The Royal Wolverhampton NHS Trust

CP50
Policy for the Management of Risks Associated with Pathology and Radiology Diagnostic and Screening Tests

Contents

1.0 Policy Statement

A clinician who requests a diagnostic or screening test must ensure that the result of that test is seen by an appropriate clinician who will take any necessary action. The ultimate responsibility lies with the consultant responsible for the care of the patient, but this may be delegated to a senior member of the team. Every clinical directorate must develop local policies to manage the risks associated with diagnostic and screening tests. The Pathology and Radiology Directorates must signal critical and, or unexpected findings urgently to the requesting clinician or an appropriate member of their department.

2.0 Definitions

Diagnostic tests are procedures such as laboratory tests and imaging investigations undertaken to guide clinical management of a patient.
Screening is examination of asymptomatic patients to detect disease.

3.0 Accountabilities

The Chief Executive

The Chief Executive has overall responsibility for Governance in the Trust and therefore is the accountable officer.

Divisional Management Teams

Divisional Management Teams will receive monthly reports of compliance and therefore must ensure that appropriate action is taken to address areas on non-compliance.

Clinical Directorate Management Teams and Clinical Leads, and Services Undertaking Diagnostic or Screening Tests

Clinical Directorate Management Teams and Clinical Leads are responsible for creating local Standard Operating Procedures (SOP's) to ensure that diagnostic and screening tests are appropriately and properly requested and that the results are seen and acted on in a timely and appropriate manner by appropriate clinical staff. All results must be "filed" using the Electronic Order Communications system (currently the Sunquest ICE system) to ensure that they have been reviewed by an appropriate person.

They must maintain accurate and up-to-date lists of clinical staff who are authorised to request diagnostic or screening tests.

Clinical Directorate Management Teams and Clinical leads must arrange for regular audits of their local SOP's and make any changes that are required to improve their processes.

Non-compliance with filing will be escalated to the Clinical Director and further non-compliance taken to the Divisional Management team.

Referrers

All clinicians who request diagnostic and, or screening tests have the following responsibilities:

- understand the rationale for requesting an investigation;
- explain the purpose and nature of the test to the patient or their carer(s) to obtain consent for the test;
- identify correctly the responsible consultant or GP on the request for a test: this ensures that the results will be directed to the right clinician;
- ensure that the results are reviewed and acted upon by an appropriate clinician in a timely manner including escalating to a more senior colleague if necessary;
- ensure the results are given to the patient or their carer(s);
- ensure that any action plan is documented in the patient's clinical record.

Sample Taker
The sample taker is responsible for ensuring that the sample is put in the correct container and that it is properly labelled. If the patient is providing their own sample, the clinical team must tell the patient or their carers how to collect, store and transport the sample correctly.

Pathology Departments
The Pathology Departments are responsible for undertaking diagnostic and screening tests accurately and promptly. They must have effective processes in place to ensure that the results of tests that are requested urgently and those with critical or unexpected findings are communicated urgently to the requesting clinical team. The Pathology Departments are responsible for advising clinicians about the investigations that are appropriate to given clinical situations.

Radiology Directorate
The Radiology Directorate is responsible for undertaking diagnostic and screening tests accurately and promptly. They must have effective processes in place to ensure that the results of tests that are requested urgently and those with critical or unexpected findings are communicated urgently to the requesting clinical team. The Radiology Directorate is responsible for advising clinicians about investigations that are appropriate to given clinical situations. They are responsible for advising patients having out-patient investigations of the expected time of issuing of the Radiology report to the requesting clinician.

There are other pathways available for urgent referrals which are covered by appropriate Standard Operating Procedure documents.

External to the Organisation
The organisation must consider external bodies which have a role in the effective management of systems to provide and manage diagnostic testing procedures. The NHS screening programmes (such as screening in pregnancy and cervical screening) have standard screening programme guidance that incorporates interpretation and reporting of results.

Accredited Laboratories
External assurances are required as part of contractual agreements. United Kingdom Accreditation Service (UKAS) is the sole national accreditation body for the United Kingdom and is recognised by the Government. ISO 15189 covers laboratory accreditation and it is the responsibility of the Black Country Pathology Services to maintain accreditation and report into the BCPS Clinical Reference Group.

Independent Contractors
External assurances are required as part of contractual agreements

4.0 Policy Detail
As a minimum the Directorate SOP's must include procedures for requesting diagnostic and screening tests (see Attachment 1) and procedures for reviewing the results, acting on them and communicating them to patients (see Attachment 2).

Local protocols for the communication of critical and unexpected findings by the Pathology and Radiology Departments are attached in (Appendix 1).

5.0 Financial Risk Assessment

There are no financial requirements for developing this policy.

6.0 Equality and Diversity Risk Assessment

This has been completed and no impact highlighted.

7.0 Maintenance

The policy will be reviewed at least every three years or sooner if dictated by changes in national guidance. The Medical Director and policy leads will be responsible for coordinating the review and ratifying any amendments prior to final approval by the Trust Management Team.

8.0 Communication and Training

ICE was rolled out to the Trust and later to the GPs in 2018 using a co-ordinated approach with Directorates and GP's informed when they were live. Future upgrades will be communicated to the Trust at the appropriate time

Part A - Document Control

Policy number and Policy version: CP50 Version 4.0	**Policy Title:** **Policy for the Management of Risks Associated with Pathology and Radiology Diagnostic and Screening Tests**	**Status:** Final		**Author: Head of Operational Radiology** **Chief Officer Sponsor: Medical Director**
Version / Amendment History	Version	Date	Author	Reason
	1.0	Jan 2012	Pathology Services Manager	New Policy
	2.0	June 2012	Pathology Services Manager	Appendix 1 and 2 added (NB. App 2 now includes Att 2 from Version 1.0) Attachment 1 and 2 format altered
	3.0	Jan. 2018	Pathology Services Manager	Full review
	3.1	Jan. 2021	Pathology Services Manager	Reviewed by Chief Medical Officer extended to September 2021 – Pending full review.
	3.2	Feb. 2021	Pathology Services Manager	Inclusion of Appendix 2 - ACPCS18 - Process for management and review of clinical samples & diagnostic tests within Primary Care Services
	4.0	Feb. 2022	Head of operational Radiology	Full review
Intended Recipients: All referrers for Radiology and Pathology tests				
Consultation Group / Role Titles and Date: Pathology – Katie New Divisional Management – Lewis Grant				
Name and date of Trust level group where reviewed	Trust Policy Group – February 2022			
Name and date of final approval committee	Trust Management Committee – April 2022			
Date of Policy issue	May 2022			

Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	February 2025 (3 years)
Training and Dissemination: Induction	
Publishing Requirements: Can this document be published on the Trust's public page: **Yes / ~~No~~** If yes you must ensure that you have read and have fully considered it meets the requirements outlined in sections 1.9, 3.7 and 3.9 of OP01, Governance of Trust-wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines, as well as considering any redactions that will be required prior to publication.	
To be read in conjunction with: N/A	
Initial Equality Impact Assessment (all policies): Completed Yes / No Full Equality Impact assessment (as required): Completed Yes / No / NA If you require this document in an alternative format e.g., larger print please contact Policy Administrator 8904	
Monitoring arrangements and Committee	Pathology IT
• **Document summary/key issues covered.** All results will be reviewed in ICE • Outpatient results will be filed by the consultant who holds the clinic • Inpatient result filing will be delegated to Junior Doctors; results requiring urgent attention or further interpretation will be ICE mailed to the relevant Consultant	
Key words for intranet searching purposes	
High Risk Policy? **Definition:** • Contains information in the public domain that may present additional risk to the public e.g. contains detailed images of means of strangulation. • References to individually identifiable cases. • References to commercially sensitive or confidential systems. If a policy is considered to be high risk it will be the responsibility of the author and chief officer sponsor to ensure it is redacted to the requestee.	**~~Yes~~ / No (delete as appropriate)** If Yes include the following sentence and relevant information in the Intended Recipients section above – In the event that this is policy is made available to the public the following information should be redacted:

Part B **Ratification Assurance Statement**

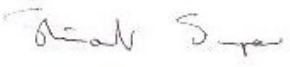
Name of document: **Policy for the Management of Risks Associated with Pathology and Radiology Diagnostic and Screening Tests**

Name of author: Stuart Simper Job Title: Head of Operational Radiology

I, the above named author confirm that:

- The Strategy/Policy/Procedure/Guidelines (please delete) presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author:

Date: 22.12.21 

Name of Person Ratifying this document (Chief Officer or Nominee):
Job Title:
Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to:
The Policy Administrator

IMPLEMENTATION PLAN

Policy number and policy version	**Policy Title**	
Reviewing Group		**Date reviewed: February 2022**
Implementation lead: Print name and contact details		
Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.		
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form	Training will be provided to clinicians as and when required on the Pathology and Radiology computer system for requesting, reviewing and filing of results.	As and when required.
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed	The guide for using ICE is on the Computer Systems page on the intranet.	
Strategy / Policy / Procedure communication; Consider 1. Key communication messages from the policy / procedure, who to and how?	The policy will be posted on the 'Policies' page of the Intranet site.	May 2022
Financial cost implementation Consider Business case development		
Other specific Policy issues / actions as required **e.g. Risks of failure to implement, gaps or barriers to implementation**		

Attachment 1

Procedure for requesting diagnostic and screening tests

All requests must be made by an authorised person.

Whenever possible requests must be completed electronically. Request forms completed manually must include the following data set:

• Patient demographic details, i.e. surname, forename, date of birth, NHS/Unit number/Unique identifier, address, sex

• Details of requestor, including contact information

• Date and time of sample

• Clinical details

• Details of treatment or drug therapy (when appropriate)

• Investigations required

• Indication of urgency

All pathology samples must be unequivocally identified with the source patient details. Failure to provide this information may lead to delay in processing samples or rejection of the request.

Information is available on the trust intranet in a number of forms including:

http://intranet.xrwh.nhs.uk/departments/pathology_services/General_Information/Information_for_Users.aspx

http://intranet.xrwh.nhs.uk/departments/pathology_services/departments/it.aspx

http://intranet.xrwh.nhs.uk/pdf/departments/Radiology/PACS_System_User_Guide.pdf

All results are validated prior to release via the electronic system to the requester.

Attachment 2

Process for recording and communication of actions*

- **Process for documenting diagnostic tests and screening results**

  All patient diagnostic test results, screening test results and actions required must be documented with the time, date of review, action taken and name of reviewer. Audit trails are available if an electronic reporting system is used to review reports. For all reports reviewed via a paper system the reviewer must record the information stated above. For further details of local procedures refer to appendix 2.

- **Process for the communication of diagnostic tests and screening results**

  Clinical documentation must reflect to whom and how the test/ screening result has been communicated to both colleagues and patient. The clinician should communicate the results and treatment options (including timescales) to the patient when appropriate.

* Local protocols/procedures must reflect the requirements of this policy.

Appendix 1

PATHOLOGY AND RADIOLOGY 'HIGHER' RISK TESTS

Pathology and Radiology shall communicate all test results within 30 minutes, critical and unexpected findings will be actively communicated to the requestor or relevant clinical team immediately.

PATHOLOGY

All pathology test results will be available as soon as they are produced on TDweb.

Critical or unexpected findings

In addition to the above, for any abnormal results outside the limits outlined in local procedures named below, the laboratory will contact the requestor or a member of the clinical staff managing a patient's care.

Clinical Chemistry telephone action limits – G3.085N.CHE

Haematology – F2.H032N.HAE

Cellular Pathology – G3.S001P.CP

Microbiology – G3.001P.MIC

RADIOLOGY

All radiology test results will be available as soon as the report is authorised. Within the Acute Trust, the results will also be disseminated by email to the patients' consultant and any other person specified by the requesting team, e.g. Consultant Secretaries', other Consultants within the speciality. GP results will be fed through electronically via EMIS although some Practices are not connected and receive the results via the post

Critical or Unexpected Findings

In addition to the circulation described above, for any report that contains critical or unexpected findings, the reporter will contact the requester or patients' consultant by telephone. The requester and the patients' consultant will also receive an email which has either "Urgent Findings", "Significant Unexpected Findings" or "Cancer Suspicious" in the subject matter of the e-mail which contains the report.

The arrangements for alternative contacts should the requester be unavailable are shown below:

- The reporter should contact the consultant responsible for the patient

- If the consultant is unavailable, the on call consultant for that speciality should be contacted
- In the unlikely event of both of the above failing, the on call physician or surgeon should be contacted

Appendix 2

Local Protocol / Template for viewing results by clinical staff and recording of actions taken, including communication of results to the patient.

The clinician interprets results using either electronic or paper based reporting systems.

It is the responsibility of the clinician requesting the test to review the results of those tests within a timely manner. If the result arrives out of normal working hours, or the requesting clinician knows they may be unavailable to receive the report (e.g. off-site or off-duty) there must be appropriate arrangements in place for handover of the case by the referrer.

It is expected that within the Acute Trust, results should be filed in ICE. Filing is making an acknowledgment that the referrer has acted appropriately on the results.

It is expected that clinicians shall take appropriate action in response to diagnostic and screening results to effect patient management within a timely manner. If an image or other test result indicates a life-threatening condition it is expected that referring clinicians will take action to respond immediately to effect patient management change.

The clinician communicates the results and treatment options to the patient, in line with patient pathways, local protocols and/or clinical judgement. This communication must be clearly documented in the clinical record (including timescales).

Ensure all patients who receive a screen positive result or high risk result have access to an appropriately trained healthcare professional to discuss options for further management.

Complete the table below to describe the local procedures relating to CP50 Policy for the Management of Risks associated with Pathology and Radiology Clinical Diagnostic and Screening tests.

Template for Local Protocol

Location/ area:	
Date issued:	
Review date:	
Name of Author:	
Name of approval committee/ individual:	
List staff group/s authorised to make requests for diagnostic and/or screening tests. All medical staff are authorised to request pathology and radiology investigation; these staff will have individual login details for pathology and radiology systems. The following staff groups are delegated to make requests under the conditions contained in specific protocols, these protocols will contain lists of staff authorised to make requests. Please list staff groups below:	
List staff group/s responsible for reviewing diagnostic and/or screening results	Initial review (checks availability of results) can be performed by: (Deleted as necessary) Administration Staff Secretarial Staff Nursing Staff Results shall be communicated to requesting Clinician and / or consultant
Following review of results, indicate how this will be recorded in clinical records and how any actions will be documented.	Options 1. Recorded directly into patients clinical notes 2. Other. Please state: