Policy for the Introduction of New Procedures, Techniques or Major Changes in Clinical Practice within SFT

Introduction of New Health Technologies

1. Aims

This Policy seeks to inform and guide Trust staff wishing to propose the introduction of new procedures or techniques to the Trust, or who wish to implement major changes in clinical practice, by detailing some of the relevant issues and outlining the process by which proposals will be considered.

2. Definitions and Scope

NICE define an interventional procedure as a procedure used for diagnosis or for treatment that involves:

- making a cut or a hole to gain access to the inside of a patient's body - for example, when carrying out an operation or inserting a tube into a blood vessel, or
- gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body - for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth, or
- using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) - for example, using a laser to treat eye problems.

For this purpose, in this Trust, new procedures include:

- New techniques including major modifications of current procedures.
- Established procedures which are new to the Trust, even when the consultant is experienced in this procedure.
- Established procedures which are new to the consultant who is using it for the first time in his or her NHS practice.
- New devices e.g. Prosthesis.

N.B.

Expanded practice for Nurses and Other Health Professionals is covered under the Framework for Developing an EPP Policy

Major changes in clinical practice or changes to published Trust guidelines are considered by the Clinical Effectiveness Steering group through the approval process.

For the purposes of this Policy, all new procedures; techniques or major changes in clinical practice are referred to as ‘new procedures’.

3. Background

Medical practitioners planning to undertake new interventional procedures should seek approval from the Trust’s Trust Management Committee before doing so. In a case where the procedure has to be used in an emergency, the procedure should be notified to the Chair of the Trust Management Committee and Chief Medical Officer within 72 hours.

The Trust may consider a number of cases when making decisions on whether to approve the introduction of new procedures, techniques or major changes in clinical practice. These include the clinical case, the business case and the commercial case. Not all applications will require the completion of a commercial case or business case.

4. Process

The Trust Management Committee will review clinical, business and commercial cases when considering whether to approve proposals submitted under this Policy. It is anticipated that all proposals should consist of a clinical and business case, though proposals that have minimal financial implications may not require the presentation of a full business case. Proposals concerning major changes to practice which may potentially impact on networked or regional service provision should also include a commercial case.

All business cases MUST be presented to the Trust Investment Group (TIG) for approval, with the clinical case, before proceeding to the Trust Management Committee.

Should there be significant doubt whether a commercial case will need to be presented, an opinion from the Trust Management Committee should be sought prior to submission. An application will be considered incomplete unless all cases are presented to the Trust Management Committee simultaneously.

The essential elements of each case are outlined below.

Clinical case

This will be prepared chiefly by the proposing clinician with assistance from the Clinical Service Lead and/or Clinical Director. The clinical case seeks to establish the clinical effectiveness (including relevant NICE guidance), training and mentoring needs, safety and risk management concerns, patient information and consent and clinical audit plans of the proposed change. The application form template for the clinical case is here https://app.eolasmedical.com/organisation/landing/null?organisationId=ORG%23staging-salisbury-nhs-foundation-trust%231120b4c7-8856-4520-934a-f2778c95fc7a&fileId=FILE%233e5b883b-ceeb-4ce5-9f84-579f8a1df001&origin=section

All clinical cases MUST be presented to the Clinical Effectiveness Steering Group (CESG) for approval before proceeding to the Trust Management Committee.

Business case

This will be prepared chiefly by the proposing clinician in conjunction with the appropriate Divisional Management Committee, with input especially from the Divisional Manager and Divisional Finance Manager. The business case seeks to establish the fundamental financial viability of the proposed change by detailing all costs, including equipment and workforce, associated with the proposed change together with agreed commissioner funding arrangements and any other financial concerns. A guide to the business case format is here: How to write a business plan: https://app.eolasmedical.com/organisation/landing/null?organisationId=ORG%23staging-salisbury-nhs-foundation-trust%231120b4c7-8856-4520-934a-f2778c95fc7a&fileId=FILE%230adccdd7-d486-4723-b867-4a9d503d6835&origin=section

All business cases MUST be presented to the Trust Investment Group (TIG) for approval before proceeding to the Trust Management Committee.

Commercial case

The commercial case will be prepared by the proposing clinician and/or Divisional Manager and will seek to establish whether the proposed changes are congruent with the Trust's strategy and whether they merit the completion of a local or regional competitor analysis. A commercial case will not usually need to be made for changes unlikely to substantially alter existing service demand.

5. Roles and Responsibilities

Clinical Governance Committee (CGC)

The Clinical Governance Committee will act on behalf of the Trust Board to assure the Trust that there is compliance with the policy. The Committee will receive annual reports each July.

Trust Management Committee (TMC)

The Committee will approve all new procedures, ensuring that the clinical, business and, where indicated, commercial cases have been made to its satisfaction.

Once approved, the Committee will ensure that the clinician introducing the procedure returns to the TMC at a specified interval with an evaluation of the safety, effectiveness and cost-effectiveness of the procedure.

Head of Clinical Effectiveness

Will oversee the process for completion of the application form ensuring that the clinical governance aspects of operator competence, consent process, patient information, audit and an evaluation process are in place.

Will ensure approved procedures are added to the Trust 'new procedures' database.

Will produce an annual report for the Clinical Governance Committee, on compliance with the Policy including procedure audit results, reported incidents and concerns.

Clinical Director and Divisional Manager

Will assist clinicians with identifying costs for example, training in the new procedure, additional workforce requirements, additional theatre space and preparation of a business case.

Will ensure the development is included in the Divisional service plan when approved by the Trust Management Committee. Submissions outside the service development plan will only be considered in exceptional circumstances.

Divisional Managers need to identify the source of revenue and capital funding for the new procedure including funding provided by commercial and other organisations and describe these in the business case.

Lead Clinician

Will discuss the proposal with the relevant Clinical Director, Head of Nursing (if a nursing procedure) and Divisional Manager and if appropriate the relevant commissioning body (ICB), and agree to support or not.

Will ensure that other departments and disciplines that may be affected by the development have been involved in the application form and provide details in the business case.

Clinician introducing the procedure

Will check whether the procedure has been evaluated or approved by NICE, by visiting their website www.nice.org.uk/guidance

Will check if the new procedure requires any products to be brought into the Trust. If this is the case, the Medical Devices Management Services (MDMS) must be made aware so that they can check Indemnity status and advise on how to proceed with regard to recording of those products, the duration in the Trust, and if there is a need for Portable Appliance Testing (PAT) review or decontamination.

Will complete application form (see Application form: https://app.eolasmedical.com/organisation/landing/null?organisationId=ORG%23staging-salisbury-nhs-foundation-trust%231120b4c7-8856-4520-934a-f2778c95fc7a&fileId=FILE%233e5b883b-ceeb-4ce5-9f84-579f8a1df001&origin=section), including gaining signatures indicating clinical case approval from Lead Clinician, Divisional Medical Director, Divisional Manager, Divisional Finance Manager and Chief Medical Officer

Will send copy of completed application to Head of Clinical Effectiveness for inclusion on new procedures database.

Keep patient informed - in all cases it is the responsibility of the clinician using a new health procedure to ensure that his or her patient is fully informed of the risks and benefits of the technique supported by full written consent indicating that they are fully informed.

Will agree to undertake a clinical audit of the outcome of the use of the new procedure within one year of introduction into practice.

Will return to the Trust Management Committee (TMC) at a specified interval after the new procedure has been approved by the TMC with an evaluation of the safety, effectiveness and cost-effectiveness of the procedure.

6. Process for monitoring compliance and effectiveness

Clinical Audit

An audit of the new procedure will be undertaken no more than one year after its introduction. The results will be presented to the Trust Management Committee.

Risk Management

Should any potential risks be identified, these will be reported by the Divisional Management Committee at the Executive Performance Review meeting. A risk assessment and addition to the risk register may be required.

Reporting

The Clinical Governance Committee will receive an annual report in July of all new procedures approved in the preceding year, together with information on audits undertaken.

Any new procedures approved in the preceding six months will be reported to the Clinical Management Board and Operational Management Board on a bi-annual basis in April and October.

7. References and associated documents

7.1 Sources of Information

National Institute for Health and Care Excellence https://www.nice.org.uk/

Into Practice Guide National Institute for Health and Care Excellence https://www.nice.org.uk/about/what-we-do/into-practice/resources-help-put-guidance-into-practice

Integrated Governance Framework Salisbury NHS Foundation Trust (March 2019)

Accountability Framework Salisbury NHS Foundation Trust (March 2019)

National Institute for Health and Care Excellence (NICE) Process for Dissemination, Implementation and Monitoring - Salisbury NHS Foundation Trust

Risk Management Policy & Procedure (Eolas) Salisbury NHS Foundation Trust

Developing Patient Information Salisbury NHS Foundation Trust

Framework for Developing an Expanded Practice Protocol Salisbury NHS Foundation Trust

8. Equality Analysis

An Equality Analysis was undertaken on 1 June 2020.

Job role and meeting titles reviewed: September 2022.

April 2026 - Policy being reviewed & updated by Ben Browne.