

Curriculum Guidance for Delivering the NHS Patient Safety Syllabus

Training in Patient Safety

Making safety active

Preventing harm before it occurs

Identifying risks and making them safe

It is time to change what we do and how we think about patient safety



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Introduction

Introduction

Foreword

We are delighted to announce the first multi-professional NHS wide Patient Safety Syllabus and Patient Safety Curriculum.

Everyone who works in health and social care is united in a common purpose to provide the very best and safest care to patients and service users. There is now a greater understanding of the need for a systems approach to safety that includes all NHS staff and the wider health and care workforce.

The syllabus is an integral component of the [NHS Patient Safety Strategy](#) and is intended to create a step-change awareness of patient safety, providing the understanding, tools, and techniques that all healthcare professionals working at all levels and across all services need to build safety for patients.

The syllabus and curriculum provide content to support patient safety activities carried out by all healthcare professionals. This includes incident investigation, creating a safety culture, using human factors and proactive risk management as well as encompassing all national safety initiatives including national alerts and key safety regulations.

This curriculum guidance document builds upon the publication of the [Patient Safety Syllabus](#) in October 2021 and the launch of the Patient Safety e-learning modules for [Level 1 \(Essentials of Patient Safety\)](#) and [Level 2 \(Access to Practice\)](#), which are accessible to all on the Health Education England eLearning for healthcare platform.

This is not the end of the process. We will continue to iterate and improve the curriculum as we learn more about patient safety. For example, given the challenges that were exacerbated by the Covid pandemic, we want to include more about patient safety inequalities and how to reduce them. Future versions of the syllabus and curriculum will pick up this issue and more.

Providing a programme of education that is multi-professional, high quality and accessible by all will build workforce capacity and capability to continuously improve patient care now and in years to come.

Professor Aidan Fowler (NHSE) Aidan Fowler, National Director of Patient Safety in England and Deputy Chief Medical Officer at the Department of Health and Social Care

Professor Wendy Reid, Medical Director, Health Education England

Training in Patient Safety - the NHS Patient Safety Syllabus

Patient safety continues to be a significant issue in healthcare and a focus of both quality improvement and academic research.

The NHS published its first Patient Safety Strategy in July 2019. As part of this, it was agreed that the first NHS-wide Patient Safety Syllabus would support a transformation in patient safety education and training in the NHS. The Patient Safety Strategy includes ambitions to develop training in the fundamentals of patient safety that would be relevant to all NHS staff, clinical and non-clinical, as well as more detailed training and education that could be incorporated into clinical and non-clinical undergraduate and postgraduate healthcare education and continuing professional development.

The syllabus is designed for all NHS staff and is structured to provide both a technical understanding of safety in complex systems and a suite of tools and approaches that will:

- Build safety for patients
- Reduce the risks created by systems and practices
- Develop a genuine culture of patient safety

The patient safety syllabus comprises five sequential domains of safety and forms the basis of the detailed curriculum guidance designed for specific levels of the NHS.

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Introduction

Purpose of this document

This document provides details of the curricular content required to deliver the patient safety syllabus. It is designed for training course providers so that they are able to design new training, or adapt their existing training, in a way that allows accreditation against the requirements of the syllabus. It will also enable learners (healthcare staff) who require the curriculum to understand the expected outcomes of the training.

Health Education England (HEE) will work with education and training providers to translate the curriculum learning outcomes into innovative education and training modules that can be delivered at pace using a blended approach of online, virtual and in person learning models.

Accreditation to meet the requirements of the NHS Patient Safety Syllabus.

To ensure a course meets the requirements of the NHS Patient Safety Syllabus, course providers will be required to seek accreditation to deliver a training course.

[Find out more](#)

Providers will be expected to demonstrate that appropriate time is allocated for each educational module to provide background, theory and practical work, to ensure individuals can meet the learning outcomes expected, and the quality standards upheld.

The syllabus and the curriculum

The NHS Patient Safety Syllabus is the starting point for patient safety education. It was developed by the Academy of Medical Royal Colleges, supported by Health Education England and NHS England. The syllabus, now in version 2.1 after consultation and review, is descriptive not prescriptive. It provides the overarching goals and capabilities expected from training and has the following attributes:

- Allows tailoring to specific disciplines and professions
- Allows incorporation of new thinking, tools and techniques
- Is developed from four themes of safety science:



- Has five sequential domains, each containing four to seven modules with key capabilities
- Fulfils the objective of providing patient safety education, tools and techniques to create safe systems and safe culture

In order to implement the patient safety syllabus, a guided curriculum is provided. This is more prescriptive and has the following attributes:

- Provides learning outcomes and content guidance for course providers
- Allows providers to design or adapt existing course offerings
- Allows providers flexibility and creativity, depending on the granularity of curriculum guidance
- Comprises five levels of training:
 - Level 1 Essentials for patient safety
 - Level 2 Access to practice
 - Level 3 Developing professional skills in patient safety (Patient Safety Practitioner)
 - Level 4 Extended expertise in professional practice in patient safety (Senior Patient Safety Practitioner)
 - Level 5 Professional patient safety expert (Senior Patient Safety Expert)

This guide provides:

- An overview of the five levels of the curriculum training
- Curriculum guidance
 - Links to e-learning for levels 1 and 2
 - Levels 3-5
 - Key literature
- The NHS Patient Safety Syllabus (tab 4) v2.1 (2022)
- List of abbreviations and acknowledgements

Overview of curriculum modules

Overview of curriculum modules

Five levels of training - the patient safety curriculum

e-learning for healthcare hosts the [first two levels of training](#)

Level 1, *Essentials for patient safety*, is an e-learning session designed to raise awareness of patient safety, focusing on risk, communication and raising concerns, and our collective responsibility for preventing harm to patients. It is intended for all staff. A second session in Level 1 is targeted at senior leaders, whose ability and responsibility for creating safety is especially significant.

[e-learning hub](#) 

Level 2, *Access to practice*, comprises two e-learning sessions setting out key concepts in safety science: systems thinking, risk management, human factors, and safety culture. They set out a common understanding and vocabulary for all staff.

[e-learning hub](#) 

Levels 1 and 2 provide a strong foundation for further professional training. Levels 3-5 provide a full professional training programme in patient safety with three levels titled:

Level 3: Patient Safety Practitioner

Level 4: Senior Patient Safety Practitioner

Level 5: Senior Expert in Patient Safety

The content and ordering of all levels of the curriculum is illustrated on the diagram on the next page.

Overview of curriculum modules

Curriculum structure



Note: the ordering and numbering of the curriculum levels 3-5 necessarily differs from that of the five domains of the original syllabus (see diagram on page 79 to see how the syllabus domains and curriculum modules relate to each other).



Curriculum guidance for levels 3-5

Each curriculum module provides:

1

An **overview** of the module, followed by a list of the knowledge, skills and behaviours expected on completion of the module

2

A series of **Learning Outcomes**, followed by **Content Guidance** to support training providers to develop content to fulfil each learning outcome

3

A list of some key references.

The mode of training and the expected time taken to deliver this content is not specified. This is to enable course providers to use a range of techniques and blended learning and to innovate ways to deliver the course content in an engaging way.

Course providers may seek to deliver content specific to one module or deliver the content of multiple modules.

Curriculum guidance for levels 3-5 Level 3

Introduction

Level 3 training builds on the foundational knowledge of levels 1 and 2 and begins to develop professional skills in patient safety.

On completing this level of training, participants will have developed key skills in human factors, non-technical skills, systems analysis and modelling and organisational learning.

Expected audience for this level of training

Participants attending training at this level are likely to be working in a role with direct patient safety responsibility, reporting to senior clinical management and working closely with risk and governance teams.

Learning outcomes

On completing level 3 training modules, participants will have a professional approach to patient safety and will have gained specific skills in each area of safety science and be able to:

- Demonstrate an understanding of safety regulations and procedures in their workplace and adopt a **systems-based** approach. They will be trained to support system analysis, design, and redesign for safety
- Conduct a systems-based local incident investigation under senior supervision as part of **risk management**
- Support and encourage **human factors** interventions and be able to use tools and techniques such as Safety Engineering Initiative for Patient Safety (SEIPS)
- Develop non-technical skills to improve communication, decision-making, leadership, and team-working. Participants will contribute to understanding and supporting staff wellbeing and workplace ergonomics
- Understand the impact of **safety culture** on patient safety, including learning from incidents and how to break the link between error and blame, and support patient and public involvement in safety and be able to advise and support staff in their professional responsibilities

Key skills

Safety science	Skills
Systems thinking	Supports systems analysis, design and re-design for safety Supports and advises on safety regulations and practices
Risk management	Conducts local, systems-based investigations
Human factors	Supports human factors interventions Uses non-technical skills including good communication, leadership for safety and team-working
Safety culture	Uses skills in learning from incidents, breaking the link between error and blame and encouraging fairness and transparency Supports patient and public involvement in safety. Supports and advises staff on medico-legal responsibilities

Module 3.1 The safety landscape

This module establishes the origins and impacts of national patient safety inquiries and reports, and places them in a local context

This module will provide:

Knowledge:

- The origins and findings of national safety reports
- The impact of safety reports, inquiries, and investigations
- Local safety data

Skills:

- Collects and uses existing patient safety data from their workplace
- Evaluates patient safety data both locally and within a national context
- Demonstrates the ability to synthesise national and local data

Behaviours:

- Promotes awareness of patient safety in their working practice
- Uses national safety reports, regulations, and safety initiatives to promote learning and inform working practices
- Interprets and uses safety data to promote learning and inform working practices

Learning outcome 1: Recognises the emergence of patient safety including the key findings of national inquiries, reports, and investigations

Content guidance:

1. Define patient safety, its origins and key public inquiries

- Provide definitions of patient safety, including its relationship to quality, harm, and error
- Explain key cultural changes in the approach to patient safety (the challenge to medical 'infallibility', the developing emphasis on openness and transparency)
- Describe the origin and major findings of national inquiries, for example:
 - Ely Hospital (1969)
 - Bristol Royal Infirmary (2001)
 - Mid Staffordshire NHS Foundation Trust (2013)
 - Morecambe Bay (2015)
 - Shrewsbury and Telford (2022)
 - East Kent (2022)

2. Describe current understanding of patient safety data

- Provide estimates of numbers of incidents resulting in levels of patient harm in NHS settings
 - To include avoidable or preventable harm
 - Considerations of comparative mortality, including Summary of Hospital-level Mortality Indicator (SHMI) and Hospital Standardised Mortality Ratio (HSMR)
- Provide case examples of patient harm
 - Discuss and challenge 'avoidability' of harm with examples
 - Describe key categories of harm

3. Describe the work of the Healthcare Safety Investigation Branch/ Health Services Safety Investigations Body (from April 2023)

- Organisational objectives in patient safety
- Key reports and responses

Module 3.1 The safety landscape



Learning outcome 2: Describes the development of patient safety initiatives and their impact

Content guidance:

1. Explain the development and findings of:

- *To Err is Human (1999)*
- *An Organisation with a Memory (2000)*
- *A promise to learn – a commitment to act: improving the safety of patients in England (2013)*

2. Describe safety initiatives in the NHS since 2000

- National Learning and Reporting System
- Learn from patient safety events (LFPSE) service
- Highlight other national safety initiatives (refer to module 3.3 *Patient safety regulations and improvement*)

3. Review current safety management in healthcare

- Explain key safety initiatives in healthcare
- The role of clinical governance
- The role of risk management
- Describe current understanding of successes and challenges in patient safety
- Describe the case and opportunities for change

Learning outcome 3: Demonstrates an understanding of local patient safety measures

Content guidance:

1. Describe the range of patient safety data and measures used in local organisations

- Mortality
- Patient safety incident reports
- Never events
- Measures of key harm, including patient falls, pressure ulcers, thromboses, urinary tract and other infections
- Delays in appointments, treatment, or diagnosis
- Delivery of vaccinations and other community interventions
- Other measures in primary and secondary healthcare

2. Set out and guide participants to conduct a task in gathering local patient safety data

- Scope the range of patient safety data available in the organisation
- Gather local patient safety data
- Study and compare patient safety data with local or national comparators
- Discuss how local and national data can be shared locally and used to learn from and improve patient safety

Key literature

- National inquiries:
 - University of Warwick NHS Patient Safety Timeline
 - Ely (1969): *Ely Hospital, Cardiff: Inquiry findings*
 - Bristol Royal Infirmary (2001): Walshe K, Offen N. *A very public failure: lessons for quality improvement in healthcare organisations from the Bristol Royal Infirmary*. Qual Health Care. 2001 Dec;10(4):250-6. doi: 10.1136/qhc.0100250... PMID: 11743155; PMCID: PMC1743445.
 - Mid-Staffordshire (2013): *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*
 - Morecombe Bay (2015): *The Report of the Morecombe Bay Investigation*
 - Ockenden review (2022): *Ockenden review: summary of findings, conclusions and essential actions*
 - East Kent (2022): *Reading the signals Maternity and neonatal services in East Kent – the Report of the Independent Investigation*
- Government documents on safety:
 - *To Err is Human: building a safer health system* (1999) Institute of Medicine
 - Donaldson L. *An organisation with a memory*. Clin Med (Lond). 2002 Sep-Oct;2(5):452-7. doi: 10.7861/clinmedicine.2-5-452. PMID: 12448595; PMCID: PMC4953088
 - Berwick D, (2013) *A promise to learn – a commitment to act Improving the Safety of Patients in England*
- Incident reporting:
 - *Learn from patient safety events (LFPSE) service*
- Patient safety today:
 - Borys, D., Else, D., Leggett, S. (2009) 1(1):19-27. The fifth age of safety: The adaptive age. *Journal of Health Services Research and Policy*
 - Illingworth, J. (2015) *Continuous improvement of patient safety: The case for change in the NHS* The Health Foundation
 - Landrigan, et al., (2010) *Temporal trends in rates of patient harm*, Landrigan et al, New England Journal of Medicine, 363(2)
 - Mannion R, Braithwaite J. *False Dawns and New Horizons in Patient Safety Research and Practice*. Int J Health Policy Manag. 2017 Dec 1;6(12):685-689. doi: 10.15171/ijhpm.2017.115. PMID: 29172374; PMCID: PMC5726317.

Module 3.2 The systems approach to patient safety

This module sets out the essential framework of the systems approach to patient safety, its greater effectiveness in preventing harm to patients and the benefits to organisational safety culture. Participants will be able to begin to analyse and improve systems

This module will provide:

Knowledge:

- The systems approach to safety
- Contemporary systems approach methods

Skills:

- Uses systems analysis techniques, such as using Safety Engineering Initiative for Patient Safety (SEIPS)
- Identifies and manages systems factors that relate to patient safety

Behaviours:

- Demonstrates a systems approach in all safety improvement activity

Learning outcome 1: Defines and describes systems thinking in healthcare

Content guidance:

1. **Review main points from level 2 Access to practice session 1, systems thinking**
 - Define systems thinking as an approach focusing on interconnected elements beyond individual contributions
 - Review the Model of Organisational Accidents and the Swiss Cheese model
2. **Introduce further approaches to systems thinking**
 - Theory of Normal Accidents
 - Examples of systems thinking and practices across professional boundaries and in other industries, including aviation, process engineering and nuclear
 - Describe High Reliability Organisations
 - Describe Safety Management Systems and their applications in industry
 - Introduce the principles of Safety II (developed further in module 4.4 *Safety II and resilience*)

Learning outcome 2: Describes contemporary models and applications of systems thinking in healthcare

Content guidance:

1. **Explain the use of models in systems thinking**
 - Why models are necessary
 - How models are developed and applied
2. **Describe contemporary approaches to modelling of healthcare systems**
 - Explain the origins and development of the Systems Engineering Initiative for Patient Safety (SEIPS)
 - Describe the elements of work systems, work processes and work outcomes in SEIPS and their interconnections
 - Describe simplified applications of SEIPS such as 'SEIPS 101'
 - Describe the tools and techniques used in SEIPS to create a model of healthcare systems
 - Explain the impact of SEIPS and other models on building patient safety, with examples
3. **Set out and guide a participant task in applying SEIPS to a defined system in the workplace**
 - Include system boundaries
 - Describe system objectives or goals
 - Include work systems, work processes and work outcomes
 - Identify risks to patients
 - Use simple tools and techniques in engaging staff

Module 3.2 The systems approach to patient safety

Learning outcome 3: Explains the implications of systems thinking as it relates to blame and human error

Content guidance:

1. Explain the impact of a systems approach on understanding human error

- Explain human error as a consequence not a cause and the 'second story' of human error
- Describe the nature and variety of system-induced human error
- Describe common 'error myths'
- Describe basics of the psychology of human error (developed further in module 4.1 *Managing human performance variability in patient safety*)

2. Describe models of accident causation in systems thinking

- Describe the difficulty of assigning causal and contributory factors to harmful events and near-misses
- Describe sequential accident models including Domino Theory and other linear models
- Describe epidemiological accident models, latent conditions, and defences in depth
- Describe systemic accident models including Functional Resonance Analysis Modelling (FRAM)
- Compare and contrast models and identify strengths and challenges of each when applied in practice

3. Explain the problems with a culture of blame

- Use case studies of patient safety incidents to explain the relationship between systems and human error
- Explain the potential conflict between professional accountability and a systems origin of error (further developed in module 3.9 *Avoiding blame and creating a learning culture through a just culture approach* and module 3.10 *Medico-legal and professional responsibilities*)

Key literature

- Managing the risks of organisational accidents, James Reason 1997, Ashgate
- Organisational accidents revisited, James Reason, 2016, Ashgate
- Normal Accidents, Charles Perrow, 1999, Princeton University Press
- Barriers and Accident Prevention, Eric Hollnagel, 2004, Ashgate
- Carayon P, Schoofs Hundt A, Karsh BT, Gurses AP, Alvarado CJ, Smith M, Flatley Brennan P. *Work system design for patient safety: the SEIPS model*. Qual Saf Health Care. 2006 Dec;15 Suppl 1(Suppl 1):i50-8. doi: 10.1136/qshc.2005.015842. PMID: 17142610; PMCID: PMC2464868.
- Holden RJ, Carayon P. (2021) *SEIPS 101 and seven simple SEIPS tools* BMJ Quality & Safety;30:901-910.
- The Human Contribution, James Reason, 2008, Ashgate
- Just Culture, Sidney Dekker, 2007, Ashgate
- Managing the unexpected, Weick and Sutcliffe, John Wiley 2001
- Building Safer Healthcare Systems, Spurgeon et al, Springer 2019
- Isherwood P, Waterson P. (2021) *To err is system; a comparison of methodologies for the investigation of adverse outcomes in healthcare*. Journal of Patient Safety and Risk Management;26(2):64-73. doi:10.1177/
- Waterson, Patrick & Catchpole, Ken. (2015). *Human factors in healthcare: Welcome progress, but still scratching the surface*. BMJ quality & safety. 25. 10.1136/bmjqs-2015-005074.

Module 3.3 Patient safety regulation and improvement

This module ensures that the participant is fully conversant with regulations that impact patient safety, recognises organisations with statutory responsibilities and other national bodies that influence patient safety

This module will provide:

Knowledge:

- The regulatory landscape in the NHS
- Key statutory and other organisations of influence in patient safety
- Key activities supported or required by national bodies

Skills:

- Applies an understanding of their responsibilities and duties to meet regulatory requirements
- Applies an understanding of meeting the requirements of national bodies, including supporting inspections and investigations
- Applies an understanding of the Duty of Candour procedures

Behaviours:

- Recognises and acts to comply with regulatory and other requirements
- Supports patients, carers and families where patients have been harmed
- Supports staff involved in patient safety incidents

Learning outcome 1: Describes the statutory regulation of patient safety and the regulating organisations

Content guidance:

1. Describe the regulatory landscape of healthcare

- Describe the organisations involved in regulation of patient safety, including:
 - Service regulators (such as the Care Quality Commission)
 - Professional regulators (such as the General Medical Council, the Nursing and Midwifery Council and the Health and Care Professions Council)
 - Health service commissioners (such as Clinical Commissioning Groups or Integrated Care Systems)
 - Other organisations which impact patient safety, including the Health and Safety Executive (HSE), the Medicine and Healthcare products Regulatory Agency (MHRA)
- Explain the evolution of regulation, its complexity, the effect of reform and restructuring and the likely effect of further change
- Explain the scope and impact of the Health and Safety at Work Act (1974) and its application in healthcare settings with regard to:
 - Health and safety at work
 - Staff well-being and safety
 - Impact on patient safety through regulation of safe working environment and safe equipment

2. Explain the range and type of activities carried out by statutory regulators, including:

- Registration and accreditation
- Monitoring, investigation, and inspection of service providers
- Quality improvement
- Data sharing and public involvement
- Monitoring of professionals and standards of care
- Representation of professionals
- Development of education and training of professionals

Learning outcome 2: Explains the purpose and activity of organisations that have a regulatory influence on patient safety

Content guidance:

1. Describe the range of organisations with regulatory influence

- Describe non-statutory organisations with regulatory influence, including organisations in the following areas:
 - Information and standards
 - Reporting accidents, incidents, near misses (including NHS England and other devolved organisations' frameworks, Serious Hazards of Transfusion (SHOT) and other healthcare reporting frameworks)
 - Professional associations
 - Royal Colleges
 - Peer review

(continued on next page)

Module 3.3 Patient safety regulation and improvement

Learning outcome 2: Explains the purpose and activity of organisations that have a regulatory influence on patient safety

(continued from previous page)

- Quality improvement
- Investigations
- Professional associations
- Unions
- Describe examples of the work in each of the above categories as they have influenced patient safety
- Describe the activities of key oversight bodies in the devolved nations, such as NHS Education for Scotland
- For NHS England, as an example, describe key activities, including:
 - NHS Patient Safety Strategy
 - National Patient Safety Improvement Programmes
 - Never Events policy and framework
 - Learning from deaths in the NHS
 - Patient Safety Incident Response Framework
 - The ‘Learn from patient safety events (LFPSE)’ service
 - National Patient Safety Alerts

Learning outcome 3: Demonstrates the ability to understand and apply procedures to comply with regulation

Content guidance:

- 1. Describe essential patient safety compliance measures at local level, including governance of:**
 - Patient safety alert compliance
 - Patient safety incident reporting and investigations
 - Mortality reviews
- 2. Explain duty of candour legislation and application, including:**
 - The legal duty on hospital, community, and mental health trusts
 - The requirement to inform and apologise to patients where mistakes have led to significant harm
 - The intention of the duty of candour to help patients receive accurate, truthful information
 - How the duty of candour legislation supports professional and ethical obligations in patient care
 - How to respond to significant harm
 - How to discuss the incident with patients, carers, families and patient safety partners
 - Support for staff involved in safety incidents and investigations

Key literature

- Regulatory landscape:
 - Oikonomou E, Carthey J, Macrae C, et al (2019) *Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare* BMJ Open;9:e028663. doi: 10.1136/bmjopen-2018-028663
 - *Duty of Candour*: (2020) Public Health England
 - *Care Quality Commission*

Module 3.4 Organisational culture and learning

This module describes organisational culture and its impact on patient safety. It sets out principles and objectives in organisational learning and the promotion of a learning culture

This module will provide:

Knowledge:

- Key concepts and models of organisational culture
- Safety culture and its link to patient safety
- Safety culture and safety behaviours in the NHS including the effect of a blame culture

Skills:

- Assesses local cultural attributes
- Evaluates local learning systems
- Identifies indicators of positive and detrimental safety culture
- Identifies learning and implements beneficial changes as a result of learning

Behaviours:

- Identifies learning opportunities in the local organisation
- Encourages the effective sharing of lessons learned in patient safety
- Promotes behaviours that reinforce a positive safety culture and challenges behaviours that are detrimental to a positive safety culture

Learning outcome 1: Describes key concepts in organisational culture

Content guidance:

- 1. Explain how organisational culture and safety culture is covered across the full curriculum guidance**
 - Review *Safety culture* in level 2 Access to practice training
 - Signpost other linked safety culture modules in levels 3-5:
 - Module 3.9 *Avoiding blame and creating a learning culture through a just culture approach*
 - Module 4.9 *Evaluating safety culture*
 - Module 5.3 *Creating a culture of patient safety*
- 2. Describe the essential concepts, questions and limitations in addressing organisational culture, including:**
 - Definitions and models of organisational culture, including:
 - Schein's Model of Organisational Culture
 - Organisational culture as an emergent property
 - Organisational culture and organisational behaviours
 - Typologies of culture and their variation within and between organisations
 - The concept, qualities, and development of High Reliability Organisations
 - Recognition of the problems in defining, measuring, and developing organisational culture

Learning outcome 2: Describes safety culture and its link to performance

Content guidance:

- 1. Describe key definitions of safety culture, including:**
 - Safety culture concepts applied in a range of safety-critical industries
 - Safety culture concepts in healthcare, with illustrative examples
 - The distinction between safety culture and safety climate
 - Key components of safety culture, including creating psychological safety, ensuring accountability, recognising and improving the importance of non-technical skills
 - The link between safety culture, leadership and quality improvement
- 2. Describe evidence of links between safety culture and patient safety**
 - Review safety culture research in healthcare
 - Describe the evidence linking safety culture to individual and organisational performance and patient safety outcomes

Module 3.4 Organisational culture and learning

Learning outcome 3: Describes examples of organisational learning in the NHS and the approach to blame culture

Content guidance:

1. Describe research into the organisational learning in the NHS, including

- Measurements, instruments used and key findings
- Evidence from qualitative studies
- The use of single- and double-loop learning systems
- Studies of organisational and senior management behaviours in the NHS

2. Review NHS policy and practice in organisational learning

- Describe recommendations for organisational learning in An Organisation with a Memory
- Describe the effect of blame culture on learning and patient safety
- Describe the response to An Organisation with a Memory and more recent reports including Ockendon with regard to learning systems and key policies relating to blame, openness and just culture

Learning outcome 4: Supports participants in exploring local cultures and learning systems

Content guidance:

1. Describe potential approaches to assessing local systems, including

- Use of discussion tools in patient safety such as the Manchester Patient Safety Framework (MaPSaF)
- Use of interviews with clinical and administrative staff
- Use of local case studies of organisational risk and incident investigations

2. Review how the local organisation shares lessons learned in patient safety

- Describe sources for patient safety learning, including:
 - Incident reports
 - Clinical audits
 - Incident investigation reports
 - Cultural surveys
 - Service and quality improvement initiatives
 - Complaints and response to complaints
- Describe and evaluate systems to share lessons across the organisation and beyond
- Discuss and demonstrate novel ways to share lessons learned

Key literature

Safety culture, safety climate and cultural typologies

- Schein, E. (1985), *Organizational Culture and Leadership*, Jossey-Bass, San Francisco
- Halligan M, Zecevic (2011) *A Safety culture in healthcare: a review of concepts, dimensions, measures and progress* BMJ Quality & Safety;20:338-343.
- Oxford handbook of organizational climate and culture. Schneider, Benjamin, Barbera, Karen M. Oxford. 2014
- *Measuring safety culture Evidence scan*, The Health Foundation, 2011

High Reliability Organisations

- *Managing the Unexpected*, Weick and Sutcliffe, Jossey Bass, 2001
- Evidence Scan - *High reliability Organisations*, The Health Foundation, 2011
- *A Framework for Safe, Reliable, and Effective Care | IHI - Institute for Healthcare Improvement*

Safety culture in NHS

- Dixon-Woods M, Baker R, Charles K, et al.(2014) *Culture and behaviour in the English National Health Service*: overview of lessons from a large multimethod study. BMJ Qual Saf;23:106–115.

Learning systems

- Nutley SM, Davies HT. (2001) *Developing organizational learning in the NHS*. Med Educ. 2001 Jan;35(1):35-42. doi: 10.1046/j.1365-2923.2001.00834.x. PMID: 11123593
- Donaldson L. *An organisation with a memory*. Clin Med (Lond). 2002 Sep-Oct;2(5):452-7. doi: 10.7861/clinmedicine.2-5-452. PMID: 12448595; PMCID: PMC4953088
- *Learn from patient safety events (LFPSE) service*

Module 3.5 Patient and public involvement in safety

At the end of this module participants will understand the benefits of patient and public involvement, drawing from the Framework for involving patients in patient safety (NHS June 2021), to improve and support an organisation-wide commitment to improve both the patient's own safety and organisational patient safety

This module will provide:

Knowledge:

- The role and purpose of patient and public involvement
- The NHS Framework for involving patients in patient safety
- The impact that safety culture has on effective patient and public involvement
- An introduction to developing patient-centred information

Skills:

- Involves patients both at an individual, organisational and community level
- Involves patients/families in the response to a patient safety incident including any investigation
- Uses case studies that demonstrate ways to engage with the patient and public to improve patient safety
- Recognises and uses required features to develop patient-centred information

Behaviours:

- Works in partnership with patients, their families and carers
- Contributes to establish a clear policy to promote and support organisation-wide engagement
- Promotes the requirement for, and use of, patient safety partners

Learning outcome 1: Recognises and uses the Framework for involving patients in patient safety (NHS June 2021)

Content guidance:

1. Define the terms patient and public involvement, for example:

- Patient involvement is where an individual, carer or family has a clear role in decision making about their care and treatment
- Public or collective involvement is having a clear role in decision making about the development, commissioning, and delivery of services
- Involvement as a continuous commitment not a one-off activity

2. Define the term patient safety partner (PSP) for example:

- PSPs are patients, carers, family members or other lay people (including NHS staff from another organisation working in a lay capacity) who are recruited to work in partnership with staff to influence and improve the governance and leadership of safety within an NHS organisation

3. Introduce and explain the history and context of the Framework and relate it to the NHS Patient Safety Syllabus

- Review the national policy and strategic drivers identified in Appendix 1 of the Framework for involving patients in patient safety

4. Explain the benefits of involving patients and the public, to include support to:

- Improve patient safety, patient experience, health outcomes, and staff experience
- Improve patient experience during and after adverse events
- Contribute to system resilience through their activities, such as checking prescriptions, chasing results, following up missed correspondence etc.
- Address health inequalities in the delivery of healthcare

5. Explain the negative impacts on patients, carers, staff, organisation when there is insufficient involvement

- Draw examples from lived experience
- Discuss emerging concepts around caring for those involved in harm incidents

6. Describe effective evaluation methods for patient engagement and involvement activities and use feedback (including from patient safety partners and patients and families) for continuous improvement

- Demonstrate the use of qualitative and quantitative techniques
- Evaluate the Framework's approach to supporting patients, families and carers involvement (Part A of the Framework)
- Evaluate the Framework's approach to the new role of patient safety partner (Part B of the Framework)

Module 3.5 Patient and public involvement in safety

Learning outcome 2: Supports organisation-wide culture and protocols for listening to and responding to patients, and sharing patient-centred information with patients (including those regarding current priorities in patient safety)

Content guidance:

- 1. Describe the characteristics and provisions for an organisation-wide approach to engaging with patients to include:**
 - Leadership support and strategy that commits to continuous patient involvement
 - Policies, procedures, and practices that encourage listening, responding to and sharing information, including safeguards for vulnerable patients
 - Patient services that facilitate engagement, such as PALS, volunteers and charities, reporting and feedback systems
 - Non-technical skills training for all staff and specific training for shared decision making (developed further in module 3.7 *Non-technical skills in clinical practice*)
 - Programmes to mentor and train patient safety partners alongside staff
 - Design and commissioning of practices that encourages patient and public involvement
 - Monitors, evaluates and innovates as a result of continuous involvement and feedback

2. Describe observable behaviours that support involving patients and carers, including to:

- Treat patients and carers (and colleagues) with civility, openness, dignity and respect
- Show empathy
- Be present and focussed and manage both verbal and non-verbal communication effectively
- Select and use appropriate language, using techniques to check understanding

3. Describe guidelines for good information design for patients that encourages them to be involved in their own safety as appropriate

- Use examples to show the development of patient-centred information by understanding user requirements and user testing etc. (Developed further in module 3.6 *Human factors and clinical practice*)
- Illustrate the range and scope of application of information design, for example out-patient communications, results, guidance, consent forms, after harm process, across all communication channels
- Describe the expertise that exists within NHS organisations (communications, patient experience) to participate in information design and disseminate information

Learning outcome 3: Works in partnership with patients and carers in key areas of safety where public and patient involvement improves patient safety

Content guidance:

- 1. Use examples of current priorities in patient safety to demonstrate how and when involvement can be used to ensure patients play an active role in their care, for example to:**
 - Recognise a deteriorating patient
 - Involve patients in catheter care and infection control
 - Improve medication safety
 - Involve patients in monitoring their condition in the community
 - Involve patients in patient safety investigations and organisational responses to adverse events
- 2. Identify case studies and participants' experiences to demonstrate where public and patient involvement improves patient safety**

Module 3.5 Patient and public involvement in safety

Key literature

- The NHS Framework for involving patients in patient safety June 2021, NHS
- Rawson, T., Moore, L., Hernandez, B., Castro-Sanchez, E., Charani, E., Georgiou, P., Ahmad, R., Holmes, A., (2016): [Patient engagement with infection management in secondary care: a qualitative investigation of current experiences](#) BMJ open; vol. 6 (no. 10); p. e011040 Publication Date: Oct 2016 Oct 31;6(10):e011040. doi: 10.1136/bmjopen-2016-011040. PMID: 27799238; PMCID: PMC5093376.
- The Patient Experience Book. NHS Institute for innovation and improvement. 2013
- O'Hara, J., Aase, K., Waring, J., O'Hara JK, et al. (2019) [Scaffolding our systems? Patients and families 'reaching in' as a source of healthcare resilience](#). BMJ Qual Saf;28:3–6. doi:10.1136/bmjqs-2018-008216
- Abigail K., O'Hara, J., Conner, M., Fletcher, S., Lawton, R. (2017) [Is there a role for patients and their relatives in escalating clinical deterioration in hospital? A systematic review](#). Health Expect Oct;20(5):818-825. doi: 10.1111/hex.12496. Epub 2016 Oct 26.
- Ocloo, J., Matthews, R. (2016) [From tokenism to empowerment: progressing patient and public involvement in healthcare improvement](#) BMJ quality & safety; vol. 25 (no. 8); p. 626-632 Publication Date: Aug 2016
- Maurer, M., Dardess, P., Frosch, D., Carman, Kristin L. (2015) [Creating Change in Health Care: Developing a Shared Understanding and Roadmap for Action](#) North Carolina medical journal; vol. 76 (no. 3); p. 161- 164 Publication Date: 2015 Publication Type(s): Research Support, Non-u.s. Gov't Journal Article
- Trew M, Nettleton S, Flemons W. (2012) [Harm to Healing – Partnering with Patients Who Have Been Harmed](#) Canadian Patient Safety Institute.

Module 3.6 Human factors and clinical practice

This module sets out the essential understanding of the role of human factors and ergonomics in supporting positive patient outcomes. Course participants will relate human factors and ergonomics principles to local work systems and apply knowledge to the management of human factors and ergonomics in healthcare

This module will provide:

Knowledge:

- The definition, role, application, and impact of human factors and ergonomics in healthcare
- Human factors and ergonomics as part of a systems approach
- The role of humans in complex systems

Skills:

- Identifies and communicates the impact of human factors and ergonomics within local work systems and within healthcare as a series of complex and interrelated systems
- Identifies and communicates the wider benefits of human factors and ergonomics - efficiency, effectiveness, ease of use, satisfaction, and staff wellbeing – as well as improving safety

Behaviours:

- Applies a human factors and ergonomics perspective in patient safety-related discussions and decisions
- Recognises and appraises the limits of human performance
- Recommends practice to minimise systems-induced error in individual practice

Learning outcome 1: Identifies the scope and role of human factors and ergonomics in supporting positive patient safety outcomes

Content guidance:

1. Explain Human Factors and Ergonomics (HFE)

- Provide definitions of HFE
- Explain the sciences that inform HFE
- Demonstrate wider benefits of HFE to improve efficiency, effectiveness, ease of use, satisfaction, and staff wellbeing
- Demonstrate the scientific, objective, and measurable impacts of using HFE
- Contrast HFE approaches to inclusive design and universal design
- Evaluate HFE's contribution to safety science, and the relationship with quality improvement
- Provide history and examples from other safety-critical industries

2. Explain HFE as a systems approach

- Describe techniques to consider the requirements of people, tasks, tools and equipment, the work environment, and the context, organisation, and system
- Review Safety Engineering Initiative for Patient Safety (SEIPS) as one method to describe a complex healthcare system (developed in module 3.2 *The systems approach to patient safety*)
- Demonstrate how interventions may impact other parts of the system or wider system functioning

3. Demonstrate examples of how HFE approaches support positive patient safety outcomes, for example:

- Define the needs and behaviour of user populations to assess or specify the design of systems, equipment, tasks, processes, and work environments
- Apply usability assessment, as part of the selection, testing, and evaluation during procurement of equipment, tools, and medical devices
- Use task analyses to understand more complex tasks, job and procedure design (developed further in module 4.2 *Task analysis and support*)
- Use a systems approach to analyse existing data sources, such as incident data, adverse events, near misses, MHRA data and alerts, complaints, etc.
- Draw from Healthcare Safety Investigation Branch/ Health Services Safety Investigations Body (HSIB/HSSIB) investigations to show the contribution of an HFE approach to national incident investigation

4. Demonstrate the breadth of practical application in healthcare in:

- Hospital building design and redesign
- Equipment, medical devices, and workplace design
- IT system design, service design, wayfinding, and signage
- Staff safety and wellbeing
- Non-technical skills training, psychological safety, individual and team performance (developed further in module 3.7 *Non-technical skills in clinical practice*)

Module 3.6 Human factors and clinical practice

Learning outcome 2: Explains the key factors that affect human performance and relates them to work systems

Content guidance:

1. Explain human capabilities and limitations, to include:

- Physical human factors and ergonomics, such as anthropometry, biomechanics, strength, physiological impact on performance, for example cold, heat stress, light
- Cognitive human factors such as attention and memory, thinking, reasoning and decision making
- Psychosocial factors, such as social, cultural, and environmental factors that impact wellbeing, motivation, lifestyle
- Other factors, such as competence, skills, personality, attitude, and risk perception

2. Explain how HFE addresses individual variability

- Explain individual variability and normal distribution
- Explain how HFE uses evidence-based data, standards, and guidelines to design for a defined 'user population'. For example:
 - Physical human factors data to assess patient moving and handling tasks, work postures and reach, movement, and repetition, monitor visibility, design and layout of workspace, safe clearances, access, egress, handrails and guards, the use of force and strength to meet task requirements, selecting and procuring equipment

- Cognitive data to assess and design tasks, processes and equipment considering mental workload, memory, decision-making, recall and recognition, mental models, etc.
- Evidence around the impact of psychosocial and other performance influencing factors

3. Describe the factors that affect human performance in work systems, to include:

- Organisational culture, leadership, resources, work procedures, communications, and external pressures from national bodies and demand on healthcare
- Job factors such as task, workload, environment, display and controls, procedures
- Individual factors such as motivation, job satisfaction, training as well as human capabilities and limitations
- Discuss the link between individual, job and organisational factors as complexity increases in healthcare
- Review 'use error' and the management of human performance (developed further in module 4.1 *Managing human performance variability in patient safety*)

Learning outcome 3: Demonstrates knowledge of the effect of human factors and ergonomics management in healthcare

Content guidance:

1. Demonstrate benefits of using an HFE approach

- Provide examples of human factors management in healthcare for example:
 - Task, job, or workplace design
 - Process, IT system design (some participants will be involved with commissioning these or providing feedback etc.) or service design
 - Service, procedure design
 - Procurement as an example of controlling risk at source
- Discuss measurement of HFE impacts (to patient safety, improvements to efficiency, effectiveness, ease of use and satisfaction) to include:
 - Time saved, rate of task completion, number of errors, ability to error correct, amount of training required, change in levels of satisfaction etc.
 - Indirect impacts, such as improved end-user readiness when users participate in requirements specification, less training, less trouble shooting, less maintenance, fewer implementation problems when equipment is selected to meet user, task, environment, and system considerations
 - Discuss the importance of improving user satisfaction when work practices are designed (faster, easier to complete, and to get it right first time), to improve staff wellbeing, staff retention, patient satisfaction

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Module 3.6 Human factors and clinical practice

Learning outcome 3: Demonstrates knowledge of the effect of human factors and ergonomics management in healthcare

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2. Describe the impact of human factors management at a work system level and system impact

- Discuss case studies or examples to illustrate impact at work system level and beyond
 - For example arranging a workplace to meet task requirements resulted in a treatment taking less time to complete (to an agreed standard). This was safer (required less time sedated) for patients, the task was easier for staff and there was a system-wide benefit of increased patient through-put and shorter waiting times
- Identify system level impact of human factors management, such as:
 - Increased patient safety, organisational performance, and increased productivity
- Use case studies to identify the potential impact when HFE has not been considered sufficiently
 - Use both safety critical industry (for example nuclear, gas, oil, or transport), and healthcare (for example the ongoing issues of look-alike-sound-alike medications, medication safety)

3. Propose ways to communicate the benefits of HFE

- Discuss ways to share and communicate HFE from work system level upwards
- Use case studies to illustrate cost benefit analyses
 - Show how to quantify the material impact of using or not using HFE
 - Identify quantifiable benefits, for example decrease in time to complete a task, increase in caseload, decrease in waiting times
 - Identify quantifiable deficits arising from insufficient consideration of HFE: time to put things right, respond to complaints, cost of compensation, turnover and absenteeism etc.

Key literature

- Xie A, Carayon P. (2015) A systematic review of human factors and ergonomics (HFE)-based healthcare system redesign for quality of care and patient safety. *Ergonomics*;58(1):33-49. doi: 10.1080/00140139.2014.959070. Epub 2014 Oct 17. PMID: 25323570; PMCID: PMC4297241.
- IISE Transactions on Occupational Ergonomics and Human Factors, Ergonomics and Human Factors in Healthcare System Design Ergonomics, Volume 6, Issue 3-4 (2018) Special edition
- Handbook of Human Factors and Ergonomics in Health Care and Patient Safety. Edited By Pascale Carayon Copyright Year 2012 2nd Edition
- Hignett S, Jones EL, Miller D, et al (2015) Human factors and ergonomics and quality improvement science: integrating approaches for safety in healthcare *BMJ Quality & Safety*;24:250-254.
- Bodyspace: Anthropometry, Ergonomics and the Design of Work, Third Edition Hardcover – Illustrated, 18 July 2005 by Stephen Pheasant, Christine M. Haslegrave

Module 3.7 Non-technical skills in clinical practice

On completion of the module, participants will demonstrate an understanding of the importance of developing non-technical skills and the need to ensure the system supports these as part of a systems-based approach to patient safety. They will be able to evaluate and apply strategies to improve non-technical skills

This module will provide:

Knowledge:

- Non-technical skills and their effect on working practice
- Different approaches to assess non-technical skills in practice
- Non-technical skills as part of systems-based approach to patient safety

Skills:

- Identifies the need for non-technical skills training and improvement
- Applies different approaches to assess non-technical skills in practice
- Applies methods and tools to develop and improve non-technical skills in self and others

Behaviours:

- Demonstrates well developed non-technical skills in their everyday work
- Acts to develop and support these behaviours in others
- Acts to help develop and support non-technical skills as part of a systems-based approach to patient safety

Learning outcome 1: Demonstrates an understanding of non-technical skills and the value of training as part of a systems-based approach to patient safety

Content guidance:

1. **Contrast technical skills and non-technical skills and the contribution to patient safety**
2. **Describe non-technical skills relevant to healthcare:**
 - Cognitive skills, such as analysing and problem solving, decision-making, developing and maintaining situational awareness, sharing mental models, understanding mental workload
 - Cognitive biases
 - Social factors, such as communication, language, approachability, and motivation
 - Personal skills, such as dealing with stress and managing fatigue
 - Discuss that these are not new skills but often ones that lack feedback and formal development
 - Describe the increasing importance of non-technical skills in complex healthcare, patient experience and patient safety and its contribution to resilient healthcare

3. Demonstrate the system factors that are required to support non-technical skills, for example:

- Workplace, IT, and equipment design can support effective communication and information flow
- Task, process, job, and work environment design can minimise noise, distractions and stress and reduce cognitive workload and time pressures
- Policies, procedures, protocols, and guidelines, designed to meet task and user requirements
- Workforce policies and procedures such as recruitment and assessment, continuous professional development, service, or role reconfiguration support the development and support of non-technical skills
- Safe work systems designed to support non-technical skills

4. Describe the development, origins and uses of training non-technical skills

- Demonstrate scientific evidence base and input from psychology
- Compare other safety-critical industries and healthcare examples to show benefits of training non-technical skills, for example: improving leadership and team performance, managing cognitive workload, enabling staff to speak-up, manage disagreement and conflict
- Discuss ways to create psychological safety for self and others

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Module 3.7 Non-technical skills in clinical practice

Learning outcome 1: Demonstrates an understanding of non-technical skills and the value of training as part of a systems-based approach to patient safety

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- 5. Demonstrate the impact of training non-technical skills on working practice, and safe, efficient, and effective task performance, for example:**
- Use of Simulation-Based Education (SBE) to provide a safe environment to practise skills and learn about teamwork
 - Ways to create psychological safety, by training to improve civility, approachability, ability to speak-up and the impact on just culture in the workplace
 - Support of a just culture and better patient and public involvement in incident investigation and more generally
 - Promote a safety culture through shared attitudes, perceptions, and beliefs with respect to risk and safety
 - Enable team debriefs in practice as an opportunity to continue team and individual development
 - Demonstrate healthcare case studies of organisations that support and develop non-technical skills and discuss the impact on patient safety

Learning outcome 2: Outlines and explains effects of the hierarchy gradient and the impact on performance

Content guidance:

1. Describe different hierarchy gradients

- Define organisational, team and professional hierarchies
- Explain a steep hierarchy gradient and why it may occur in healthcare. Compare medical, nursing and management hierarchies
- Identify potential risks associated with a 'flat hierarchy'
- Discuss the interaction of system factors and hierarchies and related issues, for example teacher as line-manager where speaking-up may be inhibited because of real or perceived impact on an individual's career progression

2. Describe leadership and effective team behaviours that promote patient safety

- Describe leadership skills and behaviours that promote patient safety, for example using authority, maintaining standards, planning and prioritisation, managing workload and resources
- Describe followship skills and team members' behaviours that support patient safety
- Demonstrate effective team performance, characteristics of successful teams. Reflect the scope, variety, and multidisciplinary nature of teams in healthcare. For example:
 - Teams that perform under pressure
 - Non-acute teams, for example community out-reach, and non-clinical teams
 - Decision making teams, for example the multidisciplinary team (MDTs)

3. Explain the impact of a steep hierarchy gradient on individual and team performance

- Demonstrate the impact on individuals and teams on the ability to speak up, approachability and civility, listening and being heard
- Describe the impact on decision-making, creativity, engagement, commitment
- Discuss the impact on wellbeing and managing stress
- Reflect on healthcare case studies and learners' experiences of steep hierarchical gradient
- Review evidence-based studies

Module 3.7 Non-technical skills in clinical practice

Learning outcome 3: Evaluates and assesses non-technical skills (communication, situational awareness, stress management, teamwork, and leadership)

Content guidance:

1. Describe the system conditions and non-technical skills that support well-performing teams

- Describe the benefits of effective teams at organisational, patient, team, and individual levels
- Describe the system challenges to effective team performance in healthcare, for example unclear role definition, instability and frequent change to team membership, the individualised nature of healthcare, membership of multiple teams
- Evaluate when the assessment of team performance is beneficial, likely outcomes and how to manage these

2. Provide examples of non-technical skills frameworks in healthcare

- Review research that underlies the development of taxonomies of non-technical skills
- Describe benefits of using behavioural rating systems to provide a structured method for training
- Consider different assessment tools, in terms of efficacy, validation, reliability, sensitivity and ease of use for different application areas
- Use non-technical skills frameworks in healthcare that describe observable behaviours, for example:
 - The Anaesthetists' Non-technical Skills (ANTS)
 - The Non-Technical Skills for Surgeons (NOTSS)
 - The Scrub Practitioners List of Intraoperative Non-Technical Skills (SPLINTS)
 - Enhancing healthcare non-technical skills: the TINSELS programme
 - Observational Skill-based Clinical Assessment tool for Resuscitation (OSCAR)

3. Demonstrate methods to assess non-technical skills

- Contrast methods of data collection, observation, simulation, team, and individual exercises. Review ethical considerations
- Contrast methods and benefits of expert evaluation, peer review and self-reflection
- Provide opportunity to conduct non-technical skills assessment with appropriate support
- Evaluate ways to integrate assessment as part of an education programme of cross-professional, multidisciplinary team development

Key literature

- Leadership and Management in Healthcare. By Neil Gopee, Jo Galloway. 3rd edition 2017
- NHS Leadership Academy [Engaging the team](#)
- Liberati, E., Farhad Peerally, M., Dixon-Woods, M. (2018) [Learning from high risk industries may not be straightforward: a qualitative study of the hierarchy of risk controls approach in healthcare](#), International Journal for Quality in Health Care, Volume 30, Issue 1, February, Pages 39–43,
- Griffin, C., Aydin, A., Brunckhorst, O., Raison, N., Khan, M., Dasgupta, P., Ahmed, K. (2020) [Non-technical skills: a review of training and evaluation in urology](#) World Journal of Urology volume 38, pages1653–1661
- Brennan PA, Davidson M. (2019) [Improving patient safety: we need to reduce hierarchy and empower junior doctors to speak up](#). BMJ. 2019 Jul 2;366:l4461. doi: 10.1136/bmj.l4461. PMID: 31266748.
- Flin, R. (2013) [Non-technical skills for anaesthetists, surgeons and scrub practitioners](#) (ANTS, NOTSS and SPLINTS). The Health Foundation
- [The Anaesthetists' Non-Technical Skills \(ANTS\) System](#) (2012) adapted from ANTS Handbook, University of Aberdeen, v1.0
- [NOTSS skills taxonomy v1.2](#), University of Aberdeen
- Flin, R., O'Connor, P. (2016) [Safety at the Sharp End: A Guide to Non Technical Skills](#). Ashgate publishers.
- A text looking at theory and practice of Non-Technical Skills and their application to safety. Pre-course info is in the HEDS HEE document. Patrick Mitchell (Ed); Human Factors for Healthcare Trainers Manual. Swan and Horn
- Health and Safety Executive resources around stress and fatigue management
 - [Stress and mental health at work](#)
 - [Human factors: fatigue](#)
- Gordon, M., Box, H., Halliwell, J.-A., Farrell, M., Parker, L. and Stewart, A. (2015) [Enhancing health care non-technical skills: the TINSELS programme](#). Clin Teach, 12: 413-417.

Module 3.8 Systems-based approach to learning from patient safety incidents

On completion of the module, participants will be able to respond to a patient safety incident using a systems-based learning response

This module will provide:

Knowledge:

- The purpose and context of learning from patient safety incidents
- Methods to maximise learning and improvement
- Methodologies used in systems-based learning responses

Skills:

- Uses a systematic approach to conducting a patient safety learning response
- Develops and monitors safety actions

Behaviours:

- Demonstrates a systems approach to learning from patient safety incidents
- Works in/leads a multidisciplinary team to carry out systems-based learning responses
- Demonstrates a systems-based approach to human performance variability
- Acts to break links between error and systems-induced human error in patient safety incident response
- Shows compassion and support to those involved in the patient safety incident response, focusing on systems learning and improvement, not blame
- Leaders *engage* compassionately with those affected by patient safety incidents (including patients, families, and staff) and *involve* those affected in a learning response (if they would like to be) and supported throughout the process

Learning outcome 1: Recognises the purpose, context and standards relating to a patient safety incident response

Content guidance:

- 1. Describe how to conduct a patient safety incident response in the context of the NHS, including:**
 - Selection of incidents and purpose of a patient safety incident response planning, including the prevention of further harm or risk to patients
 - Current mandated standards for a patient safety incident investigation (PSII)
- 2. Describe reporting and review arrangements in incident management, including:**
 - National and local reporting and learning systems
 - The role, tools and techniques provided by NHS England's Learn from Patient Safety Events (LFPSE) service
 - Their local Patient Safety Incident Response Plan
 - Mandated reporting requirements, including reports to regulators and commissioners
 - Safe work systems designed to support non-technical skills

Learning outcome 2: Adopts a systems-based approach to learning from patient safety incidents

Content guidance:

- 1. Describe the key elements of a systems-based approach**
 - Describe with healthcare examples a systems-based approach to show how a patient safety incident response focuses on understanding the impact of work system design on work processes and outcomes
 - Review the concepts of complex systems and sociotechnical systems
 - Explain the interaction between different systems components (refer to module 3.2 *The systems approach to patient safety*) as they relate to failures and risk in patient care
- 2. Explain best practice in learning response methods**
 - Describe the range of tools and techniques provided or recommended by national bodies
 - Explain that developing methodologies, or modifications or additions may be recommended or approved by regulatory bodies
 - Develop case studies that identify, analyse, and evaluate PSIIIs from healthcare and other safety-critical industries
- 3. Demonstrate a defined methodology for investigation**
 - Describe the application of SEIPS (Systems Engineering Initiative for Patient Safety) to analysing incidents

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Module 3.8 Systems-based approach to learning from patient safety incidents

Learning outcome 2: Adopts a systems-based approach to learning from patient safety incidents

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- Methodologies are expected to include:
 - A multidisciplinary team with appropriate qualifications
 - The involvement of staff and patients or their representatives
 - A summary of events leading to the incident which collates information from a range of sources (i.e. document review and unbiased, cognitive interviewing, observations, walk throughs etc.)
 - The identification and evaluation of contributory factors
 - The prioritisation of contributory factors to be addressed
 - The identification of wider systems and cultural issues that impact patient safety
 - Triangulation of information gathered through the analysis of work-as-done, cognitive interviewing, document analysis and other sources for learning and improvement
- Applies a recommended reporting format (such as the National PSII template) with key areas for improvement which are practical, effective for the prevention of future harm, and specific to individuals, departments, and organisations

4. Demonstrate the use of the outputs from incident investigations

- How to prioritise
- How to engage and discuss with stakeholders
- How to monitor and evaluate recommendations post implementation
- Refer to module 4.1 *Managing human performance variability in patient safety*, module 4.2 *Task analysis and support*, module 4.3 *Systems-based interventions in patient safety incidents* and module 4.4 *Safety II and resilience*
- Refer to national guidance on tools and safety actions

Learning outcome 3: Applies best practice in understanding and compassionately supporting those affected by patient safety incidents

Content guidance:

1. **Describe best practice in managing the wellbeing of those affected following a patient safety incident**
 - Explore the impact of patient safety incidents on those affected, including health, performance and staff retention
 - Describe the emotional, behavioural, cognitive and physical effects on those affected by patient safety incidents
 - Demonstrate skills, methods and policy knowledge required to support those affected following incidents (refer to module 3.7 *Non-technical skills and clinical practice*)
 - Identify both immediate, short term and longer-term actions required to ensure the well-being of all those affected by incidents
2. **Identify and manage human performance variability in incidents**
 - Explain the NHS just culture guide
 - Refer to modules 4.1 *Managing human performance variability* and 4.2 *Task analysis and support for guidance in building safe practice*
 - Explain the necessity to separate error in safety incidents from system-induced human error

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Module 3.8 Systems-based approach to learning from patient safety incidents

Learning outcome 3: Applies best practice in understanding and compassionately supporting those affected by patient safety incidents

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3. Describe the role of patients in and those affected by an incident or near-miss, and best practice in PSII including:

- Inclusion of patients, carers, relatives, and patient safety partners in PSIs, including the Health Service Investigation Branch's approach
- 'Being Open' or further updated guidance in this area
- Duty of Candour (refer to module 3.3 *Patient safety regulations and improvement*)
- The NHS Framework for involving patients in patient safety

4. Describe guidance and good practice in engaging and involving those affected by an incident or near-miss

- The reasons for including those affected by an incident or near-miss and their potential contribution to learning
- The engagement of those affected, including families and staff, through guidance on providing information and answering questions
- The involvement of those affected in developing a learning response to an incident or near miss

Key literature

- NHS England resources on patient safety incident response including the [Patient Safety Incident Response Framework](#), guidance, standards, learning systems, tools, and techniques

Module 3.9 Avoiding blame and creating a learning culture through a just culture approach

This module builds essential skills in avoiding inappropriate blame by applying guidance from the NHS just culture guide to human behaviour following patient safety incidents

This module will provide:

Knowledge:

- Principles and practices of a just culture guide
- Case profiles in applying a just culture guide
- Knowledge of when to use a just culture guide correctly

Skills:

- Application of a just culture guide in evaluating systems factors and human performance
- Identification of key actions following a patient safety incident

Behaviours:

- Demonstrates the ability to segregate error from blame through recognising the impact of systems on performance
- Demonstrates the ability to be transparent in applying the sequential tests of a just culture guide

Learning outcome 1: Describes the influence of systems factors on human behaviour in patient safety incidents

Content guidance:

1. Explain systems-induced human failures in healthcare:

- Build an understanding of the 'first story' and 'second story' of human error
- Describe the evidence for system factors in incidents
- Support participants in empathic appreciation of how systems affect behaviour in safety incidents, using discussion and case studies

2. Review systems and organisational factors relevant to incidents, using, for example:

- The London Protocol for systematic investigation of patient safety incidents
- Health and Safety Executive guidance
- Human factors in healthcare literature

Learning outcome 2: Describes the purpose and methodology of a just culture guide

Content guidance:

1. Explain the use of the NHS just culture guide tool:

- As a support for constructive and fair evaluation of the actions of staff who have been involved in incidents
- In defined and specific circumstances as a support for learning
- Inappropriate use of the tool

2. Describe the key principles of how to use the tool effectively

- To highlight systems interventions
- To understand human behaviour and interventions required for safety
- Describe the use of the Just Culture Guide in creating openness and transparency in culture
- Identify where and where not to share the outputs of applying the Just Culture Guide
- Describe and review case studies in applying the Just Culture Guide
- Describe best practice in supporting staff who have been involved in patient safety incidents

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Module 3.9 Avoiding blame and creating a learning culture through a just culture approach

Learning outcome 2: Describes the purpose and methodology of a just culture guide

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3. Describe the use of a just culture guide in creating openness and transparency in culture

- Identify where and when not to share the outputs of applying a just culture guide
- Describe and review case studies in applying a just culture guide
- Describe best practice in supporting staff who have been involved in patient safety incidents

Learning outcome 3: Encourages participants' application of a just culture guide through organisational case studies

Content guidance:

1. Support participants in identifying appropriate case studies

- From their own organisation with appropriate anonymisation and redactions
- Gathered from the public domain where required

2. Support participants' practical application of a just culture guide

- Demonstrate a simulation of a just culture guide using participants' case studies
- Support a discussion of the application and utility of a just culture guide

Key literature

- Just Culture, Sidney Dekker, Ashgate 2007
- Systems Analysis of Clinical Incidents: [The London Protocol](#) The revised and updated version of the original 'Protocol for the Investigation and Analysis of Clinical Incidents' first published in 1999 (Vincent et al, BMJ 1998; Vincent et al, BMJ 2000; Vincent, NEJM 2003).
- NHS England [A just culture guide](#)

Module 3.10 Medico-legal and professional responsibilities

On completion of the module, participants will understand and be able to apply the key concepts and definitions in medical ethics and law, understand different professional responsibilities and will be able to apply these to patient safety activities

This module will provide:

Knowledge:

- Key concepts and definitions in medical ethics and medical law
- The ethical and clinical issues involved with patient care
- The responsibilities and duties of different health and care staff groups and healthcare organisations
- The legal basis and requirements of coroners, coroners' inquests, and medical examiners and related law

Skills:

- Applies an understanding of medical ethics and law to patient safety activities
- Applies an understanding of ethical and clinical issues involved with patient care to patient safety activities
- Applies an understanding of responsibilities and duties of different staff groups and organisations to patient safety activities

Behaviours:

- Recognises and acts on medico-legal and ethical principles in professional practice, ensuring compliance with the underlying legal and regulatory framework in the provision of high-quality patient-centred care
- Recognises and acts on own professional responsibilities and encourages others to do the same when engaging with, and learning from, medico-legal and ethical processes

Learning outcome 1: Demonstrates an understanding of key concepts and definitions in medical ethics and healthcare law and regulation

Content guidance:

1. Define key concepts and definitions of medical ethics

- Define medical ethics in relation to patient safety
- Contrast ethics and morals
- Discuss the importance of ethics in healthcare and how these apply in practice
- Explain the legal and ethical aspects of duty of care

2. Review guidance and standards for the duties and responsibilities for all staff groups to provide safe care including:

- General Medical Council, to include:
 - Good Medical Practice
 - Professional standards and medical ethics
 - Ethical guidance for doctors
- The General Pharmaceutical Council
- Nursing and Midwifery Council, to include:
 - The Code of conduct
 - Standards for nurses, midwives, nursing associates
- Human factors in healthcare literature
- Health and Care Professions Council
 - Regulates 15 designated professionals
 - Standards of conduct, performance and ethics

- General Dental Council
- All ten regulators may be found [here](#)
- All other non-regulated staff

3. Review guidance and standards for organisational duties and responsibilities for safe care for all health and care organisations (refer to module 3.3 *Patient safety regulations and improvement*)

4. Provide an overview of the of the English legal structure system and legislation that relates to medical ethics and law in practise

- Describe the courts and their hierarchy
- Describe the operation of healthcare organisation regulators
- Describe the operation of the health and care professional regulators
- Explain civil law and criminal law as these concepts relate to medico-legal issues and patient safety
- Provide an overview of relevant legislation to include:
 - Health and Social Care Act (2012) and further instruments. (Responsibilities related to the statutory Duty of Candour, requirements on registered persons etc.)
 - Mental Capacity Act (2005)
 - Mental Health Act (2007)
 - Deprivation of Liberty Safeguards (note: soon to be replaced by the Liberty Protection Safeguards (2022))
- Identify the differences in legal structure and legislation in the four home nations

Module 3.10 Medico-legal and professional responsibilities

Learning outcome 2: Explains the ethical and clinical issues involved with patient care and patient safety

Content guidance:

- 1. Describe the legal issues when managing ethical and clinical issues in relation to patient safety, using healthcare examples to include:**
 - End of life care
 - Working with a Power of Attorney
 - Emergency care
 - Where the law intervenes
- 2. Review the management of ethical and clinical issues in patient safety drawing from case studies to include:**
 - The withholding or withdrawal of care
 - The rights of the patient to refuse care
 - Patient confidentiality, including data protection, information governance, and exceptions
 - Informed consent
 - Patient-clinician relationships
- 3. Evaluate the management of these cases including the impact on the organisation, staff, patient, etc.**
 - Compare using a patient safety theory and human factors science approach with a medico-legal approach to understand team, organisational, and system factors that contribute to care outcomes

Learning outcome 3: Recognises the legal issues surrounding clinical negligence, gross negligence manslaughter, compensation, and the accountability of individual practitioners to provide safe care

Content guidance:

- 1. Explain the duty of care to patients from a healthcare staff, organisation, and regulated healthcare professional perspective**
 - Draw examples from different staff groups
 - Discuss how the duty of care applies to practice in healthcare and how it relates to patient safety
 - Discuss the measures taken to ensure the duty of care is being met in practice
 - Refer to professional and other regulatory standards for different staff groups
 - Discuss system measures that support professionals in meeting the duty of care
 - Explain the importance and requirements for systematic record keeping
 - Discuss how the duty of care applies from an organisational perspective

2. Define clinical negligence and gross negligence manslaughter in relation to healthcare

- Explain legal tests for clinical negligence
- Explain the legal process for a clinical negligence claim
- Describe the 'presumption of innocence' and 'legal burden of proof' as these concepts relate to medico-legal issues and patient safety
- Compare civil action to criminal prosecution
- Explain the role of individual accountability and organisational accountability, including in relation to indemnity arrangements
- Explain the offence of gross negligence manslaughter as it relates to healthcare
- Understand the role of expert witnesses in relation to civil and criminal court cases

3. Describe the outcomes of legal cases

- Compare civil and criminal actions and potential outcomes, including settlement, mediation or arbitration, and compensation
- Explain how compensation and costs are awarded in relation to civil actions
- Discuss what can be learnt from claims as part of a proactive approach to patient safety

Module 3.10 Medico-legal and professional responsibilities

Learning outcome 4: Understands the legal basis of and requirements of coroners, coroners' inquests, medical examiners and related law

Content guidance:

1. Provide an overview of Inquests and the Coroner's Court

- Explain the term 'interested person' as it relates to patient safety, the potential for blame and the need for representation
- Explain the legal obligation on coroners to issue Prevention of Future Death reports where they feel there is an ongoing risk of future deaths
- Demonstrate how Prevention of Future Death reports can be used to learn about patient safety

2. Provide an introduction to giving evidence and preparing and writing a report or statement for an inquest

- Describe the role and responsibilities of medical experts

3. Provide an overview of considerations around coroner's court hearings

4. Explain the role and function of Medical Examiners and how the role relates to the process of completing a medical certificate of cause of death and the role of Coroners

Key literature

- UK Gov Database of UK legislation
- General Medical Council (GMC) Ethical Guidance for Doctors.
- Nursing and Midwifery Council (NMC) The Code of Professional standards of practice and behaviour for nurses, midwives and nursing associates.
- Health and Care Professional Council (HCPC). *Standards of conduct, performance and ethics*.
- The Faculty of Forensic & Legal Medicine <https://fflm.ac.uk/exam-regulations-guidance/>
- The Faculty of Forensic and Legal Medicine (FFLM) Recommendations: *Forensic clinicians (physicians, nurses and paramedics) as witnesses in criminal proceedings* (2020)
- Academy of Medical Royal Colleges *Acting as an expert or professional witness - Guidance for healthcare professionals* (May 2019)
- Bryden, D., Storey, I. (2011) *Duty of care and medical negligence*. Continuing Education in Anaesthesia Critical Care & Pain, Volume 11, Issue 4, Pages 124–127, Published: 19 June 2011

Level 3 - A4 print-friendly versions of modules

Click the below graphics to download a print-friendly version of each module.

Module 3.1 The safety landscape

This module establishes the origins and impacts of national patient safety inquiries and reports, and places them in a local context.

Learning outcome 1: Recognises the emergence of patient safety including the key findings of national inquiries, reports, and investigations.

Content guidance:

- Define patient safety, its origins and key principles.
 - Provide definitions of patient safety, including its relationship to quality, harm, and error.
 - Explain the cultural changes in the system to support patient safety, including the role of medical professionals, patients, and the public.
 - Describe the origins and major findings of national inquiries, for example:
 - 18 Hospital (2001)
 - United Kingdom (2001)
 - Mid Staffordshire NHS Foundation Trust (2013)
 - Manchester Bay (2015)
 - Stonewall and Helmer (2022)
 - Saif Khan (2022)
- Describe current understanding of patient safety.
 - Provide estimates of numbers of incidents leading to harm of patient harm in NHS settings.
 - Describe systems thinking as an approach to patient safety.
 - Considerations of comparative research, including Summary of Hospital Level National Inquiry (SNHI) and Health Foundation Healthcare Safety Index (HSI).
 - Provide case examples of patient harm, including and highlighting the role of patient safety.
- Describe the role of the Healthcare Safety Investigation Branch (HSIB) from April 2023.
 - Organisational objectives of patient safety.
 - Key reports and responses.

3.1 The safety landscape
[Download >](#)

Module 3.2 The systems approach to patient safety

This module sets out the essential framework of the systems approach to patient safety, its greater effectiveness in preventing harm to patients and the benefits to organisational safety culture. Participants will be able to begin to analyse and improve systems.

Learning outcome 2: Describes contemporary models and applications of systems thinking in healthcare.

Content guidance:

- Explain the use of models in systems thinking.
 - Why models are necessary.
 - How models are developed and applied.
 - Contemporary systems approach methods.
- Describe contemporary approaches to modelling of healthcare systems.
 - Use systems engineering methods for Patient Safety (SEPS).
 - Describe the elements of work systems, work processes and work outcomes in SEPS and how they relate to patient safety.
 - Describe simplified applications of SEPS such as:
 - 18 Hospital (2001)
 - United Kingdom (2001)
 - Mid Staffordshire NHS Foundation Trust (2013)
 - Manchester Bay (2015)
 - Stonewall and Helmer (2022)
 - Saif Khan (2022)
 - Describe the tools and techniques used in SEPS to model a range of healthcare systems.
- Set out and guide a participant task in applying SEPS to a defined system in the workplace.
 - Include system boundaries.
 - Describe system objectives or goals.
 - Include work systems, work processes and work outcomes.
 - Identify risks to patients.
 - Use simple tools and techniques in mapping task.

3.2 The systems approach to patient safety
[Download >](#)

Module 3.3 Patient safety regulation and improvement

This module ensures that the participant is fully conversant with regulations that impact patient safety, recognises organisations with statutory responsibilities to patient safety and the regulatory organisations.

Learning outcome 1: Describes the regulatory regulation of patient safety and the regulatory organisations.

Content guidance:

- Describe the regulatory landscape of healthcare.
 - Describe the organisations involved in regulation of patient safety, including:
 - Statutory regulators such as the Care Quality Commission.
 - Professional regulators such as the Health and Care Professions Council and the Health and Care Regulators Council.
 - Health care commissioners such as Clinical Commissioning Groups or Integrated Care Systems.
 - Other organisations which impact patient safety, including the Health and Safety Executive (HSE), the Medicines and Healthcare products Regulatory Agency (MHRA).
 - Explain the regulation of regulation, its complexity, the effect of reform and structures and the role of the regulator.
 - Explain the scope and impact of the Health and Safety at Work Act (1974) and its application in healthcare settings with respect to:
 - Health and safety of work.
 - Staff working and safety.
 - Impact on patient safety through regulation of safe working environment and equipment.
- Explain the range and type of activities carried out by statutory regulators, including:
 - Registration and accreditation.
 - Monitoring, investigation, and imposition of service providers.
 - Quality assessment.
 - Data sharing and public information.
 - Monitoring of professional standards.
 - Management of professionals.
 - Development of education and training of professionals.

3.3 Patient safety regulations and improvement
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Module 3.4 Organisational culture and learning

This module describes organisational culture and its impact on patient safety, its role in promoting and embedding an organisational learning and improvement culture, and the role of patient safety in organisational learning and improvement.

Learning outcome 1: Describes key concepts in organisational culture and its link to patient safety.

Content guidance:

- Explain how organisational culture and safety culture are defined across the full continuum of care.
 - Describe the link between safety culture, leadership and patient safety.
 - Explain the role of safety culture in patient safety.
 - Describe the link between safety culture, leadership and patient safety.
- Describe evidence of links between safety culture and patient safety.
 - Review safety culture research in healthcare.
 - Review safety culture research in healthcare.
 - Review safety culture research in healthcare.
 - Review safety culture research in healthcare.

3.4 Organisational culture and learning
[Download >](#)

Module 3.5 Patient and public involvement in safety

This module describes the role of patient and public involvement in patient safety, its role in promoting and embedding an organisational learning and improvement culture, and the role of patient safety in organisational learning and improvement.

Learning outcome 1: Recognises and uses the role of patient and public involvement in patient safety.

Content guidance:

- Define the terms patient and public involvement.
 - Describe the role of patient and public involvement in patient safety.
 - Describe the role of patient and public involvement in patient safety.
- Describe the role of patient and public involvement in patient safety.
 - Describe the role of patient and public involvement in patient safety.
 - Describe the role of patient and public involvement in patient safety.

3.5 Patient and public involvement in safety
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Module 3.6 Human factors and clinical practice

This module sets out the essential understanding of the role of human factors and ergonomics in supporting positive patient outcomes. Course participants will explore human factors and ergonomics principles to local work systems and apply knowledge to the management of human factors and ergonomics in healthcare.

Learning outcome 1: Identifies the scope and role of human factors and ergonomics in supporting positive patient safety outcomes.

Content guidance:

- Explain human factors and ergonomics (HFE).
 - Provide definitions of HFE.
 - Explain the scope and role of HFE in supporting patient safety, including its relationship to quality, harm, and error.
 - Describe the role of HFE in supporting patient safety, including its relationship to quality, harm, and error.
- Describe the role of HFE in supporting patient safety.
 - Describe the role of HFE in supporting patient safety, including its relationship to quality, harm, and error.
 - Describe the role of HFE in supporting patient safety, including its relationship to quality, harm, and error.

3.6 Human factors and clinical practice
[Download >](#)

Module 3.7 Non-technical skills in clinical practice

On completion of the module, participants will demonstrate an understanding of the importance of non-technical skills and the need to ensure the system supports them as part of a systems-based approach to patient safety. They will be able to analyse and apply strategies to improve non-technical skills.

Learning outcome 2: Demonstrates an understanding of non-technical skills and the value of training as part of a systems-based approach to patient safety.

Content guidance:

- Describe non-technical skills relevant to healthcare.
 - Explain the role of non-technical skills in supporting patient safety.
 - Describe the role of non-technical skills in supporting patient safety.
- Describe the role of non-technical skills in supporting patient safety.
 - Describe the role of non-technical skills in supporting patient safety.
 - Describe the role of non-technical skills in supporting patient safety.

3.7 Non-technical skills in clinical practice
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Module 3.8 Systems-based approach to learning from patient safety incidents

On completion of the module, participants will be able to respond to a patient safety incident using a systems-based learning response.

Learning outcome 2: Adopts a systems-based approach to learning from patient safety incidents.

Content guidance:

- Describe the key elements of a systems-based approach.
 - Describe the key elements of a systems-based approach.
 - Describe the key elements of a systems-based approach.
- Describe the role of non-technical skills in supporting patient safety.
 - Describe the role of non-technical skills in supporting patient safety.
 - Describe the role of non-technical skills in supporting patient safety.

3.8 System-based approach to learning from patient safety incidents
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Module 3.9 Avoiding blame and creating a learning culture through a just culture approach

This module builds essential skills in avoiding blame and creating a learning culture through a just culture approach.

Learning outcome 2: Describes the influence of systems factors on human behaviour in patient safety incidents.

Content guidance:

- Explain systems-based human factors in healthcare.
 - Describe the role of human factors in supporting patient safety.
 - Describe the role of human factors in supporting patient safety.
- Review systems and organisational factors in healthcare.
 - Describe the role of human factors in supporting patient safety.
 - Describe the role of human factors in supporting patient safety.

3.9 Avoiding blame and creating a learning culture through a just culture approach
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Module 3.10 Medico-legal and professional responsibilities

On completion of the module, participants will demonstrate an understanding of the importance of medico-legal and professional responsibilities in supporting positive patient outcomes. Course participants will explore the role of medico-legal and professional responsibilities to local work systems and apply knowledge to the management of human factors and ergonomics in healthcare.

Learning outcome 1: Demonstrates an understanding of key concepts and definitions in medico-legal and professional responsibilities.

Content guidance:

- Define key concepts and definitions of medico-legal and professional responsibilities.
 - Describe the role of medico-legal and professional responsibilities in supporting patient safety.
 - Describe the role of medico-legal and professional responsibilities in supporting patient safety.
- Describe the role of medico-legal and professional responsibilities in supporting patient safety.
 - Describe the role of medico-legal and professional responsibilities in supporting patient safety.
 - Describe the role of medico-legal and professional responsibilities in supporting patient safety.

3.10 Medico-legal and professional responsibilities
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Curriculum guidance for levels 3-5 **Level 4**

Introduction

Level 4 training builds on the skills and knowledge of level 3 to extend staff expertise in safety science. Level 4-trained staff will be able to contribute at a senior level in their organisation and be able to create safe systems using a wide range of proactive safety tools and techniques. These include approaches in mapping, predictive error analysis, system-based interventions, and safety culture. In incident investigation, they will be able to use their skills and knowledge of human performance to break the link between error and blame.

Expected audience for this level of training

Participants attending training at this level are likely to be working in a senior role with a significant focus on line-management responsibility for patient safety.

Learning outcomes

On completing level 4 training modules, participants will have developed the knowledge, skills and behaviours to be professional practitioners in patient safety and should be able to:

- Lead on **patient safety evaluation**, improvement and provide support to clinical and other staff working in safety
- Use a range of advanced tools and techniques to **create patient safety** in their organisation
- Incorporate Safety II and resilience approaches and be able to use tools and techniques to **build safe systems**
- Use **risk management** tools to take a proactive, consensus-based approach to preventing harm to patients, designing system-based interventions and assuring the safety of key processes in the organisation
- Have the skills to manage human error in clinical practice **and design safer systems** to prevent it
- Evaluate **safety culture**, including reporting and learning culture, and so get the best from risk management systems

Key skills

Safety science	Skills
Systems thinking	Critically applies Safety II approaches to safety Uses key tools and techniques such as checklist design and the use of the Hierarchy of Control in selecting strong, systems-based safety interventions
Risk management	Uses process mapping, hierarchical task analysis, risk analysis and predictive human error analysis techniques to help design safe systems proactively and through stakeholder consensus. Uses formal risk analysis tools to highlight where patients are vulnerable in clinical systems Assures safety by identifying and monitoring process reliability in key areas of patient safety
Human factors	Uses their knowledge of system-induced human error to prevent patient harm and respond to incidents
Safety culture	Evaluates and communicates the local safety culture in key dimensions

Module 4.1 Managing human performance variability in patient safety

On completion of the module, participants will have knowledge of human performance variability and human error and will evaluate and manage these as part of a systems approach to patient safety

This module will provide:

Knowledge:

- Psychology of human performance variability and cognitive performance
- Impact of performance influencing factors on patient safety and performance
- System-induced human error and theories of human error

Skills:

- Identifies and manages human performance variability and performance influencing factors where they impact patient safety
- Develops evidence-based safety interventions to address human performance variability and human error

Behaviours:

- Demonstrates an understanding of performance influencing factors when discussing human performance
- Decouples analyses of human error from blame
- Encourages an open, fair, and transparent approach that creates confidence in patient safety activity
- Uses the term 'human error' with caution but does not ignore the contributions of humans to patient safety risk and the need to manage this

Learning outcome 1: Applies an understanding of when human performance variability is a consequence of systems rather than an explanation of safety failures

Content guidance:

1. Define human performance variability

- Describe physical, cognitive, and social aspects of human performance. Review individual differences (developed in module 3.6 *Human factors and clinical practice*)
- Explain human performance variability as adapting to system conditions to maintain quality of care and patient safety. (May review module 4.4 *Safety II and resilience*)

2. Provide examples of system-induced human performance variability

- Explain the value of understanding both 'adaptations' that create safety and potential for human error
- Explain how this understanding informs both system (re)design and immediate solutions essential to control risk immediately, for example measures that may be taken immediately to prevent the reoccurrence of a serious incident
- Provide case studies of system-induced human performance variability and examples of solutions from healthcare and other safety critical organisations

Learning outcome 2: Applies a knowledge of performance influencing factors and understands their effect on human performance variability

Content guidance:

1. Identify and describe performance influencing factors (PIFs), to include:

- Person factors (staff and patients); demographics; physical (fatigue, strength, hunger, thirst, fitness, agility), cognitive (knowledge, skills and experience), social (home situation), other psychological (motivation, emotional stress, effect of drugs alcohol etc.)
- Job factors: hours of work, task variety, control, autonomy, authority, work relationships, satisfaction, work environment (noise, heat, light, space, ventilation, layout)
- Task requirements, level of complexity, appropriate tools, equipment and systems, routine or unusual or emergency, time available
- Team factors (supervision, peer influence)
- Organisation factors, style of leadership, safety culture work pressures, productivity and targets, communication, workforce retention, absence, and management, financial resources, and constraints.
- Wider contextual factors for example national initiatives, targets, regulation, pandemics

2. Explain how PIFs impact human performance variability to include the impact on physical, cognitive, and social behaviour

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Module 4.1 Managing human performance variability in patient safety

Learning outcome 2: Applies a knowledge of performance influencing factors and understands their effect on human performance variability

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3. Demonstrate how to manage PIFs and their impact on human performance variability. Draw from healthcare examples, such as:

- Design-led system interventions, such as task redesign to reduce complexity, and introduction of a well-designed checklist to support decision making
- Programmes to promote psychological safety

Learning outcome 3: Outlines and explains theories of human error

Content guidance:

1. Describe cognitive human performance

- Compare and contrast models of information processing to provide a framework for understanding psychological processes of perception, attention, memory, decision making, feedback, etc.

2. Describe theories of human error

- Compare and contrast different theories, concepts, and taxonomies used to analyse human error, for example Rasmussen's knowledge, skill and rule-based modes and Reason's classification of errors (slips, mistakes, active errors, and latent conditions)

- Demonstrate how analysing error modes supports an understanding of why human error occurs
- Evaluate how analysing error modes can inform interventions, for example how slips, rule-based mistakes and knowledge-based mistakes might be managed with different interventions

3. Explain human error as an unwanted variation in human performance

- Recognise all humans make errors
- Describe how many human errors arise because of system conditions, rather than describing them as a singular cause of harm
- Explain the importance of decoupling human error from blame (see module 3.9 *Avoiding blame and creating a learning culture through a just culture approach* and module 3.8 *System-based approach to learning from patient safety incidents* which provide further support and information in this area)

4. Discuss emerging changes in practice and language around the use of the term human error

- Describe limitation of approaches that focus on individual human error as (a singular) cause of safety failures, including oversimplification of incident causation, focus on frontline workers and changing their behaviour, and the implementation of inappropriate solutions or weak control measures

Learning outcome 4: Evaluates system-induced human error to design effective safety interventions

Content guidance:

1. Describe both proactive and reactive techniques to assess and evaluate system induced errors

- Provide examples of system-induced human error. For example a system presents information to users in a way that misleads their subsequent action
- Review risk assessment and risk evaluation (developed further in module 4.6 *Mapping techniques to identify risks to patients*)
- Demonstrate systems models, such as Systems Engineering Initiative for Patient Safety (SEIPS) (refer to module 3.2 *Systems approach to patient safety*)
- Demonstrate methods to categorise and describe system-induced human error (developed further in module 4.2 *Task analysis and support*)
- Demonstrate methods, such as Generic Error Modelling System (GEMS), and Systematic Human Error Reduction and Prediction Approach (SHERPA) to identify cognitive causes of human error

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Module 4.1 Managing human performance variability in patient safety

Learning outcome 4: Evaluates system-induced human error to design effective safety interventions

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2. Explain how theories of human error support design led interventions to improve patient safety

- Demonstrate solutions that address the cause of human error, for example:
 - Improved equipment design to overcome repeated rule-based mistakes
 - Repositioning of a computer monitor to improve visibility of information to overcome slips (not doing what you are meant to do), for example checking a display but recording the value incorrectly
 - Designing a process prompt list to reduce lapses (forgetting or losing where you are in a process)
- Compare and contrast the effectiveness of design led changes with interventions, such as training, coaching, and awareness-raising, that seek to make individuals behave differently
 - Further developed in module 4.7 *Designing for systems safety*

Learning outcome 5: Builds the management of human performance variability into incident investigation reports

1. Discuss the difference between the management of human performance variability and individual performance management

- Explain the role of human resources and line managers in the management of an individual's performance
- Contrast to the management of human performance variability through evidence-based recommendations to improve patient safety

2. Describe the mechanisms required to manage human error in a fair and just manner

- Review guidance from NHSEI (described fully in module 3.8 *System-based approach to learning from patient safety incidents*)

Key literature

- Shorrock, S. (2019). 'Human Factors' and 'Human Performance': What's the difference? – Humanistic Systems
- The re-invention of human error, Sidney W. A. Dekker Technical Report 2002-01
- [A just culture guide](#) NHS Improvement (2018)
- [The NHS Patient Safety Strategy: Safer culture, safer systems, safer patients](#) NHS England & NHS Improvement (2019)
- [Patient Safety Incident Response Framework](#) NHS England
- Carayon P, Xie A, Kianfar S. (2014) [Human Factors and ergonomics as a patient safety practice](#). *BMJ Qual Saf*;23:196–205
- Read, G., Shorrock, S., Walker, G., Salmon, P (2021). [State of science: evolving perspectives on 'human error'](#). *Ergonomics*, 64:9, 1091-1114,
- Higham H., Vincent C. (2021) [Human Error and Patient Safety](#). In: Donaldson L., Ricciardi W., Sheridan S., Tartaglia R. (eds) *Textbook of Patient Safety and Clinical Risk Management*. Springer, Cham
- Health and Safety Executive [Performance Influencing Factors](#)

Module 4.2 Task analysis and support

On completion of the module, participants will be able to use task analysis to analyse key tasks and use the outputs to improve patient safety

This module will provide:

Knowledge:

- Process, methods, and application of task analysis

Skills:

- Uses methods to assess tasks in the workplace
- Uses task analysis to systematically describe and analyse tasks
- Develops recommendations for redesigning healthcare systems

Behaviours:

- Focusses on representative users' performance not individuals
- Focusses on interventions at a system level

Learning outcome 1: Identifies potential for safety improvement and analyses tasks systematically

Content guidance:

1. Review how to identify potential for safety improvement

- Identify tasks to analyse (further developed in module 4.6 *Mapping techniques to identify risks to patients*) and use of a consensus approach (further developed in module 4.1 *Managing human performance variability in patient safety*)
- Develop a plan to conduct analyses including engaging with stakeholders

2. Introduce task analysis and discuss how it is used

- Define task analysis as a systematic method of breaking down work into smaller elements and examining the relationships between the elements
- Describe how this can be used, for example to perform a comparison between the capabilities required to perform a work task/system and the demands of the work
- Describe how it gives rise to information about the users (i.e. range of staff and/or patients performing the task), their goals, the steps required to meet the goal, and the impact of performance influencing factors
- Demonstrate the objective is to use the outputs to inform task (re)design to ensure that users can achieve goals safely, easily, effectively and with satisfaction
- Demonstrate the application in healthcare, for example in workplace and equipment layout to improve task effectiveness; reducing errors in medicine administration;

medical device design and evaluation; and used to develop standard operating procedures, identify training and selection requirements etc.

- Discuss strengths and limitation of task analysis

3. Demonstrate data collection and task description

- Demonstrate how to define tasks, illustrating both simple and complex task descriptions
- Identify and plan appropriate, proportionate, and useful data collection
- Demonstrate when and how to use different data collection techniques, such as activity sampling, observations, interviewing, verbal protocol analysis
- Practise data collection methods
- Demonstrate different methods to represent and record the task description from simple tables, diagrams, to software applications
- Discuss the importance of validating task descriptions

4. Demonstrate different analysis techniques used in task analysis

- Discuss how to select analysis techniques depending on how the intended outputs will be used, for example:
 - Cognitive Task Analysis used to understand the requirements for effective decision-making, problem-solving, and assessment of workload etc.
 - Hierarchical Task Analysis to decompose a goal into a series of subgoals and task components. Used for risk analysis, training specification, procedure, equipment, and task design
 - Tabular task analysis

Module 4.2 Task analysis and support

Learning outcome 2: Evaluates safety-critical tasks where support is required to minimise error and improve quality of patient safety

1. Demonstrate how a task analysis can be used as part of a risk assessment approach

- Findings from a task analysis can be used alongside methods, for example:
 - Risk analysis techniques, such as Failure Modes and Effects Analysis (FMEA) or the Fault Tree Analysis (FTA)
 - Link analysis to identify workplace or equipment requirements that support safe, efficient, and effective task performance

2. Apply task analysis to a safety critical task in healthcare

- Provide examples to illustrate each level of the hierarchy of control measures (developed in module 4.7 *Designing for systems safety*)
- Examine how outputs from task analysis can be used for understanding potential for errors and for error reduction design and strategies
- Use healthcare examples to show how outputs from task analyses can be used both reactively and proactively to control risk

Key literature

- Evaluation of Human Work (2015) Edited by John R. Wilson and, Sarah Sharples
- Lu, J., Hignett, S. (2009) [Using task analysis in healthcare design to improve clinical efficiency](#). HERD. Winter;2(2):60-9. doi: 10.1177/193758670900200205. PMID: 21161930.
- Ashley French, Melissa R. Lemke, (2019) [Task analysis](#). in Applied Human Factors in Medical Device Design
- Vincent C, Taylor-Adams S, Stanhope N. (1998) [Framework for analysing risk and safety in clinical medicine](#). BMJ;316(7138):1154–7.

Module 4.3 Systems-based interventions in patient safety incidents

This module introduces practical tools and techniques to strengthen safety in vulnerable systems. It supports responses to patient safety incidents where immediate measures are needed to prevent further harm

This module will provide:

Knowledge:

- Range and examples of system-induced failures and successes
- Range of potential safety interventions
- Relative effectiveness of safety interventions, strong and weak interventions and the hierarchy of control

Skills:

- Ability to identify appropriate safety interventions in the workplace
- Ability to design, apply, monitor, measure and share safety interventions

Behaviours:

- Recognises the need to evaluate work-as-done
- Demonstrates the ability to engage front-line staff in patient safety design
- Demonstrates flexibility and strong communication skills in designing for safety

Learning outcome 1: Describes system-induced failures

Content guidance:

1. Describe the nature of system-induced failures

- Describe the structure of systems in healthcare
- Describe how safety and/or harm to patients emerges from interacting factors in complex healthcare systems

2. Describe case studies from healthcare and other industries

- Describe, through detailed case studies, incidents and accidents in safety-critical industries, including transport, power generation, process industries and understand the applicability/limitations of transferring these lessons to healthcare
- Describe, through detailed case studies, incidents and accidents in healthcare settings
- Refer to significant events of a more general nature, such as those covered in module 3.1 *The safety landscape*
- Compare and contrast case studies from different safety-critical sectors

3. Support participants in reviewing examples of system-induced failures from their workplace

- Identify incidents and near-misses observed or recorded in participants' workplaces (Note: ensure anonymity and confidentiality)

- Support participants in discussion and analysis of these incidents to understand the impact of the system:
 - Contributory factors
 - Consequences for patients, carers, staff and their organisation
 - Responses and changes made
 - Evaluation of current level of safety through risk evaluation and process reliability

Learning outcome 2: Applies tools and techniques to improve systems safety

Content guidance:

1. Describe and illustrate key tools used to create safer clinical systems

- Provide examples of interventions from case studies, literature and participant contributions
- Describe the concept of weak and strong interventions in safety management and provide examples for discussion and evaluation
- Support participants in evaluating the effectiveness of safety interventions

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Module 4.3 Designing systems-based interventions

Learning outcome 2: Applies tools and techniques to improve systems safety

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- Explain the hierarchy of control used in safety interventions:
 - Illustrate the concept of the hierarchy of control (covered more fully in module 4.7 *Designing for systems safety*)
 - Explain the importance of system design and proactive risk analysis and continuing rather than intermittent analysis
 - Describe applications and limitations of the hierarchy of control in healthcare and other safety-critical industries
- 2. **Describe the range of potential interventions for safety in healthcare settings**
 - Describe and discuss examples of interventions including:
 - Design of IT systems and other tools to meet users' task requirements
 - Usability and effectiveness of equipment and environment
 - Job task design
 - Pathway and service design
 - Design of safe procedures using staff engagement and the surfacing of tacit knowledge (work-as-done)
 - Standardisation of safety protocols and procedures
 - Safe use of equipment, including maintenance

- Design, application and limitations of checklists
- Communication, including huddles, safety spaces, briefing and debriefing
- Application of non-technical skills, including communication, situational awareness and decision-making
- Approaches to proactive risk monitoring
- Job aid design and task support
- Safe checking procedures including independent double checking
- Specifying and selecting easier to use equipment
- Ensure the sustainability of change through monitoring for new and emerging hazards/ unexpected consequences of change

3. Describe how to develop safety interventions relating to key risks in the workplace

- Discuss how to ensure interventions address key risks, for example identifying:
 - The goal of safety intervention
 - The design and practicality of intervention
 - The measurement and evaluation of intervention
 - The sharing of relevant knowledge
- Explain how to assess if the intervention is proportional to the risk (developed further in module 4.7 *Designing for systems safety* and module 5.2 *Risk, escalation and governance in patient safety*)
- Explain how to assess risks of unexpected consequences of change and suboptimal implementation

Key literature

Checklists and design

- World Health Organization [Surgical Safety Checklist](#)
- [The Checklist Manifesto](#), by Atul Gawande, Metropolitan Books, 2009
- [Implementation of checklists in health care](#); learning from high-reliability organisations

Proactive risk monitoring

- [Proactive risk monitoring in healthcare](#) (Primo): prerequisites for deployment in diverse settings and the impact on safety culture
- Blog: [Can huddles really help?](#) Shanthi Shanmugalingam
- J E Anderson, A J Ross, J Back, M Duncan, P Snell, A Hopper, P Jaye, (2020) [Beyond 'find and fix': improving quality and safety through resilient healthcare systems](#), International Journal for Quality in Health Care, Volume 32, Issue 3, Pages 204–211
- Aspden P, Corrigan JM, Wolcott J, et al., editors. Patient Safety: Achieving a New Standard for Care. (2004) Washington (DC): National Academies Press (US); 2004. [Quality Improvement and Proactive Hazard Analysis Models: Deciphering a New Tower of Babel](#) Institute of Medicine (US) Committee on Data Standards for Patient Safety;

Learning from defects, strength of interventions, limitations:

- AHRQ [Learn From Defects Tool](#) – Perioperative Setting
- Hibbert, P., Thomas, M., Deakin, A., Runciman, W., Braithwaite, B., Lomax, S., Prescott, J., Gorrie, G., Szczygielski, A., Surwald, T., Fraser, C. (2018) [Are root cause analyses recommendations effective and sustainable?](#) An observational study, International Journal for Quality in Health Care, Volume 30, Issue 2, Pages 124–131,
- Liberati, E., Farhad Peerally, M., Dixon-Woods, M. (2018) [Learning from high risk industries may not be straightforward](#): a qualitative study of the hierarchy of risk controls approach in healthcare, International Journal for Quality in Health Care, Volume 30, Issue 1, Pages 39–43

Module 4.4 Safety II and resilience

On completion of the module, participants will understand the principles and practices of Safety I and II and be able to apply proactive and reactive approaches to improve patient safety and system resilience

This module will provide:

Knowledge:

- Principles and practices of Safety I and II
- Common core mechanisms that promote resilience at organisation, team, group, and individual level
- How resilience and Safety I and II link to support safety

Skills:

- Uses both reactive and proactive approaches and data sources to understand risk and manage patient safety
- Plans how to work with stakeholders to develop, recommend and implement modifications for managing safety using a systems approach

Behaviours:

- Recognises and works with human variability, gaps between work-as-imagined and work-as-done as a resource rather than a liability
- Creates and encourages ways to improve resilience through the anticipation, adaptation, monitoring of system risks and learning

Learning outcome 1: Recognises the key principles of Safety II theory and how they complement Safety I

Content guidance:

1. Compare and contrast definitions of safety and recognise the lack of consensus, for example definitions include:

- The avoidance of harm, injury, danger, and loss
- Acceptable level of risk, and risk reduction (described in module 3.3 *Patient safety regulations and improvement*)
- The relationship between safety and quality of healthcare
- Current working definitions of patient safety (that align with Safety I and II), for example the NHS Patient Safety Strategy 2019

2. Describe key principles of Safety I, to include:

- Safety is managed by learning from failures - reactive approach to safety
- The premise that if humans follow the procedures good outcomes prevail
- Humans seen predominantly as a liability in the system
- Adjustments or fixes are made in response to things that have gone wrong already

3. Describe the key principles Safety II to include:

- Identifies interconnected and interrelated elements in a system that make things go right
- Safety is managed by continuous anticipation of developments and events - proactive approach

- Humans are seen as a resource enabling adaptations for system resilience. (This gives rise to the recognition of a gap between work-as-imagined and work-as-done)
- Adjustments or fixes are made before things go wrong to manage safety.

4. Evaluate Safety I and Safety II

- Compare and contrast with emerging theories, for example Safety III (Nancy Leveson), Safety Differently (Sidney Dekker)

Learning outcome 2: Integrates and applies the principles and practices of Safety I and Safety II in making direct improvements to patient safety

Content guidance:

1. Evaluate how effective safety management requires proactive and reactive approaches, for example:

- Review curriculum level 2 *Access to practice* section on risk and hazard (more fully developed in module 4.5 *Risk evaluation in clinical practice*)
- Reactive approach learning from patient safety incidents (refer to module 3.8 *System-based approach to learning from patient safety incidents*)
- Proactive approaches provide a regular check to identify where shortcomings in risk control measures or defences exist and where they are most likely to appear next
- Evaluate these approaches using healthcare examples and review case studies

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Module 4.4 Safety II and resilience

Learning outcome 2: Integrates and applies the principles and practices of Safety I and Safety-II in making direct improvements to patient safety

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2. Demonstrate the use of reactive approaches applied to improve patient safety

- Identify available data sources used in reactive safety management in addition to incident and near miss data, to include staff safety and wellbeing data; staff and patient feedback; Medicines and Healthcare products Regulatory Agency (MHRA) field safety notices; national patient safety alerts; device safety alert; medicines defects and recalls, etc.

3. Demonstrate how proactive approaches are used to identify developing risks to improve patient safety

- Review the concept of proactive risk assessment
- Demonstrate dynamic risk assessments used where a situation is changing, or unpredictable
- Demonstrate other tools for proactive risk assessment, for example:
 - Workplace and task specific checklists
 - Failure Modes and Effects Analysis (FMEA) to identify potential failures, relative impact of different failures, in order to identify the parts of the process that are most in need of change
 - Functional Resonance Analysis Method (FRAM) to identify gaps between work-as-imagined and work-as-done
 - Resilience Analysis Grid (RAG)
 - Appreciative Inquiry

4. Review evidence-based interventions in Safety II and how they apply to improving patient safety

- Discuss the analyses and interpretation of data outputs from proactive and reactive activities, assess the significance of outputs, and prioritisation of actions
- Plan how to work with stakeholders to develop, recommend and implement modifications for managing safety using a systems approach
- Recognise that this is an emerging, contested and debated field of interest in healthcare

Learning outcome 3: Encourages anticipation, adaptation, monitoring, responding, and learning to address existing and developing risks as part of a resilient organisation

Content guidance:

1. Describe resilient healthcare

- Evaluate working definitions of resilience, for example:
 - The capacity to adapt to challenges and changes at different system levels, to maintain high quality care. (Siri Wigg et al 2020)
 - A healthcare system's ability to adjust its functioning prior to, during, or following changes and disturbances, so that it can sustain required performance under both expected and unexpected conditions. (The Safety II approach and Hollnagel et al.)

- Compare and contrast theories and models of resilience: engineering perspectives (system equilibrium and bounce-back), psychological perspectives (coping and adaptive behaviour) and ecological models (change, adaptation, and reorganisation)
- Recognise that this is an emerging, contested and debated field of interest in healthcare

2. Identify the interrelationships and factors that impact resilience at different organisational levels, for example:

- Macro-organisational level factors include organisational culture, leadership style, and leadership style of external agencies
- Team or group level factors include dynamics, style of supervision, leadership, and feedback
- Individual level factors to include individual performance, knowledge, skills, performance influencing factors and psychological safety

3. Define and identify common core mechanisms that promote resilience in a system, to include:

- Anticipation describes knowing what to expect and prepare for
- Monitoring (knowing what to look for) see Learning outcome 2 in this module
- Adaptation describes the adjustments and adaptations needed to align work-as-imagined (WAI) with work-as-done (WAD)

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Module 4.4 Safety II and resilience

Learning outcome 3: Encourages anticipation, adaptation, monitoring, responding, and learning to address existing and developing risks as part of a resilient organisation

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4. Create ways to encourage the anticipation, adaptation, monitoring of system risks and learning

- Evaluate current organisation resilience using tools, for example Concepts for Applying Resilience Engineering (CARE) model or Checklist for assessing institutional resilience (CAIR)
- Work with stakeholders to address shortfalls in commitment to patient safety, accountability, and advocacy for a consistent and resourced programme to improve system resilience. Review level 5 modules
- Propose actions that can be taken at macro-organisational level to promote resilience, for example:
 - Develop a consistent and restorative just culture through supportive learning
 - Increase accountability to shift away from individual blame, incivility, and bullying. (Developed in level 5 modules)
 - Demonstrate staff, patient, their families and carers' involvement and empowerment

- Propose actions at the team or group level to promote resilience, for example:
 - Develop everyday practice and learning using appreciative inquiry, planning, debriefs, and after-action reviews
 - Develop non-technical skills – review module 3.7 *Non-technical skills in clinical practice*
 - Promote the importance of inter-professional training of clinical and non-clinical members
- Propose actions that can be taken at individual level to promote resilience:
 - Increase psychological safety through just culture, training for leadership and management, civility, use of Schwartz rounds and looking after psychological safety
 - Develop skills for individual performance, knowledge, and skills
 - Train using simulation and scenarios to practise skills to cope with changing circumstances and using dynamic risk assessments
 - Recognise the potential of performance variability and adaptation as a means to minimise risk and make care safer
 - Involve patients and their families – review module 3.5 *Patient and public involvement in safety*

Key literature

- Hollnagel, E., (2015) *From Safety-I to Safety-II: A White Paper*. University of Southern Denmark, Institute for Regional Health Research (IRS), Denmark Center for Quality, Region of Southern Denmark.
- Leveson, N. (2020) *Safety III: A Systems Approach to Safety and Resilience* Aeronautics and Astronautics Dept., MIT
- Carthey, J., de Leval, M., Reason, J. (2001) *Institutional resilience in healthcare systems*. *Quality in Health Care*;10:29–32
- Verhagen MJ, de Vos MS, Sujan M, et al, (2022) *The problem with making Safety-II work in healthcare*. *BMJ Quality & Safety*;31:402-408.
- Iflaifel, M., Lim, R.H., Ryan, K. et al. *Resilient Health Care: a systematic review of conceptualisations, study methods and factors that develop resilience*. *BMC Health Serv Res* 20, 324 (2020).
- Jeffcott, A., Ibrahim, J., Cameron R. (2009) *Resilience in healthcare and clinical handover*. *Qual Saf Health Care* 18: 256-260 S
- Wiig, S., Aase, K., Billett, S. et al. (2020) *Defining the boundaries and operational concepts of resilience in the resilience in healthcare research program*. *BMC Health Serv Res* 20, 330. <https://doi.org/10.1186/s12913-020-05224-3>
- *Organizational Resilience. A summary of academic evidence, business insights and new thinking*. by BSI and Cranfield School of Management

Module 4.5 Risk evaluation in clinical practice

This module provides the essential tools to identify and evaluate risk in clinical systems and tasks, and to locate proximal and systemic causes of potential failures

This module will provide:

Knowledge:

- Hazards, risk and harm
- Potential effect of hazards and risks on patient safety and well-being
- Contributory factors as they apply to failures in tasks and systems

Skills:

- Ability to identify, evaluate and rank risks in tasks and systems
- Ability to use Failure Mode and Effects Analysis (FMEA) and Healthcare Failure Mode and Effects Analysis (HFMEA) to proactively evaluate risks
- Ability to identify contributory factors in potential failures

Behaviours:

- Demonstrates the ability to work with multi-professional consensus groups in risk evaluation
- Demonstrates the ability to understand systemic causes in risk management

Learning outcome 1: Understands key concepts of hazards and risk

Content guidance:

1. Explain the nature of hazards

- Describe the concept of hazards as conditions that could lead to or contribute to an unplanned or undesirable event
- Describe the concept of hazards as potential sources of harm to patients
- Describe and provide examples of hazards in healthcare, including those arising from equipment, environment, people, and organisational practice and culture

2. Explain the nature of risk

- Describe the concept of risk as the product of outcome and likelihood of potentially harmful conditions
- Provide examples of risks in healthcare, including risk in individual tasks, involving patients and clinicians, and risks in the wider systems of healthcare
- Describe a range of approaches to risk management in healthcare, for example ultra-adaptive, high-reliability and ultra-safe approaches

Learning outcome 2: Applies techniques to identify, evaluate and rank risks in systems or defined tasks

Content guidance:

1. Explain the context of risk evaluation in healthcare

- Discuss when risk evaluation is applicable in healthcare, including during evaluation of:
 - System change or re-design
 - Systems after safety incidents
 - Safety-critical tasks
 - Systems and proactive evaluation
 - Patient safety incidents reviews
- Discuss the importance of clear definition of the system or task boundaries
- Explain the advantages of multi-professional engagement in risk evaluation and the importance of surfacing tacit knowledge in participants through consensus-based approaches

2. Describe and demonstrate how to apply key tools in risk evaluation

- Describe Failure Mode and Effects Analysis (FMEA) and Healthcare Failure Mode and Effects Analysis (HFMEA)
- Describe and explain the use of tools for individual tasks, inventories of tasks or system maps
- Demonstrate how to use risk evaluation tools in their workplace, in order to:
 - Identify hazards
 - Calculate associated risks
 - Rank risks and prioritise actions and improvements

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Module 4.5 Risk evaluation in clinical practice

Learning outcome 2: Applies techniques to identify, evaluate and rank risks in systems or defined tasks

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3. Describe limitations of risk analysis and other approaches

- Explain problems and limitations with FMEA, including:
 - Variation and replicability of group outputs
 - Ability to address major systemic problems
- Discuss application of risk evaluation and escalation of risk (further developed in module 5.2 *Risk, escalation and governance in patient safety*)
- Describe other approaches to risk identification and management

Learning outcome 3: Applies outputs of risk analyses to determine contributory factors in potential failures

Content guidance:

1. Discuss the nature of contributory factors

- Describe and discuss contributory factors in failures or incidents/near-misses
- Use case studies to examine the effect of a range of contributory factors in:
 - Healthcare incidents
 - Other safety critical industries

2. Explore options for risk reduction in the workplace

- Taking outputs from FMEA or HFMEA, guide participants in proactively assessing causal and contributory factors
- Identify and evaluate options for managing key risks identified

Key literature

- Institute for Healthcare Improvement [Failure Modes and Effects Analysis \(FMEA\) Toolkit](#)
- VHA National Center for Patient Safety [Healthcare FMEA guidance](#)
- Human Reliability Associates [Consensus-based approach to risk](#)
- Safer Healthcare Strategies for the Real World, p29, Charles Vincent, Rene Amalberti, Springer 2016
- Franklin, B., Shebl, N., Barber, N. (2012) [Failure mode and effects analysis: too little for too much?](#) BMJ Quality & Safety;21:607-611.

Module 4.6 Mapping techniques to identify risks to patients

This module develops the ability of participants to identify risk proactively through systems mapping and supports the design or redesign of systems for safety

This module will provide:

Knowledge:

- Mapping tools and techniques, their applications, advantages, and disadvantages
- The difference between work-as-done and work-as-imagined
- Goal-oriented safety design of systems

Skills:

- Ability to define system boundaries and create a high-level process map
- Identify and evaluate risks at all levels
- Design out error traps and manage performance influencing factors

Behaviours:

- Demonstrates the ability to work with multi-professional consensus groups
- Demonstrates ability to be open in evaluating goals and system design
- Demonstrates close attention to work-as-done in evaluating risk

Learning outcome 1: Understands and applies techniques to identify system risks to patients through process mapping and Hierarchical Task Analysis (HTA)

Content guidance:

1. Describe how to use process mapping to establish a high-level description of the system addressed

- Demonstrate how to define system boundaries for different systems, such as a patient pathway, a physical department, specialism, or other basis for analysis
- Describe and practise using a systematic approach to gather information for example:
 - Walk the system/process to form an initial understanding through direct observation
 - Involve stakeholders; unlock the tacit knowledge of people involved, including patients where appropriate. No one person understands all aspects of a system, the full effects of changes or is able to identify hazards and risks to patients or staff
 - Construct a high-level process map of 6-12 steps
 - Consider using value stream mapping to identify unnecessary steps that serve no purpose (but maintain redundancies used to protect patients)
 - Share and establish accuracy with other stakeholders and update accordingly
 - Work together to add detail to the process map at the points where risks and hazards have been identified (appreciating what is up and downstream from these points)

- Evaluate where risks to patients, staff and others are present in the process map (refer to module 4.5 *Risk evaluation in clinical practice*)
- Provide worked examples relevant to healthcare

2. Describe how to use Hierarchical Task Analysis where significant risk has been identified, to include how to:

- Deconstruct systems, where there is significant risk, into critical subsystems
- Develop the activity to the level of detail that is required for the analysis of safety, with special attention to the actual task details
- Use a consensus approach as described above
- Use a systematic approach to include:
 - Identify sub-tasks necessary to achieve the goal
 - Risk-rank each task and sub-task, for example use Failure Mode Effect Analysis (FMEA) to rank risks each task and subtask, generate priorities (for later consideration of mitigations when looking to managing the risks)
 - Analyse contextual and task factors that influence why things go wrong using, for example, SEIPS model (refer to module 3.2 *The systems approach to patient safety*)
 - Apply knowledge of human error modes (module 4.1 *Managing human performance variability in patient safety*) to build an understanding of how any human failures occur
- Use data on performance influencing factors (refer to module 3.6 *Human Factors and clinical practice*)

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Module 4.6 Mapping techniques to identify risks to patients

Learning outcome 1: Understands and applies techniques to identify system risks to patients through process mapping and Hierarchical Task Analysis (HTA)

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3. Describe methods used in other industries to identify and evaluate risks that may have application to patient safety, such as:

- SHERPA (Systematic Human Error Reduction and Prediction Approach)
- STAMP (System-Theoretic Accident Model and Processes)

Learning outcome 2: Uses outputs from process mapping and HTA to structure improvement programmes in safety and quality

Content guidance:

1. Detail examples of subtasks, the associated risks to patients and staff and identify the issues to be addressed, to include:

- Failures, duplications, misdirections, missed steps etc. identified through process mapping
- Any human failure modes identified
- Contextual and task factors
- Performance Influencing Factors that may impact the task

2. Use a consensus approach to address key risks including the use of:

- The hierarchy of control and in particular the use of strong interventions and avoidance of weak interventions. Review module 4.3 *Systems-based interventions in patient safety incidents*
- A range of interventions including redesign of process (such as 'future state mapping')
- Human performance management, for example addressing error modes and their causes and managing performance influencing factors. Review module 4.1 *Managing human performance variability in patient safety*
- Review module 4.7 *Designing for systems safety*

3. Guide participants in developing consensus for solutions

- Recognise the reality of work-as-done
- Adopt a proactive, open approach to system-induced human error
- Use insights gained through process mapping and HTA to engage the support of senior staff to secure resources and support interventions required
- Create useful metrics where they are appropriate (in cases where process reliability is a key factor) and communicate through visual display
- Provide worked examples

Learning outcome 3: Applies goal-directed task analysis to establish patient safety in system design (refer to module 4.2 *Task analysis and support*)

Content guidance:

1. Demonstrate how to establish the receptivity to system re-design

- Ensure that clinicians and managers with responsibility and authority to conduct system evaluation and design are engaged with the issues and supportive of change
- Agree the boundaries of the processes under consideration and any limitations on desired outcomes and measures
- Demonstrate case studies that show that Goal-Directed Task Analysis (GDTA) is not a descriptive system analysis but a safety design tool

2. Demonstrate how to use a goal oriented HTA to build a safe system design

- Use an appropriate goal-oriented task analysis process to design safe systems
- Identify the users' major goals and sub-goals
- Ensure that safety goals are described and agreed
- Use GDTA to develop a design of system or process with safety goals adequately included
- Validate and apply the system-design which senior teams support

Module 4.6 Mapping techniques to identify risks to patients

Key literature

- Colligan, L., Anderson, J.E., Potts, H.W. et al. (2010) [Does the process map influence the outcome of quality improvement work? A comparison of a sequential flow diagram and a hierarchical task analysis diagram](https://doi.org/10.1186/1472-6963-10-7). BMC Health Serv Res 10, 7. <https://doi.org/10.1186/1472-6963-10-7>
- The use of HTA, SHERPA and STAMP:
 - Lane R, Stanton NA, Harrison D. (2005) [Applying hierarchical task analysis to medication administration errors](https://doi.org/10.1016/j.apergo.2005.08.001). Appl Ergon. 2006 Sep;37(5):669-79. doi: 10.1016/j.apergo.2005.08.001. Epub Sep 22. PMID: 16182230.
 - Embrey, David. (2009). [SHERPA: A systematic human error reduction and prediction approach](#). Contemporary Ergonomics 1984-2008: Selected Papers and an Overview of the Ergonomics Society Annual Conference. 113-119.
 - Building Safer Healthcare Systems, (2019) Spurgeon, P., Sujan, M., Cross, S., Flanagan, H. Springer
- Weale, A. (2013). [The safer clinical systems project in renal care](https://doi.org/10.1111/j.1755-6686.2013.12031.x). J Ren Care. 2013 Sep;39 Suppl 2:19-22. doi: 10.1111/j.1755-6686.2013.12031.x. PMID: 23941700.
- Iflaifel MH, Lim R, Crowley C, et al (2021) [Detailed analysis of 'work as imagined' in the use of intravenous insulin infusions in a hospital: a hierarchical task analysis](https://doi.org/10.1136/bmjopen-2020-041848) BMJ Open;11:e041848. doi: 10.1136/bmjopen-2020-041848
- Antonacci, G., Lennox, L., Barlow, J. et al. (2021) [Process mapping in healthcare: a systematic review](https://doi.org/10.1186/s12913-021-06254-1). BMC Health Serv Res 21, 342. <https://doi.org/10.1186/s12913-021-06254-1>
- [A resource for Performance Influencing Factors and predictive error analysis](https://www.humanreliability.com/software/): Human Reliability Associates Ltd, <https://www.humanreliability.com/software/> <https://youtu.be/1PEbhLbn6nE>
- A discussion of human error in medicine, error classification and PHEA: Patient Safety, 2nd edition, Charles Vincent, pages 126-139. Wiley-Blackwell 2011.
- Habraken, M., Van der Schaaf, T., Leistikow I., Reijnders-Thijssen P. (2009) [Prospective risk analysis of health care processes: a systematic evaluation of the use of HFMEA in Dutch health care](https://doi.org/10.1080/00140130802578563). Ergonomics. Jul;52(7):809-19. doi: 10.1080/00140130802578563. PMID: 19562591.
- [Goal-Directed Task Analysis \(GDTA\)](#)
- Abd Hamid, Harris & Waterson, Patrick. (2010). [Using Goal Directed Task Analysis to Identify Situation Awareness Requirements of Advanced Paramedics](https://doi.org/10.1201/EBK1439834978-c74). 10.1201/EBK1439834978-c74.

Module 4.7 Designing for systems safety

This module sets out methods to measure and manage system risks to support participants in system designs or redesign to improve patient safety

This module will provide:

Knowledge:

- Proportionality and pragmatism and its relationship to risk analysis
- What makes a 'good intervention' and how to maintain interventions over time

Skills:

- The use of risk analysis to identify robust interventions to control identified risks
- How to communicate the value of interventions to key stakeholders
- Understand the limitations and possible biases involved in risk analyses

Behaviours:

- Demonstrates the benefit of risk analysis and the value of identifying appropriate interventions within patient safety
- Uses risk analysis to prioritise hazards requiring control and implement interventions that are appropriate and proportional to manage risk

Learning outcome 1: Uses risk analysis to ensure that proportionate and pragmatic interventions are identified and implemented

Content guidance:

1. Review risk analysis (see related modules 4.2 *Task analysis and support* and 4.5 *Risk evaluation in clinical practice*)

- Demonstrate the use of task analysis to identify risk, such as:
 - Task analysis combined with the output from a Healthcare Failure Mode and Effect Analysis (HFMEA) to identify error traps (and where they occur in the task)
 - Recognise potential biases in evaluating risks and their mitigation through using a consensus, multidisciplinary approach

2. Explain the principles of proportionality and pragmatism and their use in appropriate and proportional risk management

- Define proportionality and pragmatism. Draw from definitions used by other high hazard industries, for example the nuclear industry
- Explain the purpose of these principles to ensure that the most appropriate, safety critical areas, identified risks and error traps are given the scrutiny required
- Explain how these principles can be used in patient safety. Include discussion on the challenges to adoption given the acceptability of risk in healthcare
- Demonstrate methods used to promote a proportionate and pragmatic approach to safety, such as:

- Safety Critical Task Analysis, understood as a combination of analysis techniques used to identify the areas in the task that should be subject to the most scrutiny (provide relevant examples)
- Human factors considerations that can be used to contribute to risk assessment and manage the potential for human error, for example task frequency, context, environment, complexity and interrelatedness

Learning outcome 2: Explains the concept and benefits of identifying interventions based on hierarchy of control

Content guidance:

1. Explain the concept of hierarchy of control

- Provide a definition of hierarchy of control and how it relates to reducing risk
- Provide a worked example discussing what interventions could be introduced at each point in the hierarchy

2. Explore the challenges associated with designing and implementing interventions based on the hierarchy of control

- Examine the limitations on interventions, including those related to resource
- Compare and contrast interventions at different levels of the hierarchy of control (for example additional training and the use of personal protective equipment)

Module 4.7 Designing for systems safety

Learning outcome 3: Identify suitable and effective interventions to achieve a desired outcome

Content guidance:

1. Explain the characteristics of suitable and effective interventions, to include:

- The degree to which the intervention controls the identified risk
- Where the intervention sits within the hierarchy of control
- The feasibility of intervention implementation
- The sustainability of an intervention
- The compound effect of interventions i.e. interventions that control multiple risks and their wider systems effects

2. Demonstrate the practical issues around achieving risk control

- Provide examples of where it may not be possible to eliminate or control an identified risk
- Discuss the importance of understanding the control of likelihood or severity when identifying interventions
- Review module 3.6 *Human factors and clinical practice* to review a human factors and ergonomics approach to designing interventions
- Demonstrate examples of usability guidelines and design principles
- Demonstrate how to collect data about users, task, equipment, environment, and context
- Use healthcare examples that demonstrate good design principles

Learning outcome 4: Defines the value of interventions and demonstrates how to represent the benefits to key stakeholders

Content guidance:

1. Explain how to describe the measurable benefits, impact, cost benefits to stakeholders and the organisation more broadly

- Discuss methods to communicate outputs
- Demonstrate ways to measure relative impact of interventions
- Demonstrate cost benefit analyses

Key literature

- Abd Hamid H, Waterson P. Using Goal Directed Task Analysis to Identify Situation Awareness Requirements of Advanced Paramedics. In *Advances in Human Factors and Ergonomics in Healthcare 2011*, edited V. Duffy. p. 672–80.
- Blair, E. *Safety Interventions: Strategies for Effective Design*. 2014. Professional Safety
- Dekker S. The Field Guide to Understanding 'Human Error'. Boca Raton: CRC Press; 2017 Chapter 8.
- Endsley MR. *Designing for Situation Awareness: an Approach to User-Centered Design*, Second Edition. 2016.
- Energy Institute. *Guidance on Human Factors Safety Critical Task Analysis*. 2020.
- Health and Safety Executive *Human Factors: Procedures*.
- Health and Safety Executive *INSPECTORS TOOLKIT - Human factors in the management of major accident hazards*. 2005;115.

- Health and Safety Executive *Management of risk when planning work*: The right priorities.
- Health and Safety Executive *Reducing risks, protecting people*, HSE's decision-making process. 2001. Available from:
- Health and Safety Executive *Safety signs and signals*. 1996
- Lidwell W, Holden K, Butler J. *Universal principles of design: 125 ways to enhance usability, influence perception, increase appeal, make better design decisions, and teach through design; [25 additional design principles]*. rev. and updated. Beverly, Mass: Rockport Publ; 2010. 272 p.
- Maguire R. *Safety cases and safety reports: meaning, motivation and management*. Aldershot, England; Burlington, VT: Ashgate; 2006. 176 p.
- NHS Resolution. *Risk Management Policy and Procedure*. November 2020.
- Norman DA. *The design of everyday things*. 1st Basic paperback. New York: Basic Books; 2002. 257 p.
- NS-TAST-GD-006 – *Design Basis Analysis*. Revision 5, October 2020.
- Stolovitch HD, Keeps EJ. *Beyond training ain't performance fieldbook: strategies, tools, and guidance for effective workplace performance*. Alexandria, VA: ASTD Press; 2006. 246 p.
- Liberati, Elisa & Peerally, Mohammad Farhad & Dixon-Woods, Mary. (2017). *Learning from high risk industries may not be straightforward: A qualitative study of the hierarchy of risk controls approach in healthcare*. *International journal for quality in health care: journal of the International Society for Quality in Health Care*. 30. 10.1093/intqhc/mzx163.

Module 4.8 Process reliability and safety assurance

This module introduces the concept of process reliability. It supports the safety professional in identifying and measuring the reliability of safety critical processes, using these measures for assurance, and describes how quality improvement methodologies can be applied to improve reliability where needed

This module will provide:

Knowledge:

- The type of safety critical processes where increased reliability can support improvement
- Health outcome and process reliability measures
- Range of patient safety measures and safety assurance measures
- How quality improvement methodologies can be applied to support improvement in process reliability

Skills:

- Ability to identify safety-critical processes in safety management
- Ability to measure, assess and monitor the reliability of safety critical processes
- Ability to apply key measures to provide assurance in patient safety
- Ability to support improvement in process reliability by applying quality improvement approaches

Behaviours:

- Demonstrates the ability to identify and assess reliability of safety critical processes and how quality improvement methods can be applied to support improvement

Learning outcome 1: Explains the use of process reliability in managing safety

Content guidance:

1. Identify safety-critical processes

- Explain the identification of safety-critical systems in the workplace (key related modules are module 4.5 *Risk evaluation in clinical practice* and module 4.6 *Mapping techniques to identify risks to patients* and module 4.2 *Task analysis and support*)
- Support participants in deconstructing and evaluating safety-critical processes such as handover, prescription, medication preparation, falls management
- Support participants in developing key measures of process reliability for the management of targeted systems
- Provide examples of targeted clinical microsystems or processes (such as management of the deteriorating patient, pressure ulcer management, falls management etc) and the set of key processes required to ensure outcomes (the 'safety set')

2. Describe the relationship between the reliability of key clinical processes, risk and harmful outcomes for patients

- Explain how risks to patient safety are managed by risk assessment, the required interventions and through monitoring
- Explain how outcome measures alone are insufficient in preventing patient harm
- Explain how knowledge of the reliability of processes:
 - Identifies areas of vulnerability
 - Provides safety assurance

Learning outcome 2: Describes principles and techniques for measurement in patient safety

Content guidance:

1. Explain the categories and importance and limitations of measurement in safety management, including:

- Measures of health outcomes
- Qualitative measures and assessments of systems and procedures
- Measures of process reliability

2. Describe a framework for the measurement and monitoring of patient safety

- Describe and discuss The Measurement and Monitoring of Patient Safety (Health Foundation 2013)
- Explain the principles and application of each element of the framework:
 - Harm to patients
 - Reliability
 - Sensitivity to operations
 - Anticipation and preparedness
 - Integration and learning
- Support participants in a critical analysis of their local organisation's approach to measurement of patient safety

Module 4.8 Process reliability and safety assurance

Learning outcome 3: Understands quality improvement in healthcare

Content guidance:

- 1. Explain key methodologies of quality improvement used in healthcare, including:**
 - The Model for Improvement (Institute for Healthcare Improvement) and the application of Plan Do Study Act (PDSA) cycles
 - Statistical Process Control
 - Related methodologies, including:
 - Clinical audit
 - Research
 - Service evaluation
 - Key tools and techniques used in quality improvement
- 2. Describe the evidence base for improving quality and safety in healthcare, to include:**
 - Evidence of improving discrete health outcomes for patients
 - Evidence for the reduction of harmful events
 - Advantages and limitations of quality improvement tools and techniques in healthcare

Key literature

Quality improvement methodology and critique:

- Institute for Healthcare Improvement [How to improve](#)
- Meyer GS, Nelson EC, Pryor DB, et al (2012) [More quality measures versus measuring what matters: a call for balance and parsimony](#) BMJ Quality & Safety;21:964-968.
- Backhouse A, Ogunlayi F. (2020) [Quality improvement into practice](#) BMJ 368 :m865 doi:10.1136/bmj.m865
- NHS improvement [An Overview of Statistical Process Control \(SPC\)](#) 2011

Reliability, Measurement and Monitoring of Safety:

- The Health Foundation [The measurement and monitoring of safety](#) 2013

HFE in Healthcare:

- Hignett S, Jones EL, Miller D, et al. (2015). [Human factors and ergonomics and quality improvement science: integrating approaches for safety in healthcare](#) BMJ Qual Saf;24:250–254

Module 4.9 Evaluating safety culture

This module provides a comprehensive approach to the evaluation of the safety culture of teams and of an organisation. By initiating open discussions and through the use of formal evaluation instruments, the participant can assess safety culture and begin to develop initiatives for improvement

This module will provide:

Knowledge:

- The components of safety culture
- The use of discussion and evaluation tools
- The use of different approaches to evaluation
- Sampling, data analysis and dissemination of safety information

Skills:

- Leads on safety culture discussion and evaluation
- Applies formal instruments to evaluate safety culture
- Supports staff involved in patient safety incidents

Behaviours:

- Promotes assessment of safety culture and behaviours in the organisation
- Promotes the importance of safety culture and the link to outcomes for patients and staff

Learning outcome 1: Describes the qualities of safety culture

Content guidance:

1. Explain and define safety culture, including:

- Definitions used by the Health and Safety Executive
- Descriptions used in healthcare
- The relationship of safety culture to wider organisational factors, resources, and regulatory climate
- Organisational versus team culture

2. Describe the components of a safety culture:

- Reporting culture:
 - Model of error held by the organisation
 - Usability and utility of reporting systems
 - Consequences of reporting error
 - Ability of the organisation to share learning
- Just culture:
 - Not a total absence of blame
 - An atmosphere of trust and commitment to safety
 - Clarity about acceptable and unacceptable behaviours
- Flexible culture:
 - Respect for the skills and abilities of 'front line' staff
 - Culture allows control to pass to task experts on the spot
- Learning culture:
 - Understanding how the local culture supports or inhibits learning

- Willingness and competence to learn appropriate lessons and draw conclusions from safety information
- The will and competence to create sustained improvements even when challenging
- Informed culture:
 - The organisational collection and analysis of relevant data
 - The organisation actively disseminates safety information

Learning outcome 2: Evaluates safety culture

Content guidance:

1. Describe approaches to stimulate discussion and raise awareness of safety culture

- Explain the difference between tools to stimulate discussion and create a shared vocabulary, and tools to provide quantitative assessment of the dimensions of safety culture, including
 - The Manchester Patient Safety Framework (MaPSaF) or NHS Education for Scotland Safety Culture Discussion Cards
 - Patient stories as a focus for discussion of safety
 - Use of interviews with clinical and administrative staff
 - The use of local case studies of organisational risk and incident investigations
 - The assessment of observable behaviours around civility, inclusivity, leadership, approachability

(continued on next page)

Module 4.9 Evaluating safety culture

Learning outcome 2: Evaluates safety culture

(continued from previous page)

2. Describe how to conduct a review of how lessons in patient safety are shared

- Describe sources for patient safety learning, including:
 - Incident reports
 - Clinical audits
 - Incident investigation reports
 - Cultural surveys
 - National Staff Survey
 - Model Hospital
 - Service and quality improvement initiatives
 - Complaints and response to complaints
 - Trigger tools and mortality reviews
 - Patient stories
- Describe and evaluate systems to share lessons across the organisation and beyond

3. Review the range of formal instruments used to evaluate safety culture

- Describe the form and use of instruments in the public domain and those provided commercially
- Highlight the varying dimensions incorporated in safety culture tools
- Discuss the utility and practicality of safety culture tools including the National Staff Survey
- Explain the importance of sampling, data analysis and comparisons within and between organisations
- Understand the importance of the process of measuring safety culture to support reflective conversations

Learning outcome 3: Describes the requirement and approach to supporting staff and how this affects safety culture

Content guidance:

1. Review the effect of patient safety incidents on staff involved, including:

- Physical, psychological, social, and professional harm
- Situations and incident types of especial vulnerability for staff
- Long-term consequences for staff involved in incidents
- Role of positive reporting and debriefing, for example Learning from Excellence

2. Review NHS policies and key documentation

- Describe policy recommendations for staff support in An Organisation with a Memory, and A Promise to Learn, a Commitment to Act
- Describe the effect of blame culture on learning and patient safety
- Support participants in evaluating the effect on local culture where staff have been involved in patient safety incidents

3. Demonstrate proactive approaches to providing psychological safety and wellbeing and how the NHS People Plan supports this

Key literature

Safety culture qualities and dimensions

- Health and Safety Executive [Organisational culture](#): Why is organisational culture important?
- Hollnagel E. and Woods D. (2005) *Joint Cognitive Systems: Foundations of Cognitive Systems Engineering*. Boca Raton, Taylor & Francis
- *Managing the risks of organisational accidents*, Reason 1997, Ashgate, Chapter 9
- *Building Safer Healthcare Systems*, Spurgeon et al, Springer 2019, Chapter 4 and Chapter 6
- [NHS Scotland Incident Reporting Culture](#), Extended Study - national summary report, 2007
- NHS England [Maternity and Neonatal Safety Improvement Programme](#)
- NHS England [We are the NHS: People Plan 2020/21 – action for us all 2020](#)

Safety culture evaluation

- [Measuring Safety Culture, evidence scan](#), The Health Foundation, 2011
- *Building Safer Healthcare Systems*, Spurgeon et al, Springer 2019, Chapter 7
- NHS National Patient Safety Agency [Manchester Patient Safety Framework](#)
- Healthcare Improvement Scotland [Safety culture](#)

Supporting staff involved in patient safety incidents

- Healthcare Safety Investigation Branch (2021) [Support for staff following patient safety incidents](#)
- *The Second Victim*, Dekker, CRC Press, 2013

Level 4 - A4 print-friendly versions of modules

Click the below graphics to download a print-friendly version of each module.

Module 4.1 Managing human performance variability in patient safety

On completion of the module, participants will have knowledge of human performance variability and human error and will evaluate and manage these as part of a systems approach to patient safety

This module will provide:

- Knowledge of human performance variability and cognitive performance
- Impact of physical and learning factors on patient safety and resilience
- System-induced human error and theories of human error

Skills:

- Identify and manage human performance variability and performance enhancing factors when they impact patient safety
- Develop evidence-based safety interventions to address human performance variability and human error

Behaviours:

- Demonstrate an understanding of performance variability factors when addressing human performance
- Develop safety analyses of human error from human factors
- Encourage an open, fair, and transparent approach that creates resilience in patient safety activity
- Use the term 'human error' with caution but does not ignore the contribution of human to patient safety risk and the need to manage this

Learning outcome 1: Applies an understanding of when human performance variability is a consequence of systems rather than an explanation of safety failures

Content guidance:

- Describe human performance variability**
 - Describe physical, cognitive, and social aspects of human performance
 - Differentiate between variability in module 3.6 Human Factors and clinical practice
 - Explain human performance variability as a consequence of systems conditions in relation to patient safety
 - Describe the concept of safety and resilience
- Provide examples of system-induced human performance variability**
 - Explain the value of understanding both performance variability
 - Explain the value of understanding both performance variability

Learning outcome 2: Applies a knowledge of performance enhancing factors and understands their effect on human performance variability

Content guidance:

- Identify and describe performance influencing factors (PIFs), to include:**
 - Physical (fatigue, sleep, nutrition, hunger, thirst, stress, age, cognitive load)
 - Psychological (stress, anxiety, fear, human factors, situational awareness, threat of danger, workload and workload)
 - Organisational factors, such as teaming, safety culture, work pressure, redundancy and change, communication, workflow, resources, and equipment
 - Workload (workload for example, shift, night, weekend, weekend)
 - Task requirements, level of complexity, repetitive tasks, time pressure, user interface or visual or auditory, time available
 - Team factors (experience, user interface)
 - Organisational factors, such as teaming, safety culture, work pressure, redundancy and change, communication, workflow, resources, and equipment
 - Workload (workload for example, shift, night, weekend, weekend)
- Explain how this impact human performance variability to include the impact of physical, cognitive, and social behaviour**
 - Explain human performance variability as a consequence of systems conditions in relation to patient safety
 - Describe the concept of safety and resilience
- Demonstrate how to manage PIFs and their impact on human performance variability**
 - Describe human performance variability as a consequence of systems conditions, such as task, workload, and workload
 - Explain the value of understanding both performance variability
 - Explain the value of understanding both performance variability

4.1 Managing human performance variability in patient safety
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Module 4.2 Task analysis and support

On completion of the module, participants will be able to use task analysis to analyse job tasks and use the outputs to improve patient safety

This module will provide:

- Knowledge of when, methods, and application of task analysis
- Skills to use task analysis to assess tasks in the workplace
- Use task analysis to systematically describe and analyse tasks
- Develop recommendations for redesigning workflow systems
- Assess an organisation's current performance and resilience
- Focus on interventions at a system level

Behaviours:

- Assess an organisation's current performance and resilience
- Focus on interventions at a system level

Learning outcome 1: Identifies potential task analysis methods systematically

Content guidance:

- Review how to identify potential for task analysis**
 - Identify tasks to analyse (further developed in module 4.3)
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Develop a plan to conduct analysis including managing work interruptions
- Introduce task analysis and discuss how it is used**
 - Describe how task analysis is used to identify and improve the reliability of systems
 - Describe how the can be used, for example to identify a consequence of system failure
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Develop a plan to conduct analysis including managing work interruptions
- Describe task analysis methods and their application**
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Describe how to use task analysis to identify and further develop in module 4.3

4.2 Task analysis and support
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Module 4.3 Systems-based interventions in patient safety incidents

This module introduces practical tools and techniques to investigate safety in vulnerable systems. It supports responses to patient safety incidents where immediate measures are needed to prevent further harm

This module will provide:

- Range and examples of system-induced failures
- Range of potential safety interventions
- Relate effectiveness of safety interventions, strong and weak interventions and the feasibility of control
- Ability to identify appropriate safety interventions in the workplace
- Ability to design, apply, monitor, measure and share safety interventions

Behaviours:

- Recognises the need to evaluate work as done
- Demonstrates the ability to engage frontline staff in patient safety design
- Demonstrates flexibility and strong communication skills in designing for safety throughout the process

Learning outcome 1: Describes system-induced failures

Content guidance:

- Describe the nature of system-induced failures**
 - Describe the concept of system-induced failures
 - Describe how safety errors form to patients
 - Describe how safety errors form to patients
- Describe task analysis methods and their application**
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Describe how to use task analysis to identify and further develop in module 4.3

4.3 Systems-based interventions in patient safety incidents
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Module 4.4 Safety II and resilience

On completion of the module, participants will understand the principles and practice of Safety II and II and be able to apply proactive and reactive approaches to improve patient safety and system resilience

This module will provide:

- Principles and practice of Safety II and II
- Common core mechanisms that promote resilience in organisations, teams, groups, and individual level
- How resilience and Safety II link to support safety

Skills:

- Use both reactive and proactive approaches and data sources to understand risk and manage patient safety
- Plan how to work with organisations to identify, measure and implement modifications for managing safety using a systems approach

Behaviours:

- Recognises and works with human variability, gaps between work as imagined and work as done as a resource rather than a liability
- Creates and encourages ways to increase resilience through the organisation, adaptation, monitoring of system risk and working

Learning outcome 1: Recognises the key principles of Safety II theory and how they connect to Safety I

Content guidance:

- Compare and contrast definitions of safety and resilience**
 - Describe the concept of Safety I and II
 - Describe the concept of Safety I and II
 - Describe the concept of Safety I and II
- Describe key principles of Safety II to include:**
 - Safety II is managed by learning from failures
 - Safety II is managed by learning from failures
 - Safety II is managed by learning from failures
- Describe the key principles of Safety II to include:**
 - Safety II is managed by learning from failures
 - Safety II is managed by learning from failures
 - Safety II is managed by learning from failures

4.4 Safety II and resilience
[Download >](#)

Module 4.5 Risk evaluation in clinical practice

This module provides the essential tools to identify and evaluate risk in clinical systems and tasks, and to locate proximal and systemic causes of potential failures

This module will provide:

- Knowledge of when, methods, and application of task analysis
- Skills to use task analysis to assess tasks in the workplace
- Use task analysis to systematically describe and analyse tasks
- Develop recommendations for redesigning workflow systems
- Assess an organisation's current performance and resilience
- Focus on interventions at a system level

Behaviours:

- Assess an organisation's current performance and resilience
- Focus on interventions at a system level

Learning outcome 1: Understands key concepts of hazards and risk

Content guidance:

- Explain the nature of hazards**
 - Describe the concept of hazards as conditions that could lead to contribute to an unplanned or undesirable event
 - Describe the concept of hazards as potential sources of harm to patients
 - Describe and provide examples of hazards in healthcare, including those arising from equipment, environment, people, and organisational practice and culture
- Explain the nature of risk**
 - Describe the concept of risk as the product of outcome and likelihood of potential harm to patients
 - Describe the concept of risk as the product of outcome and likelihood of potential harm to patients
 - Describe the concept of risk as the product of outcome and likelihood of potential harm to patients

4.5 Risk evaluation in clinical practice
[Download >](#)

Module 4.6 Mapping techniques to identify risks to patients

This module develops the ability of participants to identify risk proactively through systems mapping and supports the design or redesign of systems for safety

This module will provide:

- Knowledge of when, methods, and application of task analysis
- Skills to use task analysis to assess tasks in the workplace
- Use task analysis to systematically describe and analyse tasks
- Develop recommendations for redesigning workflow systems
- Assess an organisation's current performance and resilience
- Focus on interventions at a system level

Behaviours:

- Assess an organisation's current performance and resilience
- Focus on interventions at a system level

Learning outcome 1: Understands and applies techniques to identify system risks to patients through process mapping and Hierarchical Task Analysis (HTA)

Content guidance:

- Describe how to use process mapping to establish a high-level description of the system addressed**
 - Describe how to use process mapping to establish a high-level description of the system addressed
 - Describe how to use process mapping to establish a high-level description of the system addressed
- Describe how to use Hierarchical Task Analysis (HTA) to identify risks to patients**
 - Describe how to use Hierarchical Task Analysis (HTA) to identify risks to patients
 - Describe how to use Hierarchical Task Analysis (HTA) to identify risks to patients

4.6 Mapping techniques to identify risks to patients
[Download >](#)

Module 4.7 Designing for systems safety

This module sets out methods to measure and manage system risks to support participants in system designs or redesign to improve patient safety

This module will provide:

- Knowledge of when, methods, and application of task analysis
- Skills to use task analysis to assess tasks in the workplace
- Use task analysis to systematically describe and analyse tasks
- Develop recommendations for redesigning workflow systems
- Assess an organisation's current performance and resilience
- Focus on interventions at a system level

Behaviours:

- Assess an organisation's current performance and resilience
- Focus on interventions at a system level

Learning outcome 1: Understands and applies techniques to identify system risks to patients through process mapping and Hierarchical Task Analysis (HTA)

Content guidance:

- Review risk analysis (see related modules 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 4.10, 4.11, 4.12, 4.13, 4.14, 4.15, 4.16, 4.17, 4.18, 4.19, 4.20, 4.21, 4.22, 4.23, 4.24, 4.25, 4.26, 4.27, 4.28, 4.29, 4.30, 4.31, 4.32, 4.33, 4.34, 4.35, 4.36, 4.37, 4.38, 4.39, 4.40, 4.41, 4.42, 4.43, 4.44, 4.45, 4.46, 4.47, 4.48, 4.49, 4.50, 4.51, 4.52, 4.53, 4.54, 4.55, 4.56, 4.57, 4.58, 4.59, 4.60, 4.61, 4.62, 4.63, 4.64, 4.65, 4.66, 4.67, 4.68, 4.69, 4.70, 4.71, 4.72, 4.73, 4.74, 4.75, 4.76, 4.77, 4.78, 4.79, 4.80, 4.81, 4.82, 4.83, 4.84, 4.85, 4.86, 4.87, 4.88, 4.89, 4.90, 4.91, 4.92, 4.93, 4.94, 4.95, 4.96, 4.97, 4.98, 4.99, 5.00)**
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Describe how to use task analysis to identify and further develop in module 4.3
- Explain the principles of proportionality and prioritisation and their use in appropriate and proportional risk management**
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Describe how to use task analysis to identify and further develop in module 4.3

4.7 Designing for systems safety
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Module 4.8 Process reliability and safety assurance

This module introduces the concept of process reliability. It supports the safety professional in identifying and managing safety risks, using these measures for assurance, and describes how quality improvement methodologies can be applied to improve reliability where needed

This module will provide:

- Knowledge of when, methods, and application of task analysis
- Skills to use task analysis to assess tasks in the workplace
- Use task analysis to systematically describe and analyse tasks
- Develop recommendations for redesigning workflow systems
- Assess an organisation's current performance and resilience
- Focus on interventions at a system level

Behaviours:

- Assess an organisation's current performance and resilience
- Focus on interventions at a system level

Learning outcome 1: Explains the use of process reliability in managing safety

Content guidance:

- Identify safety-critical processes**
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Describe how to use task analysis to identify and further develop in module 4.3
- Describe the relationship between the reliability of key clinical processes, risk and harmful outcomes for patients**
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Describe how to use task analysis to identify and further develop in module 4.3
 - Describe how to use task analysis to identify and further develop in module 4.3

4.8 Process reliability and safety assurance
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Module 4.9 Evaluating safety culture

This module provides a comprehensive approach to the evaluation of the safety culture of teams and of an organisation. By utilising open discussions and through the use of formal evaluation instruments, the participant can assess safety culture and begin to develop initiatives for improvement

This module will provide:

- Knowledge of when, methods, and application of task analysis
- Skills to use task analysis to assess tasks in the workplace
- Use task analysis to systematically describe and analyse tasks
- Develop recommendations for redesigning workflow systems
- Assess an organisation's current performance and resilience
- Focus on interventions at a system level

Behaviours:

- Assess an organisation's current performance and resilience
- Focus on interventions at a system level

Learning outcome 1: Describes the qualities of safety culture

Content guidance:

- Explain and define safety culture, including:**
 - Definition of safety culture
 - Definition of safety culture
 - Definition of safety culture
- Describe the components of a safety culture:**
 - Reporting culture
 - Ability of the organisation to share learning
 - Just culture
 - Not a total absence of blame
 - An atmosphere of trust and commitment to safety
 - Clearly defined acceptable and unacceptable behaviours

4.9 Evaluating safety culture
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Curriculum guidance for levels 3-5 **Level 5**

Introduction

Staff completing this level of training will have completed level 4 and will have the skills to lead on patient safety through assessment, evaluation, and improvement. They will be providing knowledge and technical support to clinical and other senior staff working on safety. They will be able to take a mature, holistic view of safety and risk management and communicate this throughout the organisation.

Expected audience for this level of training

Participants attending training at this level will be further developing skills to work at a senior level in their organisation as a professional patient safety expert.

The four modules which comprise level 5 are designed for patient safety experts who will be innovators and leaders in this area, and to recognise that this goes beyond the application of existing methodologies. These materials are therefore intended to support that innovation, to highlight possibilities, and to recognise barriers and limitations.

Learning outcomes

On completing level 5 training modules participants will have the ability to work at a senior level in their organisation as a professional patient safety expert to:

- **Provide expert advice and support** to clinicians and managers at all levels of the organisation
- **Evaluate and communicate the degree of safety** in both specific areas and in the culture of the organisation and be able to determine where and how to act to keep patients free from harm

- Use a systems approach to **develop a holistic view of safety**, identifying uncontrolled risks and developing improvement interventions through the use of a safety case
- Use key **risk management** and governance systems to manage risks professionally at all levels
- Ensure that **human factors and ergonomics are integrated** throughout the organisation and that the human contribution to patient safety, staff well-being and physical ergonomics are understood and applied to improve working practices
- **Foster a culture of patient safety** and promote the principles and practices required in the measurement and monitoring of patient safety

Note to providers:

Modules in level 5 are intended to support an expert programme in patient safety improvement. Participants in level 5 training will have completed levels 1-4 or have received credits derived from previous studies; they will therefore be expected to have a high degree of professional expertise at the beginning of level 5 education and be in a position to innovate and create a continuing programme to be sure of safety.

Key skills

Safety science	Skills
Systems thinking	Take a holistic, organisation-wide approach to patient safety Builds and uses safety cases to measure, improve and manage patient safety in key areas and pathways
Risk management	Use a professional approach to risk at all levels of the organisation, including key risk management strategies Escalates uncontrolled risk proactively through organisational systems
Human factors	Integrates human factors approaches throughout the organisation Identifies key safety-critical tasks and areas including handovers and takes a systems-based approach to creating safety in each area
Safety culture	Promotes the principles of measuring and monitoring safety Shares knowledge widely through key case studies and applies sharing and consensus-building techniques to create a true safety culture

Module 5.1 Integrating human factors

At the end of this module participants will understand and be able to assess the range of application of human factors and ergonomics in healthcare and the relative impact on patient safety. They will be able to use assessment techniques to identify priority areas and be able to develop a human factors and ergonomics integration plan

This module will provide:

Knowledge:

- The scope of different applications of human factors in healthcare and their relative impact on patient safety

Skills:

- Uses data and other techniques to identify gaps and opportunities to integrate human factors and ergonomics
- Identifies good and poor practice in human factors and ergonomics and patient safety
- Demonstrates ability to develop a human factors and ergonomics integration plan

Behaviours:

- Ensures an ongoing focus on human factors and ergonomics
- Plans, supports and encourages human factors and ergonomics integration into projects
- Encourages human factors and ergonomics integration into existing processes and systems of management

Learning outcome 1: Actively identifies and develops human factors approaches to safety

Content guidance:

1. Demonstrate the scope and potential for organisation-wide human factors application. Describe the relative impact on patient safety when used in:

- System, service, and product design, for example in procurement, design of equipment, IT systems, and medical devices, estates and environmental design
- The development of new procedures, services etc, including patient communications and patient experience improvements
- Building and workplace design and layout, patient flow, way finding, etc.
- Workforce strategy, staffing, job design and ways of working including operating procedures
- Managing human performance variability (developed in module 4.1 *Managing human performance variability in patient safety*)
- Learning, development, and simulation programmes
- Organisational learning to include incident reporting and feedback
- Patient (and staff) safety and incident investigation
- Safety-critical task design, task support and usable, effective procedures (developed in module 4.2 *Task analysis and support*)

- Safety-critical handovers and communications
 - The observation of behaviours at all levels including leadership in terms of well-developed non-technical skills (developed in module 3.7 *Non-technical skills in clinical practice*)
- #### 2. Explain how to assess the current level of human factors and ergonomics integration and identify shortfalls in a given organisation
- Describe sources of data and fact-finding activities that will inform the assessment across all potential application areas (set out above), including:
 - Review of proactive and reactive safety data, outputs from task analyses and activities to manage human performance to reduce errors
 - Review of plans, quality reports, incident investigation reports, analysis of serious incidents and unexpected deaths, and near misses etc.
 - Selected interviews, for example chairs of committees, Patient Safety Management Boards, patient representatives, Freedom to Speak Up champions, representative groups of clinical staff, etc.
 - Review of the effectiveness of existing strategies, programmes (non-technical skills training, just culture, speaking up), procedures (incident investigation), that incorporate human factors
 - The use of checklists (see references)
 - Describe how to benchmark with other healthcare organisations and other safety critical industries

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Module 5.1 Integrating human factors

Learning outcome 1: Actively identifies and develops human factors approaches to safety

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- Describe how to evaluate the use of non-technical skills used in leadership, the use of staff feedback surveys, and data around speaking up, etc.
- Review key concepts in safety culture (may refer to module 3.4 *Organisational culture and learning*, module 3.9 *Avoiding blame and creating a learning culture through a just culture approach*, module 4.9 *Evaluating safety culture*, and module 5.3 *Creating a culture of patient safety*)
- Assess if known patient safety priorities have adequate human factors and ergonomics input, for example medication safety, deteriorating patient, etc.

3. Demonstrate how to report concisely the gaps, opportunities and good practice human factors and ergonomics and patient safety

- Demonstrate how to prioritise application of human factors and ergonomics based on level of risk
- Review techniques to identify, evaluate and rank risks in systems or defined tasks (see module 4.5 *Risk evaluation in clinical practice*)

Learning outcome 2: Acts to integrate human factors and ergonomics as part of all projects

Content guidance:

1. Describe the benefits of a human factors and ergonomics integration plan, to include a systematic process, prioritisation, and early and timely involvement of human factors and ergonomics

- Describe the components of a plan to include defining objectives, scope, stakeholders, activities and methods, critical success factors, time and resource, and outputs
- Describe the activities essential to a human factors and ergonomics approach to include:
- A human centred process, that involves identifying users, task, equipment, use environment, and specifying the context of the task, specifying organisational requirements, and considering all of these characteristics and requirements when considering design
 - An iterative design process that tests and evaluates against the requirements set out above

2. Demonstrate examples of a human factors and ergonomics integration plan

- Describe practical examples of ways to use these plans to support, for example the development of a safety case, a short-term service re-development or a longer-term new department building design
- Demonstrate case studies where human factors and ergonomics has been integrated into new projects, or existing processes, for example procurement, infection prevention and control
- Demonstrate a case study using the design and implementation of safety- critical handovers and communications

Module 5.1 Integrating human factors

Learning outcome 3: Ensures that human factors and ergonomics are a continuous focus of attention throughout the organisation

Content guidance:

1. Review benefits, impact, and ways to communicate human factors and ergonomics integration to the Board and organisation more broadly – review module 3.6 *Human factors and clinical practice*

- Discuss methods to communicate human factors and ergonomics integration findings and plan
- Demonstrate ways to measure the relative impact of human factors and ergonomics integration
- Demonstrate cost-benefit analyses
- Discuss ways to develop commitment to human factors and ergonomics integration
- Identify likely stakeholders, to include chairs of committees, risk and governance, Patient Safety Management Boards, patient representatives, patient experience groups, Freedom to Speak Up champions, human resources, quality, representative groups of clinical staff, etc.

- Demonstrate how to work with and engage at Board Level
- Demonstrate examples of human factors and ergonomics strategies and programmes used in other industries
- Discuss levels of human factors and ergonomics competence required
- Discuss relationship with the safety case – review module 5.4 *The safety case*

2. Provide examples of human factors and ergonomics integration in other industries

- Draw from definitions used in the military, Health and Safety Executive and other safety critical industries
- Explain how organisation-wide human factors and ergonomics integration in healthcare is a developing field of practice

3. Demonstrate how to write a human factors and ergonomics integration plan

- Define human factors and ergonomics integration
- Explore different models of human factors and ergonomics integration

Key literature

- Clinical Human Factors Group [Getting to Grips with the Human Factor – Boards Resource](#).
- Woodcock, T. (2014) [Safer Clinical Systems: Evaluation findings](#). Learning from the independent evaluation of the second phase of the Safer Clinical Systems programme.
- Rodríguez Y, Hignett S. [Integration of human factors/ergonomics in healthcare systems: A giant leap in safety as a key strategy during Covid-19](#). Hum Factors Ergon Manuf. 2021 Sep;31(5):570-576. doi: 10.1002/hfm.20907. Epub 2021 May 12. PMID: 34220185; PMCID: PMC8239590.
- Ministry of Defence (2021) JSP 912 [Human Factors Integration for Defence Systems Part 1: Directive](#)
- Ministry of Defence (2021) JSP 912 [Human Factors Integration for Defence Systems Part 2: Guidance](#)
- Clinical Human Factors Group [Selecting safe and easier to use products for healthcare using Human Factors specification and checklists](#)

Module 5.2 Risk, escalation and governance in patient safety

At the end of this module participants will understand that the identification of and management of risk is central to patient safety. They will apply a systematic approach to risk management through an organisations' quality governance frameworks to assure patient safety

This module will provide:

Knowledge:

- The impact of quality governance frameworks on patient safety
- Quality governance in a healthcare organisation
- Risk appetite
- Risk management standards
- Risk management policies and practices in a healthcare organisation

Skills:

- Risk appetite, identification, management, and ownership
- Use of risk registers at local and corporate levels
- Risk escalation processes within and beyond organisation

Behaviours:

- Promotes a systems-based approach to risk management
- Recognises and acts to improve risk control of uncontrolled and incompletely controlled risks
- Recognises how risk management supports broader quality management
- Demonstrates a balanced approach to risk with regard to the organisational risk appetite and the effect of uncontrolled risks on patient safety

Learning outcome 1: Demonstrates an understanding of quality governance

Content guidance:

1. Explain the key principles of quality governance

- Define quality governance
- Explain how key elements of quality governance impact directly on patient safety
- Describe the purpose of quality governance, including the need for:
 - A systems-based approach versus a person-based approach to risk and safety
 - The incorporation of diverse sources for insight into safety, including clinical audit, research, incident reports, incident investigations, proactive risk evaluations and task/pathway analysis, morbidity and mortality reviews, coroner's Prevention of Future Death reports (PFDs) and patient and their advocates concerns (including PALS and Complaints)
 - Robust methods of assurance and what effective assurance looks like in relation to patient safety
- Explain assurance as the removal of doubt and the need for a problem-seeking approach as opposed to a comfort-seeking approach

2. Support the participants' review of quality governance structure in their organisation

- Illustrate the organisational structure of quality governance in their local organisation, including speciality or departmental quality governance, and how this fits into an organisation-wide governance structure
- Illustrate the difference between delivery and assurance strands of these governance frameworks and how they link to the role and function of senior leaders
- Evaluate how quality governance, through systems at each level of the organisation, supports patient safety or presents opportunities for supporting patient safety
- Identify the relationship between quality governance, risk management and safety and quality management
- Evaluate and strengthen the use of local and corporate risk registers by using quality governance processes

3. Provide case studies of well-developed quality governance in healthcare

Module 5.2 Risk, escalation and governance in patient safety

Learning outcome 2: Explains risk management in relation to patient safety

Content guidance:

1. Demonstrate risk management strategy and practice in a healthcare organisation

- Describe risk management standards applied in the NHS
- Identify and explain policies in risk management applied to a healthcare organisation
- Describe common terms / definitions used
- Describe risk appetite, its importance and how this relates to patient safety
- Distinguish between risk management at a strategic level of the organisation and risk management within specialities, departments, directorates, localities or patient pathways
- Describe approaches to:
 - Risk awareness
 - Risk identification and risk evaluation (review module 4.5 *Risk evaluation in clinical practice*)
 - Risk control measures
 - Sustainability and assurance of success of the application of additional controls / mitigation strategies

2. Describe key risk mitigation strategies

- Explain the application of common risk mitigation strategies, including:
 - Risk elimination
 - Risk avoidance
 - Risk transfer

Learning outcome 3: Explains risk and safety assurance, risk ownership and escalation

Content guidance:

1. Describe risk categories and potential sources of risk in their organisation

- Describe common sources of risk to patient safety including:
 - Real-time issues with process reliability (as in the management of the deteriorating patient, falls, pressure ulcers, compliance with treatments, compliance with investigation timelines and escalation etc.)
 - Equipment, built environment, work environment
 - Medical devices, medicines, and clinical procedures
 - Variation in individual performance, team performance and issues around non-technical skills and training
 - Team / professional / interprofessional, and organisational culture and professional hierarchies
 - Specialty, departmental and organisational policies or structures
 - Workforce issues, such as level of resource, skill mix, management and supervision, staff retention
 - Other external factors

2. Explain analysis of identified risks at an organisational level

- Demonstrate the application of estimated likelihood and impact of identified risks

- Demonstrate the use of a matrix of risk based on the above, and the assignment of red, amber, green colour coding 'RAG' ratings, such as a standard 5 x 5 matrix
- Explain how some risks are incompletely controlled in an organisation (developed further in Module 5.4 *The safety case*)
- Link the management of uncontrolled or incompletely controlled risks to escalation (below, section 3)
- Describe practice and policy in managing uncontrolled risks

3. Demonstrate the policy, risk ownership and escalation in a healthcare organisation

- Describe the use of risk registers to validate and assign ownership of risks
- Describe links to the organisational performance and accountability frameworks and organisational appetite to patient safety risk
- Describe the use of the risk register to address incompletely controlled or uncontrolled risks
- Demonstrate how they achieve the requirement for openness in risk identification and escalation through, for example consensus and multidisciplinary approach to risk or through risk validation groups
- Identify the escalation pathway for their organisation
- Describe the requirements for escalation of incompletely controlled or uncontrolled risks beyond the organisation to commissioners, integrated care structures, regulators and government departments

Module 5.2 Risk, escalation and governance in patient safety

Key literature

Quality governance

- [An Introduction to Clinical Governance and Patient Safety](#) (2010) Elizabeth Haxby, David Hunter, and Siân Jaggard (ed), Oxford Academic
- [Clinical Governance in Primary Care](#), Edited by Tim van Zwanenberg, Jamie Harrison, Sir Michael Rawlins
- NHS Providers and DAC Beachcroft (2015) [‘Foundations of Good Governance: A Compendium of Best Practice \(3rd edition\)’](#)
- NHS Leadership Academy (2013) [‘The Healthy NHS Board 2013: Principles for Good Governance’](#)
- Healthcare Quality Improvement Partnership (2015) [Good Governance Handbook](#)
- NHS England (2017) [Managing Conflicts of Interest in the NHS: Guidance for staff and organisations](#)
- NHS Improvement (2017) [Development reviews of leadership and governance using the well led framework: Guidance for NHS trusts](#)

Risk Management in healthcare

- NHS Resolution [Risk Management Policy and Procedure](#) (example)
- Bullivant, J. (2017) [A simple guide to risk for members of Boards](#), Good Governance Institute
- Audit Commission (2009) [Taking it on Trust: A review of how boards of NHS trusts and foundation trusts get their assurance](#)
- Good Governance Institute (2009) [A simple Rules Guide for the NHS Board Assurance Frameworks](#)
- Vincent, C., Amalberti, R. (2017) [Safer Healthcare - Strategies for the Real World](#); Springer Open

Module 5.3 Creating a culture of patient safety

At the end of this module participants will understand the requirement for a safety culture and understand the barriers and drivers to cultural change and be able to promote the development of safety culture in their own organisation

This module will provide:

Knowledge:

- The organisational requirement in safety culture
- The options for change
- Barriers and drivers to cultural change

Skills:

- Setting out of options and interventions for cultural development
- Option appraisal of interventions
- Development of a programme for change
- Creation of a framework in the organisation for measurement and monitoring of patient safety

Behaviours:

- Promotes cultural change in all work programmes and interventions
- Demonstrates openness, positive communication in all work programmes

Learning outcome 1: Reviews the culture of the organisation

Content guidance:

1. **Demonstrate approaches and support participants to document a review and description of organisational culture**
2. **Demonstrate ways to use the review for developing, appraising and introducing positive cultural changes in the organisation**
 - Apply outputs and finding of previous modules in this training as they relate to safety culture, to include:
 - Qualitative sources such as interviews and discussions
 - Quantitative sources from appropriate cultural tools
 - Observations and appraisals of organisational values, behaviours and beliefs
 - Policies in key areas, including reporting, investigation, complaints, staff and patient feedback
3. **Describe findings in organisational culture as they relate to any models of culture and cultural typologies (review Westrum's model of organisational maturity and the Manchester Patient Safety Framework (MaPSaF))**
4. **Relate knowledge and experience in safety culture to the development of organisations beyond their local trust, department or speciality where possible:**
 - Demonstrate a knowledge of the cultures of the organisational hierarchy they work within or alongside
 - Consider the impact of cultural initiatives on related organisations
 - Work to build inclusivity in cultural change across organisations

Learning outcome 2: Identifies options for appraisal and development

Content guidance:

1. **Describe a range of potential interventions for positive cultural change**
 - This will involve including developing and implementing:
 - Strategy to increase the leadership and management commitment to patient safety
 - Strategy to assess levels of skill, training, and resources for patient safety
 - Clear allocation of responsibility and accountability
 - Policies and performance to enhance organisational transparency and openness
 - Policies and performance in relation to whistleblowing, freedom to speak up, duty of candour, public and patient engagement in safety
 - Risk management and specific cultural interventions in direct patient care such as Proactive Risk Management in Healthcare (PRIMO), the use of "huddles", and the sharing of lessons learned
 - The application of non-technical skills for individual, team and organisational behaviour (review module 3.7 *Non-technical skills in clinical practice*)
 - The reliability of mandated protocols and behaviours in protecting patients (such as checklists and handovers)
 - Explain the difference between proactive safety management and reactive safety management as it relates to discussing risk and blame
 - Demonstrate examples of the above interventions and case studies of implementation

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Module 5.3 Creating a culture of patient safety

Learning outcome 2: Identifies options for appraisal and development

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2. Describe a systematic approach to the measurement and monitoring of patient safety in their organisation

- Explain how a coherent framework for safety governance supports improvement and assurance
- Explain the key dimensions as set out in The Measurement and Monitoring of Patient Safety (Health Foundation 2013) or other suitable frameworks. This will include:
 - Anticipation and preparedness
 - Reliability
 - Learning from past harm
 - Sensitivity to operations
 - Integration and learning
- Demonstrate how to apply this framework as an appraisal of current organisation behaviour in patient safety

3. Support participants in setting goals and carrying out option appraisal

- Demonstrate the development of goals or targets in safety culture, in relation to:
 - The content of the review of their organisations (above)
 - Qualitative and quantitative data
- Support the evaluation of options for change, to include the appraisal of:

- Cost and benefit
- Likely potential success and effectiveness
- Risks
- Barriers to and drivers of cultural change and cultural interventions

- Support participants in developing a Theory of Change for interventions
- Support participants in developing appropriate metrics for evaluation, which may include the following:
 - Metrics relating to patient outcomes
 - Metrics relating each of the dimension in measuring and monitoring of patient safety (above)
 - Metrics relating to dimensions of safety culture drawn from surveys and discussions
 - Metrics relating to proactive risk assessment in key areas, pathways and departments

4. Describe the continuing development of a safety culture

- Review key principles of safety culture and the link to organisational performance
- Explain the extent and limitations of knowledge in this area
- Explain the need for continuing development and innovation in this area
- Support participants in continuing innovation and development of safety culture

Key literature

Vincent, C; Burnett, S; and Carthey, J (2013). [The measurement and monitoring of safety](#), Drawing together academic evidence and practical experience to produce a framework for safety measurement and monitoring 2013 The Health Foundation

Huddles and PRIMO

- NHS England [Can huddles really help?](#) Shanthi Shanmugalingam
- Sign up to Safety: [To huddle or not to huddle; your essential guide](#)
- [Proactive Risk Monitoring in Healthcare](#) (PRIMO) is a tool for risk management that aimed to complement existing methods by plugging the gaps in risk management strategies and procedures. The Health Foundation
- [Primo stages explained](#)

Module 5.4 Part 1 The safety case

At the end of this module participants will have knowledge of the principles and key concepts of creating a safety case in healthcare and be able to use this as a tool to protect patient safety and fulfil governance requirements

This module will provide:

Knowledge:

- Understand the purpose of safety cases and how they should be used effectively within patient safety
- Understand how to prepare and produce a safety case

Skills:

- How to use safety cases to effectively promote continuous improvement within patient safety
- How to use safety cases as communication tools to promote the importance of safety and its value to patient safety

Behaviours:

- Becomes a spokesperson for the benefit of safety cases and their value to patient safety
- Actively seeks to employ safety cases within patient pathways wherever appropriate

Learning outcome 1: Explains the benefit of a safety case

Content guidance:

1. Define the term 'safety case'

- Draw from formal definitions used in other safety-critical industries (see references), for example 'A safety case is a logical and hierarchical set of documents that describes risk in terms of the hazards presented by the facility, site and the modes of operation, including potential faults and accidents, and those reasonably practicable measures that need to be implemented to prevent or minimise harm'

Note: The definition from the nuclear industry would need modification for use in the patient safety domain

2. Define the terms used in safety cases

- Define and provide examples of the terms risk, probability, severity, hazard, accident or incident, residual risk
- Demonstrate examples of clear and precise language used in a safety case

3. Explain the benefits of a safety case

- Discuss the cost benefits of producing a safety case
 - Demonstrate the cost of producing a safety case. For example x% of the total cost of a 'Project' was dedicated to the safety case

- Provide examples of the costs associated with accidents occurring in healthcare
- Provide examples of the use of safety cases including:
 - To support change management
 - To promote continuous improvement
 - To assess the impact of residual risk
 - To control the potential for accidents to as low as reasonably practicable (defined later in this module)
 - To promote safety
- Demonstrate a rationale and/or business case for developing safety cases

4. Explain the principle of safety targets

- Provide examples of targets used in other safety industries to demonstrate that a process, service, equipment or task is 'safe enough'
- Introduce the principles of 'so far as is reasonably practicable' (SFAIRP) and 'as low as reasonably practicable' (ALARP)
- Compare and contrast qualitative versus quantitative assessment of safety and how these link to safety targets

Module 5.4 Part 1 The safety case

Learning outcome 2: Explains how safety cases can be applied to patient safety

Content guidance:

1. Explain the differences between the NHS and other industries

- Explain the NHS is a more organic organisation than many other high hazard industries where safety cases are typically applied
- Explain the NHS as a complex sociotechnical system. Compare this with other safety-critical industries. Recognise that defining system boundaries within the NHS maybe challenging, but can be based on patient pathways, departments or specialities

2. Demonstrate how safety cases can be applied to patient safety

- Explain the objective for patient safety is likely to be in achieving continuous improvement
- Discuss the use of safety cases to compare, monitor and evaluate interventions. For example using safety assessment techniques can be utilised before and after the introduction of an intervention to assess its effectiveness
- Explain issues around using the safety case in the evaluation of the safety of a pathway, department, or speciality
- Provide a case study example to demonstrate how one might use safety cases to demonstrate good health and safety practice

Learning outcome 3: Explains how to prepare for safety case development, understands the pre-requisites required and how the assessment should be bounded

Content guidance:

1. Explain how to define the boundary for safety case analysis

- Explain the necessity of considering the complexity of the system under analysis (refer to module 3.2 *Systems approach to patient safety*). Consider the number of interactions, and if the system under consideration is self-contained or does it impact an entire functional area
- Explain how to consider the sources of risk within the system and how these risks could be realised as patient harm
- Explain the need to consider the environment, personnel and temporal factors when defining the boundary of the system
- Explain the use of system diagrams to capture the boundary of the system under analysis (link back to module 3.2 *Systems approach to patient safety*)
- Explain the need to regularly review the defined system and its boundary. Discuss the strengths and limitations of defining system boundaries

2. Explain how to define the aims and objectives of the safety case

- Demonstrate how to capture objectives, benefits, scope of the safety case as terms of reference but also to use for communication of the safety case
- Reinforce the aims of the safety case, the need to define the part of the system under scrutiny

Learning outcome 4: Applies a safety case within patient safety to identify hazards, risks, safeguards, mitigation, and recovery

Content guidance:

1. Explain how to identify hazards

- Discuss the methods and techniques available to identify hazards
- Review module 3.2 *Systems approach to patient safety* and module 4.5 *Risk evaluation in clinical practice*

2. Demonstrate how to integrate human factors into a safety case

- Reinforce the importance of considering human factors in safety cases
- Discuss the available human factors methods that can be used to identify hazards. Proposed methods to focus upon are Human HAZOP, SHERPA, PHEA and the more system focused technique of STAMP. Also, include discussion of other beneficial human factors techniques such as Task Analysis, User Journeys etc.
- Explain how human factors can be integrated with other hazard identification techniques
- Build on the previous case study example from the healthcare domain to include the consideration of human factors

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Module 5.4 Part 1 The safety case

Learning outcome 4: Explains how to apply a safety case within patient safety to identify hazards, risks, safeguards, mitigation, and recovery

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3. Demonstrate how to integrate the concept of risk within a safety case

- Review module 4.5 *Risk evaluation in clinical practice*
- Reinforce the importance of considering risk within a safety case, for example risk classification allows the hazards of greatest likelihood / severity to be given the most scrutiny etc.)
- Discuss how risk should be classified within patient safety (drawing primarily from module 4.5 *Risk evaluation in clinical practice*)
- Build on the previous case study example from the healthcare domain to include the consideration of risk

Key literature

- Office for Nuclear Regulation (2019) *The Purpose, Scope, and Content of Safety Cases*. Revision 7.
- Office for Nuclear Regulation (2020) *Periodic Safety Review (PSR)*. Revision 8
- Ministry of Defence (2007) *Safety Management Requirements for Defence Systems* Part 1 Issue 4
- Spurgeon P, Sujan M-A, Cross S, Flanagan H. (2019) *Building safer healthcare systems: a proactive, risk-based approach to improving patient safety*. Springer
- Maguire R. *Safety cases and safety reports: meaning, motivation and management*. Aldershot, England; Burlington, VT: Ashgate; 2006. 176 p.
- Sujan MA, Habli I, Kelly TP, Pozzi S, Johnson CW. (2016) *Should healthcare providers do safety cases? Lessons from a cross-industry review of safety case practices*. *Safety Science*. 84:181–9.
- Kirwan B. *A guide to practical human reliability assessment*. Bristol, PA: Taylor & Francis; 1994. 592 p
- Froome P. *Independent Safety Assessment of Safety Arguments*. In: Redmill F, Anderson T, editors. *Constituents of Modern System-safety Thinking* [Internet]. London: Springer London; 2005 [cited 2021 Dec 13]. p. 37–47

Module 5.4 Part 2 The safety case

This module, the second of two expert modules on safety cases, provides guidance on the practicalities of creating a safety case in healthcare and their use in proactive safety management

This module will provide:

Knowledge:

- How to use a safety case to identify safeguards, mitigation and recovery measures
- How to maintain a safety case
- How to present a safety case to best suit the audience

Skills:

- Uses a safety case to effectively promote continuous improvement within patient safety
- Uses the safety cases as communication tools to promote the importance of safety and its value to patient safety

Behaviours:

- Becomes a spokesperson for the benefit of safety cases and their value to patient safety
- Actively employs safety cases within patient pathways wherever appropriate

Learning outcome 1: Applies a safety case within patient safety to identify hazards, risks, safeguards, mitigation and recovery

Content guidance:

1. Explain how to identify safeguards, mitigations and recovery

- Define the terms safeguard, mitigation and recovery
- Explain how to identify safeguards, mitigations and recovery measures to control identified hazards
- Explain the importance of the hierarchy of control in identifying suitable safeguard, mitigation and recovery measures
- Explain how to identify the safeguard, mitigation and recovery measures using established methods. This will build on methods including HAZOP (Hazard and Operability), STAMP (System-Theoretic Accident Model and Processes) etc. In addition, it is important to include consideration of the human error identification methods of SHERPA (Systematic Human Error Reduction and Prediction Approach), PHEA (Predictive Human Error Analysis) etc.

Learning outcome 2: Evaluates the outcomes from the safety case development to identify appropriate interventions and their implications on residual risk

Content guidance:

1. Explain how to evaluate interventions, for example focussing on:

- The degree to which the intervention controls the identified hazard
- Whether there are any more appropriate / comprehensive interventions available (referring back to hierarchy of control)
- The importance of avoiding 'knee jerk' interventions. Such interventions tend to have a very narrow focus when in reality systemic factors are at play
- Whether the intervention is practical and possible to implement
- Ease of maintaining the intervention
- Whether anything foreseeable could defeat the intervention (for example forthcoming or likely system change)
- To what degree does it reduce the residual risk
- The interaction of interventions, for example are they supportive of, or in contradiction with one another

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Module 5.4 Part 2 The safety case

Learning outcome 2: Evaluates the outcomes from the safety case development to identify appropriate interventions and their implications on residual risk

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2. Explain how to assess residual risk that remains as a result of the identified intervention

- Demonstrate the rerun of a subset of the previously conducted safety analysis, for example FMEA or SHERPA etc. to evaluate residual risk(s)
- Demonstrate case studies to evaluate interventions

3. Explain how to implement interventions

- Explain the importance of including representative users and stakeholders in the development, design, and implementation of interventions with reference to module 3.6 *Human factors and clinical practice*
- Describe upstream and downstream impacts of interventions, how to assess these as well as considering supporting changes, for example, a procedural change may require updates to guidance documents
- Explain the importance of monitoring and review of interventions

Learning outcome 3: Explains how to maintain a safety case to ensure that it remains 'live'

Content guidance:

1. Explain the importance of updating, maintaining, and revalidating a safety case

- Explain the importance of maintaining a valid safety case that reflects current hazards, risks and mitigations. Explain potential issues of an invalid safety case and the impact on patient safety
- Discuss that a safety case remains valid for a period of time and becomes invalid, for example when there are changes in, for example:
 - Workforce
 - Policies, procedures, etc
 - Environmental changes
 - Change in use cases
 - The introduction of interventions (refer to Learning outcome 4)
 - New learning or experience captured
 - Emergent failure mode is uncovered

2. Explain how and when to use periodic reviews

- Discuss how the frequency of periodic review might be determined in healthcare and the factors that determine frequency. (Note, the provided reference for periodic reviews is taken from the nuclear industry where a period of 10 years is typically used. It is likely more appropriate to impose far more frequent reviews within patient safety)
- Discuss why and when other reviews should take place (taking into account the examples from point 1)
- Discuss the importance of independent review in ensuring the validity of a safety case

3. Explain the importance of safety culture and its role in improving the widespread adoption of safety case intent (refer to module 5.3 *Creating a culture of patient safety*)

- Explain how to engage with the Board, communicating the safety case and influencing policy

Module 5.4 Part 2 The safety case

Learning outcome 4: Explains how to present a safety case to promote stakeholder acceptance and adoption

Content guidance:

1. Explain the importance of safety case presentation

- Explain the importance of matching presentation style to the intended safety case audience
- Explain that a safety case can only be considered a success if it is implemented appropriately and completely

2. Discuss the different safety case presentation styles available

- Discuss the merits of various presentation styles, for example:
 - Goal structuring notation
 - Claims, arguments, evidence
 - Barrier analysis
- Discuss the most appropriate options for presenting safety cases within healthcare (refer to the references)

Key literature

- Office for Nuclear Regulation (2019) *The Purpose, Scope, and Content of Safety Cases*. Revision 7.
- Office for Nuclear Regulation (2020) *Periodic Safety Review (PSR)*. Revision 8
- Ministry of Defence (2007) *Safety Management Requirements for Defence Systems* Part 1 Issue 4
- Spurgeon P, Sujan M-A, Cross S, Flanagan H. (2019) *Building safer healthcare systems: a proactive, risk-based approach to improving patient safety*. Springer
- Maguire R. Safety cases and safety reports: meaning, motivation and management. Aldershot, England; Burlington, VT: Ashgate; 2006. 176 p
- Sujan MA, Habli I, Kelly TP, Pozzi S, Johnson CW. (2016) *Should healthcare providers do safety cases? Lessons from a cross-industry review of safety case practices*. *Safety Science*. 84:181–9.
- Kirwan B. A guide to practical human reliability assessment. Bristol, PA: Taylor & Francis; 1994. 592 p
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Level 5 - A4 print-friendly versions of modules

Click the below graphics to download a print-friendly version of each module.

Module 5.1 Integrating human factors

At the end of this module participants will understand and be able to assess the range of applications of human factors and ergonomics to healthcare and the relative impact on patient safety. They will be able to use assessment techniques to identify priority areas and be able to develop a human factors and ergonomics integration plan.

Learning outcome 1: Actively identifies and directs human factors approaches to safety

Content guidance:

- Demonstrate the scope and potential for organisation-wide human factors applications. Describe the relative impact on patient safety where it is:**
 - System, service, and product design, for example measurement, design of equipment, IT systems, and clinical devices, systems and environmental design
 - The development of new procedures, services etc, including patient communication and public response requirements
 - Building and workflow design and layout, patient flow, way finding, etc
 - Healthcare settings, staffing, job design and work of existing existing operating procedures
 - Managing human performance variability (developed in module 4.1 Managing human performance variability, a patient safety)
 - Learning, development, and simulation programmes
 - Organisational learning to include incident reporting and feedback
 - Patients (and staff) safety and incident investigation
 - Safety-critical task design, task support and workload (developed in module 4.2 Task analysis and support)
 - Safety-critical hardware and communications
 - The observation of behaviours of all levels including hardware in use of well-managed non-technical skills (developed in module 3.7 Non-technical skills in clinical practice)
- Explain how to assess the current level of human factors and ergonomics integration and identify shortfalls in a given organisation**
 - Describe the nature of task and task history actions that will inform the assessment of areas of potential application areas that need attention, including:
 - Review of policies and practice safety data, including human factors and ergonomics data
 - Review of policies, quality reports, incident investigation reports, analysis of human factors and ergonomics data, and near miss data

Behaviours:

- Encourage an ongoing focus on human factors and ergonomics
- Plans, supports and encourages human factors and ergonomics integration into existing processes and systems management
- Encourages human factors and ergonomics integration into existing processes and systems management

5.1 Integrating human factors Download

Module 5.2 Risk, escalation and governance in patient safety

At the end of this module participants will understand that the identification of and management of risk is central to patient safety. They will apply a systematic approach to risk management through an organisation's quality governance frameworks to assure patient safety.

Learning outcome 1: Demonstrates an understanding of quality governance

Content guidance:

- Explain the key principles of quality governance**
 - Define quality governance
 - Explain how key elements of quality governance, including the concept of quality governance, including the need for:
 - A risk-based approach versus a process based approach to risk and safety
 - The recognition of diverse sources, for example into safety, including clinical and non-clinical, including patient communication and public response requirements, and task/behaviour analysis, mobility and mobility issues, complex functions of Patient Safety reports (PSS) and patient and their education systems (including RCUJ and Complaints)
 - Risk to the system, including reporting, investigation, complaints, staff and patient feedback
 - Explain assurance as the removal of doubt and the need for a position-vesting approach as opposed to a confirm-vesting approach
- Support the participants' review of quality governance structure in their organisation**
 - Explain the organisational level of quality governance in their own organisation, including service or departmental quality governance, and how the fit into organisation-wide governance structures
 - Explain the difference between delivery and assurance elements of these governance frameworks and how they fit to the role and function of the patient
 - Explain how quality governance, through systems based level of the organisation, supports patient safety or presents opportunities for supporting patient safety
 - Identify the relationship between quality governance, risk management and safety and quality management
 - Evaluate and strengthen the use of local and corporate risk registers by using quality governance processes
- Provide case studies of well-developed quality governance in healthcare**

Behaviours:

- Promotes a systems based approach to risk management
- Recognises and acts to improve risk control of uncontrolled and incompletely controlled risks
- Recognises how risk management approach broadly applied to the organisational risk register and the effect of uncontrolled risks on patient safety

5.2 Risk, escalation and governance in patient safety Download

Module 5.3 Creating a culture of patient safety

At the end of this module participants will understand that the requirement for a safety culture and understand the barriers and drivers to cultural change and be able to promote the development of safety culture in their own organisation.

Learning outcome 1: Reviews the culture of the organisation

Content guidance:

- Demonstrate approaches and support participants to document a review and description of organisational culture**
 - The organisational requirement in safety culture
 - The systems for change
 - Barriers and drivers to cultural change
- Demonstrate ways to use the review for developing, supporting and maintaining positive cultural changes in the organisation**
 - Qualitative sources such as interviews and documents
 - Qualitative sources from appropriate cultural tools
 - Observations and analysis of organisational values, behaviours and beliefs
 - Risk to the system, including reporting, investigation, complaints, staff and patient feedback
- Describe findings in organisational culture as they relate to any models of culture and cultural strategies (London Western model of organisational maturity and the Manchester Patient Safety Framework (MPSF))**
 - Relate knowledge and experience in safety culture to the development of organisations beyond their local trust, department or specialty
 - Explain the importance of safety culture in the development of organisations
 - Demonstrate a knowledge of the cultures of the organisational maturity they work within or develop
 - Consider the impact of cultural initiatives on related organisations
 - Work to build maturity in cultural change across organisations

Behaviours:

- Supports cultural change in all work programmes and interventions
- Demonstrates openness, positive communication in all work programmes

5.3 Creating a culture of patient safety Download

Module 5.4 Part 1 The safety case

At the end of this module participants will have knowledge of the principles and key concepts of creating a safety case in healthcare and be able to use this as a tool to protect patient safety and fulfil governance requirements.

Learning outcome 1: Explains the benefit of a safety case

Content guidance:

- Define the term 'safety case'**
 - Draw from formal definitions used in other safety-critical industries (see references)
 - Explain how a safety case is a tool and framework used to demonstrate that the safety of the system provided by the health care system is acceptable, including potential risks and hazards, and the reasonably practicable measures that need to be implemented to prevent or minimise harm
- Define the terms used in safety cases**
 - Define and provide examples of the terms risk, probability, severity, harm, accident or incident, medical risk
 - Demonstrate examples of clear and precise language used in a safety case
- Explain the benefits of a safety case**
 - Describe the cost of producing a safety case, the benefits of the tool and of the 'Project' cost deducted to the safety case
 - Provide examples of the use of safety case thinking
 - To support change management
 - To promote continuous improvement
 - To assess the impact of medical risk
 - To control the potential for accidents to occur as reasonably practicable defined later in the module
 - To promote safety
 - Demonstrate a separate and/or business case for developing safety cases
- Explain the principle of safety targets**
 - Provide examples of safety case of other safety industries to demonstrate that a process, service, equipment or task is 'safe enough'
 - Describe the principle of 'as far as is reasonably practicable' (ALARP) and its use as a necessary practicality (ALARP) and its use as a necessary practicality (ALARP)
 - Compare and contrast qualitative versus quantitative assessment of safety and how these link to safety targets

Behaviours:

- Understand the purpose of safety cases and how they should be used effectively within patient safety
- Understand how to prepare and produce a safety case
- How to use safety cases to effectively promote continuous improvement within patient safety
- How to use safety cases as communication tools to promote the importance of safety and to value to patient safety
- Become a spokesperson for the benefits of safety cases and their value to patient safety
- Actively seeks to employ safety cases within patient pathways wherever appropriate

5.4 Part 1 The safety case Download

Module 5.4 Part 2 The safety case

This module, the second of two expert modules on safety cases, provides guidance on the practicalities of creating a safety case in healthcare and their use in proactive safety management.

Learning outcome 2: Evaluates the outcomes from the safety case development to identify appropriate interventions and their implications on medical risk

Content guidance:

- Explain how to evaluate interventions, for example following on:**
 - The degree to which the intervention controls the identified hazard
 - Whether there are any more appropriate / complementary interventions available following back to hierarchy of control
 - The frequency of existing, new and interventions. Such interventions tend to have a very finite life when safety systems factors are at play
 - Whether the intervention is practical and possible to implement
 - Whether anything foreseeable could defeat the intervention or might be following in 'to or fully system change'
 - What degree does include the medical risk
 - The direction of interventions, for example the supportive of, or in conjunction with, the patient
- Explain how to assess medical risk that results as a result of the identified intervention**
 - Demonstrate the use of a subset of the previously controlled safety analysis, for example HAZOP or FMEA, to assess medical risks
 - Demonstrate case studies to illustrate interventions
- Explain how to implement interventions**
 - Explain the importance of involving representative users and stakeholders in the development, design and implementation of interventions with reference to module 2.5 Human factors and clinical practice
 - Describe systems and downstream impacts of interventions, how to assess these as well as considering supporting changes, for example, operational change may require updates to guidance documents
 - Explain the importance of monitoring and review of interventions

Behaviours:

- How to use safety cases to identify safety gaps, mitigation and recovery measures
- How to maintain a safety case
- How to present a safety case to test with the audience
- Use a safety case to effectively promote continuous improvement within patient safety
- Use the safety case as a communication tool to promote the importance of safety and to value to patient safety
- Recognise a spokesperson for the benefits of safety cases and their value to patient safety
- Actively employ safety cases within patient pathways wherever appropriate

Learning outcome 1: Applies a safety case within patient safety to identify hazards, risks, safeguards, mitigation and recovery

Content guidance:

- Explain how to identify safeguards, mitigations and recovery**
 - Explain the terms safeguard, mitigation and recovery
 - Explain how to identify safeguards, mitigations and recovery measures to control identified hazards
 - Explain the importance of the hierarchy of control in identifying viable safeguards, mitigations and recovery measures
 - Explain how to identify the safeguards, mitigations and recovery measures using established methods. This will build on methods including HAZOP (Hazard and Operability) and FMEA (Failure Modes and Effects) and, in addition, it is important to include consideration of the human error identification methods of SHELRS (Swiss Cheese Human Error Reduction and Prediction Approach), PRA (Probable Human Error Analysis)

5.4 Part 2 The safety case Download

The NHS Patient Safety Syllabus

The NHS patient safety syllabus

NHS Patient Safety Syllabus v2.1

Click to download the syllabus

NHS Patient Safety Syllabus

Training for every member of staff across the NHS

Making Safety Active:

- Preventing harm before it occurs
- Identifying risks and making them safe
- It is time to change what we do and how we think about patient safety



V 2.1 (June 2022)

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Key domains and underpinning knowledge

The domains of this syllabus are presented below as a linear sequence although there are inevitable dependencies and synergies between them. To understand this and to support the structure and content of each domain, the syllabus sets out the key outcomes for each domain and the underpinning knowledge and expertise required at each stage.

Figure 1: Five domains in the patient safety syllabus

The rationale used in developing the domains embodies a spiral of learning, with each domain building on and deepening the work carried out in previous domains. The elements of underpinning knowledge and expertise fall into four key themes that run through each of the domains and, through the unfolding of further knowledge within each domain, will build to a comprehensive understanding in each area.

The syllabus has now been translated into guidance for training providers to create discrete learning modules to form a curriculum. These will be discrete for the purposes of educational design, but inevitably the skills in different domains will integrate in different ways in a behavioural context depending on the demands of each situation. From the curriculum, staff will be able to select those modules of most significance to their work – perhaps focusing on systems-based incident review, or on human factors. The design of the learning modules, and the incorporation of an ‘Essentials for patient safety’ module for all staff, will enable staff and patients to benefit quickly from the clear focus on patient safety and inclusion of an ‘Access to practice’ module provides essential elements of the four key themes of the syllabus for those who choose to develop their expertise further.

The four key themes of underpinning knowledge and expertise are:

- Systems thinking
- Human factors
- Risk expertise
- Safety culture.

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Foreword

Patient safety is more vital than ever as we emerge from the Covid-19 pandemic, with NHS resources under pressure

The first NHS England Patient Safety Strategy was launched at the Patient Safety Congress in July 2019 to describe ways in which the NHS will continuously improve patient safety, building on the foundations of a safer culture and safer systems.

The Academy of Medical Royal Colleges has worked with colleagues from the University of Warwick to develop this new NHS Patient Safety Syllabus to complement it as the basis for education and training for staff throughout the NHS.

This syllabus represents an exciting new approach to patient safety, incorporating an emphasis on a proactive approach to identifying risks to safe care and including systems thinking and human factors. This sets the scene for a step change in thinking about patient safety which should lead to significant gains as it reaches a critical mass of trained practitioners.

We look forward to continuing our work with NHS England as specific curricula are developed for all staff groups.

Everyone stands to benefit from improved patient safety.

Professor Dame Helen Stokes-Lampard
Chair of the Academy of Medical Royal Colleges

“CQC welcomes the development of the patient safety syllabus and its curriculum guidance which represents an opportunity to understand the factors that are essential foundations of safety, and will help everyone think differently about how to provide the consistently safe care that must underpin all services in the NHS.”

Victoria Vallance, CQC’s Director of Secondary and Specialist Healthcare

“Developing an NHS patient safety syllabus for the NHS is a core part of the NHS Patient Safety Strategy. The initial training material (levels 1 and 2) are now available online and early evaluations have been extremely positive.

The team at the Academy of Medical Royal Colleges has now transformed the remainder of the syllabus into a full set of educational modules (levels 3,4 and 5). This will allow delivery to begin in earnest which, alongside an accreditation process, will ensure consistent, high-quality patient safety education and training is provided to the NHS.

This material, which focuses on both proactive and reactive approaches to patient safety, alongside key areas like systems thinking and human factors, will provide staff with a common set of concepts, helping to create a positive culture of patient safety, and ultimately lead to safer care.”

Dr Aidan Fowler, National Director of Patient Safety, NHS England and NHS Improvement

NHS Patient Safety Syllabus v2.1 3

Systems approach to patient safety

1. The safety landscape

- 1.1 Has knowledge of national learning reports and can describe key findings
- 1.2 Has knowledge of essential safety procedures, including reporting, safety alerts and regulatory requirements
- 1.3 Applies lessons from key case studies in patient safety
- 1.4 Analyses patient harm levels to evaluate the safety of the area

2. Systems approach to patient safety

- 2.1 Recognises and describes the effect of systems design on risk and safety
- 2.2 Outlines the principles of direct and latent failures and of performance-influencing factors
- 2.3 Describes safety approaches used in other safety-critical industries
- 2.4 Explains the fundamentals of human factors and human performance
- 2.5 Acts to break the link between error and blame by describing system-induced error in all incident responses and reports

3. Safety II and resilience

- 3.1 Recognises the key principles of Safety-II theory and how they may complement Safety-I
- 3.2 Encourages anticipation, adaptation, monitoring, and responding, to address existing and developing risks
- 3.3 Has detailed knowledge of evidence-based interventions in Safety-II and how they apply to improving patient safety
- 3.4 Is able to integrate and apply the principles and practices of Safety-II in making direct improvements in patient safety

4. Organisational culture and learning

- 4.1 Recognises organisational culture and the principles of safety culture
- 4.2 Explains the effect of blame culture on organisational learning
- 4.3 Analyses and evaluates safety culture and organisational learning
- 4.4 Contributes to sharing lessons learned in patient safety and promotes a learning culture

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National patient safety syllabus 2.0

Mapping of syllabus content onto curriculum modules

This table shows a list of the syllabus domains and capabilities in the left-hand column, while the right-hand column shows where those are covered within the curriculum modules

Syllabus domains 1-5 and capabilities within each domain	Title/location in relevant curriculum modules
1. Systems approach to patient safety	
a. The safety landscape	3.1 The safety landscape
b. Systems approach to patient safety	3.2 Systems approach to patient safety
c. Safety II and resilience	4.4 Safety II and resilience
d. Organisational culture and learning	3.4 Organisational culture and learning
e. Patient and public involvement in safety	3.5 Patient and public involvement in safety
f. Medical legal and professional responsibilities	3.10 Medical legal and professional responsibilities
g. Patient safety regulations and improvement	3.3 Patient safety regulations and improvement
h. Learning from and managing complaints (for future inclusion)	n/a
2. Learning from incidents	
a. Investigating patient safety incidents	3.8 System-based approach to learning from patient safety incidents
b. Designing system-based interventions	4.3 Systems-based interventions in patient safety incidents
c. Managing human performance variability in patient safety	4.1 Managing human performance variability in patient safety
d. Avoiding blame and creating a learning culture through a just culture approach	3.9 Avoiding blame and creating a learning culture through a just culture approach

Syllabus domains 1-5 and capabilities within each domain	Title/location in relevant curriculum modules
3. Human factors, human performance, and safety management	
a. Human factors and clinical practice	3.6 Human factors and clinical practice
b. Task analysis and support	4.2 Task analysis and support
c. Non-technical skills in clinical practice	3.7 Non-technical skills in clinical practice
d. Process reliability and safety assurance	4.8 Process reliability and safety assurance
4. Creating safe systems	
a. Risk evaluation in clinical practice	4.5 Risk evaluation in clinical practice
b. Mapping techniques to identify risks to patients	4.6 Mapping techniques to identify risks to patients
c. Designing for systems safety	4.7 Designing for systems safety
d. Evaluating safety culture	4.9 Evaluating safety culture
5. Being sure about safety	
a. Integrating human factors	5.1 Integrating human factors
b. Risk, escalation, and governance in patient safety	5.2 Risk, escalation and governance in patient safety
c. Creating a culture of patient safety	5.3 Creating a culture of patient safety
d. The safety case	5.4 The safety case

Abbreviations and acknowledgements

Abbreviations and acknowledgements

List of abbreviations

ANTS

Anaesthetists' Non-technical Skills

CAIR

Checklist for Assessing Institutional Resilience

CARE

Concepts for Applying Resilience Engineering

CIEHF

Chartered Institute of Ergonomics and Human Factors

CHFG

Clinical Human Factors Group

CQC

Care Quality Commission

FMEA

Failure Modes and Effects Analysis

FTA

Fault Tree analysis

FRAM

Functional Resonance Analysis Modelling

GEMS

Generic Error Modelling System

GMC

General Medical Council

GDTA

Goal-Directed Task Analysis

HAZOP

Hazard and Operability

HCPC

Health and Care Professions Council

HFMEA

Healthcare Failure Mode and Effect Analysis

HTA

Hierarchical Task Analysis

HSE

Health and Safety Executive

HSIB/HSSIB

Healthcare Safety Investigation Branch/
Health Service Safety Investigations Body

HSMR

Hospital Standardised Mortality Ratio

HFE

Human factors/ ergonomics

LFPSE

Learn From Patient Safety Events

MaPSaF

Manchester Patient Safety Framework

MHRA

Medicine and Healthcare products
Regulatory Agency

NLRS

National Learning and Reporting System

NOTSS

Non-Technical Skills for Surgeons

OSCAR

Observational Skill-based Clinical
Assessment tool for Resuscitation

PALS

Patient Advice and Liaison Service

PHEA

Predictive Human Error Analysis

PSII

Patient safety incident investigation

PSIRF

Patient safety incident response framework

PSIRP

Patient safety incident response plan

PSP

Patient Safety Partners

PSS

Patient Safety Specialists

PIF

Performance-influencing factors

PDSA

Plan Do Study Act - a common methodology
for quality improvement

PRIMO

Proactive Risk Monitoring in Healthcare -
A tool for risk management

QI

Quality Improvement

RAG

Resilience Analysis Grid

RCA

Root Cause Analysis

SCTA

Safety Critical Task Analysis

SBE

Simulation-Based Education

SEIPS

Safety Engineering Initiative for Patient Safety

SHERPA

Systematic Human Error Reduction and
Prediction Approach

SHMI

Summary Hospital-level Mortality Indicator

SPLINTS

Scrub Practitioners List of Intraoperative
Non-Technical Skills

STAMP

System-Theoretic Accident Model and Processes

TINSELS

Training In Non-technical Skills to Enhance
Levels of Medicines Safety

WAD

Work-as-done

WAI

Work-as-imagined

Abbreviations and acknowledgements

Quality assurance in the development of the curriculum guidance

Both the syllabus and the modules for curriculum guidance have been subject to a process of systematic review. The development of the syllabus was guided by a multi-professional Advisory Group (see acknowledgements below) hosted at the Academy of Medical Royal Colleges (AoMRC), and the Health Education England (HEE) Patient Safety Programme Board. Development of the syllabus content was subjected to a broad external consultation followed by subject-specific expert 'task and finish' groups organised, hosted, and chaired independently by HEE to address issues of content, structure, and terminology.

The development of curriculum levels 1 and 2 was guided by multiple rounds of review by groups of key stakeholders and future users of the material, accessed through electronic surveys, and by detailed text and presentation reviews by experts at HEE, AoMRC and NHS England.

Curriculum levels 3-5 were reviewed by an expanded internal team at AoMRC, drawing in experts in human factors and safety science, and each curriculum guidance module was further reviewed by two external reviewers, including patient safety experts, prominent academics, and clinicians active within these fields.

There will be a regular review programme established for the syllabus and curriculum. The next review point is likely to be Quarter 4, 2024.

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- Clinical Human Factors Group
- Care Quality Commission
- Council of Postgraduate Medical Deans
- Council of Deans of Health
- Department of Health Northern Ireland
- General Medical Council
- Health and Care Professions Council
- Healthcare Safety Investigation Branch
- Health Education England
- Health Education and Improvement Wales
- Lay representatives
- Medical Schools' Council
- National Association of Clinical Tutors
- NHS Clinical Commissioners
- NHS Education for Scotland
- NHS Employers
- NHS England and Improvement
- Nursing and Midwifery Council
- Royal College of General Practitioners
- Royal College of Midwives
- Royal College of Nursing
- Royal College of Physicians including its Chief Registrar Programme
- Royal Pharmaceutical Society
- Society and College of Radiographers
- UK Foundation Programme

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Curriculum Guidance for Delivering the NHS Patient Safety Syllabus

Training in Patient Safety

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