

Report on the Breast Surgery Service

County Durham and Darlington NHS Foundation Trust

Review visit carried out on: 15-17 January 2025

Report issued: 11 April 2025

A service review on behalf of:

The Royal College of Surgeons of England

Association of Surgeons of Great British and Ireland (ASGBI)

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Please note that Appendix B has been removed from this version of the report because the inclusion of specific information such as dates could result in disclosure of patient identifiable information. Findings arising from the case reviews are captured in Section 3 – conclusions. Further personal-identifiable information, included in Appendix E has been redacted and Appendix F, which comprises only personal identifiable information has been removed.

1. Introduction and background

On 31 July 2024, Dr Neil O'Brien, Chief Medical Officer, North East and North Cumbria Integrated Care Board ('the ICB'), wrote to the Chair of the Invited Review Mechanism (IRM) to request an invited service review of the County Durham and Darlington NHS Foundation Trust ('the Trust') Breast Surgical Service.

The request was made against the background of issues raised by external peer review, which had been confirmed by an internal audit. The Northern Cancer Alliance (NCA) Breast Managed Clinical Network ('the network') had undertaken work to address treatment variation. Following this, the Trust asked the NCA to conduct a limited external peer review of its symptomatic surgical breast service. 1 It was reported that Model Hospital 2 data had identified that the Trust's Breast Surgery Service was a system outlier in terms of re-excision rates³, which was also confirmed by an internal audit. Details of the external review can be found at Appendix A, section A1.2.

The request for this invited review identified the following findings from the NCA review:

- Evidence to suggest deviation from national guidelines and best practice in the diagnostic workup of breast conditions and surgical treatment.
- Potential discrepancy between the size on imaging against that found at surgery/pathology (breast radiology was not part of the NCA review remit and no breast radiologists were on the NCA review panel).
- The NCA reviewers believed neoadjuvant chemotherapy⁴ should have been offered in some cases and there were no documented reasons as to why this had not happened (there was no access to oncology notes and no non-surgical oncologist on the NCA review panel).
- Issues were identified with the quoracy, structure and effectiveness of the MDT meeting and wider MDT working.

In response to the NCA audit, the ICB and Trust had created a set of actions to support the service, which included:

- Having external oncoplastic surgical input into the weekly Trust Breast MDT.
- Establishing a pathway for external second opinion for all patients whose MDT outcome was mastectomy, to ensure patients had access to oncoplastic breast surgery techniques.
- Sourcing capacity from a Consultant Oncoplastic Breast Surgeon from another Trust to provide leadership and support internal review processes, duty of candour⁵, recruitment of oncoplastic surgeons and service strategy.

In requesting an invited review, the ICB raised the following specific questions:

1. To understand whether the Trust delivers a safe, effective, up to date diagnostic breast service, particularly in relation to breast radiology and possibly non-surgical oncology.

¹ A symptomatic breast surgery service is one that specialises in performing surgical procedures on patients experiencing breast-related symptoms (e.g., lumps, nipple discharge, skin changes), which could potentially indicate breast cancer and require prompt diagnosis and treatment.

² https://model.nhs.uk/

³ Breast re-excision is a surgical procedure to remove additional breast tissue after initial breast conserving surgery, to ensure clearance of all cancer cells.

⁴ Neoadjuvant therapy is treatment given as a first step to shrink a tumour before the main treatment, usually surgery, is given. Examples of neoadjuvant therapy include chemotherapy, and hormone therapy. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/neoadjuvant-therapy

⁵ https://www.gov.uk/government/publications/nhs-screening-programmes-duty-of-candour/duty-of-candour

- 2. To understand whether the Trust delivers a safe, effective, up to date breast surgical service particularly in relation to the range of treatments offered including referral to other providers as required.
- 3. To review the local peer review to offer an opinion on whether any other appropriate actions could be taken in the short term.
- 4. To offer expert advice and guidance on any system-wide actions required based on the outcome of 1 and 2.

This request was considered by the Chair of the RCS England IRM and a representative of the Association of Surgeons of Great Britain and Ireland, and it was agreed that an invited service review would take place.

A review team was appointed, and an invited review visit was held on 15-17 January 2025. The appendices to this report list the <u>members of the review team</u>, the <u>individuals interviewed</u>, the <u>service overview information</u>, the <u>documents provided to the review team</u> and the <u>clinical records reviewed</u>.

The invited service review report was issued on 11 April 2025. An amended invited service review report was issued on 24 April 2025 to more accurately reflect the overview of the Trust at section 1.1 (page 5), the reason for the NCA review at section 1.2.2 (Appendix A, page 29), and the structure of the care groups and reporting lines at sections 1.4.1 and 1.4.2 (Appendix A, page 32).

1.1 Overview of the Trust

At the time of the invited review, the Trust was a member of the collaboration of North Cumbria and North East NHS bodies Integrated Care System⁶.

The Trust's services were organised into six care groups: Urgent and Emergency Care; Medicine (including stroke and elderly care), Surgery, Community Services, Family Health and Clinical Specialist Services.

The Trust provided acute services at Darlington Memorial Hospital (DMH) and University Hospital North Durham (UHND), and elective inpatient and day case surgery at Bishop Auckland Hospital (BAH). There were some smaller contracts with Public Health England for bowel screening, diabetic retinopathy, ante-natal and new-born (ANNB) and cervical screening and dental care; and with specialist commissioners (mainly for drugs, intensive care and neonatal care) and Youth Justice.⁷

The Trust had a combined CQC rating of good, although it was rated 'requires improvement' for 'Safe', reflecting concerns relating to emergency care at UHND and other issues; none were specific to the breast surgery service.^{8 9}

1.2 Overview of the Breast Service

The Trust offered a symptomatic breast service. Screening patients with a cancer diagnosis received treatment at other units.

⁶ https://northeastnorthcumbria.nhs.uk/

⁷ https://api.cqc.org.uk/public/v1/reports/25b1a034-4dd9-4543-bdda-2a6ef0f9d03d?20210114232044

⁸ https://www.cqc.org.uk/provider/RXP

⁹ On 23 April 2025 RCS England was informed by the ICB and Trust that, while urgent and emergency care was rated RI for 'Safe' at the time of the review visit, CQC published its final inspection report on emergency care at UHND on 14 January 2025, which rated the service 'Good' for 'Safe'. However, at this point both the CQC and Trust websites still showed the 3 December 2019 report as the latest published report.

The breast service was provided by three substantive consultant surgeons, two locum consultant surgeons, an associate specialist and a team of specialist nurses. One of the substantive consultant surgeons was not undertaking clinical activity with the Breast Service at the time of the invited review. Further details on staffing can be found at Appendix A, section A1.4.

One-stop clinics were provided at DMH, UHND, and Bishop Auckland Hospital (Appendix A, section A1.5). However, half of patients referred into the Trust's one stop clinics were seen outside normal Trust clinics: either they were seen in an independent sector clinic (outsourced) or in clinics held on the Trust premises out of hours and run by a private company (insourced) at evenings and weekends, with the same individual running both services.

The Trust website detailed that patients could usually expect to receive the results of biopsies within 48 hours, cancer surgery was within 31 days, and excisional biopsy within two weeks.¹⁰

A breast reconstruction service was offered including contralateral balancing where requested. Oncoplastic techniques were used to improve cosmetic outcomes after excision and radiotherapy.¹¹

Breast radiology was based within the Trust. The Trust was served for oncology by the two regional cancer centres in Newcastle and Middlesbrough. Patients travelled to The James Cook University Hospital to receive radiotherapy. ¹² The only other site in the region where radiotherapy was provided was in Newcastle.

The Breast Care Nursing Service comprised a team of Breast Care Nurses who worked closely with the specialist breast surgeons and other clinicians, as well as the Clinical Research Team. ¹³ Patients were expected to have regular contact with the Breast Care Nurses until approximately three months after finishing all treatments.

The Trust had a single weekly Breast MDT meeting.

¹⁰ https://www.cddft.nhs.uk/services/surgery

¹¹ https://www.cddft.nhs.uk/services/surgery

¹² https://www.cddft.nhs.uk/services/surgery

¹³ https://www.cddft.nhs.uk/services/cancer-info-support/cancer-teams/breast-care

2. Terms of Reference (TOR) for the review

The following terms of reference for this review were agreed prior to the RCS England review visit between the RCS England and the healthcare organisation commissioning the review.

Review of the Breast Surgery/Breast Radiology and Breast Non-Surgical Oncology service at County Durham and Darlington NHS Foundation Trust ('CDDFT') under the Invited Review Mechanism.

Background

The review team will consider the standard of care provided by the breast surgery/breast radiology and breast non-surgical oncology service, following an internal audit and external peer review by the Northern Cancer Alliance (NCA) which reported that there was evidence to suggest deviation from national guidelines/best practice in the diagnostic workup of breast conditions and surgical treatment. Additionally, in a number of cases reviewed, there appeared to be a discrepancy between the size on imaging against that found at surgery/pathology, and in some cases it appeared neoadjuvant chemotherapy should have been offered and there was no documented reasons in the surgical or MDT notes as to why it was not received.

Review

The review will involve:

- Consideration of background documentation regarding the breast surgery/breast radiology and breast non-surgical oncology service including the peer review report produced by NCA and findings from a GIRFT visit in December 2024.
- A clinical records review of 30¹⁴ cases put forward by CDDFT/ NHS North East and North Cumbria Integrated Care Board.
- Interviews with members of the breast surgery/breast radiology and breast non-surgical oncology service, those working with them to provide the service and other relevant members of staff.

Terms of Reference

In conducting the review, the review team will consider the standard of care provided by the breast surgery/breast radiology and breast non-surgical oncology service, including with specific reference to:

- Whether CDDFT delivers a safe, effective, up to date diagnostic breast service particularly in relation breast radiology and possibly non-surgical oncology.
- Whether CDDFT delivers a safe, effective, up to date breast surgical service particularly in relation to the range of treatments offered including referral to other providers as required.
- MDT processes and team working including attendance and quoracy, structure, recording
 of discussion, decisions made and effectiveness of MDT meetings
- Clinical governance

Conclusions and recommendations

The review team will, where appropriate:

¹⁴ The review team were able to review 28 clinical records whilst on-site during the review visit

- Form conclusions as to the standard of care provided by the Breast Surgery (Breast Radiology and Breast Non-Surgical Oncology) service including whether there is a basis for concern in light of the findings of the review.
- Make recommendations for the consideration of the Medical Director of County Durham and Darlington NHS Foundation Trust and the Chief Medical Officer of NHS North East and North Cumbria Integrated Care Board as to courses of action which may be taken to address any specific areas of concern which have been identified or otherwise improve patient care.

The above terms of reference were agreed by the College, the healthcare organisations and the review team on 3 January 2025.

3. Conclusions

This section sets out the review team's conclusions against each of the TOR.

3.1 Diagnostic breast service

The review team were asked to consider whether CDDFT delivers a safe, effective, up to date diagnostic breast service, particularly in relation to breast radiology and possibly non-surgical oncology.

The service had been under considerable scrutiny, by GIRFT¹⁵ (Appendix A, section A1.1) and a breast surgery peer review by the NCA (Appendix A, section A1.2). Concern regarding the findings of these reviews and potential duty of candour implications had led the Trust to develop a detailed service improvement plan (Appendix A, section A1.2.14-1.2.15). At the time of this invited review, the Trust had appointed an external clinical lead (from another Trust within the region) for the breast service and two new oncoplastic surgeons were awaited to join the small surgical team that delivered breast surgery (Appendix A, section A1.4). The review team heard of aspirations not only to subject the breast service to the same degree of scrutiny and peer review as screening units, but potentially to align the symptomatic services at DMH and UHND with two local screening centres (Appendix A, section A1.3).

A recurring message from interviews was that there was a challenged dynamic amongst the surgical team, who were said to work in silos, not as a cohesive team (Appendix A, section A1.4). The consultant surgeons were frequently described as resistant to change and some working practices gave rise to concerns. Set against this were accounts that the breast surgeons worked extremely hard, under pressure and with insufficient resources to meet demand. A recurring message was that the surgical team had responded professionally to the scrutiny placed on the service and engaged positively with this invited review. This led to a sense of optimism amongst the review team, and some within the service, that the conditions were right to reconfigure the breast service.

The overriding conclusion reached by the review team was that the Trust's breast service operated as two distinct services. A divide was evident between the North and South of the geographical area served by the Trust – with DMH the locale for the South, and UHND the locus for the North. Much of the information received by the review team related to the North. The review team considered 26 clinical records, and these mostly related to breast services provided in the North, which managed between 250 to 280 breast cancers each year, with a surgical team comprising just two consultant surgeons and an associate specialist. The review team were unable to establish the number of breast cancers managed by the service in the South, which was smaller and relied upon just one locum consultant surgeon at the time of the review (a substantive consultant surgeon had stepped back from breast clinical activity). It was clear that while the breast service was managed by the Trust as a single service, in practice two separate services were running, with different surgical, radiology and oncology staff and no evidence of meaningful integration. At MDT, each consultant presented their own patients with little indication of patients benefitting from any alternative views on proposed management to achieve a consensus. The review team considered that, if this MDT style of working does not change, there will be no opportunity for the newly appointed surgeons to influence surgical practice across the wider patient group.

3.1.1 Two-week-wait (2WW) breast clinics

The 2WW outpatient clinics were the first port of call for the breast service. Between the end of 2002 and end of 2024, more than 26,000 outpatients were seen in these clinics (Appendix C), and there was insufficient outpatient capacity within the service to meet patient demand. This was demonstrated by the fact that, at the time of the review, half of patients referred into the Trust's diagnostic pathway were seen in clinics provided at evenings and at weekends, either outsourced

¹⁵ Getting It Right First Time https://gettingitrightfirsttime.co.uk/

(to Spire Ltd) and provided at Spire Washington Hospital, or insourced (to Durham Surgical Services Ltd) and provided on Trust premises (Appendix A, <u>section A1.5</u>). Both the outsourcing and insourcing arrangements were run by one of the consultant surgeons based at UHND. One outcome of this was said to be that out of 13,500 referrals, 8,000 were under the name of this one consultant surgeon. The numbers of patients seen by individual consultant surgeons across the service varied widely.

The review team heard a range of concerns expressed by staff regarding the outsourcing and insourcing arrangements – from worries over the patient to staff ratio and the impact in terms of compassionate care in the communication of a cancer diagnosis, to concern regarding the cost of these arrangements (which were on a fee per patient basis), and a lack of consistency with routine in-hours NHS clinics (Appendix A, section A1.5.8-1.5.13).

The review team were concerned that provision by Durham Surgical Services Ltd and Spire Ltd did not appear to meet The Royal College of Radiologists' (RCR) guidance on screening and symptomatic breast imaging. ¹⁶ ¹⁷ This guidance recommends that breast biopsies should be image guided (page 6), as image guided biopsy has a higher accuracy rate than clinical core biopsy (this message echoes earlier guidance ¹⁸). However, the review team heard from interviewees that significant numbers of patients seen in the Spire clinic received a clinical core biopsy, even though their cancers were visible on imaging. The reason for undertaking clinical core biopsy was said to be because it was "faster" and took pressure off radiologists. The provision of clinical core biopsies instead of image guided biopsies was also a finding of the NCA peer review. A high clinical core biopsy rate can lead to an increased risk of missing a lesion or a patient requiring multiple biopsies with a delay in diagnosis. Case A9 – one of the clinical records reviewed – demonstrated the risks associated with a clinical core biopsy that missed a small breast cancer and there were subsequent delays in diagnosis and treatment. Clinical core biopsy can also mean there is no confirmation that a biopsy represents the radiological findings or is radiologically marked, which is contrary to best practice.

Routine ultrasound of the contralateral breast was also observed, which was also contrary to best practice guidelines and one of the contributing factors to the time pressure on radiologists/radiographers.

Fine needle aspiration (FNA) was another example of where the outsource and insource clinics did not appear to align with national guidelines (there was some indication it was also happening during in-hours clinics). The NCA peer review found that FNA was often being used instead of core biopsy, leading to repeat investigations. None of the breast radiologists/radiographers undertook FNAs, which meant they were mostly clinical (i.e., performed by the breast surgeons). Practice across the surgical team varied – with one surgeon estimated to perform three FNAs a week and others performed them "very sparingly". RCR guidance is clear that core biopsy is preferable to FNA as it allows differentiation between in situ disease and invasive cancer which is vital for patient management (page 6). FNA should be limited to cases where core biopsy is impossible.

The one stop clinics provided by Durham Surgical Services Ltd and Spire Ltd out of normal weekday hours were reported to feature significantly in national patient experience data in terms of dissatisfaction with the speed of consultations. Those interviewed reported widely different numbers of patients seen per clinic in this setting, but all described it as high turnover. It was reported to not be unusual for a Friday evening insourced clinic to run on until 23:30 and the review

¹⁶ https://www.rcr.ac.uk/media/0dkh5y5d/rcr-publications_guidance-on-screening-and-symptomatic-breast-imaging-fourth-edition november-2019.pdf

¹⁷ The review team's observations regarding NHS patients seen in one stop breast clinics at the Spire Washington Hospital were based on the accounts of interviewees and clinical record review, under the terms of reference for this review. It was outside the remit of this review to specifically consider the levels of service by Spire for these NHS patients.

 $^{{}^{18}\,\}underline{https://associationofbreastsurgery.org.uk/media/cvtju1zs/best-practice-diagnostic-guidelines-for-patients-presenting-with-breast-symptoms.pdf}$

team questioned the impact of this on patient experience, as well as on those delivering such a service.

The delivery of so much clinical activity outside normal clinical time represented a significant financial burden on the service, preventing investment in a more sustainable model of delivery of breast services. The review team concluded that the Trust must focus on aligning inhouse NHS capacity with demand. Outsourcing and insourcing should be tools used for when there is an unexpected uplift in demand or drop in capacity. These arrangements had become normalised within the Trust and posed risks for service continuity given the reliance on the individual surgeon who led both the outsourcing and insourcing arrangements.

The review team identified opportunities to run the inhouse clinics more efficiently. These included better allocation of patients across clinics (the process for allocation was unclear). Another was reducing follow ups. There appeared to be a great deal of follow up and some appeared to be unnecessary (including follow up ultrasounds for benign and primary hormone patients). There were also opportunities in terms of making better use of the multidisciplinary team, specifically the breast care nurses, who felt constrained in terms of what they could offer the service, with an impact on recruitment and retention (Appendix A, section A1.4). The breast physician also appeared to be an underused and undervalued resource, despite their experience over many years as an independent practitioner.

NHS England's guide on clinical and operational improvement of outpatient services may be helpful in optimising outpatient clinic provision.¹⁹

3.1.2 Breast radiology

Breast radiology capacity was described as one of the biggest pressures in terms of cancer performance, and the key limiting factor in reducing a dependency on the outsourcing and insourcing of the diagnostic breast service. Two radiologists and one consultant radiographer covered clinics held in the North and the South. In-hours clinics were busy, and they also supported the outsourcing/insourcing clinics on rotation (a Saturday all day clinic was said to involve radiologists seeing 38 to 40 new patients).

These pressures were leading to practices generally not seen in other breast radiology services, such as combined mammography and ultrasound reports, which were said to be done for expediency (Appendix A, A1.5.16-1.5.21). Undertaking clinical core biopsies instead of ultrasound guided core biopsy was another example of service pressures driving practice, instead of clinical outcomes. A recurring theme from the record review was regular ultrasound evaluation of the contralateral breast. The review team also observed what appeared to be a high level of regular imaging follow up of patients on primary endocrine treatment as well as routine follow up of benign lesions (fibroadenoma)²⁰. Imaging outcomes were rarely recorded in Somerset Cancer Register as part of the evidence of such important discussions.

There was a lack of Vacuum Assisted Excisions (VAEs) or Vacuum Assisted Biopsies (VABs)²¹, which some interviewees contrasted with the other symptomatic centre in the region.

This invited review was not a radiology review, and the consultant breast radiologist on the review team was limited to looking at radiology images using a laptop, nevertheless, some errors were identified in imaging reports (<u>section 3.5.1</u> and <u>section 3.5.2</u>). The review team also observed the use of skin marking, which is not an effective method of marking impalpable tumours and could be one of the factors leading to the high re-excision rate.

¹⁹ https://www.england.nhs.uk/long-read/outpatient-services-a-clinical-and-operational-improvement-guide/

²⁰ Association of Breast Surgery Summary Statement: Management of Fibroadenomas. <u>abs-summary-statement-fibroadenomas-v1.pdf</u>

²¹ Vacuum Assisted Excision (VAE) and Vacuum Assisted Biopsy (VAB) of the breast https://www.gatesheadhealth.nhs.uk/resources/vacuum-assisted-biopsy-and-vacuum-assisted-excision-of-the-breast/

Breast radiology assessment of new patient clinics should follow a standardised format across the geographical area served by the Trust, wherever it is reported, as per the national guidance.²²

The Trust had invested in state-of-the-art mammography equipment.²³ However, issues were reported with the quality of ultrasound equipment at UHND. Breast radiology equipment needs to match that required to support provision in a screening unit, with the same standards of quality assurance.

The review team concluded that alignment with a screening service would bring benefits in terms of radiology, including strengthening recruitment to CDDFT by offering more for prospective candidates, as well as in terms of peer review. It would also embed data collection and audit at the same standard of Breast Screening Quality Assurance and allow learning and personal development for the radiology team. Breast Screening Standards require mammography readers to read at least 5,000 mammograms per year and regularly undertake PERFORMS assessment.²⁴

3.1.3 Non-surgical oncology

The review team explored whether neoadjuvant chemotherapy treatment to downstage (i.e., to shrink or downsize a tumour before surgery) was offered to patients (Appendix A, 1.5.22-1.5.29). The review team heard from several interviewees that oncologists follow regional guidance and apply a 2 cm rule (i.e., only for tumours larger than 2 cm)²⁵. The review team observed from the clinical records some examples of patients where there was no documented evidence to show that neoadjuvant treatment had been discussed or offered in clinical scenarios where such patients may have received primary systematic therapy in other units and would have had a discussion about this possibility (section 3.3.3). The ESMO Clinical Practice Guideline set out the latest position for diagnosis, treatment and follow up of early breast cancer (2024)²⁶.

Less use of neoadjuvant treatment may lead to more mastectomies and limits the opportunity for patients to be counselled regarding reconstruction. While an early surgical operation date may seem an advantage, time needs to be allowed for patients to access the support and be able to process all the information to make a truly informed decision on their surgical management. This is particularly true for those considering reconstruction.

The decision over whether to offer neoadjuvant therapy was said to be made at the MDT meeting. There was only one case across the 28 reviewed where the review team identified on the Somerset Cancer Register that the patient was referred for neoadjuvant chemotherapy (A18). There was no documented discussion of the possibility of neoadjuvant treatment across the other cases. The review team concluded that closer attention was needed to ensure this is part of MDT discussion, for relevant patients, and to documenting such discussion.

3.1.4 Breast pathology

The review team observed good pathology turnaround times for postoperative specimens and for core biopsies (Appendix A, section 1.5.30-1.5.32). A turnaround time of 7 days for post-operative specimens was regarded by the review team as an example of excellence. HER2²⁷ testing was the exception as it

²² https://www.rcr.ac.uk/media/0dkh5y5d/rcr-publications_guidance-on-screening-and-symptomatic-breast-imaging-fourth-edition_november-2019.pdf

²³ https://www.cddft.nhs.uk/about-us/news/cddft-invests-state-art-mammography-equipment-university-hospital-north-durham

²⁴ https://www.gov.uk/government/publications/breast-screening-guidance-for-image-reading/breast-screening-guidance-for-image-reading

²⁵NHS Northern Cancer Alliance. Breast Cancer Clinical Guidelines. Version 4. 27.04.2022.

²⁶ https://www.esmo.org/guidelines/guidelines-by-topic/esmo-clinical-practice-guidelines-breast-cancer/early-breast-cancer

²⁷ HER2 stands for human epidermal growth factor 2. Some breast cancers have large amounts of a protein called HER2. https://www.cancerresearchuk.org/about-cancer/breast-cancer/getting-diagnosed/tests-breast-cancer-cells

was outsourced to Newcastle, and delays in awaiting the outcome of HER2 testing were a feature of several MDT records. It was understood there were plans to bring HER2 testing in-house within the next few years.

There were four breast pathologists, of which three predominantly covered the breast MDT. There appeared to be good teamworking and by sharing the workload this facilitated different opinions that the review team concluded must be to the benefit of specimen analysis.

However, insourcing work created additional pressure on this team by increasing workload without any additional payment. This contrasted with the surgeons and radiologists involved in providing the insourcing and outsourcing clinics, who received separate payments.

3.2 Breast surgical service

The review team were asked to consider whether CDDFT delivers a safe, effective, up to date breast surgical service particularly in relation to the range of treatments offered including referral to other providers as required.

3.2.1 Range of treatments offered

The review team believed the breast surgical service was not encompassing the breadth of procedures expected of a modern breast service. This included low breast conserving rates and the absence of a dedicated breast abscess pathway (Appendix A, 1.6.8-1.6.12).

The practice of routinely including the skin over tumours when undertaking wide local excisions was said to have stopped only recently. The review team considered this was outdated practice with no evidence of oncological benefit and a significant risk of increased breast shape distortion as a result. This should only be necessary for those breast cancers that involve the skin, which is rare.

There was some indication in the clinical records of unnecessary axillary clearance (i.e., in the absence of clear preoperative evidence of cancer in the axillary lymph nodes) (Appendix A, 1.6.33-1.6.35). One account was that the axillary clearance rate was 30%; the review team were not able to verify this. Axillary clearance leads to significant patient morbidity. At the conclusion of the review visit, the review team had recommended an immediate action for there to be a protocol for patients that no axillary clearance happened without preoperative evidence of nodal involvement, together with clear, informed consent. If a sentinel node was not identified by whichever localisation technique was used, only a 4-node sample should be undertaken. Standard practice, if sentinel node localisation fails, is to undertake a 4-node sample, not to undertake an axillary clearance.

The review team identified in the clinical records some evidence of a discrepancy between the procedure the patient had been consented for and the procedure undertaken. For example, this included not being consented for axillary clearance. Other highlighted issues included underuse of some theatre lists (principally an all-day list on a Monday at UHND) and a reported refusal by some consultant surgeons to allow patients to be redistributed from the busiest surgeons to those with capacity (which may require arrangements for additional clinic review). The review team observed from the clinical record review that some operating times were extremely swift, and appeared too quick for mastectomy and node surgery (see section 3.5.3 for details). There were some cases that raised questions over the clinical decision making of the operating surgeon and/or their surgical skill set and ongoing professional development (returned to at recommendation 3).

The suboptimum evidence of assessment of the extent of disease radiologically pre-operatively undoubtedly contributed to the high re-excision rate. This was also contributed to by the lack of intra-operative assessment of wide local excision specimens. This will be improved with the use of

a Faxitron²⁸ machine in theatres (at the time of the review visit it was understood that a Faxitron machine was being procured by the Trust).

3.2.2 Mastectomy and reconstruction

The data demonstrated a high mastectomy rate: the NCA peer review put the primary mastectomy rate at 38% and overall mastectomy rate at 48.6%, and only 7.5% of mastectomy operations had a breast reconstruction (Appendix A, 1.6.13-1.6.18). Reasons offered to explain the higher mastectomy rate included the symptomatic nature of the service and presentations with large tumours, patient demographics, and patient resistance to travel to other centres for radiotherapy. However, there was also said to be little use of local flaps and breast preserving techniques, the reasons for which were not clear. Overall, the review team concluded that service pressures had squeezed the time available to thoroughly counsel patients on different surgical options and insufficient attention had been paid to the impact of breast deformity on patients. There were opportunities to draw on the skills of breast care nurses in this respect.

The review team identified in the clinical records examples of mastectomies where conservative surgery could have been considered, and there was very little documented discussion of reconstruction (see section 3.5.3). The Trust had a relatively low volume reconstruction practice, which was also described to the review team as a "delayed reconstruction" practice (Appendix A, 1.6.19-1.6.29). Several reasons were offered for this, echoing some of those around mastectomy, but also practical challenges in securing operating time for breast and plastic surgeons together. There was no facility for joint operating, which created pressures on surgeons to undertake reconstructions at weekends. Breast cancer reconstruction cases had been once every two months until the end of 2024, however a focus on explaining to patients the option of immediate or deferred reconstruction had seen six cases in the first few weeks of January 2025 alone. Theatre scheduling of such cases will therefore become a more pressing issue.

Concerns over the duty of candour had led to changes in practice regarding reconstructive options, with a patient information leaflet introduced to give patients the option of a second opinion at a neighbouring hospital (Appendix A, 1.6.30-1.6.32). There had reportedly been some resistance to handing out this leaflet to patients, which others described as well received.

The review team concluded that the service needs to further develop the pathway for reconstruction. There will be a need to bring radiologists and oncologists onboard when the two new oncoplastic surgeons start, to ensure cohesive planning of patient care. The arrival of the oncoplastic surgeons brings the potential to develop a dedicated oncoplastic MDT (or at least a dedicated section within the breast MDT for discussion of oncoplastic patients).

The MDT will need clear leadership for patients to benefit from the transformation planned through the appointment of two new oncoplastic surgeons. The MDT lead will need expert support so that they can contribute to the patient discussion while the Somerset Cancer Register record is completed contemporaneously and agreed by all those in the room. Any change to patient management protocols and pathways will need to be agreed by all members of the MDT for the patient to be presented with a consistent personalised plan. Important additional information will need to form part of the MDT discussion including breast size, shape and potential surgical options that have been discussed with the reason for the planned surgical intervention. This should include patient comorbidity factors, frailty scoring and, ideally, photographs. Accurate recording of the size of cancers and possible ductal carcinoma in situ (DCIS) on both mammography and ultrasound, and in proportion to the whole breast size, should be recorded and discussed. Decision making should include the proportion of the breast that needs to be treated (e.g. 20% volume) and discussion about the appropriateness of neoadjuvant therapy.

The review team explored why there was examination of the margins of a mastectomy and then reoperations on some mastectomy patients. They heard that one surgeon did not remove all the

²⁸ The Faxitron® machine is a radiological system that allows users to take specimen images during an operation.

breast tissue. A mastectomy should include removing as much breast tissue as possible at initial operation. Posterior margin involvement is a consideration for radiotherapy but not further surgery. Re-operation on mastectomy patients for close margins is outside normal breast surgical practice. The review team observed two cases (A7 and A10) where there was a need for re-excision following a mastectomy, which raised concerns regarding routine mastectomy technique.

While it was difficult to judge cosmetic outcomes within this review, due to the lack of evidence of any photographic records of patient outcomes or recording of breast dimensions preoperatively, high re-excision rates cause additional breast deformity and high mastectomy rates without reconstruction adversely affect long term patient well-being.

3.2.3 Day surgery, follow up and patient-initiated follow up (PIFU)

Despite the service pressures facing the team, there appeared to be some resistance to pathway refinements that could deliver efficiencies and benefit patient care. All breast surgery patients at UHND were admitted to the elective ward for overnight stays and attempts at converting cases to day surgery had been short-lived (Appendix A, 1.6.36-1.6.38). Most breast surgery patients were day cases at DMH. Similarly, there were different approaches to patient-initiated follow up (PIFU) across the two sites and across the consultant surgeons at UHND (Appendix A, 1.6.39-1.6.42).

There should be a single Trust-wide policy on the pathway for patients undergoing breast surgery, including agreement on the approach normally taken to day surgery, discharge and follow up. Many units now perform virtually all breast surgery on a day case basis. The breast service should embrace PIFU, as part of efforts to personalise outpatient care, avoid unnecessary follow up, and make best use of clinical time. Most of the breast cancer follow up should be under the PIFU pathway.

3.3 MDT decision making

The review team considered MDT processes and team working including attendance and quoracy, structure, recording of discussions, decisions made and effectiveness of MDT meetings.

3.3.1 MDT structure, timing and processes

The review team heard that the Trust had been working to achieve a unified MDT for 14 years. This had not been successful and instead two breast MDTs – one for the South and one for the North – ran sequentially (Appendix A, section A1.7). This was contrary to effective MDT working. A transformational process is needed to integrate the two MDTs into one. The new clinical lead was expected to introduce changes to the MDT in March 2025 and will require senior leadership support in achieving this (including reflecting the review team's conclusions under section 3.2.2).

It took 25 minutes for the MDT meeting observed by the review team to get underway due to IT difficulties (interviewees reported such delay to be a regular issue). There were many cases where HER2 results or CT scans were not available and the patient was not ready for discussion. This pointed to a need to strengthen processes for preparing the MDT and removing cases that were not ready for discussion. The average breast MDT was understood to have had a caseload of 97, which many interviewees described as too large. A template could be used to standardise the information gathered on each case, which would help with screening.

Ensuring there is appropriate MDT support from cancer services is vital to deliver an efficient and effective MDT. All members of the MDT should be job planned to attend for the whole MDT and the lead should have preparation time recognised in their job plan to streamline the process. Appropriate IT support to deliver this is vital, particularly since some members joined remotely and the quality of patient discussions was significantly impacted by connectivity issues. The recording of MDT discussions on the Somerset Cancer Register needs to improve significantly from its current level.

There was a need for consistent administrative support, with turnover in MDT coordinators described as an issue. At the same time there was a need to support these coordinators and empower them, together with breast care nurses, to speak up as part of the breast service.

3.3.2 MDT chairing and leadership

There was no clear MDT leadership demonstrated. The South MDT was led by the substantive consultant surgeon, and they were said to have chaired this part of the MDT efficiently until stepping back from the MDT shortly before the invited review. A locum consultant surgeon had stepped in to lead discussion of cases relating to the South. When the North MDT began, one consultant surgeon presented their cases and then left, followed by the breast physician, and the consultant surgeon with the largest caseload. This approach provided no opportunity to segment the MDT according to radiology or surgery or oncology or allow for plastic surgeons to join for discussion of cases where reconstruction might be considered.

3.3.3 Teamworking and clinical decision making

The review team were concerned that there was no evidence of breast surgeons contributing to the discussion of a colleague's case in the MDT observed, and more broadly from information gathered, which meant each patient was subjected only to an individual surgeon's opinion on their cancer pathway. There appeared to be a lack of challenge or discussion, which was reflected in some of the clinical records reviewed. All members of the MDT should feel able to contribute and speak up during these meetings. Some recent improvement was reported with the involvement in the MDT of the new clinical lead and one other surgical colleague from the network, who dialled into the meeting.

3.3.4 Recording MDT outcomes

The clinical record review revealed extensive indication of suboptimal documentation on the Somerset Cancer Register. Several interviewees described issues with the MDT coordinator capturing outcomes accurately. This was exacerbated by the lack of clear leadership, which is important to support the MDT coordinator in recording outcomes.

3.4 Clinical governance

3.4.1 Breast governance

Clinical governance for the breast surgery service was under the auspices of general surgery. Aspects of the breast service relating to radiology, pathology, oncology and reconstruction came under the governance mechanisms of the relevant specialties. There were no breast-specific governance arrangements, despite the size of the service and the number of cancers managed each year.

Clinical governance includes regular review of unit data, being distributed in a timely manner such that individuals can review their own data – and act upon it, where necessary. If governance is combined with general surgery, it cannot be specific in terms of data collection. Breast patients require specific provision that is sometimes distinct to general surgery (e.g., around venous thromboembolism (VTE) prophylaxis).

Clinical governance needs to cover the entirety of the service. Particular attention should be paid to ensuring patients seen outside of Trust's normal provision experience the same level of service and clinical governance as those within NHS provision, and that the Royal College of Radiologists (RCR) standards for breast patients are met.

With two oncoplastic surgeons joining the Trust imminently, the review team concluded there was an opportunity to refocus on breast cancer patients and develop specialist clinical governance involving the entirety of the multidisciplinary team. The new clinical lead was reported to have introduced monthly breast meetings (described as business meetings), although the impact of these was yet to be felt by the service. As these meetings develop, it will be important to maintain a

clear delineation between discussion of breast activity and service ('business') and breast clinical governance. This might require having separate leads, agendas and minutes.

All members of the breast MDT should be involved in clinical governance. In addition to that required for regular appraisal and revalidation, there should be breast MDT specific protocols and governance, which incorporate all members of the MDT.

All staff who support the breast service should feel a sense of ownership over service outcomes and patient experience and not just for the hospital in which they work (North or South). There was a need for the Trust to better disseminate the outcome of reviews, such as GIRFT, the NCA peer review, and the findings of this invited review, together with progress against action plans. The wider multidisciplinary breast team should be part of discussions regarding current provision and strategic plans.

3.5 Clinical record review

The review team were requested, as part of the service review, to consider 30 clinical records selected by the Trust. Review was completed of 28 clinical records – 2 of the remaining clinical records were incomplete at the time of review (lacking the images and reports from Gateshead radiology). The clinical record review notes can be found in <u>Appendix B</u>.

Please note that Appendix B has been redacted because of the potential for disclosure of patient identifiable information. The findings from the reviews are captured in 3.5 below.

3.5.1 Assessment

The review team considered assessment of the patient, including history taking, examination and diagnosis. Breast cancer assessment tends to involve triple assessment: clinical, radiological and, if necessary, a biopsy. Some elements will also be relevant to 'investigations and imaging' (at section 3.5.2).

This phase of care was most likely to be graded as demonstrating an acceptable standard of care. Across the 28 cases reviewed, 19 cases were graded 'acceptable' under this heading, 7 were graded 'room for improvement', and 2 were graded 'unacceptable'.

The gradings of **room for improvement** reflected the review team's observations that:

- The patient was frequently followed up despite normal findings on repeat imaging (A14)
- The ultrasound report did not specify size of recurrence and axillary nodal status at time of recurrence (A2); an error was identified in the ultrasound report (A3); microcalcifications showing on the initial mammogram were not reported (A21)
- Diagnostic tests (e.g., core biopsy, FNA, punch biopsy) was not undertaken when this would have been appropriate (A3), or not in a timely way (A14), or not the right test (A24)
- There was no evidence of pre-operative mammography prior to symmetrisation surgery and when incidental DCIS was found, no documented offer of primary reconstruction or reexcision surgery in a patient with a previous history of mastectomy and reconstruction (A22)

The gradings of **unacceptable** reflected the review team's observations, as follows:

- There was no documented clinical examination at primary presentation following referral after CT, and no localisation technique was undertaken (A4)
- Clinical core biopsy was recommended by radiology, despite clear evidence that image guided biopsies have greater accuracy than clinical core biopsies (A7)

3.5.2 Investigations and imaging

The review team considered whether appropriate investigations and imaging were requested and

delivered. This phase of care was most likely to be graded as demonstrating an acceptable standard of care. Across the 28 cases reviewed, 20 cases were graded 'acceptable', 6 cases were graded 'room for improvement', and 2 cases were graded 'unacceptable'.

The gradings of **room for improvement** reflected the review team's observations that:

- CT and PET CT happened at the request of the patient, raising questions over the pathway (A2)
- Nipple cytology was unnecessary cytology (A25)
- Diagnosis of Paget's disease of the nipple was delayed, due to delay in undertaking punch biopsy (A14)
- Preoperative imaging should have identified that there were five positive nodes (A15)
- Suitable imaging was undertaken but microcalcifications were missed (A21)
- A core biopsy should have been undertaken; instead, the patient had unnecessary surgery for benign disease (A24)

The gradings of **unacceptable** reflected the review team's observations, as follows:

- The review team were unable to access breast imaging from the assessment in the Spire Washington Hospital. A clinical core biopsy was undertaken despite U3 lesion seen on ultrasound (guidance from the RCR states that patients with U3-5 findings should undergo needle biopsy²⁹) and there was no clear reason for the additional FNA (A9)
- Initial imaging demonstrated two areas of concern on mammogram and no comment was made on the second lesion on the ultrasound report, and the second area on mammogram was not pursued as part of the surgical planning (A4)

3.5.3 Treatment

The review team considered whether the treatment offered was appropriate, including clinical decision making, case selection, operation or procedures.

This phase of care was most likely to be graded room for improvement or unacceptable, and more cases were graded unacceptable under this heading than for any other phase of care. Across the 28 cases reviewed, 6 cases were graded 'acceptable', 17 cases were graded 'room for improvement', and 5 cases were graded 'unacceptable'.

The gradings of **room for improvement** reflected the review team's observations that:

- There was no documented evidence to indicate discussion or consideration of neoadjuvant therapy when this might have been expected (A3, A7, A11, A17, A21, A23)
- There was a lack of documentation on the choices offered to the patient, including conservative surgery, re-excision or oncoplastic breast preservation (A3, A13, A14, A20, A21, A22)
- There was no documented evidence that reconstruction was offered (A3, A7, A10, A11, A13, A14, A20, A22, A23)
- It was difficult to understand why further surgery was needed following a mastectomy (A7, A10)
- There were significant delays between diagnosis and surgery (A17)
- The patient had what the review team believed to be unnecessary surgery (A24, A25, A26)

The gradings of **unacceptable** reflected the review team's observations, as follows:

- Axillary clearance was undertaken without preoperative evidence of axillary disease, or otherwise unnecessarily, or without the patient's consent (A2, A6, A15, A16)
- There was a significant delay (4 months) between the decision to undertake open biopsy from a clinical core biopsy and excision biopsy taking place, which delayed the diagnosis (A9)

²⁹ https://www.rcr.ac.uk/media/0dkh5y5d/rcr-publications_guidance-on-screening-and-symptomatic-breast-imaging-fourth-edition_november-2019.pdf

• It was not evident that consideration was given to conservative surgery plus radiotherapy, even though the patient had not had radiotherapy following their first operation several years earlier. Potentially, the patient should have had further wide local excision and should not have had an axillary clearance (A2)

Four clinical records reviewed related to patients seen initially in a clinic at the Spire Washington Hospital (assumed to be NHS patients). Of these four cases, three were graded room for improvement in terms of treatment (A20, A21, A23), and one was graded unacceptable care (A9).

Some surgical procedures appeared to be undertaken with great swiftness. This included a mastectomy and dual technique sentinel node biopsy in 28 minutes (A1); a mastectomy and sentinel node biopsy in 37 minutes (A10); an excision biopsy in 9 minutes (A9); and excision of benign thickened breast tissue in 10 minutes, which the review team considered to have been unnecessary (A24).

3.5.4 Teamworking

The review team considered evidence in the clinical records of teamworking, including communication, MDT discussions and working with colleagues. This phase of care was most likely to be graded as demonstrating an acceptable standard of care. Across the 28 cases reviewed, 17 cases were graded 'acceptable', 8 cases were graded 'room for improvement', and 1 case was graded 'unacceptable'. There was insufficient information to reach a grading for 2 cases.

The gradings of **room for improvement** reflected the review team's observations that:

- There should have been better MDT discussion of the treatment options for the patient (A3, A7, A10, A17, A21)
- It was not evident that there was oncoplastic/plastic surgery discussion to increase the chance of conservation surgery or reconstruction (A3, A20, A21, A22)
- A significant delay (3 months) between presentation and surgery suggested opportunities for better teamworking between surgery and oncology (A18)

The grading of **unacceptable** reflected the review team's observations, as follows:

In many breast units, the MDT would have considered neoadjuvant chemotherapy as an
option to allow time for the genetics result so that this could be discussed in the MDT and
the surgical options discussed with the patient, including reconstruction. Best practice
would allow the patient time to consider the results of any genetic testing prior to
undergoing bilaterial mastectomy. This indicated poor recording of interdisciplinary team
working (A23)

Of the four cases relating to patients seen initially in a clinic at the Spire Washington Hospital, two were graded room for improvement in terms of teamworking (A20, A21), and one was graded unacceptable care (A23).

3.5.5 Consent and communication

The review team considered communication with the patient, their family and/or carers, their GP and patient consent. This phase of care was most likely to be graded as demonstrating an acceptable standard of care. Across the 28 cases reviewed, 18 cases were graded 'acceptable', 5 were graded 'room for improvement', and 3 were graded 'unacceptable'. There was insufficient information to reach a grading for 2 cases.

The gradings of **room for improvement** reflected the review team's observations that:

• The patient declined radiotherapy following surgery; it was not clear that this was discussed at initial surgical planning or that there was discussion of alternative approaches to axillary clearance (A5). There is evidence that omission of radiotherapy following surgery can lead

- to a high local recurrence rate, particularly in patients with high-risk tumours, as in this case.
- There was no documented discussion with the patient of alternative approaches or offer of reconstruction (A3, A7)
- The consent paperwork for the second surgery was too wide in scope (A10)

The gradings of **unacceptable** reflected the review team's observations, as follows:

- There was no documentation to indicate the patient was offered conservative surgery (A2)
- The patient was not consented for axillary clearance (A6)
- The patient underwent an operation, associated with significant morbidity, without providing informed consent for this to happen (A15)

The review team concluded there were 2 cases where the **duty of candour** should be considered.

- Case A2. There was no evidence that conservative surgery was considered in this patient, who underwent a mastectomy. The patient had had a previous wide local excision for in situ cancer and no radiotherapy. When she had a recurrence, most units would offer a further wide local excision with radiotherapy or a mastectomy. It is not clear that this was even considered. In addition, an axillary clearance was also undertaken. The review team concluded that the duty of candour should be considered with respect to the mastectomy and the axillary clearance. An axillary clearance is not indicated for recurrent DCIS. It is not standard to undertake a sentinel node biopsy at the time of wide local excision for papillary carcinoma as it is equivalent to DCIS. There were seven nodes in the axillary clearance and the standard minimum number of nodes in a clearance in the NHSBSP surgical guidelines is 10. This patient had undergone a previous sentinel node biopsy, which might explain why there were fewer than 10 nodes on this occasion, however the review team believed the patient should not have undertaken the axillary clearance at all.
- Case A16. The patient had a previous wide local excision and radiotherapy in 2019. She had a recurrence in 2023 and had a mastectomy, together with an axillary node clearance with no preoperative evidence of axillary disease and the histology showed 0/13 lymph nodes. The patient went on to have a contralateral risk reducing mastectomy (i.e. prophylactic surgery) in 2024 and was given blue dye and radioisotope for sentinel node biopsy, which was not indicated no nodes were found and the patient should not have been considered for axillary surgery. The review team concluded that the duty of candour should be considered as identification of nodes is unnecessary as part of prophylactic surgery.

3.5.6 Record keeping

Across the 28 cases reviewed, 17 cases were graded 'acceptable' under this heading, 10 were graded 'room for improvement', and 1 was graded 'unacceptable.

The gradings of **room for improvement** reflected the review team's observations that:

- It was difficult to visualise all the relevant clinical records across multiple systems for recording information (A2, A3, A6, A7, A28)
- Discrepancies were observed between imaging reports and MDT record (A4, A6), and a report of localisation appeared to be linked to incorrect images (A4)
- The review team encountered challenges in accessing imaging documentation and initial MDT discussion relating to a patient first seen in the Spire Washington Hospital (A9)
- There was a lack of documentation to indicate what was discussed or offered to the patient (A12, A21, A23)

The grading of **unacceptable** reflected the review team's observations, as follows:

• The review team could not identify a record to explain why the plan for the patient was primary surgery and why neoadjuvant treatment was not discussed. There was no recording of the initial assessment size on the Somerset Cancer Register (A11).

Overall, three out of four clinical records reviewed concerning patients seen in a clinic at the Spire Washington Hospital were graded room for improvement, highlighting potential issues around information sharing between Spire Ltd and the Trust (A9, A21, A23).

3.5.7 Follow-up

The review team considered for each case whether the patient required further follow-up or intervention to ensure their clinical safety. Several patients were under the care of oncology. There were no cases where additional clinical follow up was considered necessary.

4. Recommendations

4.1 Urgent recommendations to address patient safety risks

The recommendations below are considered to be highly important actions for the healthcare organisation to take to ensure patient safety is protected.

- 1. There should be a protocol for patients that no axillary clearance happens without preoperative evidence of nodal involvement, together with clear, informed consent. Specifically:
 - If a sentinel node is not identified by whichever localisation technique is used, only a 4-node sample should be undertaken.
 - o The protocol should reflect the latest evidence.
- 2. Until the breast service can offer VAB/VAE inhouse, the Trust should establish referral pathways for patients to receive these investigations at other breast screening centres.
- 3. The clinical record review and feedback from some interviewees indicated that certain members of the surgical team may benefit from refreshing their knowledge and skills in areas such as:
 - o mastectomy (e.g. case A10) and reconstruction
 - indications for sentinel lymph node / axillary node clearance (case A16) in modern breast cancer practice
 - o what action to take when sentinel lymph node identification fails (case A15).
- 4. The Trust should consider its responsibilities set out in the Duty of Candour Procedure under Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Regulation 20 in the following cases:
 - o Case A2
 - o Case A16
 - o Case A25

4.2 Recommendations for service improvement

The following recommendations are considered important actions to be taken by the healthcare organisation to improve the service.

- 5. The Trust should introduce changes to the format of the breast MDT. Specifically:
 - Core participants should have allocated job planned time for MDT preparation.
 - Breast care nurses should play a role in screening the MDT list for cases that are not ready for discussion (e.g., where investigations are incomplete) and these cases should be deferred until the next meeting.
 - The meeting should have a strictly observed start time. The aim should be to conclude the meeting in three to four hours. Necessary and reliable IT support should be provided to ensure optimum MDT functioning.
 - Job plans should enable core members to participate in 75% of MDT meetings and for the entire duration of the MDT for surgical and radiological colleagues. A record of attendance should be formally received by the MDT every six-months and provide an opportunity to discuss any barriers to participation.
- 6. The following information should form part of the recorded MDT discussion:
 - o Breast size, shape and potential surgical options.
 - o The reasons for the planned surgical intervention.
 - o Patient comorbidity factors, frailty scoring and, ideally, photographs.

- Accurate recording of the size of cancers and possible DCIS on both mammography and ultrasound, and in proportion to the whole breast size.
- The proportion of the breast that needs to be treated (e.g. 20% volume).
- o The appropriateness of neoadjuvant therapy.

7. The Trust should introduce changes to the leadership of the breast MDT. Specifically:

- There should be a clear distinction between the person/people responsible for the overall MDT process (including governance, data and linkages with regional cancer meetings), and the role of chairing an individual MDT meeting and the person responsible for recording the MDT discussions contemporaneously.
- There should be discussion within the breast team regarding meeting chairing options (including whether one person assumes this responsibility for a fixed term or whether it is shared amongst senior team members on rotation, as part of efforts to strengthen teamworking).
- The MDT Chair will need expert support so that they can contribute to the patient discussion while the Somerset Cancer Register record is completed contemporaneously and agreed by all those in the room.
- There should be a 'wash-up' immediately after the MDT meeting, between the Chair and MDT coordinator, to ensure accurate capture of outcomes (and reasons) on Somerset Cancer Register.
- There should be a consistent MDT coordinator whilst transformation of the breast MDT takes place.
- 8. Consideration should be given to establishing a dedicated oncoplastic MDT (or a dedicated section within the breast MDT for discussion of oncoplastic patients o The two new oncoplastic surgeons should work with plastic surgeons, radiologists and oncologists, to develop a pathway for all oncoplastic/reconstruction procedures.
- 9. A demand and capacity analysis should be undertaken to inform the required capacity within the Trust to meet patient demand for 2WW one-stop breast clinics. Specifically:
 - Investment in staffing (clinical, managerial and administrative), equipment, and estate, is needed to ensure that capacity is commensurate with that needed to meet patient demand.
 - Outsourcing and insourcing should be limited to periods of unexpected variability in demand and commissioned on an exception basis (not part of routine clinic provision).
 - The allocation of new patients to clinics should be considered, with a view to providing a more equitable distribution of patients to consultant surgeons. This is important to ensure safe and effective care for patients and to avoid overreliance on any one clinician (and related risk to service continuity).
 - Emphasis should be given to reducing unnecessary follow up (see recommendation 8), including imaging follow up of fibroadenoma, which is not evidence based and would free up imaging capacity.
- 10. The breast service should develop a single Trust-wide policy on the pathway for patients undergoing breast surgery, including on the approach normally taken to day surgery, discharge and follow up.
- 11. The breast service should fully embrace PIFU, as part of efforts to personalise outpatient care, avoid unnecessary follow up, and make best use of clinical time. Specifically:
 - Most of the breast cancer follow up should be under the PIFU pathway.
 - o The service should aim to reduce significantly rates of follow up for benign disease.

- A policy should be developed for the follow up required for patients on primary hormone treatment, with the aim of reducing existing follow up rates and requesting repeat ultrasound scans only where there are clinical concerns.
- 12. The breast care nurses should be provided with time, resource and a mandate to develop and extend their skillsets. Specifically:
 - Opportunities should be explored for breast care nurses in such areas as seeing new patients, PIFU, and end of treatment.
 - The breast care nursing team should be supported to develop specialist skills, for example, in genetic testing and around reconstruction.
 - The breast care nurses should be regarded as core members of the breast service team and included in meetings relevant to the breast service, as well as in transformation plans.
- 13. The breast physician should be supported to provide services that reflect their breadth of expertise, as an integral part of the multidisciplinary team and an independent practitioner. Specifically:
 - o Providing outpatient clinics for new patients as an independent practitioner.
 - Helping to develop the Trust's breast pain service.
 - Contributing to teaching (e.g. of breast care nurses), service development and research.
- 14. The breast service should develop a breast abscess pathway, reflecting NICE topic guidance on mastitis and breast abscess (revised 2025)³⁰ and drawing on existing pathways at other units.
- 15. The Trust should engage the network in discussion to ensure the region is following the latest guidelines on neoadjuvant therapy, especially as these are rapidly changing.³¹ Indications for primary systemic therapy related to survival benefit were clearly offered to patients but indications related to surgical planning such as down staging to avoid a mastectomy or postponing surgery to allow for genetic testing and discussion of mastectomy and reconstruction were not observed in the review.
- 16. Aspirations to align the two CDDFT units with screening centres should be developed into strategic options. Potential benefits include:
 - supporting the provision of radiology and helping to build the resilience needed for service continuity.
 - o improving localisation of difficult to feel / impalpable lesions (instead of relying on skin marking, which is unreliable).
 - enabling screening patients diagnosed with breast cancer to receive treatment closer to home.
- 17. There should be dedicated quality improvement resource to drive transformation within the breast service. The Associate Director of Operations for the Surgery Care Group has a broad remit. Dedicated quality improvement expertise is required to deliver the level of service improvement required. This could offer a secondment opportunity for someone within the network.
- **18.** The Trust should develop specialist clinical governance for the breast service. Specifically:

31 https://www.esmo.org/guidelines/guidelines-by-topic/esmo-clinical-practice-guidelines-breast-cancer/early-breast-cancer

³⁰ https://cks.nice.org.uk/topics/mastitis-breast-abscess/

- This should involve the whole MDT and interdisciplinary team, including breast care nurses and other staff involved in providing the breast service.
- There should be focused governance for the oncoplastic surgery service as it becomes established within the Trust.

4.3 Additional recommendations for consideration

The following recommendations are for the healthcare organisation to consider as part of its future development of the service.

- 19. Team job planning should be undertaken for the breast surgical team, breast physician, and radiologists (including consultant radiographer) to deliver efficient and effective care, taking into consideration the recommendations for change outlined above. All members of the MDT should have the entirety of the MDT meeting in their job plan.
- 20. All clinicians should be supported to engage in continuing professional development (CPD) to enable ongoing learning and skills development. Specifically:
 - contractual allocation of study leave averages 10 days per year. During the transformation process, all surgeons should demonstrate attendance at breast specific national and regional meetings for at least five days.
 - the breast surgical team should reflect as a team on surgical practice identified in this report as outdated (e.g., some axillary clearance surgery) and demonstrate learning from the most up to date evidence.
 - Specialist breast relevant CPD should be a feature of individual personal development plans, with reflection and learning.
- 21. The Trust should ensure that where outsourcing happens, there are clear protocols for information sharing regarding patient investigations. This will rely on having good communication links between difference providers and clear documentation of findings, reports and procedures.

4.4 Responsibilities in relation to this report

This report has been prepared by the Royal College of Surgeons of England and Association of Surgeons of Great Britain and Ireland under the IRM for submission to the healthcare organisation which commissioned the invited review. It is an advisory document, and it is for the healthcare organisation concerned to consider any conclusions and recommendations reached and to determine subsequent action.

It is also the responsibility of the healthcare organisation to review the content of this report and in the light of these contents take any action that is considered appropriate to protect patient safety and ensure that patients have received communication in line with the responsibilities set out in the Health and Social Care Act 2008 (Regulated activities) Regulations 2014, Regulation 20.³²

4.5 Further contact with the Royal College of Surgeons of England

³² The Health and Social Care Act 2008 (Regulated Activities)
Regulations, 2014: http://www.legislation.gov.uk/uksi/2014/2936/contents/made

Where recommendations have been made that relate to patient safety issues the Royal College of Surgeons of England will follow up with the healthcare organisation that commissioned the invited review to ask it to confirm that it has taken to action to address these recommendations.

If further support is required by the healthcare organisation the College may be able to facilitate this. If the healthcare organisation considers that a further review would help to assess what improvements have been made the College's Invited Review service may also be able to provide this assistance.

Appendix A – Information provided to the review team

The following section represents a summary of the information provided to the review team during the interviews held, in the documentation submitted and in any clinical records reviewed.

This section is largely organised according to the <u>Terms of Reference</u> agreed prior to the review but also takes account of the themes that emerged whilst reviewing this information. Information provided by interviewees during their interviews is presented as it was reported to the review team at the time of their review and circumstances may have changed subsequently. It is summarised in an amalgamated and anonymised format.

The information presented will sometimes reflect the viewpoints of individual staff members and some viewpoints described may be contradictory or may have been expressed in the absence of further, substantiating information. Noting these viewpoints is not intended to imply their factual accuracy. The information in this section does not necessarily represent the review team's opinions, which are provided in the Conclusions section of this report.

A1.1 GIRFT review 2024

- 1.1.1 The NCA comprised of 8 foundation trusts, of which there were 6 breast services providers:
- 1.1.1.1 Four screening centres (Gateshead Health NHS Foundation Trust; Newcastle Upon Tyne NHS Foundation Trust; North Cumbria Integrated Care NHS Foundation Trust; North Tees and Hartlepool NHS Foundation Trust)
- 1.1.1.2 Two symptomatic only units (CDDFT; Northumbria Healthcare NHS Foundation Trust)
- 1.1.1.3 One treatment only, no diagnostics (South Tees Hospitals NHS Foundation Trust; part of MDT with North Tees)
- 1.1.1.4 One Trust did not offer a breast surgery service (South Tyneside and Sunderland Foundation Trust; provided by Gateshead Health NHS Foundation Trust for this population).
- 1.1.1 There were two radiotherapy centres: Newcastle Hospitals NHS Foundation Trust and South Tees Hospitals NHS Foundation Trust.
- 1.1.2 According to the GIRFT dataset (dated 10 December 2024), the Breast Pain Pathway had been established in five of the six Breast Services Providers. Areas of excellence reported by GIRFT included that the Faster Diagnosis Standard (FDS)³³ was achieved at a rate of 93.8%, and those diagnosed with cancer 81.25% (July 2024). Newcastle had been highlighted as a positive outlier. Staging data completeness had improved (from 49.5% to 78% in the previous 12 months). A Primary Chemoprevention pathway was in development for the system. Challenges included addressing variation between Trusts in terms of the following: implementation of Best Practice Timed Pathway; National cancer programme audit; Equipment availability by provider; Screening versus symptomatic only sites; Imaging staff resilience (recruitment and retention challenges); Geography (mix of urban and rural / distance to travel to services); Health Inequalities and health literacy. The trusts in the Northern Alliance covered a complex geographical area with poor public transport links.

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³³ The FDS exists to ensure people are told they have cancer or that cancer is excluded, within a maximum of 28 days from referral. https://www.england.nhs.uk/long-read/faster-diagnostic-pathways-implementing-a-timed-breast-cancer-diagnostic-pathway-guidance-for-local-health-and-social-care-systems/

- 1.1.3 The future vision for breast services across the NCA included a task and finish group to review North East and North Cumbria (NENC) breast cancer services provision previous work suggested linking screening centres with symptomatic centres to improve recruitment, training and retention of staff. Specialist pathways in development included primary chemoprevention, BRCA testing, and menopause symptom support.
- 1.1.4 According to the GIRFT dataset, CDDFT covered a population of 430,600. Highlights included: radiology support for all one stop clinics; a large workload was managed by a small team; a newly appointed GP with a special interest to help with breast pain, triage, and bone health; appointment of two new oncoplastic surgeons, two new breast nurses, and band 4 MDT support. The following 'work in progress' was detailed:
- 1.1.4.1 setting up regular business and governance meetings;
- 1.1.4.2 streamlining follow up pathways;
- 1.1.4.3 setting up a breast pain clinic; improving plastic pathways;
- 1.1.4.4 streamlining and modernising the MDT with appropriate support;
- 1.1.4.5 establishing regional radiology links;
- 1.1.4.6 bringing HER2 testing in-house;
- 1.1.4.7 developing VAE, VAB capability;
- 1.1.4.8 establishing oncoplastic MDT.
- 1.1.5 Challenges were detailed as follows: underinvestment in the radiology workforce diagnostic delays; lack of theatre availability breaches; busy MDT issues with documentation and support; issues with split site working/joint approach and pathways; no abscess pathway; job plans limiting ability for common time for work with plastics, business and governance meetings; lack of cohesion with management, although regular meetings.
- 1.1.6 CDDFT was observed by GIRFT as unusual from a data perspective as screening patients were not repatriated (for historic reasons). This was not usual practice nationally and meant local patients detected through screening must travel away from their local hospital for treatments. GIRFT observed that, from a patient perspective, it added to the geographical complexity within this region. It also meant the Trust was expected to be a data outlier for some metrics.
- 1.1.7 The Trust's breast service managed a higher proportion of patients aged over 70 years (47%, compared to a national/alliance average of appropriately 34%) and a lower proportion of patients of screening age (31.5% compared to approximately 50% nationally/alliance). Patients served by the Trust and the NCA breast services were more likely to be deprived (25.6% compared to 14.4% nationally). DCIS³⁴ at the Trust was 6.6%, compared to a national/alliance average of approximately 11.5%.
- 1.1.8 Good practice at CDDFT, as highlighted by GIRFT, was that CDDFT was entering into the BCIR³⁵ and UKNFR³⁶; a consistently good FDS target; inpatient length of stay had been brought down; the number of reoperations on same breast within 1-year had come down; there were no emergency readmissions. GIRFT recommended: "CDDFT day cases look good but an opportunity to improve / Team to review the number of benign breast excisions / Oncoplastic MDT to be established once trust has

³⁴ Ductal carcinoma in situ (DCIS) is an early breast cancer. https://www.cancerresearchuk.org/about-cancer/breast-cancer/types/ductal-carcinoma-in-situ-dcis

³⁵ Breast and Cosmetic Implant Registry https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry

³⁶ UK National Flap Registry https://associationofbreastsurgery.org.uk/professionals/audits-registries/uk-national-flap-registry

- successfully recruited new surgeons / Trusts providing a free flap service should be clear on the out of hours responsibility for patients requiring attention to the microvascular anastomosis and this should be job planned accordingly".
- 1.1.9 GIRFT noted (observational notes) there had been a reduction in re-excision rates since its last visit (in 2019). Although there was a relatively low volume reconstruction practice, patients were offered a balanced range of reconstructive options. There were low readmission rates after reconstructions, and no take backs for autologous reconstructions (where data available).
- 1.1.10 GIRFT recommended a range of generic and bespoke action points, which are reflected in the findings below.

A1.2 Breast Surgery Peer Review NCA 2024

- 1.2.1 An earlier GIRFT Breast review of CDDFT had taken place in 2019 and identified several areas for improvement. This, together with informal concerns raised about the quality of the CDDFT Breast Service by a neighbouring Trust, set the backdrop for an NCA 'treatment variation' peer review, which took place in June 2023. This found that CDDFT was a consistent NENC system outlier in terms of re-excision rates (and mastectomy rate as a secondary outcome measure). As a symptomatic unit, there was an expectation of variation when compared to screening units, but local comparison to the other symptomatic units was reported to demonstrate notable variation.
- 1.2.2 The CDDFT Breast Surgery Peer Review NCA 2024 report referred to a meeting organised by the NCA in February 2024, to discuss the outcome of the breast cancer treatment variation audit that was carried out as a national requirement by all cancer Alliances using The Model Hospital and the National Audit of Breast Cancer in Older People (NABCOP) treatment variation data for all trusts. Discussion was reported to have led to "a suggestion of some potentially outdated breast surgical practice". This prompted a surgical peer review of the CDDFT service, facilitated by the NCA and led by a Consultant Oncoplastic Surgeon and NCA Breast Surgical Clinical Lead (based at another trust in the network). Three Breast Units from the North East of England, including representation from the other regional symptomatic service, and an oncoplastic surgeon, were also involved with the review. A decision was made to perform the review on all breast surgery operations/Somerset MDT activity for 2023.
- 1.2.3 The review identified 694 breast operations performed at CDDFT in the calendar year 2023. The re-excision rate in this dataset was 26%; internal audit performed by a Consultant Breast Surgeon at CDDFT was said to have captured a re-excision rate of 31.4%. The figures aligned with Model Hospital data and the GIRFT report, and represented a deviation from the regional and national average.
- 1.2.4 The primary mastectomy rate was 38%. The overall mastectomy rate (which includes completion mastectomy for previously involved margins after breast conserving surgery) was 48.6%. Looking at Model Hospital data this placed CDDFT as an outlier compared to the NENC system. The national average included data from both screening and symptomatic units. Screening units tended to have a lower mastectomy rate than symptomatic units. Screen detected cancers tended to be smaller than symptomatic presentations.
- 1.2.5 The review found that 7.5% of mastectomy operations had a breast reconstruction, which was considered a low number, as noted in the GIRFT report from 2019.

Nationally a minimum recommendation for proportion of mastectomy patients who should have a reconstruction is set at 25%.

- 1.2.6 The review noted that skin was taken routinely over tumours when tumour did not involve skin (144/186 patients), which was described as "an outdated practice". The report stated: "Routine excision of skin which is not involved by cancer is not necessary to achieve oncological outcomes and is likely to result in more distortion of the breast due to altering the nature of the breast skin envelope".
- 1.2.7 None of the available documentation made note of breast size and characteristics so an accurate assessment of excision weight versus breast volume could not be made, however specimen weights of 80g+ without level 1 or 2 oncoplastic techniques were reported as likely to result in breast deformity.
- 1.2.8 The report observed that 19% of patients did not have a one stop assessment performed in one clinic visit. It appeared that patients had the initial ultrasound and mammogram assessment and then came back for an image guided biopsy a few hours later. The report stated: "There may be service considerations that are the reason for this however this practice represents increase in clinic footfall and reduced efficiency."
- 1.2.9 The report detailed that most patients assessed in one particular clinic did not have image guided biopsy and instead the clinician performed clinical/palpation guided biopsy. The report described this as accepted practice for cases where there is a discrepancy with imaging (i.e. where imaging does not show a lesion but the clinician can palpate one), adding that for the vast majority of cases the recommendation was to perform an image (ultrasound) guided biopsy, stating: "Breast Radiology is an interventional specialty and the accuracy of image guided biopsy is higher than for clinical core biopsy." This was thought to be evidenced by the finding that a proportion of patients had to re-attend for repeat biopsy due to initial non diagnostic biopsy.
- 1.2.10 The four clinical experts who carried out the review agreed a traffic light system to categorise their findings. Red, represented work outside of national guidelines / standard of care; amber, represented a deviation from a standard of care/routine accepted practice that may not be documented in guidelines; green, no concerns found. In terms of breast cancer operations, 44% were categorised as red; 45% as amber; an 11% as green. Red concerns were that:

1.2.10.1 1.2.10.2	no breast reconstruction was offered; incomplete imaging/diagnostic workup leading to suboptimal surgical plan;
1.2.10.3	outdated practice (e.g., mastectomy due to 'multifocality' without full investigation workup, or mastectomy offered due to tumour size >4cm or age criteria);
1.2.10.4	MDT recommendation at variance with diagnostic workup; upfront diagnostic axillary node clearance for staging purposes;
1.2.10.5	surgical plan changed on the day – breast conservation/re-excision to mastectomy;
1.2.10.6	surgical recommendation made before neoadjuvant chemotherapy and plan unchanged by complete radiological response;
1.2.10.7	13/42 cases involved tumours that were potentially suitable for neoadjuvant chemotherapy but did not receive it, the reasons for which were not clear.

1.2.11 Amber concerns included:

- 1.2.11.1 uninvolved skin taken over tumours routinely (not indicated, outdated practice);
- 1.2.11.2 routine use of 'Nipple Cytology';
- 1.2.11.3 FNA instead of core biopsy leading to repeat investigations;
- 1.2.11.4 clinical core biopsy instead of image guided core biopsy leading to repeat investigations;
- 1.2.11.5 suboptimal documentation of options discussed with patient; brief or incomplete MDT documentation.
- 1.2.12 Operations for B2 (benign) breast lesions were more likely to be rated green (65%). Operations for B3 (atypical) breast lesions were rated red in 47% of cases, amber in 10%, and green in 42%.
- 1.2.13 The review report concluded that there was "evidence to suggest deviation from national guidelines/best practice in the setting of diagnostic workup of breast conditions and surgical treatment options." The review did not look at oncological outcomes and there was no suggestion or suspicion that oncological outcomes were being compromised.

Duty of candour

- 1.2.14 The review team received a Trust report on 'consideration of breast surgery services and duty of candour'. The Trust was first advised of the outcome of the peer review in verbal feedback received in April 2024. In response, amongst the actions taken, the Trust Medical Director mandated that, from 8 May 2024, every breast cancer MDT meeting should have an external specialist (at the time of the invited review an oncoplastic breast surgeon) present, and that all patients listed for a mastectomy would be subject to a second, external, specialist opinion. Any patient listed to undergo a mastectomy would, where appropriate, be offered immediate breast reduction at a screening site.
- 1.2.15 A detailed service improvement plan was put in place. Linked to this, an external clinical lead was appointed and the Trust decided to recruit two oncoplastic surgeons (see A1.4 Staffing) and committed to undertake a review of the mastectomy cases outlined in the peer review report. In October 2024, the Board was informed that discussions were taking place with Gateshead Health NHS Foundation Trust to explore the joint appointment of breast radiologists, and that patient reviews and legal advice were being taken to determine where and how the statutory duty of candour needed to be fulfilled.

A1.3 The breast service at the time of the invited review

1.3.1 The review team heard that the Trust was "very supportive" of the ICB's decision to commission this invited review. There was said to be an appetite within both the ICB and the Trust to gain assurance regarding the "quality and safety" of the breast service. There was a plan to use this IRM report as "an instrument for change", building on some of the changes already made in response to previous reviews. The duty of candour with respect to mastectomy and the availability of oncoplastics was a key concern. There was an imperative to reach a "definitive position" on these issues, as well as on quality and safety.

- 1.3.2 GIRFT had observed a high level of engagement between the Trust and the NCA, including regular communications and evidence of financial support for service improvement (GIRFT observational notes). One of the main motivations reported by interviewees for the NCA was reducing variation, and clinicians across the network were said to be increasingly motivated to achieve the same quality standards. There were calls for the CDDFT breast service to be subject to the "same degree of scrutiny and same degree of peer review as in [the] screening units".
- 1.3.3 There was a recognition that the structure of breast services in NENC was unusual and some long-held aspirations were reported to develop closer alignment with screening services, as part of a managed clinical network. The NHS England direction was said to be to align symptomatic services with screening ones. One option aired was for the two CDDFT units to be split and aligned with screening centres, with DMH working with North Tees and Hartlepool NHS Foundation Trust and for UHND working with the Gateshead Health NHS Foundation Trust. Staff across these units were said to already have good working relationships. The Queen Elizabeth Hospital in Gateshead was reported to have the ability to absorb the additional radiological workload, however North Tees was expected to need to recruit additional radiologists.
- 1.3.4 Resistance to such plans was anticipated from some CDDFT clinicians. There was talk of a need for cultural change and to the time it takes to achieve a change in mindset, particularly given the small size of the breast surgical team. There was a worry that the breast service was fragile and that imposing change too quickly could pose a "greater risk to patients" if clinicians were to withdraw from the service.
- 1.3.5 Another viewpoint was that the Trust and staff were open to this invited review and the conditions were right to change the configuration of services. A recurring message was that clinicians within the breast service had engaged positively to the prospect of this review and reacted professionally to the scrutiny placed on the service.

A1.4 Staffing

Clinical leadership

- 1.4.1 The Trust had six care groups, one of which was Surgery. The Surgery Care Group had six directorates, each with its own clinical director, general manager and matron, one of which covered General Surgery. General Surgery comprised three specialties including breast surgery. The Executive Medical Director and Deputy Chief Executive, a colorectal surgeon, had been Care Group Director for Surgery since 2014. Breast surgery had come under the remit of the Associate Director of Operations, Surgery Care Group, since 2018, first as general manager and then as Associate Director of Operations. An Associate Director of Nursing, Surgery Care Group, managed six matrons, including the matron for general surgery, which incorporated breast surgery.
- 1.4.2 Breast, colorectal and upper gastrointestinal surgery each had their own clinical lead, reporting to a Clinical Director for General Surgery, who reported to the Care Group Director. Until 6 months before this review, one of the Breast Surgeons at UHND had been clinical lead for 13 years. This surgeon was asked to step down as clinical lead and was praised by several interviewees for responding very professionally to this request. Since September 2024, a Consultant Oncoplastic Surgeon from North Tees and Hartlepool NHS Foundation Trust had assumed the role of clinical lead. This surgeon was also the NCA Breast Surgical Clinical Lead who led the peer review of CDDFT in 2024.

- 1.4.3 The new clinical lead was described by some as a "breath of fresh air", and it was hoped they would provide the service with a sense of strategic direction. They were reported to have worked hard on engagement and had begun regular breast meetings of the whole team said essentially to be "business meetings". There had been two breast meetings with clinicians (in October and December 2024), which were reported to have focused on information sharing and the need for change, including a changed MDT format, PIFU pathways and redistributing the workload. The breast team meeting held in December 2024 focused on feedback from the most recent GIRFT review. The review team heard that some members of the breast team had refused to attend these meetings, although better attendance was reported at the most recent meeting.
- 1.4.4 There was recognition that the clinical lead needed to be someone working on site and that "a person coming and leaving is not ideal". There were plans for the clinical lead to undertake clinical activity on site under a contract paid for by the NCA from March 2025. This would also allow the clinical lead to mentor two new consultant oncoplastic surgeons shortly to join the Trust.

Surgical and medical staff

- 1.4.5 The breast surgical service was provided by four consultant surgeons, all of long-standing with the Trust:
- 1.4.5.1 A consultant general surgeon who had worked at UHND for two decades.
- 1.4.5.2 A consultant breast, endocrine and general surgeon at UHND also for two decades, and clinical lead for 13 years, who had come off the general on call but still performed hernia and gall bladder operations.
- 1.4.5.3 A consultant general and breast surgeon at DMH, who had been part of the unit for 15 years and continued to participate in the general on call. This surgeon was not undertaking breast clinical activity at the time of the IRM review.
- 1.4.6 A specialty doctor in breast and general surgery, who was going through the portfolio (CESR) pathway³⁷, had worked at DMH as a locum consultant since 2023. This surgeon needed oncoplastic experience to complete the requirements for the portfolio pathway and was expected to need to gain this at another trust.
- 1.4.7 Another associate specialist had been working as a locum consultant and had been on long-term sick leave since late 2024.
- 1.4.8 At UHND there was an Associate Specialist for Breast Surgery, who continued to undertake general surgery (but had come off the on-call rota) and had been part of the service since the breast unit opened in 1999. This surgeon worked mostly under the direction of one of the consultant surgeons at UHND.
- 1.4.9 A specialty doctor supported clinics and provided some theatre assistance (they did not undertake any independent operating), mainly at DMH.
- 1.4.10 Interviewees spoke of a "challenged dynamic" amongst the surgical team. The consultant surgeons were said to work in an individualistic way and not as a cohesive team. A "North-South divide" was described, as was a lack of flexibility and willingness to adapt to changes. Within the North, silo working was described between the two consultant surgeons, although there was a close working relationship between one of the consultants and an associate specialist. Within the South, a close working relationship was reported between the consultant surgeon who had stepped backfrom

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³⁷ The Portfolio Pathway (formerly known as the CESR) pathway is the route to specialist registration for doctors who have not completed a GMC-approved training programme.

clinical practice and the less experienced locum consultant. The new clinical lead was credited by some with trying to drive a more cohesive team dynamic.

- 1.4.11 Issues were raised regarding the "challenging behaviours" of some of the consultant surgeons at both units, including an unreasonable response to requests, and aggressive and confrontational behaviours. One of the surgeons was described as "probably the most difficult person to work with in the Trust", although this same surgeon was very popular with patients, scored highly in patient feedback, and would be the first choice for one interviewee should they ever require breast surgery. A lack of transparency was alleged in the working practices of one consultant surgeon and another surgeon. Some competency concerns were raised regarding two surgeons, with a need highlighted for closer supervision.
- 1.4.12 A recurring theme was that the surgical team worked extremely hard, managing large patient caseloads, and demonstrated a real commitment to patient care. A tendency of "heads down" and getting on with it was reported, although it was remarked that "the hamster wheel is not turning in the right direction". They were said to be working under a lot of pressure, with insufficient resourcing to meet demand.
- 1.4.13 A breast physician (formerly a GP with a special interest in breast) had been appointed to the Trust within the preceding 6 months. This individual had been a breast physician part time since 2010 and started working for the Trust in June 2023, initially on 4 sessions a week and then on 8 PAs³⁸. Issues were raised regarding utilisation of this breast physician, who had yet to receive a job plan. They were employed to work cross-site and were to lead a new breast pain pathway. They had covered the clinics of the locum consultant at DMH who had been on sick leave, however there were also accounts of resistance from both managers and clinicians to the breast physician providing such cover, on the grounds they were not a consultant. The review team heard that, in a previous Trust, the breast physician had run an autonomous practice and was able to offer a full breast service to new patients and follow ups, except for providing surgery. Resistance to this at CDDFT had meant the breast physician was running a clinic alongside a consultant (i.e., as a trainee might), which some regarded as poor utilisation of the breast physician.
- 1.4.14 Two oncoplastic breast surgeons had been appointed and had not started in post at the time of the review. One will be based in DMH and one in UHND. Their job plans were not yet finalised, but they were said to be coming into post with "their eyes open". It was hoped these new surgeons would help to alter the dynamics of the current surgical team. There had not been any trainees within the breast service for two years, due to the lack of exposure to oncoplastic procedures. It was hoped this would change with the appointment of these two new surgeons.
- 1.4.15 The Trust report on 'consideration of breast surgery services and duty of candour' stated that the Trust was in discussion with a further breast surgeon in the region, with a view to a one-year secondment to help support the establishment of the oncoplastic surgery service.
- 1.4.16 There were calls for additional surgical support at UHND. It was reported that a consultant post was advertised several times and there had been no applicants, which led to the decision to develop the locum consultant posts. There did not appear to be any appetite amongst the existing consultant surgeons to give up their general surgery (and in one case endocrine) practice to focus solely on breast surgery.

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³⁸ Programmed activities (PAs) are blocks of time in which contractual activities are performed

1.4.17 There was some awareness that the age profile of the current substantive surgical workforce required thought to be given at a regional level to succession planning.

Radiology

- 1.4.18 Two consultant radiologists and one consultant radiographer covered clinics held in the North and the South. Another consultant radiologist had taken flexible retirement. The consultant radiographer had retired and returned.
- 1.4.19 The radiology service was described as "very fragile for a long time" and the rate limiting factor in terms of managing demand for the breast service. One account was that over the last two decades, six breast radiologists had left the organisation and only one had joined.

Breast care nursing

- 1.4.20 At the time of the review, there were:
- 1.4.20.1 1 x band 7 breast care nurse who covered both sites (full time)
 1.4.20.2 2 x band 6 breast care nurses at DMH (both full time)
- 1.4.20.3 2 x band 6 breast care nurses at UHND (1 x full time; 1 x 30hours)
- 1.4.20.4 1 x band 6 breast care nurse working cross site (funded by the NCA on a 12-month fixed term contract 6 months at each site)
- 1.4.20.5 1 x band 6 breast care nurse had been out to advert twice
- 1.4.20.6 2 x band 4 coordinators (both part time and not substantive roles).
- 1.4.21 The review team heard accounts that the breast care nurses (clinical nurse specialists) were previously all band 7 and the current establishment was thought to be "underbanded and under-resourced" compared with the other symptomatic unit in the region.
- 1.4.22 Retention was reported to be a problem in the South (i.e., DMH) and recruitment of replacement breast care nurses was described as "quite difficult". A "very high turnover" in breast care nurses at DMH was blamed on the behaviours of some clinicians. Exit interviews were said to have highlighted human factors as the main reason for departures. The review team heard of examples where nursing staff had felt "embarrassed and humiliated" by clinicians in public meetings, including being the recipients of derogatory language. One consultant surgeon was said to have held back the breast care nurses in terms of preventing them from fully utilising their clinical and prescribing skills. Attempts to persuade this consultant to recognise their potential were reported to have been unsuccessful.
- 1.4.23 There were calls for investment to be made into the breast care nursing team and to support an expansion in their skillsets and the services they could offer patients. "Huge caseloads" were said to prevent their participation in skills development training, such as courses in breast examination. There was no specialisation within the team, although there were aspirations for one nurse to run a menopausal clinic and it was hoped that two members of the team could utilise their plastics reconstruction skills when the new oncoplastic surgeons started. It was said that the team had "so many ideas but not the resources to do them". Caseloads were also said to be inhibiting the ability to train and invest in new clinical nurse specialists.
- 1.4.24 The breast care nurses did not see new patients. There was a view that there were insufficient numbers to support patients with a new diagnosis. Another account was that they were quite junior and needed training before this could happen. Nurse led clinics

- were mainly focused on holistic needs and care planning. PIFU was described as limited, with narrow eligibility criteria. Work was underway to re-write the PIFU criteria.
- 1.4.25 There was a sense that the nursing team were excluded from decision-making regarding the breast service or meetings to discuss the outcome of external reviews. It was hoped that the new clinical lead would change this and bring learning from teamworking with breast care nurses at their home trust.
- 1.4.26 GIRFT noted that the Trust was "unusual as it does not have a dedicated secondary CNS" i.e., a specialised service provided by a clinical nurse specialist (CNS) specifically focusing on supporting patients with secondary (metastatic) breast cancer. GIRFT reported that members of the breast care nursing team considered this would be a positive development for their team.

General and executive management

- 1.4.27 There was some criticism of the general management team for providing insufficient support to the clinical team. A lack of visibility of managers was alleged and it was reported that there were no team meetings with service managers and "no discussion about anything". An example was a reported lack of discussion regarding the 2019 or 2024 GIRFT reports. Challenges with IT to support the weekly MDT meeting were cited as another example of a lack of support, as was insufficient resourcing (in terms of staff and equipment) to meet demand. Emails were said to have been sent to managers several times, over a number of years, asking for a Faxitron machine (to support high resolution breast imaging), scout guidance (to precisely locate a non-palpable breast lesion during surgery), and in-house HER2 testing (to identify the HER2 protein and determine which treatments were likely to be most effective), reportedly all to no avail. The Trust report 'consideration of breast surgery services and duty of candour' stated that a Faxitron machine had been procured.
- 1.4.28 The review team also heard a perception that the service managers had been "out of their depth" in trying to manage a "disorganised and dysfunctional" breast unit and a team of clinicians who did not work well together.
- 1.4.29 Fractured relationships were identified between specific clinicians and "management" (it was unclear what level of management some comments related to).

Interdisciplinary teamworking

- 1.4.30 Good working relationships were reported in radiology, nursing teams, and administration teams.
- 1.4.31 Good team working as also reported at DMH, with surgeons, oncology, plastics, breast care nurses, and a pharmacy colleague reported to meet as a team periodically. The most recent team meeting was said to have been in February 2024; before that it was 2020, with the first such meeting in 2019.

A1.5 Diagnostic breast service

Outpatient capacity, outsourcing and insourcing

1.5.1 The service overview information detailed that 26,833 outpatients were seen between 01 December 2022 and 30 November 2024. Interviewees reported that approximately

120 new referrals were received each week. There were 18 breast clinics each week, with a mix of new and follow up patients. The following one stop clinics were held:

- 1.5.1.1 UHND Tuesday, Wednesday and Friday mornings (3 clinics / week); including radiology and with up to 12 new slots per clinic.
- 1.5.1.2 DMH all day clinics on Tuesday and Thursday (4 clinics / week), with radiology.
- 1.5.1.3 Spire Washington Hospital one evening and one all day clinic (3 clinics per week); with radiology.
- 1.5.1.4 Insourced up to 4 or 5 clinics per week (varying depending on demand), held at evenings and weekends.
- 1.5.1.5 In addition to the one stop clinics, there were additional mixed clinics for new and review / results patients.
- 1.5.2 The most recent GIRFT review observed that overbooking of clinics was a challenge for this service. It noted some differences across the two sites in terms of practice, and that out of hours clinics were seen as normal.
- 1.5.3 The all-day clinics at DMH were reported to see 40 patients 10 new in the morning and 10 new in the afternoon, and the rest were follow ups. A radiologist was present all day. Another clinic had reduced to five new patients in a half day, to accommodate new patients arising over the weekend, and 10 follow ups, including elderly patients on primary hormone therapy.
- 1.5.4 At UHND, it was reported that one surgeon saw 10 to 12 patients on average in a onestop half day clinic. Another surgeon saw eight new patients in a 3.5-hour clinic, participating in two each week.
- 1.5.5 The breast service was reported to have been very challenged from a capacity perspective and had "always" outsourced between 40% and 50% of its capacity. At the time of the review, approximately 50% of capacity was provided inhouse and the other 50% via outsourcing/insourcing. Two arrangements were described, one serving the South of the region and one serving the North.
- 1.5.6 Spire Washington Hospital was outsourced to run one stop clinics serving the North of the region, mainly on a Tuesday evening. The clinics were run by one of the consultant surgeons based at UHND and a consultant radiologist, mainly based at UHND but who also ran some clinics at DMH. There was no breast care nurse at this clinic.
- 1.5.7 Insourcing was via Durham Surgical Services Ltd and involved running clinics at DMH. These clinics tended to be run on Friday evenings, Saturdays and some Sundays, and staffed by one surgeon, one radiologist and a mammographer. The director of Durham Surgical Services was the same consultant surgeon who ran the outsourced clinics at Spire Washington Hospital. An associate specialist would undertake one of the insource clinics every fortnight. Another surgeon who no longer worked for the NHS was also reported to cover some of these clinics. There was no breast care nurse at the insourced clinics.
- 1.5.8 The volume of patients to staff ratio was raised as an issue. The review team heard concerns that too many patients were seen in these clinics and those running them had been asked to reduce the numbers. At an insource clinic on a Sunday, 30 patients would be seen between 08:30 and 16:00/17:00. Those running the clinic had been asked to stop going over 30 patients (previously it was reported that 40 or more patients

may be seen by one clinician in the Sunday clinic). The Friday evening clinic was reported to last from 17:00 to 21:00 and see 20 patients. Another account was that 25 to 30 patients would be seen in a Friday evening and that it was not unusual for the clinic to run on until 23:30. One perspective was that the surgeons in these clinics would see four or five patients an hour.

- 1.5.9 Considerable concern was expressed by several interviews regarding the outsourcing and insourcing arrangements. The insourcing service was described as "frankly atrocious", with "patients in and out and in and out" and very little time spent with them. The speed of consultations was said to be reflected in negative feedback from patients in the national cancer survey. The review team heard throughput was so high that patients were losing out in terms of compassionate care. This was compounded by the absence of a breast care nurse to support these clinics, and sometimes breast care nurses did not receive details of patients who came back to the NHS hospitals to receive treatment.
- 1.5.10 Another concern was that these arrangements were not meeting Association of Breast Surgery (ABS) guidelines. It was reported that a significant number of patients seen in the Spire Washington Hospital underwent clinical core biopsy. The patients would be seen and undergo imaging, but to reduce the burden on the radiologist, the clinician would take the biopsy at the end of the clinic. The insourced clinics held on site were thought to be more consistent with the guidelines.
- 1.5.11 It was reported that one surgeon performed one or two clinical core biopsies and three FNAs each week in clinic.
- 1.5.12 The cost of the arrangements was also a concern and thought by some to be overly generous.
- 1.5.13 There was discomfort that one surgeon ran both the outsourcing and insourcing. The review team heard that out of 13,500 referrals, 8,000 were under the name of this one surgeon. There were calls for the Trust to recommission the outsourcing and insourcing to a body of surgeons and for there to be a better distribution of referrals.
- 1.5.14 Opportunities were identified to use a brand-new hospital in Bishop Aukland as part of the solution and to create capacity. An application had been submitted for this to become an elective hub. Some resistance to this idea was reported amongst the consultant surgeons.
- 1.5.15 The GIRFT 2024 report observed that CDDFT needed "to ensure their pathways are aligned and equitable across both sites." Regarding the outsourcing of clinics, GIRFT observed: "This Trust is doing out of hours one stop clinics, and this has been happening for such a long time it is seen as normal. Clinics are also overbooked on a weekly basis. Whilst ad hocs [ad hoc clinics] are essential for timely treatment during peaks of activity Trusts requiring regular ad hoc activity and overbooking should do a demand and capacity review to ensure the service can be properly resourced. The length of clinic slots seemed reasonable after discussion this seems to be 10-15 minutes for a new patient and 30 for a treatment planning slot. There did not seem to be a clear agreement across the two sites, and it was commented on that two patients may be booked into one slot. Clinic templates for new patients and for treatment planning should be agreed and standardised for all clinicians on both sites."

Breast radiology

- 1.5.16 The team of breast radiologists and consultant radiographer were perceived to work well together and to provide a good service. Clinics were busy and the main issue described was insufficient radiology staff to meet demand. At UHND, one radiologist would see 12 or 13 new patients over 3.5-4 hours. The Friday insourced clinics were said to be more productive because there was less traffic through the hospital and radiologists could see 18 or 19 patients over 4 hours. The Saturday clinic ran from 09:00 to 18:00 and more than 30 patients would be seen by one radiologist, with a maximum of 38-40 patients (which involved running on beyond 18:00).
- 1.5.17 A recurring message was that the breast radiology service was very fragile and relied on a small team, some of whom had retired and returned. Recruitment of radiologists was reported to be a challenge. There was a worry that the departure of one of the substantive radiologists left would be "the end of radiology". Developing a hub and spoke model with North Tees and Hartlepool NHS Foundation Trust and the Queen Elizabeth Hospital, part of the Gateshead Health NHS Foundation Trust, was regarded by some as "vital".
- 1.5.18 Questions had been raised regarding the sizing of breast cancers and consultants from a neighbouring unit were said to have expressed concerns. There was a plan for three radiologists to conduct a radiology review in early 2025 of the same cohort of cases from 2023 that the NCA surgeons reviewed, and other patients where diagnosis was delayed. The Trust sought assurance around the quality and safety of radiology and about developing best practice. Radiology was contrasted with the arrangements for oncology, and the assurance offered that the oncology teams worked in screening centres and were part of other MDTs.
- 1.5.19 There was a sense that the pressures on radiology were leading to practices that did not align with practice in other centres. For example, it was reported that some members of the team created a combined mammogram and ultrasound report for expediency. There were said to be significant differences in the reporting of mammograms across radiologists, and a lot less ultrasound guided imaging compared to other centres. Many clinical core biopsies and breast FNAs were said to be undertaken in the evening clinics.
- 1.5.20 Issues were also raised over the quality of the ultrasound equipment used within UHND.
- 1.5.21 GIRFT observed that there was no VAB (vacuum assisted biopsy) or VAE (vacuum assisted excision) service on site, to support the diagnosis of breast lumps and remove non-cancerous lumps. Interviewees said this was in contrast with the other symptomatic centre. GIRFT suggested that, in the short term, these patients could have their diagnostic VAB/VAE elsewhere.

Non-surgical oncology

- 1.5.22 The Trust was served for oncology by the two regional cancer centres in Newcastle and Middlesbrough. Oncologists at the Freeman Hospital (part of Newcastle Hospitals NHS Foundation Trust) served patients in the North and oncologists at The James Cook University Hospital in Middlesborough (part of South Tees Hospitals NHS Foundation Trust) served the South.
- 1.5.23 Some interviewees expressed disappointment that there was no physical presence of oncology, given the size of the breast service. Oncologists dialled into the UHND section of the MDT and sometimes signal difficulties undermined their contributions.

- 1.5.24 Separate clinical oncologists covered the radiotherapy side of treatment. As a group, the breast oncologists were said to communicate effectively, and annual meetings were held within the region where protocols were discussed.
- 1.5.25 A recurring theme regarding oncology related to whether neoadjuvant therapy was offered to down stage surgical treatment.
- 1.5.26 The decision over whether to offer neoadjuvant therapy was said to be made at the MDT meeting. In terms of triple negative breast cancer patients³⁹ and those who might be HER2 positive, the review team heard that discussions were individualised. Emphasis was placed on the amount, and toxicity, of chemotherapy given as a neoadjuvant therapy, compared with adjuvant therapy (given after primary treatment) and the need to ensure the patient was sufficiently fit for extended chemotherapy. Fertility issues and fertility sparing were other considerations. The 2cm was said to be "a hard cut off" with certain drugs.
- 1.5.27 Delays while awaiting HER2 results was another area where questions were raised over neoadjuvant therapy.
- 1.5.28 One of the catalysts for the NCA peer review was a meeting at which one of the Trust's consultant surgeons made a comment thought to indicate potentially outdated surgical practice. During interviews, the review team heard that a surgeon was alleged to have said that the decision to undertake a mastectomy for tumours over 4cm in size was made by the oncologist at the MDT. This was reported to have upset oncology colleagues, who were clear that they did not make decisions regarding mastectomy. A cut off of 4cm for mastectomy was said to represent outdated practice.
- 1.5.29 A regional non-surgical oncology review was underway, and restructuring was anticipated due to the pressures on oncology. It was anticipated that hubs would be established. Breast services were not the most pressurised oncological services and waiting times were described as within acceptable limits, with a 3 week wait to start systemic adjuvant treatment.

Breast pathology

1.5.30 Four consultant breast pathologists covered the breast service and three of these predominantly covered the breast MDT. Also, three of the four were involved in reporting of breast screening work and participated in annual external quality assessment.

- 1.5.31 They had a large cytology caseload, including nipple cytology and clinical FNA. Most of the cytology was undertaken by breast surgeons.
- 1.5.32 The average turnaround from pathology for a postoperative surgical specimens varied but was thought mostly to be within 7 working days. Patients could expect to receive the results of biopsies within 48 hours.
- 1.5.33 GIRFT observed that diagnostic cores were reported to be available within 5 working days however this did not include full biology and HER2 testing was undertaken off site, which could lead to delays it was said that it took up to 3 weeks to obtain HER2 results as the testing took place in Newcastle. There were plans to bring HER2 testing

³⁹ https://www.cancerresearchuk.org/about-cancer/breast-cancer/types/triple-negative-breast-cancer

inhouse by 2027/2028, and this was expected to bring down the turnaround time to 5 working days.

A1.6 Breast surgical service

- 1.6.1 When a patient returned for the result of a breast biopsy, a breast care nurse would be present. There was a view that patients were given the available options. Emphasis was placed on giving patients the time they needed in clinic and a follow up telephone call was always arranged for the following week.
- 1.6.2 It was reported that 250 to 280 cancers (accounts differed on the number) were diagnosed at UHND annually. It was pointed out this meant there were 250-280 cancers for two consultant surgeons and one associate specialist (a third locum consultant surgeon was on sick leave). Not all these required operations and some of those who did need surgery were passed to DMH for their operation. All breast cases diagnosed at the outsourcing or insourcing clinics were managed through the "North MDT" (i.e., the section of the MDT that covered UHND) as the patients came under the name of the surgeon who ran the Spire clinics and Durham Surgical Services Ltd. There were no insourcing theatres for breast surgery (although this existed for general surgery and benign lumps may be added to a general surgery list).
- 1.6.3 There was a lack of awareness amongst interviewees of the number of cancers diagnosed in the South (i.e. from DMH).
- Theatre space was reported to be protected for cancer activity. Some issues were raised with effective theatre utilisation by some of the surgical team, who undertook a mixture of full and half day lists. There were differing accounts of how many cases were performed on a full day list in UHND (held on a Monday), which was mostly a consultant surgeon and associate specialist operating together. The review team heard that on average, 2-3 cases were undertaken on this full day list; although another account was that an average of five cases, mostly breast cancer patients but some parathyroid surgeries, were undertaken on this all day list. There were half day lists at DMH, each comprising two cases. It was commented that the Monday list at UHND "stands out" as one that could be better utilised. There were also some waiting list initiative (WLI) theatres lists at weekends.
- 1.6.5 In 2024, GIRFT observed that access to theatres was "a challenge for this service". The data period GIRFT looked at showed a much lower 62-day performance compared to the high FDS and suggested pathway analysis was needed to explain areas that needed focus.
- 1.6.6 There was some criticism of a perceived organisational focus on meeting "waiting list targets". Some resistance was expressed to suggestions to put patients on waiting lists of surgeons considered to have spare capacity, without the surgeon having met the patient in clinic first.
- 1.6.7 GIRFT observed a need to establish a clear pathway for "robust and efficient out-of-hours coverage for breast surgery patients", which was managed by the general surgical team but was likely to require review with expansion of the oncoplastic service. GIRFT also drew attention to the importance of having a clear out of hours responsibility for patients requiring attention to the microvascular anastomosis (post free flap surgery).

Range of treatments offered

- 1.6.8 GIRFT observed that the Trust had low breast conserving rates; that there was a need to continue to monitor re-excision rates, which while improved were still "a high outlier", which was said to further support access to VAE/VAB; and to monitor implant loss rates. GIRFT remarked that CDDFT was unusual in not having a dedicated breast abscess pathway, adding this should be developed as the Trust was a high outlier for this. Once fully staffed and issues with clinic and theatre capacity had been addressed, GIRFT said consideration should be given to offering local screening patients the option of treatment in their local hospital.
- 1.6.9 Concerns were raised over certain breast surgical practices. This included decision making with respect to skin over tumours when the tumour did not involve the skin, which was described as "bizarre". Historically, the service "always" removed skin over tumour, however this practice was said to have changed relatively recently and was happening less. Where it continued, it was reported to have been a smaller area unless the tumour was close to the skin. It was also reflected in the consenting process.
- 1.6.10 There was said to be "no doubt" that there was overtreatment. The re-excision rate was high, which was said to lead to more surgery.
- 1.6.11 There was some disagreement that excision margins did not align with national standards, or with some of the other concerns raised by the peer review, which had left some staff feeling unappreciated. There were said to have been misunderstandings regarding margins, and that practice reflected NICE guidelines, which at that stage stated for 1mm for clearance and 2mm for DCIS⁴⁰. The unit had still been using wires up to 8 months ago and it was said "margins are always going to be an issue whilst we only had wires."
- 1.6.12 Concern was voiced regarding the operative techniques used by certain members of the surgical team (not consultant surgeons). Some outdated techniques, including removal of skin over tumours, were alleged and a need highlighted for some skills to be refreshed. It was reported that "quite a lot of surgery" was not undertaken by consultants and for "a significant proportion" the consultant was not scrubbed in.

Mastectomy

- 1.6.13 The NCA peer review (2024) identified the primary mastectomy rate as 38% and the overall mastectomy rate (including completion mastectomy for previously involved margins after breast conserving surgery) was 48.6%. Some members of the surgical team were aware of their own mastectomy rate (25% in one surgeon, with 75% having breast conservation). Others were unable to provide their mastectomy rate. Day case mastectomy was said to be "slightly below" the national rate and was starting to increase.
- 1.6.14 The socio-economic profile of the local population was thought to explain the higher rate of mastectomy, as was the nature of the service as symptomatic only. It was stated that "a not inconsiderable number of patients don't have any teeth" the implication being that breast deformity was not a priority concern for some patients. It was also said that it was not unusual for patients to be resistant to the idea of travelling to Middlesborough for radiotherapy and some were said to have opted for mastectomy for

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⁴⁰ Ductal carcinoma in situ

this reason. Good patient satisfaction was referred to in defence of the service provided.

- 1.6.15 The review team also heard that there appeared to be little use of local flaps and breast preserving techniques, with the focus instead on lumpectomy or mastectomy and leaving the breast as it looked. As a symptomatic service, patients were said often to present with large tumours and there was a belief that mastectomy would therefore be the natural option for many.
- 1.6.16 The review team explored why there was examination of the margins of a mastectomy and then reoperations on some mastectomy patients. It was said that one surgeon did not remove all the breast tissue. Other accounts were that re-operating post a mastectomy was "a rarity" for one surgeon, this was less than once a year. There was some discussion of case A10, concerning a patient who underwent mastectomy and was taken back to surgery where an ellipse of skin and mastectomy scar was removed. It was decided with the plastic surgeons to try to get clearance of margins on the inferior and lateral aspect. It was considered safer to "go through some clear tissue".
- 1.6.17 Some criticism was made of the GIRFT report in 2019, which was said to have included mastectomies by plastic surgery as part of gender reassignment.
- 1.6.18 One member of the surgical team had a private practice. The processes in place within the Trust were reported to be the same in the private sector with respect to mastectomy (this included offering a second opinion with respect to full or partial breast reconstruction options returned to below).

Reconstruction

- 1.6.19 GIRFT (2024) observed "a relatively low volume reconstruction practice", adding that patients were offered a balanced range of reconstructive options. The NCA peer review (2024) found that 7.5% of mastectomy operations had a breast reconstruction, which was considered a low number, with a national minimum recommendation for 25% of mastectomy patients to have a reconstruction.
- 1.6.20 The review team heard that, historically, the culture of the service had been to delay breast reconstruction, such that the unit was described as a "delayed reconstruction unit".
- 1.6.21 There was an expectation within the unit that any patient offered a mastectomy would be offered reconstruction and that if this was declined, the reasons for this would be documented. However, it was also reported that documentation around this could fall short. The letter to the GP was said to offer a wide local or mastectomy and was expected to offer reconstruction. All patients received a copy of the letter unless they requested not to. The MDT coordinator was expected to record the offer of reconstruction and whether it had been declined.
- 1.6.22 Internal analysis of mastectomies carried out at UHND was reported to show that, out of 51 mastectomies in 2024, only three had no mention of reconstruction (either documented discussion with the patient or in an MDT meeting); seven had immediate reconstruction; and in 20 cases, it was the patient's decision not to have reconstruction. Some patients were turned down for reconstruction by plastic surgery or had deferred reconstruction to a later date.
- 1.6.23 Patient choice was cited as the main reason why there was not more reconstruction.

 There was a view that patients required a comprehensive discussion with someone who

could undertake reconstruction to make an informed decision and that these skills were not present within the surgical team, in the absence of any oncoplastic surgeons. The symptomatic nature of the unit was also thought to be a factor, with patients presenting later than in screening units. It was also reported that there had been cases where surgeons had changed plans post MDT and proceeded with mastectomy without discussion in the MDT of reconstruction. The high volume of patients seen in the unit was thought to cause delays to reconstructions. The lack of an oncoplastic MDT was thought to be an issue, and specialist reconstruction breast care nurses had left the Trust.

- GIRFT had observed (2024) that plastic surgery was provided on site: plastic surgeons operated in UHND and undertook clinics in DMH. The plastic surgeons provided a reconstruction service for both implant based and autologous reconstruction. The breast surgeons did not perform chest wall perforator flaps but some of the plastic surgeons were developing this service. GIRFT reported that the breast surgeons provided a skin sparing mastectomy service for the immediate reconstruction patients but were not job planned to do so. There was no oncoplastic MDT and it was thought there could be closer working between the breast and plastic surgeons. GIRFT emphasised ensuring that pathways were in place to allow patients to have access to all forms of reconstruction. It recognised that the case-mix of CCDFT meant they would not be one of the higher trusts for immediate reconstruction but there was an opportunity to allow for more oncoplastics and reconstruction.
- 1.6.25 GIRFT observed there was no facility for joint operating between breast and plastic surgeons or for two consultant breast surgeons operating. The plastic surgeons undertook deep inferior epigastric perforator (DIEP) flap cases as joint consultant cases.
- 1.6.26 Interviewees reported challenges in finding joint lists with plastic surgeons and theatre organisation was described as the biggest block. The review team were informed that, often, weekends had to be used to operate on a case as there was no dedicated space. There were calls for a smoother process for referral for reconstruction. Under the current system, referrals for patients who wanted immediate reconstruction had to be responded to with haste as the patient was often about to breach. This was said to put patients under pressure to decide whether they wanted an immediate or delayed reconstruction, and whether they wanted it to be implant-based. It then put clinicians under pressure to find an operation date. If immediate, issues were reported in aligning theatre availability with the breast and plastic surgeons.
- 1.6.27 The breast MDT did not have access to photography, although there was said to be a photography service available every day in both hospitals. Reconstructions took place in the absence of photographs.
- 1.6.28 It was reported that, up until the end of 2024, there had been a breast cancer reconstruction case once every 2 months. Since 2025 and the time of the review visit, there had been six cases. This was said to reflect that breast cancer clinics had been "hammering reconstruction" and that patients were being given the option of immediate reconstruction, which allegedly they were not given previously. There was a worry over how the service would cope with the "floodgates opening".
- 1.6.29 There was optimism that the new clinical lead and the two new oncoplastic surgeons joining the Trust would move things forward, including having a dedicated oncoplastic MDT. There were calls for a collaborative approach in terms of job plans and dedicated theatre lists.

Referral to other providers

- 1.6.30 Concerns regarding the duty of candour had led to changes in practice regarding reconstructive options. Since there had not been any oncoplastic surgeons on the team, patients were advised that reconstruction would involve internal referral to plastic surgeons. A patient information leaflet had been introduced specific to external referral for breast surgery and was to be given to patients at the one stop clinic when they had a biopsy. The leaflet stated: "Some surgical procedures are not available at County Durham and Darlington NHS Foundation Trust. These relate to some full or partial breast reconstructive options. If the team decide that you are eligible for any of the surgical procedures which are not offered at CDDFT, then you will be offered the opportunity to meet with the breast surgical team at one of our neighbouring hospitals to discuss your surgical treatment options".
- 1.6.31 The hospitals providing further breast surgical services included: Royal Victoria Infirmary, Newcastle upon Tyne; Queen Elizabeth Hospital, Gateshead; North Tees and Hartlepool NHS Trust, Stockton on Tees / Hartlepool. Patients were to sign the form indicating either that they wished to be referred for consideration of other surgical options, if appropriate, or that they did not wish to be referred and understood that this may limit the surgical options available to them.
- 1.6.32 The review team heard that patients offered a second opinion were "quite willing to have a second opinion from elsewhere". However, resistance to handing out the leaflet was also reported, on the grounds that it was "unnecessary" and not aligned with "best clinical practice". Some objection was made to the expected timing of handing the leaflet to patients at the one stop clinic; and that MDT discussion of the patient happened in "the presence of peers from nearby screening units" and there was a pathway for referring care to another trust.

Axillary clearance

- 1.6.33 The review team asked about surgical protocols for sentinel lymph node biopsy⁴¹. It was reported that there was an axillary clearance rate⁴² of 30%.
- 1.6.34 The approach taken to seeking consent was reported to be that if difficulties were encountered in locating the lymph glands, it may be necessary to undertake more dissection and remove more axillary nodes.
- 1.6.35 Discussion regarding the axilla was said to have been "a hot topic in MDT". The ATNEC trial⁴³ (comparing standard axillary treatment with no axillary treatment post-surgery in early-stage breast cancer patients) was active in patients going through DMH but not patients of UHND.

Day surgery

1.6.36 GIRFT (2024) observed that CDDFT needed to review day case rates for mastectomies.

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⁴¹ A sentinel lymph node biopsy (SLNB) is a way of checking the lymph nodes in the armpit for cancer cells. https://www.macmillan.org.uk/cancer-information-and-support/treatments-and-drugs/surgery-to-the-lymph-nodes-for-breast-cancer

⁴² Axillary clearance refers to surgery to remove most or all the lymph nodes in the armpit (axilla). https://www.cancerresearchuk.org/about-cancer/breast-cancer/treatment/surgery/remove-lymph-nodes https://associationofbreastsurgery.org.uk/professionals/research/trials/open-recruiting/atnec

- 1.6.37 In 2024, it was noted that all breast surgery patients at UHND were admitted to the elective ward. The reasons for this were said to be unclear but it was agreed to trial discharging patients on the same day. A pathway was created and was said to have worked "perfectly" for 3 months, until surgeons resumed booking patients back onto the ward for overnight stays.
- 1.6.38 At DMH, most breast surgery patients were day cases, even elderly patients. Only those patients with significant co-morbidities or complications stayed in.

Follow up and PIFU

- 1.6.39 GIRFT noted (2024) that different PIFU models were operating across the two sites. The model at UHND involved a virtual review and GIRFT considered it likely that these patients would appear in data as follow up patients. There was discussion about aligning the PIFU pathways across the two sites.
- 1.6.40 Some interviewees identified opportunities to reduce the number of routine follow ups through better implementation of PIFU. There was said to be an "enormous amount" of unnecessary follow up. Cancer patients were seen as a follow up to have their results and then were seen 6 monthly thereafter. In terms of fibroadenoma (noncancerous breast lumps), there was reported to be wide variation in follow up, with one clinic reported to follow up fibroadenoma for several years with rescanning. The review team heard: "There's a lot of follow up of everything, when there doesn't need to be".
- 1.6.41 At the time of the invited review, the arrangements for PIFU were very uneven and described as a "shallow PIFU system", lacking robustness. At UHND, the patients of one surgeon were on PIFU, but those of another were not. The eligibility criteria were reported to be "narrow". At DMH, resistance by one consultant to allowing the roll-out of PIFU was reported, however steps in this direction were being made. PIFU was one of the areas where clinical nurse specialists were said to have been held back in terms of skills development.
- 1.6.42 Patients requiring clinical attention outside follow up appointments could be seen by the breast team at DMH via same day emergency care (SDEC) services. Patients usually telephoned the clinical nurse specialists as the first port of call and would be brought to clinic if appropriate. There were no nurse led clinics or rooms to use. In UHND, patients would be brought to a structured clinic for review. There were said to be highly trained clinical nurse specialists at the SDEC at UHND who could undertake drainage of abscess, for example, but it was reported none of the surgeons would attend the SDEC. At DMH there was thought to be a good relationship with the SDEC.

A1.7 MDT decision making

1.7.1 A recurring theme was that the MDT was not functioning effectively as a single integrated MDT covering both DMH and UHND. Instead, two separate MDTs ran sequentially. The MDT was said to be functioning better than it had by the time of the invited review. This reflected feedback following the NCA peer review, which had led to a breast action plan. Actions for the MDT centred on technology – such as assessing sound quality and moving to MS Teams; actions around start times, chairing and support; and clinical quality – such as agreeing a standard order of documenting decisions, and optimising use of Somerset Cancer Register. There was an objective to standardise the way the MDT worked with other MDTs across the Trust.

- 1.7.2 Some actions had reinforced a divide between the North and South. Emphasis had been placed on external review strongly supporting having a joint MDT, however it was stated in the action plan that "due to current interpersonal relationships it may be in the interest of efficiency to keep the MDTs separate temporarily with the absolute aim of unifying the MDT as the only viable and collegial option in the medium and long term." Therefore, the action plan allowed for keeping the MDTs as they were currently run (mostly separate) but to ensure both the North and South remained logged on for the whole MDT to encourage and improve Trust wide engagement.
- 1.7.3 Changes were planned to the MDT in March 2025. Achieving change to date had been difficult, with resistance reported from some of the consultant surgeons. The review team heard the breast MDT had been "the most difficult MDT to transform because of personalities within the team", and that the Trust had been working to achieve a unified MDT for 14 years. There was said to have been some suspicion of the NCA review due to those involved coming from screening units. However, others voiced a clear objective for CDDFT's breast service to be subject to the same degree of scrutiny and peer review as in the screening units.

MDT structure, timing and processes

- 1.7.4 The breast MDT took place weekly on Wednesday afternoon. It was due to begin at 12:45, but delays getting started were reported to be a common occurrence. The meeting was said mostly to be 4 hours in length.
- 1.7.5 Cases were referred into the MDT by email or via tracking by the MDT coordinator. The breast MDT had been supported by several different MDT coordinators, with differing levels of experience. Frequent changes in administrative staff was said to be an issue, as was the reported ability of successive MDT coordinators to capture all the relevant details within the meeting, which could sometimes run at pace. It was commented that MDT coordinators needed additional training in medical terminology and how to record meeting outcomes. Simple things, such as the age of the patient, were said not to be readily available, and resistance was reported to having a template to record basic patient information. At the time of the review, an interim MDT coordinator, who also had experience of other MDTs, was covering in the absence of one breast MDT coordinator (band 4). A second breast MDT coordinator (also band 4) had been appointed and was undergoing training.
- 1.7.6 The breast MDT always began with the "South MDT", which tended to involve discussion of 20 to 30 cases, each, from the two consultant surgeons. The North MDT was due to begin at 14:00, however the South MDT usually finished between 14:00 and 14:30, according to interviewees. One of the consultant surgeons based at UHND was "only paid until 14:30" and left the meeting after presenting their own cases. The breast physician would present their cases, before finally the other consultant surgeon presented their cases (estimated to be at least three-quarters of the North caseload) with an associate specialist. On average 60 cases from UHND would be discussed.
- 1.7.7 In total, an average of 97 cases were reported to be discussed at the weekly breast MDT. It was estimated that a third were "bring backs" because they had not been ready for MDT discussion at the previous meeting. Pressure was reported to discuss cases even where colleagues had flagged that they were not ready. It was reported that the MDT discussed the same patients "over and over again while awaiting HER2 [results]". It was said that sometimes radiology had not prepared the report on a case. The review team heard that at one MDT meeting, 12 patients in the North and six in the South were not ready for discussion. Other opportunities to streamline the caseload included

- "removing inadequate cytology from the system". GIRFT considered there was opportunity to streamline the MDT to allow for discussion of oncoplastic cases.
- 1.7.8 In the South, there was said to be a rigid structure of seeing the patient in clinic on a Tuesday, biopsy results were discussed at the MDT on a Wednesday, and then the surgeons would come back to the patient with a plan on Thursday.
- 1.7.9 The size of the MDT caseload was highlighted as an issue by several respondents. It was said to pose challenges in terms of maintaining concentration over such a large number of cases. IT difficulties could slow the process down. It was said that "IT can be awful", with radiology unable to display images on more than one occasion.
- 1.7.10 The caseload was exacerbated by extra clinics at weekends, which was said to create huge numbers of patients to discuss. The documentation from the insourced clinics was reported to be standard and in keeping with routine NHS clinics. For NHS patients seen in the Spire Washington Hospital, information was said to be pushed through to the Trust the next day, with radiology reports faxed and then scanned on to the CDDFT system. In practice, it was reported it could take days for the Trust to get hold of images taken at the Spire. Image transfer was only done for those cases discussed in the breast MDT.
- 1.7.11 It was remarked that it was not clear at the MDT whether a patient seen at the Spire Washington Hospital was an NHS or private patient.

Preparation

- 1.7.12 The cut off time for cases to be added to the MDT case list was Tuesday lunchtime for UHND and 16:00 for DMH, due to a clinic held on Tuesday afternoon. The MDT coordinator sent a provisional list to both teams on Monday at 16:00, with additions added on Tuesday.
- 1.7.13 The breast pathologists received the MDT list on Tuesday afternoon, sometimes Wednesday morning. They had a points-based system, which allowed 4 hours preparation time usually 2.5 hours preparation and 1.5 hours in the meeting. This was described as "just enough for a normal MDT", but not if the MDT was very busy, as the breast MDT often was.
- 1.7.14 GIRFT observed (2024) that the teams involved (surgery/radiology/pathology) should have time in their job plans to allow for MDT preparation.

MDT chairing and leadership

- 1.7.15 The North and South MDTs were led by the surgeons. There was no overarching MDT lead.
- 1.7.16 The South MDT was led by the only substantive consultant surgeon, who had stepped back from the MDT at the time of the invited review. This part of the meeting was said to have been chaired efficiently and was well structured, however there had been complaints of a lack of tolerance of the MDT coordinator if they could not keep up or made mistakes. A locum surgeon at DMH had stepped in to lead discussion of cases in the South MDT. This surgeon was said to be managing this well although they were thought to be carrying a lot of responsibility, given they were not a substantive consultant surgeon and still required support and some additional training.

- 1.7.17 It was said to be harder to identify a lead for the North MDT, as one consultant surgeon, followed by the breast physician, and another consultant surgeon, presented their cases in succession. These arrangements were thought to reflect relationships between the surgical team.
- 1.7.18 Since June 2024, the external clinical lead had been attending the MDT, and another colleague involved in the NCA peer review dialled into the MDT when they could.
- 1.7.19 Aspirations were voiced to have a single MDT lead who would run the meeting as a combined process, so that radiology and surgery could be discussed together, with all core members participating.

Teamworking and clinical decision making

- 1.7.20 Some tension was said to have been observed in the breast MDT meeting, but no behaviours that "crossed the threshold". "MDT etiquette" was described as improved; whereas previously it was said there used to be several conversations happening in the room, this was no longer the case. Recurring feedback was that the meeting was "disjointed" and split between the North and South, with no discussion happening across the two teams. The North and South MDTs were said to "run almost independently".
- 1.7.21 A good working relationship was repeatedly referred to between the consultant surgeon and locum consultant surgeon in the South, together with good working relationships with the oncologists supporting the South MDT.
- 1.7.22 In the North MDT, the first consultant surgeon left after presenting their cases and if the other consultant surgeon (with at least two-thirds of cases) was not present, the Associate Specialist would present them alone. Having the external clinical lead and colleague participate in the meeting had helped to provide for surgical discussion. The North MDT team also comprised of the breast physician, breast care nurses, one radiologist and one pathologist. One oncologist was present in the room and one dialled in remotely.
- 1.7.23 Two plastic surgeons participated in the MDT one for the North and one for the South. No attempts were reported to separate off patients who might be suitable for discussion involving the plastic surgeons.
- 1.7.24 There was a sense that MDT decision making was led by the breast surgeons, who told the MDT what they were planning to do, and other attendees were expected to watch. Mostly the MDT "goes along with the plan", it was said. It was suggested that comorbidities were not discussed.
- 1.7.25 There were differing accounts over the input oncologists provided into discussion, who were variously reported: "not to say an awful lot"; to "speak out" and suggest a different route for treatment; and, to be "quite old fashioned and powerful and vocal". Some discomfort was expressed that participants could not always see the oncologists on screen "half the time".
- 1.7.26 A new radiologist aligned with the South MDT was reported to "speak out", while others were described as less challenging. Breast care nurses were reported to say little and felt constrained in speaking out. It was reported that MDT coordinators had felt scared and unsupported in some meetings. The review team heard that "MDT coordinators are not respected enough even to have an opinion".

1.7.27 GIRFT observed that the breast MDT rarely had research nurse support and recruitment into breast trials was "extremely low" given the Trust's size.

Recording MDT outcomes

- 1.7.28 MDT decisions were recorded by the MDT coordinator and displayed on a large screen in the MDT meeting room. Those dialling in to the meeting could see the outcome screen if they dialled into a second meeting. Oncologists and radiologists could see all screens.
- 1.7.29 Generally, participants checked that outcomes were recorded accurately; no one person carried responsibility for checking this. Sometimes a hurry to move on to the next patient was reported and it would fall to the MDT coordinator to ask the meeting to slow down.
- 1.7.30 Some criticisms were made of the Somerset Cancer Register software, which was said to be "not appropriate" for the task of recording MDT decisions. There was a view that a drop-down list would help, and support audit of outcomes, such as trying to understand rates of reconstruction following mastectomy.
- 1.7.31 Some weaknesses were highlighted with documentation post the MDT, in terms of reported failures to document the reasons why an MDT decision was not followed through and documenting the patient's agreement with this.
- 1.7.32 Waits between initial operations and further treatment to the margins were highlighted as an issue in the North.

A1.8 Clinical governance

- 1.8.1 There were no specific clinical governance arrangements for the breast team.
- 1.8.2 Clinical governance of the breast surgical service had been part of general surgery governance. The general surgery governance meetings took place six times per year on a bi-monthly basis. All elective activity was cancelled to facilitate attendance at these meetings. Examples of the minutes from these meetings were shared with the review team. Specialty governance fed into Care Group Governance meetings, with items escalated and disseminated as appropriate. Minutes from the specialty governance meetings were shared with the review team within the Care Group Governance papers.
- 1.8.3 The review team were provided with the Trust's mortality review form. Breast cases were discussed as part of wider general surgery morbidity and mortality (M&M) meetings.
- 1.8.4 There were reported to be plans to develop specific breast surgery clinical governance, as much of the general surgery governance was not relevant to breast surgery. The most recent governance meeting was said to featured two items relevant to the breast team (including figures around day surgery management of mastectomy) but this was reported to be unusual. It was said to be a large meeting and some interviewees believed they would feel more comfortable in a smaller meeting focused specifically on breast services. Attendance by the breast team at the general surgery governance meeting was unclear.
- 1.8.5 The new clinical lead for the breast service had introduced monthly meetings for the breast service, although these were described as 'business meetings'.

- 1.8.6 Breast radiology came under the governance arrangements for general radiology.

 Likewise, breast pathology governance fell under wider pathology governance arrangements. Clinical governance was said to work well within the plastic surgery unit, which was in a different directorate.
- 1.8.7 There was an acknowledgement that the surgical team had been "absolutely swamped" and this was thought to have stifled their ability to engage in improvement work. There was a sense that service pressures had impacted the ability of some to maintain their continuing professional development. Trust policy was said to limit attendance at meetings, such as the Association of Breast Surgery annual meeting, to one surgeon at a time, which meant that surgeons could only attend this meeting once every four years. No issues were reported in attending local meetings.

Incidents and risk

- 1.8.8 There had been no major harm incidents reported. One moderate harm incident in the previous 2 years was declared in the service review document, however this turned out to be a thyroid patient so was therefore outside the parameters of this review (the incident was coded to the surgeon who conducted both breast and thyroid procedures).
- 1.8.9 The main themes arising from incidents categorised as minor or no harm were: delays in treatment >104 day cancer breaches (root causes analysis took place for each patient to understand the cause of delays and lessons learned); and issues with pathology samples (patient demographics).
- 1.8.10 There were two risks on the Care Group risk register specific to the breast service. First, that breast patients would not be seen within the 2-week standard (linked to capacity issues), and second, lack of radiology cover during annual leave / sickness (associated with minimal radiology workforce, which meant a lack of radiology cover during times of absence).

Complaints

4 0 44 4

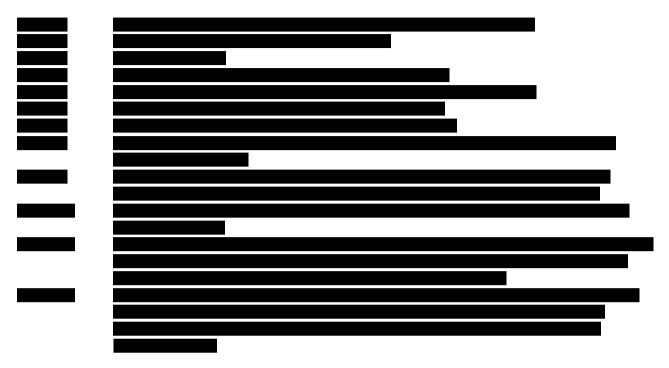
1.8.11 The breast service distinguished between informal complaints, which were managed informally, and formal complaints. Details of 18 informal complaints were shared with the review team and covered the following issues:

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1.8.11.1	Communication and information sharing with patients (x 4)
1.8.11.2	Delay in diagnosis and treatment (x 4)
1.8.11.3	Attitude of medical staff (x 3)
1.8.11.4	Other clinical treatment / procedure issues (x 2)
1.8.11.5	Appointment issues (x 2)
1.8.11.6	Consent issues (x 1)
1.8.11.7	Documentation issues (x 1)
1.8.11.8	Patient's privacy and dignity (x 1)

1.8.12 There had been 11 formal complaints about the breast service in the previous 2 years. The main trends reported in a document shared with the review team by the Trust were: lack of communication, incorrect diagnosis, and a different procedure carried out than expected. Interviewees added further detail to these headings, stating that some complainants had felt rushed, with limited time to ask questions, and that their dignity had not always been maintained.

1.8.13 Details of 12 complaints were shared with the review team (as part of a zip file), two of which appeared to be general surgery complaints relating to thyroid surgery. These were described as follows:



- 1.8.14 The breast service was described as "not a high complaint service" and it was reported that complaints were quickly resolved.
- 1.8.15 The speed of consultations in the outsourcing and insourcing clinic was said to be reflected in negative feedback from patients in the national cancer survey (as highlighted in section A1.5.9). Some interviewees said this feedback had not shown in monthly quality assurance of complaints and remarked that there were very few formal complaints about the outsourcing and insourcing clinics. It was unclear whether, or how, a complaint from an NHS patient seen at the Spire Washington Hospital came back into the Trust's governance system.

Appendix C – Service overview information

Prior to the review visit the healthcare organisation was asked to complete the following 'service overview form'. The information presented below is what was provided.

Information request	Number	Additional notes		
Local information				
Catchment population	650,000	Large geographical location		
Sites providing specialty service	3	University Hospital of North Durham (UHND)		
		Darlington Memorial Hospital (DMH)		
		Bishop Auckland Hospital (BAH)		
Personnel numbers				
Consultant Surgeons within	5	(Substantive)		
specialty service		(Substantive)		
		(Substantive)		
		(Trust Locum)		
		(TrustLocum)		
Surgeons within wider team	0	N/A		
Surgical registrar posts	1	1 Dedicated Trust Doctor for Breast Service		
Junior doctors supporting the	0	There are currently no juniors supporting the Breast		
service		Service		
Details of on-call				
Consultant surgeon on-call	N/A	No breast service on call – out of hours issues picked		
		up by general surgery on call team		
Surgical registrar on-call	N/A	No breast service on call – out of hours issues picked		
		up by general surgery on call team		
Facilities				
Service dedicated ward beds	N/A	No dedicated ward. Breast patients are managed via		
		trust elective beds and day surgery unit		
ICU beds	21	10 at UHND, 11 at DMH for all services		
HDU beds	N/A	Included in IT numbers as managed interchangeably		
		as ITU /HDU beds depending on staffing ratios		
Theatres used by the service	1 per site	Theatres at UHND and DMH as part of whole		
		Theatre complex		

Inpatient elective lists per week	8-10	Approx 8-10 breast half-day theatre sessions per
		week (4-5 all-day lists) depending on annual leave

Day case elective lists per week	N/A	Breast IP and DC lists are combined and included in			
		numbers above			
Emergency lists per week	24/7	24/7 emergency list available at UHND and DMH but			
		used by all specialties			
New patient clinics per week	18	Breast clinics have a mix of new and review patients			
Follow up clinics per week	N/A	Included above as breast clinics have a mix of new			
		and review patients			
Activity numbers per year for the past two years					
Outpatients seen	26,833	1 st December 22 to 30 th November 24			
Acute admissions	138*	1 st November 22 to 31 st October 24			
		NOTE: The Acute Admissions numbers are Emergency Admissions with a breast related HRG, however the vast majority of these are presentations through Surgical SDEC			
Elective admissions	1,111	1 st November 22 to 31 st October 24			
Number of patients undergoing	304	1st November 22 to 31st October 24			
surgery – specify total and	Elective				
number of emergency, inpatient	Inpatients,				
and day case procedures	807 Day				
	cases				
18 week breaches	39	Current DTI Spanshot (16.12.24)			
		Current PTL Snapshot (16.12.24)			
Patients on elective waiting list	508	Current PTL Snapshot (16.12.24)			
	(admitted				
	and non-				
	admitted)				
Clinical governance arrangen	nent for the	•			
MDT meeting frequency	Weekly	Wednesday PM			
Time scheduled for MDTs	12:45 – 15:45	Average of 92 cases discussed (over last 12 weeks)			
Average consultant surgeon	83.3%	Range 70-94%			
MDT attendance (%)	00.076	Tango 10 5470			
	Monthly	Those are run as Coneral Surgery MANA meetings			
M&M meeting frequency	Monthly	These are run as General Surgery M&M meetings			
		split by the two main sites and include breast cases			
		as appropriate (numbers are low)			

Time scheduled for M&M	1 hour	Meeting is for all General Surgery cases, breast case		
		numbers are low		
Average consultant surgeon	Variable	Breast surgeons attend every M&M meeting (if not on		
M&M attendance (%)		leave) in the South. Attendance is lower in the North		
		and tends to be only when there are breast cases to		
		discuss		
Number of audit days last year	6	Clinical activity is cancelled for audit / clinical		
		governance days		
Time scheduled for audit days	3hrs	Half days (as part of General Surgery)		
Other regular governance	Bi-monthly G	General Surgery Business Meeting (breast included in		
meetings	these meetings			
	Monthly breast business meetings (introduced in November 24)			
National databases submitted to	tional databases submitted to COSD submission to the National Disease Registration			
	and this feeds into the two national breast audits coordinated by the			
	National Cancer Audit Collaborating Centre(NATCAN)			
	Cancer Waiting Times submission			
Complaints, incident reporting and SUIs in the last two years				
Number of incidents		21 – No Harm		
		23 – Minor Harm		
		1 – Moderate Harm		
		1 – Near Miss		
Number of SUIs	0	N/A		
Number of patient complaints	11	Formal		
		Quick Resolution		
Number of never events	0	N/A		

Appendix D – Documents received during the review

The following items of documentation were provided to the review team before, during or after the review visit. It is requested that the healthcare organisation responsible for commissioning the review retains a copy of all items of documentation for its own records, and to be in a position to make it available on request and to comply with information access requests. Once the RCS England issues the report, it will not keep a copy of this information indefinitely.

- CDDFT Service Overview Form
- Clinical Record Review Log
- Darlington Memorial Hospital site map
- Governance meetings
- Mortality review form
- Clinical governance meeting minutes 30 January 2024
- Incidents, complaints and risks
- GIRFT Breast Surgery County Durham and Darlington NHSFT data pack, 10/12/24
- GIRFT Breast Surgery County Durham and Darlington NHSFT observation notes, 10/12/24
- CDDFT Breast Surgery Peer Review NCA 2024
- Breast Action Plan January Update
- Report on consideration of Breast Surgery Services and Duty of Candour
- Breast zip file containing breast complaints overview of 12 cases and 11 password protected files (the review team could not access these files)
- External referral for breast surgery patient information leaflet

Appendix E – List of interviewees

The following individuals were interviewed as part of this invited review. The RCS England provided guidance on who it considered relevant to the <u>Terms of Reference</u> and the individuals listed were selected by the healthcare organisation that commissioned this review.

