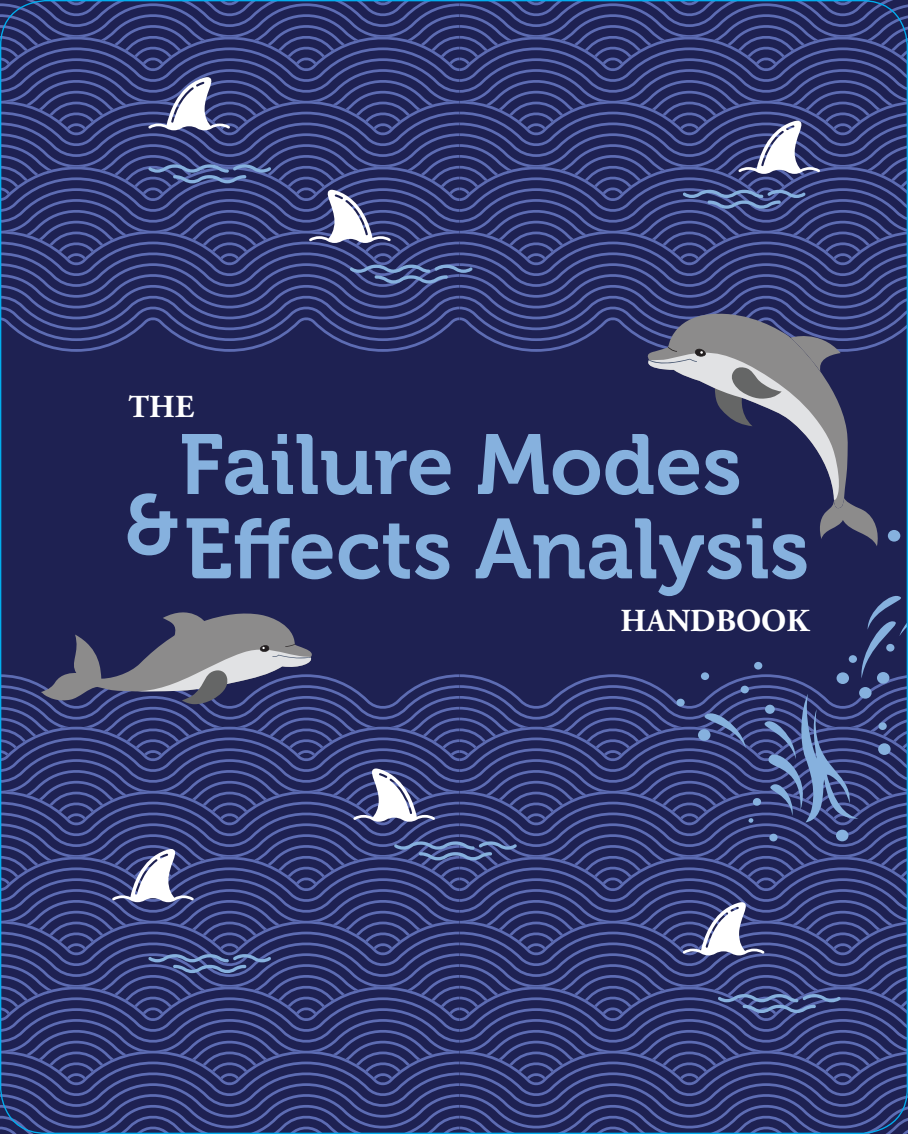
THE
Failure Modes
& Effects Analysis
HANDBOOK

This publication is produced by the Institute of Healthcare Quality (IHQ), Group Quality.

If you have any suggestions or feedback, please email ihq@nhg.com.sg.

May 2024

Foreword

As we present this handbook, I am reminded of the enduring wisdom in Albert Einstein's words: "We cannot solve our problems with the same thinking we used when we created them".

In the ever-evolving landscape of healthcare, our commitment to quality and safety remains unwavering.

Despite the remarkable advancements in medical science and technology, we continue to face challenges in the form of errors and adverse events. It is precisely these challenges that underscore the critical importance of quality improvement tools to redesign our systems, enhance reliability and ultimately, improve patient outcomes.

I encourage all members of our healthcare community to embrace the principles and practices outlined in this handbook. By doing so, we not only address current challenges but also proactively work towards preventing future adverse events.

Together, we can create a healthcare system that is not only responsive to problems but also resilient in preventing them.

Dr Tung Yew Cheong
Group Chief Quality Officer
National Healthcare Group

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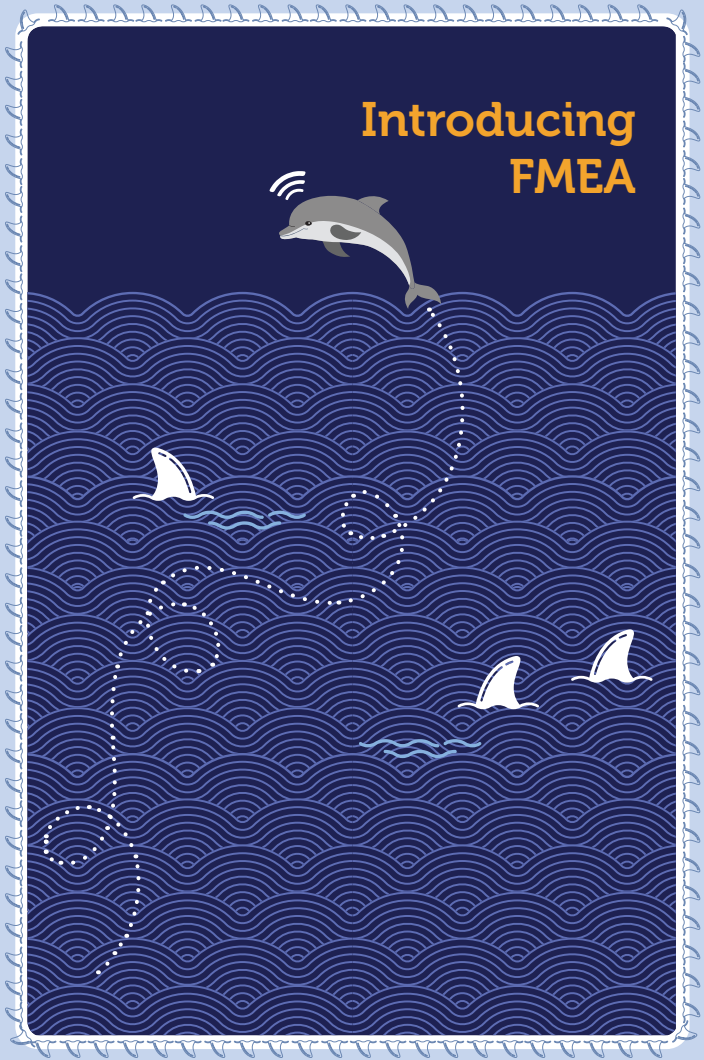


What is Failure Modes and Effects Analysis (FMEA)?

Failure Modes and Effects Analysis (FMEA) is a systematic, proactive tool for evaluating a process. By identifying where and how it might fail, and assessing the relative impact of different failures, we are able to identify parts of the process that are most in need of change[1]. It is also useful in addressing errors and near-misses encountered in real-life experiences, as well as potential risks that may be present in current healthcare processes.

Although FMEA was historically developed outside the healthcare industry, it is now being used in healthcare to assess the risks of failure in patient care processes and identify key areas for improvement. To do this, we must proactively assess risks so we can put in place measures that will reduce the likelihood of harm.

Established healthcare standards have also evolved to increase the emphasis on preventing the risks of harm to patients and staff in a proactive manner, instead of addressing incidents retrospectively after they have occurred.

[1] Institute for Healthcare Improvement, (2017), Failure Modes and Effects Analysis Tool, Retrieved from http://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx

How do you define terms used in FMEA?

Potential failure modes

- Ways in which a process or sub-process can fail to provide the intended function or expected result
- Ways in which a potential failure can be observed

Potential effects

- Consequences of potential failures when they occur
- Impact of potential failures on systems, operations, services, processes, and equipment

Potential causes

- Elements or defects that may allow or cause failures to occur and result in the potential effects

Why do failures occur?

Failures can be latent or active. Unlike active failures, latent failures are not readily observed.

Active errors almost always involve frontline staff and occur at the point of contact between a human and some aspect of a larger system such as a human–machine interface. Latent errors, however, are accidents waiting to happen where the failures of organisation or design allow inevitable active errors to cause harm[2].

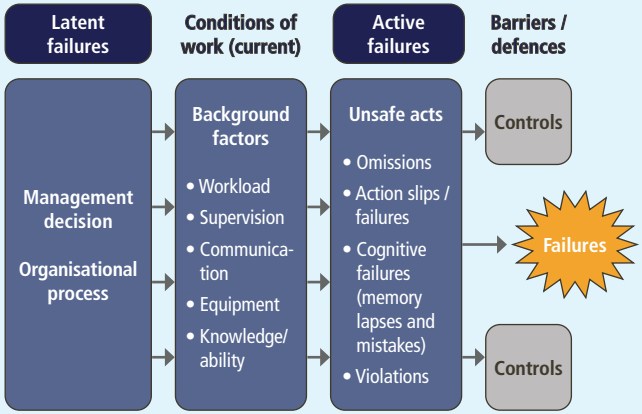


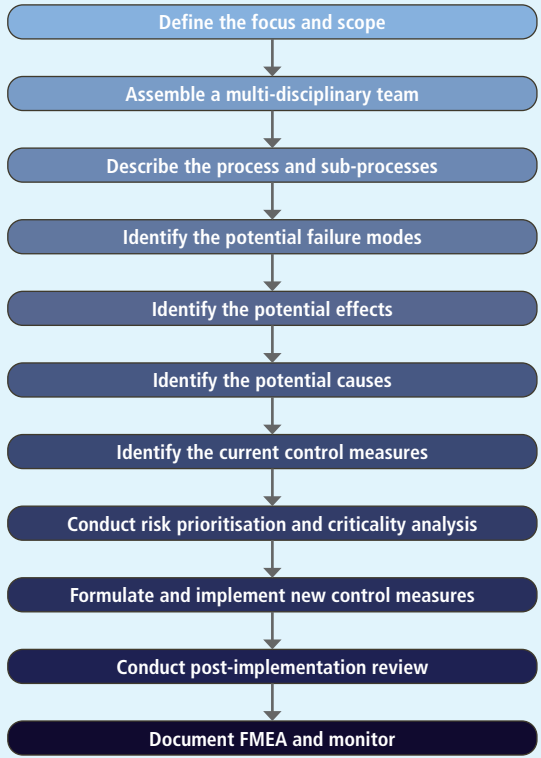
Figure 1: Stages of development of organisational accidents

[2] PSNet. (2017, June). Systems Approach, Retrieved from https://psnet.ahrq.gov/primers/primer/21/systems-approach

Latent failures
- Attributed to management decisions or organisational process
- Can exist for many years in a system without causing an incident ("accidents waiting to happen")
- Often manifest when combined with local or task factors

Active failures
- Unsafe acts made by operators performing the processes
- Effects can be felt almost immediately
- Can be influenced by error-producing conditions

Steps of conducting FMEA



Step 1

Define the focus and scope

As FMEA is a resource-intensive tool, it is important to define the focus and scope of the FMEA clearly.

Define the focus

The focus of the FMEA can be high-risk areas or highly-complex processes. Using a risk assessment matrix can be useful in determining the high-risk areas to focus on.

	Consequence				
Likelihood	Insignificant 1	Minor 2	Moderate 3	Major 4	Extreme 5
Almost certain – 5	5	10	15	20	25
Likely – 4	4	8	12	16	20
Possible – 3	3	6	9	12	15
Unlikely – 2	2	4	6	8	10
Remote – 1	1	2	3	4	5

RISK Low Medium High

Reference: The NHG Enterprise Risk Management Handbook

Figure 2: Example of risk assessment matrix

Define the scope

- Define the scope (start and end points of process)
- Define the timeline (start date and end date)

Tip

Leadership should be involved at a very early stage to define the scope and depth of the process that is to be evaluated

Step 2

Assemble a multi-disciplinary team

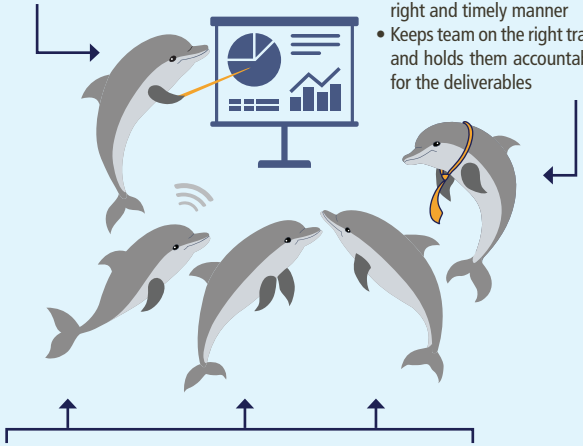
Who should be in the FMEA team?

- Staff from all areas involved
- Staff with fundamental knowledge of the process
- Someone with FMEA expertise
- People with different levels of experience
- People with different levels of functional responsibilities
- Subject matter experts
- "Fresh pair of eyes"
- Someone who understands patient's perspectives

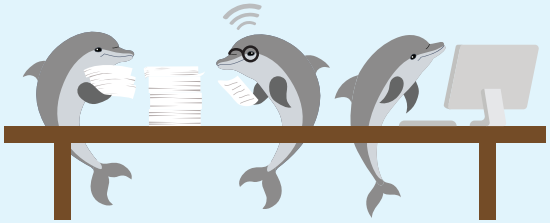
Key roles in FMEA team

Facilitator
- Provides FMEA expertise to ensure FMEA is done correctly

Team leader
- Ensures FMEA is done in a right and timely manner
- Keeps team on the right track and holds them accountable for the deliverables



Team members
- Commits fully to FMEA process and participates actively
- Contributes constructively and is open during discussion



Other team functions

Data collection | Data analysis | Documentation

Tip

The deeper the level of detail required to assess risk (i.e. at the sub-process or component levels), the greater the amount of technical expertise required

Step 3

Describe the process and sub-processes

The FMEA team needs to have a clear and accurate understanding of the process and sub-processes.

All team members must examine the graphical representation of the process and sub-processes — either in a flowchart or Value Stream Mapping. Process steps should be verified. This will ensure that they are accurately described in sufficient details and help the team achieve clarity.

When there are doubts over certain process steps, the team should clarify with staff involved in these process steps to obtain a complete and accurate picture. It is also important for the team to observe these process steps at the workplace or actual sites.

Having a clear graphical representation of the complete process and sub-processes will help the team to review the appropriateness of the FMEA's focus and scope, as well as the FMEA team composition. For a large and complex process, the team can subsequently determine the need to re-scope the FMEA based on available resources and the given timeline, and undertake a more manageable scope.

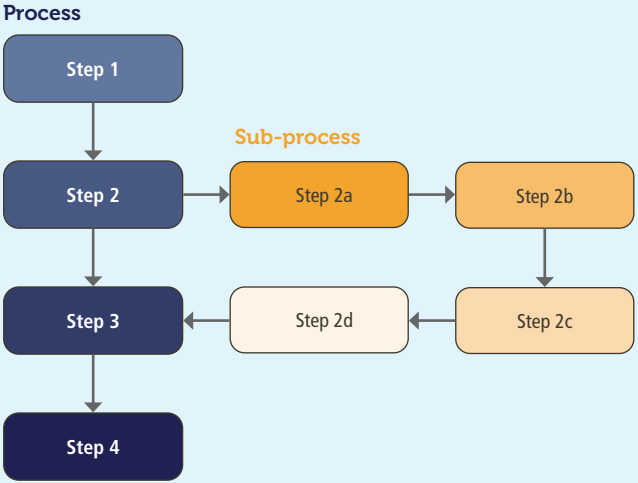


Figure 3: Example of flow chart

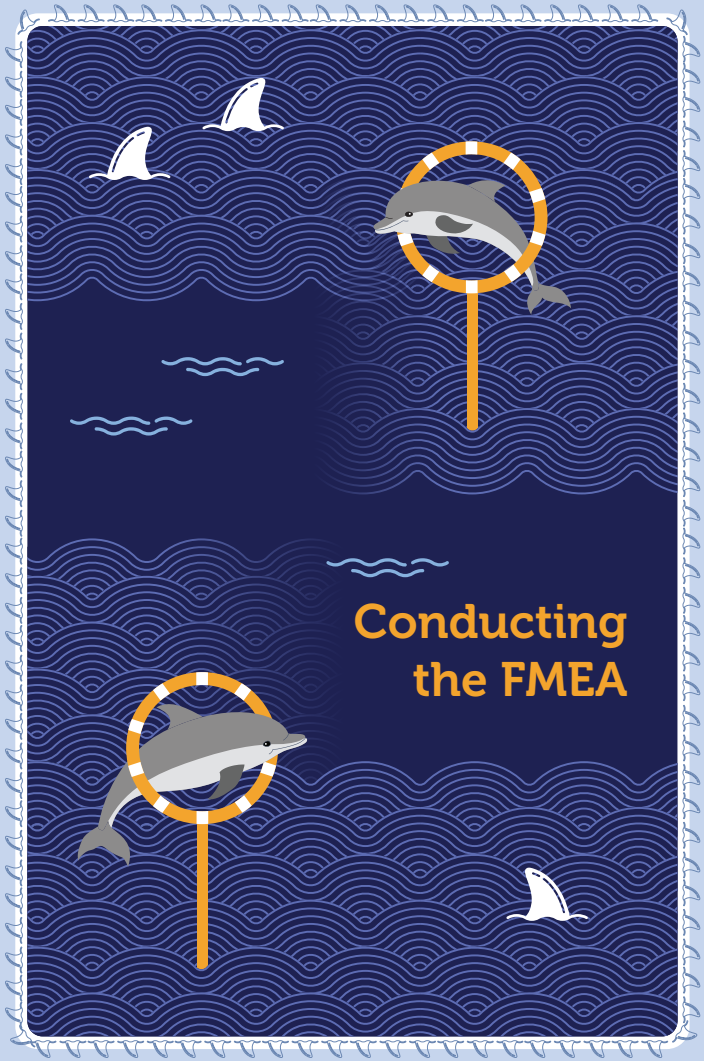
Tips

What should you consider when gathering information on process steps?

- What is the intended function of the process step?
- What is the expected outcome of this process step?
- Who are involved in this process step?
- What were the previous failures, errors and near-misses?
- Are there any control measures in place?

Column(s) to complete in FMEA worksheet

No.	Process step


Conducting
the FMEA

Step 4

Identify the potential failure modes

Failure modes are the ways in which a process or sub-process can fail to provide the intended function or expected results. They are ways in which potential failures can be observed in the process or sub-processes. For example, instead of saying "faulty printer", the failure mode should be stated based on what is observed — "unable to load paper".

It is important to link back to the purpose of the process step when identifying potential failure modes. This includes looking at the intended function and expected outcome of the process step.

The FMEA team needs to ask:
In what ways can this process step possibly fail?
I know that this process step fails when _____ is observed

Failure modes include:
- Failure to perform an intended function within defined requirement limits
- Inadequate or intermittent performance of the intended function
- Performing an unintended function

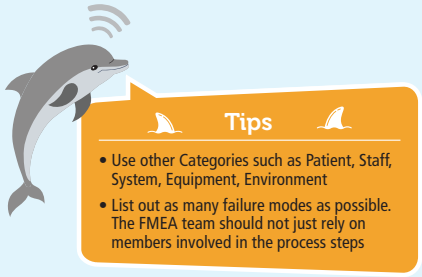
Failure modes are not restricted only to failures that have occurred previously, or near-miss cases, but also potential failures that could happen but have not happened in reality.

Classification of potential failures

Use different aspects of potential failures — 5Ms (man, method, material, machine, milieu), as guidance for identification of possible failure modes.

Man	• Patients, family members • Hospital staff
Method	• Procedures • Steps in performing task
Material	• Forms, checklists • Reference guides
Machine	• Medical technology • Equipment, devices
Milieu	• Environmental factors • Temperature, radiation

Figure 4: Different aspects of potential failures



Tips

- Use other Categories such as Patient, Staff, System, Equipment, Environment
- List out as many failure modes as possible. The FMEA team should not just rely on members involved in the process steps

Column(s) to complete in FMEA worksheet

No.	Process step	Failure modes

Step 5

Identify the effects

Effects are:

- Consequences of the failure modes when they occur
- Viewed as the impact of failure modes on systems, operations, services, processes and equipment or users

The FMEA team will find these guiding questions helpful:

- What are the possible effects of this failure mode?
- What can this failure mode possibly lead to?

It is important to list all the effects clearly with sufficient details for each failure mode so the team may score the severity score appropriately in subsequent parts of FMEA.

Similar effects should not be omitted because they are repetitive. The potential causes leading to these effects may vary due to different contexts.

Tips

- There may be a few effects for each failure mode
- Be clear and specific in the effects (i.e. are there more than three words in the description?)

Column(s) to complete in FMEA worksheet

No.	Process step	Failure modes	Effects	Severity
			Low	
			Medium	
			High	

Step 6

Identify the potential causes

Each potential cause must be viewed in the context of the specific failure mode and its corresponding effect. There may be a single cause or multiple potential causes for each set of failure mode and its corresponding effect.

It is important not to omit potential causes just because they are repetitive, but to list as many possible potential causes as they can. While the potential causes may be the same, they may have different likelihood of occurrence for different sets of failures modes and effects. Additionally, the control measures for the same potential cause can vary with different contexts (i.e. specific failure modes and effects).

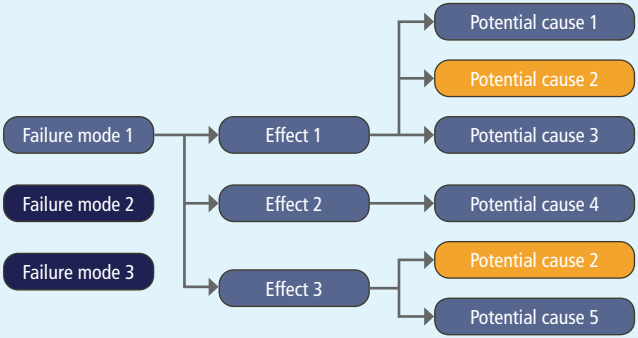


Figure 5: Relationship interlinking failure modes, effects, and potential causes

If the team encounters difficulties in identifying potential causes, they should consult the domain experts of the process steps for inputs.

The FMEA team will find it helpful to ask:

- Why does the failure mode result in this effect?

After completing this segment, the team must review the failure modes, effects and potential causes as a whole, and ensure that they are interlinked correctly and are coherent with the specific process step (and the intended function of this step).

Tips

Check back your worksheet using these statements:

1. When I can observe this [failure mode], it can lead to [effect], because of [cause]

2. [Cause] might contribute to [failure mode], leading to [effect]

3. [Cause] can lead to [effect] when [failure mode] occurs

The more specific you are in each failure mode, effect, and cause, the easier it is for the FMEA team to understand. Avoid generalising

Column(s) to complete in FMEA worksheet

No.	Process step	Failure modes	Effects	Severity	Potential causes	Likelihood of occurrence

Step 7

Identify current control measures

Current control measures are measures that are currently in place to control the risks of failure by one or more of the following ways:

- Preventing failures from occurring
- Reducing likelihood (frequency) of occurrences of failures
- Improving detectability of failures when they occur
- Reducing severity of effects when failures occur

Current control measures can be the same for different sets of failure modes, effects and potential causes. Some control measures may be highly effective in addressing the identified risks, while others may be weak control measures (e.g. reminder labels/signs) or have poor staff compliance.

It is important to list out every current control measure and indicate important remarks such as "poor staff compliance" or "inconsistently practised in different clinics".

Reviewing current control measures provides a baseline of what has been currently put in place so that the team can determine whether to keep, enhance or change to a different control measure.

Tip

Sometimes, there is no current control measure in place and the team has to indicate this during the FMEA

Column(s) to complete in FMEA worksheet

No.	Process step	Failure modes	Effects	Severity	Potential causes	Likelihood of occurrence	Current control measures	Detectability

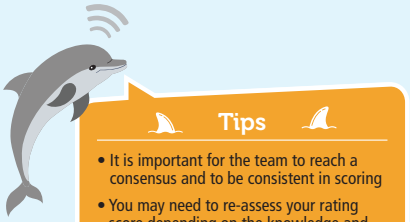
Step 8

Conduct risk rating prioritisation and criticality analysis

As FMEA is a resource intensive risk reduction tool, it is essential to conduct risk prioritisation and criticality analysis. It is impossible to fix every identified risk at the same time. Hence, there must be a systematic risk prioritisation approach to prioritise the identified risks.

Risk rating— How to score?

There is a need to score the severity, likelihood of occurrence and detectability before we can prioritise the potential risks. Score sequentially and horizontally in the worksheet using your institution's policy or guideline.



Tips

- It is important for the team to reach a consensus and to be consistent in scoring
- You may need to re-assess your rating score depending on the knowledge and expertise of your team

The table below can be used as a guide. Please follow your institution scoring whenever available.

- Severity (1-10)

How severe an effect will be when a failure mode occurs

Rating	Classification	Description (examples)
1	None	Not apparent; No effect
2	Very minor	Not apparent; Minor effect
3	Minor	A nuisance to the patient or staff
4	Very low	Lowered effectiveness
5	Low	Patient complaint
6	Moderate	Potential ineffectiveness
7	High	High patient dissatisfaction
8	Very high	Ineffective service or treatment outcome
9	Extremely high	Regulatory non-compliance
10	Dangerously high	Injury or death

Figure 6: Example of scoring table for severity

The table below can be used as a guide. Please follow your institution scoring whenever available.

• Likelihood of occurrence (1-10)

How likely a potential cause will occur and result in the corresponding failure mode and effect

Rating	Classification	Description (examples)
1	Very remote	Failure occur only in exceptional circumstances (e.g. every 10 to 30 years)
2	Remote	Rare; Possibly could occur at some time (e.g. every 5 to 10 years)
3	Uncommon	Very few failures expected (e.g. every 2 to 5 years)
4	Unlikely	Unlikely that failure will occur (e.g. every 1 to 2 years)
5	Low	Might occur at some time (e.g. once every year)
6	Moderate	Occasional failures (e.g. once to twice every year)
7	Fairly high	Probably occur in most circumstances (e.g. several times every year)
8	High	Probably and likely to occur; Repeated failures (e.g. once every month)
9	Very high	Very frequent failure (e.g. once every week)
10	Almost certain	Inevitable failure (e.g. once every day to several times every week)

Figure 7: Example of scoring table for likelihood of occurrence

The table below can be used as a guide. Please follow your institution scoring whenever available.

• Detectability (1-10)

How effective the current control measure is to detect or control a potential cause of a failure mode occurring

Rating	Classification	Description (examples)
1	Almost certain	Controls certain to detect/control as it has been error-proofed by process/product design
2	Very high	Controls almost certain to detect/control
3	High	Controls have a good chance to detect/control
4	Moderately high	Controls may detect/control
5	Moderate	Control is achieved with indirect or random checks only
6	Low	Detectable by charting methods (Statistical Process Control)
7	Very low	Controls have chance of detection/control via visual check
8	Remote	Controls have poor chance of detection/control
9	Very remote	Controls will probably not detect/control
10	Almost impossible	Absolute certainty of non-detection and no control in place

Figure 8: Example of scoring table for detectability

Prioritisation — How to prioritise risks?

Risk prioritisation in FMEA utilises the calculation of Risk Priority Number (RPN) that provides a risk rating for the identified risks. A higher RPN score indicates a higher potential of risk.

The RPN can be calculated as indicated below:

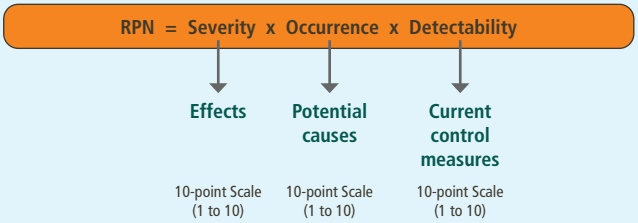
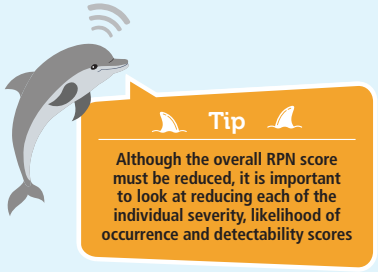


Figure 9: Formula for calculating Risk Priority Number (RPN)

After calculating the RPN score, the team has to prioritise the identified risks by ranking the risks beginning with the highest RPN score.



Criticality analysis — How to conduct criticality analysis?

Criticality analysis acts as a supplement to the RPN assessment. Look out for critical risks that need to be addressed adequately even if they may not have a high RPN. It is essential to examine the following four factors to determine criticality and further risk prioritisation:

- single-point failure (or leading to catastrophic system failure)
- high severity + high likelihood of occurrence
- high severity + low detectability
- frequently-occurring potential causes with high likelihood of occurrence

This will ensure that all critical risks are reviewed by the team so that they are evaluated and recommended for corrective provisions.

Column(s) to complete in FMEA worksheet

No.	Process step	Failure modes	Effects	Severity	Potential causes		Likelihood of occurrence	Current control measures	Detectability	RPN score

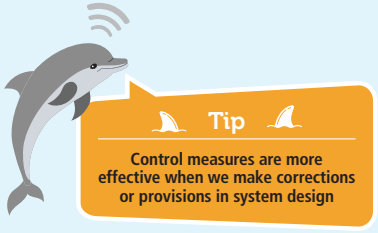
Step 9

Formulate and implement new control measures

After conducting risk prioritisation and criticality analysis, the team has to formulate and implement new control measures to address the prioritised risks identified.

Consider new control measures in one or more of the following ways to address the prioritised risks:
- Prevent failures from occurring
- Reduce likelihood (frequency) of occurrences of failures
- Improve detectability of failures when they occur
- Reduce severity of effects when failures occur

Some tips to guide the team in formulating new control measures:
- Consider system level changes or process re-design
- Error-proof against human errors
- Simplify the process and reduce the number of steps
- Standardise the process, where appropriate
- Build redundancy into the process wherever necessary
- Reduce dependency on inspection for quality control
- Engage staff and stakeholders to understand the rationale behind the control measures for effective implementation
- Reminders are effective only when used appropriately
- Reminders and roll-calls for staff are generally not effective



Stronger actions	Intermediate actions	Weaker actions
• Architectural/physical plant changes • New device with usability testing before purchasing • Engineering control or interlock (forcing functions) • Simplify the process and remove unnecessary steps • Standardise equipment or process or caremaps • Tangible involvement and action by leadership in support of patient safety	• Increase in staffing/ decrease in workload • Software enhancements/ modifications • Eliminate/reduce distractions (sterile, medical environment) • Checklist/cognitive aid • Eliminate look-and-sound alike • Write down read back • Enhanced documentation/ communication • Redundancy	• Double checks • Warnings and labels • New procedure/ memorandum/policy • Training • Additional study/ analysis

Reference: VA National Center for Patient Safety Root Cause Analysis Tools

Figure 10: Examples of different types of actions

After formulating new control measures, the team needs to identify the functional role(s) in charge of implementation, as well as the timeline for implementation and review. Due to limited resources in healthcare institutions, it will be appropriate to implement the high-impact, low-cost control measures first, and plan the high-impact, high cost-control measures within a suitable timeframe.

Continued from previous section

RPN score	New control measures	Role-in-charge of implementation	Implementation timeline	Completion date

Review

Conduct post-implementation review

After implementing new control measures, the team has to conduct a post-implementation review to evaluate their effectiveness in addressing the identified risks by rescoring the RPN.

The new RPN score should decrease if the new control measures are effective.

If the new RPN score increases or remains the same after the implementation of new control measures, this will warrant the team to review whether the new control measures are effective or may have introduced new aspects of risk to the process.

Tip

A decrease in RPN may not be sufficient. The team needs to assess if the new risk level is acceptable by the team and organisation based on the established risk threshold limit

Rescore the RPN to evaluate the effectiveness of new control measures

After re-scoring the RPN, the team has to decide whether the new control measures need to be enhanced to further reduce the risk level to their established risk threshold limit, or to be replaced with other new control measures.

If other new control measures were to be implemented, the RPN score will have to be re-scored again after their implementation and the team has to conduct another post implementation review.

Column(s) to complete in FMEA worksheet

RPN score	New control measures	Role-in-charge of implementation	Implementation timeline			Completion date	Severity	Likelihood of occurrence	Detectability	New RPN score

Readers may access a fully worked example online. Kindly refer to the QR Code below.

http://bit.ly/2sXu5YD

Document FMEA and monitor

FMEA is a "living document" and having good FMEA documentation is highly beneficial to an organisation. The completed FMEA can serve as the baseline to update and monitor risks, especially where there are major changes to the high-risk area or process.

Conclusion

We hope this guide will provide healthcare professionals with an understanding of the conceptual principles behind FMEA. Remember that FMEA is a structured risk management activity that involves potentially a large group of staff, providers and patients.

It is probably not easy to move away from traditional root cause analysis methods, into proactively predicting and preventing failures from occurring. Conducting a FMEA requires both an open mind and contribution from people with relevant expertise.

The advantage of FMEA is that it is designed to provide quick visibility to more obvious failure modes, and their consequences. These help the leadership responsible for the system to manage which risks to prioritise. It is a continued effort that requires active revisits from the leadership and the FMEA team.

The best way to look at FMEA is to treat it as a live document and to always ask ourselves what could possibly fail.

Adding years of healthy life

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