Leicestershire Partnership NHS Trust

# Policy for the Development of Local Procedural Documents for Clinical Diagnostic Tests and Screening Procedure

This document provides Trust-wide guidance for the development of local procedures designed to manage the risks associated with the process of clinical diagnostic testing and screening

**Key words:** Diagnostic, screening, procedure

**Version:** 6

**Approved by:** Clinical Effectiveness Group

**Ratified By:** Quality Forum

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**Type of Policy:** Clinical

Please add if this policy is sensitive and cannot be made Public on the website.

## Contents

# Policy On A Page

## SUMMARY & AIM

This policy provides organisation-wide guidance for the development of local procedures and is designed to manage the risks associated with the process of clinical diagnostic testing and screening.

This policy aims to enable all staff to ensure that all diagnostic tests undertaken within the Trust are managed to minimise the risk to patients and improve the patient outcome and quality of care. The purpose of this policy is to provide a framework for the Trust to ensure robust systems are in place for the communication of diagnostic testing. This includes ensuring that all specialties have in place a suitable Standard Operating Procedure (SOP) which outlines the process for the communication (both dissemination and receipt) of diagnostic results, in particular urgent or unexpected findings.

## TARGET AUDIENCE:

- Requesting clinicians
- Clinical Service Managers
- Members of DMT

## TRAINING

No further training needs have been identified.

## KEY REQUIREMENTS

Each clinical area is required to review the clinical diagnostic tests and screening procedures undertaken within the service to determine the focus of the local procedural documents.

Each clinical area of LPT is required to produce local guidance to provide direction for healthcare staff in relation to their duties and the procedures to be adopted for clinical diagnostic testing and screening.

The clinician who requests a test is responsible for reviewing, acting and communicating the result and taking appropriate action, even if the patient has been discharged from care at the point the result is received.

Areas of concern as highlighted through incident reporting system should be reviewed for compliance with the policy and escalated through from Directorate to the Clinical Effectiveness Group.

The principles of shared decision making should also form part of these processes – Patients should have the reason for the test discussed with them and be informed of the results even if they are within normal limits

## 1.0 Quick look summary

This policy aims to enable all staff to ensure that all diagnostic tests undertaken within the Trust are managed to minimise the risk to patients and improve the patient outcome and quality of care. The purpose of this policy is to provide a framework for the Trust to ensure robust systems are in place for the communication of diagnostic testing.

### 1.1 Version control and summary of changes

| Version number | Date | Comments (description change and amendments) |
|---|---|---|
| 1 | August 2012 | Harmonisation |
| 2 | March 2013 | Information Update of Clinical Governance Leads |
| 3 | February 2016 | Reviewed by PSG. No changes to content required |
| 4 | December 2018 | Routine review of policy |
| 5 | February 2022 | Routine review of policy |
| 6 | August 2024 | Routine review of policy, including wider input from Healthwatch |

### 1.2 Key individuals involved in developing and consulting on the document

- Heather Darlow, Trust Lead for QI and Quality Governance
- Tracy Ward, Head of Patient Safety
- Saskya Falope, Head of Nursing, DMH
- Zayad SAUMTALLY, Head of Nursing, FYPCLDA
- Sarah Latham, Head of Nursing, CHS
- Hari Subramaniam, Deputy Medical Director
- Sam Hamer, Associate Medical Director
- Lynn MacDiarmid, Consultant Nurse
- Graham Johnson, Associate Clinical Director
- Rohit Gumber, Associate Medical Director
- Emma Wallis, Deputy Director of Nursing and Quality
- Michelle Churchard, Deputy Director of Nursing and Quality
- Tracey Allan-Jones, Healthwatch Manager on behalf of Healthwatch Rutland
- Trust Policy Experts

## 1.2 Governance

**Level 2 or 3 approving delivery group – Clinical Effectiveness Group**

**Level 1 Committee to ratify policy – Quality Forum**

## 1.3 Equality Statement

Leicestershire Partnership NHS Trust (LPT) aims to design and implement policy documents that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account the provisions of the Equality Act 2010 and promotes equal opportunities for all. This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity.

If you would like a copy of this document in any other format, please contact lpt.corporateaffairs@nhs.net

## 1.4 Due Regard

LPT will ensure that due regard for equality is taken and as such will undertake an analysis of equality (assessment of impact) on existing and new policies in line with the Equality Act 2010. This process will help to ensure that:

- Strategies, policies and procedures and services are free from discrimination.
- LPT complies with current equality legislation.
- Due regard is given to equality in decision making and subsequent processes.
- Opportunities for promoting equality are identified.

Please refer to due regard assessment (Appendix 4) of this policy

## 1.6 Definitions that apply to this policy

**Consent:** a patient's agreement for a health professional to provide care. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing. For the consent to be valid, the patient must:

- be competent to take the particular decision;
- have received sufficient information to take it and not be acting under duress.

**Due Regard:** Having due regard for advancing equality involves:

- Removing or minimising disadvantages suffered by people due to their protected characteristics.
- Taking steps to meet the needs of people from protected groups where these are different from the needs of other people. Encouraging people from protected groups to participate in public life or in other activities where their participation is disproportionately low.

## 2.0 Purpose and Introduction/Why we need this policy

This document acknowledges the risks associated with the process of diagnostic testing and screening procedures and describes the LPT wide process for the development of Service Specific Local Procedure /Standard Operating Procedures (SOPs) to manage these risks and improve the quality of care. Inadequate referral information, poor communication of test results to the requester and inadequate arrangements for the follow up by requesters are all acknowledged as national patient safety issues. This document provides robust organisation-wide guidance on how to develop specific guidance to support local processes of requesting, undertaking, verifying and communicating the results of all diagnostic tests and screening procedures. Acknowledgement is giving to the role of carers in supporting the sharing and understanding of diagnostic testing for their loved ones.

This policy sets LPT's intentions in relation to the minimum standards and procedures for the process of communicating the results of diagnostic tests.

As part of the patient safety strategy published in July 2019, involvement of patients and families in providing safer care is key. As such feedback in the communication of the results of diagnostic tests should be reinforced in all contacts and patients actively encouraged to ensure they receive the results from their tests be they normal or not.

As part of the fundamental standards and Regulation 17: Good Governance, the CQC would expect to see a process, not only the safe handling and recording of results but how we safely manage the patients care i.e that we receive the results, act on them and inform the patient.

World Patient Safety Day on 17th September 2024 highlighted improving diagnosis for patient safety including the importance of listening to patients as well as accessibility and timeliness.

NICE NG197 Shared decision-making guideline, covers how to make shared decision making part of everyday care in all healthcare settings. It promotes ways for healthcare professionals and people using services to work together to make decisions about treatment and care. It includes recommendations on training, communicating risks, benefits and consequences, using decision aids, and how to

embed shared decision making in organisational culture and practices.

## 3.0 Policy Requirements

The objectives and intended outcomes of establishing robust processes for all clinical diagnostic tests and screening procedures are:

- That the clinical diagnostic test or screening procedure is appropriate for the patient's requirements;
- To consider when diagnosis can be made on clinical presentation alone;
- The procedures/structures in place for the clinical diagnostic test or screening procedure are identified;
- To identify healthcare staff with the authority to authorise/proceed with the test or screening procedure;
- To consider stating those that may not have authority;
- To describe the process regarding informed consent which should involve a verbal discussion and the use of patient/service user information where appropriate, giving due consideration to confidentiality and the specific needs of the patient/service user. Where a patient does not have capacity to consent the consent policy should be referred to for guidance. Reference should be made to the LPT Accessible Information Standard policy for further guidance.
- That there are systems in place to ensure that the sample(s), where relevant, have been taken, correctly labelled, prepared, transported and dispatched to comply with the agreed protocols/standing operating procedures (SOPs) of the service;
- That the organisation may consider, when it is appropriate, to request an acknowledgement from the receiving laboratory for specific samples be it verbal or written;
- That the clinical diagnostic test or screening result is received by the appropriate manual/electronic system;
- To agree the mechanism by which the dissemination of the clinical diagnostic test or screening result is made, i.e. by telephone, by paper or by electronic means;
- To agree the mechanism for all patient/service users who undergo a clinical diagnostic test or screening procedure to

be informed of their results (including a screen negative or low risk result), pre- advised of the expected time frame for feedback of results and actively encouraged to enquire when results are not received within agreed timeframes;

- To agree the mechanism for all patient/service users who receive a screen positive result or high risk result to have access to an appropriately trained healthcare professional to discuss options for further management;

- To agree the mechanism for recording the outcome and any subsequent follow up required (ensuring arrangements are clear when the requestor is not available);

- That all clinical diagnostic test or screening processes are the subject of effective systems of monitoring, evaluation, and review.

- The consideration of time frames for communicating high risk results including a clear escalation route for the patient if the expected timeframe is breached.

- Where follow up appointments are needed following results given, there should be a clear requirement for offering patient choice of site where possible.

- The role of carers should be acknowledged in all associated SOPs and policies and that their role is essential and that appropriate information sharing protocols are considered where appropriate.

## 3.1 Standard Operating Procedure for the management of diagnostic tests

- Each Directorate or clinical area if appropriate, that is in receipt of diagnostic tests should have in place a clear procedure/SOP which details how to request tests and access the systems to do so. There is flexibility for services to define what procedure works best for the; however they should in all cases outline their standards as detailed below. It is best practice for the SOP to include the following information as a minimum and should highlight any risks with the agreed process.

a) Patient consent to test
b) The requesting of diagnostic tests
c) The receiving and reviewing of diagnostic tests
d) Missing test results
e) Delayed test results
f) Interpreting of diagnostic test results

g) Actioning diagnostic test results
h) Recording actions taken, in particular urgent or unexpected findings
i) MDTs
j) Informing the patient of the results
k) Incorrect results or misdiagnosis
l) Filing, storing and retention of diagnostic test results

# 4.0 Duties within the Organisation

## 4.1 The Requesting Clinician

The clinician who requests a test is responsible for reviewing, acting and communicating the result and taking appropriate action, even if the patient has been discharged from care at the point the result is received.

As a minimum the requesting clinician should:

- acknowledge the results;
- read and act upon and document the results in the patients' record.
- have a clear process as to how to access reports for tests/examinations that have been requested;
- ensure that all test requests are documented in the EPR (Electronic Patient Record) for each individual patient including when they were reviewed and acted upon;
- have a robust system in place for handover to ensure that in their absence the diagnostic tests they have requested are followed up. Additionally, a robust handover should be in place whereby tests requested that have not have not yet been reported on are identified as outstanding at the point of handover.
- Have a process for feeding back to patients
- Understanding the 'digital preference' of patients should be considered to ensure that any digital-first drive does not disadvantage patients unable to access tech/devices.

## 4.2 Clinical Service Lead

- Ensure that their clinical area, if appropriate has in place a SOP which clearly outlines the principles of practice in relation to diagnostic testing and that this is followed

## 4.3 Directorate Management Team

- Ensuring appropriate assurance and oversight that a Standard Operating Procedure for the Management of Diagnostic Tests are

developed when required in their designated areas within their scope of responsibility.

### 4.4 Clinical Effectiveness Group

- Responsible for overseeing the delivery of this policy and monitoring compliance

## 5.0 Consent

Clinical staff must ensure that consent has been sought and obtained before any care, intervention or treatment described in this policy is delivered. Consent can be given orally and/ or in writing. Someone could also give non-verbal consent if they understand the treatment or care about to take place. Consent must be voluntary and informed and the person consenting must have the capacity to make the decision.

In the event that the patient's capacity to consent is in doubt, clinical staff must ensure that a mental capacity assessment is completed and recorded. Someone with an impairment of or a disturbance in the functioning of the mind or brain is thought to lack the mental capacity to give informed consent if they cannot do one of the following:

- Understand information about the decision
- Remember that information
- Use the information to make the decision
- Communicate the decision

## 6.0 Monitoring Compliance and Effectiveness

Monitoring tools must be built into all procedural documents in order that compliance and effectiveness can be demonstrated.

Be realistic with the amount of monitoring you need to do and time scales

| Page/Section | Minimum Requirements to monitor | Method for Monitoring | Responsible Individual /Group | Where results and any Associate Action Plan will be reported to, implemented and monitored; (this will usually be via the relevant Governance Group). Frequency of monitoring |
|---|---|---|---|---|
| | Standard operating procedure for diagnostic testing to be in place for each Directorate or clinical area as appropriate | Assurances provided and reported through directorate highlight reports to CEG | CEG | Annual |
| | Review of Incidents and TCS for themes and learning regarding 3.1 | Learning identified reported through directorate highlight reports to CEG | CEG | As and when |

## 7.0 References and Bibliography

NICE NG197 Shared decision making, https://www.nice.org.uk/guidance/ng197, and this is the introductory paragraph from the main page of the website.

LPT Accessible Information Standard policy

Department of Health. (2007). Priority Areas First Round - 03. London: Department of Health. Available at: www.dh.gov.uk

Department of Health. (2007). Transport of Infectious Substances – best practice guidance for microbiology laboratories. London: Department of Health. Available at: www.dh.gov.uk

National Patient Safety Agency. (2004). Right patient – right care. London: National Patient Safety Agency. Available at: www.npsa.nhs.uk

• Infection Prevention and Control Policy for Managing and Transporting Specimens

• Consent to treatment policy

Care Quality Commission, Safe Care and Treatment

## 8.0 Fraud, Bribery and Corruption consideration

The Trust has a zero-tolerance approach to fraud, bribery and corruption in all areas of our work and it is important that this is reflected through all policies and procedures to mitigate these risks.

Fraud relates to a dishonest representation, failure to disclose information or abuse of position in order to make a gain or cause a loss. Bribery involves the giving or receiving of gifts or money in return for improper performance. Corruption relates to dishonest or fraudulent conduct by those in power.

Any procedure incurring costs or fees or involving the procurement or provision of goods or service, may be susceptible to fraud, bribery, or corruption so provision should be made within the policy to safeguard against these.

If there is a potential that the policy being written, amended or updated controls a procedure for which there is a potential of fraud, bribery, or corruption to occur you should contact the Trusts Local Counter Fraud Specialist (LCFS) for assistance.

## Appendix 1 Training Needs Analysis

| **Training topic:** | Delete answers that are not applicable * | |
|---|---|---|
| Type of training: (see study leave policy) | Not Required^ | |
| Directorate to which the training is applicable: | | |
| Staff groups who require the training: | | |
| Regularity of Update requirement: | | |
| Who is responsible for delivery of this training? | | |
| Have resources been identified? | | |
| Has a training plan been agreed? | | |
| Where will completion of this training be recorded? | | |
| How is this training going to be monitored? | | |
| **Signed by Learning and Development Approval name and date** | | Date: |

## Appendix 2 The NHS Constitution

- The NHS will provide a universal service for all based on clinical need, not ability to pay.
- The NHS will provide a comprehensive range of services.

**Shape its services around the needs and preferences of individual patients, their families and their carers  Answer yes**

**Respond to different needs of different sectors of the population  yes**

**Work continuously to improve quality services and to minimise errors  yes**

**Support and value its staff  yes**

**Work together with others to ensure a seamless service for patients  yes**

**Help keep people healthy and work to reduce health inequalities  yes**

**Respect the confidentiality of individual patients and provide open access to information about services, treatment and performance  yes**

## Appendix 3 Due Regard Screening Template

| Section 1 | |
|---|---|
| Name of activity/proposal | Development of Local Procedural Documents for Clinical Diagnostic Tests and Screening Procedures |
| Date Screening commenced | September 2024 |
| Directorate / Service carrying out the assessment | Enabling |
| Name and role of person undertaking this Due Regard (Equality Analysis) | Heather Darlow, Trust Lead for QI and Quality Governance |
| Give an overview of the aims, objectives and purpose of the proposal: | |
| AIMS:<br>The aim of the document is to ensure that all clinical diagnostic tests and screening procedures undertaken within the organisation are appropriately managed to minimise the risk to patients and to improve patient outcome and quality of care. It emphasises clear communication and record keeping. | |
| OBJECTIVES:<br>Clinical diagnostic testing and screening procedure is appropriate for the patient's requirements. | |

| Section 2 | |
|---|---|
| Protected Characteristic | If the proposal/s have a positive or negative impact please give brief details |
| Age | NA |
| Disability | NA |
| Gender reassignment | NA |
| Marriage & Civil Partnership | NA |
| Pregnancy & Maternity | NA |
| Race | NA |
| Religion and Belief | NA |
| Sex | NA |
| Sexual Orientation | NA |
| Other equality groups? | NA |

| Section 3 | |
|---|---|
| Does this activity propose major changes in terms of scale or significance for LPT? For example, is there a clear indication that, although the proposal is minor it is likely to have a major affect for people from an equality group/s? Please tick appropriate box below. | |
| Yes | No ☑ |
| High risk: Complete a full EIA starting click here to proceed to Part B | Low risk: Go to Section 4. |

| Section 4 |
|---|
| If this proposal is low risk please give evidence or justification for how you reached this decision: |
| No impact established in the introduction of this policy. |

| | | | |
|---|---|---|---|
| Signed by reviewer/assessor | Heather Darlow | Date | 12th September 2024 |
| *Sign off that this proposal is low risk and does not require a full Equality Analysis* | | | |
| Head of Service Signed | Heather Darlow | Date | 12th September 2024 |

## Appendix 4 Data Privacy Impact Assessment Screening

| | | |
|---|---|---|
| Data Privacy impact assessment (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet Individual's expectations of privacy.<br>The following screening questions will help the Trust determine if there are any privacy issues associated with the implementation of the Policy. Answering 'yes' to any of these questions is an indication that a DPIA may be a useful exercise. An explanation for the answers will assist with the determination as to whether a full DPIA is required which will require senior management support, at this stage the Head of Data Privacy must be involved. | | |
| **Name of Document:** | **Development of Local Procedural Documents for Clinical Diagnostic Tests and Screening Procedures** | |
| **Completed by:** | **Heather Darlow** | |
| **Job title** | **Trust Lead for QI and Quality Governance** | **Date 12th September 2024** |
| **Screening Questions** | **Yes / No** | **Explanatory Note** |
| **1.** Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document. | No | |
| **2.** Will the process described in the document compel individuals to provide information about them? This is information in excess of what is required to carry out the process described within the document. | No | |
| **3.** Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information as part of the process described in this document? | No | |
| **4.** Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used? | No | |
| **5.** Does the process outlined in this document involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics. | No | |
| **6.** Will the process outlined in this document result in decisions being made or action taken against individuals in ways which can have a significant impact on them? | No | |
| **7.** As part of the process outlined in this document, is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or | No | |

| | | |
|---|---|---|
| other information that people would consider to be particularly private. | | |
| **8.** Will the process require you to contact individuals in ways which they may find intrusive? | No | |
| **If the answer to any of these questions is 'Yes' please contact the Data Privacy Team via Lpt-dataprivacy@leicspart.secure.nhs.uk In this case, ratification of a procedural document will not take place until review by the Head of Data Privacy.** | | |
| **Data Privacy approval name:** | | |
| **Date of approval** | | |

Acknowledgement: This is based on the work of Princess Alexandra Hospital NHS Trust