IMPROVING QUALITY THROUGH SIMULATION

A quality improvement based framework to guide simulation interventions following key events in healthcare

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Index

Background

A critical incident in Wales resulted in a significant adverse event. A root cause analysis was carried out, which recommended multidisciplinary simulation training. The quality and safety team involved in supporting the follow up to this case asked for advice from the simulation team at Health Education and Improvement Wales (HEIW) regarding how to proceed. This raised the question: should we adopt a systematic approach to guide the development of simulation based interventions after key events in healthcare environments?

Whilst there is ample literature on the use of simulation for quality improvement (QI), there is no described process to develop and apply a simulation response for improvement after clinical events in a quality assured and reproducible manner. HEIW offered its interprofessional expertise both in simulation and QI to outline an easy-to-use framework to guide design of simulation related activity following key clinical events. A collaboration with the Association for Simulated Practice in Healthcare (ASPiH) and the Society for Simulation in Europe (SESAM) led to the gathering of national and international perspectives and expertise which have contributed to this document.

We propose that, when developing a simulation-based response, consideration should be given to issues such as:

- Is simulation being used for the right reasons?
- Should simulation be part of a wider process to support improvement?
- How will simulation be most beneficial?
- What else needs to be considered?

This framework aims to guide simulation-based responses following key events in healthcare, and is based on QI principles. It provides a step-by-step guide to the design of simulation based interventions to improve patient safety, including who to engage and how to incorporate best practice. It also signposts to guidance for intervention evaluation and further information through links embedded in the text.

Additionally, any simulation based intervention should adhere to relevant standards, such as those provided by ASPiH [1] or INACSL [2].

The QI philosophy underpinning this framework is The Deming System of Profound Knowledge®. [3] Deming's holistic approach to leadership and management ties together seminal theories in four interrelated areas: appreciation for a system, understanding variation, theory of knowledge and human behaviour.

Other QI and safety approaches bolstering this framework include psychology of change, [4] model for Improvement, [5] PDSA cycles [6] and other approaches [7] as well as translational simulation, [8] safety II [9] and SEIPS. [10,11]

This framework aims to be useful to anybody in the health and care community that wishes to be involved in developing a simulation response following an event or, more widely, in improvement through the use of simulation.

Embracing simulation for improvement: a 5 step guide

Simulation is a learning tool [12] that supports development through experiential learning by creating or replicating a particular set of conditions which resemble real life situations. It should provide a safe environment where participants can learn from their mistakes without any danger to patients, allowing individuals to analyse and respond to these realistic situations, with the aim of developing or enhancing their knowledge, skills, behaviours and attitudes.

Simulation based education and training (SBET) has a crucial role in improving [13] the quality of care for patients. However, it might be easy to jump to the conclusion that simulation training [14] will solve any issues identified after critical incidents, whilst underlying system difficulties might not be appropriately addressed. Simulation expertise may contribute to training and debriefing on safety behaviours, but can also play a significant role in process mapping and system testing.

Quality improvement (QI) methodology can be used to inform the approach to simulation design and employ SBET most efficiently. Conversely, simulation may be used for improvement in a variety of ways. As an example, let's consider it in relation to the PDSA cycle, [6] a well known QI approach.

PDSA stands for PLAN a change, DO (carry out the change), STUDY its impact and ACT on the results observed. Simulation can be applied at any of these stages: to aid the planning of an improvement intervention, as the improvement action per se, to study the effect of an improvement initiative, or as a response following the first 3 steps.
Simulation also allows rapid PDSA cycles. For further information we recommend reading Translational simulation: not'where?' but 'why?'. [8]

It is rare that expertise in simulation and QI are available simultaneously.
This guide should support simulation, QI and safety teams in identifying:

- key events that can lead to development of learning through simulation, including positive events
- how simulation methodologies could be most beneficial in this context
- relevant simulation and safety guidance
- applicable quality improvement principles.

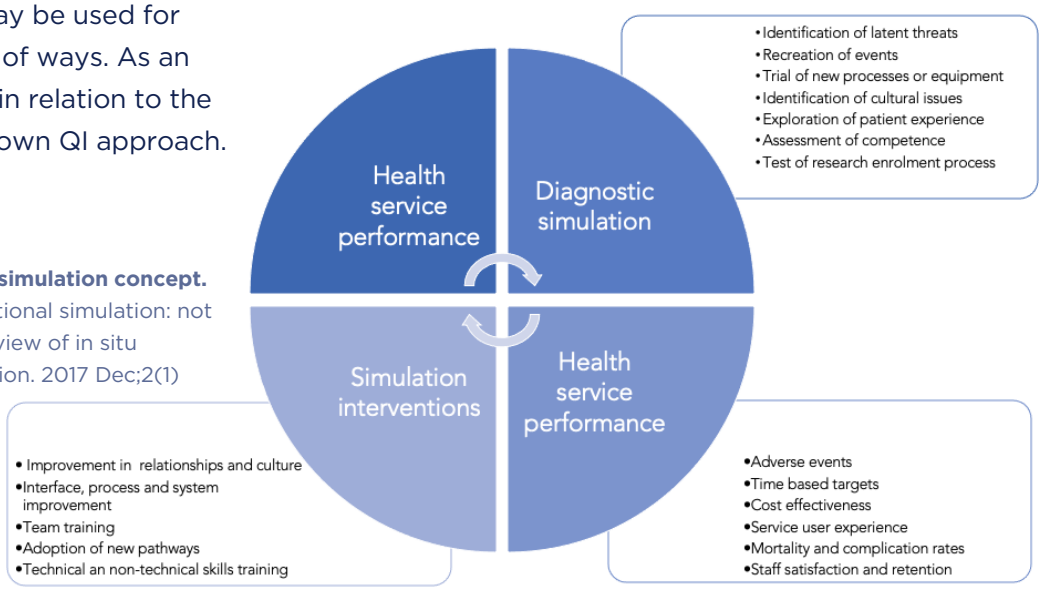


Illustration of the translational simulation concept. Adapted from Brazil V. Translational simulation: not 'where?'but 'why?'A functional view of in situ simulation. Advances in Simulation. 2017 Dec;2(1)

The five steps:

Event	What is a key event?
Who	Who needs to be involved in the process?
What	What needs to be done?
How	How will simulation contribute?
Next	How should we share the learning?

Step 1

Event

What is a key event?

A key event can be defined as any circumstance that triggers the consideration of simulation to promote learning and improvement. This includes the introduction of new processes, challenging clinical situations with positive outcomes, near misses or critical events.

Current perspectives on patient safety have shifted from focussing on learning from risk and failure (safety I) to understanding the determinants of success (safety II). [9] As a consequence, our attention should be redirected towards identifying drivers for learning and improvement from failure, success [15] and everyday variation.

The key event becomes a driver for change or learning, contributing to workforce engagement in patient centered system design [10] and improvement. This way, key events motivate staff to contribute to improvement. [4]

Simulation may also be used for improvement purposes without the need for a trigger event. From this point of view, simulation for improvement could be classified as either proactive or reactive:

- Proactive simulation would include its use for induction and training of new staff, prior to the introduction of new processes, for system redesign, or as part of routine system testing, as proposed in the PREPARED framework (appendix 4).
- Reactive simulation interventions would comprise those following challenging situations with positive outcomes, identification of system weaknesses, near misses or critical events.

Whilst this document is focussing on guidance for simulation intervention after events (reactive), the principles described can also be applied to proactive simulation.

Step 2

Who

Who needs to be involved in the process?

Before designing the intervention, we consider the following questions:

1. What system are we trying to understand?
2. What teams/professions are part of this system?
3. What teams can contribute to the design or delivery of the intervention?
4. What teams/individuals can contribute to making the intervention successful?
5. How will this intervention affect each of them?
    a. Who will benefit from the intervention?
    b. Who could be affected negatively?
    c. How can we manage barriers?

Healthcare systems are inherently complex, [16] and need to be understood in order to develop an appropriate intervention. A collaborative approach has the benefit of providing multiple perspectives on a given system, leading to a better understanding of all processes, their connections and the impact of changes.

All individuals who are part of the system under review, and those taking part in the intervention (including simulation and quality improvement teams), should be identified to facilitate both better understanding of the problem and the design of future improvements. These might include doctors, nurses, allied healthcare professionals, ancillary staff, administrative staff, managers, patients, user groups and educators.

A stakeholder analysis is the process of identifying these people before the intervention is designed. The potential impact on all individuals and teams involved is explored, including groups who may be negatively affected as a result of the intervention or change. This can be represented in a table and updated as the project evolves.

Step 3

What

What needs to be done?

We ask different members of the team to look at the system we are interested in from different perspectives and agree on an overall representation that reflects everyday working (what happens most of the time): this is process mapping. Simulation may be a useful tool at this stage.

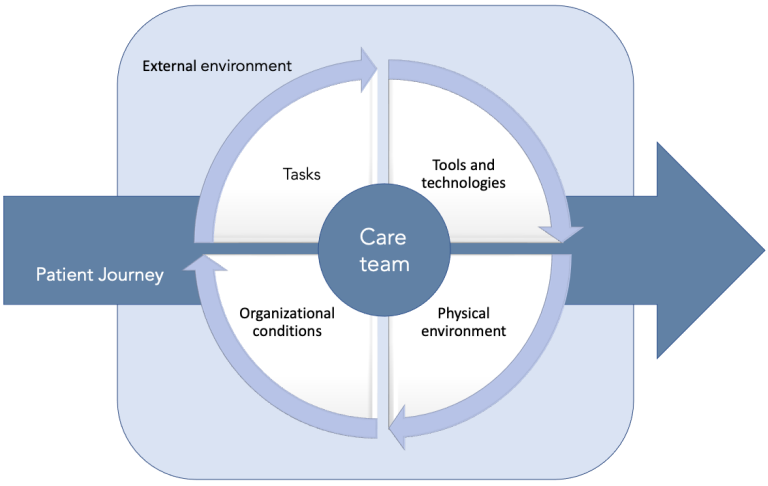
Then we consider the improvement approach:

- What are we trying to accomplish?
- How will we know that a change is an improvement?
- What changes can we make that will result in an improvement?

Understanding the system

Relevant individuals and teams that will contribute to the intervention design should now focus on understanding the system, i.e., the individuals and processes working towards a common healthcare goal. This will allow us to better define the focus of the intervention and help determine how best to use simulation expertise.

A useful framework to aid identifying relevant components and elements of the system is SEIPS, which looks into work system design for patient safety, [11] influence of human factors [17] and human centered design. [10]



Components of the SEIPS model. Adapted from Carayon P, Wooldridge A, Hoonakker P, Hundt AS, Kelly MM. SEIPS 3.0: Human-centered design of the patient journey for patient safety. Applied ergonomics. 2020 Apr 1;84:103033.

QI utilises a number of different approaches [7] and techniques that can help us to understand the system and inform the design of interventions, for instance process mapping.

Core Principles of Process Mapping:

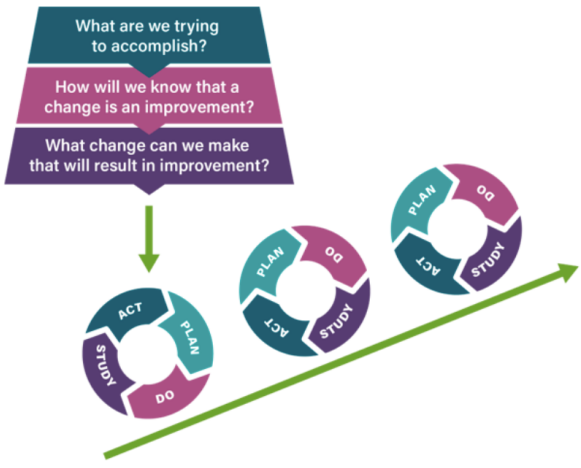
- Processes in Healthcare are often complex and multi-layered, involving many different individuals and systems along a single patient journey. With this in mind: it is important to consider the boundaries of the process under review.
- Look at what really happens in the system, this may be different to what you think should happen.
- Process mapping should reflect the everyday working of the system, so look at what happens most of the time.
- Ask different members of the team to look at the process from different perspectives and agree on an overall representation.
- Look at the process from the perspective of the patient or carer.
- Create a diagram or flowchart to represent the process.

We propose that simulation may be an incredibly useful tool during process mapping, as it allows us to immerse ourselves in the process without interfering with clinical practice. As an example, simulating a new process, or replicating a near miss might allow key individuals to visualise clinical realities and analyse aspects of the system such as vulnerabilities, strengths, educational needs or resource requirements.

Model for Improvement

Once we understand the system, the Model for Improvement [5] guides us to identify what needs to be done by proposing 3 questions:

- What are we trying to accomplish?
- How will we know that a change is an improvement?
- What changes can we make that will result in an improvement?

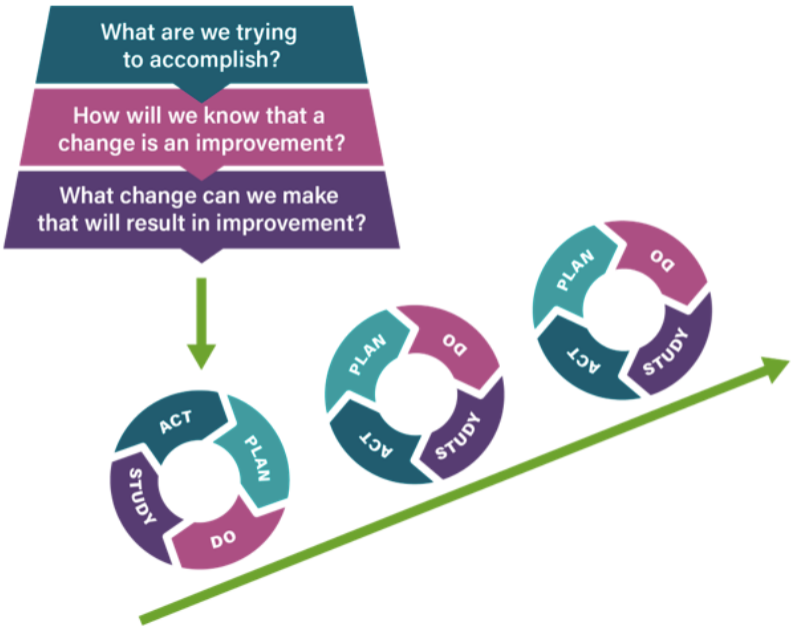


1. **What are we trying to accomplish?**
    - What is the aim of the project? Define SMART (specific, measurable, achievable, realistic, timely) objectives for the project.

2. **How will we know that a change is an improvement?**
   Consider what specific measures will be used. This should include how data can be collected during the project. Consider both quantitative and qualitative measures as part of planned PDSA cycles.

    - **Outcome measures** evaluate the performance of the system under study, are directly related to the aim of the project and assess the impact of changes in the system
    - **Process measures** evaluate the activity within the system and are linked to PDSA cycles
    - **Balancing measures** evaluate potential impacts elsewhere in the system (unintended consequences) of changes that are being tested as part of PDSA cycles. This allows us to identify if adaptations designed to improve one part of the system may affect another component with beneficial or disruptive results

3. **What changes can we make that will result in an improvement?**
   The changes can be designed with simulation methodology as a process mapping tool, delivered through simulation based education and training or tested through a simulation-based intervention.



Step 4

How

How will simulation contribute?

Simulation-based methodologies could be particularly useful

- For system testing
- To train and educate
- To facilitate system focused event debriefing

Also consider

- Individual and team wellbeing
- Blended learning options
- Evaluation and adaptation (iterative approach)

1. What is the role of simulation?

Simulation can take many shapes depending on location, modality and fidelity. [18]

It has been proposed that when simulation is used with a focus on improving healthcare processes and outcomes it should be referred to as translational simulation, [8] which can be embedded into everyday practice. [19]

Before developing a simulation based response, we should consider collaboratively how to benefit from simulation expertise. At this stage, simulation-related methodology and expertise may assist with

- testing the system
- providing education and training (by itself or in the context of blended learning)
- event debriefing, i.e., facilitation of shared reflective practice and system focussed collaborative learning from the real key event.

System testing simulation allows us to explore existing or new processes and pathways, evaluate ease of use of checklists and prepare for the use of new equipment or facilities.
It may be carried out "in situ" (at the point of care) or in simulation facilities, depending on the circumstances. Useful approaches include

- The PREPARED framework, providing broad guidance for system testing (appendix 4)
- A conceptual framework for simulation-based clinical systems testing [20] prior to the opening of a new facility, using Failure Mode and Effect Analysis (FMEA) [21]
- A guide to Simulation-based Hospital Design Testing SAFEE: A Debriefing Tool to Identify Latent Conditions in Simulation-based Hospital Design Testing [22]

Simulation-based education and training may encompass knowledge, skills and attitudes, and focus on technical abilities, application of drills, non-technical skills and/or team performance.
Consideration must be given to how this intervention aligns with multi-professional requirements, whether it requires the inclusion of deliberate practice, and how clinical variation will be captured.
Useful guidance can be found in

- Simulation in healthcare education: A best evidence practical guide [23]
- Standards on inter-professional SBET [24] provided by INACSL
- Building impactful system focused simulation [25]

Debriefing is an inherent element of simulation-based education and training. [26] It consists of facilitated discussions guiding participants to reflect on simulated experiences. When applied to real events in healthcare we call it clinical debriefing. [27] This is a guided meeting during which teams discuss, interpret and learn from recent events.

We must consider whether it will be used to promote learning and improvement or as a therapeutic tool [28]. The former may be achieved through tools such as PEARLS, [29] TALK, [27] INFO, [30] REFLECT, [31] or DISCOVER-PHASE [32] whilst the latter will require specialist mental health professional input.

2. What else do we need to consider?

Explore what else may contribute to the success of the intervention, in particular: staff wellbeing needs, blended learning possibilities and usefulness of iterative approaches.

- How will we support individual and team well-being before, during and after the intervention? Consider including the local wellbeing team early in the process. Ensure psychological safety (the degree to which people perceive the environment as being supportive of interpersonally risky behaviours) during the intervention [33] and more specifically within debriefing. [34]
- Blended learning:
  Would the individuals and teams benefit from additional learning modalities?
  Consider providing learning opportunities such as interactive lectures, seminars, workshops, e-learning resources, videos or podcasts.
  What is the right sequence of activities for optimal impact?
- Evaluation and iterative approach:
  Remember to evaluate process, outcome and balancing measures (see step 3, p10).
  A useful iterative approach is the use of sequential PDSA cycles. [6] In this case you might want to consider: What happened during the cycle that you did not expect? How did the experience of PDSA help?

Step 5

Next

How should we share the learning?

We can learn from all stages: key event, stakeholder analysis, process mapping and intervention (training, debriefing or system testing).

This learning must be fed back and disseminated as appropriate.

We must endeavour to protect the psychological safety of individuals and teams involved throughout the whole process.

The information shared should focus on the learning and adhere to SQUIRE 2.0 reporting guidance.

Learning during this process is expected to be derived from the key event, stakeholder analysis, a greater understanding of the system by using improvement techniques (such as process mapping) and the intervention itself. *Therefore, learning can be derived from each stage of the framework as well as its entirety.*

This learning must be fed back to the teams and stakeholders involved as well as disseminated to the wider departments and organisation [35] where appropriate, including consideration of communication with patient safety teams. This might translate into organisational change, as lessons learned in the planning and delivery of the simulation intervention are adapted to different environments.

At this stage it is paramount to ensure the psychological safety of all individuals and teams involved in the key event in order to minimise second victim [36] phenomena.

Any publications or reports should focus on the learning, rather than the intervention and adhere to SQUIRE 2.0 [37] standards.

We should also consider whether the learning could be shared externally through meetings, conferences and/or publication. This might take place either within healthcare fora and include multi-professional clinicians, or collaborating with Higher Education Institutions for the benefit of undergraduate and postgraduate learners.

Further considerations

This document aims to provide a useful and practical introduction to designing simulation for improvement. It refers to key documents, but it must be noted that this field continues to evolve and thus readers might wish to appraise themselves of the newest relevant literature.

With regard to the wording chosen, in particular with reference to “understanding the system”, the authors recognise that healthcare systems are inherently complex adaptive systems. However, by adopting such an approach, we are seeking to understand its component parts and how their interactions lead to emerging behaviours and outcomes.

We hope that you find this guide informative and helpful.

Any comments on the usefulness of this guidance are welcome, as well as any suggestions for its improvement. To do so, you may contact the lead author via cristina.diaz-navarro@wales.nhs.uk

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Appendix 1

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Appendix 2

Summary

Developing simulation interventions following key events

1. What is a key event?

Any circumstance that triggers the consideration of simulation to promote learning and improvement. This includes the introduction of new processes, challenging clinical situations with positive outcomes, near misses or critical events.

2.Who needs to be involved in the process?

What system are we trying to understand?
What teams/professions are part of this system?
What teams can contribute to the design or delivery of the intervention?
What teams/individuals can contribute to making the intervention successful?
How will this intervention affect each of them?

3.What needs to be done?

What specific issue needs addressing? Process mapping (including simulation).
What are we trying to accomplish?
How will we know that a change is an improvement?
What changes can we make that will result in an improvement?

4. How will simulation contribute?

Potential roles of the simulation-based component: System testing, education and training or event debriefing.
Also consider:staff wellbeing, blended learning approachand iterative evaluation.

5.How should we share the learning?

We can learn from all stages. This learning must be fed back and disseminated adhering to SQUIRE 2.0 reporting guidance.
Protect the psychological safety of individuals and teams involved.

Appendix 3

Worksheet

Developing simulation interventions following key events

What is the key event?	Circumstance that triggers the consideration of simulation to promote learning and improvement.	
Who needs to be involved in the process?	What system are we trying to understand? What teams/professions are part of this system? What teams can contribute to the design or delivery of the intervention? What teams/individuals can contribute to making the intervention successful? How will this intervention affect each of them?	
What needs to be done?	What specific issue needs addressing? Process mapping What are we trying to accomplish?How will we know that a change is an improvement? What changes can we make that will result in an improvement?	
How will simulation contribute?	System testing? Education and training? Event debriefing? Also consider: staff wellbeing, blended learning approach and iterative evaluation	
How should we share the learning?	Learn from all stages. Feedback Dissemination SQUIRE 2.0 guidance Protect psychological safety	

Appendix 4

‘PREPARED’ tool:
Designing and delivering complex simulation system tests

The design and delivery of in-situ simulations that go beyond running simple clinical scenarios in small teams is a growing challenge.

Clinical care for children is often complex and increasingly involves multiple teams, different professionals, complex clinical pathways and multiple physical locations within healthcare institutions. Testing these systems and processes using simulation is important but challenging. The PREPARED tool can assist clinicians, healthcare staff and simulation educators with this.

The PREPARED tool has been designed by the Bristol Medical Simulation Centre’s paediatric point of care simulation programme.

It embeds 8 key steps into practice:

i. define the clinical problem
ii. appropriateness of the methodology
iii. learning outcomes
iv. engagement with teams
v. safety considerations and staff preparedness
vi. effective simulation design and delivery
vii. inclusive debrief with output
viii. disseminating learning

BMSC Bristol Medical Simulation Centre

BMSC Bristol Paediatric Simulation Programme

PREPARED Description

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1. **Define the clinical problem**

Need to decide what the potential situation is that poses a significant threat or challenge patient safety, to teams, staff, equipment or other resources. Includes specifying if and how this problem relates to previous or potential risk or governance.

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2. **Appropriateness of the methodology**

Clarify or confirm that point of care or in-situ simulation is the correct methodology for testing the system for this particular situation

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3. **Learning outcomes**

Be clear about what the intended outputs of the system test will be. Is it to examine clinical knowledge or skills; test the use of equipment; observe human factors and interactions; test the function of a pathway or algorithm?

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4. **Engagement with teams**

It is vital to have a collaborative approach with the different teams that may be involved. This could be ward or theatre based teams, specialist teams, emergency department, site or management teams or even agencies external to the hospital.

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5. **Safety considerations and Staff preparedness**

Development of the system test should include clear consideration of the possible threats of the exercise. The hospital or wider team should not only be aware of the planned simulation but should have an opportunity to discuss potential risks of the simulation delivery itself.

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6. **Effective Simulation Design and Delivery**

Scenario to create simulated situation clearly designed and written and required equipment identified. Ensure there is sufficient staffing to allow the simulation to run effectively. This may include 'shadowing' of medical emergency team, for example.

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7. **Inclusive Debrief with Output**

Debrief must be delivered, ideally by a 'neutral' faculty, for all those participating in the simulation. This requires careful planning about debrief structure, place and space for the debrief, guided facilitation and an expressed view about what the outputs should be from the debrief e.g. suggestions for improving the pathway being tested.

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8. **Disseminating learning**

Following the simulation exercise it is important to collate the learning and points raised during the simulation and to formalise a mechanism for sharing this learning widely with relevant teams, governance structures, education groups and the wider organisation

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