Royal Cornwall Hospitals NHS Trust

Policy Under Review

Please note that this policy is under review. It does, however, remain current Trust policy subject to any recent legislative changes, national policy instruction (NHS or Department of Health), or Trust Board decision. For guidance, please contact the Author/Owner.

Information Category	Detailed Information
Document Title:	Diagnostic Test Reporting and Acknowledgement Procedures for Pathology and Clinical Imaging Policy V4.0
This document replaces (exact title of previous version):	Diagnostic Test Reporting and Acknowledgement Procedures for Pathology and Clinical Imaging Policy V3.0
Date Issued / Approved:	June 2021
Date Valid From:	September 2021
Date Valid To:	October 2025
Author / Owner:	Sarah Pointon, Pathology Quality and Governance Manager and Health and Safety Lead. Glenda Shaw, Clinical Imaging Quality and Service Improvement Lead.
Contact details:	01872 252582 and 01872 255086
Brief summary of contents:	Framework for communication and actions required throughout the diagnostic pathway.
Suggested Keywords:	Diagnostic Test, Pathology, Clinical Imaging.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Clinical Imaging Clinical Governance Group. Pathology Quality and Governance Meeting. Clinical Support Care Group Governance Meeting.

Information Category	Detailed Information
Manager confirming approval processes:	Jemma Moore Head of Business and Quality Assurance Clinical Support Care Group.
Name of Governance Lead confirming consultation and ratification:	Kevin Wright
Links to key external standards:	NPSA Safer Practice Note 16, 2007 “Early identification of failure to act on radiological imaging reports”. NHSLA Risk Management Standard 5.7 “Diagnostic Testing Procedures”.
Related Documents:	Policy for the Introduction of New Interventional Procedures. Pathology User Guide. Pathology Specimen Acceptance Policy. Protocol for Referral to Clinical Imaging. Clinical Guideline for the Reporting of Clinical Imaging Examinations and Procedures.
Training Need Identified:	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pathology

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.

Diagnostic Test Reporting and Acknowledgement Procedures for Pathology and Clinical Imaging Policy

V4.0

September 2021

Table of Contents

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the *Information Use Framework Policy* or contact the Information Governance Team
rch-tr.infogov@nhs.net

1. Introduction

1.1. The diagnostic pathway begins when a test is indicated and a request is generated, progresses via the diagnostic process and ends when a report is acted upon by the requester/Responsible Health Care Professional. Failures at any point in this pathway may lead to delays in the care of the patient, sometimes with serious clinical consequences.

1.2. This version supersedes any previous versions of this document.

2. Purpose of this Policy/Procedure

There is an absolute need for clear pathways that identify how, when and to whom results should be communicated and acted upon. This policy provides the framework for achieving this aim.

3. Scope

This policy applies to all those who request/refer and need to act on the results of Pathology or Clinical Imaging diagnostic tests and to those who process these tests.

4. Definitions / Glossary

Requester – Generic term for any individual requesting a test. This will include the following terms used on the Maxims system:

- HCP [Health Care Professional] – Can Order Tests (including Radiology if IRMER Trained), Can Mark Results as Checked (Acknowledged), Can mark results for review
- Responsible HCP – The named individual responsible for the order and therefore the result
- Standard User – Can order tests under their own name (Pathology Only) or order tests to be approved by an HCP, Can Mark Results as Seen, can mark results for review

CITS - Cornwall Information Technology Services

CRIS - Clinical Radiology Information System

Duty Holder- duty holders under IRMER are: The 'Referrer' who requests the exposure. The 'Practitioner' who decides whether the exposure can be justified as doing more good for the patient than harm. The 'Operator' who carries out the various 'practical aspects' of the exposure, including the 'clinical evaluation' of the images produced.

MAXIMS - The electronic clinical record system used within RCHT

PACS - Picture Archive Communication System

Practitioner- A registered healthcare professional who is entitled, in accordance with the employer's procedures, to take responsibility for an individual medical exposure. The primary role of this duty holder is to justify the medical exposure.

Referrer- A registered healthcare professional who is entitled, in accordance with the employer's procedures, to refer individuals for medical exposures.

SBAR-D - Situation, Background, Assessment, Recommendation, Decision. A structured method for communicating critical information adopted by RCHT in October 2014

Winpath - Pathology information system

ICE – GP Pathology testing electronic requesting system

5. Ownership and Responsibilities

5.1. *Role of Individual Staff*

All healthcare staff involved in the diagnostic pathway – including Doctors, Nurses, Healthcare Assistants/Support workers and approved Professions Allied to Medicine (Biomedical Scientists, Radiographers, etc.) are responsible for:

- Being aware of this policy and any documents referred to within it
- Adhering to any requirements described in this policy pertaining to their role in the diagnostic pathway
- The specific responsibilities of requesters/referrers (Responsible HCPs, HCPs and Standard Users) are described in section 6.3 of this policy.

5.2. *Role of Line Managers*

Line managers are responsible for:

- Ensuring their staff follow those processes and procedures relevant to the part they play in the diagnostic pathway.
- Conducting stringent recruitment checks to ensure that only appropriately qualified and registered members of staff request, undertake or authorise tests.
- On-going checks of professional registration, training and competence.

5.3. *Role of Specialty Directors*

It is the responsibility of the Specialty Directors to ensure that "safety net" processes are in place within their specialties so that every Radiology and Pathology result requested from within RCHT is acted upon.

5.4. *Role of Clinical Support Care Group Governance Care Group Management Board (CSCG Gov DMB)*

The CSCG Gov DMB is responsible for the development, approval and communication of this policy.

6. Standards and Practice

6.1. *How the diagnostic test is requested*

It is the responsibility of the requester/referrer to complete the request form accurately, clearly indicating the Responsible HCP.

6.1.1. Clinical Imaging

- The Protocol for Referral to Clinical Imaging informs requesters of their legal responsibilities when requesting imaging procedures, highlights the RCHT referral criteria and provides the access to relevant information and training. There is a specific protocol for the approval of non-medical requesters
- All imaging requests are made in writing either electronically via MAXIMS (RCHT Clinicians) ICE (GP requests) or under certain exceptions via email. The content of the referral is detailed within the imaging referral protocol and must fulfil IR(ME)R requirements

6.1.2. Pathology

- The process for requesting Pathology investigations is described in the Pathology Specimen Acceptance Policy and the Pathology User Guide, including information on how to make urgent requests, sample labelling and transport arrangements

All the referral documents identified above are available via the Documents Library.

6.2. *How the requester is informed of test results*

6.2.1. Test results are available electronically to both RCHT clinicians (via MAXIMS and PACS) and GPs (via GP link, MAXIMS and PACS).

6.2.2. The Clinical Guideline for the Reporting of Clinical Imaging Examinations and Procedures describes the criteria and process for reporting Critical, Urgent or Unexpected Significant findings.

6.2.3. Appendix 3 describes the processes to be followed for reporting abnormal laboratory results and Clinical Imaging results that require immediate clinical action.

6.2.4. The process by which results are captured for review at MDT meetings must be robust - and procedures determined locally by the meeting organiser in agreement with the Laboratory or Clinical Imaging - to ensure that serious results are reviewed.

6.3. *Actions to be taken by the test requester/Responsible HCP*

6.3.1. "Safety net" procedures must be established within each Specialty to ensure all results are acted upon in a timely manner and high risk diagnoses and results are not inadvertently missed. The procedure must take account of patients moving from area to area within a hospital and being discharged before results are received.

6.3.2. Critical, Urgent or Unexpected Significant findings (Clinical Imaging) or abnormal results (Pathology) telephoned to wards often require escalation for medical team attention - this should be done in line with the SBAR-D escalation procedure.

6.3.3. The Responsible HCP will take responsibility for ALL investigations requested by them or in their name but the responsibility for acknowledging a result can be appropriately delegated. In MAXIMS, results default to the Responsible HCP. However, the person who actually requested the test (HCP or Standard User) can also search under their name and find the result.

6.3.4. The requester is responsible for reviewing any urgent results requested during their shift and passing that responsibility on if they finish their shift. For those tests requested where the patient has moved to another area before the result is available, responsibility for the patient passes to the clinician responsible for the patient in that area. Test results will still be the responsibility of the clinician who requested any tests prior to their transfer.

6.3.5. It is incumbent on the Responsible HCP to ensure that he or she personally checks the reporting systems on a regular basis for investigation results and then acts on the information with the necessary degree of urgency. If they are unable to do this they must delegate the responsibility to a colleague. Failure to do this will put patients at risk.

6.4. *How the patient is informed of test results*

It is the responsibility of the Responsible HCP to consider how, when and what to tell the patient.

6.5. *Minimum Documentation Requirements*

6.5.1. Requests received are recorded on the Pathology Winpath GP ICE system and Clinical Imaging CRIS systems.

6.5.2. Results reported via MAXIMS must be acknowledged by the requester/Responsible HCP unless agreed alternative

mechanisms are in place. These alternative mechanisms must be clearly defined in the relevant specialty "safety net" procedures."

6.5.3. Results telephoned to the ward must be recorded in the relevant Pathology or Clinical Imaging systems e.g. MAXIMS or CRIS.

6.5.4. Communication of test results between clinical staff receiving results and other healthcare staff must be recorded in the notes.

6.5.5. Verbal or written communication with the patient or their GP must be recorded appropriately.

6.6. *Risk Management*

6.6.1. Diagnostic testing procedures are evaluated at the time of introduction in compliance with the RCHT Policy for the Introduction of New Interventional Procedures.

6.6.2. All Clinical Imaging examinations are vetted by a practitioner and a decision made to proceed on the risk versus clinical benefit. This is particularly pertinent where there is a high radiation dose associated with the examination.

6.6.3. Consent for investigations is obtained by the Responsible HCP in compliance with their Organisation's consent policy.

7. Dissemination and Implementation

This policy will be placed on the Cornwall & Isles of Scilly Health Community Documents Library with notification to all users via email. It will also appear on the Pathology and Clinical Imaging A-Z of Services Intranet pages.

8. Monitoring compliance and effectiveness

Element to be monitored	Acknowledgement of results by the test requester/Responsible HCP
Lead	Specialty Directors
Tool	Report of percentage acknowledged results by Specialty (generated by CITS)
Frequency	Weekly initially and then monthly
Reporting arrangements	Reports will be reviewed through Specialty/Care Group Governance process
Acting on recommendations and Lead(s)	The Specialty/Care roup Committee which reviews the report will delegate recommendations and action planning to the appropriate lead. Required actions will be identified and completed in a specified timeframe
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within the minimum achievable timescale. A lead member of the Specialty will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

9. Updating and Review

This policy will be reviewed every three years or sooner if circumstances suggest this may be necessary.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion & Human Rights Policy' or the Equality and Diversity website.

10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Diagnostic Test Reporting and Acknowledgement Procedures for Pathology and Clinical Imaging Policy V4.0		
This document replaces (exact title of previous version):	Diagnostic Test Reporting & Acknowledgement Procedures for Pathology & Clinical Imaging Policy V3.0		
Date Issued/Approved:	June 2021		
Date Valid From:	September 2021		
Date Valid To:	September 2024		
Directorate / Department responsible (author/owner):	Sarah Pointon, Pathology Quality and Governance Manager and Health & Safety Lead Glenda Shaw, Clinical Imaging Quality and Service Improvement Lead		
Contact details:	01872 252582 and 01872 255086		
Brief summary of contents	Framework for communication and actions required throughout the diagnostic pathway		
Suggested Keywords:	Diagnostic Test, Pathology, Clinical Imaging		
Target Audience	RCHT	CFT	KCCG
	✓		
Executive Director responsible for Policy:	Medical Director		
Approval route for consultation and ratification:	Clinical Imaging Clinical Governance Group Pathology Quality and Governance Meeting Clinical Support Care Group Governance Meeting		
General Manager confirming approval processes	Jemma Moore Head of Business and Quality Assurance Clinical Support Care Group		
Name of Governance Lead confirming approval by specialty and care group management meetings	Kevin Wright		
Links to key external standards	NPSA Safer Practice Note 16, 2007 “Early identification of failure to act on radiological imaging reports” NHSLA Risk Management Standard 5.7 “Diagnostic Testing Procedures”		
Related Documents:	Policy for the Introduction of New Interventional Procedures Pathology User Guide		

	Pathology Specimen Acceptance Policy Protocol for Referral to Clinical Imaging Clinical Guideline for the Reporting of Clinical Imaging Examinations and Procedures			
Training Need Identified?	No			
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only	
Document Library Folder/Sub Folder	Clinical / Pathology			

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*
April 2012	1.0	Initial Version	No data
October 2014	2.0	Complete revision to reflect implementation of electronic results acknowledgement	Malcolm Owen, Lead BMS Benjamin Rock, Consultant Radiologist Janet Gardner, CSSC Governance Lead
May 2019	3.0	Document reviewed and updated to include ICE, template updated	Sarah Pointon, Pathology Quality and Governance Manager and H&S Lead Glenda Shaw, Imaging Quality & Service Improvement Lead
June 2021	4.0	Document reviewed and updated to new template	Sarah Pointon, Pathology Quality and Governance Manager and H&S Lead Glenda Shaw, Imaging Quality & Service Improvement Lead

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

<table>
<tr><th colspan="6">Section 1: Equality Impact Assessment Form</th></tr>
<tr><td colspan="6">Name of the strategy / policy /proposal / service function to be assessed
Diagnostic Test Reporting and Acknowledgement Procedures for Pathology and Clinical Imaging Policy V4.0</td></tr>
<tr><td colspan="3">Directorate and service area:
Pathology and Clinical Imaging,
Clinical Support Care Group</td><td colspan="3">Is this a new or existing Policy?
Existing</td></tr>
<tr><td colspan="3">Name of individual/group completing EIA
Sarah Pointon/Glenda Shaw</td><td colspan="3">Contact details:
01872 252582 and 01872 255086</td></tr>
<tr><td>1. Policy Aim
Who is the strategy / policy / proposal / service function aimed at?</td><td colspan="5">Establish the framework for communication and actions required throughout the diagnostic pathway</td></tr>
<tr><td>2. Policy Objectives</td><td colspan="5">Minimise the risks associated with the management of diagnostic test results</td></tr>
<tr><td>3. Policy Intended Outcomes</td><td colspan="5">To ensure that the diagnostic process contributes the maximum benefit to the treatment of patients</td></tr>
<tr><td>4. How will you measure the outcome?</td><td colspan="5">Report of percentage acknowledged results by Specialty (generated by CITS)</td></tr>
<tr><td>5. Who is intended to benefit from the policy?</td><td colspan="5">Patients</td></tr>
<tr><td rowspan="3">6a). Who did you consult with?

b). Please list any groups who have been consulted about this procedure.</td><td>Workforce</td><td>Patients</td><td>Local groups</td><td>External organisations</td><td>Other</td></tr>
<tr><td>X</td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="5">Please record specific names of groups:
Clinical Support Care group
Pathology Quality and Governance Meeting
Clinical Imaging Clinical Governance Group</td></tr>
<tr><td>c). What was the outcome of the consultation?</td><td colspan="5">No concerns that the policy could have any differential impact</td></tr>
</table>

7. The Impact
Please complete the following table. If you are unsure/don't know if there is a negative impact you need to repeat the consultation step.

Are there concerns that the policy **could** have a positive/negative impact on:

Protected Characteristic	Yes	No	Unsure	Rationale for Assessment / Existing Evidence
Age		X		
Sex (male, female non-binary, asexual etc.)		X		
Gender reassignment		X		
Race/ethnic communities /groups		X		
Disability (learning disability, physical disability, sensory impairment, mental health problems and some long term health conditions)		X		
Religion/ other beliefs		X		
Marriage and civil partnership		X		
Pregnancy and maternity		X		
Sexual orientation (bisexual, gay, heterosexual, lesbian)		X		

If all characteristics are ticked 'no', and this is not a major working or service change, you can end the assessment here as long as you have a robust rationale in place.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment:	**Sarah Pointon, Pathology Quality and Governance Manager and H&S Lead** **Glenda Shaw, Imaging Quality & Service Improvement Lead**

If you have ticked 'yes' to any characteristic above OR this is a major working or service change, you will need to complete section 2 of the EIA form available here: Section 2. Full Equality Analysis

For guidance please refer to the Equality Impact Assessments Policy (available from the document library) or contact the Human Rights, Equality and Inclusion Lead india.bundock@nhs.net

Appendix 3. Procedure for Telephoned Pathology Lab Results

Results will only be given by telephone in the following circumstances:

- Unexpected abnormal results which might require urgent clinical correlation to ensure patient safety (each laboratory will have a list of specified criteria)
- Those where telephoning has been requested in advance for clinical reasons (however please note that current electronic systems are likely to provide a faster result than an agreed telephone call)

Where a telephone call is required to transmit laboratory results:

- Results will only be transmitted to a named healthcare professional
- The laboratory employee transmitting the results will document the name of the healthcare professional and the date and time of the phone call for audit purposes
- Only one patient's results will be reported by telephone at one time to reduce transcription error

Appendix 4. Clinical Imaging Results Admin Actions

Urgent unexpected findings protocol:

- At regular intervals throughout the day, PAs will access InSight WebPacs and review the ‘For Admin Action’ folder.
- Consultant Radiologists, SpRs and Reporting Radiographers will add patients to this folder if urgent further action is required. This might include recall for further imaging, or telephoning the referrer to bring the result to their attention in a timely manner.
- PAs to follow instructions placed within the ‘For Admin Action’ folder and make a note on the tracker - S:\TR15\xraysrv\CI Secs\Secretaries\Urgent results\Urgent Results 2018.xls. In addition, a note will be placed within the pertinent event on the patient’s CRIS record.