Leicestershire Partnership NHS Trust

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.

Key Words:	Diagnostic, Screening	
Version:	4	
Adopted by:	Quality Assurance Committee	
Date Adopted:	20 August 2019	
Name of Author:	Anthony Oxley, Head of Pharmacy	
Name of responsible committee:	Patient Safety Group	
Date issued for publication:	August 2019	
Review date:	December 2021	
Expiry date:	1 July 2022	
Target audience:	All clinical staff	
Type of Policy	Clinical ✔	Non Clinical
Which Relevant CQC Fundamental Standards?	Safe care	

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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

All LPT Policies can be provided in large print or Braille formats, if requested, and an interpreting service is available to individuals of different nationalities who require them.

Did you print this document yourself?
Please be advised that the Trust discourages the retention of hard copies of policies and can only guarantee that the policy on the Trust website is the most up-to-date version.

For further information contact:

Trust Lead - Risk & Patient Safety

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	Diagnostic procedures such as laboratory tests
Screening	Examination of patients with no symptoms to detect unsuspected disease.
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.

1.0 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.

Each clinical area of LPT (see 'definitions') 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 carry out a baseline assessment of the clinical diagnostic tests and screening procedures undertaken within the service to determine the focus of the local procedural documents (see **Appendix 2** - Lists of example clinical diagnostic tests and screening procedures undertaken by clinical area).

2.0 Clinical Areas, LPT

LPT is registered with the Care Quality Commission to provide the regulated activity of Diagnostic and Screening procedures at all Trust registered locations:

Coalville Community Hospital
Broom Leys Road
Coalville
Leicestershire
LE67 4DE
Evington Centre

Leicester General Hospital
Gwendolen Road
Leicester
Leicestershire
LE5 4QG

Fielding Palmer Cottage Hospital
Gilmorton Road
Lutterworth
Leicestershire
LE17 4DZ

Hinckley and Bosworth Community Hospital
Ashby Road
Hinckley
Leicestershire
LE10 3DA

Leicestershire Partnership NHS Trust (covers a variety of care settings)
Trust Headquarters, Riverside House
Bridge Park Rd
Thurmaston
LE4 8PQ

Loughborough Hospital
Hospital Way
Loughborough
Leicestershire
LE11 5JY

Melton Mowbray Hospital
Thorpe Road
Melton Mowbray
Leicestershire
LE13 1SJ

Rutland Memorial Hospital
Cold Overton Road
Oakham
Rutland
LE15 6NT

St Luke's Hospital
33 Leicester Road
Market Harborough
Leicestershire
LE16 7BN

Stewart House (Narborough)
The Rise
Stewart Avenue
Narborough
Leicestershire
LE19 4SL

The Agnes Unit
Gorse Hill
Anstey
Leicester
Leicestershire
LE7 7GX

The Bradgate Mental Health Unit
Glenfield Hospital
Groby Road
Leicester
Leicestershire
LE3 9EJ

3.0 Introduction

The purpose 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.

Without clear communication and record keeping there is the potential for:

- Confusion over whether a clinical diagnostic test or screening procedure has been undertaken
- Tests to be undertaken unnecessarily
- The patient not being aware of the procedure to access results
- The patient thinking that 'no news is good news'.
- Tests not being undertaken
- Results not being acted on appropriately

4.0 Scope of the Policy

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.

5.0 Roles and responsibilities

5.1 Divisional Directors and Managers

- Ensuring appropriate and effective local procedural documents are developed when required in their designated areas within their scope of responsibility.

5.2 Clinical Governance Committees

- Ensuring deficiencies in complying with this procedural document are addressed through monitoring of remedial action plans.

5.3 Clinical Governance Leads

- Monitoring compliance with this procedural document
- Providing support to Clinical Service Leads to enable them to fulfil their role in relation to this procedural document.

5.4 Clinical Service Leads

- Developing local procedural documents in their designated area as required in accordance with this procedural document
- Implementation of local procedural documents in their designated area.

6.0 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 despatched 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;

- That the clinical diagnostic test or screening result is received within agreed time frames 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.

A template procedural document is included as appendix two which should be used for the development of local procedural documents. This template provides guidance on the detail to be included in all local procedural documents and ensures that they are in the corporate style.

7.0 Implementation Plan and Training Requirements

Support will be provided to those individuals responsible for developing local procedural documents by the relevant Clinical Governance Lead.

8.0 Monitoring compliance/Audit Arrangements

Compliance with this procedural document will be measured by a review by the Clinical Governance Leads of the local policies developed by each of the clinical areas listed in appendix one to address clinical diagnostic tests and screening procedures.

The findings will be communicated to the Clinical Governance Committees in an annual report. The Clinical Governance Committee will monitor implementation of remedial action plans developed to address any deficiencies identified.

9.0 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	A. Oxley	**Date**	11.03.19
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
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

Leicestershire Partnership NHS
NHS Trust

Guidance for development of Clinical Diagnostic tests and screening procedures

(Name of clinical area)

Summary

The summary of the document may be provided either in writing or in the form of an algorithm

Introduction

The purpose of the document is to ensure that all clinical diagnostic tests and screening procedures undertaken within *(name of the clinical area)* are appropriately managed to minimise the risk to patients and to improve patient outcome and the quality of care.

Without clear communication and record keeping there is the potential for confusion over whether a clinical diagnostic test or screening procedure has been undertaken. This document outlines the objectives and intended outcomes of the process being described, for example:

- 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 and structures in place for the clinical diagnostic test or screening procedure are identified;
- Identify healthcare staff with the authority to authorise/proceed with the test or screening procedure;
- To consider stating those that may not have authority;
- 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;

- That there are systems in place to ensure that the sample(s), where relevant, have been taken, correctly labelled, prepared, transported and despatched 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;

- That the clinical diagnostic test or screening result is received within agreed time frames by the appropriate (electronic) system;

- The agreed 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;

- The agreed 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;

- The agreed 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;

- The agreed 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.

Scope

All qualified and unqualified healthcare staff taking part in diagnostic and/or screening processes.

Roles and responsibilities

Consultation and Communication with Stakeholders / Support Services / Commissioned services

This section should identify the organisation's expectations in relation to the involvement of stakeholders/support services/commissioned services (including contractual monitoring arrangements) and patient/service users, in the processes around clinical diagnostic testing or screening procedures.

Support Services/Stakeholders development and implementation of standing operating procedures (SOPs), relevant to the clinical diagnostic tests or screening procedures undertaken by the organisation; ensuring a timely response to a request for a clinical diagnostic test or screening procedure through agreed protocols; ensuring the prompt transmission of authorised clinical diagnostic test or screening results to requesting healthcare staff through agreed protocols.

Clinical Director/Director of Nursing

This section should describe the role of the clinical director and/or the director of nursing in the development of organisation-wide and local procedural documents to manage the risks associated with clinical diagnostic tests or screening procedures.

Healthcare Staff

This section should include the responsibilities of healthcare staff by discipline, involved in all stages of the process for clinical diagnostic tests or screening procedures:

adherence to SOPs or equivalent protocols;

requesting a clinical diagnostic test or screening procedure only when the result will influence diagnosis or management;

that all clinical diagnostic tests or screening procedures must be undertaken by authorised healthcare staff following appropriate training where necessary;

where the use of a laboratory service is required healthcare staff must ensure that the information includes:

- *the recording of the correct patient details;*
- *the request for the correct clinical diagnostic test or screening procedure;*
- *the details of the appropriate healthcare staff member for return of the clinical diagnostic test or screening result and subsequent action.*

Where a clinical diagnostic test or screening procedure does not require laboratory analysis the undertaking and outcome of this activity should be documented in the appropriate media;

recording the receipt of the clinical diagnostic test or screening result, the interpretation and the consequent management plan should be recorded in the appropriate media;

the agreed mechanism for the process on how results are communicated to the patient and other appropriate healthcare staff members;

ensuring that appropriate actions are taken and documented, and that the method of communication is recorded, i.e. face-to-face contact, phone call, letter, e-mail, fax, etc.

Administrative Staff
making/recording the delivery of clinical diagnostic tests or screening procedures to support services,
recording the receipt of clinical diagnostic test or screening results,
identifying the organisation's preferred method of receipt (electronic, paper or by telephone for specific test or screening results).

Clinical Informatics
ensuring that robust systems are in place which involve the receipt and filing of paper held records;
providing the electronic infrastructure for continuous performance management and monitoring of clinical diagnostic test or screening ordering and results management.

Duties External to the Organisation
The organisation should consider external bodies which have a role in the effective management of the systems to provide and manage clinical diagnostic tests or screening procedures.

Accredited Laboratories
External assurances required as part of contractual agreements.

Diagnostic Services
External assurances required as part of contractual agreements.

Independent Contractors
External assurances required as part of contractual agreements.

Clinical diagnostic tests and screening procedures

Process for requesting clinical diagnostic tests or screening procedures

This section should include those healthcare staff with the authority to request and carry out clinical diagnostic tests or screening procedures where appropriate. It should also encompass how staff go about requesting tests and screening procedures (e.g. forms to be completed etc)

Process for the receipt of the clinical diagnostic test or screening results

This section should state the local process for the receipt of a clinical diagnostic test or screening result in line with the strategic document.

Process for taking action on clinical diagnostic test or screening results

This section should state the local process regarding the actions required for a clinical diagnostic test or screening result in line with the strategic document.

Process for documentation of clinical diagnostic test or screening results

This section should state the agreed process for recording clinical diagnostic tests or screening results, which should include the minimum information required about the patient/service user, the clinical diagnostic test or screening procedure undertaken in line with the strategic document and the actions taken in response to the results.

Process for the communication of clinical diagnostic test of screening results

This section should state the local procedures to describe the processes in place to inform patients/service users and relevant healthcare staff of the results in line with the strategic document, giving due consideration to confidentiality, sensitivity of results and the specific needs of the patient/service user.

Implementation plan and training requirements

Describe how the processes will be implemented and what training, if any, will be available to support the effective use of the policy.

Monitoring / audit requirements

Describe the process that will be followed to monitor the compliance with the document. This should include auditable standards or key performance indicators against which the document will be monitored, who will be responsible for monitoring against these standards, how frequently monitoring will take place, and the group which will receive the report.

References

Include references to ensure a clear evidence base.

Associated Documents

Cross-reference all related trust documents which may be relevant to the topic covered here.

Appendices

Include any items that would make it easier for the policy to be followed and put into practice.

Eg : Audit trail Flow charts Tool kits Templates

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	
Division(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

Monitoring compliance

Ref	Minimum Requirements	Evidence for Self-assessment	Process for Monitoring	Responsible Individual / Group	Frequency of monitoring
Pg. 10	Review of the local policies developed by each of the clinical areas (Appendix 3)	PSG made aware of any changes	Clinical Governance Leads	Clinical Governance Committee /Leads	Annually

Appendix - 6

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 - 7

Stakeholder and Consultation

Key individuals involved in developing the document

Name	Designation
Heather Darlow	Governance Lead –CHS
Helen Wallace	Governance & Development Manager
Anthony Oxley	Head of Pharmacy
Victoria McDonnell	Previous Head of Patient Safety

Circulated to the following individuals for comments

Name	Designation
Claire Armitage	Lead Nurse – Adult Mental Health
Nikki Beacher	Head of Service
Michelle Churchard-Smith	Head of Nursing AMH/LD
Satheesh Kumar	Consultant Psychiatrist
Liz Tebbutt	Facilities Manager
Helen Wallace	Governance & Development Manager
Steve Walls	Clinical Duty Manager

Appendix - 8

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:	**Anthony Oxley**	
Job title	**Head of Pharmacy**	**Date 23rd May 2019**

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:	Sam Kirkland, Head of Data Privacy
Date of approval	04/06/2019

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