TOOL: Failure Mode and Effects Analysis

What is the tool?

The FMEA Method attempts to identify all possible failures (what might go wrong) in a process and identifies the potential causes and effects of these failures before they occur. The team can then take proactive steps to prevent or minimize process failures.

When should the tool be used?

FMEA can be used during a quality improvement project's planning phase to help identify and prioritize areas for improvement based on a risk calculation.

Example: A hospital is implementing a new medication dispensing process and wants to prevent medication errors.
(Adopted from IHI, referenced below)

Step in process	Potential failure mode	Potential causes of failure	Potential failure effects	Likelihood of occurrence (1-10)	Likelihood of detection (1-10)	Severity (1-10)	Risk score	Actions to reduce occurrence of failure
Orders are written for new medications.	The first dose may be given prior to the pharmacist's review of the orders.	Medication ordered may be available and easily accessed in the dispensing machine.	Patient may receive incorrect medication, incorrect dose or a dose via an incorrect route.	6	5	5	150	Assign clinical pharmacists to patient care units so that all medication orders can be reviewed as they occur.
Orders are written to discontinue a medication or change the existing order.	Orders are written to discontinue a medication or change the existing order.	All doses needed for a 24-hour period are delivered to the drawer. Multi-dose vials may be kept in the patient-specific drawer. Medications are available in the dispensing machine.	Patient may receive medications that have been discontinued or the incorrect dose of a medication that has been changed.	8	5	8	320	Schedule pick-ups of discontinued medications, including refrigerated medications, twice per day. Use dispensing machine screen to verify all information regarding current and discontinued medications prior to each administration.
Orders are written for a non-standard dose of a medication.	Nursing staff may prepare an incorrect dose when manipulating the medication.	Staff prepare the dose using medications from the dispensing machine and manipulate them to get the dose ordered.	Patient may receive an incorrect dose.	3	5	8	120	Prepare all non-standard doses in the pharmacy and dispense each as a patient-specific unit dose.

REFERENCES:

1. CMS. "Guidance for Performing Failure Mode and Effects Analysis with Performance Improvement Projects."
2. Institute for Healthcare Improvement. "Failure Modes and Effects Analysis."