

Policy for Developing Local Guidelines and Operating Procedures for Clinical Diagnostic Tests and Screening

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Version Control Sheet

Version	Section / Para / Appendix	Version / Description of Amendments	Date	Author / Amended by
1	All	Document amended to reflect LCHS management structure	July 2010	Risk Manager
2	3	Definitions added	July 2010	Risk Manager
3	7	Link to LCHS policy for the Development of Policies added	July 2010	Risk Manager
4	9	Additional monitoring of the policy added	July 2010	Risk Manager
5	All	Document amended to incorporate NHSLA standards and reflect LCHS Trust management Structure & renumbering from CPS13a to P_CS_10	February 2012	Dr P Mitchell
6	All	Minor amendments and format changes. Updated to reflect organisational governance	July 2014	Kim Todd

		structures		
6.1		Extended	August 2016	Corporate Assurance Team
6.2		Extended	January 2017	Corporate Assurance Team
6.3		Extended	September 2017	Corporate Assurance Team
6.4		Extended	February 2018	Corporate Assurance Team
7		Change of NHSLA to NHS Resolution throughout document Addition at 8.4 in reference to actioning results when they appear on SystemOne front screen (or any other electronic/paper system)	July 2018	Kim Todd
8		Review – no change to content and amended to new policy format	September 2020	Janine Elson Laura Dilley

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Procedural Document Statement

Background Statement Poor management and organisation of systems and processes relating to clinical tests, diagnostic procedures and screening carries a significant risk in terms of reducing patient safety and quality of care experienced. Subsequent to this, the organisation is exposed to increased chances of complaint and litigation, increased costs due to complications and extended periods of care, untoward scrutiny from commissioners and public bodies, adverse media interest and loss of good reputation. All clinical services utilising clinical diagnostic tests and screening procedures must be able to demonstrate that such tests are requested, carried out and followed up according to best practice guidelines, current evidence base and in a timely fashion that maximises quality of care, patient experience and maintains a safe clinical environment both to patients and staff. The main objective of the policy is to minimise the risk of misdiagnosis or failure/delay in diagnosis, to improve patient outcomes and the quality of care in line with NHS Resolution Standards.

Responsibilities Compliance with the policy is the responsibility of all LCHS staff.

Training Service leads, clinical managers and directors are responsible for ensuring that there is appropriate training for relevant staff that underpins the effectiveness of procedures and guidelines developed in line with this policy.

Dissemination LCHS website; e-mail and team brief

Resource implication This policy should direct and reinforce best practice guidelines and thus implement the more efficient use of currently deployed resources with respect to clinical diagnostic tests and screening procedures.

Consultation It is expected that managers and clinical staff developing local guidelines and procedures will consult with

colleagues and subject experts as well as this policy to ensure fitness for purpose, quality impact assessment and safety

Monitoring

The Local Quality Assurance Groups and the Clinical Safety and Effectiveness Group will ensure that local procedures are produced and reviewed in accordance with this policy.

Equality Statement

As part of our on-going commitment to promoting equality, valuing diversity and protecting human rights, Lincolnshire Community Health Services NHS Trust is committed to eliminating discrimination against any individual (individual means employees, patients, services users and carers) on the grounds of gender, gender reassignment, disability, age, race, ethnicity, sexual orientation, socio-economic status, language, religion or beliefs, marriage or civil partnerships, pregnancy and maternity, appearance, nationality or culture.

1. Introduction

There are many diagnostic and screening tests performed in Lincolnshire Community Health Services everyday on both inpatients and patients in the community. Lincolnshire Community Health Services needs to be assured that these tests are requested or carried out correctly, are accurate and that the results of these tests lead to the correct diagnosis and appropriate patient care.

2. Purpose

The purpose of this policy is to assist health care professionals to develop local policies to ensure that the appropriate tests required for a patient are taken and a clear evidence based rationale is given for the decision. The results from diagnostic and screening tests are appropriately processed, issued and acted upon. The main objective of the policy is to minimise the risk of misdiagnosis or failure/ delay in diagnosis, to improve patient outcomes and the quality of care.

3. Scope of policy

The policy is relevant to all health care professionals employed by Lincolnshire Community Health Services involved in requesting, obtaining and actioning clinical diagnostic and screening tests.

This policy will be strongly recommended to independent practitioners as good practice guidance.

Within this policy the following definitions have been adopted:

Clinical Diagnostic Tests: procedures such as laboratory tests which are routinely performed on patients in specific situations to facilitate diagnosis

Screening: examination of people with no symptoms to detect unsuspected disease

4. Supporting Data

Delayed diagnosis is one of the most common reasons for medico-legal claims. Some of the reasons for this include:

- Reports misfiled in notes
- Dysfunctional communication between healthcare staff and between healthcare staff and patients
- Incomplete or inadequate record keeping

A perfect system that ensures all test results are dealt with is extremely difficult to achieve but developing local guidelines and procedures for clinical diagnostic and screening testing can reduce the risk considerably.

5. Responsibilities

5.1 Chief Executive

The Chief Executive has ultimate accountability for ensuring the provision of high quality, safe and effective services within Lincolnshire Community Health Services.

5.2 Heads of Service/Senior Managers

Heads of Service/Senior Managers are responsible for ensuring that local guidelines and procedures are developed, implemented and regularly audited in the areas where clinical diagnostic and screening testing takes place.

5.3 Clinical Staff employed by Lincolnshire Community Health Services

All clinical staff are responsible for applying the principles contained within the local guidelines and procedures.

5.4 Staff employed by Lincolnshire Community Health Services

All staff are responsible for carrying out designated duties outlined within the local guidelines and procedures.

6. General Principles

The General Principles that must apply to the development of local procedures are:

- The individual that initiates the original investigation is responsible and accountable for tracking, validating, documenting, acting upon and informing the patient and/or General Practitioner or responsible hospital consultant of the results.
- There must be a systematic Lincolnshire Community Health Services wide approach to the validation of results that require skilled interpretation to support diagnosis or treatment that applies to all staff including medical staff.
- All staff must be involved in developing explicit local clinical diagnostic and screening testing procedures for those elements of the process that they are involved in.
- There must be staff training about the clinical diagnostic and screening testing process so that each member of staff understands how his or her role contributes to the overall process.
- Local working practices must not be allowed to diverge from local procedures.
- If an individual feels that there is a better way of working, they must discuss with their line manager and a change must be agreed at departmental level and the local procedure revised. All staff involved will need to be made aware of the changes.
- All cases of non-conformance with the local procedure should be recorded and brought to the attention of the line manager and a Lincolnshire Community Health Services incident form completed via DATIX.
- Lincolnshire Community Health Services will ensure that, following clinical diagnostic tests and screening undertaken by its staff, only accredited laboratories and diagnostic services will be used for the analysis. Such accreditation will be verified as part of the contractual discussions.

- The local procedures should be written in line with the Lincolnshire Community Health Services Organisation-wide Policy Framework (P_CoG_04).

7. Content Of Local Procedure

7.1 Requesting clinical and screening tests

Each area must define within their procedure:

- The circumstances when diagnostic tests are not appropriate and, when a patient refuses a test, a clear rationale of evidence base explained to the patient when and documented in the patient record.
- The procedure for requesting clinical tests e.g. who can request a test; who carries out the tests; types of forms required to be completed; transport required etc.
- Which tests are appropriate to be carried out and a clear rationale of evidence base explained to the patient and/or carer and documented in the patient's record
- Which members of staff are able to request tests
- The qualifications/training required by individuals to carry out each test
- The process for requesting emergency tests e.g. mode of reply, how quickly emergency tests should be reported on
- Method of requesting and recording e.g. Choose and Book, SystemOne
- Method of sharing information on requested clinical tests to patient's GP
-

7.2 Reporting clinical and screening tests

The following must be included:

- How the clinical tests are reported on and what is considered acceptable e.g. electronically, paper, telephone etc.

- The process in place to ensure that the person who requested the test is aware of the results including who is responsible for acting on the tests if the person who requested them is not available for any reason
- The procedure for ensuring test results are explained to the patient/carer and recorded in the patient's health record
- The process undertaken if the results do not fit the clinical picture or previous sequence of results (this is especially relevant to point of care testing)
- The mechanism for the transfer of results from the medical device to the patient's record (with the exception of Chlamydia, where it is not allowed)
- Who is responsible for tracking the results if the patient has been moved from one clinical setting to another

7.3 Interpretation of clinical and screening tests

The procedure must state the people who will be responsible for interpreting clinical tests results.

These people must have the relevant skills and training to undertake this process.

If only interim results are available and if clinicians have any doubts about their interpretation they should ensure that they consult with senior colleagues with the team.

Some tests will require skilled interpretation e.g. a written/dictation report from a specialist consultant or other specialist clinician (e.g. radiographer) trained in interpretation skills. The types of tests requiring this will usually be carried out under the SLA agreement with the commissioned provider reporting on them by appropriate personnel in the relevant acute trust.

7.4 Actioning test results

Results must be acted upon as soon as possible. It is the responsibility of the clinical team that initiates the original and subsequent investigations to ensure that the results are acted upon. The local procedure must give details on the process in

place to ensure that this is achieved. This needs to include the instruction that staff must be aware that results may appear on SystemOne (or any other electronic/paper system) when a patient's record is entered and this information must be read, noted and acted upon as required.

7.5 Recording the actions taken

The local procedure must outline the way that actions taken after testing will be recorded. This should include:

- Informing the patient of the results of the tests and agreeing treatment if necessary.
- Recording the actions taken in the patient's health record.
- Highlighting any changes in care plans.
- When tests should be repeated if necessary and the need to inform the patient.

7.6 Reporting incorrect or missed diagnosis

The procedure must outline the procedure to be taken if a test result is missed or if the reporting is incorrect. This needs to include:

- The need for an incident form to be completed via DATIX.
- The person to be contacted if an error is made
- When the patient should be told about the error.
- The process for carrying out an investigation into what went wrong.
- How lessons will be learnt and incorporated into local practice and policy.

7.7 Monitoring the effectiveness of the guideline of procedure

The local procedure must give details of how:

- It is to be monitored giving specific timescales for audit
- The committee/group that will look at the audit results
- A date when the procedure is going to be reviewed

The monitoring must include a regular audit looking specifically at the interpreting and actioning of clinical test results on at least a quarterly basis and reports to the local service clinical governance and risk forum.

8. Appendices

Equality analysis appendix

9. Review of document

This policy will be due for review in 2 years' time. An earlier review may be warranted if one or more of the following occurs:

- As a result of regulatory or statutory changes or developments
- Due to the findings or outcomes from incidents and root cause analysis
- Or any other relevant or compelling reason

Appendix __ Equality Analysis

NB - It is the responsibility of the author / reviewer of this document to complete / update the Equality Analysis each time it has a full review and to contact the Equality Diversity and Inclusion Lead if a full equality impact analysis is required

Equality Impact Analysis Screening Form

Title of activity	Policy for Developing Local Guidelines and Operating Procedures for Clinical Diagnostic Tests and Screening		
Date form completed	September 2020	Name of lead for this activity	

Analysis undertaken by:		
Name(s)	Job role	Department
Janine Elson	Deputy Medical Director	

What is the aim or objective of this activity?	Policy
Who will this activity impact on? <i>E.g. staff, patients, carers, visitors etc.</i>	Staff, patients

Potential impacts on different equality groups:

Equality Group	Potential for positive impact	Neutral Impact	Potential for negative impact	Please provide details of how you believe there is a potential positive, negative or neutral impact (and what evidence you have gathered)
Age	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Disability	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gender reassignment	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Marriage & civil partnerships	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pregnancy & maternity	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Race	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Religion or belief	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sex	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sexual Orientation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Additional Impacts <i>(what other groups might this activity impact on? Carers, homeless, travelling communities etc.)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

If you have ticked one of the above equality groups please complete the following:

Level of impact

	Yes	No
Could this impact be considered direct or indirect discrimination?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, how will you address this?		

	High	Medium	Low
What level do you consider the potential negative impact would be?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If the negative impact is high, a full equality impact analysis will be required.

Action Plan

How could you minimise or remove any negative impacts identified, even if this is rated low?
How will you monitor this impact or planned actions?
Future review date: September 2022