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Royal Cornwall Hospitals NHS Trust

Diagnostic Testing Procedures Within the Endoscopy Department Policy

V4.0

January 2023

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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

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. Endoscopy testing supports many clinical decisions both in the diagnosis of new conditions and the monitoring and treatment of existing ones. As such it sits within the overall therapeutic procedures clinical pathway.

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

2. Purpose of this Policy/Procedure

This policy sets out an approved documented process whereby the risks associated with diagnostic testing procedures within Endoscopy (Gastroenterology) are managed through the provision of local policies and procedures which are implemented and monitored. It has been developed to ensure these risks are minimised through the provision of clear information, guidance and expectation. No patient's treatment should be delayed because of delays in the availability of Diagnostic information and the objective of this document is to ensure that this does not happen, recognising that communication problems are often the root of such delays; there is an absolute need for clear pathways that identify how, when and to whom the results should be communicated. This policy is aimed at those who provide and those who use the Endoscopy services.

3. Scope

This policy applies to all those who request Endoscopy diagnostic tests and those who receive process or need to act on the results of these. The Medicine and Emergency Department Divisional Governance Management Board is responsible for the development, approval and communication of this policy and monitoring compliance with it.

4. Definitions / Glossary

NHSLA	National Health Service Litigation Authority
CITS	Cornwall IT Services
CRIS	Clinical Radiology Information System
DBMS	Database Management section within CITS
GP	General Practitioner
MAXIMS	Electronic clinical record system designed
PACS	Picture Archive Communication System
RCHT	Royal Cornwall Hospitals NHS Trust
SCORPIO	Endoscopy Reporting System

OGD	Oesophago-gastroduodenoscopy
COLON	Colonoscopy
EUS	Endoscopic Ultrasound
EBUS	Endoscopic Bronchoscopy Ultrasound
BRONCH	Bronchoscopy
ERCP	Endoscopic Retrograde cholangiopancreatography
FSIG	Flexible Sigmoidoscopy
ENTEROSCOPY	Direct visualisation of the small bowel.

5. Ownership and Responsibilities

5.1. The strategic and operational roles responsible for the development, management and implementation of the policy are shown below.

5.2. **Role of the Managers**

Line managers are responsible for:

- Conducting stringent recruitment checks to ensure that only appropriately qualified and registered staff undertake and authorise test results and ongoing checks of professional registration
- Ongoing checks of training & competence to perform those tests within the scope of activity of individual staff
- Ensuring that staff follow those processes and procedures described in the Standards and Practice section relevant to the part they play in the diagnostic pathway

5.3. **Role of Individual Staff**

- The diagnostic pathway begins when a request is generated, then endoscopy is performed, samples may be taken and ends when a report is received by the requester and acted upon
- Administrative staff in Endoscopy have a role to play in ensuring appointments are booked and appropriate preparation instigated
- Endoscopy based administrative staff ensure that all endoscopy reports are emailed to GP's daily and that reports have crossed over to MAXIMS in a timely manner

- All staff members are responsible for:

  Being compliant with this policy and any documents referred to within it pertaining to their part in the diagnostic pathway.

5.4. Role of Governance Leads

It is the responsibility of governance leads to ensure that processes are in place within specialties which ensure that every Endoscopy result requested from within RCHT is acted upon. The responsibility for acting on an endoscopy result is with the referrer. This is ensured by the mandatory checking of results which are transferred from Scorpio to MAXIMS.

6. Standards and Practice

6.1. Content

This section is used to describe information regarding practices, systems and processes staff are expected to follow:

6.2. Diagnostic tests provided by the service

OGD

COLON

FSIG

EUS

EBUS

ERCP

BRONCH

ENTEROSCOPY

6.3. How diagnostic testing procedures are risk assessed

6.3.1. Vetting - Policy is centred on vetting procedures. All outpatient procedures are vetted except DTT OGD where there is a shared protocol.

6.3.2. Diagnostic testing procedures are evaluated at the time of introduction (e.g., to check that the procedure is ‘fit for purpose’). Risk assessment tends to be reactive to changes such as the introduction of new guidelines or equipment or changes to existing equipment (e.g., with age) which require that the current level of risk is reassessed. There are specific guidelines for anticoagulants (British society for

gastroenterology (BSG) Endoscopy in patients on antiplatelet or anticoagulant therapy, including direct oral anticoagulants.

6.3.3. Patients are sent procedure specific information. Patient information sent out to the patient prior to the test. These information leaflets are updated annually. This includes key topics such as fasting, sedation, medication, and consent.

6.4. Measures that need to be in place for the diagnostic test to enable any preparation of the patient (e.g., fasting) required

Where these are required, this will be indicated in User guides/requesting information or specific information provided for patients.

6.5. Identifying the process for ensuring that informed consent is obtained prior to a diagnostic test

All patients are consented before going into the procedure room by a nurse who is competent in the consent process. For ERCP/EBUS/EUS or Bronchoscopy the consent process is completed by the consultant performing the test. Patients without capacity to consent have a form 4 completed as per trust policy which should be completed prior to them attending the endoscopy unit. Associated Teams are contacted for support for example the Learning Disability team. There is also a countywide database which identifies patients who will need extra support at the time of referral.

6.6. Reporting of Endoscopy Procedures

6.6.1. All reports are generated exclusively through Scorpio and transferred across to maxims. Direct to test from GP's are entered on to maxims by the vetting consultant. It is the responsibility of the requesting clinician to complete the request form accurately indicating the requesting clinician.

6.6.2. Pathology specimens are signed and checked before the patient leaves the room. Results go to MAXIMS inbox of referring consultant. Patients with suspected malignancy will have their results in 14 days. The endoscopist will refer the suspected cancer patient to the Multidisciplinary Team at the time of writing the endoscopy report. The Colorectal Cancer Clinical Nurse Specialist (CNS) attends the endoscopy unit during office hours. Outside of these hours the patient is given a contact card. The CNS is emailed by the endoscopist to contact the patient the next working day.

6.6.3. Within Endoscopy specimens are requested via a paper system and a printed-out request form giving details of the endoscopy. The request is generated through the Scorpio system. The request forms are completed and checked with the samples and transferred to a specimen box in the endoscopy room awaiting transfer to pathology. The specimen box is emptied twice a day.

6.6.4. Referrals are made according to trust policy.

6.6.5. The only non-medical referrers are the hepatology nurse consultant, the senior IBD nurse, the colorectal 2 week wait nurse and the bowel cancer screening nurse practitioners.

6.6.6. All Endoscopy requests are made in writing electronically via MAXIMS. The content of the referral is detailed within the Endoscopy referral template and is in keeping with BSG guidelines. All two week wait (2WW) endoscopies have a Scorpio report sent as two week wait. Non 2WW endoscopies can have samples sent under the discretion of the consultant.

6.7. Systems in place to ensure that the sample(s) are correctly identified and labelled, prepared and transported

Samples generated within endoscopy have an electronic request generated on Scorpio attached to the paper form. These forms are signs, and the samples are checked in line with the WHO (World Health Organisation) checklist and are signed and checked prior to the patient leaving the procedure room. This is audited monthly and fed back to the governance team/ nursing team so any issues can be discussed.

6.8. Ensuring that diagnostic tests are received within agreed time frames

The Joint Advisory Group provides guidance around reporting times for specimens for e.g., two week wait patients should receive their results in 14 days.

6.9. How the clinician treating the patient is informed of the result, including timescales

6.9.1. Endoscopy results are available electronically to RCHT clinicians via maxims immediately and GPs are emailed within 24 hours.

6.9.2. Pathology results are available electronically to both RCHT Gastroenterologists (via MAXIMS) and GP's (via GP Link).

6.9.3. Pathology results are viewed in MAXIMS and the user will have the opportunity to:

- Close the result without changing the status (an audit trail is kept)
- Mark the result as seen but allocate this to another clinician
- Mark the report as checked

6.9.4. Pathology analytical Standard Operating Procedures (SOP) includes a section "Reporting of results, reference interval, critical values and interpretation". Pathology reporting arrangements are described in SOP [PA G MP ALL PATHREPORT]; separate SOPs describe arrangements for escalating and recording urgent / unexpected / significantly abnormal results which affect the immediate management of the patient e.g., by telephoning (excluding

Histopathology). Turnaround times for individual tests are listed in the Pathology User Guide found on the trust intranet.

6.9.5. Endoscopy Reports, pathology reports and endoscopy images can be viewed at MDT meetings, individually and at a teleconference.

6.10. How the patient is informed of the result, including timescales

6.10.1. The responsibility for passing pathology results to patients lies with the referring clinician. Patients are given a printed copy of the endoscopy report and the findings are explained before discharge by one of the nursing team.

6.10.2. For a new diagnosis of colon cancer, most patients are seen by the colorectal clinical nurse specialist and or the endoscopist (currently the Upper GI CNS does not offer this service and the endoscopist tells the patient the likely diagnosis They are told that histology and further radiological imaging will be ordered and completed within 14 days. They are offered the choice of being phoned with the results or waiting for the outcome of the multidisciplinary meeting.

6.11. Actions to be taken by the clinician, including timescales

6.11.1. The requesting Consultant will take responsibility for ALL investigations requested by them or in their name In MAXIMS results on inpatients default to going back to the Consultant who is currently in charge of the patient, under whose name the tests are requested.

6.11.2. It is for the responsible clinician to ensure that he or she personally checks the reporting systems on a regular basis for the investigation results and then acts on the information within the report with the necessary degree of urgency. If they are unable to do this for example going on leave, they must hand the responsibility over to a colleague.

6.11.3. By and large inpatient results will be signed off by the team who is currently looking after the patient. Outpatient results will usually be signed off by the Consultant under whose name the test was requested.

6.11.4. Referral to the cancer MDT provides a safety net for delayed histology or staging radiology investigations to be identified.

6.12. Minimum Recording Requirements

6.12.1. Requesting:

- Requests received by Pathology are recorded on the Winpath Computer system
- Requests received by Imaging are recorded on the CRIS system and MAXIMS

6.12.2. Informing the patient.

6.12.3. Records are kept of any written correspondence with the patient or their doctor in the electronic notes (MAXIMS). Records are kept of discussions (in person or over the telephone) in the notes.

6.12.4. When recording results within the patient's record the minimum information which must be included is:

- Forename and surname
- NHS/Hospital number
- For unknown patients a coded identifier may be used
- Test or procedure
- Date and time investigation was performed (Imaging) or sample taken (Pathology)
- Interpretive comments made/conclusion reached may be recorded
- Hospital discharge summaries should record confirmed diagnosis and any outstanding investigations

6.13. How the clinician treating the patient is informed of the result, including timescales

6.13.1. Pathology and radiology results must go to the regular clinicians' inbox in MAXIMS to be checked off and acted upon within 14 days.

6.13.2. The Maxims system is also monitored throughout the day by a separate team in CITS. The Maxims software application has an inbuilt interface that monitors incoming HL7 messages from various other applications such as PAS, Winpath (pathology results only at the moment) CRIS (request status updates and results). The only outgoing HL7 messages from Maxims currently are Radiology order requests which feed through to CRIS.

6.13.3. The transfer of information from Scorpio to Maxims is monitored by the Clinical Admin Lead for Endoscopy.

6.13.4. Requesters should check that they have received all reports back (allowing for diagnostic turnaround times) and that results have been correctly documented and acted upon (including telephoned reports/results) and patients informed as appropriate on an ongoing basis as part of their safety net procedures.

6.13.5. Pathology incident reports are analysed annually for Pathology reports which are sent to the wrong location (e.g., due to computer registration errors or postal errors). Complaints and errors are reported on the DATIX incident reporting system. They are investigated by the endoscopy nurse manager or a deputy in their absence. The DATIX are discussed at a monthly governance meeting.

6.13.6. Endoscopy incident reports are reviewed monthly for trends in reporting errors and, where these occur, incidents are investigated appropriately, corrective actions are taken and lessons disseminated through the directorate's governance structure (Governance Group, Directorate meeting and Operational meetings), or Trust structures via the Divisional Quality Group. Risk assessment is facilitated by the risk register.

7. Dissemination and Implementation

The document will be placed on the Cornwall & Isles of Scilly Health Community Documents Library with notification of 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

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	1. Informing the clinician treating the patient of the result; ensuring they are looked at/acknowledged-choose those tests assessed as the highest risk. 2. Reporting timescales. 3. Acting on, documenting, and informing the patient of the result - choose those tests assessed as highest risk. 4. Others are monitored by internal audit systems within the Endoscopy Dept. and by the Clinical Lead.
Lead	Endoscopy Lead
Tool	Scorpio
Frequency	Weekly/Monthly/ Quarterly dependent on audit required.
Reporting arrangements	Reports will be reviewed Governance and Management Committees as well as Divisional Data Quality Group. Each report should contain a summary and action points to enable these to be readily identified; these should be discussed and recorded in meeting minutes. The lead or committee is expected to read and interrogate the report to identify deficiencies in the system and act upon them.

Information Category	Detail of process and methodology for monitoring compliance
Acting on recommendations and Lead(s)	The Committee which reviews the report will delegate recommendations and action planning, for any or all deficiencies and recommendations within reasonable timeframes, to the appropriate committee, department, or 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 team will be identified to take each change forward where appropriate. This will be determined at the Gastroenterology monthly meeting.

9. Updating and Review

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

9.2. Where the revisions are significant and the overall policy is changed, the author will ensure the revised document is taken through the standard consultation, approval, and dissemination processes.

9.3. Where the revisions are minor, e.g., amended job titles or changes in the organisational structure, approval can be sought from the Executive Director responsible for signatory approval, and can be re-published accordingly without having gone through the full consultation and ratification process.
9.4. Any revision activity is to be recorded in the Version Control Table as part of the document control process.

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 and 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

Information Category	Detailed Information
Document Title:	Diagnostic Testing Procedures Within The Endoscopy Department Policy V4.0
This document replaces (exact title of previous version):	Diagnostic Testing Procedures Within The Endoscopy Department Clinical Guideline V3.0
Date Issued/Approved:	November 2022
Date Valid From:	January 2022
Date Valid To:	January 2025
Directorate / Department responsible (author/owner):	Gastroenterology / Endoscopy dept. Dr Paul Fortun / Sister Amanda Phillips
Contact details:	01872 252113 / 253247
Brief summary of contents:	This policy sets out an approved documented process whereby the risks associated with diagnostic testing procedures in Endoscopy are managed.
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:	Gastroenterology Governance Management
General Manager confirming approval processes:	Roz Davies
Name of Governance Lead confirming approval by specialty and care group management meetings:	Maria Lane
Links to key external standards:	None required
Related Documents:	None
Training Need Identified?	No

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Gastroenterology

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
24 July 2012	V1.0	Initial Issue	Amanda Tullett and Tim Mumford
17 Sept 2012	V 2.0	Comments	Paul Fortun, Lisa Ivers, Tim Mumford
12 June 2019	V3.0	Updated version onto latest Trust template.	Dr Paul Fortun / Sister Amanda Phillips
24 November 2022	V4.0	Minor changes to document Document changed from Clinical Guideline to Policy to align with content	Dr Paul Fortun

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

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Diagnostic Testing Procedures Within The Endoscopy Department Policy V4.0
Directorate and service area:	Gastroenterology
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Dr Paul Fortun / Sister Amanda Phillips
Contact details:	01872 252113 / 253247

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	The policy is aimed at service users of the endoscopy unit.
2. Policy Objectives	To provide clear guidance on the processes around Diagnostic Testing Procedures Within the Endoscopy Department.
3. Policy Intended Outcomes	To maintain best practice
4. How will you measure each outcome?	Review at Endomax and Governance Meetings
5. Who is intended to benefit from the policy?	The Endoscopy Service and Patients

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: No • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: Yes
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Endoscopy Clinical Lead – Paul Fortun Gastroenterology Governance Group
6c. What was the outcome of the consultation?	To review and update the policy as out of date and not relevant.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** **No**

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

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: Dr Paul Fortun

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis