WARWICK MEDICAL SCHOOL

Warwick Reliable Care Basic Methodology

Getting Started with Reliability

Mark-Alexander Sujan

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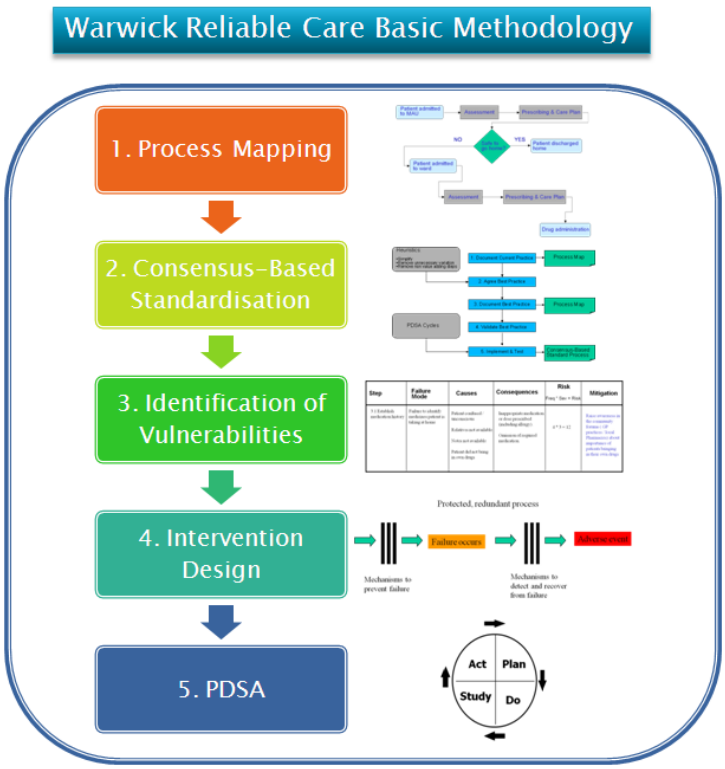


Getting Started with Reliability

Mark-Alexander Sujan

Warwick Medical School

Introduction

Patients can expect the delivery of the right care every time they come in contact with the NHS. Despite the best efforts and hard work of staff within the NHS, there is evidence that best care is not delivered consistently.

Current levels of reliability of care processes often are poor. We need to consider the reliability of care processes explicitly and make improvements proactively before adverse events happen in order to ensure that the NHS delivers and meets patients' expectations: *the right care at the right time, every time.*

- Process mapping and consensus-based standardisation are your first steps towards more reliable and safer care. These techniques provide a shared understanding of the way care is delivered and produce more consistent and predictable care processes.
- Failure Mode and Effects Analysis is a systematic process for the proactive identification of major vulnerabilities within your care processes. It allows you to prioritise your risks and to allocate your improvement resources accordingly.
- Interventions aimed at improving the reliability and safety of care include mechanisms for preventing failures, to detect and make visible failures that have occurred and to support the recovery from failures before patients come to harm.

Section 1: Process Mapping & Consensus-Based Standardisation

First steps towards reliable and safer care: Understanding of processes and minimisation of unnecessary variation

Process mapping allows organisations to understand how care is delivered and reduce unnecessary variation

Many different roles and individuals are involved in patient care. As a result, people and organisations often only possess a partial and fragmented understanding of how care is delivered in practice, even if they work within that process themselves. Process mapping is a group-based approach that elicits the knowledge from the people involved in the process and records this in a graphical representation (*process map*). The process map supports people in looking beyond their own activities towards a shared understanding of the entire care process.

During the development of the process map, it often emerges that there are many different ways in which the process can be performed. A successful first step towards the design of reliable and safer care is the definition of a *consensus-based standard process* that eliminates unnecessary variation while at the same allowing for the required clinical autonomy of healthcare professionals. In this way, care processes become consistent and predictable to the individuals who are delivering the care.

Process & System Definition

Analytical patient safety and improvement methods (e.g. FMEA, see Section 2) require some form of process or system definition and representation. The consensus-based standard process and the process map form the basis for these methods. Without a properly documented process it is not possible to apply more sophisticated safety and improvement methods.

The strength of process mapping lies in the elicitation of input from all people involved in the care process and in the graphical representation of their knowledge, thereby developing a shared vision and a culture of safety.

Benefits of Process Mapping

- Elicits tacit knowledge about how care is delivered from operational staff
- Provides a graphical representation of care processes and develops a shared understanding
- Facilitates consensus-based standardisation in order to reduce unnecessary variation and to allow for consistency and predictability of care processes
- Forms the basis for subsequent patient safety and improvement work

- Develops a shared vision and culture of safety

Modelling Notations

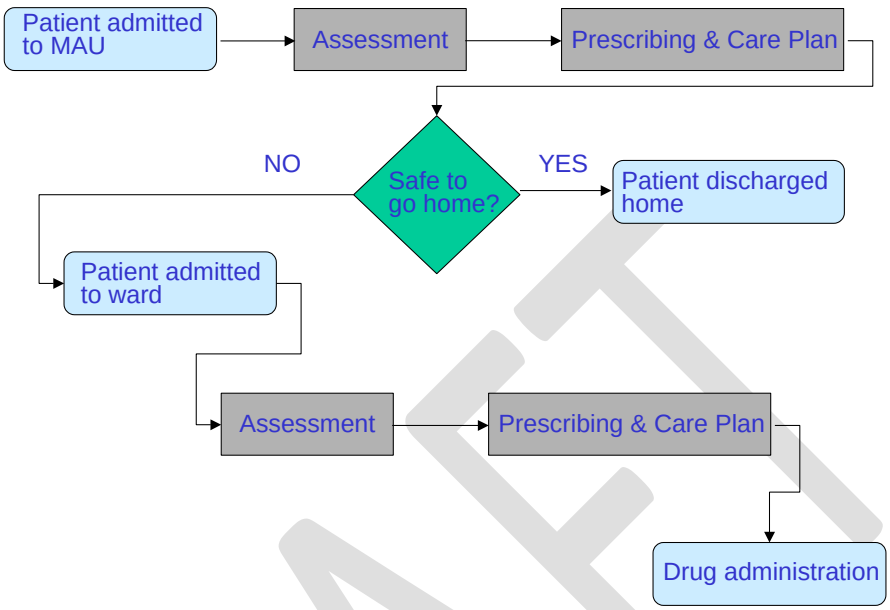
A process map is a model of a process (or system, activity, workflow) and therefore a simplification and an abstraction of real life. The choice of what you are modelling, how you are modelling it and to what level of detail, is dependent on the purpose of the modelling activity.

There are many different modelling notations currently in use. As a rule of thumb, you should use the modelling notation that makes most sense to you. In this guide, we will work with two notations: activity diagrams and Hierarchical Task Analysis.

Activity Diagrams

The process is represented as a sequence of steps. Simple, binary (Yes/No) decision points can be included and represented by a diamond-shaped box. This modelling notation is often useful to represent at a high level the basic steps of the process under consideration.

Example: Simple patient journey



Hierarchical Task Analysis

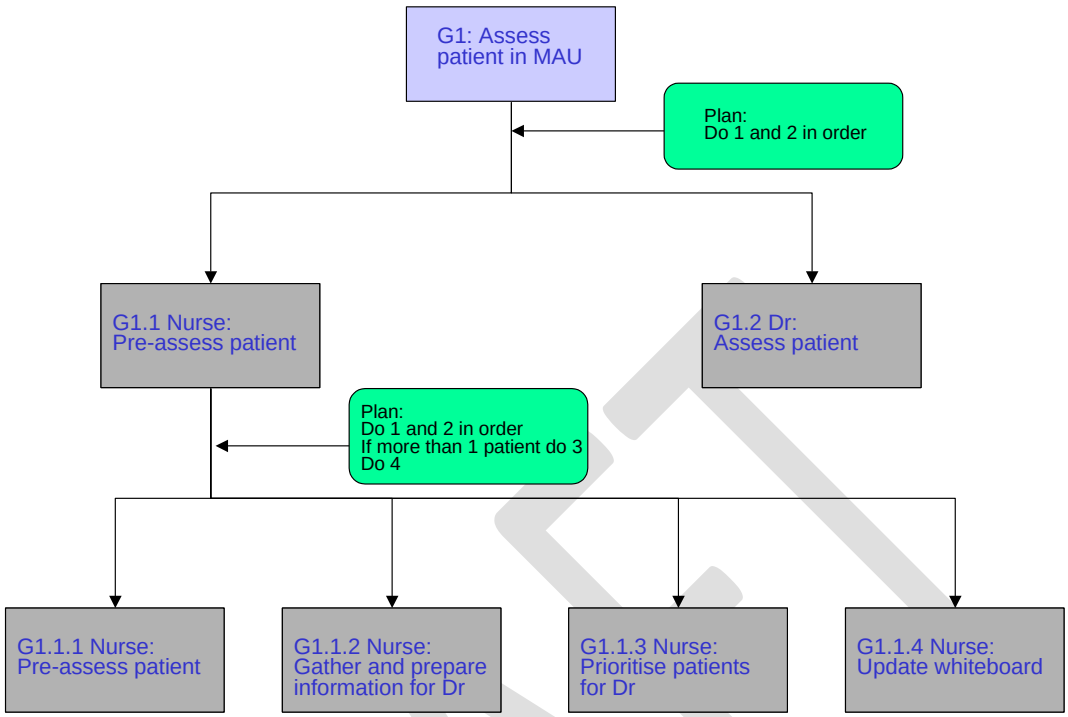
Hierarchical Task Analysis (HTA) is a well-known technique for modelling human activity. From a person's (or different roles) perspective you need to consider in a top-down fashion what the essential goal of the activity is and through what sub-goals or actions this is achieved. HTA also allows you to specify the conditions under which certain elements of the activity are to be carried out (the *plan*). This enables you to represent more complex tasks that may have decision points, concurrent elements, timers or other forms of triggers.

The main strengths of HTA are:

- The hierarchical decomposition allows you to develop the activity up to the level of detail that is required for your purposes.
- The specification of the conditions (*plan*) under which certain steps of the activity are carried out, enables the representation of complex activities.

You can use HTA to develop in more detail the basic steps of the process represented in the activity diagram.

Example: Patient assessment in MAU



Getting started with Process Mapping & Consensus-Based Standardisation

Decide on the process

You need to decide which process you are going to look at. Often, incident reporting data, Trigger Tools or other sources of patient safety information provide you with an indication of what you may want to consider.

Example

Incident reports may show that there are a number of adverse drug reactions and a significant number of near misses in a hospital. A subsequent pharmacist intervention may reveal that the prescribing error rate was higher than acceptable. It could thus be decided to focus on the process of medicines management and prescribing.

Walk the process

Get a feeling for what the process entails, what it looks like in practice and who is involved.

- Walk the process from the patient's perspective (or from the perspective of relevant information flow).
- Document this as a high-level process map (activity diagram).
- Don't get caught up in the detail yet.

Start focussing

The high-level process map serves as a starting point, but does not contain any detail. With many processes it would be cumbersome to get everybody who is involved together at the same time and it would require too much time to discuss all the details. Use the high-level process map to start focussing on a part of the process (a process in itself) that you want to investigate in detail.

Example

Medicines management as a process in the hospital may entail the entire patient journey starting with the patient's arrival at the hospital e.g. with the ambulance service, assessment in A&E or MAU, their admission and stay on a ward until the time they are discharged home again. With reference to the incident report data and in consultation with a representative from pharmacy, it could be decided to focus on the process of prescribing upon admission to MAU. This would also make sense because it is at the start of the process and in this way errors could be prevented early on before they propagate through the system.

Assemble the process mapping team

- Process mapping is conducted in a multi-disciplinary setting.
- The team should include representatives of all major stakeholder groups that are involved in the care process.
- You will need a facilitator with experience in process mapping.
- Ideally, the team should not comprise of more than 6 – 8 members.

How to identify who should be involved

- Carry out observations of the process.
- Interview key roles and find out with whom they are interacting.
- Identify where information (or equipment / materials etc) comes from and to whom it is passed on to.
- Interview "peripheral" (to the process) roles to understand whether they have a stake in the process.

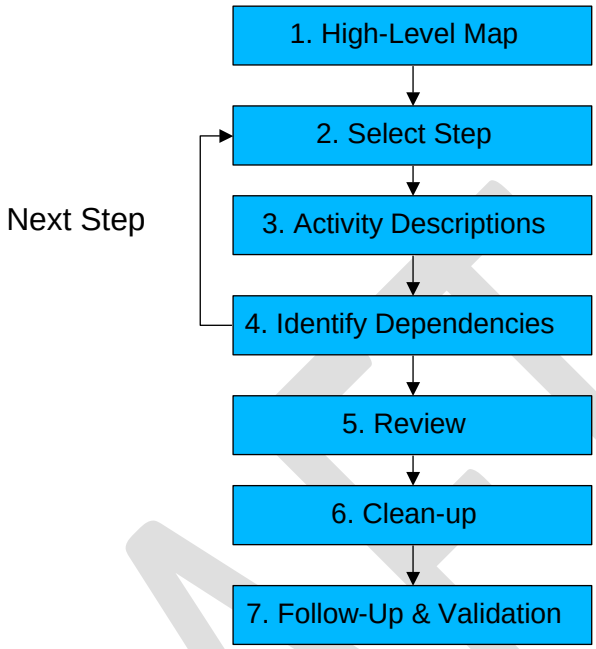
Example

Observations carried out on MAU may focus initially on junior grade doctors as the main actors of the prescribing process. Subsequently, it may become apparent that also Clinical Service Managers admitting the patient, nurses carrying out a pre-assessment, clerks fetching notes, nurses administering drugs, pharmacists reviewing drug charts and various other roles have a stake in the process.

Conducting the Process Mapping Session

- Process mapping is a creative process – ensure that changes to the map can be done quickly and efficiently. Use post-it notes that can be moved around or a computer representation that is projected and clearly visible to all of the participants.
- Explain the purpose of the process mapping session.
- Ensure that everybody understands who the other participants are and why they are participating.

The figure illustrates a typical process mapping process:



1. High-Level Map

- Review the high-level process map.
- Identify whether any major steps have been missed out on, represented in the wrong order etc.

2. Select Step

- With the aid of the process map, select the next step.
- Either start at the beginning or pick a step of interest that you want to develop in more detail.

3. Activity Descriptions

- Elicit from the participants their contribution to the selected step and their view on how this step is performed in actual practice.
- Aim to stick to the level of detail that is required by your purposes and avoid getting caught up in discussions about specific detailed elements that are not relevant for the understanding of the process.
- Structure and document the activity using HTA.

4. Identify Dependencies

- Are there other roles who have a direct effect on this activity or who are affected by it?
- Where does the information used during the activity come from? Where does it go to?
- Have you got sufficient detail about these dependencies?

You can then proceed in the same fashion to the next step in the process.

5. Review

- Take a step back and review the entire process map.
- Is the process map still consistent and does it make sense?
- Where is further detail needed?
- Where have additional roles been identified that need to be consulted?

6. Clean-Up

- Clean up the process map by reviewing and ordering the hierarchical break down.
- Ensure all plans and preconditions are documented.
- Ensure everything is properly labelled.

7. Follow-Up and Validation

- This step follows the process-mapping meeting.
- Seek further information from additional roles that have been identified during the meeting.
- Validate the map with staff not present at the meeting. Does it make sense to them?

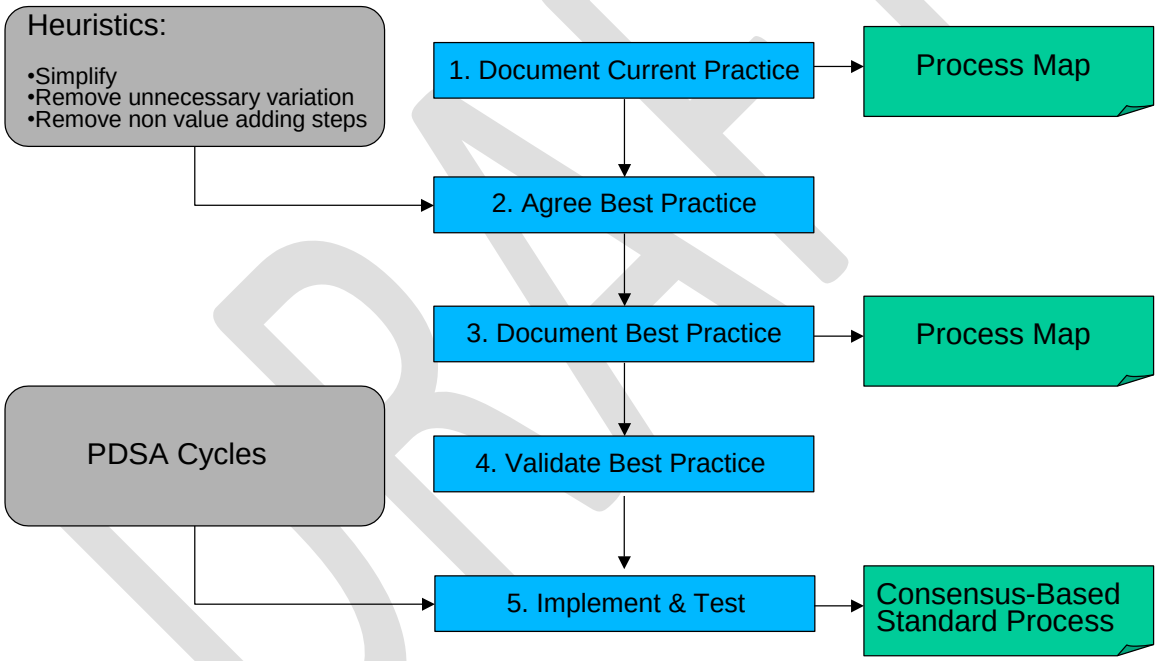
Consensus-Based Standardisation

Many care processes such as patient and information handover are not standardised. You may have experienced this during the process mapping as people may have been struggling in articulating clearly how an activity is carried out. Different ways of performing an activity may be equally valid, but there are good reasons to try to standardise processes where this is possible:

- Standardised processes are more consistent and predictable.
- People know what to expect and it is easier to spot errors.
- It is easier to assess and validate a single process and to ensure that it reflects best practice
- People new to the process can be integrated more quickly and safely.

Getting Consensus

The figure below illustrates a simple process for consensus-based standardisation. You can include this activity within the process mapping meeting or you can schedule a separate meeting with the same or another group of representative individuals.



1. Document Current Practice

This is the process mapping activity described in detail above.

2. Agree Best Practice

The aim of this step is to agree on an acceptable process that reflects best practice. The different ways of performing the process are reviewed. Some simple heuristics for standardisation can be useful:

- Simplify the process where possible.

- By consensus, remove unnecessary variation from the process, but retain flexibility to accommodate exceptions.
- Eliminate wasteful and non value-adding steps.

3. Document Best Practice

Capture and document the consensus in a revised process map.

4. Validate Best Practice

At the end of the meeting or during a separate meeting, the consensus-based standard process map needs to be validated with:

- other representative individuals to ensure they share the consensus.
- management and other non-clinical roles who may have a stake in the organisation and management of the process.
- human factors and patient safety experts.

5. Implement & Test

The consensus-based standard process map represents a concept. The concept has been validated in Step 4 and at this stage needs to be implemented and tested in clinical practice.

It is recommended to employ a Plan-Do-Study-Act approach to implement and test the changes to the process in an incremental fashion.

Getting consensus is important to ensure that the standardised process is adopted in practice.

Active involvement and consideration of all relevant stakeholders ensures:

- Clinical experiences are considered and incorporated
- The process remains practical
- Barriers to adoption are overcome and active buy-in by staff is secured
- Staff feel empowered and take ownership
- A shared vision and culture of safety is established

Section 2: Failure Mode and Effects Analysis (FMEA)

Identification of major vulnerabilities of care processes

Failure Mode and Effects Analysis (FMEA) allows organisations to identify pro-actively major vulnerabilities of their processes which could impair their ability to deliver the right care to patients at the right time.

Healthcare organisations routinely identify and review those events that have caused patient harm (e.g. through Root Cause Analysis) in order to generate learning on how to improve their processes and systems. However, there is also much to be learned from *systematically* identifying things that could go wrong *before* an incident or adverse event has occurred. Failure Mode and Effects Analysis (FMEA) is a method that supports organisations in identifying situations that may cause harm and in assessing the associated risks in a proactive and structured way. This provides an analytical basis for prioritising patient safety and improvement efforts.

FMEA originated in other high-risk industries and has been employed in sectors such as automotive, aviation and railways for many years. More recently it has been adopted in healthcare and is now promoted by patient safety bodies, such as the NPSA and the Veterans Affairs (VA) in the US.

Patient Safety Risk Analysis and Risk Control

FMEA is a method for conducting patient safety risk analysis and feeds into the control of identified patient safety risks. It is an essential part of an organisation's safety management system and can be used both to review existing processes as well as to assess new processes. The strength of FMEA lies in its systematic approach and the input from all people involved in the care process, thereby contributing to the development of a shared vision and a culture of safety.

Benefits of Applying FMEA

- Provides systematic identification of vulnerabilities of care processes
- Develops shared understanding of the patient safety risk those vulnerabilities pose

- Allows prioritisation of risk in order to focus on those vulnerabilities that pose the highest risks to patient safety
- Drives the development of patient safety improvements
- Develops a shared vision and culture of safety

Getting started with FMEA

Assemble the FMEA review team

- FMEA is conducted in a multi-disciplinary setting.
- The team should include representatives of all major stakeholder groups that are involved in the care process.
- You will also need a facilitator who has experience in conducting FMEA review sessions.

FMEA requires a process map or task representation that was described in Section 1. If you have already developed a process map and decided on the focus of your FMEA review, then this will support you in identifying the roles that should be part of your FMEA review team. Ideally, the team should not comprise of more than 6 – 8 members.

Example - FMEA review team for process: Prescribing on admission

Participants selected for the FMEA review session may include:

- FMEA facilitator
- Clinical Services Manager
- Junior grade Dr
- Middle-grade / senior Dr
- Pharmacist
- Staff nurse

Review the process map / task representation

Before you start the actual FMEA, you should review the process map or task representation with the participants in order to ensure that there is a shared understanding of the process. Alternatively, if you have not yet developed a process map, this should be your first activity following the guidance provided in Section 1.

- Ensure that participants regard their role adequately represented by the process map
- Be prepared to change / amend the process map in response to participants' comments
- Don't get caught up in operational details at this stage unless absolutely essential for the understanding of the process and its vulnerabilities
- Make sure everybody is happy and ready to proceed

Conducting the FMEA

The FMEA template

The FMEA is conducted with the support of the FMEA template. The outputs of the team are recorded on the template according to the FMEA process outlined on the following pages.

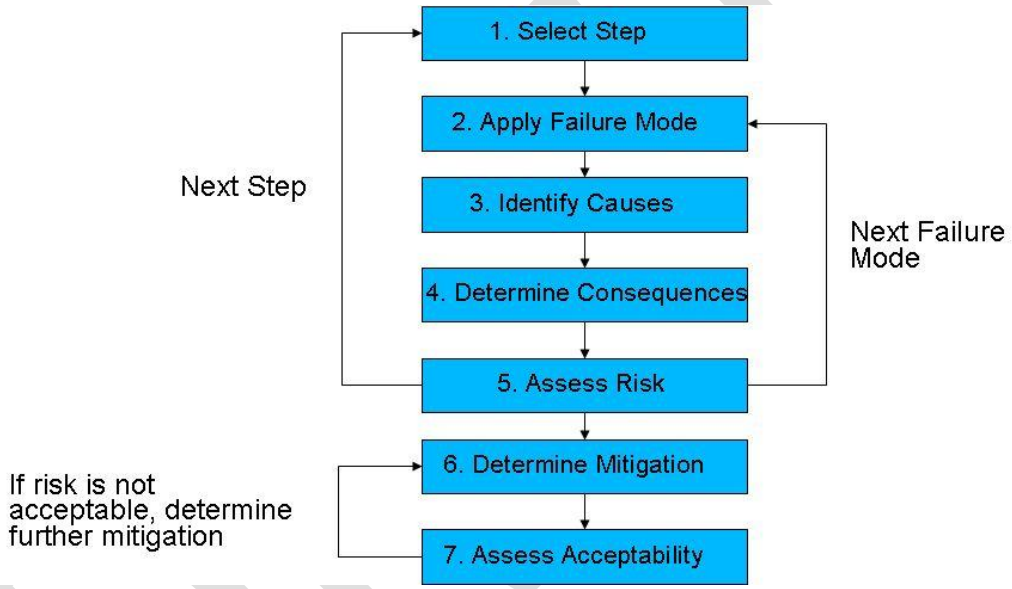
Step	Failure Mode	Causes	Consequences	Risk Freq * Sev = Risk	Mitigation

Print and fill in the FMEA template to a large scale or fill it in electronically using a projector so that all of the participants can refer to it.

The FMEA process

The figure illustrates the FMEA process.

- Explain the FMEA process to the participants and ensure that everybody is happy to proceed.
- FMEA covers steps 1 – 5 (these are part of the patient safety risk analysis).
- FMEA provides a preliminary input to steps 6 and 7 (patient safety risk control).



1. Select Step

- With the aid of your process map or task representation, select the next step in the process.
- Enter this step in the corresponding section on the FMEA template.

2. Apply Failure Mode

- Get the team to reason about a possible way in which this step can fail.
- You do not need to elicit all possible failure modes straight away as the FMEA process is iterative, reviewing one failure mode at a time.
- Record the failure mode on the FMEA template.

3. Identify Possible Causes

- Elicit from the team possible causes that may lead to this failure.
- Record the possible causes on the FMEA template.

Example: FMEA Prescribing on Admission – Step: Establish Medication History

Step	Failure Mode	Causes	Consequences	Risk Freq * Sev = Risk	Mitigation
3.1 Establish medication history	Failure to identify medicines patient is taking at home	Patient confused / unconscious Relatives not available Notes not available Patient did not bring in own drugs			

4. Determine Consequences

This step is the most important and insightful step of the FMEA review session as it provides valuable insights into the ways in which failures may propagate throughout the system and the potential for harm they possess. This is really what you want to know and sufficient time should be allowed for this step.

- Ask the team to identify possible consequences of the failure mode under consideration.
- Allow sufficient time for exploration of failure scenarios.
- Record the output on the FMEA template.

Example:

Step	Failure Mode	Causes	Consequences	Risk Freq * Sev = Risk	Mitigation
3.1 Establish medication history	Failure to identify medicines patient is taking at home	Patient confused / unconscious Relatives not available Notes not available Patient did not bring in own drugs	Inappropriate medication or dose prescribed (including allergy). Omission of required medication.		

5. Assess Risk

Performing the quantitative risk assessment is the most difficult step of the FMEA. Within the FMEA review team:

- Assign a score to the frequency with which the failure occurs.
- Think about what the failure usually means in terms of the work and to what extent the patient is immediately affected.
- Assign a score to the severity of the consequences of the failure (*credible worst case*).
- Assign a risk score to the failure: **Risk = Frequency score x Severity score**

Having completed the risk assessment for the failure mode under consideration, you need to go back to step 2 and ask the team to identify further failure modes and repeat the same process until you have covered all failure modes for this step. You then proceed to the next step.

The risk score can be used to prioritise the failure modes for subsequent further analysis and mitigation.

Example:

Step	Failure Mode	Causes	Consequences	Risk Freq * Sev = Risk	Mitigation
3.1 Establish medication history	Failure to identify medicines patient is taking at home	Patient confused / unconscious Relatives not available Notes not available Patient did not bring in own drugs	Inappropriate medication or dose prescribed (including allergy). Omission of required medication.	4 * 3 = 12	

The Risk Matrix

The risk assessment of Step 5 can be supported by tools such as the NPSA Risk Matrix. This 5x5 matrix provides 5 discrete categories for the frequency and the severity of a failure. Depending on the category into which the frequency / severity fall, a score can be assigned and the overall risk can be approximated.

	Likelihood				
Consequence	1	2	3	4	5
	Rare	Unlikely	Possible	Likely	Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

Extension:

In healthcare, the risk score is sometimes calculated factoring in explicitly the likelihood of detection of a failure, i.e. **risk = frequency x detection x severity**. Bear in mind that the score for the likelihood of detection needs to be assigned inversely.

Risk Component	Low	High
Frequency	1	5
Severity	1	5
Detection	5	1

Input to Risk Control

Steps 6 and 7 already fall into the subsequent activity of risk control where you decide on measures to reduce and control the risk of those failures that pose high levels of risk. During the FMEA review meeting you can start prioritising the failures and elicit views from the participants about possible improvements and risk control interventions. These will be preliminary deliberations that are a useful stimulus for the intervention stage as outlined in Section 3.

Step 6: Determine Mitigation

Elicit views from the participants about possible interventions.

Step 7: Assess Acceptability

Reason together with the participants about whether the proposed interventions would reduce the risk to an acceptable level.

Example

Step	Failure Mode	Causes	Consequences	Risk Freq * Sev = Risk	Mitigation
3.1 Establish medication history	Failure to identify medicines patient is taking at home	Patient confused / unconscious Relatives not available Notes not available Patient did not bring in own drugs	Inappropriate medication or dose prescribed (including allergy). Omission of required medication.	4 * 3 = 12	Raise awareness in the community forums (GP practices / local Pharmacies) about importance of patients bringing in their own drugs

Issues to watch out for

- The systematic way of thinking about the process and possible failures within the multi-disciplinary team is more important than the precise estimation of frequency and severity scores.
- The FMEA session often is scheduled for half a day, since longer sessions may become tedious and it may be difficult to free up time for participants.
- A single FMEA session will usually not solve all of your problems. Instead, it provides insights where you require further analysis.
- FMEA is just one tool within your safety tool box. You need to understand its uses and appreciate its limitations.
- Always check the FMEA outputs with common sense and compare them to the outputs from your other analysis tools.

Presenting the results

- The detailed information recorded in the FMEA template is a valuable source for patient safety management and improvement activities.
- The quantitative outputs are particularly attractive for communicating quickly to management and other people not involved in the FMEA review process why particular areas of the process were selected for further analysis and improvement.

Section 3: Failure Prevention, Detection & Recovery

Designing interventions for more reliable and safer care

Interventions designed for preventing, detecting and recovering from failures allow organisations to enhance the reliability and safety of care

Care processes are usually not designed specifically with reliability in mind. Techniques such as FMEA (see Section 2) provide an understanding of where failures may occur, their causes and their consequences for the care provided to patients. This enables the design and implementation of interventions aimed specifically at enhancing the reliability and safety of care. Such interventions are *redundant* mechanisms to prevent failures, to detect and make visible where failures have occurred and to support recovery from those failures before patients come to harm.

The design and implementation of such interventions is an iterative process that should be supported by Plan-Do-Study-Act (PDSA) cycles and appropriate measurement.

Patient Safety Risk Analysis and Risk Control

The application of hazard identification and risk analysis techniques, such as FMEA (see Section 2), provides a systematic understanding of the main vulnerabilities of the care process under consideration. The risk posed by these vulnerabilities needs to be addressed and controlled. Risk control can be achieved through:

- preventing failures from happening
- detecting where failures have occurred and recovering from these failures before they cause harm.

This is illustrated in the figure below.

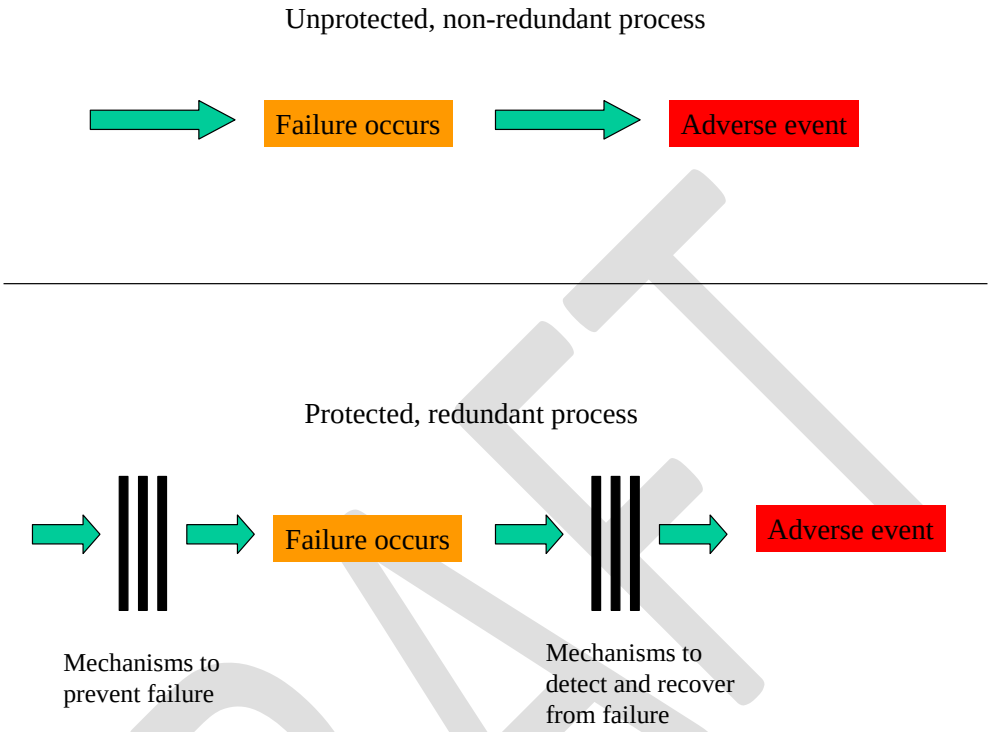


Figure 1: Many healthcare processes are unprotected. Reliability of care processes can be enhanced by adding mechanisms (hence the term *redundant*) to the process that are aimed specifically at preventing failures and at detecting and recovering from failures.

Example

The application of FMEA to a prescribing process in a hospital may provide evidence that the failure to establish the patient's medication history carries significant risks that need to be controlled. Subsequent analysis may identify a number of contributory factors:

- GPs are not prompted to send the medication history
- GPs may forget to send the medication history
- GPs may send the medication history to the ward, but the patient may be in a different location

How can we prevent this failure? And how can we detect when this failure has occurred and recover from it?

In order to prevent the failure, a new procedure and an addition to the admission form could be created. The new procedure may require that GPs be prompted explicitly to send the medication history and a box on the admission form needs to be ticked to indicate that the medication history has been requested.

In order to detect the failure, the existing process could be changed in such a way that the medication history is now to be sent to the requesting service manager rather than to the ward directly. The service manager is in a better position to keep track of requested medication histories and can check at regular intervals for outstanding requests. In case of a missing medication history (detected failure), the service manager would contact again the GP.

There are different kinds of interventions that can be considered to prevent and recover from failures

Designing and implementing a specific intervention for enhancing the reliability of a care process always draws on local expertise and needs to take into account the cultural and organisational context.

There are a few common classes of intervention types (*barrier systems*) from which frequently solutions are derived:

Barrier System	Description	Infection Control Example
Physical	A failure is prevented / recovered from through a physical intervention, e.g. lead lining for radiation safety	Isolation of patients to prevent spread
Functional	A pre-condition is set up that needs to be fulfilled before the process can continue, e.g. lock on a door or password on a computer (need to have key / know password)	Keyboard will stop working if not wiped wet at regular intervals
Symbolic	A failure is prevented / recovered from through signs and symbols, e.g. warning signs about possible radiation	Signs about hand hygiene on entrance to wards
Procedural / Cultural	A failure is prevented / recovered from through the introduction of a procedure or through cultural constraints, e.g. radiation safety procedure	Procedures and peer pressure for hand hygiene

Common failure detection mechanisms

Frequently encountered failure detection mechanisms include:

- **Make failures visible:** design processes and activities in such a way that it is obvious or easy to determine when a failure has occurred, e.g. the use of a mattress that is self-soiling when micro perforations are present (infection control).
- **Checking:** ensure that everything is as intended by performing a separate check, e.g. the frequently encountered double-checking by another person
- **Provide information redundancy:** through redundant information sources, discrepancies and errors can be detected, e.g. the use of hospital number, name and date of birth for patient identification.
- **Check for consistency:** take a step back and reason about whether everything makes sense, e.g. rather than simply calculating a dose twice (which could be based on faulty data), think about whether the calculated dose is within an appropriate range for the particular drug and patient.
- **Close the communication loop:** feed back the information to the sender to detect problems during information transfer, e.g. reading back information on the phone.
- **Set watchdog timers:** allocate responsibility for checking on whether a particular activity or process has been completed, e.g. querying the lab if requested results have not been forwarded within a specified time.

Example

Recall the example described earlier on. We can now determine the nature of the proposed interventions for the prescribing process:

- **Failure prevention:** achieved through the combination of a procedural and symbolic barrier system (new procedure to prompt GPs for medication history; tick box on the admission form)
- **Failure detection:** achieved through a watchdog timer (services manager checks at regular intervals on whether medication history has been received)
- **Failure recovery:** achieved through a procedural intervention (services manager contacts GP again)

Practical tips for designing interventions

Each problem may require a different solution and this guide describes general concepts rather than specific solutions. A few practical tips for designing your interventions include:

- Can you eliminate the hazard? For example, the use of substances that do not cause allergic reactions (where applicable) eliminates the risk of an allergic reaction.
- What have you learned from previous experience about the hazard / failure? E.g. from incident reports or root cause analysis?
- What have others done? E.g. other comparable institutions or guidance available from relevant bodies?
- Involve your staff and listen to their expertise!
- Use the classification provided above for *additional* stimulus for your thinking.
- Which interventions provide the greatest expected benefit considering the associated costs?
- For which interventions could you provide measures to ensure their effectiveness?

Practical tips for implementing interventions

It is difficult to design the perfect intervention for reliable and safer care in one go.

- Use an iterative approach to design and implement your intervention.
- Go through PDSA cycles starting with a small population and increasing the scope gradually.
- Determine appropriate measures to ensure you're on the right track.
- Be prepared to take evidence into account that may suggest that the intervention is not working as intended.
- Consult further guidance such as the NHS Institute's improvement guide!

ACKNOWLEDGEMENTS

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