Leicestershire Partnership NHS Trust

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

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

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Name of Author:	Heather Darlow, Head of Clinical Quality and Governance	
Name of responsible committee:	Clinical Effectiveness Group	
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Type of Policy	Clinical ✔	Non Clinical
Which Relevant CQC Fundamental Standards?	Regulation 12: Safe Care and Treatment	

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 the policy

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E : LPT.policy@nhs.uk

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 advances 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, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

In carrying out its functions, LPT must have due regard to the different needs of different protected equality groups in their area. This applies to all the activities for which LPT is responsible, including policy development, review and implementation.

Due Regard

The Trusts commitment to equality means that this policy has been screened in relation to paying due regard to the general duty of the Equality Act 2010 to eliminate unlawful discrimination, harassment and victimization and advance equality of opportunity and foster good relations.

This is evidenced by ensuring that relevant processes for consent to any form of clinical intervention have been followed.

In addition to the examples highlighted above, equality monitoring of all relevant protected characteristics to whom the policy applies will be undertaken. Robust actions to reduce, mitigate and where possible remove any adverse impact will be agreed and effectively monitored.

This policy will be continually reviewed to ensure any inequality of opportunity for service users, patients, carers and staff is eliminated wherever possible.

Definitions that apply to this Policy

Diagnostic tests	A test or investigation such as pathology tests, imaging and endoscopy performed to determine diagnoses; monitor patients during treatments and to inform future treatment options.
Screening	Screening is a process of identifying apparently healthy people who may be at increased risk of a disease of condition. They can then be offered information, further tests and appropriate treatment to reduce their risk and /or any complications arising from the disease of condition.
Non Invasive Procedures	A procedure that does not penetrate the body, for example ultra sound and X-Ray
Minimally Invasive Procedures	A procedure (surgical or otherwise) that is less invasive than open surgery, for example taking blood for screening tests.
Invasive Procedures	A procedure requiring insertion of an instrument, device or substance (like a contrast medium) into the body through the skin or a body orifice.
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.

1. Summary

This document 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.

We need to be assured that standards are in place to support the process of requesting, undertaking, verifying and for the purposes of this policy – communicating the results; both amongst the appropriate clinical colleagues and equally as important to the patients**.**

2. Clinical Areas in LPT

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.

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 (see **Appendix 1** - Lists of example clinical diagnostic tests and screening procedures undertaken by clinical area).

3. Introduction

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

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 new patient safety strategy published in July 2019 involvement of patients and families in providing safer care is key. As such feedback in the communicating 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

4. Scope of the Policy

Diagnostic tests can be used to determine what conditions, diseases or syndromes a patient has or is likely to develop. These tests are integral to the management of patients and their associated conditions. Because of the variety of tests employed, the range of professional reviews and the subsequent actions that may occur, there is an absolute need for clear pathways that identify how, when and whom the tests should be communicated to and what action they should take upon receipt.

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.

This policy applies to all service leads in each clinical area with responsibility for establishing safe processes for managing the delivery of clinical diagnostic testing and screening procedures within Leicestershire Partnership NHS Trust.

Examples of the clinical diagnostic tests and screening procedures undertaken in each of the clinical areas are listed in appendix two.

5. Roles and responsibilities

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

Clinical Service Leads

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

Directorate Directors and Managers

- 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.

Clinical Effectiveness Group

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

6. Clinical Diagnostic Tests and Screening Procedures

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

7. Standard Operating Procedure for the management of diagnostic tests

- Each Directorate or Specialty 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 within each SOP for services to define what procedure works best for them; 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) The requesting of diagnostic tests
  b) The receiving and reviewing of diagnostic tests
  c) Missing test results
  d) Delayed test results
  e) Interpreting of diagnostic test results
  f) Actioning diagnostic test results
  g) Recording actions taken, in particular urgent or unexpected findings
  h) MDTs
  i) Informing the patient of the results
  j) Incorrect results or misdiagnosis
  k) Filing, storing and retention of diagnostic test results

8. Implementation Plan and Training Requirements

Support will be provided to those individuals responsible for developing local procedural documents by the Head of Clinical Quality and Governance.

No further training needs identified

9. Monitoring compliance/Audit Arrangements

Ref	Minimum Requirements	Evidence for Self-assessment	Process for Monitoring	Responsible Individual / Group	Frequency of monitoring
	Standard operating procedure for diagnostic testing to be in place for each clinical area	Assurances provided and reported through directorate highlight reports to CEG	Directorate governance arrangements	CEG	Annually
	Review of Incidents and TCS for themes and learning regarding diagnostic testing	Learning identified reported through directorate highlight reports to CEG	Directorate governance arrangements	CEG	As and when

10. References and Link to other documents

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

Appendix -1 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	February 2019
Directorate / Service carrying out the assessment	Patient Safety Group
Name and role of person undertaking this Due Regard (Equality Analysis)	Anthony Oxley
Give an overview of the aims, objectives and purpose of the proposal:	
AIMS: 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: 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	
Disability	
Gender reassignment	
Marriage & Civil Partnership	
Pregnancy & Maternity	
Race	
Religion and Belief	
Sex	
Sexual Orientation	
Other equality groups?	

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 <u>tick</u> 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:			
Discussion at PSG			
Signed by reviewer/assessor		**Date**	
Sign off that this proposal is low risk and does not require a full Equality Analysis			
Head of Service Signed		**Date**	

Appendix - 2 List of Clinical Diagnostic Tests and screening procedures

The list below shows some of the most commonly used diagnostic and screening procedures. The list is not exhaustive and only provides an indication of the range of clinical diagnostic tests, measures and screening procedures undertaken.

6-8 week neonatal check
Alcohol Screening
Bladder scanning
Blood glucose
Blood pressure
Bloods for Microbiology
Bloods for Haematology
Bloods for Biochemistry
BMI
Chlamydia screening
Dementia Screening
Doppler scans
ECG
GADS – Gilliam Asperger's Disorder Scale
GARS – Gilliam Autism Rating
Mental Health Screening
Oxygen saturation
Peak flow
Post Natal Check
Pregnancy testing
Respiratory rate
Temperature
Urinalysis
X-ray

Appendix – 3 SOP Template

All services to be covered by a Standard Operating Procedure for the Management of Diagnostic Tests

LPT SOP template to be followed detailing the process to include:

- Requesting clinical and screening tests
- Receiving, reporting and interpretating clinical and screening results
- Reporting clinical and screening test issues

SOP Template - Mar 20.doc

Appendix - 4 Training Needs Analysis

Training Required	YES	NO✓
Training topic:		
Type of training: (see study leave policy)	☐ Mandatory (must be on mandatory training register) ☐ Role specific ☐ Personal development	
Directorate(s) to which the training is applicable:	☐ Adult Mental Health & Learning Disability Services ☐ Community Health Services ☐ Enabling Services ☐ Families Young People Children ☐ Hosted Services	
Staff groups who require the training:	*Please specify…*	
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?	☐ ULearn ☐ Other (please specify)	
How is this training going to be monitored?		

Appendix - 5 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	☐✓
Respond to different needs of different sectors of the population	☐✓
Work continuously to improve quality services and to minimise errors	☐✓
Support and value its staff	☐✓
Work together with others to ensure a seamless service for patients	☐✓
Help keep people healthy and work to reduce health inequalities	☐✓
Respect the confidentiality of individual patients and provide open access to information about services, treatment and performance	☐✓

Appendix - 6 Stakeholder and Consultation

Key individuals involved in developing the document

Name	Designation
Heather Darlow	Head of Clinical Quality and Governance
Tracy Ward	Head of Patient Safety
Jane Gourley	Head of Compliance

Circulated to the following individuals for comments

Name	Designation
Sudip Ghosh	
Steph O'Connell	
Angela Richardson	
Peter Felix	
Jeanette Bowley Williams	
Fabida Aria	
Margot Emery	
Zayad Sautamally	
Michelle Churchard	

Appendix - 7

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.
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	**Head of Clinical Quality and Governance**	**Date 5th May 2022**

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 other information that people would consider to be particularly private.	Yes	**No change to previous policy**
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