stock

*From: E. Williams and R. Talley "The Use of Failure Mode Effects and Criticality Analysis in a Medication Error Subcommittee" *Hospital Pharmacy* 1994 (Apr); 29(4): 331-338

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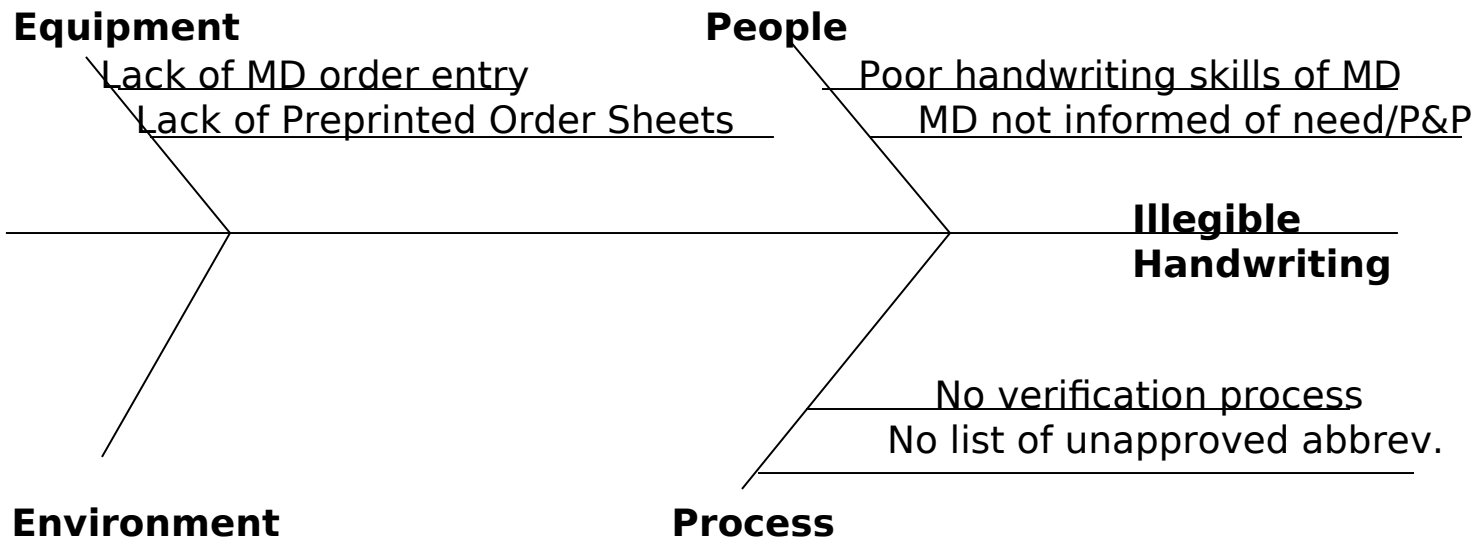
Requirements of LD.5.2

- For the most critical effects, conduct a root cause analysis to determine why the variation (the failure mode) leading to that effect may occur

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Step 5

- Conduct root cause analysis of top CI failure modes



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Requirements of LD.5.2

- Redesign the process and/or underlying systems to minimize the risk of that failure mode or to protect patients from the effects of that failure mode

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Step 6

- Brainstorm actions that could reduce the criticality index starting with failure modes that have the highest CI value that:
  - Decrease likelihood of occurrence
  - Decrease the severity of effects
  - Increase the probability of detection

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Requirements of LD.5.2

- Pilot test and implement the redesigned process.

- Identify and implement measures (indicators) of the effectiveness of the redesigned process.

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Requirements of LD.5.2

- Implement a strategy for maintaining the effectiveness of the redesigned process over time.

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Note similarities to PI

- PI.2 The new/modified process is designed well.
  - PI.2.1 Performance expectations are established for new/modified processes
  - PI.2.2 The performance of new/modified processes is measured
- PI.5 Improved performance is achieved and sustained over time

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Remember

- Take small bites – keep it simple.
  - FMEA on PCA
- Think: “what could possibly go wrong”
  - Or what has gone wrong frequently in past
- Any modification to the process, creates new risk points.

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Parting Thought

- On survey, JCAHO is currently not evaluating how good your FMEA process is.
- JCAHO is evaluating whether you used a proactive process (that includes the elements of the intent) to determine risk points and then took action to reduce the risk

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Questions?