

Development process

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Introduction

The rationale for the development of Patient Safety Learning's Standards began with research into 'Why is harm persistent?' and publication of our Green Paper entitled *A Patient-Safe Future* - creating a proposition for change and patient safety improvement based upon quantitative and qualitative data, insights and evidence.

After further extensive consultation, this major initiative was followed by our report, *A Blueprint for Action*, published in 2019.

Drawing on twenty years of research into patient safety and avoidable harm, this report analysed why patient safety is a major and persistent problem and set out the systemic causes of unsafe care. It detailed the practical actions needed to address the foundations of safer care for patients and progress towards a patient-safe future.

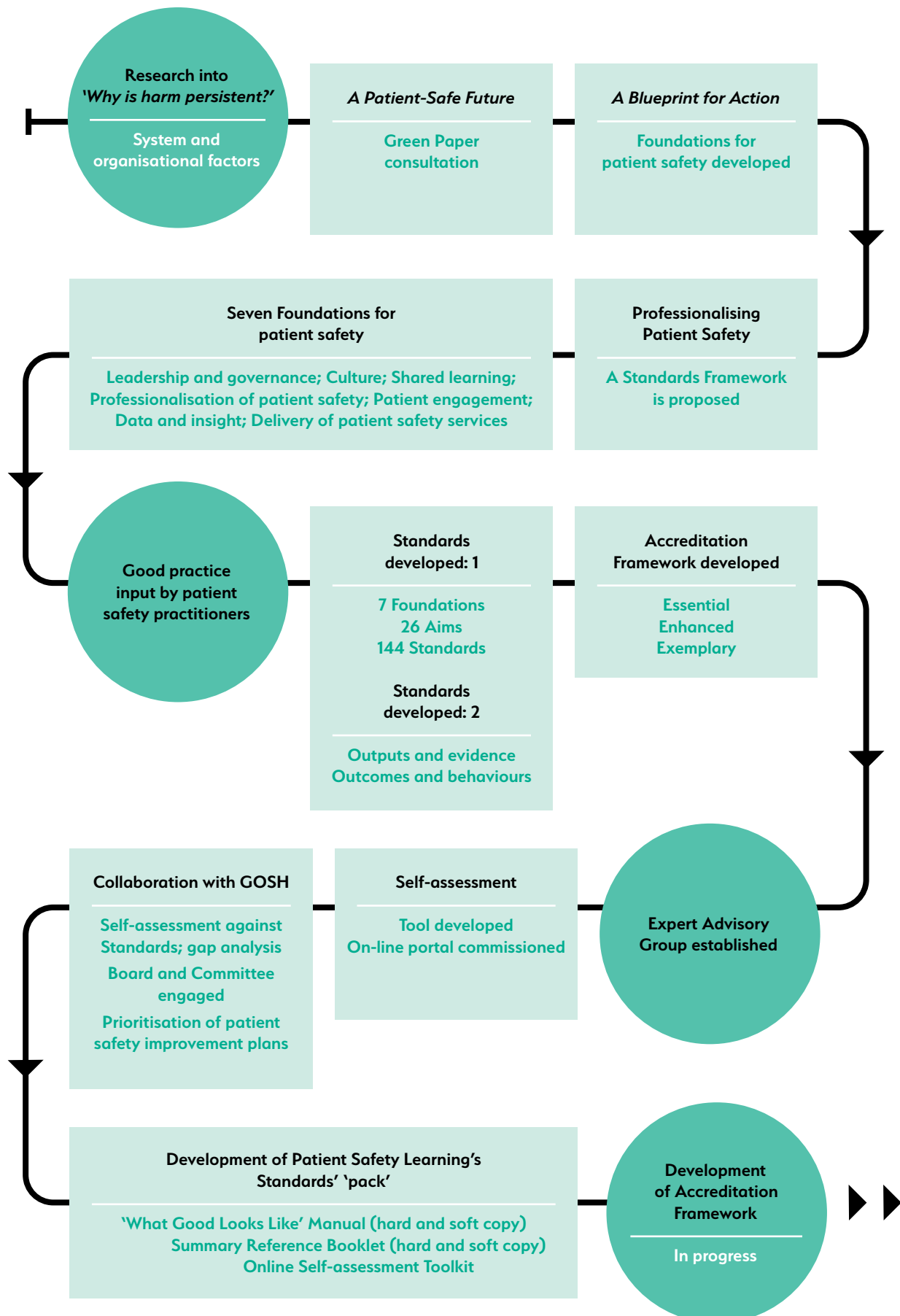
In *A Blueprint for Action* we identified that a key challenge that health and social care organisations face is that they don't have standards for patient safety in the way that they do for other safety issues; and those that they do have are insufficient and inconsistent. There is an absence of a common framework to underpin consistent care, with organisations lacking the means to demonstrate and measure their safety performance.

The introduction of organisational patient safety standards will enable health and social care organisations to apply evidence-based criteria for evaluating, managing and improving patient safety performance, thereby minimising the risk of harm resulting from patient safety incidents.

Since the publication of *A Blueprint for Action*, Patient Safety Learning has developed a proprietary set of patient safety Standards, building on seven 'Foundations for patient safety' and adopting a rigorous and evidence-based approach. (See Appendix 1.)

More detail about the way these Standards were planned, developed and evaluated is illustrated in the flowchart and narrative on the following pages.

How the Standards were developed



Development Process Framework

Phase 1 Development

Identification of rules and parameters for the Standards and the approach to be adopted in developing them.

- Rules and parameters agreed:
 - The Standards must be reflective of best practice in patient safety, current research, evidence and experience as reflected in *A Blueprint for Action* and updated to reflect current research, trends and guidance
 - The Standards must take into account the patient perspective as well as that of clinical staff, patient safety experts, managers, academics and leaders
 - They must go beyond current regulatory and policy requirements, which are insufficient or not being implemented effectively, thereby failing to ensure patient safety
 - They must not just duplicate statutory requirements (e.g., H&S) but complement them as appropriate. Links or duplications are identified through the source references
 - They must reference and reflect the findings of significant patient safety reports and publications, e.g., statutory investigation and inquiry reports
 - They must be focused on outcomes rather than actions to avoid the application of the Standards being implemented as a 'tick-box' exercise.
- Approach agreed:
 - The Standards must be informed by experts with relevant skills/experience, including patient safety leaders, Human Factors experts, clinicians, academics, healthcare transformation leaders and discussion with regulators such as CQC
 - They must facilitate compliance with relevant current requirements by regulators e.g., CQC KLOE and Single Assessment Framework for patient safety and well-led; NHSE Patient Safety Strategy
 - They must adopt a Human Factors approach to make them more readily accessible and acceptable to potential users
 - They must demonstrate good practice in standards' development, with regards to format, language and assessment methodology.

Phase 2 Development:

The approach adopted in planning, including milestones and timescales.

- Standards' development plan defined and agreed:
 - The six Foundations identified in *A Blueprint for Action* were agreed as the starting point and overall framework, with the addition of a seventh Foundation: 'Delivery of patient safety services'
 - Project plan developed and agreed with activities and resources, timeframes and key milestones
 - Initial scope of the Standards agreed as being focused on NHS Trusts, with the possibility to expand into other areas in the future
 - Inputs from practitioners in patient safety were obtained via workshops and follow-up engagement
 - Oversight and review through Patient Safety Learning's Board of Trustees.

Phase 3 Development:

A version of the Standards was developed for design and publication through an iterative process of drafting, informed by expert input.

- Individual Standards drafted, within a framework that makes them easy for organisations to use and Patient Safety Learning to assess against:
 - 7 Foundations; 26 Aims; 144 Standards (criteria)
 - 'What Good Looks Like' developed for each standard
 - Outputs and evidence
 - Outcomes and behaviours
 - 'Weightings' agreed: Patient Safety Learning's proprietary three-level (3Es) accreditation ranking: Essential / Enhanced / Exemplary, along with definitions
 - Compliance gradings agreed: Met / Partly met / Not met / Not applicable, along with definitions
- Experts were identified and approached, with an Expert Advisory Group formed
- Amendments made following expert input e.g., ensuring the strengthening of the focus on 'outcomes'
- Suite of support tools identified and developed.

Phase 4 Development:

Road test the Standards via collaborative projects with Patient Safety Learning clients engaged in strategic patient safety improvement projects.

- Collaboration with GOSH:
 - Self-assessment against the Standards and gap analysis
 - Board and Committee engagement
 - Development of prioritisation plans informed by an outcomes and measurement framework
 - These plans informed an organisation-wide Patient Safety Transformation Programme with new resourcing and governance arrangements
- Evaluation of Standards' wording to ensure it is clear and unambiguous
- Development of client feedback mechanisms to inform future versions.

Phase 5 Development:

Design and publish V1.0 of the Standards, including support tools, that together comprise Patient Safety Learning's Standards 'pack'.

- 'What Good Looks Like' manual (hard and soft copy): a practical guidance workbook that features the full version of Patient Safety Learning's Patient Safety Standards, complete with associated references
- Summary Reference booklet (hard and soft copy): a simplified, quick reference document
- An online self-assessment toolkit to capture progress in meeting all of the relevant patient safety Standards. Results can be reviewed in easy-to-understand graphs, with a document library that is automatically created and brings patient safety resources (e.g., file attachments and links) together in one place
- 'How to' guidance for implementation, including support around the interpretation of the Standards and development of improvement prioritisation and improvement planning e.g.,
 - Information, engagement and reporting to Executive and Non-Executive leaders, including Board and team development
 - Staff engagement and communication
 - Improvement patient safety prioritisation planning e.g., driver diagrams, outcomes and measurement framework, etc.
- Access to other organisations that are using Patient Safety Learning's Standards for their own improvement journey: delivering collaboration and shared learning.

Phase 6 Development:

Design and deliver an Accreditation Framework for those organisations that would value an external assessment and recognition of their work to improve patient safety.

- As a natural follow-on to the Standards, Patient Safety Learning has also developed an Accreditation Framework. Accreditation enables organisations to have their patient safety performance and delivery formally evaluated against Patient Safety Learning's Standards
- Structured around a three-level ranking of Essential, Enhanced and Exemplary, accreditation is a specific element of the 'Professionalisation of patient safety' Foundation
- Accreditation is based upon a multi-stage assessment and evaluation process, supported by Patient Safety Learning's external and independent specialist consultants and assessors. Positive performance against the Standards represents the cornerstone of success
- Accreditation can be undertaken as a 'one-off' event to achieve a base-line score, or approached as part of an on-going process of learning and improvement, assessed over a number of years. This can provide a core element of an organisation's quality assurance process and inform regulatory assessment by CQC and others
- Patient Safety Learning's Accreditation Framework is a work-in-progress, accompanied by regular updates.

Appendix

Green Paper: *A Patient-Safe Future*
A Blueprint for Action

The seven Foundations for patient safety

Examples: 'What Good Looks Like' manual
and toolkit

Green Paper: *A Patient-Safe Future*



Above: Patient Safety Learning's Green Paper, *A Patient-Safe Future*

A Blueprint for Action



Above: Patient Safety Learning's original research and policy report, *A Blueprint for Action*

The seven Foundations for patient safety



Based on our original research and policy document *A Blueprint for Action* (2019), Patient Safety Learning has identified seven Foundations for patient safety:

- Leadership and governance
- Culture
- Shared learning
- Professionalisation of patient safety
- Patient engagement
- Data and insight
- Delivery of patient safety services.

Each of these Foundations is supported by specific patient safety Aims, totalling 26 across all seven, with clearly defined Standards (144) underpinning each.



Leadership and governance

1. Patient safety is a core purpose
2. Patient safety is embedded in governance
3. Organisation has a patient safety plan
4. New services are designed for safety
5. System leadership
6. Organisational leadership for patient safety



Culture

7. Patient safety culture tackles blame and fear
8. Promotes patient safety improvement
9. Role of HR



Shared learning

10. Learning goals for improving patient safety
11. Learning from near misses
12. Learning from investigations
13. Learning from feedback and complaints
14. Learning from others
15. Shares learning with others



Professionalisation of patient safety

16. All staff are suitably qualified and experienced
17. Specialist skills in patient safety and human factors



Patient engagement

18. Commitment to patient engagement
19. Organisational systems for engaging with patients
20. Patient engagement in their own care
21. Patient engagement if things go wrong
22. Patient engagement for safer care



Data and insight

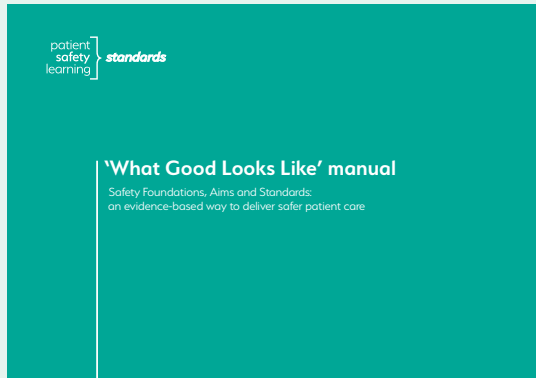
23. Metrics and data to measure and manage patient safety



Delivery of patient safety services

24. Services are delivered safely
25. Workforce planning
26. Workforce deployment

The Standards 'pack'



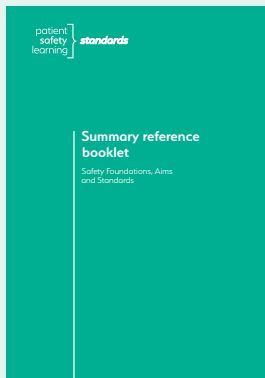
Leadership and governance

Aims

1. Patient safety is a core purpose of the organisation. (Patient safety is central to priorities for service delivery, investment, reporting and support.)
2. Patient safety is embedded in governance and risk management. (All decisions are informed by and consider patient safety.)
3. There is an organisation patient safety plan with accompanying objectives and measures that ensure implementation. (The organisation can achieve its patient safety goals because patient safety is planned and delivered.)
4. New services are designed for safety. (Safety is built into the planning and delivery of new services, mitigating the risk of unintended consequences of avoidable harm.)
5. System leadership – health and social care as an effective safety system. (Patient safety is embedded into healthcare design and delivery.)
6. Organisational leadership for patient safety. (Patient safety behaviours are modelled and promulgated from the top down.)



Leadership and governance 7



Summary reference booklet

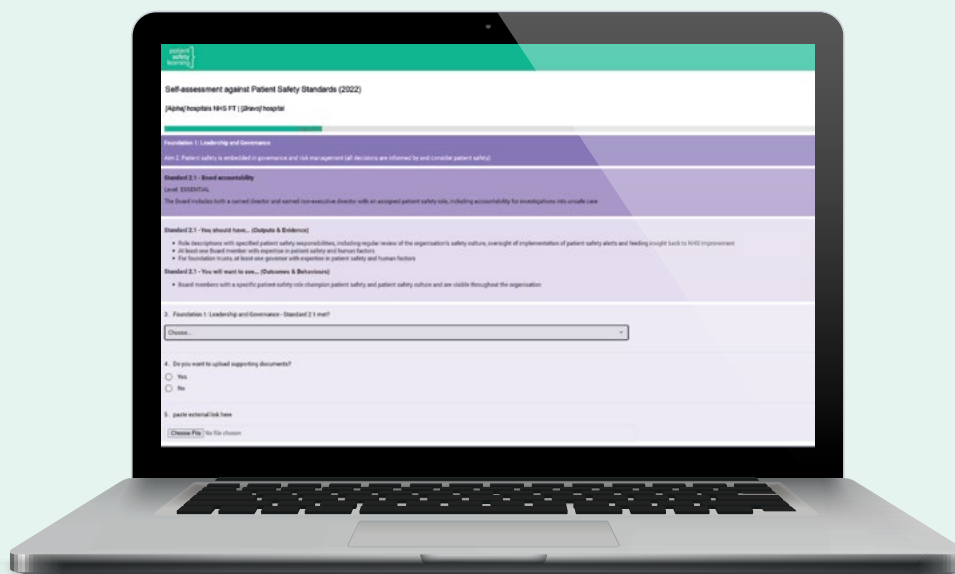
Safety Foundations, Aims and Standards

Leadership and governance Aim 2:	Patient safety is embedded in governance and risk management. (All decisions are informed by and consider patient safety.)
Standard 2.1 Board accountability	The Board includes both a named director and named non-executive director with an assigned patient safety role, including accountability for investigations into unsafe care.
Standard 2.2 Non-executive Director leadership, learning from deaths	The Board includes a named non-executive director to oversee the organisation's approach to learning from death.
Standard 2.3 Training and support	Board Members and Governors are provided with training and support to ensure their competence in relation to patient safety matters.
Standard 2.4 Decision frameworks	There are decision frameworks and processes to ensure patient safety.
Standard 2.5 Culture of patient safety, impact assessment, risk management, Board priorities	Patient safety impact assessment informs Board priorities for service delivery.
Standard 2.6 Building capability	The Board invests in building capability within the organisation to enable staff to contribute to the improvement of patient safety services.

Summarised Patient Safety Aims 8

Above: Examples from the 'What Good Looks Like' manual

Left: Examples from the Summary reference booklet



Above: Example page from the Patient Safety Standards self-assessment toolkit



If you would like to know more about the services and support available to you from Patient Safety Learning, please contact us at hello@patientsafetylearning.org

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