ACADEMI GWELLIANT CYMRU
IMPROVEMENT CYMRU ACADEMY

GIG CYMRU NHS WALES

Improvement Cymru Academy Toolkit Guide

Failure Modes and Effects Analysis

What is Failure Modes and Effects Analysis?

Failure Modes and Effects Analysis (FMEA) is a standardised approach for conducting a proactive analysis of a system or process in a systemic way. FMEA is used as a risk identification and reduction tool and is used so we can prevent product or process safety issues before they occur. It is also called Potential Failure Modes and Effects Analysis, or Failure Modes, Effects, and Criticality Analysis (FMECA).

Rationale

FMEA allows you to focus and understand the impact of potential risks within your processes and services and evaluate performance. It allows you to identify and evaluate risks to assess the impact that failures may have. By doing this you can identify parts of the process that need improving. You can do this through asking what could go wrong? (Failure Modes), why would the failure happen? (Failure Causes) and what would be the consequences of each failure? (Failure Effects). The ultimate goal of FMEA in healthcare is patient safety.

Background

FMEA originated in the United States military in the late 1940s and has been used for decades since. It was developed to reduce variation and potential failures in munitions production and proved to be a highly effective tool. Because of its effectiveness, the National Aeronautics and Space Administration (NASA) adopted the tool in the 1960s.In the 1970's FMEA was adopted by the automotive industry, particularly by Ford Motor Company who used this method in response to the safety and public relations issues with the Pinto model car. It has since been recognised as an important safety tool in delivering safe patient care and has been adapted by the Institute of Healthcare Improvement (IHI) and others for use in healthcare systems.

When to use Failure Modes and Effects Analysis

You would use FMEA for a process you are about to put into place to try and predict what could go wrong, the causes of it and the consequences of it. This will allow you to address the systems potential safety concerns ahead of time.

How to use Failure Modes and Effects Analysis

Step 1 – Decide a process to evaluate with FMEA.

FMEA evaluation works best with process that do not have too many sub-processes. If you have a large, complex process then it is better to apply FMEA evaluation to a part of the process so that it is easier to evaluate risk and performance.

Step 2 – Choose your team.

For your team, you will need to identify everyone involved in the process you are evaluating at any point. This could range across multidisciplinary professions. Some individuals may not need to be part of the entire FMEA, but they should be involved in the steps of the process that they are involved with because other individuals may not fully understand their part in the process and the risks involved.

Step 3 – List all the steps in the process.

To design a process map, you will need to include all of your team who are involved in the process which you have identified in the previous step. You will need to agree on the order of the steps and map the process as it is completed - not how it should be completed.

Step 4 – Complete the table with your team.

Steps in the process	Failure Modes	Failure Causes	Failure Effects	Likelihood of occurrence (1-10)	Likelihood of detection (1-10)	Severity	RPN	Actions to reduce error	Person Responsible
1									
2									

With your team, you will need to complete FMEA table, discussing each step with the team members who are involved in that part of the process.

The first column asks you to list the process step number. With your team, you will then need to list anything that could go wrong within that step of the process in the failure modes column. List all the possible causes for each failure modes you have identified in the failure causes column and list all the possible consequences for each failure modes you have identified in the in the failure effects column. You may have more than one failure mode for each step. You will then need to decide how likely the failure is to occur on a scale of 1-10 (with 10 being the most likely).You will need to decide how likely the failure is to be detected on a scale of 1-10 with 10 being the most likely NOT to be detected and you will need to decide on the likelihood of severity of harm if the failure mode does occur with 10 being most likely to cause severe harm.

Using the information, you have decided from the likelihood of occurrence, likelihood of detection and severity, you can calculate a risk profile number (RPN). Use this equation:

Likelihood of occurrence x likelihood of detection x severity

The lowest score is 1 and the highest possible score will be 1000. If you would like to calculate the total risk profile number for the entire process, you will need to add all the RPNs for each failure mode.

The last column allows us to list action points to improve safety which is important for the failure modes that have a high RPN.

Step 5 – Use the risk profile number (RPN) to plan improvements.

Failure modes that have a high RPN should be the first priority to improve and focus your efforts on. That is not to say that other RPNs are not as important and RPNs with a low score are unlikely to really effect the process if they are eliminated and therefore efforts on them should be a low priority.

What next?

Choose a current process you are involved with to perform FMEA. You could select a process to analysis through audits, complaints, number of incidents of a particular issue etc… Once you have decided to perform a stakeholder analysis to identify

team members who need to be involved in the process, map out the process with your team.

Helpful tips

Once you have identified the proves you are going to improve, perform a stakeholder analysis to identify members involved in the process to work together to map out the process (See the Involving Others toolkit guide). Start with a high-level process map and build on this to create a more detailed map. You should write down steps as they are performed – not how they should be performed. A type of process map called a Swim Lane Diagram (see process mapping toolkit guides) can help to identify what team members are responsible for each part of the process.

Additional Resources

If you are interested in learning more about how improvement practices can benefit your workplace, we offer a range of training courses. Visit our website for more information.https://phw.nhs.wales/services-and-teams/improvement-cymru/improvement-cymru-academy/ or email us improvementcymruacademy@wales.nhs.uk to find about the improvement courses we offer.

Further reading

Institute of Healthcare Improvement (2017). QI Essentials Toolkit: Failure Modes and Effects Analysis (FMEA). Accessed from https://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx?PostAuthRed=/resources/_layouts/download.aspx?SourceURL=/resources/Knowledge%20Center%20Assets/Tools%20-%20FailureModesandEffectsAnalysisFMEATool_3fd4e6fd-b819-4f14-89ba-fb3563dd4e2d/QIToolkit_FailureModesandEffectsAnalysis.pdf (Accessed 9 Aug 2023)

Institute of Healthcare Improvement (2019). What is the Failure Modes and Effects Analysis (FMEA) tool? Accessed from https://www.youtube.com/watch?v=PIEzR5uhqnw (Accessed 9 Aug 2023)

Shaymma, M., El-Awadu, M. (2023). Overview of Failure Mode and Effects Analysis (FMEA): A Patient Safety Tool. Global Journal on Quality and Safety in Healthcare.,6(1). pp24–26. Accessed from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10229026/ (Accessed 21 Dec 2023)