Royal Cornwall Hospitals
NHS Trust

Clinical Imaging for the assessment and management of reporting discrepancies and Duty of Candour notification

V3.0

January 2024

Purpose of this Protocol

1.1. This policy details the process to be undertaken when a radiological discrepancy is identified which could have contributed to a patient suffering moderate or severe harm. The purpose ensures the RCHT Clinical Imaging department, and any external providers contracted by RCHT, meet their obligations under the statutory Duty of Candour.

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

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

The Trust has a duty under the Data Protection Act 2018 and UK 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 UK 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 UK 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

2. Guidance for this Protocol

2.1. Background

Nationally discrepancies in reporting radiology images can range from 8-12%. RCHT radiology has a robust procedure for discrepancy review and has a process to alert the Trust and referring clinician of such discrepancies [Appendix A]. The clinical implication of such discrepancies is variable but will, in a number of cases, have resulted in moderate and severe harm. The challenge is to commission a robust and effective clinical response. There are no good national models to follow.

2.2. The parties

This policy relates to the provision of radiology reporting services when undertaken by RCHT Radiologists and reporting Radiographers and reporting services provided by external providers on behalf of the Royal Cornwall Hospitals NHS Trust.

2.3. Scenarios covered by this policy

- A Radiologist or reporting Radiographer (subsequently referred to as 'the Reporter') reporting for The RCHT Clinical Imaging department or an external provider identifies, in the course of their work, a potential error which has occurred in the interpretation of a prior imaging study.
- A Clinician identifies a potential reporting error in a current or prior imaging study and highlights this to a RCHT Reporter.

2.4. What the Reporter will do

- If the potential error is discovered in the course of reporting a further imaging study, the Reporter will make appropriate reference to the prior imaging in their report and, if they feel that moderate or severe patient harm may have occurred as a result of an error in interpretation, the Reporter will refer the case to the Clinical Imaging Specialty Director or deputy if the former is absent. This will be communicated electronically by placing the appropriate imaging study in a shared folder on the RCHT Insignia PACS system titled **'Governance Discrepancies'.**
- A Reporter reporting for an external provider will communicate potential errors, which could have caused moderate or severe harm, to the Clinical Imaging Specialty Director or deputy as per their employer's Duty of

Candour policy.

- If the potential error comes to light outside the reporting environment (e.g. in an MDT meeting or via direct contact from a Clinician), the Reporter will add an addendum to the report and will refer the case to the Clinical Imaging Specialty Director or deputy using the mechanism described above.

2.5. What the Clinical Imaging Specialty Director or deputy will do

2.5.1. Consult with Consultant Radiologist colleagues to assess whether or not an error has occurred: sends e-mail from 'Radiology Governance Discrepancies' generic e-mail account to three Consultant Radiologist colleagues [see e-mail in Appendix A]. These will be selected in rotation using the following criteria:

- They are able to review the case in a timely fashion.
- The case does not pertain to their area of subspecialty expertise.
- They are not involved in the reporting of the case.

2.5.2. A reporting error is confirmed in cases where the majority of the 3 colleagues respond YES to question 1 and NO to question 2.

2.5.3. If a reporting error is confirmed they will inform the appropriate RCHT Specialty Director, Clinical Governance Lead and Specialty Management Team within the specialty caring for the patient, or the patient's General Practitioner using a standard template letter [Appendix B]. This is to allow the Clinician to assess whether harm has occurred as a result of the error.

2.5.4. The Clinical Imaging Specialty Director or deputy will inform any RCHT Reporter(s) who are implicated in this process, that a letter to the patient's responsible clinician has been sent.

2.5.5. If the error involved an external provider or reporting services, a copy of this letter will be sent to them.

2.5.6. If the Clinician confirms that moderate or severe harm has occurred and that the reporting error has contributed to this, the Clinical Imaging Specialty Director or deputy will record the incident on the Trust's incident reporting system [Datix] (unless this has already been done).

2.5.7. Regardless of whether or not an error has occurred and whether or not harm might have occurred as a result, the Clinical Imaging Specialty Director or deputy will consider whether there are learning points which should be shared with other Radiologists, and if so refer to the case to the Radiology Learning Meeting.

2.6. **What the appropriate Clinical Specialty Director or deputy will do**

2.6.1. Discrepancies are alerted to the RCHT Specialty Director, Clinical Governance Lead and Specialty Management Team.

2.6.2. The Specialty Director (or delegated doctor) reviews the case, summarises and makes a judgement on harm. The harm review should be informed by other relevant staff and information. An MDT can be used as appropriate.

2.6.3. The doctor undertaking the review will feedback the outcome to the Clinical Imaging Specialty Director.

2.6.4. Harm graded as: none, mild, moderate or severe.

2.6.5. Moderate and Severe harm will trigger a Trust response (Datix, Duty of Candour discussion with the patient and consideration of whether the incident is a Serious Incident).

The principle is that the appropriate Specialty Director fulfils the Duty of Candour and is the main point of contact for the patient.

If Duty of Candour has been triggered, the usual timescales and actions detailed within the Trust's Being Open: Duty of Candour Policy apply (verbal conversation to take place immediately, follow up letter with investigation findings to be sent within 10 days). Compliance with Duty of Candour is monitored bi-monthly at the Trust's Incident Review and Learning Group. Compliance at care group level is monitored through the care group governance meeting which is also the mechanism to feedback learning.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	When a radiological discrepancy is identified which could have contributed to a patient suffering moderate or severe harm and to ensure the RCHT Clinical Imaging department, and any external providers contracted by RCHT, meet their obligations under the statutory Duty of Candour.
Lead	Imaging Quality and Service Improvement Lead.
Tool	Minutes from Trust's Incident Review and Learning Group and Clinical Imaging Governance Group.
Frequency	Compliance with Duty of Candour is monitored bi-monthly at the Trust's Incident Review and Learning Group.
Reporting arrangements	Audits will be reported to the Clinical Imaging Clinical Governance Group, which meets monthly. Minutes of the meeting will record decisions and any necessary actions.
Acting on recommendations and Lead(s)	Any recommendations will be communicated from Clinical Imaging Governance Group.
Change in practice and lessons to be shared	Discussed and communicated from Clinical Imaging Clinical Governance Group.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

4.2. Equality Impact Assessment.

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

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title	Clinical Imaging protocol for the assessment and management of reporting discrepancies and Duty of Candour notification V3.0.
This document replaces (exact title of previous version)	Clinical Imaging protocol for the assessment and management of reporting discrepancies and Duty of Candour notification V2.0.
Date Issued/Approved	November 2023.
Date Valid From	January 2024.
Date Valid To	January 2027.
Directorate/Department responsible (**author/owner)**	Clinical Support Care Group/Clinical Imaging/Glenda Shaw, Quality and Service Improvement Lead.
Contact details	01872 255086.
Brief summary of contents	To ensure appropriately trained Radiologists and Reporting Radiographers have a robust discrepancy reporting policy in place to support Trust Duty of Candour obligations.
Suggested Keywords	Clinical Imaging IR(ME)R Radiologist Reporting Radiographer Discrepancy Reporting Duty of Candour CI.GEN.PPG.58
Target Audience	**RCHT:** Yes

Information Category	Detailed Information
	CFT: No **CIOS ICB:** No
Executive Director responsible for Policy	Chief Medical Officer.
Approval route for consultation and ratification	Clinical Imaging Governance Group. Clinical Support Care Group Governance Meeting.
General Manager confirming approval processes	Richard Andrzejuk, Care Group General Manager Clinical Support.
Name of Governance Lead confirming approval by specialty and care group management meetings	Kevin Wright.
Links to key external standards	Ionising radiation (Medical Exposure) Regulations.
Related Documents	• RCHT Positive Patient Identification Policy and Procedures. • RCHT Policy for Consent to Examination or Treatment. • RCHT Policy to Manage Information and Records. • RCHT Ionising Radiation Safety Policy.
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/Clinical Imaging.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
September 2019.	1.0.	Document created	Tom Sulkin, Speciality Director.
February 2021.	2.0.	Document reviewed and updated. Template updated to incorporate Trust requisite format and appendices	Tom Sulkin, Speciality Director.
November, 2023.	3.0.	3-year mandatory review. No change to content. Trust template updated.	Tom Sulkin, Speciality Director.

All or part of this document can be released under the Freedom of Information Act 2000 All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years. This document is only valid on the day of printing.

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). 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	Clinical Imaging protocol for the assessment and management of reporting discrepancies and Duty of Candour notification V3.0.
Directorate and service area	Clinical Imaging.
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)	Glenda Shaw, Imaging QSI Lead.
Contact details	01872 25068.

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)	To support Radiologists and Reporting Radiographers in providing a robust discrepancy reporting policy as national guidance is deemed poor.

Information Category	Detailed Information
2. Policy Objectives	To ensure appropriately trained Radiologists and Reporting Radiographers have a robust discrepancy reporting policy in place to support Trust Duty of Candour obligations.
3. Policy Intended Outcomes	Any discrepancy reporting is done in a standardised fashion supporting Trust Duty of Candour.
4. How will you measure each outcome	Through robust discrepancy reporting to be documented to withstand scrutiny by external audit.
5. Who is intended to benefit from the policy	Patients through robust discrepancy reporting as appropriate.
6a. Who did you consult with (Please select *Yes* or *No* for each category)	• Workforce: Yes • Patients/visitors: No • Local groups/system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	Discussed under Clinical Imaging Governance Group.
6c. What was the outcome of the consultation	No impact.
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	
Marriage and civil partnership	No	
Pregnancy and maternity	No	

Protected Characteristic	(Yes or No)	Rationale
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:
Glenda Shaw, Imaging QSI Lead.

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.