Failure Mode and Effects Analysis (FMEA)

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Manager, Quality, Safety, & Performance Improvement, QHR

Agenda

- FMEA Purpose
- FMEA Team and Method
- Practice Scenario
What Is Failure Mode and Effect Analysis (FMEA)?

• Systematic method of identifying and preventing product and process problems before they occur
  ▪ Aimed at prevention of failure and improvement in detectability
  ▪ Doesn’t require previous adverse event or near miss
  ▪ Multidisciplinary team of subject matter experts
History of Failure Mode and Effect Analysis (FMEA)

For fifty years, goal has been, and continues to be, to prevent accidents from occurring

Why?

• Change is constant
  • The healthcare environment is dynamic; changes may affect the process causing unintended consequences

• Avoid Cost
  • Defects can cause patient harm, may impact staff, excess costs of care

• Ease
  • Less work and less harm to be proactive, rather than reactive

• Avoid barriers
  • Proactive approach avoids the barriers to improvement that occur after an actual event (shame, blame, fear, embarrassment)
When To Conduct an FMEA

- Any existing high-risk process
  - Not recently evaluated
  - Recently changed

- New process with unknown risk

Definitions

- **Failure Mode**: A way that a process can fail to provide the anticipated result
- **Cause**: The reason the step in the process failed
- **Root Cause**: The underlying reason the process failed
- **Effect**: An undesirable outcome (consequence) of the cause(s) of failure
- **Effective Control Measure**: Barrier that eliminates or substantially reduces likelihood of hazardous event from occurring
**Process Analysis Score & Risk Priority Number**

- **Risk Probability Number (RPN)**
  - Numeric score that is used to help rank order the failure modes/effects.
  - High RPN
    - The worst case is represented by those defects which are severe, likely to occur, and difficult to detect.
    - High RPN indicates priority for improvement.

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**FMEA vs. RCA**

**Similarities:**
- Focus on system issues
- Interdisciplinary team of subject matter experts
- Use of a process flow diagram
- Scoring of events
- Use of cause/effect questions and tools
- Results in plan of action

**Differences:**

<table>
<thead>
<tr>
<th></th>
<th>RCA</th>
<th>FMEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrospective</td>
<td>Triggered by event</td>
<td>Triggered by process change or perception of risk</td>
</tr>
<tr>
<td>Triggered by event</td>
<td>Scoring of severity/probability</td>
<td>Scoring of severity/probability/detectability</td>
</tr>
</tbody>
</table>
Agenda

FMEA Purpose

FMEA Team and Method

Practice Scenario

First FMEA Steps – Review Data & Identify Team Members
Pre-Work & Project Charter

• Pre-work
  ▪ Data collection
  ▪ Observation
  ▪ Draft scope and charter
  ▪ Approval
  ▪ Review:
    o Regulations
    o Literature
    o Evidence-based practices/protocols

FMEA Name
Patient Identification in the Emergency Department

Sponsors
Hospital CEO and CDO

Purpose
Twenty-three patient identification “near miss” events were reported at the Hospital from Jan to Oct 2015. The hospital has selected this high risk area for proactive analysis and process redesign.

Aim
Using the FMEA process, this multidisciplinary team will evaluate patient identification failure modes. Re-design the parts of the process which have the greatest severity of risk or greatest frequency of risk for error in patient identification. Initiate tests of change by 10/30/15. ‘Standardize’ new process and communicate to all staff by 11/15/15. Goal is to reduce zero near miss events of patient or specimen identification by December 2015.

Scope
Evaluate the patient identification process from Emergency Department arrival until inpatient nursing assessment. Includes two events in the ED: 1) blood sample sent to lab and 2) patient sent to Radiology. The FMEA will address patient identification wrist bands, specimen labels, staff roles and handoffs.

Team
Team Leaders: __________________________

Team Members:
Admitting/Patient Access
  • Patient Access Registrar
  • Patient Access Supervisor ED
  • ED Nurse Manager
  • ED RN
  • ED Medical Technician
  • ED Unit Clerk Transport
  • Transport Staff Lab
  • Blood Bank Registered Medical Technologist Radiology
  • Radiology Technologist Service Excellence
  • Lead Physician IT

Identify the Team Members & Set Roles

FMEA Topic: ____________________________________________

Date Started __________ Date Completed_____________

Team Members
1. ____________________________ 4. ____________________________
2. ____________________________ 5. ____________________________
3. ____________________________ 6. ____________________________

Team Leader ____________________________

YES / NO Are all affected areas represented?

YES / NO Are different levels (management, front line, clinical) and types of knowledge (clinical, regulatory, process expertise, data) represented on the team?

(Name) Who will maintain records of project charter/ current process/ scoring/ action items/ decisions?
FMEA Usually Lasts Six to Twelve Meetings

- **Pre-meeting**
  - Identify the topic
  - Select the team

- **1st team meeting**
  - Diagram process
  - Identify sub-processes
  - Verify scope of work with advisor

- **Additional team meetings**
  - Visit the workstation(s) to observe the process
  - Verify that all processes and sub-process steps are correct
  - Brainstorm failure modes
  - Assign individual team members to consult with process users
  - Identify failure modes causes
  - Refine failure mode causes on the basis of user input
  - Identify corrective actions and assign follow-up responsibilities
  - Assign team members to follow-up with the individuals charged with taking corrective action. Refine corrective actions based on feedback
  - Test the proposed changes
  - Meet with top management to obtain approval for all actions

- **Post team meetings**
  - The advisor follows up with the responsible parties until all actions are complete

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Process Flow & Identification of Failure Modes/ Effects

1. Identify FMEA Topic
2. Define Scope of Work
3. Gather Current Data/ Policy/ Regulation for Reference
4. Create Multidisciplinary Team Including Front Line Staff
5. Flow Current Process & Identify Failure Modes/ Effects
6. Score Frequency
7. Score Potential Impact
8. Score Risk Priority Number & Score
9. Identify Countermeasures & Test
10. Standardize the New Process
Current State Process Flow & Identification of Failure Modes

Scenario: Patient arrives to ED and within 15 min, is unable to communicate

Learn Through Questioning

• A systematic approach of asking questions:
  ▪ How is it that...?
  ▪ What do we know about . . .?

• Keep going until your answer to “why” is:
  ▪ I don’t know (and probably don’t need to)
  ▪ I don’t care
    o “It fell because of gravity.”
    o “Why is there gravity?”
    o “I don’t care.”

Source: Konrad C. Nau, MD. Professor and Chair WVU Dept Family Medicine-Eastern Division
Tools To Help Discover Root Cause

- Tools to help us understand and describe the problem areas:
  - Force field analysis (driving and restraining forces)
  - Five Whys (ask “why” five times to get to root causes)
  - Cause and effect diagram (fishbone)

5 Whys

- My car will not start (the problem)
  - Why? - The battery is dead (first why)
  - Why? - The alternator is not functioning (second why)
  - Why? - The alternator belt has broken (third why)
  - Why? - The alternator belt was well beyond its useful service life and has never been replaced (fourth why)
  - Why? - I have not been maintaining my car according to the recommended service schedule (fifth why, root cause)

Source: Ghirassi / WPIC / UPMC / Univ of Pittsburgh / 2009
**Injury**
- Fall
- Wet Surface
- Leaky Valve
- Seal Failure

**Fall**
- Wet Surface
- Leaky Valve
- Seal Failure
- Not Maintained

**Wet Surface**
- Leaky Valve
- Seal Failure

**Leaky Valve**
- Seal Failure

**Seal Failure**
- Not Maintained

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**Cause and Effect Diagram (6 Categories)**

Factors contributing to defect XXX

- Measurements
  - Calibration
  - Microscopes
  - Inspectors
  - Humidity
  - Temperature
  - Environment
- Materials
  - Alloys
  - Lubricants
  - Suppliers
  - Engager
  - Brake
  - Speed
- Personnel
  - Shifts
  - Training
  - Operators
  - Machines
Identify Effects of Each Failure Mode

ED RN
- Collect ID at ED Arrival
- RN selects wrong Pt from master list

Registrar
- Verify ID in ED
- Pt not given band
- Pt wears incorrect band

Attach to Pt
- Pt not green band
- Pt not wearing ID band

Place orders
- Pt removes band

Label stand in ED
- Patient is eager to be seen and approaches the ED RN
- Patient doesn’t provide accurate patient ID info
- Patient is too violent for staff to ask for information
- Patient is not aware of the ID process
- RN has not seen Pt

Staff pick up ED Patient for RAD
- Pt pick up is not at the patient’s wrist
- Pt pick up is not at the patient’s wrist
- Pt pick up is not at the patient’s wrist

ID in RAD
- Pt pick up is not at the patient’s wrist
- Pt pick up is not at the patient’s wrist
- Pt pick up is not at the patient’s wrist

Admitting process ID
- Pt not wearing ID band
- Pt not wearing band
- Pt not wearing band

Inpatient Floor ID
- No ID
- No ID (Pt not given)
- No Pt ID

List effects for each failure mode
### Score Effects & Causes

1. Effect: Wrong labels on blood tubes
   - Cause: Unaware of previously listed allergies
   - Score: Medium

2. Effect: Wrong billing info
   - Cause: No photo ID
   - Score: High

3. Effect: RN selects wrong Pt from master list
   - Cause: ED RN collects ID at ED arrival
   - Score: Low

### Score Using FMEA Template

<table>
<thead>
<tr>
<th>ED RN</th>
<th>Improper Medication</th>
<th>Physical Injuries</th>
<th>Potential Effect of Failure</th>
<th>Severity (Rate/Frequency)</th>
<th>Occurrence</th>
<th>Detection</th>
<th>Mitigation</th>
<th>Future State Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>No photo ID</td>
<td>Wrong labels on labeled tubes</td>
<td>Unknown of products on allergies</td>
<td>Wrong billing info</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
<td>Improve identification</td>
</tr>
</tbody>
</table>

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### Scoring Scale

<table>
<thead>
<tr>
<th>Severity Rating</th>
<th>Severity Description</th>
<th>Frequency/Occurrence Rating</th>
<th>Frequency/Occurrence Description*</th>
<th>Likelihood of Detection Rating</th>
<th>Likelihood of Detection Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No impact on the results of the entire process. No negative impact on patient care.</td>
<td>1</td>
<td>Infrequent, almost never would happen (1/2000 or &lt;10% of the time)</td>
<td>1</td>
<td>Simple to identify, a lot of steps in the process that would prevent this from happening</td>
</tr>
<tr>
<td>3</td>
<td>Mild impact on the results of the process. Low negative impact on patient care.</td>
<td>3</td>
<td>Could happen – 1 out of 5 years (1/100 or 20% of the time)</td>
<td>3</td>
<td>Fairly easy to detect, several steps to prevent it from happening</td>
</tr>
<tr>
<td>5</td>
<td>Moderate impact on the results of the process. Moderate impact on patient care.</td>
<td>5</td>
<td>Likely to happen – once a year (1/200 or 50% of the time)</td>
<td>5</td>
<td>Moderately detectable, fair number of fail safe systems to prevent an error</td>
</tr>
<tr>
<td>7</td>
<td>Significant impact on the results of the process. Impact on patient care would be moderately high.</td>
<td>7</td>
<td>Very likely to happen – once a month (1/100 or 75% of the time)</td>
<td>7</td>
<td>Difficult to detect, only one step to prevent the failure from happening</td>
</tr>
<tr>
<td>10</td>
<td>Entire process could fail. Definite negative impact on patient care.</td>
<td>10</td>
<td>Will happen at least once/ day (1/20 or 95% of the time)</td>
<td>10</td>
<td>Impossible to detect, no steps to prevent it from being detected by someone</td>
</tr>
</tbody>
</table>

* Frequency Note: For most patient care events, refer to the narrative descriptions. For very high frequency events, e.g. receiving lab orders, it may be useful to refer to the alternate scoring for counts. As a team, choose the most appropriate scale and maintain the same scoring system for both current and future data.

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### Enter Failure Mode and All Associated Effects

<table>
<thead>
<tr>
<th>Major Process Step</th>
<th>Potential Failure Mode</th>
<th>Potential Effect of Failure</th>
<th>SEVERITY (How severe is the effect of this failure?)</th>
<th>OCCURRENCE (How often will this cause of this failure occur?)</th>
<th>Current Method to Prevent this Failure</th>
<th>Current Method to Detect this Effect</th>
<th>DETECTION (How reliably can we detect the cause?)</th>
<th>RISK PRIORITY NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID at Arrival</td>
<td>RN selects wrong Pt ID</td>
<td>Wrong label on blood</td>
<td>6 (Least Severe)</td>
<td>Rate 1-10</td>
<td>None</td>
<td>None</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pt ID not verified</td>
<td></td>
<td></td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unaware of allergies</td>
<td>9 (Moderate Severe)</td>
<td>10+Occurs daily or more</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Check Pt ID at VISITORS later in stay</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wrong billing info</td>
<td>4 (Severe)</td>
<td>Rate 1-10</td>
<td>None</td>
<td>None</td>
<td>10</td>
<td>1</td>
</tr>
</tbody>
</table>

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Calculate RPN & Identify Priorities for Improvement

RPN: Multiply Severity, Occurrence, Detection

<table>
<thead>
<tr>
<th>Major Process Step</th>
<th>Potential Failure Mode</th>
<th>Potential Effect of Failure</th>
<th>SEVERITY (How severe is the effect of this failure?)</th>
<th>OCCURRENCE (How often will this cause of this failure occur?)</th>
<th>DETECTION (How reliably can we detect the cause?)</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID at Arrival</td>
<td>RN selects wrong Pt in EMR</td>
<td></td>
<td>Rate 1-10/10=Most Severe</td>
<td>Rate 1-10/10=Most Occurs daily or more</td>
<td>Rate 1-10/10=Unable to detect</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wrong label on blood</td>
<td></td>
<td>6 x</td>
<td>10</td>
<td>None</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>540</td>
</tr>
<tr>
<td></td>
<td>Unaware of allergies</td>
<td></td>
<td>9 x</td>
<td>8</td>
<td>None</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>72</td>
</tr>
<tr>
<td></td>
<td>Wrong billing info</td>
<td></td>
<td>4 x</td>
<td>6</td>
<td>None</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>96</td>
</tr>
</tbody>
</table>
Prioritizing Which Failure Mode to Control

- High risk prioritization number (RPN)
- High severity (regardless of RPN)
- Failure mode will result in failure of the larger system
  - Single point of weakness
- Failure mode or its cause would not be easily detectible upon failure and could reach the patient

Priorities:
High RPN, High Severity, Single Point of Weakness, Poor Ability to Detect

<table>
<thead>
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<th>OCCURRENCE (How often will this cause of this failure occur?)</th>
<th>Current Method to Prevent this Failure</th>
<th>Current Method to Detect this Effect</th>
<th>DETECTION (How reliably can we detect the cause?)</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID at Arrival</td>
<td>RN selects wrong Pt in EMR</td>
<td>Wrong label on blood</td>
<td>6</td>
<td>2</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10</td>
<td>10</td>
<td>None</td>
<td>None</td>
<td>1</td>
<td>540</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>9</td>
<td>9</td>
<td>None</td>
<td>None</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>3</td>
<td>None</td>
<td>None</td>
<td>3</td>
<td>72</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td>4</td>
<td>None</td>
<td>None</td>
<td>4</td>
<td>96</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10</td>
<td>10</td>
<td>None</td>
<td>None</td>
<td>10</td>
<td>96</td>
</tr>
</tbody>
</table>

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Decide to Accept Result or Test Interventions; Re-Score & Standardize Effective Process

Actions and Outcome Measures

- Decide to “eliminate,” “control,” or “accept” the cause of the failure mode
- Describe an action for each prioritized failure mode cause that will eliminate or control it
- Identify outcome measures that will be used to analyze and test the re-designed process
- Identify a single, responsible individual by title to complete the recommended action
- Indicate whether top management has concurred with the recommended actions
Select Measures of Success & Take Action

Select measure of success & test interventions for each prioritized failure mode

Success Factors for FMEA Teamwork

• Make it manageable
  • Make sure the team really understands the definitions and scoring
  • Narrow the list of failure modes/ causes
  • Selecting no more than 25 failure modes will help make the process and timeline feasible

• Avoid simple negative descriptors
  • Examples: “poorly,” “inadequate”
  • Use a more accurate, clear statement
    o “The teaching manual was poorly written” vs
    o “Start and stop times are not documented in the teaching protocol”

• Check in with executive sponsor after each meeting
  • Share findings, process understanding
  • Explain planned interventions
  • Ensure leadership support
Success Factors for FMEA
Action Plans & Implementation

• Create local ownership
  ▶ Assign process owners to lead tests of change, capture data, report measures
  ▶ Owners should be people who work in the department where the process takes place

• Spread the safe culture mindset
  ▶ Focus on learning and process reliability, since any person in an unreliable process can make an error
  ▶ Demonstrate to staff that we can make dangerous situations detectable through FMEA
  ▶ Empower the front line staff to make a difference

• Stay confident and knowledgeable with your quality tools
  ▶ Aim for one or more FMEAs a year
  ▶ Collaborate with other quality leaders to share methods and success factors

Agenda

- FMEA Purpose
- FMEA Team and Method
- Practice Scenario
Practice Scenario – Choose One Failure Mode

Failure Mode and Effects Analysis: Arrival to work
Date last updated: 5/7/15

Current State Process: (Highlighted process steps here. Each process step in this current state flows correspondingly to a "Shape: Process Step" below)

- Wake up
- Shower & brush teeth
- Dress
- Drive to work
- Arrive at office

Future State Process

<table>
<thead>
<tr>
<th>Step</th>
<th>Failure Mode</th>
<th>SEVERITY</th>
<th>OCCURRENCE</th>
<th>DETECTION</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wake up</td>
<td>Alarm fails to ring</td>
<td>Low Severe</td>
<td>Rate 1-3</td>
<td>Rate 1-3</td>
<td>12-36</td>
</tr>
<tr>
<td>Dress</td>
<td>No clean shirt</td>
<td>Low Severe</td>
<td>Rate 1-3</td>
<td>Rate 1-3</td>
<td>12-36</td>
</tr>
</tbody>
</table>

Resources & Further Reading

- Agency for Healthcare Research and Quality

- Institute for Healthcare Improvement
  - http://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysis.aspx

- The Joint Commission

- American Society for Quality
FMEA Work Products

- Simple diagram of major process steps
- List of known best practices or critical to quality requirements for future state
- Current state process map with all steps, including identified barriers and problems
- Root cause tools if discussion/investigation was required to understand cause of failure mode (fishbone, five whys)
- Excel sheet with scoring for process
- Future state process map
- New standard work or protocol

Alternate FMEA Scoring Examples
VA FMEA with Hazard Analysis

HFMEA Subprocess Step: 3B1 - Respond to Alarms

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Potential Causes</th>
<th>Scoring</th>
<th>Decision Time Analysed</th>
<th>Actions &amp; Rationale for Stopping</th>
<th>Outcome Measure</th>
<th>Person Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>3B1a</td>
<td>Ignored alarm (desensitized)</td>
<td>Low</td>
<td>N N Y</td>
<td>Reduce noise alert in hospital by changing alarm parameters to fit patient physiological condition and replace electrodes with better quality that do not become detached.</td>
<td>Yes</td>
<td>Management</td>
</tr>
<tr>
<td>3B1b</td>
<td>Didn’t hear, care giver left area</td>
<td>Low</td>
<td>N N Y</td>
<td>Alarms will be broadcast to Central Station with retransmission to pagers provided to care staff.</td>
<td>Yes</td>
<td>Management</td>
</tr>
<tr>
<td>3B1c</td>
<td>Didn’t hear, volume too low</td>
<td>Low</td>
<td>N N Y</td>
<td>Alarms will be broadcast to central station within 4 months; complete by mm/dd/yy.</td>
<td>Yes</td>
<td>Management</td>
</tr>
<tr>
<td>3B1d</td>
<td>Didn’t hear alarm, remote location (doors closed to isolation room)</td>
<td>Medium</td>
<td>N N Y</td>
<td>See 3B1b See 3B1b</td>
<td>Yes</td>
<td>Management</td>
</tr>
<tr>
<td>3B1e</td>
<td>Caregiver busy, alarm does not broadcast to backup</td>
<td>Medium</td>
<td>N N Y</td>
<td>Enable equipment feature that will alarm in adjacent room(s) to notify caregiver or partner(s).</td>
<td>Yes</td>
<td>Management</td>
</tr>
</tbody>
</table>

AHRQ FMEA Model

REPs Table:

<table>
<thead>
<tr>
<th>REPs</th>
<th>HEV</th>
<th>X</th>
<th>OCU</th>
<th>X</th>
<th>DEI</th>
<th>≈ REPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Close door</td>
<td>10</td>
<td>0</td>
<td>10</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Wrong patient</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Wrong location</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Recommended actions:

- High REPs (Scores above 10) require immediate attention and may require additional actions or recommended actions.

Recommended actions for Low REPs should be aligned to maintain care quality and patient safety.
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The Quorum Difference is the extraordinary combination of consulting guidance and operations experience that enables client healthcare organizations to achieve a sustainable future.
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Thank you

Intended for internal guidance only, and not as recommendations for specific situations. Readers should consult a qualified attorney for specific legal guidance.