

REPORT CLASSIFICATION	✓	CATEGORY OF PAPER	✓
Official	✓	Proposes specific action	
Official: Sensitive Commercial		Provides assurance	✓
Official: Sensitive Personal		For information only	

BOARD	
29 JULY 2025	
Report Title:	County Durham and Darlington NHS Foundation Trust Breast Services – Royal College of Surgeons (RCS) Report
Purpose of report	
<p>This report shares the commissioned review of the County Durham and Darlington NHS Foundation Trust (CDDFT) Breast Surgery Service conducted by the Royal College of Surgeons (RCS).</p> <p>It outlines the Trust's response, the associated patient safety incident, and the North East and North Cumbria ICB (NENC ICB) actions taken to improve service quality, safety, and oversight. It seeks Board assurance and guidance on any further required actions.</p>	
Key points	
<p>County Durham and Darlington NHS Foundation Trust (CDDFT) was identified as an outlier in breast surgery outcomes during a Northern Cancer Alliance (NCA) treatment variation review. This led to a peer review, a Getting It Right First Time (GIRFT) review, and the RCS Invited Review.</p> <p>The RCS was commissioned by NENC ICB and conducted its review in January 2025, concluding in April 2025. The final report, excluding patient-identifiable appendices, is now publicly available and was shared with CDDFT and NENC ICB.</p> <p>In response, a Breast Surgery Oversight and Delivery Group was established, co-chaired by the Chief Medical Officer of the NENC ICB and the NHS England Regional Medical Director. This group, involving CDDFT, NENC ICB, the Care Quality Commission (CQC), and other stakeholders, was set up to coordinate and monitor progress.</p> <p>CDDFT implemented a comprehensive improvement plan including governance enhancements, service redesign, external clinical leadership, and equipment investment. The ICB made clear the need for duty of candour with patients assessed as having experienced potential harm in light of both the NCA review and the RCS review. CDDFT has actioned this.</p> <p>Despite several improvements and actions having been agreed by CDDFT and some clear early improvements, a patient safety incident in early 2025 revealed shortcomings in embedding the improvement work into practice. This triggered a formal independent investigation which is ongoing.</p> <p>There remains continuing concern regarding the oversight and management of services delivered via a Limited Liability Partnership (LLP) or Subsidiary Organisation. As such, the ICB has written to all Trusts to ensure they have robust governance, including Board oversight of patient quality and safety for their LLPs and any subsidiary arrangements. The ICB has sought assurance of the Board oversight arrangements and reminded all Trusts of the requirement within the NHS standard contract to seek approval from the ICB for sub-contracting arrangements.</p>	

Please note that this paper focuses on the ICB's response to the RCS Invited Review. NHS England, as the regulator, are also in discussion with the Trust regarding the required improvements.

Summary of current position, patient impact and actions taken

The RCS report identified serious concerns about patient safety, service consistency, clinical governance, and MDT (multidisciplinary team) practices. In response, CDDFT initiated a comprehensive improvement plan.

The patient impact is significant. Three groups have been identified as potentially affected:

1. Patients who may have undergone unnecessary or excessive surgery,
2. Patients who had inadequate biopsy samples,
3. Patients whose biopsies may have missed diseased tissue.

As of July 2025, to date in total, CDDFT have opened 191 incidents relating to Breast Surgery look back exercises and closed 123. CDDFT has contacted affected patients directly and maintained open communication through a helpline and email support. Twelve patients have been formally notified under duty of candour.

The Breast Surgery Oversight and Delivery Group continues to monitor implementation, ensure accountability, and coordinate support across all workstreams, including primary care and CQC engagement.

Looking ahead, the ICB will commission a Royal College of Radiologists review, strengthen subcontracting governance across providers, and realign breast services with screening centres to improve quality and consistency. CDDFT's safety review and clinical look-back remain ongoing, with plans for regular reporting and public updates.

This reflects a system-wide effort to restore service quality, maintain transparency, and rebuild patient trust.

Risks and issues

- Risk of delayed diagnosis or misdiagnosis of breast cancer identifying harm and duty of candour via clinical look-back.
- Sustaining service capacity during a change period may impact cancer waiting times and patient experience.
- Sustaining a breast service in CDDFT whilst maintaining clinical leadership to support implementation of the comprehensive action plan.

Assurances and supporting documentation

- A clinical reference group with external clinical expertise has been established within CDDFT.
- An external governance review has been commissioned by CDDFT.
- A practical public facing communications approach has been taken by CDDFT.
- A Breast Surgery Delivery and Oversight Group considers the work of the various workstreams to oversee and receive assurance in relation to progress and improvements within the service at CDDFT.

Recommendation/action required

The Board is asked to

- Receive and note the contents of the Invited Review of the CDDFT Breast Surgery Service conducted by the RCS and acknowledge the impact on patients.
- Note the immediate and proposed actions to monitor and improve services.
- Recognise the need to commission a Royal College of Radiologists review as part of the ongoing incident management.
- Note NHS England and the ICB's ongoing oversight of CDDFT breast services via the Breast Surgery Oversight and Delivery Group.

Acronyms and abbreviations explained						
NENC ICB – North East and North Cumbria Integrated Care Board RCS – Royal College of Surgeons NCA – Northern Cancer Alliance CDDFT – County Durham and Darlington NHS Foundation Trust MDT - Multidisciplinary Team CQC - Care Quality Commission QIG – Quality Improvement Group CRG - Clinical Reference Group LMC – Local Medical Committee LLP - Limited Liability Partnership						
Sponsor/Approving Executive Director	Dr Neil O'Brien, Chief Medical Officer					
Date approved by Executive Director	22 July 20/25					
Report author	Alison Featherstone, Managing Director, Northern Cancer Alliance for NENC ICB					
Link to ICP strategy priorities (please tick all that apply)						
Longer and Healthier Lives						✓
Fairer Outcomes for All						✓
Better Health and Care Services						✓
Giving Children and Young People the Best Start in Life						
Relevant legal/statutory issues						
Note any relevant Acts, regulations, national guidelines etc						
Any potential/actual conflicts of interest associated with the paper? (please tick)	Yes		No		N/A	✓
Equality analysis completed (please tick)	Yes		No		N/A	✓
If there is an expected impact on patient outcomes and/or experience, has a quality impact assessment been undertaken? (please tick)	Yes		No		N/A	✓
Essential considerations						
Financial implications and considerations	Not applicable					
Contracting and Procurement	Contracting and procurement advice is provided by Director of Contracting.					
Local Delivery Team	Chief Delivery Officer has been engaged in this work and GP clinical lead for County Durham is a member of the Breast Surgery Oversight and Delivery Group.					
Digital implications	Not applicable					
Clinical involvement	Chief Medical Officer NENC ICB and Regional Medical Director NHS England chair the Breast Surgery Oversight and Delivery Group. Medical Director CDDFT and Clinical Director Northern Cancer Alliance are members of the Breast Surgery Oversight and Delivery Group.					

	GP clinical lead and local Local Medical Committee (LMC) secretary have been consulted and are members of the Breast Surgery Oversight and Delivery Group. CDDFT has a clinical reference group in place which includes external clinical expertise.
Health inequalities	Health inequalities are considered as part of each workstream and particularly in relation to the clinical reference group.
Patient and public involvement	Not applicable
Partner and/or other stakeholder engagement	Not applicable
Other resources	Not applicable

County Durham and Darlington Foundation Trust Breast services – Royal College of Surgeons Report

1. Introduction

In 2024, County Durham and Darlington NHS Foundation Trust (CDDFT) was identified as an outlier in breast surgery outcomes during a Northern Cancer Alliance (NCA) breast treatment variation review. This prompted a NCA peer review and led to NENC ICB determining the need to commission a Royal College of Surgeons (RCS) Invited Review. The RCS Invited Review was conducted in January 2025, and the report made available to CDDFT and the ICB in April 2025.

A fortnightly Breast Surgery Oversight and Delivery Group, co-chaired by the Chief Medical Officer of NENC ICB and the Regional NHS England Medical Director, was established to oversee the improvements required as recommended in the RCS Invited Review. Despite several improvements and actions having been agreed and some clear early improvement efforts, a patient safety incident in early 2025 revealed further actions were required in the interests of patient safety to ensure improvement work is embedded into practice. The scope of the Breast Surgery Oversight and Delivery Group was broadened and there was an immediate cessation of outsourced breast diagnostic services by the Trust. The membership of the CDDFT clinical reference group has also expanded in response to this incident.

Please note, there is a breast surgery response programme in place in CDDFT with ongoing work related to patient safety and governance. This paper seeks to explain some of the emerging findings from that work. The Board will receive further updates on any future findings.

CDDFT will report on what has occurred, the reasons behind it, the impact on patients, and the actions being taken in response to both the RCS Invited Review and the ongoing patient safety investigation.

This report summarises risks, patient impact, and the actions taken to address service quality and safety.

2. Background

As part of the NCA Treatment Variation Workplan for 2023/24, CDDFT was identified as both a system and national outlier for breast surgery re-excision rates using Model Hospital data within the North East and North Cumbria region. The Trust subsequently agreed to participate in a peer review, led by the NCA, which took place during April and May 2024.

The peer review raised concerns regarding some practice that was not in line with current national recommendations and due to the limited scope of the review, the clinical lead suggested a Royal College review may be useful. These concerns were reported by CDDFT to the ICB in May 2024.

An action plan was developed to address the issues identified, with regular meetings between the Medical Directors for CDDFT, NENC ICB, NHS England and the NCA. Immediate actions included sourcing sessions from an external clinical lead to provide enhanced leadership to the service including work on duty of candour, improvements in the

weekly breast multi-disciplinary team (MDT) meeting to include external breast expertise attendance, prioritising recruitment of surgeons with expertise in oncoplastic surgery and ensuring patients were offered the opportunity to access services at other hospitals if not available at CDDFT. Progress against the action plan was also monitored through the ICB's quality meetings with the Trust as well as via an NHS England Rapid Quality Review group.

In collaboration with the ICB, in July 2024, the Trust agreed that the ICB commission the RCS to carry out a comprehensive review of the breast surgery service. This review was completed in January 2025. While awaiting the RCS review, CDDFT also accepted an offer to participate in an individual service review in December 2024 as part of the Getting It Right First Time (GIRFT) NENC system-wide breast services review which reported in February 2025.

Following both reviews, CDDFT examined the findings, created improvement plans, and started implementing measures to address the recommendations.

However, in early 2025, a patient safety incident occurred. Upon investigation, CDDFT found that some of the planned changes that had been agreed in response to the initial NCA peer review and GIRFT report had not yet been fully implemented. It concluded that, had these changes been in place, the incident might have been prevented. Consequently, CDDFT initiated a formal patient safety investigation, independent of the breast surgery service, and undertook a full review of the service. This review is ongoing.

3. Royal College of Surgeons (RCS) Review

The RCS team reviewed documentation, conducted case reviews, and interviewed clinical and non-clinical staff. The review was conducted between 15 and 17 January 2025. Initial feedback was given verbally at the end of the visit, and the final report was made available to both parties in April 2025.

The RCS handbook for Invited Reviews states that a summary of specified content and recommendations must be published. However, in the interest of transparency, both the ICB and CDDFT are publishing the full report, excluding the appendices where patient-identifiable information may be present.

The review examined background documentation related to breast surgery, breast radiology, and breast non-surgical oncology services. This included the peer review report produced by the NCA and findings from a GIRFT visit in December 2024.

It also involved a review of clinical records for cases submitted by CDDFT and the ICB, as well as interviews with members of the breast surgery, breast radiology, and breast non-surgical oncology teams, along with colleagues who work with them and other relevant staff.

The report shared today gives a thorough summary of the CDDFT breast service, including diagnostics, outpatients, radiology, non-surgical oncology, and pathology. However, most of the report focuses on the breast surgical service. It also looks at MDT working and the breast cancer MDT meeting, as well as the clinical governance for the service.

The report made four recommendations to address patient safety and further recommendations related to service improvement particularly for the MDT meeting and working, clinical leadership, a need to have consistency for the services on both hospital sites and to further develop plans across the North East and North Cumbria to align with

screening centres. Additional recommendations involved the need to embed quality improvement and to develop specialist clinical governance for the breast service.

Urgent recommendations to address patient safety risks

1. There should be a protocol for patients that no axillary clearance happens without pre-operative evidence of nodal involvement, together with clear informed consent.
2. Appropriate access to clear referral pathways for patients to receive investigations at other breast screening centres if not available at CDDFT.
3. Consider refresher training for some of the surgical team members.
4. The Trust should consider its responsibilities for duty of candour for three cases.

There were further recommendations to consider including the need for team job planning and to support staff in ongoing learning to further develop their skills. The report also noted that there should be clear protocols for information sharing where outsourcing is used.

3.1. County Durham and Darlington NHS Foundation Trust response

CDDFT had already developed a comprehensive improvement plan in response to the NCA peer review, the 2024 GIRFT report, and verbal feedback from the RCS review. Key actions undertaken as part of this plan include:

- Establishing a Clinical Reference Group, incorporating external clinical expertise, to support the duty of candour and conducting a retrospective review of cases to assess any potential harm. This group now also includes external radiology specialists too.
- Launching a transformation workstream to implement the recommended service improvements.
- Conducting an internal review of clinical governance, supported by an external evaluation.
- Developing a communications and engagement strategy.
- Appointed two new consultant surgeons with advanced oncoplastic expertise. Prior to their appointment the Trust had developed a second opinion pathway for oncoplastic surgery.
- Securing external clinical leadership for the service, including leadership of the MDT meetings.
- Investing in surgical equipment to enhance service delivery.
- Engaging with the CQC, who are working with CDDFT to ensure the necessary regulatory assurance is achieved.

The ICB is assured by the plan developed and particularly the involvement of external clinical leadership and the appointment of consultants with advanced oncoplastic expertise.

3.2. ICB assurance and governance

The ICB has supported and monitored CDDFT actions throughout. A timeline of key actions is set out below. The Breast Surgery Oversight and Delivery Group was established in March 2025 to further enhance and coordinate assurance. As well as CDDFT, the ICB and regional members, the group includes invitations for CQC and primary care stakeholders to attend.

The Breast Surgery Oversight and Delivery Group considers the work of the various workstreams to oversee and receive assurance in relation to progress and improvements within the service at CDDFT. The group functions as an operational sub-group of the already established Quality Improvement Group with a wide range of members. The group provides assurance that the clinical reference group complete a look back exercise with patient recall and duty of candour as required.

The group provides advice and support to facilitate the required improvement plans and provides a mechanism for direct assurance for the milestones and achievements of CDDFT's improvement plan. This oversight mechanism does not replace the statutory accountabilities of CDDFT or partner organisations.

Timeline of key actions and ICB response

Date	Action	Summary	ICB assurance and governance
April-June 2024	NCA treatment variation audit initiated local peer review. Report shared June 2024.	Concerns raised regarding clinical approaches, and service integration. Immediate actions were put in place to include enhanced leadership, strengthened MDT and referral pathways. Recruitment of oncoplastic expertise and other investment also agreed.	<ul style="list-style-type: none"> • CDDFT action plan in place. • ICB monitoring via Quality Improvement Group (QIG). • NHSE informed. • Duty of candour requested. • Review of non-surgical oncology practice requested.
July 2024	RCS review commissioned	Based on NCA initial assessment further understanding was necessary.	<ul style="list-style-type: none"> • As above.
Dec 2024	GIRFT planned breast NENC system visit. Individual visit to CDDFT agreed as part of the review.	Observation report noted Trust as an outlier in data metrics because it does not repatriate screening patients, unlike other Trusts where over 30% of breast service patients come from screening. Supported the improvement plans in place.	<ul style="list-style-type: none"> • Continue plan for RCS review. • QIG meetings continue to monitor improvements. • NCA asked to review current service model.

Jan 2025	Independent NCA review of non-surgical oncology	Subset of patients reviewed from initial NCA review. Patients offered treatment in line with national guidance.	<ul style="list-style-type: none"> • N/A
Jan 2025	RCS review	See full report.	<ul style="list-style-type: none"> • Further external clinical leadership supported. • Enhanced oversight agreed for various workstreams.
Feb 2025	Patient safety incident	As part of the work of CDDFT enhanced clinical expertise a patient safety issue was noted which raised concerns with diagnostic processes.	<ul style="list-style-type: none"> • CDDFT end all outsourcing for breast service. • CRG extend current clinical review. • Radiology review to be commissioned. • Breast Surgery Oversight and Delivery Group membership broadened.
April 2025	RCS report available to CDDFT and the ICB	See full report.	<ul style="list-style-type: none"> • Report shared with the ICB and CDDFT board. • Immediate safety mitigations and action plans developed. • Reporting fortnightly to Breast Surgery Oversight and Delivery Group.

4. **Current position**

In early 2025, a patient safety incident revealed that some improvements had not yet been embedded. This led to the cessation of an outsourced diagnostic service in February 2025, creating temporary capacity pressures. The Breast Surgery Oversight and Delivery Group continues to track progress and provide operational assurance. A communications strategy has been launched to support patients and GPs. The review is ongoing.

Following the patient safety incident in 2025 which resulted in a formal patient safety investigation, immediate actions included:

- CDDFT ceased its outsourced diagnostic service, reducing current capacity. The NENC Mutual Support Coordination Group is working with partners, to manage the impact on capacity and meet ongoing demand. This is causing some delays in patient pathways.
- CDDFT engaged with patients through open, direct communication, including a dedicated helpline and email address that remain available for sharing concerns or experiences. Patients whose care was reviewed, whether concerns were found or not, are being contacted personally in line with the duty of candour. CDDFT has committed to publishing a patient-facing update alongside the RCS report, including a summary of findings, actions taken, and a video message from the Executive Director of Nursing. Continued engagement will include structured briefings, media updates, and accessible channels to ensure transparency, learning, and support throughout the process.

- CDDFT continued engagement with primary care with regular updates being shared with GPs and primary care providers to keep them informed throughout the review process.
- The NHS Standard Contract General Condition 12 is clear that providers are responsible for subcontracting. Providers should gain approval from the ICB before subcontracting to another provider. The ICB are undertaking a review of current subcontracting arrangements with all providers.
- A Royal College of Radiologists review will be requested by the ICB and in the interim the Trust have secondary checks and safety measures in place including external radiology support.
- The Breast Surgery Oversight and Delivery Group, a sub-group of the Quality Improvement Group, oversees progress across workstreams. It ensures clinical review processes are followed, including patient recall and duty of candour.
- The ICB is working with Providers to develop a service model that aligns the service with screening centres.

4.1. Impact on patients

There are three main groups of people impacted by these findings. Those who may have had excessive or unnecessary surgery, people who have had a biopsy, but the sample may have been inadequate or where the sample has missed the impacted tissue. It should be noted that there is always the potential for biopsies to be inadequate and there is an expected range for this. There will also be some people who have been in the service and will be anxious that any treatment they have had may not have been correct.

This work is ongoing with the Clinical Reference Group in CDDFT doing a look back at cases where people may have come to potential harm. The figures below are therefore the position as of July 2025:

- In total, to date, CDDFT have opened 191 incidents relating to Breast Surgery look back exercises and closed 123.
- Of the closed incidents, in 11 cases there was moderate harm
- In a further 61 cases there was minor harm.
- Some 68 cases remain open, pending external expert review.
- 12 patients have been seen as duty of candour.

CDDFT has also set up a helpline for anyone who is worried about any treatment or contact they have had with the service. The contact information for patient enquiries or feedback is:

- Email: cddft.breastservices@nhs.net
- Helpline: 0191 3332126

5. Summary

As part of routine audit work for the NCA, CDDFT agreed to a local peer review as it was noted as different to local peers. The review noted that some practice was not in line with current national recommendations and it was suggested further review may be warranted. The RCS Invited Review was requested within a couple of months of the peer review findings being available following initial work to put in place immediate improvement actions.

Whilst awaiting the review, the ICB monitored the delivery of the CDDFT action plan to ensure service improvement were put in place as part of the agreed action plan. The GIRFT visit in December 2024 provided some assurance as to why CDDFT would be a data outlier and supported the improvement plans that were in place as well as making further

recommendations. The RCS review made some further recommendations to improve patient safety, governance and service improvement to which CDDFT again responded proactively.

Whilst putting in place enhanced assurance via a Breast Surgery Oversight and Delivery Group there was a patient safety incident which was recognised in part by the work of the improved clinical expertise and new appointments in the multi-disciplinary team at CDDFT, both of which had been requested by the ICB to support the service. The response to this latest incident is ongoing but as part of this ongoing work a Royal College of Radiologists review has now been agreed and in the interim CDDFT have secondary checks in place. This report will be shared once completed as will an update from the CDDFT breast surgery response programme.

6. Recommendations

The Board is asked to:

- Receive and note the contents of the Invited Review of the CDDFT Breast Surgery Service conducted by the RCS and acknowledge the impact on patients.
- Note the immediate and proposed actions to monitor and improve services.
- Recognise the need to commission a Royal College of Radiologists review as part of the ongoing incident management.
- Note NHS England and the ICB ongoing oversight of CDDFT breast services via the Breast Surgery Oversight and Delivery Group.

7. Appendices

Appendix 1 - Royal College of Surgeons Invited Review Report

County Durham and Darlington NHS Foundation Trust's report into the Breast Surgery Review can be found [here](#).

Author: Neil O'Brien, Chief Medical Officer
Alison Featherstone, Managing Director, Northern Cancer Alliance

Sponsoring Director: Neil O'Brien, Chief Medical Officer

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