Failure Modes & Effects Analysis (FMEA) Tool

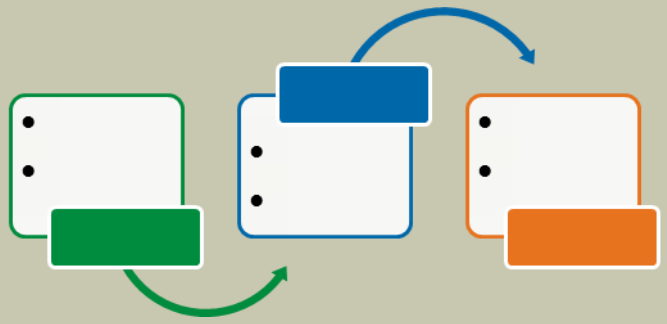
Presented by: Alexia Eslan, JSI

Wednesday, March 14

12-1 PM MT

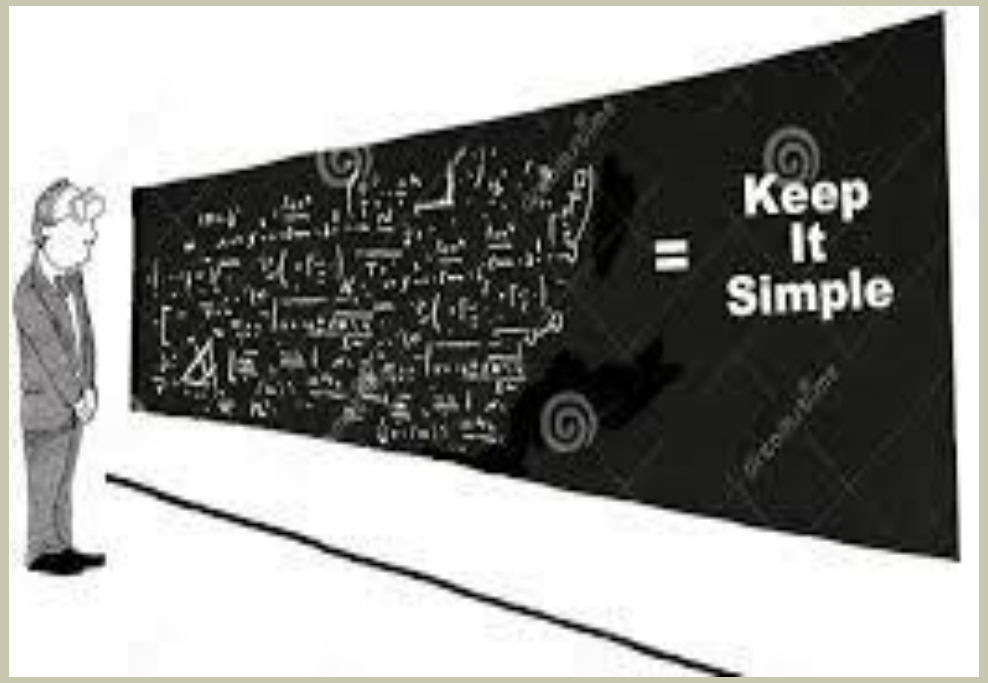
Goals for Today

- When and why to use the FMEA tool
- How to use it and possible tailoring
- Provide an example of how one clinic used it



The Lean Method

An approach to operations improvement. Emphasis is on reducing waste, developing smooth workflow, and creating a culture responsive to patient needs.



Definition - FMEA

A structured approach to:

- Evaluate a new process design
- Identify ways in which a process can fail
- Estimate the risk associated with specific steps
- Prioritize actions that should be taken to reduce the risk
- Evaluate the current control plan

Primary Directive:

- Identify ways the process can fail and eliminate or reduce the risk of failure

Role of a Process FMEA

- Key tool of team to evaluate and improve a new process in a **preemptive** manner (before failures occur)
- Used to **prioritize** resources to ensure process improvement efforts are beneficial to the “customer” (patient, staff, providers, etc.)
- Used to **document** completion of projects
- Should be a **dynamic** document, continually reviewed, amended, updated…

Definition of Terms

Failure Mode

- ✓The way in which a specific process step fails – if not detected and either corrected or removed, will cause “Effect” to occur.

Anything that a team member can foresee going wrong is considered a Failure Mode.

Definition of Terms

Effect

- ✓Impact on team or patient expectations/needs and downstream processes.
- ✓The relationship between the Failure Mode and the Effect is not always one-to-one.

Cause

- ✓Sources of process variation that causes the Failure Mode to occur.

Definition of Terms

Current Controls

- ✓Systematized methods/devices in place to prevent or detect failure modes or causes.
- ✓Prevention consists of fool proofing, automated control and set-up verifications.
- ✓Controls consist of audits, checklists, inspection, testing, training, standing orders, policies & procedures, preventive maintenance, etc.

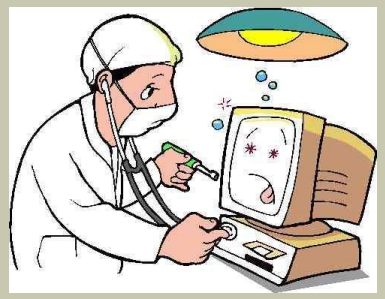
FMEA Model

Controls

Cause

Prevention

Failure Mode



Detection

Effect

Detection


The TOOL

FMEA Tool Template

(*Tailor as appropriate*)

FMEA Form

Process: _____ Prepared By: _____

Responsible: _____ FMEA Date (Orig.): _____ (Rev.): _____

Step in Process	Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY (1 - 10)	Potential Causes	Likelihood of OCCURRENCE (1 - 10)	Current Controls	Likelihood of DETECTION (1 - 10)	Risk Priority Number (RPN)	Action(s) Recommended	Person Resp.	Actions Taken	SEVERITY (1 - 10)	OCCURRENCE (1 - 10)	DETECTION (1 - 10)	Revised RPN
Number steps starting with 1 in order of occurrence	What is the process step?	In what ways could the step or feature go wrong?	What is the impact on the team or patient if this failure is not prevented or corrected?		What causes the step or feature to go wrong? (how could it occur?)		What controls exist that either prevent or detect the failure?			What are the recommended actions for reducing the occurrence of the cause or improving detection?	Who is responsible for making sure the actions are completed?	What actions were completed (and when) with respect to the RPN?				
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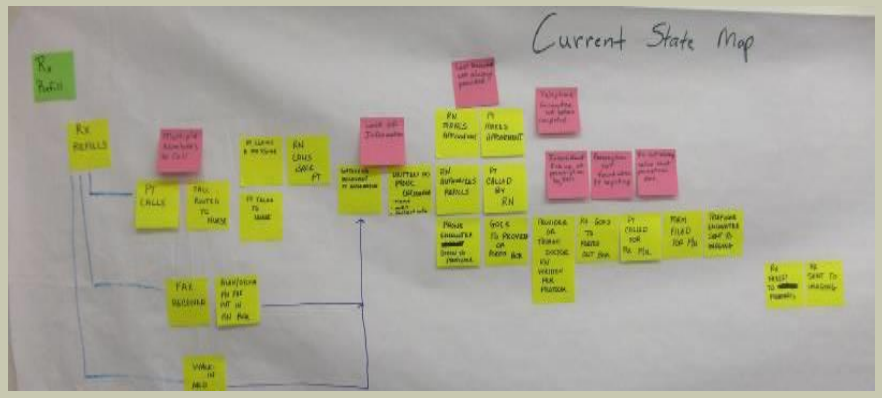
First Steps

1. Identify the new process
2. Identify a lead and team
3. Map out process



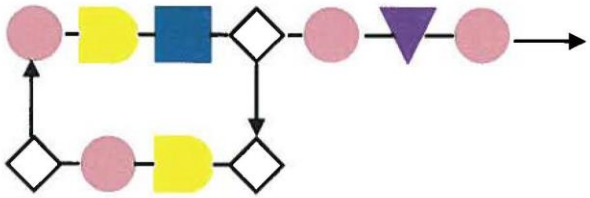
Process Mapping

The point of mapping is not the map, but understanding the flow of information and material.

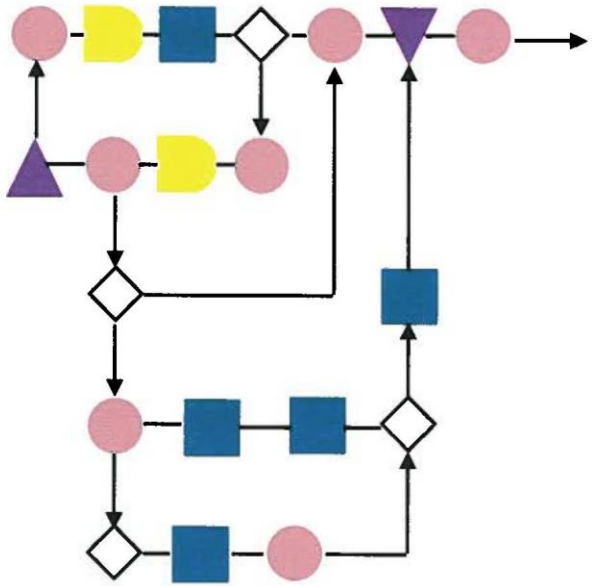
There are at least 3 Versions of each Map

(Usually)

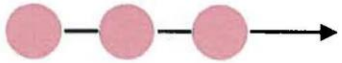
What You *Think* It Is...



What It *Actually* Is...



What You Would *Like It To Be...*



Two Main Sections

FMEA Form

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Responsible: _____ FMEA Date (Orig.): _____ (Rev.): _____

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FMEA Tool Completion Steps

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FMEA Tool Completion Steps

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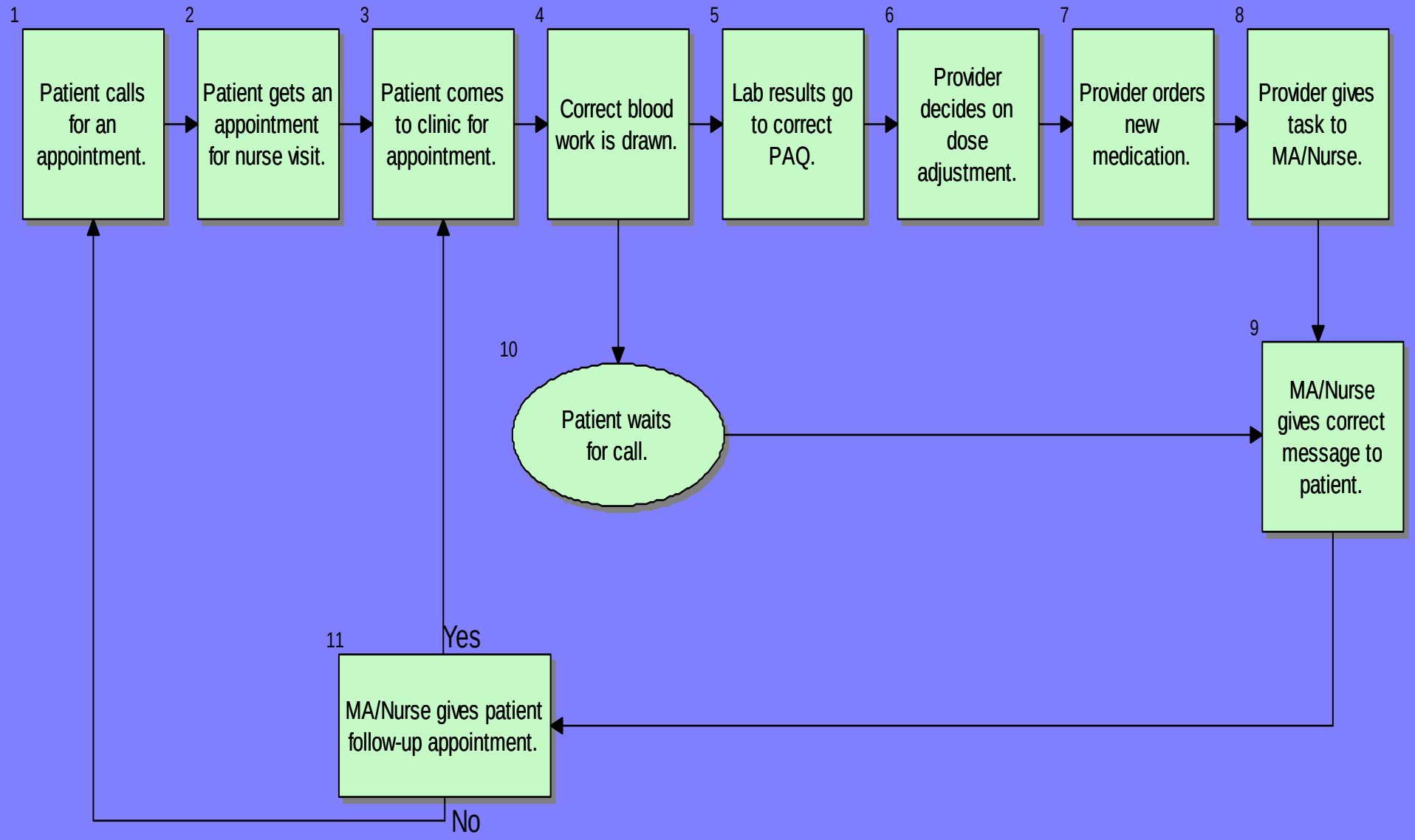
Let’s View an Example

Ongoing Warfarin Management

Warfarin (Coumadin)

- Oral anticoagulant most frequently used to control and prevent blood clots
- Safe and effective use a challenge
  - Prescribing the right dose
  - Goal of anticoagulant therapy is to administer the lowest possible dose of anticoagulant to prevent clot formation or expansion
  - Doses are adjusted to maintain the patient's International Normalized Ratio (INR)

Ongoing Warfarin Management



FMEA Tool Example (*Screen Share*)

FMEA Form

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Tips for Success

- Have an assigned lead to help with the process management
- The time invested upfront preventing possible failures will save you a lot of time down the line once you implement the process.
- Bringing together a cross-functional team to complete the tool and work on solutions helps empower all team members.
- The RPN will give you a clear action plan on what steps to focus on, and how to prioritize steps.
- What turns out to be the highest RPN, can be very surprising.

Reminders

- Questions: tap@jsi.com
- Recording: tap.adobeconnect.com/TBC