Step guide to implement the BSI PAS 1616:2016 Healthcare - Specification for provision of clinical services.

for Accreditation and Healthcare Providers

Guide purpose

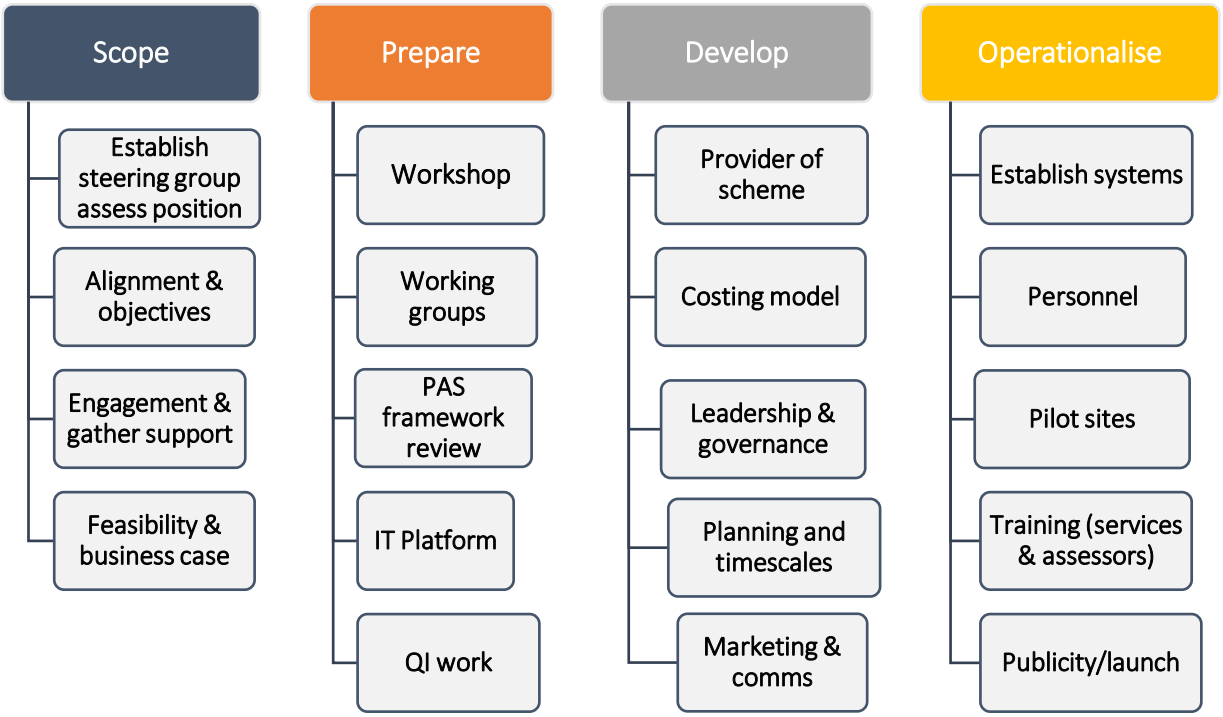
- This guide is aimed at any accreditation provider or healthcare organisation that plans to:
  - adopt the PAS1616 framework as part of a new accreditation scheme or
  - transition an existing accreditation scheme to the PAS1616 standard or
  - adopt the framework as a quality improvement tool or governance framework.

- The guide aims to assist the reader with the implementation process and to ensure that it is undertaken correctly and that all anticipated benefits are realised.
- It links to other guides in the HQIP series namely:
  - o CSAA workstream 4: BSI PAS1616 - Healthcare – Provision of clinical services – Specification [1].
  - o *CSAA workstream 5:* Clinical Service Accreditation (CSA): Requirements for IT systems [2].
  - o *CSAA workstream 6:* Preparing for development of a clinical service accreditation scheme: A good practice guide [3].
- The reader should use these documents alongside this guide (See reference section page 14.

Who might use this guide?
• Representatives from accreditation departments /schemes who plan to use the PAS1616 framework to underpin accreditation schemes (new and existing). • Representatives from healthcare organisations who plan to implement the PAS 1616 framework in clinical services.

- Diagram 1 summarises the key stages in developing an accreditation scheme. Adopting the BSI PAS1616 standard is one of the key stages.

Diagram 1. Stages in the development of an accreditation scheme for a clinical service



The 'scope' and 'prepare' sections of this diagram are described in more detail in the CSAA Workstream 6: Preparing for development of a clinical service accreditation scheme: A good practice guide [3].

Background to the BSI PAS1616 Framework.

- The British Standards Institute (BSI) was commissioned as part of the Clinical Service Accreditation Alliance work to develop a Publicly Available Specification (PAS). PAS 1616:2016 Healthcare – Provision of clinical services – Specification for clinical services is a document that standardises elements of a product, service or process. PAS 1616:2016 can be used to help clinical services achieve their potential more quickly and to enhance or increase collaboration.
- BSI PAS1616 provides an agreed common framework for organisations and clinical service accreditation schemes.
- It aims to reduce burden for organisations and schemes by providing a consistent approach to accreditation with a common language and approach.
- It provides organisations with a tool to improve clinical services and to monitor progress.
- It provides organisations with effective monitoring and oversight.

- By following the same standard and structure it provides a greater opportunity to share service improvements & approaches to achieving the standard.

Diagram 2 – Framework potential

BSI PAS1616 framework potential
Support: a framework of requirements that provides a roadmap for all clinical services to follow **Share:** knowledge resource: sharing examples of good practice, innovation etc. **Reduce:** duplication and effort **Consistency:** model supports a common approach **Levers:** working towards a standard supported by the regulator

- The majority of the BSI PAS 1616 framework is generic and as such can be used for any clinical specialty or service.
- Consistency in the application of the framework is key if the benefits of a common approach are to be realised:
    - Meeting the standards ensures that a service has the same evidence to comply with regulatory requirements.
    - A consistent approach to accreditation in all clinical specialties will reduce burden and the cost of achieving the standards.
    - Allows for more potential of cross-speciality shared learning

- Appendix A provides an abbreviated summary of the entire BSI PAS 1616 framework with the details of all clauses. It is mapped to the CQC key lines of enquiry (example 1).

Example 1 – PAS 1616 alignment to CQC KLOES

Navigating the system	CQC KLOE
4.4.1 The clinical service provides a navigation guide with an explanation of how clinical service users can navigate the clinical pathways.	**C2.3** **R3.5, R5.5**
4.5.3 The clinical service monitors journey times across clinical pathways and keeps clinical service users informed if journey times are expected to exceed locally set targets.	**R3.1, R3.6, R3.7**

- Table 1 provides a high-level summary of the 10 requirements. It is expected that all the clauses are fully considered and adopted in part or in full.

Table 1 -BSI PAS 1616 Standard - A generic specification for all Clinical Services.

BSI PAS 1616 Standard - Clauses	
1. Leadership, strategy and management	6. Clinical effectiveness
2. Operational delivery of the clinical service	7. Clinical service users with complex needs
3. Systems to support clinical service delivery	8. Staffing a clinical service
4. Person centred care	9. Improvement, innovation & transformation
5. Risk and safety	10. Educating the future workforce

- The underpinning of PAS 1616 with service specific requirements requires a working group with both clinical and specialist expertise.
- Some of these service-specific criteria (such as regulatory requirements) will be mandatory but others will not be. Thus, some discretion and negotiation will be required to agree what should be included.
- It is expected that all 10 domains will be included in the minimum requirements for accreditation of a clinical service and that these will 'stretch' the service and demonstrate excellence. Specific evidence requirements will need to be agreed and adjusted from the separate template (See reference to access/download the version created by HQIP).
- Similar or same evidence may support a number of requirements. It's important to consider each of these and adjust to suit the clinical service.
- There are some critical steps to consider when adapting PAS1616 to a specific service (table 2).

Table 2 -PAS 1616 adoption principles.

General principles of PAS 1616 adoption
1. Adhere to the agreed standard and structure
2. Include all of the 10 domains
3. Develop underpinning service-specific criteria
4. Set/adjust evidence requirements to suit the needs of the service
5. Develop service-specific guidance
6. Gather feedback from services to improve the framework and feedback to the BSI.

Why adopt the BSI PAS1616 standard?

- Healthcare and Accreditation providers aim to ensure high quality professional care for their patients. However, complex clinical and management processes, time constraints, and multiple demands pose challenges that may contribute to risk. Implementation of the BSI PAS1616 standard, as a foundation for clinical or business processes, provides a range of organisational benefits.
- Adoption and implementation of the PAS 1616 standard may help to improve patient safety, drive efficiency, effectiveness and cost reduction in service delivery. One of the core principles of development of PAS content was to improve effectiveness, efficiency and value. It was anticipated that through the application of the standards that this would be achieved (table 3).

Table 3 – PAS 1616 examples to support effectiveness, efficiency and value.

Ethos, culture & professionalism	**1.1.2** The clinical service works collaboratively across health and social care boundaries to create a culture in which there is a shared vision, **coordinated effective care** is delivered and change is managed.
Leadership governance and stakeholder involvement	**1.3.10** The leadership team identifies characteristics that will impact on the clinical service: the needs of the local population, including proximity; disease burden; national and local requirements; **best value for money;** and promotion of the clinical service.
Referrals, appointments and admissions	**4.5.2** The clinical service reviews do not attend (DNA) rates. Actions are taken to improve attendance at appointments.

Implementation overview.

- This guidance will ensure a consistent approach to adoption of the PAS1616 framework:
  - Providers must plan in advance for the adoption of PAS1616 and develop coherent arrangements for implementation involving all key players, resources, training and infrastructure requirements.
  - Taking early steps to disseminate and promote PAS1616 guidance to key stakeholders will ensure better engagement about what is expected. It will help to overcome early barriers to adopting and implementation
  - Assess the current state of play – what is the baseline of the clinical service and how much work has been done already?
  - Involve patient groups early.

The next section summarises the recommended sequence to implement the PAS 1616 Framework.

High-level steps to implementation of the BSI PAS1616 standards

To ensure successful implementation of the BSI PAS1616 in clinical or business processes, the following high-level implementation steps are recommended:

Step 1: Review the PAS 1616 framework and its suitability for the clinical service
Step 2: Establish a working structure/technical group
Step 3: Facilitate a workshop to adopt and adapt the PAS 1616 framework
Step 4: Complete testing and feedback
Step 5: Launch the PAS1616 framework
Step 6: Monitor, refine and expand

Step 1: review the PAS 1616 framework and its suitability for the clinical service.

- There will be many clinical and management processes that will benefit from adoption of the PAS1616 framework. It is therefore important to gather as much information as possible to understand options and opportunities for implementation of PAS1616. Simply put, this information is needed to understand the areas you want to improve and where it will have the greatest impact. The more information, the more effective the implementation will be.
- It is essential to facilitate a small meeting with key representatives to consider the adoption of the PAS 1616 framework. The following questions should be considered:
    - **What problem(s) are we trying to solve?**
        a) *Consider what the starting position is for the clinical specialty and what is the scale of the challenge that needs to be addressed. If standards already exist, then how will this new framework help?*
    - **What are the main areas that need change?**
        a) *Are we clear about what work needs to be done? how will the specific elements of the PAS1616 framework address these deficit areas. Being clear about this from the beginning will make service engagement in the process clearer*
    - **What is the scope and scale of the work to be done to achieve the requirements?**

a) *How much work needs to be done and does this need a phased approach? are there priority areas to start with e.g. clinical effectiveness?*

- **What is the route to continual service improvement?**
  a) *How will we support services to improve, who is best to deliver this?*

- **Are we clear about the principles of adoption?**
  a) *How should we adopt and apply the PAS1616 framework (page 5). Will a phased implementation plan work best?*

Step 1 - expected outcome
The key stakeholders within the organisation should develop a clear understanding of the potential that implementation of the PAS1616 standard offers in an organisation or accreditation scheme.

Step 2: establish a technical working group

- Once the decision has been made to fully adopt the PAS1616 framework, a small technical working group should be formed, (see table 4).
- It is important to have a clear purpose and to support the implementation of the PAS1616. Clinical leadership is fundamental.
- A service-based accreditation scheme requires collaboration at national level between the health professionals involved in the service and patient organisations. It also requires alignment with other improvement initiatives such as national audits etc. to ensure that clinical teams work to a united view of quality and do not duplicate effort
- Members of the technical working group will be mainly clinical a but they will require support from other professionals within the organisation. For an accreditation scheme this would usually, but not exclusively, be the following:

Table 4 – Technical working group

Technical working group – suggested membership
1. Scheme clinical lead or equivalent
2. Technical expert standards advisor - usually from the organisation/accreditation body
3. Other professionals representing the specialty e.g. nurses, physio, commissioners etc.
4. Patient organisations
5. Lay representative

- The provider may already have internal standards expertise or need to commission a person with PAS1616 standards knowledge, in which case this person will need to ensure they have the latest information to help navigate through and understand the framework for:
    - alignment of goals
    - education and training,
    - engagement in other working groups to engage with peers and contribute to the standards development process.
- The role of the technical group is to:
    - to communicate tasks and responsibilities
    - develop and facilitate a workshop to adopt and underpin the PAS 1616 framework, such as mapping against any pre-existing standards/ criteria to underpin the PAS 1616 framework in partnership with key stakeholders
    - facilitate continued remote work to develop the standards
    - Identify specific issues arising from the review that need further investigation and support
    - document and finalise pilot accreditation standards for testing and feedback.
- The next key technical task is to produce specific criteria, guidance and evidence requirements to underpin PAS1616. There may be one or several groups working on different sections of the PAS framework.

Step 2 - expected outcome
A technical working group will only be functional if all participants understand the overall aim of adopting and implementing PAS1616. The group has responsibility for ensuring that underpinning service-specific standards are correctly applied.

Step 3: facilitating a workshop to adopt and adapt the PAS 1616 framework.

- Preceding the first workshop a Webex/conference call should be organised to:
    - introduce the aims of the project
    - explain BSI PAS1616 framework with an overview of requirements
    - explain working group and roles.
- A one-day workshop of key stakeholders should follow within two weeks to:
    - review all the requirements of the PAS1616 framework
    - map existing quality standards, national guidelines and other known specialty-specific criteria to the PAS 1616 framework
    - review and consider key evidence requirements for all requirements.

- Some of the PAS requirements will need to be underpinned by specific criteria (example 1) in order for PAS 1616 to be relevant to that clinical service, underpinning might need to include:
    - any regulation or national requirements relevant to that service
    - national targets, including waiting times targets
    - audits
    - quality standards/metrics
    - guidelines

Example 1 - PAS1616 with underpinning criteria and evidence.

1. Leadership, strategy and management		
Sub Clause	Underpinning guidance/criteria	Suggested evidence.
1.1.1 The clinical service works collaboratively across health and social care boundaries to create a culture in which there is a shared vision, coordinated effective care is delivered and change is managed.	• It is recommended that the provision of services should be agreed with the following stakeholders as a minimum: – service users and their carers – staff members – local and, where relevant, national service and systems planners and funders – The local health and social care boards (or equivalent bodies); and all organisations involved in the treatment and/or care of service users.	1. Agreed provision of services document. 2. The description of the service includes relationships with linked and other services, patient groups and services that share a common purpose. (Operational policy).

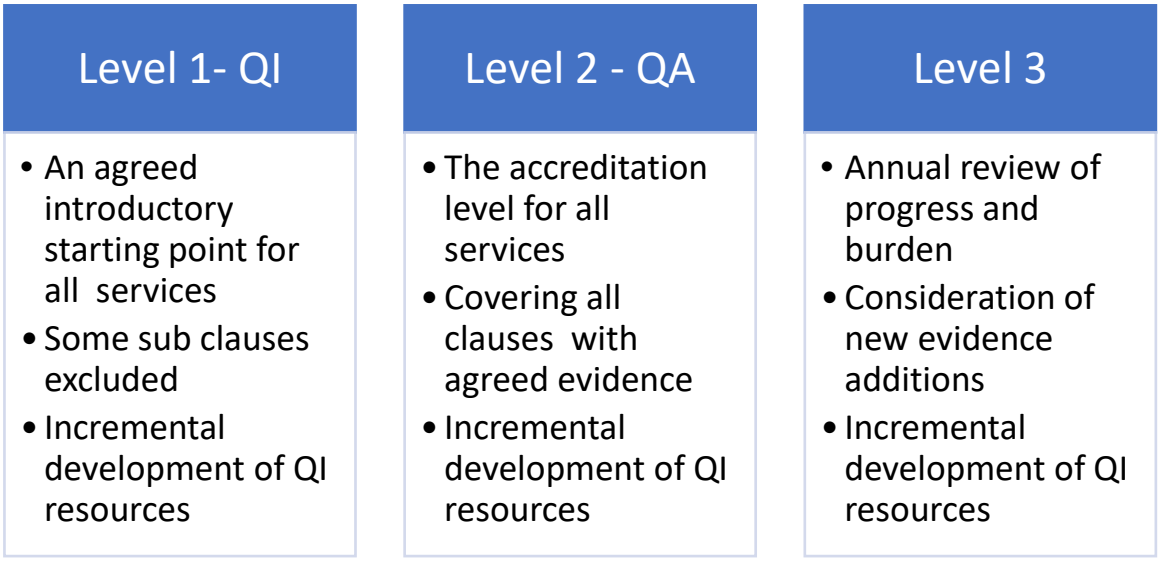
- Consideration should be given to the baseline for clinical services, in particular the gap between how much work has been done already and what needs to be done to achieve the full requirements. Refer to appendix A of the guidance, preparing for development of a clinical service accreditation scheme: A good practice guide [3].
- It is strongly recommended that working groups conduct a high-level assessment to identify priority areas that will need a special focus and support. This could be done using the following criteria:

Areas to consider	H	M	L
Organisational value from implementation			
Capability to implement			
Drive to implement			
Cost of Implementation			
Time / ease of implementation			
Change management requirements			
Overall business benefit			

This will enable an organisation to reach a fact-based decision about the best clinical or business process to use to start the implementation of the PAS1616 framework.

- A phased approach to the full adoption of the PAS 1616 framework may be considered over a three-year cycle e.g. diagram 3.

Diagram 3 -PAS 1616 phased implementation cycle.



The technical working group may highlight a specific starting point for all services or key areas for actions based on the initial baseline assessment e.g. clinical effectiveness to establish data collection and audit.

- **level 1:** There is no formal assessment of this. It is described as a quality improvement stage where services are working towards the agreed framework. This should also be supported through an IT webtool to facilitate self-assessment.
- The development of QI resources and shared learning to support early adoption of the framework will need to be developed. <u>This is not covered in this guidance.</u>

- **Level 2:** is the formal accreditation assessment against the full BSI PAS1616 framework resulting in an accreditation award.
- **Level 3:** includes the annual review of progress post implementation and is referred to later in this guidance.
- It is expected that further work to refine the BSI PAS1616 will need to be completed following the workshop through the technical working group and a project manager/team. The role of the project manager and support team to progress the work to full implementation.

Step 3 - expected outcome
The BSI PAS1616 framework with underpinning criteria and evidence requirements have been mapped and understood. A phased implementation plan with a specific objective has been agreed, and clear requirements and realistic deadlines set.

Step 4: Complete testing and feedback

- It is important to ensure that the completed PAS1616 framework is fit for purpose and IT processes are functioning.
- There should be a defined period of remote consultation (2-4 weeks) with stakeholders and users. This should include feedback of the standards and evidence. This will enable modification of any service-specific underpinning criteria and evidence requirements based on feedback.
- The project team may also choose a small group of suitable partners for first stage implementation and testing of the IT webtool. These should be sufficiently diverse to allow testing of as many situations as possible.
- First stage implementations may occur in a test or a live environment. There should be a plan in place, including scope and timelines. The findings of this activity will help to further refine any processes. During these first implementations it is important to provide adequate support. It follows that teams (including IT providers) have allocated sufficient resources to assist support implementation.

Step 4 - expected outcome
Testing and feedback is complete, ensuring that the framework is fit for purpose and and that IT and management processes are ready to support a full launch.

Step 5: Launch the BSI PAS1616 framework

- There must be a clear engagement and communications strategy
- Training for future users is essential. Training materials and documents should be developed by the project team and tested with a subgroup of users. Training should include

    - A comprehensive BSI PAS1616 framework training programme/workshop
    - A training pathway that will integrate remote, face-to-face and interactive learning styles.

Step 5 - expected outcome
All necessary training will have been developed and undertaken by the end of this step. The new framework and process is now live.

Step 6: Monitor, refine and expand

- Once the PAS 1616 framework and IT system has been implemented, it is important that its adoption is constantly reviewed
- Periodic checks should be undertaken to ensure the framework and supporting processes remain effective. It is important to consider if the new framework still meets the original objectives or not.
- In addition, it is recommended that the entire process is reviewed annually to not only make refinements based on feedback, but also to introduce new developments.

Step 6 - Expected outcome
Continuous improvement of the framework will be based on monitoring and feedback, this will ensure that it meets the needs of the user.

References

1. CSAA workstream 4: *BSI PAS1616 - Healthcare – Provision of clinical services – Specification.* *https://www.hqip.org.uk/resource/bsi-pas-1616-2016-healthcare-provision-of-clinical-services-specification/#.XnJKQi10c1I*
2. *CSAA workstream 5:* Clinical Service Accreditation (CSA): Requirements for IT systems. https://www.hqip.org.uk/wp-content/uploads/2018/02/clinical-service-accreditation-csa-requirements-for-it-systems.pdf
3. *CSAA workstream 6: Preparing for development of a clinical service accreditation scheme: A good practice guide.* *https://www.hqip.org.uk/wp-content/uploads/2018/02/clinical-service-accreditation-csa-preparing-for-development-of-a-csa-scheme-good-practice-guide.pdf*
4. BSI PAS1616 standards summary with evidence requirements 2018. *https://www.hqip.org.uk/resources/?fwp_resource_type=guidance#.*

Appendix A – PAS 1616 – clauses and mapping to CQC key lines of enquiry (KLOES).

https://www.cqc.org.uk/sites/default/files/20171020-adult-social-care-kloes-prompts-and-characteristics-final.pdf

All clauses, sub clauses and guidance

1	1. Leadership, strategy and management		
	Sub-clause	**Requirement**	**CQC KLOEs**
1.1	***Ethos, culture & professionalism***	**1.1.1** The clinical service defines and publishes the ethos of their clinical service.	WL-1.1, WL-1.2, WL-1.3, WL-1.4,WL-1.6, WL-3.2, WL-3.8
		1.1.2 The clinical service works collaboratively across health and social care boundaries to create a culture in which there is a shared vision, coordinated effective care is delivered and change is managed.	E-4.1, E-4.2, E-4.5 R-2.5 WL-2.3, WL-3.2, WL-7.4, WL-7.5
1.2	***Clinical service description***	**1.2.1** The clinical service develops a clinical service description describing the scope of the clinical service provided (including whether research or training is undertaken.	R-1.1 E-4.5
		1.2.2 The clinical service description is agreed with, and made available to, stakeholders.	R-1.2, R-2.5 E-4.5
1.3	***Leadership governance and stakeholder involvement***	**1.3.1** The clinical service has a leadership team that is visible, approachable and available to all staff members.	C-1.4 WL-1.3, WL-1.5,WL-1.7
		1.3.2 The clinical service documents the members of the leadership team, their roles and responsibilities, including a lead clinician with overall responsibility and accountability for the clinical service and a staff member responsible for risk management.	WL-1.3, WL-4.3, WL-5.4
		1.3.3 The leadership team identifies and documents stakeholders, key relationships and lines of accountability.	WL-2.3, WL-3.8, WL-4.3, WL-4.4
		1.3.4 The clinical service creates a method for how the identified stakeholders are to be involved in the planning, delivery and review of the clinical service.	E-3.1, E-4.1, E-4.2, WL-4.4, WL-7.2, WL-7.5
		1.3.5 The clinical service ensures governance processes are aligned with those of the organisation(s) involved in the clinical service.	WL-4.2, W5.1
		1.3.6 The leadership team leads on the development of strategy and business planning for the clinical service involving stakeholders in this process.	WL-1.2, WL-1.4, WL-2.2, WL-2.5, WL-7.2, WL-7.3
		1.3.7 The leadership team leads on the improvement, innovation, transformation and further development of the clinical service.	WL-1.4, WL-5.3

		1.3.8 The leadership team leads on the development of staff members to become clinical service leaders.	E-3.1
		1.3.9 The leadership team plans how and where the clinical service is delivered.	R-1.1, R-1.2, R-1.3 R-1.4, R-1.5
		1.3.10 The leadership team identifies characteristics that will impact on the clinical service: the needs of the local population, including proximity; disease burden; national and local requirements; best value for money; and promotion of the clinical service.	R-1.3, R-1.4, R-1.5 R-2.1, R-2.3 WL-2.5, WL-5.6
		1.3.11 The leadership team establishes a procedure for staff members that includes the sharing of information and raising general concerns such as challenging questionable and/or poor clinical practice.	S-2.6 C-1.4 WL-3.5, WL-3.7, WL-4.5
		1.3.12 The leadership team establishes and implements a communication procedure for the clinical service so that staff members are made aware of new statutory information and other requirements that impact on the delivery of the clinical service, including updates on quality, safety and clinical governance.	S-5.1 WL-1.3, WL-2.3, WL-4.2, WL-5.1 WL-6.2
		1.3.13 The leadership team establishes and implements a procedure for promoting the health and wellbeing of staff members.	WL-3.7
		1.3.14 The leadership team establishes and implements a procedure for promoting the clinical service to referrers and potential clinical service users.	None
		1.3.15 The leadership team reviews and agrees with stakeholders the clinical service description and scope, and where it is delivered.	R-1.4, R-2.4 WL-1.6, WL-4.4, WL-7.1, WL-7.2, WL-7.3

2	**Operational delivery of the clinical service**		
	Sub-clause	**Requirement**	**CQC KLOEs**
2.1	***Clinical service operating plan***	**2.1.1** The clinical service develops and implements an annual operating plan.	R-1.1, R1.3, R1.4, R1.5, R2.1
2.2	***Clinical service delivery***	**2.2.1** The leadership team is responsible for implementing and reviewing the objectives in the clinical service operating plan.	R-1.1 WL-1.6, WL-2.5
		2.2.2 The leadership team has contingency plans in place for exceptional circumstances that might impact on clinical service delivery.	S-2.1

3.	**Systems to support clinical service delivery**

	Sub-clause	Requirement	CQC KLOE Map
3.1	***Roles and responsibilities***	**3.1.1** The clinical service has defined roles and responsibilities for each area of facilities, equipment and IT management, in accordance with the clinical service operating plan.	R-1.3, R-1.4
3.2	***Assessment of facilities and equipment***	**3.2.1** The clinical service carries out an assessment of the facilities and equipment required to deliver the clinical service as part of the clinical service operating plan.	E-1.3 S1-1.8, S-1.9 R-1.3, R-1.4
3.3	***Plans, procedures and programmes***	**3.3.1** The clinical service has a plan to address shortfalls, replacement and purchase of facilities and equipment.	S-1.9 R-1.3
		3.3.2 The clinical service has a procedure in place to identify how improvements can be made by decommissioning or commissioning facilities, equipment and IT	S-1.10
		3.3.3 The clinical service has procedures for the checking of equipment prior to use and the identification and reporting of equipment failures and faults.	S-1.10
		3.3.4 The clinical service has a planned programme of inspection, calibration and maintenance of its clinical equipment.	S-1.10
3.4	***IT systems and electronic data management***	**3.4.1** The clinical service identifies information standards and IT systems designed to allow the collection, management and monitoring of data to support clinical service delivery.	S-2.4 WL-6.5, W-6.6
		3.4.2 The clinical service has a documented procedure for the storage of data and includes the requirements for back up, retention, archiving and any encryption.	S-2.3
3.5	***Document management***	**3.5.1** The clinical service has a document management system conforming to those of the organisations involved in the service, and where applicable, implement a procedure for the control of documents and information required by the clinical service.	S-2.3 C-3.3

4	Person Centred Care		
	Sub-clause	**Requirement**	**CQC KLOE Map**
4.1	***Clinical service user expectations and rights***	**4.1.1** The clinical service communicates to clinical service users both what they can expect from the clinical service and information on their rights	E-1.2, E-1.4, E-4.3,E-5.2 C-1.1, C1.4, C1.5, C1.6 C2.2, C2.4, C3.2 R-2.3, R-2.4, R-2.6, R-2.7, R-2.8, R-2.9, 2,10 R-3.3, R-3.4

		4.1.2 The clinical service requires its staff members to involve the clinical service users when making shared decisions about all aspects of their treatment and/or care.	**E-1.4, E-5.2, E-5.3, E-6.2** **C-1.1, C1.2, C1.3, C2.3, C1.4, C1.5, C2.1, C2.5, C3.2** **R-2.3, R-2.4, R-2.6, R-2.7, R-2.8, R-2.9, 2,10** **W4.2, WL-7.2**
4.2	***Dignity and respect***	**4.2.1** The clinical service establishes and implements policies and procedures to respect and protect clinical service users and their belongings at all times during their treatment and/or care while on the clinical service premises.	S-1.3, S-1.6 C-1.2, C1.3, C1.5 C-2.5, C3.1, C3.2
4.3	***Responsibilities of the clinical service user***	**4.3.1** The clinical service shall communicate to the clinical service user their responsibilities.	**S-4.4** **C-1.6,C2.1, C2.2**
4.4	***Navigating the system***	**4.4.1** The clinical service provides a navigation guide with an explanation of how clinical service users can navigate the clinical pathways.	**C-2.3, C2.7** **R-3.5, R5.5**
		4.4.2 The clinical service sets and publishes clinical service targets for journey times in clinical pathways for urgent and routine referrals from initial referral to the point of treatment and/or discharge from the clinical service.	**S-2.3** **R-2.3**
4.5	***Referrals, appointments and admissions***	**4.5.1** The clinical service has a documented procedure for the implementation and management of clinical service user booking systems.	**S-2.4** **R-3.1, R-3.2, R-3.3, R-3.5, R-3.7**
		4.5.2 The clinical service reviews do not attend (DNA) rates. Actions are taken to improve attendance at appointments.	**R-3.5**
		4.5.3 The clinical service monitors journey times across clinical pathways and keeps clinical service users informed if journey times are expected to exceed locally set targets.	**S-2.3** **R-3.1, R-3.6, R3.7**
		4.5.4 The clinical service has policies and documented procedures for admissions, with supporting information for clinical service users	**R2.5, R-3.2, R-3.7**
		4.5.5 The clinical service monitors and reviews inappropriate referrals, and develops an improvement plan to reduce them.	**None**
		4.5.6 The clinical service has a procedure for the review of treatment and/or care of clinical service users who are admitted as emergencies.	**E-1.1** **R-3.4**
		4.5.7 The clinical service has a procedure for the management of clinical service user transitions within the clinical service, out of the clinical service, to self-care or to other services.	**S-2.3**

		4.5.8 The clinical service sets, monitors and reviews metrics for routine and emergency admissions.	**R-3.6**
		4.5.9 The clinical service reports the results of the monitoring and review of the metrics (for **4.5.8)** and includes things it is going to improve in a plan.	**None**
		4.5.10 The clinical service provides clinical service users with a named person or point of contact to answer their questions and help **them** navigate the clinical service.	**E-1.6** **R-2.6, R-3.7**
4.6	***Clinical Care***	**4.6.1** The clinical service documents person-centred treatment and/or care plans, based on the needs of the individual clinical service user.	**S-1.3, S-1.6, S-1.8, S-4.4** **E-1.1, E-1.5, E-1.6, E-1.7** **R-2.6**
		4.6.2 The clinical service identifies published clinical pathways for clinical service users and compiles written and visual information for clinical service users to support these clinical pathways.	**E-1.1, E-1.7** **C-2.3** **R-3.5, R5.5**
		4.6.3 The clinical service undertakes and records a clinical risk assessment of individual clinical service users.	**S-1.7, S-2.5, E-1.5, E-5.4** **WL-5.4**
		4.6.4 Identified risks relating to a clinical service user are discussed between clinical teams during handover.	**S-1.7, S-2.4** **E-4.1, E-5.4** **WL-5.4**
		4.6.5 As part of a clinical risk assessment; the clinical service monitors the use of restraint of clinical service users who lack mental capacity, for its necessity and proportionality.	**S-2.7** **E-1.4, E-6.2, E-6.3** **WL-4.5**
		4.6.5 The clinical service offers clinical service users copies of correspondence about their treatment and/or care.	**E-1.5**
		4.6.6 The clinical service conforms to national clinical procedures that require written consent.	**E-6.1, E-6.2,E-6.3**
		4.6.7 The clinical service, where applicable, implements and monitors the use of safety checklists.	**S-2.5, S3.1, S-5.1** **E-4.1**
4.7	***Clinical service performance and feedback***	**4.7.1** The clinical service defines procedures for the measurement of patient report clinical outcomes. (PROMS)	**E-2.1, E2.2, E-2.3** **WL-6.3**
		4.7.2 The clinical service establishes and implements procedures that enable clinical service users to feed back their views on their experience within the clinical service confidentially.	**C-3.3** **R-1.2, R-4.1, R-4.2, R-4.3, R-4.5** **WL-6.1**

		4.7.3 The clinical service informs all clinical service users of how to make comments on, and suggestions for improvements.	**R-4.2** **WL-6.1**
		4.7.4 The clinical service actively encourages clinical service users to provide feedback in confidence, by using a variety of methods.	**C-2.6** **R-1.2, R-4.1, R-4.2, R-4.3, R-4.5, WL-6.1, WL-7.1**
		4.7.5 The clinical service captures, records and investigates concerns and complaints.	**R-1.2** **R-4.1, R-4.3**
		4.7.6 The clinical service triangulates feedback from clinical service users with other feedback and data, and learning from adverse events to make it as accurate as practicable.	**C-2.6** **R-1.2, R-4.1, R-4.2** **R-4.3, R-4.5** **WL-6.1, WL-7.1, W8.3**
4.8	***Improvement plan***	**4.8.1** The clinical service develops and implements an improvement plan with objectives and timescales in response to clinical service user feedback, concerns and complaints.	**R-1.2, R-4.4, R-4.5** **WL-3.5, W8.3**
		4.8.2 Action taken and improvements made by the clinical service in response to clinical service users' views is reported to staff members and made available in summary form to clinical service users and stakeholders on an annual basis.	**R-4.4, R-4.5** **WL-7.2, WL-7.3, WL-8.3, WL-8.4**

5	**Risk and safety**		
	Sub-clause	**Requirement**	**CQC KLOE Map**
5.1	***General***	**5.1.1** The clinical service shall communicate to staff members the individuals who have roles and responsibilities for the management of risks within the clinical service.	**S-1.5, S-1.6, S-1.7, S-6.1, S6.2** **WL-5.4**
		5.1.2 The clinical service implements procedures to safeguard clinical service users in line with organisational requirements and the health and safety of staff members.	**S-1.1, S-1.2,S-1.5, S-1.6, S-1.7** **S-2.7**
		5.1.3 The clinical service communicates findings from risk management activities to staff members including risk mitigation plans, risk reduction activities and the results of risk assessments and associated metrics.	**S-1.1, S1.7, S-2.7, S-6.2** WL-5.4
		5.1.4 The clinical service sets metrics that include nationally and locally agreed indicators and targets for risk reduction to enable benchmarking against similar clinical services.	**S-5.1,S-5.2** **WL-5.4**
		5.1.5 The clinical service publishes safety improvement targets, identified in the metrics set by the clinical service.	**S-5.1**

5.2	***Risk assessment***	**5.2.1** The clinical service, through a programme of risk assessment, identifies and monitors known risks associated with specific clinical procedures; and potential clinical and non-clinical risks at the clinical service level.	**S-2.7, S-5.4** **WL-5.4**
5.3	***Incidents, adverse events and near misses***	**5.3.1** The clinical service has a documented procedure detailing how incidents, adverse events and near misses are reported, managed and investigated.	**S-5.4, S-6.2**
		5.3.2 The clinical service implements and/or uses a reporting system that enables the recording and maintenance of information about incidents, adverse events or near misses, and collation and analysis of data for continued monitoring and evaluation.	**S-5.4, S-6.2** **WL-6.6**
		5.3.3 The clinical service implements a procedure to respond to all incidents, adverse events and near misses. This includes notifying clinical service users affected by adverse events and documenting notification in their records.	**S-3.1, S-6.2**
		5.3.4 The clinical service implements changes in response to identified risks within defined and agreed timescales.	**S-5.1, S-6.3**
5.4	***Registering and recording risks***	**5.4.1** The clinical service records identified risks in a risk register, including non-conformities identified during an internal or external audit or assessment.	**S-1.1, WL-5.1, WL-5.3, WL-5.4**
5.5	***Risk reduction and mitigation***	**5.5.1** The clinical service has risk reduction and mitigation procedures, aligned to those of the organisations involved in the delivery of the clinical service. The outputs of this monitoring process are reviewed on a regular basis.	**S-6.5** **WL-5.3**
5.6	***Lessons learned***	**5.6.1** The clinical service determines how the information and data collected about incidents, adverse events and near misses is used to inform and improve existing treatment and/or care practices within and beyond the clinical service.	**S-5.2, S-6.3**
		5.6.2 The clinical service communicates lessons learned with other clinical services, organisations and national knowledge resources to share knowledge and to mitigate risk.	**S-5.2, S-6.3, S-6.4, S-6.5**

6	**Clinical effectiveness**		
	Sub-clause	**Requirement**	**CQC KLOE Map**
6.1	***General***	**6.1.1** The clinical service, where relevant, identifies and participates in local audit/assessment programmes and national audit/assessment programmes.	**E-2.1, E-2.4, WL-5.3**
6.2	***Quality metrics***	**6.2.1** The clinical service identifies and reviews all guidelines, clinical pathways, quality standards, benchmarking data and KPIs relevant to the clinical service.	**E-2.1** **WL-6.3, WL-6.6**

		6.2.2 The clinical service creates a list of metrics based on national guidance and local need and monitors these continuously.	**E-2.1** **WL-6.3**
6.3	***Monitoring, reviewing and improving quality***	**6.3.1** The clinical service creates a method for capturing, and a process for reviewing, the quality metrics.	**E-2.1** **WL-6.3, WL-6.4**
		6.3.2 The review of metrics includes a comparison with benchmarked data when it is available	**E-2.1, E-2.2, E-2.3** **WL-6.3, WL-6.6**
		6.3.3 The clinical service creates a quality improvement plan based on the review of metrics, which has defined objectives and timescales for completion.	**E-2.2, E-2.4** **WL-6.4**
		6.3.4 The clinical service implements the quality improvement plan and ensures that the plan's objectives have been achieved within agreed timescales.	**E-2.4** **WL-6.3, WL-6.4, WL-8.1**
		6.3.1 The clinical service provides staff members with the support, training and time to undertake improvement initiatives.	**E-2.4** **WL-2.4**
6.4	***Research***	**6.4.1** The clinical service states in the clinical service description whether or not research is carried out and how clinical service users and stakeholders are involved in all stages of research undertaken.	**None**
		6.4.2 The clinical service keeps a register of all research undertaken in the clinical service, including ethics approval, where relevant.	**None**
6.5	***Clinical record keeping***	**6.5.1** The clinical service identifies and conforms with national standards for record keeping as applicable to the clinical service.	**S-3.2**
		6.5.2 The clinical service implements procedures for the validation of the clinical content of data in central returns.	**WL-6.6, WL-6.7**
		6.5.3 The clinical service requires its staff members to collaborate with clinical coders to improve the accuracy of clinical coding.	**WL-6.6, WL-6.7**
		6.5.4 The clinical service checks a random selection of clinical service user records for adherence to national standards, validation of clinical content and accuracy of clinical coding.	**S-3.1**

7	**Clinical service users with complex needs**	
	Sub-clause	**Requirement**
7.1	***Identification***	**7.1.1** The clinical service identifies categories of clinical service users with complex needs and/or problems.	**E-5.1** **R-2.2, R-2.5**

7.2	***Improving care***	**7.2.1** The clinical service identifies ways in which the care and experience of clinical service users with complex needs can be improved cost-effectively and how these improvements can be integrated into relevant clinical pathways and protocols.	WL-5.3
7.3	***Responsibility and coordination of care***	**7.3.1** The clinical service provides staff members with information on the groups of clinical service users with complex needs within the clinical service.	**E-5.1** **R-2.2, R-2.5**
		7.3.2 The clinical service provides staff members with the guidance, resources, training and time required to care for service users with complex needs.	**E-1.6** **R-2.2, R2.5**

8	**Staffing a clinical service**		
	Sub-clause	**Requirement**	**CQC KLOE Map**
8.1	***Workforce planning***	**8.1.1** A review of the workforce in terms of skill mix, and an impact assessment is undertaken a minimum of once a year, or whenever there is a significant change in the clinical service.	**S-2.1**
		8.1.2 The clinical service has a workforce development plan in anticipation of future demands on the clinical service.	**S-2.2**
		8.1.3 When unforeseen circumstances arise in the service where the required skill mix cannot be met, there are processes in place to safeguard clinical service delivery.	**S-2.1, S-2.2** E-3.1 WL-5.3
		8.1.4 The clinical service has a rota and a roster for staff members and the workforce according to clinical service activity and the skill mix required to support it.	**S-2.1, S-2.2, S-2.3,S-2.6** E-3.1
		8.1.5 The clinical service has processes and tools available for collecting data on staff members.	**S-1.4** E-3.5 WL-3.8
8.2	***Recruitment, orientation and induction***	**8.2.1** The clinical service complies with the policies and documented procedures for staff member recruitment of the organisations involved in the delivery of the clinical service, where applicable.	**S-2.3** **WL-4.5**
		8.2.2 The clinical service implements a clinical service-specific orientation and induction programme, which new staff members and those with a change in role, are required to complete and document.	**E-3.3, E-3.4**
		8.2.3 At the completion of the orientation and induction programme the clinical service requests and acts on feedback on the recruitment, orientation and induction processes from staff members.	**None**

8.3	***Continuing professional development (CPD)***	**8.3.1** The clinical service implements an appraisal process for staff members.	**E-3.3, E-3.5** **WL-3.6, WL-5.2**
		8.3.2 The clinical service implements a 360°feedback process for members of the leadership team.	**E-3.5** **W-1.1, WL-3.3, WL-5.2, WL-7.1**
8.4	***Staff member training***	**8.4.1** The clinical service has training plans and training programmes in place for staff members.	**E-3.2, E-3.3, E-3.4** **E3.1, E3.2** **E3.3, E3.4**
		8.4.2 The clinical service implements a process to assess staff members as competent before using techniques and specialist equipment.	**S-2.3** **E-3.4, E-3.5**
		8.4.3 Training that requires interventions outside the clinical service and how this can be resourced is identified in the training plan.	**E-3.2**
		8.4.4 The clinical service has documented procedures in place for staff members who have the responsibility for, and supervision of, students, trainees and observers.	**E-3.3, E-3.4**
		8.4.5 The clinical service maintains outcomes and results of the training undertaken and training records of all educational and professional development activities for staff members.	**E3.2**
8.5	***Development and capability to deliver high quality training***	**8.5.1** Lessons learned and outcomes from training and education are shared with the staff members in the clinical service.	**None**
		8.5.2 The clinical service identifies ways of improving the efficiency and effectiveness of professional development.	WL-5.6
8.6	***Teamwork and staff member support***	**8.6.1** The clinical service implements processes to support staff members in team working and networking with similar clinical services.	**E-4.1** **WL-3.9**
		8.6.2 Staff members are informed of the processes in place to raise concerns about any aspect of the clinical service or clinical team including disrespectful, discriminatory or abusive behaviour or harassment.	**S-6.1** **E-3.5** **WL-3.1, WL-3.4, WL-5.1**
		8.6.3 Clinical team members are supported in generating and implementing ideas for improvement of the clinical service, team, and environment.	**E-3.4** WL-3.9
		8.6.4 The clinical service has processes in place for team members to provide informal and annually submitted formal feedback about the clinical service.	**S-2.6** **WL-3.1, W3.2, W3.3, WL-7.1, WL-8.4**
		8.6.5 The clinical service creates and documents action plans in response to staff member feedback indicating what it does not consider necessary to change, and why, as well as which changes can be made in response to feedback received, and how these can be achieved.	**S-2.6** **WL-3.3,WL-3.9, WL-7.1**

9	Improvement, innovation, and transformation		
	Sub-clause	**Requirement**	**CQC KLOEs Mapping**
9.1	***Improving value: preventing disease and reducing disease burden and costs***	**9.1.1** The clinical service develops and documents a quality improvement plan in accordance with operational aims and objectives and in consultation with staff members.	**E-2.4** **WL-5.3, WL-8.1, WL-8.4, WL-8.5**
9.2	***Improvement***	**9.2.1** The clinical service develops and documents measurable objectives for improvement initiatives.	**E2.6** **W2.8, W5.3, W5.4, WL-8.1, WL-8.4, WL-8.5**
		9.2.2 The clinical service disseminates the quality improvement plan to staff members throughout the clinical service and allocates time, resources and staff member training to achieve it.	**E2.6** **WL-8.1, W8.2**
		9.2.3 The clinical service reviews monitors, reports and evaluates the quality improvement plan and resources required to achieve it.	**WL-8.1, WL-8.4, WL-8.5**
9.3	***Innovation***	**9.3.1** The clinical service develops an innovation programme.	**WL-5.6, WL-8.4, WL-8.5**
		9.3.2 Identified areas of innovation to be implemented are included in the quality improvement plan.	WL-5.6, WL-8.1
9.4	***Transformation***	**9.4.1** The clinical service identifies and carries out an options appraisal of transformation opportunities.	**WL-5.6, WL-8.1**
		9.4.2 The leadership team, in collaboration with service and systems planners and funders, develops and agrees a transformation strategy for the clinical service for opportunities identified. In 9.4.1. The transformation strategy is reviewed once a year as a minimum.	**WL-2.2, WL-2.4, WL-2.5, WL-4.1, WL-7.4, WL-7.5**
		9.4.3 The leadership team, in agreement with stakeholders and organisations, develops plementation plan.	**WL-2.4, WL-2.5, WL-2.6 WL-4.1, WL-7.2, WL-7.3, WL-7.4, WL-7.5**
9.5	***Evaluation***	**9.5.1** The leadership team evaluates improvement, innovation and transformation activities, collating information and data to support future change.	**WL-2.5, WL-4.1**

10	Educating the future workforce		
	Sub-clause	**Requirement**	**CQC KLOE Map**

10.1	***Leadership, culture and ethos of education and training***	**10.1.1** Where students and trainees form part of a clinical service, the clinical service shall conform to requirements **10.1** to **10.6** inclusive.	**None**
		10.1.2 The clinical service shall have a staff member with overall responsibility for students and trainees.	**None**
		10.1.3 Students and trainees are informed of the procedures in place to raise concerns about disrespectful, discriminatory or abusive behaviour, or harassment.	**WL-3.4,** WL-5.1
		10.1.4 The clinical service shall notify clinical service users of the clinical service's responsibility for training the future workforce.	**None**
10.2	***Quality of teaching and training***	**10.2.1** The clinical service assesses, prior to allocation to a student or trainee, that mentors, teachers and trainers are competent to undertake the training role, willing to teach and have the time to train and meet the needs of the relevant curricula.	**None**
10.3	***Resources***	**10.3.1** The clinical service determines the resources required for the training of students and trainees to meet the curricula.	**None**
10.4	***Organisation of training for future workforce***	**10.4.1** The clinical service provides students and trainees with a description of what they should expect of their training experience.	**None**
		10.4.2 The clinical service provides students and trainees with a training plan that meets the expected curricula as set out and agreed with the relevant institution(s).	**None**
		10.4.3 The clinical service allows students and trainees opportunities to discuss and resolve any differences in expectations of training provision within the training plan.	**None**
10.5	***Assessment and supervision***	**10.5.1** The clinical service acts in accordance with the guidance for assessment issued by the commissioners of training and informs the students and trainees of the assessment process.	**None**
10.6	***Feedback***	**10.6.1** The clinical service seeks, reviews and acts on feedback from students and trainees on their training within the clinical service.	**WL-7.1**
		10.6.2 The clinical service uses feedback from students and trainees to carry out improvements to the training plan.	**WL-7.1**