

Health Economic Evaluation of Community Breast Pain Clinics

07/10/2024



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Acknowledgements

Like most clinical service developments, many people have contributed over a long period of time.

The implementation of the EMBPP, including the national evaluation and report, has been facilitated through a collaborative agreement between Roche Products Limited and HITS (Health Improvement Transformation Strategies), a Community Interest Company: it has allowed the implementation to be rolled out at pace and scale and we have benefited from their experience in improving healthcare. Without the support of Roche, the implementation of this transformation pathway would have happened, but without question at a slower pace. We are therefore grateful to Roche for its support and the impetus it brought to the implementation programme.

The authors would also like to acknowledge and thank Joined Up Care Derbyshire (JUCD) which supported the first population-based Community Breast Pain Clinics across Derbyshire and the pilot team across primary and secondary care, both clinicians and managers, who made this a successful implementation.

The authors also acknowledge that the implementation of the EMBPP, both across East Midlands and subsequently nationally, would not have happened across the wide geographical area and number of Cancer Alliances in England without the support and input of East Midlands Cancer Alliance (EMCA). We are particularly grateful to Mr Michael Ryan, Head of Service, EMCA, for his continued support without which the project would not have had the breadth of uptake across the East Midlands and other Cancer Alliances.

The East Midlands Academic Health Science Network (now known as Health Innovation East Midlands) supported the project at its very early inception in 2015 and then again for an East Midlands audit which in turn provided support for the expansion of the audit and evaluation across multiple Cancer Alliances.

We thank the members of both the Steering Committee and the Operational Committee for this 'national' audit. The names of each are shown in **Appendix 1(a) & 1(b)** respectively. Each of the Cancer Alliances had representatives on both committees and we are grateful to them all for giving their time not only for the committee meetings, but when necessary, supporting the project practically to ensure it was successful. We had representation from the Association of Breast Surgery (ABS) on both Committees: the Steering Committee through the President, Miss Leena Chagla and Vice President, Miss Sarah Downey, and on the Operational Committee through Miss Carol-Ann Courtney, who is the East Midlands ABS Representative and a member of the Clinical Practice and Standards Committee leading on breast pain pathway implementation. We are grateful to them for their support and guidance throughout the national phase of evaluation of the EMBPP reported here.

Acknowledgements

We thank the Primary Care Stratified Medicine Research Group (PRISM) at the University of Nottingham, and in particular Professor Nadeem Qureshi, for their provision of the family history questionnaire (FHQ).

We thank FaHRAS for their role in promoting EM pathway transformation and support of the service implementation.

We are grateful to patients who allowed their data to be used for the improvement of the NHS clinical care as shown in this audit and who also participated in the anonymous PROMs questionnaire.

East Midlands Breast Pain Pathway Implementation Team

Professor John Robertson,

Professor of Surgery & Consultant Breast Surgeon, University Hospitals of Derby & Burton NHS Foundation Trust.

Email: john.robertson17@nhs.net

Mr Mark Sibbering

Consultant Breast Surgeon,

Royal Derby Hospital,

University Hospitals of Derby & Burton NHS Foundation Trust.

Email: mark.sibbering@nhs.net

Dr Thilan Bartholomeuz

GP and Clinical Lead, Mid Nottinghamshire Place Based Partnership

Email: thilan.bartholomeuz@nhs.net

Mrs Veronica Rogers

Advanced Nurse Practitioner

Derby

Mr Kevin Clifton

Cancer Project Manager and Pathway Lead

Chesterfield Royal Hospital NHS Foundation Trust

Email: kevin.cliftonl@nhs.net

Breast Pain Clinic Acronyms

Cancer Alliance	Centre(s)	Acronym	Cohort
Cheshire &	Countess of Chester	CoCH	В
Merseyside	Hospital NHS		
	Foundation Trust		
	Mersey and West	STHK	Α
	Lancashire Teaching		
	Hospitals NHS Trust		
East Midlands	Kettering General	KGH	Α
	Hospital NHS		
	Foundation Trust		
	Leicester, Leicestershire	LLR PCL	Α
	and Rutland Patient		
	Care Locally		
	Nottingham University	NUH	Α
	Hospitals NHS Trust		
	University Hospitals of	UHDB/CRHFT	Α
	Derby and Burton NHS		
	Foundation Trust/		
	Chesterfield Royal		
	Hospital NHS		
	Foundation Trust		
	(Derbyshire)		
	United Lincolnshire	ULH	Α
	Hospitals NHS Trust		
East of England	East Suffolk and North	ESNEFT	Α
(North)	Essex Foundation Trust		
	North West Anglia	NWA	Α
	NHS Foundation Trust		
East of England	East and North	ENH	Α
(South)	Hertfordshire NHS		
	Trust		
Humber and North	Northern Lincolnshire	NLAG	Α
Yorkshire	and Goole Hospitals		
	NHS Foundation Trust		
	York and Scarborough	YSTH	Α
	Teaching Hospitals		
	NHS Foundation Trust		
LSCCA (Lancashire	East Lancashire	ELHT	Α
and South Cumbria)	Hospitals NHS Trust		
North Central	Royal Free London	RFL	В
London	NHS Foundation Trust		

South Yorkshire	Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trusts (Doncaster)	DBTH	A
	Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trusts (Bassetlaw)	DBTH (Bassetlaw)	В
West Midlands	University Hospitals of Derby and Burton NHS Foundation Trust (South Staffordshire)	UHDB (S. Staffs.)	А

Glossary of Terms

2WW - Two Week Wait

ABS – Association of Breast Surgery

ANP – Advanced Nurse Practitioner

BCDC - Breast Cancer Diagnostic Clinic

CBPC - Community Breast Pain Clinic

DCIS – Ductal Carcinoma In-Situ

EM – East Midlands

EMAHSN – East Midlands Academic Health Science Network

EMCA – East Midlands Cancer Alliance

EMBPP – East Midlands Breast Pain Pathway

FDP - Faster Diagnostic Pathway

GIRFT – Getting It Right First Time

GPSI – GP with a Special Interest

JUCD – Joined Up Care Derbyshire

NHSE – National Health Service England

NHSBSP - National Health Service Breast Screening Programme

NICE - National Institute of Health and Care Excellence

OSC – One Stop Clinic

PROMs – Patient Reported Outcome Measures

RCR – Royal College of Radiologists

SOP – Standard Operating Procedure

1 Executive summary

Breast pain (mastalgia) as a standalone symptom is no longer regarded as having an association with breast cancer. However, this presentation within primary care often still results in an urgent referral into a Breast Cancer Diagnostic Clinic (BCDC) (previously a 2-week-wait (2WW) breast cancer pathway), even though most patients presenting with breast pain alone continue to be managed successfully in primary care. Such referrals not only add burden to BCDCs, but also cause unnecessary patient anxiety and diagnostic tests for these patients.

The East Midlands Breast Pain Pathway (EMBPP) is a novel service, and first in the UK, tackling the rising number of BCDC referrals. These new, community-based clinics aim to improve patient care and experience while simultaneously providing a system-wide improvement. To determine whether the clinics can be adopted at further sites, this evaluation uses quantitative analysis of Community Breast Pain Clinic (CBPC) data, Patient Reported Outcome Measures (PROMs) and cost data to assess the impact on patients and care pathways within seventeen centres in nine cancer alliances across England and compares it to the standard of care.

Patient experience

This service delivery transformation has been incredibly well-received by patients with breast pain only, with 98.7% of patients suggesting they would recommend the service to friends and family, among numerous other positive quantitative and qualitative PROMs. This is particularly important when staff reporting of patients' experience when attending appointments at a BCDC in a hospital setting is fairly unanimous that it often causes anxiety.

Cost-saving

There is also evidence that these community clinics have generated a financial return. Across all sites in Year 1 of the clinics, the healthcare system received back £1.26 for every £1 they invested in the CBPC. This rises to £1.40 in Year 2.

Patient safety

A key feature of the EMBPP has been to ensure that the population of women with breast pain only who are seen in these community clinics have a low incidence of breast cancer. This has been achieved through excluding women with a previous personal breast cancer history which, unrelated to breast pain, puts them at a higher risk of developing a second breast cancer and, for this reason, these patients are referred directly to the BCDC. The EMBPP also assesses future risk of breast cancer by carrying out a familial breast cancer risk assessment based on National Institute of Health and Care Excellence Clinical Guidance 164 (NICE CG164); this identifies patients at potentially increased risk who may be referred to the local familial cancer services, while at the same time providing reassurance to the remainder of patients at population/'near population' risk.

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For the EMBPP to be accepted as a new service delivery model option nationally it must also provide evidence supporting its safety across a wide geographical area. Accepting that no healthcare pathway for a symptom not associated with breast cancer will be 100% accurate in detecting incidental cases of breast cancer, it is important to confirm prospectively that i) the incidence of breast cancer in patients with breast pain only is low, ii) that even in a low risk population the pathway results in identifying the vast majority of even incidental breast cancers and iii) patients at future increased risk of breast cancer are identified and guided to appropriate screening programmes.

The total number of patients seen in CBPCs in Cohort A was 7,205. 24 patients were diagnosed with breast cancer within 12-months of their CBPC appointment, but not all patients had completed a full 12 months follow up period. In addition, 4 of these patients were ineligible for the CBPC due to the specified exclusion criteria. For all patients in Cohort A, the incidence of breast cancer was 3.3 per 1,000 (95% Confidence Interval: 2.2-5.0 per 1,000). When excluding ineligible patients, this incidence rate drops to 2.8 per 1,000 (CI: 1.8-4.3 per 1,000).

3,819 patients had a full 12-month follow-up period after their CBPC appointment, with 17 cancer diagnoses during that time period and 3 of those patients were ineligible for the CBPC due to the specified exclusion criteria. For the patients with a full 12-month follow-up period, the incidence of breast cancer was 4.5 per 1,000 (CI: 2.8-7.1 per 1,000). When excluding ineligible patients from this cohort, the incidence rate drops to 3.7 per 1,000 (CI: 2.2-6.2 per 1,000). As predicted from the literature, the incidence of breast cancer in the population of patients eligible for the CBPC is low (Jahan et al., 2022).

Data on all twenty-four patients with a breast cancer diagnosis indicates no evidence of delays to care or any cases of breast cancer missed through this new referral route. For the 13 patients with a direct referral from the CBPC, the mean follow-up time between their CBPC appointment and their breast cancer diagnosis was 24 days.

Family History

6903 patients completed a familial risk assessment appropriate for primary care (ie NICE Clinical Guidance 164). Of these, 12.2% were assessed as being at potentially above population risk. This offers the opportunity to refer these women to specialist familial cancer services for further advice and management, where if appropriate they can be enrolled in an imaging surveillance programme so that subsequent cancer diagnoses may be made at an earlier stage. This addresses 'unmet need' which fits with the NHS Long Term Plan (2019) "to strengthen its contribution to prevention and health inequalities" through improving "uptake of screening and early cancer diagnosis for people who currently miss out".

The 87.8% that were assessed as at population / 'near population' risk can be reassured that they do not need further follow up and can be managed in primary care. 19.4% of the women in this group had one or more members of their family with a history of breast cancer that did not

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significantly raise their personal breast cancer risk but may have caused anxiety and led to their presentation with breast pain symptoms.

While 31.6% (i.e. 12.2% + 19.4%) had one or more members of their family with a history of breast cancer, 96.6% of patients (i.e., three times more) found the breast cancer risk assessment helpful. This is likely to reflect other causes for patients' concern about their future breast cancer risk (eg non-blood related relatives or friends diagnosed with breast cancer or concern due to social media/news stories relating to breast cancer). In addition to identifying current 'unmet need' of patients at increased risk, the reassurance to those not at risk is likely to be one reason for the very low return rate to CBPCs or a subsequent referral by primary care to a BCDC.

Therefore, overall, the clinics offer significant benefits in terms of patient experience, financial return and no safety concerns have been raised.

East Midlands Breast Pain Pathway Website Resources

As a result of this work, website resources housed on the East Midlands Cancer Alliance website have been created that provide information for patients, the public and health care professionals about breast pain. This can be accessed using the following link:

East Midlands Breast Pain Pathway - East Midlands Cancer Alliance

The website provides information about breast pain and its management, as well as a detailed description of the EMBPP and the results of pathway implementation to date.

A Toolkit for health care professionals interested in implementing the EMBPP as part of their service is currently being finalised. This will include multiple resources developed by services that already use the pathway to assist those wishing to follow. This will be launched in November 2024 in a password protected area of this website. Access to the health care professionals area of the website will require completion of a <u>registration form</u> using an NHS or ac.uk email address and those registered will be advised when the Toolkit is available for use.

2 Introduction

2.1 Overview of Breast Pain Services

At least up to 70% of women over the age of 16 experience breast pain at some stage of their lives, and in 10 to 20% of cases, it is severe (Kataria et al., 2014; Cook et al., 2020).

The challenge with a presentation of breast pain within primary care is it can lead to an urgent referral to BCDCs (previously a 2WW breast cancer pathway referral). This leads to patient anxiety, often exacerbated by further investigations once seen in secondary care. It also adds additional pressure on these constrained urgent cancer pathways.

As a result of multiple publications, breast pain as the only symptom is no longer regarded as having an association with breast cancer (Jahan et al., 2022). In 2021, NHSE stated "Based on NG12, in the absence of associated red flag symptoms, ie lump or skin changes, breast pain alone is not a symptom of cancer and should not be automatically referred on an urgent cancer pathway." (NHS Publications approval reference: 001559). In 2024 NHSE has also provided guidance that "breast pain as a sole symptom is rarely a presenting feature of breast cancer, occurring in approximately 70% of women. It is not a sign of cancer but can take many months to resolve. In the presence of a normal examination patients can be reassured and may not need imaging" (NHS England, 2024). Despite the literature and NHSE guidance, patients are still frequently referred onto breast care pathways (Cook, et al., 2020), causing more demand for an already stretched service.

Therefore, patients are referred down pathways that lead to unnecessary anxiety, investigations and ultimately add pressure to BCDCs that are already running under significant pressure.

The optimisation of these cancer pathways has become increasingly important, not only due to the already highly demanded services, but also with the introduction of the Faster Diagnosis Standard, a new NHS England standard which measures performance on three metrics: The 28-day Faster Diagnosis Standard (75%), a 62-day referral to treatment standard (85%) and a 31-day decision to treat to treatment standard (96%) (NHS England, 2023). It is becoming increasingly important to decongest these pathways and move breast pain only patients out of suspected cancer referral pathways. Recent NHS England (2024) Breast Cancer Faster Diagnostic Pathway guidance recommends the evaluation and establishment of "new pathways for management of patients with symptoms of breast pain" to reduce congestion in the diagnostic clinics.

2.1.1 Key challenges of current referral patterns for breast pain

Given that previous publications indicate breast pain as the only symptom has no association with breast cancer, it is important that referral patterns for patients with breast pain only are evaluated

and optimised. Currently, non-optimised pathways are causing significant challenges to the system, including overutilisation of health care services (Kushwaha et al, 2018).

Increased demand for urgent Breast Cancer Diagnostic Clinics

Nationally, there is an increasing pressure on BCDCs. Many Trusts are having to set up additional clinics, often out-of-hours, to manage the additional demand. Women with breast pain only are one of the drivers of this increased pressure, with up to 41% of attendees at these 'one-stop-clinics' being women presenting with breast pain as their only symptom (Association of Breast Surgery, 2022).

Increased tests, including ultrasounds and mammograms

With each BCDC appointment there is a chance that investigations are done to gain further information on the patient's symptoms and rule out cancer. Equally referral to a secondary care BCDC raises expectation among patients that such investigations are necessary for their complaint. Furthermore, this expectation may be increased if the GP says to the patient that they are referring them for tests or specifically a mammogram or ultrasound. This growing demand for diagnostic tests within the urgent BCDC pathway, is of significant concern particularly for patients with breast pain only. The British Society of Breast Radiology (2023) has recently issued a statement "Breast pain is not an indication for breast imaging and therefore patients presenting with breast pain (general or focal) ONLY should not be offered imaging."

Significantly, there are major staff shortages within the breast imaging profession, with the UK now suffering a 29% shortfall of clinical radiologists, which will rise to 40% in five years without action (RCR, 2022). As a result, many breast services are struggling to continue to support rising demand for tests.

Alongside staff shortages, diagnostic capacity in the NHS in England had been reported to be much lower than that in many other developed countries prior to the COVID-19 pandemic. The relative lack of diagnostic equipment and workforce is now hampering recovery from the pandemic, though there is a push to establish community diagnostics hubs nationally (Richards et al., 2022).

2.2 Research and Evidence on the Benefits of CBPCs

It has been established that there is no association between breast pain as the only symptom and breast cancer and this is a common presentation which is usually managed in primary care. Yet when a patient presenting to a GP with breast pain only needs to be referred to secondary care, it is usually to a BCDC.

This leads to unnecessary anxiety for the patient, further heightened by sitting in clinical areas with patients who do have 'red flag' symptoms and then further exacerbated when the clinician requests mammograms and/or ultrasound scans. It also leads to added pressure on urgent breast

cancer diagnostic pathways, leading to delays and pressure on staff and in the most severe cases, delays to breast cancer diagnosis and care in other patients.

This is where the EMBPP could deliver significant benefits to patients, staff and the health system.

Through implementation of CBPCs there is the hope that a significant proportion of the pressures on the BCDC referral pathway could be alleviated and patients with breast pain only could have better experiences with their care. Existing research has identified the following benefits of community-based breast pain care:

- Improved care of patients with breast pain only
- Reduction in demand for urgent BCDC referrals
- Reduction in unnecessary diagnostic tests, including mammograms and ultrasounds
- Increased awareness of familial risk of breast cancer with objective risk assessment

The rest of this section reviews the available literature in more detail.

2.2.1 Absence of a causal relationship between breast pain and breast cancer

The literature detailing the absence of a causal relationship between breast pain and breast cancer is outlined in **Table 1**.

Table 1. Reports of patients presenting with breast pain only (Jahan et al., 2022)

A .1	v			Bilat/Unilat	Cancers	Cancers/1000	Known	FU ()		FH
Authors	Year	n	Age	(%)	(n)	pts	concordant	(months)	Bxs	(%)
Duijm et al (NED)	1998	987	10-86	24/76	8 (0.8%)	8	4 vs 4	48	-	N/A
Barton et al (US-MA)	1999	169	40-69	N/A	2 (1.2%)	12	N/A	-	-	18
Leung et al (US-MA)	2005	99	23-77	Focal	0	0	N/A	29	2	32
Masroor et al (PAK)	2009	55	34-63	Focal	0	0	0	18	4	N/A
Howard et al (US-MA)	2012	916	-	60/40	6 (0.6%)	6	3 vs 3	12	65	21
Leddy et al (US-SC)	2013	257	12-85	Focal	3 (1.2%)	12	3 vs 0	12	21	15
Noroozian et al (US- MI)	2015	617	23-88	19/81	2 (0.3%)	3	1 vs 1	24	28	15
Arslan et al (TKY)	2016	789	16-74	60/40	1 (0.2%)	2	N/A	-	-	N/A
Cho et al (US-NC)	2017	413	23-86	Focal	0	0	0	24	51	-

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Chetien et al (US-PA)	2017	236	18-83	N/A	1 (0.4%)	4	N/A	-	2	-
Kushwaha et al (US- TX)	2018	799	13-92	26/71	1 (0.12%)	1	0 vs 1	24	17	38
Fonseca et al.	2019	795	16-92	N/A	5 (0.6%)	6	N/A	N/A	31	17
UHDB (UK)	2020	125	17-83	N/A	0	0	0	N/A	N/A	26
Total	-	6256	-	-	29 (0.46%)	4.6	11/20	-	-	-
Post 2000	-	5100	-	-	19 (0.37%)	3.7	7/12	-	-	-

Bilat, bilateral; Bxs, biopsies; FH, % patients with family history; FU, follow-up; UHDB, University Hospitals Derby and Burton; Unilat, unilateral.

These studies indicate that across all studies the incidence rate of cancers in this cohort of patients is 4.6 per 1,000 patients. This lowers to 3.7 per 1,000 patients when looking at all studies post 2000 (Jahan et al., 2022). When two additional studies are included (Owen et al 2019, Dave et al 2022) the figures for incidence rate of cancers are 4.9 per thousand and 4.4 per thousand for all studies included and when looking at all studies post 2000 respectively (Robertson, personal communication)

Therefore, the available literature shows the chance of a patient having breast cancer is very low when presenting with breast pain alone. These rates are well below the level recommended for population-based screening in the NHS. Further, the literature finds that even for the cancers detected, approximately 50% were not related to the patient's symptoms in that the cancer diagnosed was in the contralateral breast to that the patient complained of pain in (Jahan et al., 2022). In the more recent publications by Owen et al and Dave et al noted above, pain and cancer were also ipsilateral concordant in around only 50% of cases.

Therefore, the literature supports the conclusion that breast cancer in a patient with only breast pain is coincidental, with breast cancer in the concordant breast found to be \sim 1.9:1000 (Jahan et al., 2022).

2.2.2 Increased awareness of family history risk factors

Interestingly, some of the literature outlined in **Table 1** also looked at family history in the cohort of patients. In these reports, more patients with breast pain had a stated family history of breast cancer than you would expect to find within the population. These results ranged from 15%–38%, but the significance of the family history in relation to the individual's personal breast cancer risk was not formally assessed.

This is an important finding as knowledge of family history risk is important to raise awareness about risk factors and to promote appropriate screening behaviours. Family history of diseases such as breast cancer is associated with increased perceived risk (Acheson, et al., 2010), but when

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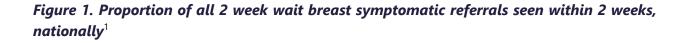
an objective familial breast cancer risk assessment is performed many of these patients are found not to be at significant increased risk. It is also important to note that discussions about family history risk factors with primary care physicians have been found to be low, with the proportion of patients reporting having been asked about family history of cancer and informed about cancer prevention issues found to be 35.1% and 26.4%, respectively (Kartal et al., 2018). This may be due to a lack of confidence among GPs at calculating or counselling risk of breast cancer. In one study 90% and 83% of GPs reported themselves to be "not confident or little confident" about calculating or counselling about risk of breast cancer respectively (Campbell et al 2003).

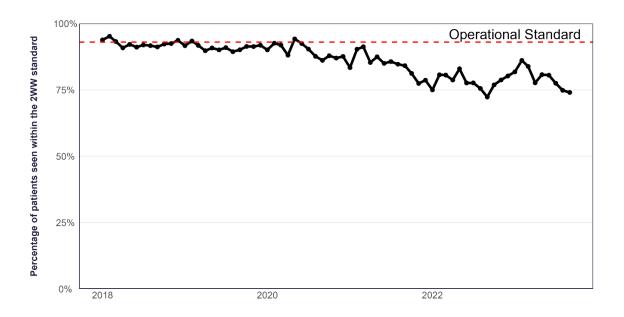
Through the development of a novel and innovative EMBPP there is the chance to tailor the patient's pathway to ensure these discussions take place, for example, eligibility for dedicated family history screening during a CBPC attendance. This may help improve attendance at life-saving screenings in the sub-population of patients identified on objective risk assessment as being at elevated risk of developing breast cancer.

2.2.3 Reduce overutilisation of healthcare resources

Increased demand for urgent 2WW breast cancer services

Following the pandemic Trusts across the country have been struggling to cope with demand for 2WW pathway appointments for breast cancer. This struggle is illustrated in **Figure 1** where the percentage of patients seen within the 2WW standard had dropped below the 93% operational standard and continued to decrease since the pandemic, resulting in a national percentage of around 75% when NHS England stopped publishing the 2WW standard statistics in September 2023.





With risks of delays to the patient pathway and treatment target breaches, it is important that steps are taken to reduce pressures on the system. With the evidence that breast pain as the only symptom has no association with breast cancer, referrals onto the 2WW pathway for breast pain only are unnecessarily increasing demand for appointments and contributing to the capacity breaches. Therefore, options to safely divert these patients to community-based clinics could significantly improve the current picture. This meets the NHS England (2024) Faster Diagnostic Pathway guidance that those with breast pain only pathways should "reduce unnecessary and inappropriate imaging", allowing 2WW clinics limited resources to be used effectively.

Increased tests, including ultrasounds and mammograms

Data indicates that for patients with breast pain only, each patient referral results in 0.64 and 0.27 mammograms and ultrasounds respectively (Jahan et al., 2022).

For example, one study of 799 patients with a mixture of diffuse (30%), focal (30%) and non-localised (40%) breast pain reported on the number of imaging examinations performed (Kushwaha et al., 2018). This shows that 624 mammograms (78% of patients), 550 breast ultrasounds (69%) and 8 MRIs (1%) were performed. There were also 17 image guided examinations (2%) that were performed to enable a biopsy to be taken. For all these imaging

¹ https://www.england.nhs.uk/statistics/statistical-work-areas/cancer-waiting-times/#cwt-statistics-up-to-september-2023

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examinations (n=1199), one breast cancer in the contralateral asymptomatic breast was diagnosed.

With mammograms and ultrasounds costing £66.49 and £67.20 each respectively² within the NHS (and even more in private healthcare), each unnecessary scan poses a significant cost to the health system. It also exacerbates the anxiety felt by patients when placed on an urgent cancer diagnostic pathway. Avoiding unnecessary imaging is a key part of the Faster Diagnostic Pathways guidance (NHS England, 2024).

² 20/21 reference costs were inflated 23/24 healthcare inflation values.

3 CBPC Pathway Overview

3.1 Background to the Evaluation

The CBPC is a novel service, and first in the UK, tackling the rising tide of breast symptomatic clinic 2WW referrals. Prior to establishing CBPCs, approximately 20% of 2WW referrals to BCDCs had breast pain only as their symptom (Jahan et al., 2022). This was further supported by the findings of a prospective audit of reasons for referral to 2WW clinics in a large breast cancer unit over a 12 month period which reported that 1,972 out of 10, 830 (18%) women, were referred with breast pain only (Dave et al 2022), Breast pain only is not a symptom of breast cancer - as already noted in recent NHS England guidance that "breast pain alone is not a symptom of cancer and should not be automatically referred on an urgent cancer pathway".

To manage the increasing pressures and demands on existing 2WW diagnostic cancer services, a transformation of the 2WW breast cancer pathway is necessary. This has been achieved by the establishment of dedicated CBPCs. These clinics aim to improve patient care and experience while simultaneously providing a system wide improvement (primary, secondary & tertiary care).

Initial analysis of a pan-Derbyshire audit/evaluation (Royal Derby and Chesterfield Royal Hospitals), has shown that primary care can reduce urgent 2WW referrals, improve patient care and experience through the establishment of a CBPC. This transformative change also increases urgently required capacity within secondary care breast services, particularly as part of the national recovery and restoration plan.

Subsequent analysis of the East Midlands audit/evaluation (UHDB/CRHFT, LLR PCL, ULH, KGH and NUH) has similarly shown that CBPCs offer a financial return and are perceived positively by patients through anonymised Patient Reported Outcome Measures (PROMs). In addition to this, the breast cancer incidence rate for women with breast pain only who fulfilled the inclusion and exclusion criteria for the CBPC was 3.2 (Cl: 1.4-6.9 per 1,000). This is well within the normal population estimates covered in the literature and well below the level recommended for population-based screening in the NHS, providing reassurance for the safety of the CBPCs.

The implemented programme has the potential to increase capacity of the BCDC pathway by up to 20%, and in doing so will reduce delays in diagnosis currently experienced in many parts of the country. Secondary and tertiary care also benefit through the identification and referral of more women at increased familial breast cancer risk following an objective, reproducible NICE compliant risk assessment. As well as improving referrals from primary care of patients at increased risk of breast cancer, this also reassures patients assessed to be at population or 'near population' risk who do not require referral to familial cancer services.

More information on the CBPC pilots can be found here: East Midlands Cancer Alliance

3.2 Endorsements

The EMBPP has recently had several endorsements by NHS England through inclusion in the joint Getting It Right First Time (GIRFT) and Cancer Programmes (GIRFT 2024) Best Practice Timed Diagnostic Cancer Pathways Guidance, and also in the Breast Cancer Faster Diagnosis Evaluation Case Studies (NHS England, 2024).

It has also been supported by various healthcare providers and professional groups such as Cancer Alliances, NHS Trusts, and the Association of Breast Surgery – not least through their involvement in this national audit/evaluation.

It also received the 'High Commendation' (Runner up) in the "Primary & Community Care Innovation of the Year' award in the 2022 Health Service Journal awards.

3.3 The National Evaluation Period

3.3.1 The design

Figure 2 details the structure of the CBPCs. The clinics were designed with several key components:

- 1) A clinic for patients with breast pain only (exclusion criteria apply);
- 2) Clinics based in a community/primary care setting;
- 3) An experienced breast clinician (GP with a Special Interest [GPSI], Advanced Nurse Practitioner [ANP] or Hospital Doctor) confirms no clinical abnormality following a clinical examination and that the patient has no other symptoms;
- 4) Family History Risk Assessment triage according to NICE CG164 referral guidelines for primary care

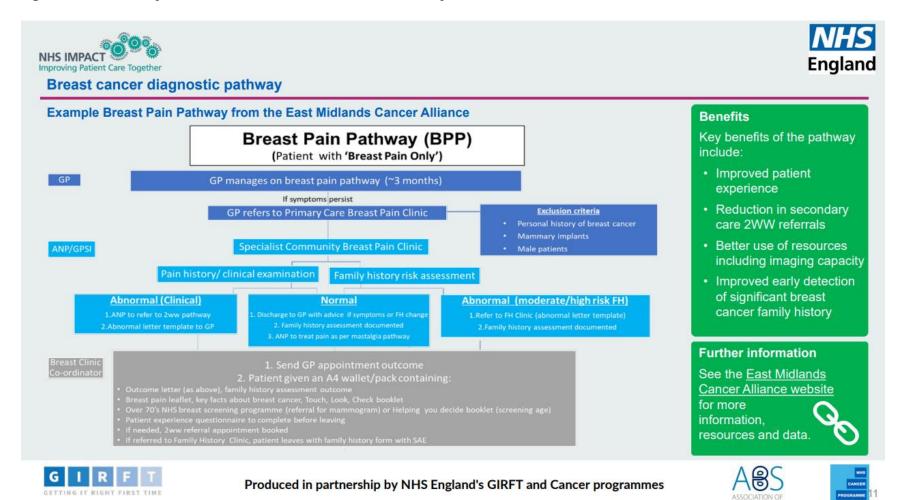
The exclusion criteria for the clinics are:

- Previous personal history of breast cancer
- Mammary implants
- Male patients

Figure 2 shows the EMBPP and was included within GIRFT guidance³ as an example of best practice.

³ <u>https://gettingitrightfirsttime.co.uk/wp-content/uploads/2024/03/BestPracticeTimedDiagnosticCancerPathwayssummary-guide-March-24-V3.pdf</u> (Slide 11)

Figure 2. Community Breast Pain Clinic – Breast Pain Pathway*



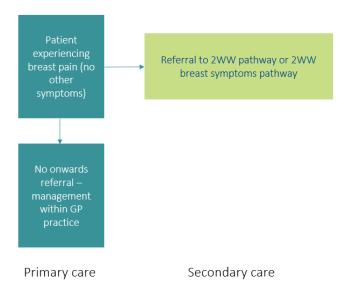
*https://gettingitrightfirsttime.co.uk/wp-content/uploads/2024/03/BestPracticeTimedDiagnosticCancerPathwayssummary-guide-March-24-V3.pdf (Slide 11)

3.3.1 Changes to the pathway

Pre-intervention patient pathway

Historically, patients experiencing breast pain as their only symptom would be either managed within primary care with no onward referral (the majority of such patients) or referred to the 2WW pathway (**Figure 3**).

Figure 3. Pre-intervention patient pathway



Post-intervention patient pathway

Since the introduction of CBPCs, patients presenting with breast pain as their only symptom, where the GP wishes to have more specialised input regarding their breast pain, now have a specialised referral route (**Figure 4**). Patients are directed to a CBPC where they receive an assessment of their pain symptom, a breast examination by an experienced breast clinician and to aid triage an objective, reproducible breast cancer family history-based risk assessment for primary care as per NICE CG164. This meets new NHS England (2024) Faster Diagnostic Pathway guidance, by triaging all referrals and diverting patients away from One Stop Clinics for "those at low risk of a cancer diagnosis who do not have red flag symptoms".

CBPC Pathway Overview

All sites in the national audit to date have used the FaHRAS software tool to carry out the NICE CG164 risk assessment and aid management decisions.⁴ This has facilitated the collection of family history by the patient prior to their CBPC appointment such that an objective reproducible risk assessment is available to the clinician at the very start of their consultation with the patient. It also means that the clinician requires no specialist knowledge of familial breast cancer risk.

Dependant on the results of these interventions, the patient can be:

- i) discharged back to their primary care clinician
- ii) referred to a BCDC for further investigation of any clinical concern

and / or

referred to a familial cancer specialist service if they are deemed to be at increased risk of developing a breast cancer in the future.

Close links and referral to BCDCs for "any patients that present with red-flag symptoms" is an important part of the EMBPP CBPC, as indicated in the Faster Diagnostic Pathway guidance (NHS England, 2024).

⁴ The use of the FaHRAS software was not mandated. It has been used as it helps manage family history assessments - eg it simplifies the calculation of risk by CG164 guidelines in the clinic, makes the assessment reproducible between centres and facilitates management outcomes for everyone. It also allows a copy of the risk assessment to be shared with the patient, the GP and stored behind the NHS firewall. The latter also facilitates auditing of family history across the population(s).

Patient experiencing breast pain (no other symptoms)

Referral to breast pain clinic:
Assessment/ family history (FaHRAS)

Referral to breast pain clinic:
Assessment/ family history (FaHRAS)

Familial cancer specialist service

Primary care

Secondary care

Figure 4. Post-intervention patient pathway

3.3.2 Participating Centres

This report on the national audit includes data from 17 centres from 9 different Cancer Alliances across England. These centres and cancer alliances cover a large area of England, that is illustrated in **Figure 5**.

For those centres identified as Cohort A, all CBPC attendances until the 29th of February 2024 are included in this report, with any subsequent BCDC attendances also recorded until the 30th of April 2024. This was to allow at least two months for the last clinic attendees to potentially be diagnosed with breast cancer if they had been referred directly from the CBPC to a BCDC.

For centres listed as Cohort B, who have been operating for less time than Cohort A sites, all CBPC attendances have been recorded and the CBPC data used in this report. This was to evaluate patient populations across different Cancer Alliances, varying geographic areas with often different demographics and to evaluate clinic outcomes (ie discharged back to Primary Care, onwards referral to BCDCs or referral to familial breast cancer services) and the same PROMs questionnaires.

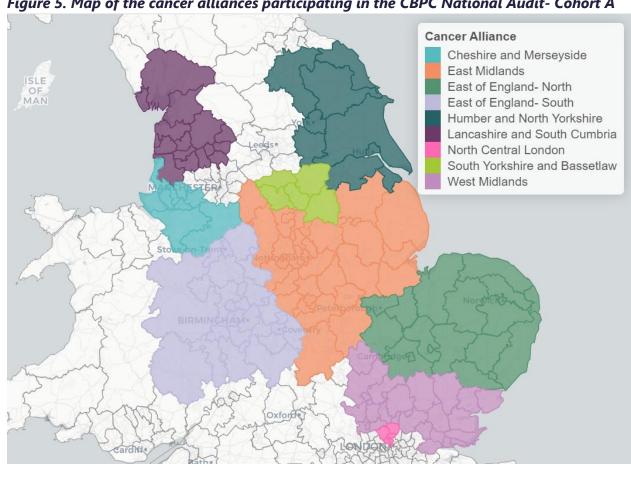


Figure 5. Map of the cancer alliances participating in the CBPC National Audit- Cohort A

3.3.3 Implementation Timeline

The clinics have all commenced on different dates. **Table 2** shows the implementation timeline.

Table 2. Implementation Timeline

Date	Description	Cancer Alliance	Report Cohort
June 2021	Breast Pain Clinics established in UHDB/CRHFT	East Midlands	А
December 2021	Breast Pain Clinics established in ESNEFT	East of England (North)	А
January 2022	Breast Pain Clinics established in LLR PCL	East Midlands	А
March 2022	Breast Pain Clinics established in NWA	East of England (North)	Α
March 2022	Breast Pain Clinics established in ULH	East Midlands	А
June 2022	Breast Pain Clinics established in YSTH	Humber and North Yorkshire	А
July 2022	Breast Pain Clinics established in KGH	East Midlands	А

CBPC Pathway Overview

July 2022	Breast Pain Clinics established in NLAG	Humber and North Yorkshire	A ⁵
October 2022	Breast Pain Clinics established in DBTH	South Yorkshire	Α
October 2022	Breast Pain Clinics established in UHDB (S. Staff.)	West Midlands	Α
November 2022	Breast Pain Clinics established in NUH	East Midlands	Α
December 2022	Breast Pain Clinics established in ELHT	Lancashire and South Cumbria	Α
May 2023	Breast Pain Clinics established in ENH	East of England (South)	Α
August 2023	Breast Pain Clinics established in STHK	Cheshire and Merseyside	Α
February 2024	Breast Pain Clinics established in DBTH (Bassetlaw)	South Yorkshire	В
March 2024	Breast Pain Clinics established in CoCH	Cheshire and Merseyside	В
May 2024	Breast Pain Clinics established in RFL	North and Central London	В

 5 Due to difficulties with data submission, NLAG's CBPC data only runs until the 31^{st} of October 2023, with all available follow-up data updated on the 31^{st} of January 2024

4 Methodology

The evaluation uses a mixed method methodology, combining patient feedback through PROMs with data obtained from the National Core Dataset with secondary care and family history data. Data on the costs of the clinic was also collected via an online survey, and these costs were verified in interviews. Staff interviews were conducted during Spring 2024 to extract additional insights into CBPCs that will be included throughout the report.

Quantitative and qualitative analysis was completed using RStudio⁶. Pseudonymised data on patients care from the CBPCs, secondary care (where applicable) and FaHRAS obtained from each CBPC, covering each evaluation period. At the time of this evaluation, each clinic has been open for differing periods (as outlined in Section 2.2.3.). All data collected from the evaluation start date has been included.

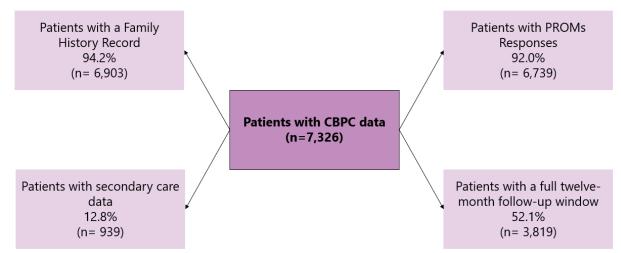
Most of the criteria set out for the CBPCs are controlled, including a clinic for patients with breast pain only, the clinic is held within a community setting and uses a family history risk assessment tool based on NICE CG164. Not only is the NICE CG 164 an objective risk assessment but the software tool used (FaHRAS) in this evaluation also ensured it was both objective and reproducible: this allows comparison of family history results between centres which will be presented and discussed later. The final requirement of the EMBPP – i.e. a "experienced breast clinician" running the clinic, was a decision made by the clinic. There is an opportunity for different models (e.g. consultant breast surgeons, ANPs, breast cancer nurses, GPSI) which in turn could produce variation between centres, particularly in terms of the percentage of onward referrals from the CBPC to the BCDCs. To begin to assess the impact of this, data has been presented at both centre and cancer alliance level, where appropriate, within this report. This is particularly important when looking at factors such as referral rates to secondary care where small variations in referral rates can have significant impacts on the generation of financial returns by the clinics.

The number of patients evaluated is displayed in **Figure 6** below.

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⁶ RStudio Team (2021). RStudio: Integrated Development Environment for R. RStudio, PBC, Boston, MA URL http://www.rstudio.com/.

Figure 6. Number of patients evaluated



5 Current use of the CBPCs

5.1 Descriptive statistics of population utilising CBPCs

The data indicates that 7,326 attendances were logged across the seventeen centres and nine Cancer Alliances taking part in the national audit.

The age of the patient was accurately recorded for 7,299 attendances. **Table 3** shows that the median age of a patient attending a CBPC across these sites was 48 years old (range 16 - 92). RFL is not included within the range calculation as it was the one trust which submitted aggregate figures. Details of the age distribution by trust can be found in **Appendix 2**.

Table 3. Descriptive statistics of patient age

Descriptive statistics of patient characteristics		
Variable N Statistic ⁷		
Age at attendance	7,299	48 (16, 92)
¹ Median (Range)		

Table 4 indicates that the patients who attended a CBPC had an average Indices of Multiple Deprivation (IMD) score of 6. This is an aggregation of 5,666 IMD entries. This is a measure of deprivation, with a value of 10 representing the least deprived areas and 1 representing the most deprived areas. The levels of deprivation within patient cohorts varied between sites, with CoCH, ENH, LLR PCL and YSTH seeing the patients from the least deprived areas (7) and DBTH seeing the patients from the most deprived areas (3), this can be found in **Appendix 3**.

Table 4. Descriptive statistics of patient Index Multiple Deprivation (IMD) score

Descriptive statistics of patient characteristics		
Variable ⁷	N	Statistic ²
IMD Score	5,666	6 (1, 10)
Note: IMD: The Index of Multiple Deprivation	, a measure of relative deprivation for small areas.	
² Median (Range)		

The ethnicities of the patients that attended the CBPC were also recorded; these statistics can be found in **Table 5.** This shows that 55% of patients that attended the CBPC were white. 5.5% of patients were Asian, 3.0% were mixed and 1.6% were Black. 1.6% of patients identified their ethnicity as something that did not fit into the prior categories and due to data collection issues, 34% of patients' ethnicities are unknown. Among patients with known ethnicity, 18% identified as non-white, while 82% identified as white. The split in the ethnicity within the non-white population was not precisely the same demographic as nationally across the UK, most likely due to the

locations of the centres implementing the EMBPP. However, 18% of attendees identifying as non-white does show that the population attending CBPCs was ethnically diverse.

Table 5. Descriptive statistics of patient ethnicity

Descript	tive statistics of patient characteristics
Variable	Statistic ⁷
Ethnicity	
White	3,997 (55%)
Asian	401 (5.5%)
Mixed	223 (3.0%)
Black	117 (1.6%)
Other	116 (1.6%)
Unknown	2,472 (34%)
¹ n (%)	

5.2 Patient follow-up recommendation

The outcomes of the CBPC attendances were tracked and are displayed in **Table 6** and **Figures 7a**, **7b** and **7c**. Overall, 887 (12%)⁷ patients who had an appointment at the CBPC were directly referred to a BCDC. This shows that almost 6,500 patients avoided a direct referral to the BCDC as a result of the CBPC. A breakdown by cancer alliance can be found in **Appendix 4**.

Table 6. Descriptive statistics of patient outcomes

Summary of the discharges an	Overall
/ariable	$N = 7326^{7}$
Referral to Breast Cancer Diagnosis Clinic	
No Onward Referral	6,439 (88%)
Referral to Breast Cancer Diagnosis Clinic	887 (12%)

This percentage varied between Cancer Alliances (**Figure 7a**), individual centres (**Figure 7b**) and the staffing model used (**Figure 7c**). The aggregated percentages by Cancer Alliance range from 6% to 21%. The average percentage referred to the BCDC was 12.1% across all centres.

From a Cancer Alliance perspective, East of England (South) only referred 6% of their patients to secondary care, whilst East of England (North) referred 21% of their attendees to secondary care.

⁷ Note: The figures for YSTH include patients who were sent for Scans due to the different model employed at that provider

Of providers in Cohort A, KGH referred the lowest proportion of their CBPC attendees (5.5%), whilst NWA of East of England (North) Cancer Alliance referred the highest proportion of their attendees (26.7%). In Cohort B, CoCH referred only 4.1% of their patients to secondary care.

Considering the staffing models of these centres, the most popular model is a nurse-led clinic. Nurse-led models had both the lowest and highest rates of referral to secondary care, with this inconsistency between sites likely reflecting differences in clinic maturity and staff experience. These were both key themes that were extracted from Spring 2024's staff interviews, with staff indicating that as they spent more time working in the CBPCs, they became more confident with discharging patients. This was reflected in the majority of discussions across site and early time-series data indicated that referral rates decreased over time.

However, due to small sample sizes at some CBPC centres, the confidence intervals are quite large. Therefore, at this stage we would not draw definite conclusions regarding this point.

Another factor that could significantly affect the rate of referral to secondary care is the effectiveness of triage processes in clinics. If patients are inadvertently seen with symptoms additional to breast pain they are more likely to require BCDC referral after CBPC attendance. Again it is likely that triage processes would improve with time leading to a decrease in referral rates.

Figure 7a. Proportion of patients referred to a breast cancer diagnostic clinic from the CBPC, by Cancer Alliance.

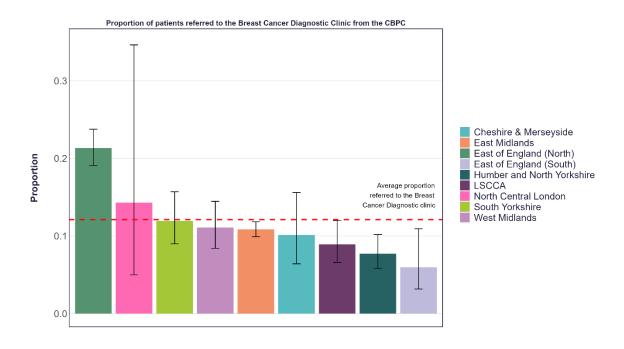


Figure 7b. Proportion of patients referred to a breast cancer diagnostic clinic from the CBPC, by centre.

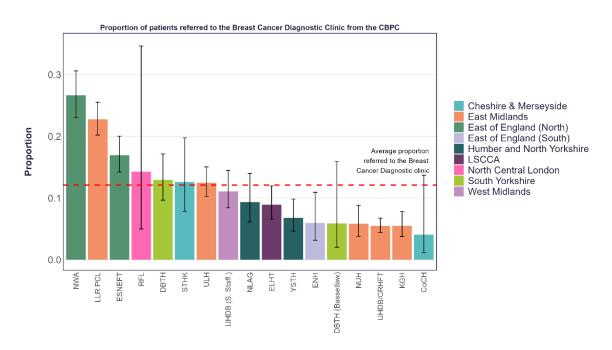


Figure 7c. Proportion of patients referred to a breast cancer diagnostic clinic from the CBPC, by staffing mix.

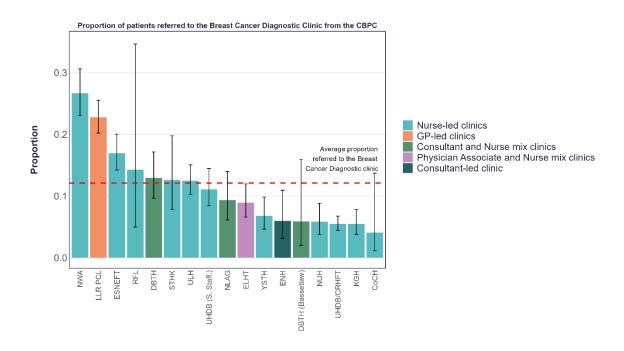


Table 7a indicates that 872 secondary care appointments⁸ took place within 3 months for patients that had attended a CBPC. Of these patients, 824 (94%) attended a BCDC following a direct referral from the CBPC.

The remaining 5.5% of patients were referred into secondary care by their GP (4.7%) or by the screening programme (0.8%). A breakdown by Cancer Alliance can be found in **Appendix 5.**

There are some discrepancies in the numbers of patients referred when compared to **Table 6**. 67 patients were referred by the CBPC to the BCDC but do not have a secondary care record. This may be because they did not attend their appointment, their appointment hadn't happened at the time of the data submission or data quality issues.

One patient was simultaneously referred by the CBPC and the GP to the secondary care appointment. This patient was recorded as a 'GP' referral in their secondary care record. Five patients have a BCDC outcome of "Other" but are listed as a direct CBPC referral.

Table 7a. Descriptive statistics on referral source

Summary of the appointments in BCDC for patients seen in a CBPC

, , , , , ,	
Variable	Overall N = 872 ⁷
Referral type	
Direct referral from the CBPC	824 (94%)
Re-referral from their GP	41 (4.7%)
Referral following breast screening	7 (0.8%)
¹ n (%)	

The number of patients attending the BCDC represent a very small proportion of total CBPC attendances (**Table 7b**). The data shows 88% of the 7,326 patients that attended a CBPC did not require a onward referral to a BCDC and were discharged after the clinic with no subsequent referral back to primary care or a referral to the national screening programme.

Only 41 patients (0.6%) of CBPC attendees were referred back to a secondary care BCDC by their GP within 3 months of their CBPC appointment. This low rate is another indication of patient satisfaction with the service provided at the CBPC.

Table 7b. Descriptive statistics on referral source for all patients

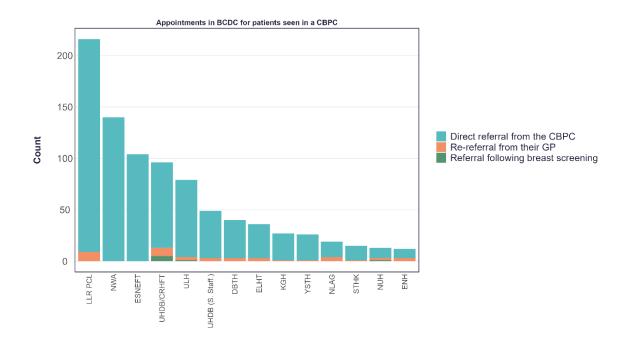
⁸ 872 secondary care appointments include the number of patients sent for scans. These are recorded as 'CBPC' referrals

Summany of the	annointments	in	RCDC for patier	ate coon in a (RDC

Variable	Overall N = 7326^{7}
Source of referral to secondary care	
No Secondary Care Appointment	6,454 (88%)
Direct referral from the CBPC	824 (11%)
Re-referral from their GP	41 (0.6%)
Referral following breast screening	7 (<0.1%)
n (%)	

Figure 8 indicates that there is some variation in both the number of patients and the referral sources for their secondary care appointments, but that overall the vast majority of referrals to the BCDC were from the CBPC.

Figure 8. Centre breakdown, referral source



5.3 CBPC and secondary care results – Family History Screening

One of the features of the CBPC pathway is that it includes a family history risk assessment and triage according to NICE CG164. This is completed to i) to help provide an objective assessment of a patient's future risk of breast cancer which is reproducible and nationally recommended/accepted and ii) to assist clinic staff manage that risk assessment by providing

local guideline recommendations for subsequent discharge or referral to / discussion with the local familial cancer services.

NICE recommendations generated from FaHRAS, the software used in this audit⁹, can be defined as:

- **Population risk** patient has no relatives with breast cancer and does not need further follow up.
- 'Near Population' Manage in primary care patient has relatives with breast cancer but does not need further follow up.
- Above Near Population Discuss with secondary care or refer to secondary or tertiary care patient has relatives with cancer (including breast) and/or genetic mutations and requires discussion or referral with secondary or tertiary care.

The data displayed in **Table 8** and **Figures 9a** and **9b** shows that of the 6,903 patients who have a FaHRAS record, 68% had no relative with breast cancer (Population Risk). 19% had at least one relative with breast cancer, but that did not significantly raise their breast cancer risk (Near Population Risk) and required no offer of referral to a familial cancer service or further follow-up. A breakdown by detailed recommendation and cancer alliance can be found in **Appendix 6**.

Table 8. Summary of follow-up recommendations for patients

Summary of recommendations			
Variable	Overall $N = 6903^{T}$		
Recommendation			
Population Risk	4,720 (68%)		
'Near Population'	1,338 (19%)		
Above Near Population Risk	845 (12%)		
⁷ n (%)			

The proportion of patients that required an offer of a referral to a familial cancer service varied by Cancer Alliance (**Figure 9a**) and centre (**Figure 9b**). The highest percentages requiring further management for Cancer Alliances were found within West Midlands Cancer Alliance and the Cheshire and Merseyside Cancer Alliance - 16%. The lowest percentage (10%) was found in North Central London Cancer Alliance (it should be noted that the numbers seen in this Cancer Alliance during the audit period were relatively small). The centre with the lowest percentage of patients requiring further management by a familial cancer service was LLR PCL (6%), whereas at CoCH, 23% of their patients were recommended to have a further referral to a familial cancer service (it

⁹ The use of the FaHRAS software was not mandated. It has been used as it helps manage family history assessments – eg, it simplifies the calculation of risk by CG164 guidelines in the clinic, makes the assessment reproducible between centres and facilitates management outcomes for everyone. It also allows a copy of the risk assessment to be shared with the patient, the GP and stored behind the NHS firewall. The latter also facilitates auditing of family history across the population(s).

should be noted that the numbers seen at this centre during the audit period were relatively small). The average percentage of patients that required follow up across all centres and Cancer Alliances was 12.2%.

Figure 9a. Proportion of patients requiring further management, by Cancer Alliance

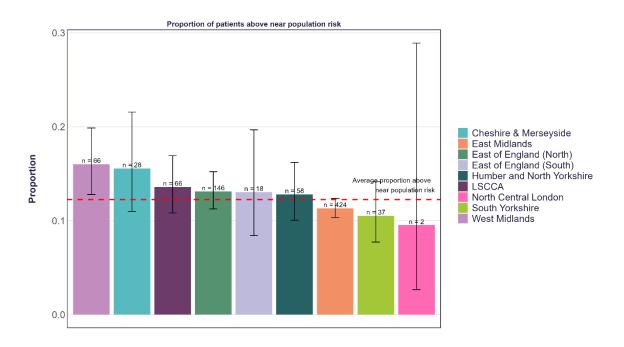
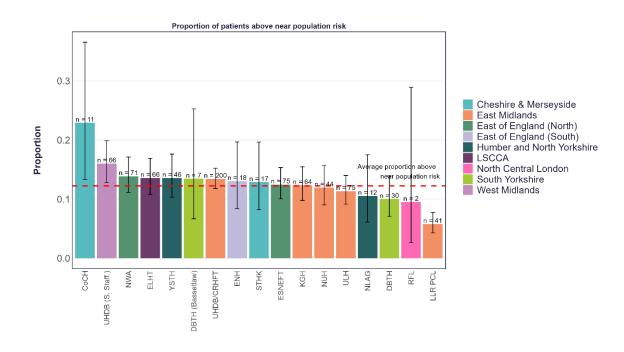


Figure 9b. Proportion of patients requiring further management, by centre



Current use of the CBPCs

From the above graphs and tables, we can see little variation in familial risk between Cancer Alliances and individual centres involved in the National Audit. Each of these centres has used NICE CG164 and all centres have also used the FaHRAS software. These guidelines and software provide both objective risk assessment and reproducibility. This means that any differences seen in familial risk are not due to differences in the risk assessment undertaken at individual centres.

This was the first large prospectively collected breast cancer risk assessment within primary care carried out across multiple centres spanning several Cancer Alliances which has used the same risk assessment criteria and software. Therefore, this was an objective and reproducible familial risk assessment and while it shows some variation at the extremes, for the majority of Cancer Alliances (**Figure 9a**) and centres (**Figure 9b**) there is very little variation in the proportion of patients at increased risk. This is useful in providing a baseline as regards significant familial risk in this population of patients and may be used for inputting to future planning for familial cancer services.

However, there are some caveats with the data to consider. Firstly, some of this variation may be explained by low sample sizes, as evidenced by the wide confidence intervals. Additionally, the data does not currently allow us to understand whether differences between Cancer Alliances or Centres is driven by significant 'pockets' of patients with ethnic (e.g. Ashkenazi Jewish), racial (e.g. Asian or Black) or demographic (e.g. elderly) differences which significantly increase or decrease the proportion at risk above or below the average percentage of 12.2% reported in this evaluation. Therefore, additional interrogation of this data is required before further conclusions can be drawn.

6 Patient Safety

It is also important that CBPCs represent a low-risk pathway. This section outlines the prospectively defined patient safety and effectiveness metrics used to assess the EMBPP.

6.1 Cancer diagnoses

In the follow-up data collected to date, there have been 24 cancers diagnosed within 1 year of attendance at the CBPC. **Table 9a** shows where these were diagnosed and **Table 9b** shows the referral route for each cancer diagnosis.

Thirteen patients who were referred directly from the CBPC to the BCDC were subsequently diagnosed with cancer. This shows the importance of clinical examination in picking up cancer cases in patients only experiencing breast pain. Seven patients were diagnosed through breast screening. Of these seven patients, three were aged between 50 and 70 in the routinely invited screening age group. Four were older than 70 years old, which shows the importance of promoting the continued availability of breast screening on request in this age group which is routinely done at CBPCs.

The total cancers include four patients who were ineligible for the CBPC, due to meeting one or more of the exclusion criteria. Following the first of these diagnoses, a Standard Operating Procedure (SOP) was developed to try and prevent these patients from being referred to the CBPC in future – e.g., by making prior personal history of breast cancer a specified exclusion criteria on the referral form – and secondly by triaging out any such referrals. The SOP also addresses how to deal with patients with personal prior history of breast cancer who still manage to be seen in the CBPC (e.g. where a GP doesn't mention the patient's personal history of breast cancer in their referral letter). The reason for making prior personal history of breast cancer an exclusion criterion is that these patients are at three times the annual risk of developing another breast cancer compared to the normal population which has never had a prior breast cancer. This puts patients with a prior breast cancer into a high-risk population who should be assessed in a BCDC.

The two ineligible patients at UHDB/CRHFT were deemed ineligible for the CBPC as they both had a personal history of breast cancer. The first of these was subsequently referred to the BCDC by their GP with new breast symptoms and led to the introduction of the Exclusion Criteria SOP. As a result, the second patient was a direct CBPC referral to the BCDC. The ineligible patient from NUH was referred to the BCDC via Screening and should not have been referred or seen in the CBPC clinic because they fulfilled the exclusion criteria of a prior personal history of breast cancer. The ineligible patient from ESNEFT was deemed ineligible as they had itchiness around the nipple and was a direct CBPC referral to the BCDC.

Two of these ineligible cases occurred early after the introduction of a CBPC at their respective sites and before the SOP for dealing with patients with a prior personal history of breast cancer

Patient Safety

was established. The other two patients were seen after the change in practice with the introduction of a new SOP and they were referred from the CPBC to the BCDC, even though there were no abnormal clinical findings, and led to the subsequent cancer diagnosis following imaging.

Table 9a. Cancer diagnoses, by centre

Centre	Number of Eligible Cancers	Number of Ineligible cancers	Total cancers
DBTH	0	0	0
UHDB/CRHFT	6	2	8
ELHT	2	0	2
ENH	0	0	0
ESNEFT	2	1	3
KGH	1	0	1
LLR PCL	2	0	2
ULH	2	0	2
NWA	3	0	3
NUH	1	1	2
STHK	0	0	0
UHDB (S. Staff)	0	0	0
YSTH	1	0	1
NLAG	0	0	0
Total	20	4	24

Table 9b. Cancer diagnoses, by centre and route

Centre	Direct CBPC referral	Subsequent GP referral	Breast Screening	Total cancers
UHDB/CRHFT	2	1	5	8
ELHT	0	2	0	2
ESNEFT	3	0	0	3
KGH	1	0	0	1
LLR PCL	2	0	0	2
ULH	1	0	1	2
NWA	3	0	0	3
NUH	1	0	1	2
YSTH	0	1	0	1
Total	13	4	7	24

6.2 Breast cancer incidence

For the cohort of patients seen so far in CBPCs for which we have secondary care data (Cohort A sites - 7205 patients), the number of breast cancers was 24 giving an incidence of breast cancer of 3.3 per 1,000 (95% Confidence Interval: 2.2-5.0 per 1,000).

However as highlighted in the above report, there have been 4 patients that have been referred to the CBPC inappropriately. This is because they met the exclusion criteria by having a personal history of breast cancer. By removing these patients from the prevalence estimates, the incidence of breast cancer drops to 2.8 per 1,000 (95% Confidence Interval: 1.8- 4.3 per 1,000).

Of 3819 patients with full 12-month follow-up data, ie, patients seen before 1st May 2023, the number of breast cancers was 17. This means that the incidence of breast cancer was 4.5 per 1,000 (95% Confidence Interval: 2.8- 7.1 per 1,000). Excluding 3 ineligible patients with a prior personal history of breast cancer from the patient group that had twelve months of follow-up data, the prevalence estimates drop to 3.7 per 1,000 patients (95% Confidence Interval: 2.2 – 6.2 per 1,000).

Patients who have not had a full twelve-months since their CBPC appointment (3386 patients) have an incidence rate of 2.1 per 1,000 (CI: 1.0 - 4.3 per 1,000), when excluding ineligible patients, this drops to 1.8 per 1,000 (CI: 0.8 - 3.9 per 1,000). This highlights the importance of having a twelve-month period of follow-up for this evaluation.

The incidence in patients presenting with 'breast pain only' has been reported to be on average 4.6 per 1,000 (Duijm et al., 1998; Barton et al., 1999; Leung et al., 2005; Masroor et al., 2009; Howard et al., 2012; Leddy et al., 2013; Noroozian et al., 2015; Arslan et al., 2016; Cho et al., 2017; Chetien et al., 2017; Kushwaha et al., 2018, Fonseca et al., 2019). Therefore, the incidence at the CBPCs so far is below population incidence levels reported in the literature. However, both the prevalence rates with and without excluding the ineligible patients have confidence intervals that fall within the population prevalence expectation.

Only including patients that have received a full twelve months of follow-up time and excluding patients with a prior personal history of breast cancer, this cohort of patients with an incidence of breast cancer of 3.7 per 1,000 patients (95% Confidence Interval: 2.2 – 6.2 per 1,000) is actually lower than the literature on patients with breast pain only (Jahan et al. 2022) and much lower than the incidence used for selecting patients for mammographic screening in the NHSBSP. Indeed, the number of patients in this National Audit is comparable to the total number of patients reported in the literature review by Jahan et al (2022).

Of the 20 eligible cancer diagnoses, 9 were ipsilateral (45%), 7 were contralateral (35%), 1 was bilateral (5%) and 3 had an unknown site (15%). Interestingly, when different routes to diagnoses are considered, direct referrals from the CBPC to the BCDC resulted in 11 cancer diagnoses, of which 7 were ipsilateral (64%). Conversely, the 6 diagnoses through the screening referral route

resulted in 4 contralateral cases (67%) and the 3 cases diagnosed through GP re-referral were a mix of bilateral, contralateral and unknown sites.

This prospective National Audit has confirmed the low incidence of breast cancer within 12 months of a CBPC appointment in this population of women with 'breast pain only' who fit the inclusion and exclusion criteria. The evaluation also shows that of those 14/3,819 patients who developed a breast cancer within 12 months 10/14 were detected and diagnosed within 3 months of their CBPC appointment either via onward referral from CBPC to a BCDC or through recommended screening mammography – meaning only 4/3,819 patients were diagnosed with a breast cancer in the period between 3 – 12 months post CBPC appointment.

6.3 Time gap between CBPC referral, diagnostic clinic attendance and cancer diagnosis

As noted in the introduction of this report, breast pain alone is not a symptom of breast cancer. As such the diagnosis of a breast cancer in this population is an incidental finding to their presenting symptom. Nevertheless, for these cancer patients, it is important that attendance at the CBPC looks to detect at the clinic any abnormal finding and to minimise delay in investigation and diagnosis – thereby also minimising delay of their cancer treatment. This section outlines the time gaps at key milestones of the pathway. A breakdown by cancer alliance can be found in **Appendix 7** and a breakdown by referral route can be found in **Appendix 8**.

6.3.1 Onward referrals to breast cancer diagnostic clinics

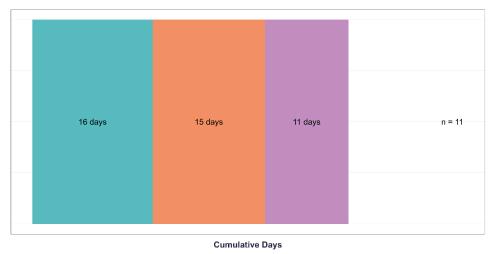
Thirteen out of a total of 24 patients subsequently diagnosed with breast cancer were referred to a breast cancer diagnostic clinic because of their attendance at the CBPC. These 13 diagnoses were made at seven centres, spanning two Cancer Alliances. Eleven of these patients were eligible for the pathway. The average time through the pathway is shown in **Figure 10.** The average time between referral and CBPC appointment for these patients was 16 days. They spent an additional 15 days waiting between their CBPC appointment and their onward breast cancer diagnostic appointment and a further 11 days till diagnosis. On average, they spent a cumulative 42 days from referral to diagnosis.

A breakdown of their journeys throughout the CBPC pathway is found in **Table 10**. The time spent from referral to the CBPC, and diagnosis ranged from 24 days to 76 days.

Of these 13 patients, two were ineligible for the EMBPP as highlighted by an asterisk in **Table 10.** Therefore 11 patients who fulfilled the EMBPP criteria went on to be referred to the BCDC and be diagnosed with a breast cancer. Of these, 7 patients had breast cancer that was ipsilateral to their breast pain, 2 patients had contralateral breast cancer and for 2 patients the site of cancer in relation to initial breast pain was unknown. It might be anticipated that a majority of breast cancers diagnosed through this route would be ipsilateral as the clinician at the CBPC had identified

additional findings to breast pain only at the CPBC necessitating the referral. The type of cancer in all known cases was invasive, which again would fit with clinically apparent breast cancers.

Figure 10. Time gap between CBPC referral and cancer diagnosis for eligible patients



Gap Between Referral and CBPC Appointment
Gap Between CBPC Appointment and Secondary Care Appointment
Gap Between Secondary Care Appointment and Diagnosis

Table 10. Cancers diagnosed- CBPC referral route.

Patient	Time between CBPC and breast cancer diagnostic clinic	Time between CBPC and diagnosis	Time between referral and diagnosis	Site of Cancer in relation to initial breast pain	Type of Cancer
1*	13	17	29	Ipsilateral	Invasive
2	8	27	37	Ipsilateral	Invasive
3	11	18	29	Ipsilateral	Invasive
4	18	25	76	Contralateral	Invasive
5	26	27	43	Unknown	Unknowr
6	11	14	24	Unknown	Unknowr
7	18	20	36	Ipsilateral	Invasive
8	20	26	34	Ipsilateral	Invasive
9	8	21	36	Ipsilateral	Invasive
10	12	47	54	Contralateral	Invasive
11	6	19	27	Ipsilateral	Invasive
12	23	37	58	Ipsilateral	Invasive
13*	6	15	50	Ipsilateral	Invasive

^{*} Patient excluded due to ineligibility for the CBPC pathway

6.3.2 Subsequent referrals through asymptomatic screening

The second route to breast cancer diagnosis is via breast screening programmes following their CBPC attendance. Seven patients in the audit were diagnosed with cancer through this route. These seven patients were diagnosed at three different centres in one cancer alliance.

Table 11 displays the patient journeys of the seven patients that were referred to the BCDC by a screening appointment after their CBPC attendance. The time from initial referral to the CBPC to diagnosis ranged from 35 days to 287 days. Three of these patients had ipsilateral breast pain to the subsequent breast cancer diagnosis when attending the CBPC, whilst the other 4 had contralateral breast pain to the cancer diagnosed. Five of these patients were diagnosed with invasive breast cancer, whilst the other 2 patients in this grouping had ductal carcinoma in situ (DCIS).

There was one ineligible patient in this cohort. This patient had a previous history of breast cancer and did not fulfil the criteria for CBPC attendance. They were diagnosed with ipsilateral DCIS.

The staff interviews highlighted the importance of signposting patients who were eligible to attend screening programmes to the appropriate centres. This is highlighted by seven patients being diagnosed with breast cancer after a CBPC appointment and attending for screening.

Table 11. Cancers diagnosed- Screening referral route.

Patient	Time between CBPC and breast cancer diagnostic clinic	Time between CBPC and diagnosis	Time between referral and diagnosis	Site of Cancer in relation to initial breast pain	Type of Cancer
1	15	28	35	Contralateral	Invasive
2	55	57	67	Ipsilateral	DCIS
3	58	58	70	Contralateral	Invasive
4*	118	126	146	Ipsilateral	DCIS
5	261	267	273	Contralateral	Invasive
6	266	272	287	Ipsilateral	Invasive
7	93	101	108	Contralateral	Invasive

^{*} Patient excluded due to ineligibility for the CBPC pathway

6.3.3 Subsequent referrals by the GP

Another avenue for patients to get re-referred into the breast cancer diagnostic clinics after attending the CBPC is a subsequent referral from their GP. Four patients with a subsequent breast cancer diagnosis, were referred to the BCDCs through this route from 3 different centres in 3 different Cancer Alliances.

Table 12 displays the patient journeys of the 4 patients that were referred to the BCDC via their GP after their CBPC attendance. Three of the 4 fulfilled the inclusion and exclusion criteria of the EMBPP. The time from initial referral to the CBPC to diagnosis ranged from 109 days to 171 days. Two of these patients attended the CBPC with bilateral breast pain and one with breast pain contralateral to the site of cancer. All these patients presented with new symptoms. All these patients were diagnosed with invasive breast cancer.

There was one ineligible patient in this cohort. This patient attended the CBPC with bilateral breast pain. They later developed new nipple retraction and were subsequently diagnosed with ipsilateral invasive breast cancer. This was mammographically occult even at the time of the breast cancer diagnostic clinic referral. The patient also had a previous history of bilateral breast cancer and therefore did not fulfil the inclusion criteria for a CBPC attendance.

Table 12. Cancers diagnosed- GP referral route.

Patient	Time between CBPC and BCDC	Time between CBPC and diagnosis	Time between referral and diagnosis	Time between CBPC and referral to	Site of Cancer in relation to initial	Type of Cancer
		_	_	BCDC	breast pain	
1*	41	98	109	21	Bilateral	Invasive
2	142	153	165	133	Contralateral	Invasive
3	162	171	171	149	Bilateral	Invasive
4	114	122	157	90	Unknown	Unknown

^{*} Patient excluded due to ineligibility for the CBPC pathway

Monitoring of CBPC attendees for a subsequent breast cancer diagnosis within one year of clinic discharge will be important and should continue as each clinic is established and matures to ensure that similar quality outcomes reported in this National Audit – clinical and PROMs – are delivered by each new CBPC. Patients diagnosed with breast cancer within 12 months of CBPC appointment should ideally be diagnosed by the routes described in 6.3.1 and 6.3.2. Any patient diagnosed following referral by the GP, risks being identified as a possible "missed" diagnosis by the CBPC, even though this may not be the case when such cases are reviewed in detail – eg the patient may have a new symptom, the laterality of the cancer may be non-concordant with the original breast pain, the cancer is mammographically occult, the time to diagnosis of the cancer is 11+ months, etc.

7 Patient Experience

Throughout this evaluation, Patient Recorded Outcome Measures (PROMs) have been collected prospectively to measure patient experience. This is done in the form of a fully anonymised questionnaire. The anonymised questionnaire was given to and completed by patients after their attendance at the CBPC, and covers the patient experience before, during and after their CBPC attendance.

7.1 Experience prior to CBPC attendance

Experiences prior the CBPC attendance were recorded by these PROMs surveys. 75% of the 6,606 respondents stated that the GP indicated that breast pain alone was not a symptom of breast cancer, whilst a quarter of patients had not been given this reassurance by their GP (**Table 13**). When looking at this by Cancer Alliance and centre, it appears that the more established clinics have a higher percentage of patients reporting they had been informed that breast pain alone was not a symptom of breast cancer (**Appendix 9**). This higher percentage may reflect a change over time as local GPs become aware of the new service and the messaging around the service that breast pain alone is not a symptom of breast cancer. GP education from the start of CBPC service provision may therefore be useful and should be considered as a basic aspect to any implementation plan.

Indeed, GP education was one of the key themes extracted from interviews with staff members across sites. Some sites indicated that GPs were brought into the process of setting up the clinic and thus primary care was on board with the project from the start of the clinics. Other clinics identified issues with GP referrals during their clinics. To rectify this, administrative staff indicated that they sent out letters to GPs indicating their incorrect referrals. Education events at GP training events have also been run by some centres, whilst other centres have distributed posters about the CBPC to be put up in GP surgeries or have amended their referral form to better inform GPs of the Community Breast Pain Pathway. This includes highlighting on the BCDC referral form the CBPC service aiming to avoid patients being inappropriately referred.

The PROMs survey also captured that 63% of patients were referred to the CBPC by their GP after only one visit to their GP for this episode of breast pain. A further 25% of patients had visited their GP twice before being referred to the CBPC, and 11.6% of patients had three or more GP appointments before being referred to the CBPC. Once again, the dataset while containing over seven thousand patients, doesn't allow looking at individual GP referral patterns or even individual GP practices.

Of the respondents, 42% indicated that they had experienced previous episodes of breast pain which had led them to seek a GP's advice and guidance.

Table 13. Summary of PROMs responses – patient experience in primary care

Response

kesponse		
Question	N	Statistic ¹
Did your GP advise you that breast pain is not a symptom of breast cancer?	6,606	
No		1,630 (25%)
Unsure		3 (<0.1%)
Yes		4,973 (75%)
How many times have you seen your GP for this episode of breast pain prior to being referred to this clinic?	6,668	
0		10 (0.1%)
1		4,224 (63%)
2		1,664 (25%)
3		473 (7.1%)
4		140 (2.1%)
5 or more		157 (2.4%)
Patient has experienced previous episodes of breast pain that required them to see their GP	6,645	2,785 (42%)
¹ n (%)		
<u> </u>		

7.2 Patient activation

The next aspect of the patient experience that the PROMs survey looked at was the degree to which attendance at the CBPC led to increased patient activation (**Figure 11**). Patient activation refers to patient's involvement in decisions related to their care.

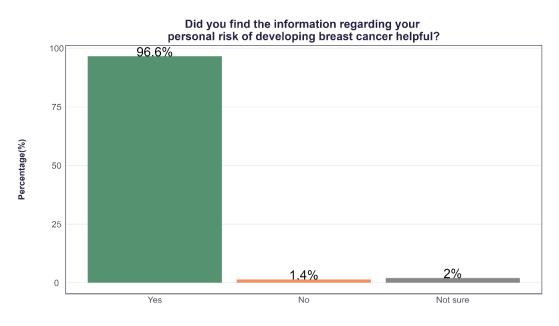
A key issue regarding patient activation is whether the patients found the advice given out at the CBPC helpful. The responses to this question indicate an overwhelming majority of patients (97.5%) received helpful advice which was relevant to them during their attendance at the CBPC.

Figure 11. Did you find the breast pain advice you received helpful?



Additionally, when patients were further asked whether they found the information regarding their personal risk of developing cancer helpful, a similar story was portrayed **(Figure 12)**. 96.6% of patients thought that this information was helpful to them.

Figure 12. Did you find the information regarding your personal risk of developing breast cancer helpful?



This data is particularly interesting given that as noted in **Table 13**, the objective risk assessment shows that 31% of patients had one or more member of their family with a history of breast cancer,

yet 97% found the risk assessment helpful. This identifies there are most probably reasons other than personal family history that may have made patients concerned about breast pain only and their risk of developing a breast cancer – e.g., a non-blood related family member, or a close friend or a work colleague may have been diagnosed recently with breast cancer; media reporting (e.g., the 'Angelina Jolie' effect; patient simply unsure of what their own risk was, etc). Whatever the reason, the familial risk assessment appeared to be valued by virtually all patients and is likely to be one reason for the very low return rate to CBPCs or a subsequent referral by GPs to a BCDC (0.6% within 3 months of their CBPC visit).

A further future benefit is in the identification of 'unmet need' among patients at increased risk who by referral to a familial cancer services unit will if appropriate be enrolled in an imaging surveillance programme and as a result many of the subsequent cancer diagnoses are likely to be at an earlier stage disease as shown by previous randomised mammographic screening studies of women aged 50-70 years (as per the NHSBSP) and cohort studies of women aged 40 – 49 years (FH01 collaborative teams, 2010) and between 35-39 years (Evans et al., 2019). This fits with the NHS Long Term Plan which is "to strengthen its contribution to prevention and health inequalities" through improving "uptake of screening and early cancer diagnosis for people who currently miss out" (NHS, 2019).

7.3 Patient reassurance

Patient reassurance with the breast pain advice that they received at the CBPC was also measured in the PROMs survey (**Figure 13**). 98.0% of patients who attended a CBPC felt reassured by the advice that they received. Only 1.2% CBPC attendees expressed that they were not reassured after their attendance at the CBPC.

This is also an important PROM in that for a condition such as 'breast pain only' which does not carry an increased risk of breast cancer, patient reassurance needs to be one of the positive outcomes for such patients. As a secondary result this will also contribute to the low re-referral rate back to the CBPC or BCDC. Equally this empowers women regarding self-management and addressing health anxiety.

Did you feel reassured by the breast pain advice you received?

98%

75

0

1.2%

0.8%

Yes

No

No

Not sure

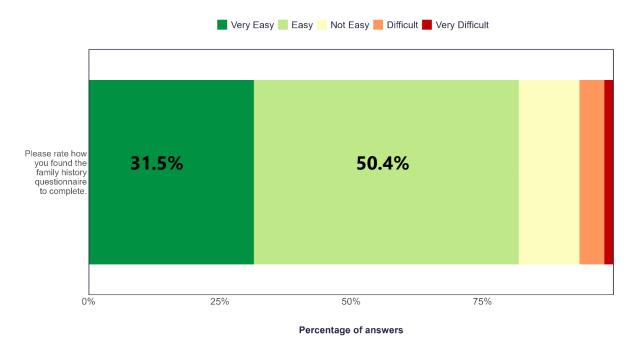
Figure 13. Did you feel reassured by the breast pain advice you received?

7.4 Ease of use

The PROMs survey also asks patients about how easy they found the family history questionnaire to complete **(Figure 14a)**. 81.9% of patients found the validated questionnaire either very easy or easy to complete. 11.6% found it 'not easy' but also not difficult. Overall, only 6.5% found the family history questionnaire difficult or very difficult which is a low for a general population of patients. It also means that 93.5% of patients did not find it difficult or very difficult to complete.

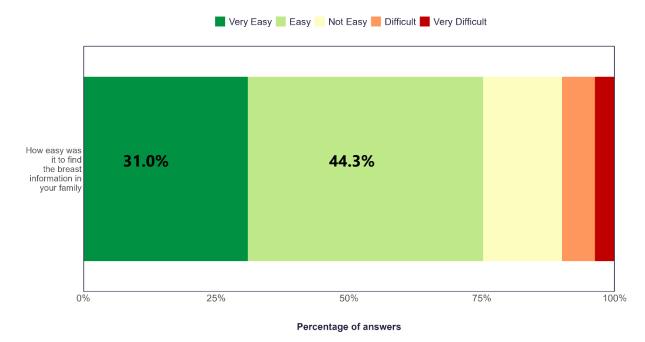
The PROMs survey also asked patients to reflect on how easy it was to find the breast cancer information in their family (**Figure 14b**). 75.3% of patients found this information either very easy or easy to discover. 14.9% of patients found this information not easy but also not difficult, while 9.9% found it difficult or very difficult to find. Again, this means 90.1% of patients did not find it difficult or very difficult to obtain the breast cancer information in their family requested by the questionnaire.

Figure 14a. Summary of PROMs responses – ease of use (questionnaire)



Note: Very Easy = 31.5%, Easy = 50.4%, Not Easy = 11.6%, Difficult = 4.7%, Very Difficult = 1.8%

Figure 14b. Summary of PROMs responses – ease of use (family history)



Note: Very Easy = 31.0%, Easy = 44.3%, Not Easy = 14.9%, Difficult = 6.2%, Very Difficult = 3.7%

The questionnaire did not drill down to the next level and identify from the 6.5% of patients who found completing the questionnaire difficult/very difficult, why this was the case – i.e. whether this reflected the difficulty in them obtaining details of their breast cancer family history from other

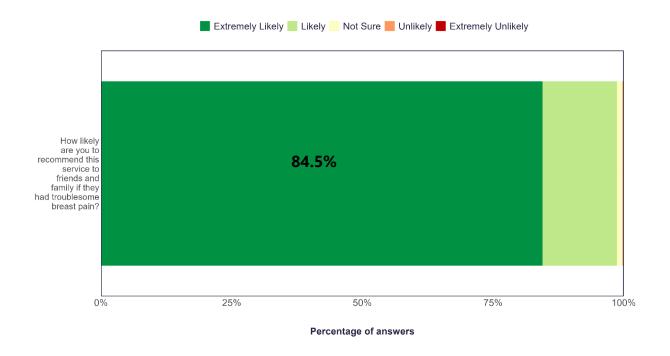
family members or if they were referring to completing the form itself. This is something which we would plan to try and establish going forward. Either way it is reassuring that most patients (81.9%) found completing the questionnaire very easy/easy to complete and 93.5% did not find it difficult/very difficult to complete.

Of note, the majority of family history questionnaires sent out to patients prior to their CBPC appointment were in paper format. Some interviews with staff members revealed that patients who found using computers difficult may struggle with an online form if the Trust that operates the CBPC is paperless.

7.5 Patient satisfaction

Additionally, patients were asked whether they would recommend the CBPC service to a friend or a family member if they were to experience troublesome breast pain in the future (**Figure 15**). 98.7% of patients expressed that they would be either extremely likely or likely to recommend this service. 1.1% of patients expressed that they were unsure whether they would recommend this service to a friend, whilst only 0.2% of patients expressed that they were either unlikely or very unlikely to recommend this service to a family member or a friend.

Figure 15. How likely are you to recommend this service to friends and family if they had troublesome breast pain?



 $Note: Extremely\ likely=84.5\%,\ Likely=14.2\%,\ Not\ sure=1.1\%,\ Unlikely=0.1\%,\ Extremely\ Unlikely=0.1\%$

Overall anonymised PROMs show that the EMBPP with CBPCs result in excellent patient experience of the clinical service. Figures 12–14 show the PROMs for the whole population of patients reported in this national audit. The PROMs satisfaction was very high for all Cancer Alliances and all the centres showing the patient experience was very reproducible across all sites.

7.6 Qualitative analysis: comparison between feelings pre- and post-attendance

The final questions of the PROMs provided qualitative assessment rather than the quantitative assessment (sections 6.1–6.5 above) and allowed patients to respond about their feelings preand post-attendance at the CBPC. These word clouds show the size of the words proportionately to the number of times it appears in a response.

Analysis of their responses highlights a high frequency of negative feelings such as "nervous", "anxious" and "worried" prior to the patient's experience of the CBPC (Figure 16a). After attending the CBPC and speaking to a professional, more positive sentiments were expressed by patients, such as "reassured", "relieved" and "happy" (Figure 16b). Staff also observed that patients felt more relaxed in a community setting rather than a hospital setting.

Figure 16a. How did you feel before attending the CBPC?



Figure 16b. How did you feel after attending the CBPC?



8 Value for Money

8.1 The cost of the Clinics

Cost estimates are provided in **Table 14**. For the purposes of this analysis, these estimates have been scaled to represent annual costs for all clinics run. The below costs were based on each individual Trust submissions. As these costs are by Trust rather than per clinic, they do not all reflect the same number of clinics.

The number of clinics run is one driver of variation in these costs, variation here is also caused by differences in staffing models, set-up costs and estate costs, The breakdown of costs can be found in **Appendix 10.**

Table 14. Costs per year of the pilot, by Trust

Centre	Staff Model (Lead Clinician)	Year 1 Cost (Set-Up Costs)	Year 2/3 Cost (Run/Maintain)
DBTH	Consultant/Band 6 Nurse	£87,913	£81,355
UHDB/CRHFT	Band 8a Nurse	£92,104	£91,154
ELHT	Physician Associate/Band 8a Nurse	£46,138	£34,138
ENH	Consultant	£45,884	£50,113
ESNEFT	Band 7 Nurse	£74,447	£69,304
KGH	Band 8a Nurse	£45,229	£45,229
LLR PCL	GP	£49,824	£50,274
ULH	Band 7 Nurse	£84,638	£77,638
NWA	Consultant/Band 7 Nurse	£78,593	£63,018
NUH	Band 7 Nurse	£43,203	£40,690
STHK	Band 8a Nurse	£33,470	£66,223
UHDB (S. Staff)	Band 8a Nurse	£29,745	£29,745
YSTH	Consultant Triage/Nurse	£45,513	£45,513
NLAG	Band 7 Nurse (w/ consultant cover)	£48,819	£46,120

8.1.1 Quantified benefits

Through the redirection of patients to CBPC, patients no longer require a referral to a BCDC. Therefore, we can calculate this cost saving.

8.1.2 Assumptions

To complete this analysis, we have used a few assumptions, including:

- BCDC referrals: It is assumed that all attendances at a CBPC would have otherwise been referred into a BCDC. On the foundation of this assumption, we use data from the pilots to estimate how many BCDC referrals were averted. Some patients who attend a CBPC are still later referred to a BCDC, which is accounted for in our estimates. This may be a BCDC appointment and accompanying scans or just diagnostic scans.
- Cost savings of the reduction in BCDC appointments: The assumptions and calculations are outlined in detail below
- For sites not functioning for a full 12 months: Costs were made proportional for the number of months that they have been open.

8.1.3 Reduction in BCDC appointments

For this calculation, we have used the past twelve months of CBPC attendances to calculate the number of averted BCDC attendances. Where clinics have not been functioning for twelve months, this has been done using all months available and scaling costs down.

Using this calculation, 3,385 BCDC appointments are expected to be avoided. Therefore, using reference costs adjusted for inflation, there is an anticipated saving of £809,421.



Note: 20/21 reference costs were inflated using 23/24 healthcare inflation values.

8.1.4 Reduction in Mammograms and Ultrasound Scans

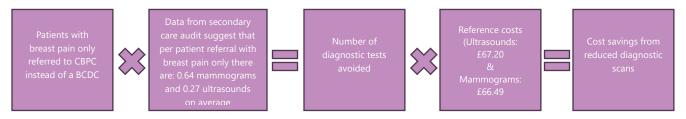
Alongside savings from the BCDC avoidance, there is also a saving associated with the reduction in diagnostic scans, namely mammograms and ultrasounds.

For mammograms, using the total number of avoided BCDC appointments of 3,385 in the first year of the clinics, there is a saving of £144,043. This uses an assumption from the secondary care audit which states that 0.64 mammograms are completed per BCDC referral (Jahan et al., 2022). It

also uses the reference cost which states that a mammogram costs £66.49 per scan (inflated using 23/24 healthcare inflation values).

Please note, a relatively small percentage of patients are sent for mammograms without a BCDC appointment. When these additional mammogram costs are factored in, the total mammogram cost saving for these patients drops to £143,113.

For ultrasounds, prior research from a secondary care audit found there are 0.27 scans per BCDC attendance (Jahan et al., 2022). We use the reference cost per scan is £67.20, inflated using 23/24 healthcare inflation values. Therefore, over the first year of the pilot there is anticipated to be a saving of £61,417.



Note: 20/21 reference costs were inflated 23/24 healthcare inflation values. YSTH Mammogram costs were subsequently subtracted from these cost savings.

8.2 Cost-Benefit Analysis

This analysis then looks at the costs and benefit of the last twelve months of the pilot across all pilot sites, using the figures outlined above.

8.2.1 Cost Benefit Analysis in Year 1

Using the benefits quantified as part of this evaluation, the overall benefit to cost ratio is 1.26 in the first year (**Table 15**). Therefore, for each £1 spent, the health system receives £1.26 in benefits.

Most sites in this cost benefit analysis have generated a financial return, however six sites, have a cost benefit ratio (CBR) that is lower than 1. However, of these six sites, five have a CBR > 0.85.

Table 15. Cost Benefit Analysis (Year 1)

Centre	Estimated total Y1 benefits	Estimated total Y1 costs	CBR	Net benefit
DBTH	£41,375	£87,913	0.47	-£46,538
UHDB/CRHFT	£159,203	£92,104	1.73	£67,099
ELHT	£97,074	£46,138	2.10	£50,936
ENH	£41,675	£45,884	0.91	-£4,209
ESNEFT	£65,360	£74,447	0.88	-£9,087
KGH	£64,761	£45,229	1.43	£19,532
LLR PCL	£105,836	£49,824	2.12	£56,012

Total	£1,013,952	£805,520	1.26	£208,432
NLAG	£43,474	£48,819	0.89	-£5,345
YSTH	£63,130	£45,513	1.39	£17,616
UHDB (S. Staff)	£77,053	£29,745	2.59	£47,308
STHK	£31,181	£33,470	0.93	-£2,288
NUH	£68,658	£43,203	1.59	£25,455
NWA	£69,125	£78,593	0.88	-£9,468
ULH	£86,048	£84,638	1.02	£1,410

8.2.2 Cost Benefit Analysis in Year 2

In year 2, all sites except DBTH, NLAG and NWA generate a financial return (CBR > 1), with DBTH and NLAG increasing their CBR from 0.55 to 0.88 and 0.89 to 0.91 respectively. The total CBR across all clinics is 1.40 in year 2 (**Table 16**).

However, NWA has stopped generating a positive financial return in year 2. This is driven by a fall in the number of avoided BCDC referrals from 85% to 62% in year 1 and 2 respectively.

For sites that have not been functioning for a full 24 months, their costs were made proportional for the number of months that they have been functioning in their second year. The sites that haven't been open for 24 months are DBTH, ELHT, KGH, ULH, NWA, NUH, UHDB (S. Staffs), YSTH and NLAG.

Table 16. Cost Benefit Analysis (Year 2)

Centre	Estimated total	Estimated total	CBR	Net benefit
	Y2 benefits	Y2 costs		
DBTH	£80,651	£120,232	0.67	-£39,581
UHDB/CRHFT	£319,606	£183,259	1.74	£136,347
ELHT	£120,460	£53,340	2.26	£67,120
ESNEFT	£145,412	£143,752	1.01	£1,660
KGH	£139,715	£75,340	1.85	£64,375
LLR PCL	£211,371	£100,098	2.11	£111,273
ULH	£195,181	£157,808	1.24	£37,373
NWA	£115,896	£139,367	0.83	-£23,471
NUH	£95,942	£56,358	1.70	£39,584
UHDB (S.				
Staffs)	£109,733	£40,747	2.69	£68,986
YSTH	£108,371	£77,186	1.40	£31,185
NLAG	£58,464	£63,855	0.92	-£5,390
Total	£1,700,802	£1,211,341	1.40	£489,462

8.2.3 Cost Benefit Analysis in Year 3

Only three sites have been running into a third year. These sites are UHDB, ESNEFT and LLR PCL. All sites generate a financial return or are cost neutral in the third year, with a total CBR of 1.56 (**Table 17**).

Table 17. Cost Benefit Analysis (Year 3)

Centre	Estimated total	Estimated total	CBR	Net benefit
	Y3 benefits	Y3 costs		
UHDB/CRHFT	£425,141	£251,437	1.69	£173,704
ESNEFT	£160,103	£160,651	1.00	-£548
LLR PCL	£220,666	£105,745	2.09	£114,921
Total	£805,910	£517,833	1.56	£288,077

8.3 Other benefits

Alongside the benefits quantified as part of this analysis, there are other considerations which are difficult to fully quantify at this time. These benefits include –

- Reducing pressures on the BCDCs with the potential to remove up to 20% of BCDC referrals with breast pain only leading to shorter waiting times. Given that the Getting it Right First Time Breast Surgery (GiRFT) National Specialty Report stated that there were approximately 50,000 referrals to BCDCs a month, around 10,000 may be due to referrals from low-risk patients with breast pain only in England (GIRFT, 2021). Removing these referrals from the BCDCs would have the potential to impact time to diagnosis, time to first treatment and therefore longer-term outcomes.
- There is a current workforce crisis in radiology, and in particular breast radiology. The EMBPP helps focus diagnostic imaging capacity on those with the greatest need and most likely to be diagnosed with breast cancer.
- Identifying individuals at increased familial breast cancer risk and enrolling them into an appropriate screening programme has the potential to lead to detection of earlier stage breast cancers which previous studies have reported improved cancer outcomes.
- Environmental benefits as patient travel time should decrease as they could attend a CBPC in the community rather than travelling to large secondary care centres. This is in line with the NHS Carbon Footprint Plus, including reaching net zero for all emissions that the NHS influences by 2045 (NHSE, 2022).

9 Findings and Next Steps

9.1 Findings

Health Economics

From a health economic perspective, when the EMBPP was assessed across all sites the clinic has proven to generate a financial return. Across all sites in Year 1 of the clinics, the healthcare system received back £1.26 for every £1 they invested in the CBPC. This rises into £1.40 in Year 2. This shows that this pathway is economically viable nationally.

Of the 14 sites in Cohort A, 8 generated a financial return on investment in year 1, with the CBR ranging from 2.59 to 1.02. Six sites did not generate a return on investment in year 1, however, five of these had a CBR > 0.85.

There are a number of reasons for the variation. The first is the cost of the clinic, namely the cost of the staffing model deployed by each site and the associated estate costs. Where sites had multiple clinicians covering a single clinic or more senior clinicians running the clinic the ongoing run costs were higher. Similarly, where clinics required payment for their estate costs as opposed to NHS owned sites, costs were higher without representing an opportunity for increased savings.

In keeping with this, three of these six sites generated a financial return in year 2. Of the remaining three sites, two have seen improvements in their CBR. For example, DBTH moved from 0.47 to 0.67 between their first and second year. The overall CBR also increased in year 2 from 1.26 to 1.40.

Improvements in the CBR in year 2 reflect both a reduction in start-up costs and the phased implementation of the clinics. As is common in pilots, the phased implementation caused underutilised clinics in the first year as referrals from GPs increased and the staff became more confident in the clinics. Additionally, clinics were continually learning and undergoing training to help increase productivity and reduce onward referrals.

One centre which is an outlier is NWA. NWA's CBR dropped from 0.88 to 0.83 between their first and second year. This is driven by a fall in the number of avoided BCDC referrals from 85% to 62% in year 1 and 2 respectively. This corresponds with the clinic no longer employing a consultant to support clinical activities. Although the costs decreased due to this staffing change, referrals into secondary care increased, reducing overall benefits. This emphasises the importance of an experienced breast clinician working in CPBCs.

It is also important to note that this analysis used conservative estimates for the proportion of BCDC referrals which require mammograms and ultrasounds to be conducted. Therefore, these benefits are likely to be higher in practice.

Findings and Next Steps

Patient Safety

In terms of safety, so far 20 patients who were eligible for the EMBPP have been diagnosed with cancer within twelve months of a CBPC attendance. Eleven patients were referred to the BCDC pathway through the CBPC and were subsequently diagnosed. For these patients, the average time from referral to diagnosis was 42 days.

Additionally, six patients were diagnosed through mammographic breast cancer screening. All patients attending CBPCs are provided with information regarding their eligibility for the NHSBSP and advised to participate in mammographic screening. Three of the six patients were diagnosed within 3 months of their CBPC appointment, and any breast cancer diagnosed within this 3 months' time-window were prospectively deemed to have been detected through their CBPC appointment. The other three patients were diagnosed between 108 – 287 days post CBPC appointment.

Three eligible patients were diagnosed through being referred back to the BCDC by the GP, all ≥ 3 months from being seen in the CBPC.

Cancer Prevalence

One of the primary findings from this evaluation is that the cancer prevalence, both total (3.3 per 1,000 people, CI: 2.2-5.0) and excluding patients who weren't eligible (2.8 per 1,000 people, CI: 1.8-4.3), is below the average found in patients presenting with 'breast pain only' in previous studies (4.6 per 1,000 people).

We do not currently have a full twelve months of follow-up data for all 7,326 patients so this may rise slightly when 12 months follow-up becomes available. For the 3,819 patients that we do have a full twelve months of follow-up data for, this prevalence rate is 4.5 per 1,000 (CI: 2.8-7.1 per 1,000). When excluding ineligible patients, this becomes 3.7 per 1,000 (CI: 2.2-6.2 per 1,000) for patients who fulfil the EMBPP criteria. This is comparable to the values found in the reviewed literature.

Patient Experience

A major finding is that the anonymised PROMs were positive across all sites and very reproducible for all measurements. For example, 98.7% of patients expressed that they would be either extremely likely or likely to recommend this service. This shows that patients like this service and demonstrates the value of relieving the anxiety and concern around the breast cancer pathway that these patients would have otherwise been referred into.

9.2 Considerations

9.2.1 Clinic Maturity

When comparing the last twelve months of data, we must consider that clinics will get more efficient as they mature, and staff settle into the new model of care. The same consideration must

be made for when staffing models or the staff themselves are changed. For example, there is huge variation in the amount of time that the clinics have been open. UHDB/CRHFT have been open since June 2021, whereas STHK have only been open since August 2023, giving them only 6 months until this audit ended. Therefore, we would expect to see as the clinics remain open for a longer period, that they would get more efficient and clinical effectiveness would increase, whilst also increasing the economic benefits of the clinic. From conversations with staff and plotting referral rates over time, clinic maturity has a big impact on referral rates, mainly due to the confidence of staff.

9.2.2 Staffing Models

Another consideration is the staffing models employed by each site. Eleven sites use a nurse-led model, three sites use a consultant-nurse combination, one site is led by a Physician Associate-Nurse combination whilst the remaining two sites are led by a GP or a Breast Physician.

This differentiation across sites could explain different referral rates. However, data to date does not show a conclusive association between one staff group and higher referral rates. One hypothesis is that instead of staff group, the referral rates may instead be affected by the seniority and number of years' experience in breast clinics the staff member has. A deep dive on the individual staff involved in these pilots is required to confirm this.

9.2.3 Familial Breast Cancer Risk

The initial data shows some variation between centres in the percentage of patients identified at potentially increased risk of breast cancer. However, this does not appear to be statistically significant, but does require further investigation.

Interestingly, on average 12% of patients seen within the CBPCs have an increased risk of breast cancer above 'near population' risk. At first sight this might appear lower than reported in the literature (15-30%, Table 1). However, these previous studies didn't define a family history and indeed if having one or more family member being diagnosed with breast cancer gives one a family history then this audit reports that 31% of patients had one or more family member having been diagnosed with breast cancer, while 12% (ie approximately one third of this cohort) had a family history which carried a significantly increased risk of breast cancer. The current audit may therefore be considered to have a similar percentage of patients with a family history. A further fact to consider is that there are currently wide confidence intervals for many sites. This is due to low sample sizes, as some clinics are still in their first few months of operation. Therefore, it is important this continues to be monitored.

Addressing this 'unmet need' fits with the NHS Long Term Plan (NHS, 2019) to decrease health inequalities" through improving "uptake of screening and early cancer diagnosis for people who currently miss out" and strengthening the NHS' contribution to cancer prevention. Given the

increasing focus on breast cancer prevention (UK Government, 2023), identification by primary care of individuals at increased risk of breast cancer and suitable for prevention strategies will be increasingly important.

9.3 Recommendations

From conversations with clinicians and administrative staff in Spring 2024, this evaluation has developed a diagram indicating the ideal pathway for a CBPC. This is displayed in **Figure 17**. The ideal pathway contains guidance for triaging patients in and out of the CBPC and the BCDC. It also contains best practice of tracking key performance metrics within the Trust to ensure that the CBPC is operating in the most efficient way. Key performance metrics include discharge rates from the CBPC and clinic attendances. Whilst this pathway is only illustrative, it has been developed with the help of experienced clinicians who have run Community Breast Pain Clinics.

Figure 17. Patient Pathway in a CBPC clinic

Best Practice: Primary care should be notified of Pathway allows patients with higher and more any triaging via a letter urgent clinical needs to be seen sooner in the **BCDC Pathway Best Practice:** Triaging should be done by someone with clinical experience GP (or other primary care clinician) should conduct an examination before referral to CBPC GP refers Patient to BCDC via ERS **BCDC** Triaging ineligible Triaging eligible patients into the patients out of the CBPC Patient is referred to the BCDC by the CBPC CBPC **BCDC** GP refers patient to CBPC via ERS CBPC GP Patient is discharged from the CBPC Gp discharges patient **Discharged Discharged** Referral to GP via ERS Best Practice: ERS should have a list of Best Practice: Key performance metrics should be exclusionary Criteria and allow direct referral to tracked by the clinic (such as discharge rates, the CBPC clinic attendances)

9.3.1 Clinic SOPs

As mentioned, throughout this national audit, usually in the immature stages of the clinic, some patients were referred to the CBPCs even when they met defined exclusion criteria. Key exclusion criteria include personal history of breast cancer, presence of any implants or the patient is male. In the initial stage of implementing and establishing the early CBPCs some patients with 'breast pain only' who also had a personal history of breast cancer were sent to the clinics. One of these patients was subsequently diagnosed with breast cancer early in the establishment of the CBPCs. As a result, a prior personal history of breast cancer became one of three exclusion criteria.

It is imperative that CBPCs have a clear Standard Operating Procedure in place to minimise the risk that patients are incorrectly referred to a CBPC and to deal with the scenario where a GP omits to mention a patient has a personal history of breast cancer. For example, a set list of questions could be asked to each patient at the beginning of their appointment to ensure that they are eligible for the CBPC, although this has the disadvantage of the patient having reached the clinic and taken up an appointment before it is confirmed they are eligible to be seen at the CBPC. Alongside this, it is important that this is clearly communicated with GPs with sufficient and continued education provided. Staff interviews reflected this need for sufficient and continued GP education, and suggestions from the interviews include guidance posters for GP surgeries, education events at GP training evenings and information provided on the Electronic Referral System. Alternatively, the referring doctor may have to confirm there is no personal prior history of breast cancer before being able to refer the patient to a CBPC.

9.3.2 Staffing Models

Eleven of the seventeen sites in this evaluation employ a nurse-led model for their clinics. The referral rates from CBPC to the BCDCs vary considerably between these eleven clinics. For example, four clinics that employ a nurse-led model are the lowest referrers to the BCDCs, whereas the top referrer is also a nurse-led clinic. This may be due to clinic maturity and the staff experience at the highest referring site not being as high as at the lower referring four; this was reflected within conversations with staff members. Overall, it appears nurse-led clinic models are associated with lower referral rates. However, it is important that more research is conducted to understand the difference in referral rates and whether this is solely due to the staffing models or if other factors are in play, like clinic maturity, staff experience and effectiveness of clinic triage.

10 References

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Appendix

Appendix 1. Names of Steering Committee and Operational Committee Members

a) Steering Committee

Organisation	Name	Role
EMCA	Mike Ryan	Head of Service EMCA
ABS	Miss Leena Chagla	President of ABS
ABS	Miss Sarah Downey	Vice President (President-Elect) of ABS
Cancer Alliances		
EMCA	Ellie Gutteridge	Consultant Breast Surgeon, Nottingham University Hospitals NHS Trust
Humber & North Yorkshire	Jenny Piper	Consultant Breast Surgeon, York Teaching Hospital NHS Foundation Trust
West Midlands (South Staffs)	Mark Sibbering	Consultant Breast Surgeon, University Hospitals of Derby & Burton NHS Foundation Trust
South Yorkshire	Clare Rogers	Consultant Breast Surgeon, Doncaster & Bassetlaw Hospitals NHS Foundation Trust
East of England (North)	Kate Jackman	Improvement Delivery Lead, East of England Cancer Alliance
East of England (South)	Jane Harper	Cancer Programme Lead, Hertfordshire & West Essex Integrated Care Board (ICB)
Lancashire & South Cumbria CA	Inder Kumar	Consultant Breast Surgeon, East Lancashire Hospitals NHS Trust
Merseyside & Cheshire	Sonia Bathla	Consultant Breast Surgeon, Mersey and West Lancashire Teaching Hospitals NHS Trust
RM Partners (London West)	Nicky Roche	Consultant Breast Surgeon, The Royal Marsden Hospital NHS Foundation Trust
North Central London CA	Claire Stephens	GP & Co-Clinical Director, North Central London (NCL) Cancer Alliance

b) Operational Committee

Organisation	Name	Role
Association of Breast	Carol-Ann	East Midlands Representative & member
Surgery (ABS)	Courtney	of ABS Clinical Practice & Standards
		Committee

Cancer Alliances

East Midlands	Julie Stone	Senior Elective Care Manager, NHS
East Midlands	Dinesh	Leicester, Leicestershire & Rutland ICB Consultant Breast Surgeon, United
Humber & North Yorkshire	Thekkinkattil Jennifer Smith	Lincolnshire Hospitals NHS Trust Consultant Breast Surgeon, Northern Lincolnshire & Goole NHS Foundation Trust & Breast Clinical Delivery Group Lead, Humber & North Yorkshire CA
Humber & North Yorkshire	Karen Lindley	Project Support Officer, Humber & North Yorkshire CA
West Midlands	Kelly Mandeley	Manager, University Hospitals of Derby & Burton NHS Foundation Trust
West Midlands	Lisa Rose	Advanced Nurse Practitioner, University Hospitals of Derby & Burton NHS Foundation Trust
South Yorkshire	Aysha Goodyear	Advanced Nurse Practitioner, Doncaster & Bassetlaw Hospitals NHS Trust
South Yorkshire	Claire Rogers	Consultant Breast Surgeon, Doncaster & Bassetlaw Hospitals NHS Trust
East of England (North)	Vanessa Hewick	Breast Services Manager and Lead Nurse, North West Anglia NHS Foundation Trust
East of England (North)	Habib Tafazal	Consultant Breast Surgeon, North West Anglia NHS Foundation Trust
East of England (South)	Fahad Matin	Programme Manager – Planned Care East & North Hertfordshire & West Essex ICB
East of England (South)	Harleen Deol	Consultant Breast Surgeon, East & North Hertfordshire NHS Trust and Eastern Regional Representative ABS
Lancashire & South Cumbria	Suzanne Gawne	Consultant Breast Surgeon, East Lancashire Hospitals NHS Trust
Lancashire & South Cumbria	Tom Anderton	Senior Project Manager Lancashire & South Cumbria Cancer Alliance & NHSE Alliance Pathway Lead: Breast NHS Cancer Programme
Merseyside & Cheshire	Sonia Bathla	Consultant Breast Surgeon, Mersey & West Lancashire Teaching Hospitals NHS Trust
Merseyside & Cheshire	Ashley Breckell	Senior Quality Improvement Project Manager, Merseyside & Cheshire CA
North Central London	Tina Keheller	Lead Nurse for Breast Services, Royal Free London NHS Foundation Trust
North Central London	Muneer Ahmed	Consultant Breast Surgeon, Royal Free London NHS Foundation Trust

Appendix

RM Partners (London West)	Lindsay Farthing	Programme Lead -Earlier & Faster Diagnosis, RM Partners
RM Partners (London West)	Nicky Roche	Consultant Breast Surgeon, The Royal Marsden Hospital NHS Foundation Trust

Appendix 2. Descriptive statistics of patient's age, by Cancer Alliance and Provider

Descriptive statistics of patient characteristics

Variable	N	N =	Cheshire & Merseyside $N = 168^{7}$			(South)		N =	London	South Yorkshire N = 360 ⁷	
Age at attendance	7,320	48 (16, 92)	49 (16, 82)	48 (16, 92)	48 (16, 90)	48 (18, 85)	47 (17, 87)	49 (18, 88)	49 (34, 78)	48 (16, 86)	49 (16, 92)

Descriptive statistics of patient characteristics

Variable	N	DBTH N = 309 ⁷	ELHT N = 435 ⁷	ENH N = 151 ⁷	ESNEFT N = 637 ⁷	KGH N = 493 ¹	LLR PCL N = 949 ⁷	NLAG N = 213 ⁷	NUH N = 343	NWA N = 523 ⁷	STHK N = 119 ⁷	(S. Staff.) N = 415 ⁷	UHDB/CRHFT $N = 1514^{7}$	ULH N = 730 ⁷	YSTH N = 368 ⁷
Age at attendance	7,199	46 (17, 86)	49 (18, 88)	48 (18, 85)	48 (19, 85)	47 (19, 89)	45 (16, 90)	45 (17, 82)	50 (17, 90)	48 (16, 90)	47 (16, 82)	49 (16, 92)	50 (16, 88)	49 (17, 92)	48 (17, 87)

Descriptive statistics of patient characteristics

		CoCH	DBTH (Bassetlaw)	RFL
Variable	N	$N = 49^{7}$	$N = 51^{7}$	$N = 21^{1}$
Age at attendance	121	52 (24, 81)	54 (16, 79)	49 (34, 78)
¹ Median (Range)				

Appendix 3. Descriptive statistics of patient's IMD, by Cancer Alliance and Provider

Descriptive statistics of patient characteristics

V ariable ¹	N	N =	Cheshire & Merseyside $N = 168^2$	Midlands	(North)	England (South)		N =	London	Yorkshire	
IMD Score	5,666	6 (1, 10)	7 (1, 10)	6 (1, 10)	6 (1, 10)	7 (2, 10)	7 (1, 10)	NA (Inf, -Inf)	NA (Inf, - Inf)	3 (1, 10)	4 (1, 10)

Note: IMD: The Index of Multiple Deprivation, a measure of relative deprivation for small areas.

Descriptive statistics of patient characteristics

								LLR					UHDB (S.			
V ariable ¹	N	N =	N =	N =	N =		N =	N =	N =	N =	N =	N =	N =	UHDB/CRHFT N = 1514 ²	N =	
IMD Score	5,617	6 (1, 10)	3 (1, 10)	NA (Inf, - Inf)	7 (2, 10)	6 (1, 10)	NA (Inf, -Inf)	7 (1, 10)	NA (Inf, - Inf)	6 (1, 10)	6 (1, 10)	NA (Inf, - Inf)	4 (1, 10)	6 (1, 10)	6 (1, 10)	7 (1, 10)

⁷ **Note:** IMD: The Index of Multiple Deprivation, a measure of relative deprivation for small areas.

Descriptive statistics of patient characteristics

		Overall	СоСН	DBTH (Bassetlaw)	RFL
Variable ⁷	N	$N = 121^2$	$N = 49^2$	$N = 51^2$	$N = 21^2$
IMD Score	49	7 (1, 10)	7 (1, 10)	NA (Inf, -Inf)	NA (Inf, -Inf)

¹ **Note:** IMD: The Index of Multiple Deprivation, a measure of relative deprivation for small areas.

Appendix 4. Descriptive statistics of patient outcomes, by Cancer Alliance

Summary of the referrals and discharges per cancer alliance

7326 ¹	Merseyside $N = 168^{7}$	$Midlands$ $N = 4029^{7}$	England (North) N = 1163 ⁷	England (South) N = 151 ⁷	and North Yorkshire N = 582 ¹	N = 437 ¹	Central London N = 21	South Yorkshire $N = 360^{7}$	West Midlands $N = 415^7$
6,439 (88%)	151 (90%)	3,592 (89%)	915 (79%)	142 (94%)	537 (92%)	398 (91%)	18 (86%)	317 (88%)	369 (89%)
887 (12%)	17 (10%)	437 (11%)	248 (21%)	9 (6.0%)	45 (7.7%)	39 (8.9%)	3 (14%)	43 (12%)	46 (11%)
	(88%)	(88%) 151 (90%) 887 17 (10%)	(88%) 151 (90%) (89%) 887 17 (10%) 437 (11%)	(88%) 151 (90%) (89%) 915 (79%) 887 17 (10%) 437 (11%) 248 (21%)	(88%) 151 (90%) (89%) 915 (79%) 142 (94%) (89%) 915 (79%) 142 (94%)	(88%) 151 (90%) (89%) 915 (79%) 142 (94%) 537 (92%) 887 17 (10%) 437 (11%) 248 (21%) 9 (6.0%) 45 (7.7%)	(88%) 151 (90%) (89%) 915 (79%) 142 (94%) 537 (92%) (91%) (91%)	(88%) 151 (90%) (89%) 915 (79%) 142 (94%) 537 (92%) (91%) 18 (86%) (88%) 17 (10%) 437 (11%) 248 (21%) 9 (6.0%) 45 (7.7%) 39 3 (14%)	(88%) 151 (90%) (89%) 915 (79%) 142 (94%) 537 (92%) (91%) 18 (86%) 317 (88%) (88%) 17 (10%) 437 (11%) 248 (21%) 9 (6.0%) 45 (7.7%) 39 3 (14%) 43 (12%)

² Median (Range)

² Median (Range)

² Median (Range)

Appendix 5. Descriptive statistics on referral source, by Cancer Alliance

Summary of the referral sources to secondary care per cancer alliance

Overall N = 872 ¹	Cheshire & Merseyside N = 15 ⁷	East Midlands N = 431 ⁷	East of England (North) N = 244 ⁷	East of England (South) N = 12 ⁷	Humber and North Yorkshire N = 45 ⁷	LSCCA N = 36 ⁷	South Yorkshire N = 40 ⁷	West Midlands N = 49
824 (94%)	14 (93%)	401 (93%)	244 (100%)	9 (75%)	40 (89%)	33 (92%)	37 (93%)	46 (94%)
41 (4.7%)	1 (6.7%)	23 (5.3%)	0 (0%)	3 (25%)	5 (11%)	3 (8.3%)	3 (7.5%)	3 (6.1%)
7 (0.8%)	0 (0%)	7 (1.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	N = 872 ⁷ 824 (94%) 41 (4.7%)	N = Merseyside 872 ⁷ N = 15 ⁷ 824 (94%) 14 (93%) 41 (4.7%) 1 (6.7%)	N = Nerseyside N = 15' Midlands N = 431' 824 (94%) 14 (93%) 401 (93%) 41 (4.7%) 1 (6.7%) 23 (5.3%) 7 0 (0%) 7 (1.6%)	Overall N = 872¹ Cheshire & Merseyside N = 15¹ East Midlands (North) N = 244¹ England (North) N = 244¹ 824 (94%) 14 (93%) 401 (93%) 244 (100%) 41 (4.7%) 1 (6.7%) 23 (5.3%) 0 (0%) 7 0 (0%) 7 (1.6%) 0 (0%)	Overall N = N = 872¹ Cheshire & Merseyside N = 15¹ East Midlands (North) N = 244¹ England (South) N = 12¹ 824 (94%) 14 (93%) 401 (93%) 244 (100%) 9 (75%) 41 (4.7%) 1 (6.7%) 23 (5.3%) 0 (0%) 3 (25%) 7 0 (0%) 7 (1.6%) 0 (0%) 0 (0%)	Overall N = N = N = N = N = N = N = N = N = N	Overall N = N = N = N = N = N = N = N = N = N	Overall N = N = N = N = N = N = N = N = N = N

Appendix 6. Summary of follow-up recommendations for patients, by detailed recommendation and Cancer Alliance

Summary of recommendations

	Overall
ariable	$N = 6903^{7}$
ecommendation	
Population Risk	4,720 (68%)
'Near Population'	1,338 (19%)
Refer to Secondary Care	497 (7.2%)
Discuss with Secondary Care	316 (4.6%)
Refer to Tertiary Care	32 (0.5%)

Appendix

Summary of recommendations per cancer alliance

Variable	Overall N = 6903 ¹	Cheshire & Merseyside N = 180 ⁷	East Midlands N = 3747	East of England (North) N = 1114	East of England (South) N = 138 ⁷	Humber and North Yorkshire N = 453 ⁷	LSCCA N = 486 ⁷	North Central London N = 21 ⁷	South Yorkshire N = 352 ⁷	West Midlands $N = 412^7$
Recommendation										
Population Risk	4,720 (68%)	113 (63%)	2,597 (69%)	739 (66%)	93 (67%)	316 (70%)	341 (70%)	19 (90%)	244 (69%)	258 (63%)
'Near Population'	1,338 (19%)	39 (22%)	726 (19%)	229 (21%)	27 (20%)	79 (17%)	79 (16%)	0 (0%)	71 (20%)	88 (21%)
Refer to Secondary Care	497 (7.2%)	15 (8.3%)	247 (6.6%)	90 (8.1%)	12 (8.7%)	33 (7.3%)	34 (7.0%)	1 (4.8%)	28 (8.0%)	37 (9.0%)
Discuss with Secondary Care	316 (4.6%)	13 (7.2%)	166 (4.4%)	51 (4.6%)	4 (2.9%)	19 (4.2%)	28 (5.8%)	0 (0%)	9 (2.6%)	26 (6.3%)
Refer to Tertiary Care	32 (0.5%)	0 (0%)	11 (0.3%)	5 (0.4%)	2 (1.4%)	6 (1.3%)	4 (0.8%)	1 (4.8%)	0 (0%)	3 (0.7%)
¹ n (%)										

Appendix 7. Additional time between CBPC and subsequent Breast Cancer Diagnostic Clinic attendance, by Centre

Provider	Time between referral and CBPC attendance (days)	Time between CBPC attendance and Secondary Care Appointment (days)	Time between CBPC attendance and Cancer Diagnosis (days)
СоСН	9.3	NA	NA NA
DBTH	11.4	13.4	NA
DBTH (Bassetlaw)	13.5	NA	NA
ELHT	24.4	23.8	137.5
ENH	14.5	13.3	NA
ESNEFT	37.2	13.1	19.4
KGH	20.2	17.2	26.0
LLR PCL	18.7	7.3	18.9
NLAG	17.6	13.0	NA
NUH	22.3	37.6	73.5
NWA	24.6	20.5	34.4
STHK	10.9	5.4	NA
UHDB (S. Staff.)	13.5	18.4	NA
UHDB/CRHFT	11.3	22.6	81.6
ULH	16.0	16.8	146.0
YSTH	20.3	162.0	165.0
Overall	18.6	15.9	53.2

Appendix 8. Median and range of time gaps for patients diagnosed with cancer, by referral route.

Time - Days (Median & range)

					3 -,	
Referral source	Number of patients		Gap from referral to CBPC	Gap from CBPC to Breast Cancer Diagnostic Clinic	Gap from CBPC to diagnosis	Gap from Breast Cancer Diagnostic Clinic to diagnosis
		Median	12	12	21	7
BPC	13	Min	7	6	14	1
		Max	51	26	47	35
		Median	11.5	128	137.5	10
GP	4	Min	0	41	98	8
		Max	35	162	171	57
		Median	10	93	101	6
Screening	7	Min	6	15	28	0
		Max	20	355	272	13

Appendix 9. GP advice to Patients prior to CBPC attendance, by Cancer Alliance and centre

Did your GP advise you that breast pain is not a symptom of breast cancer?

Variable	Overall N = 6739 ⁷	Cheshire & Merseyside N = 183 ⁷	East Midlands N = 3565 ⁷	East of England (North) N = 1032	East of England (South) N = 199 ⁷	Humber and North Yorkshire N = 481 ⁷	N = 482 ⁷	North Central London N = 8 ⁷	South Yorkshire N = 348 ⁷	West Midlands N = 441
Yes	4,973 (75%)	133 (75%)	2,707 (77%)	746 (75%)	146 (83%)	340 (73%)	348 (75%)	6 (75%)	229 (66%)	318 (72%)
No	1,630 (25%)	44 (25%)	823 (23%)	251 (25%)	30 (17%)	123 (27%)	116 (25%)	2 (25%)	118 (34%)	123 (28%)
Unsure	3 (<0.1%)	0 (0%)	0 (0%)	3 (0.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
¹ n (%)										

Did your GP advise you that breast pain is not a symptom of breast cancer?

						LLR					UHDB			
Variable	DBTH N = 302 ⁷	N = 482 ¹	ENH N = 199 ⁷	ESNEFT N = 603 ⁷	KGH N = 478 ⁷		NLAG N = 166 ⁷	NUH N = 333 ¹	NWA N = 429 ¹	STHK N = 136 ⁷	(S. Staff.) N = 441 ⁷	UHDB/CRHFT N = 1605 ⁷	ULH N = 589 ¹	YSTH N = 315 ¹
Yes	199 (66%)	348 (75%)	146 (83%)	456 (78%)	349 (73%)	434 (79%)	104 (67%)	243 (78%)	290 (70%)	93 (72%)	318 (72%)	1,235 (77%)	446 (76%)	236 (77%)
No	102 (34%)	116 (25%)	30 (17%)	126 (22%)	128 (27%)	114 (21%)	52 (33%)	70 (22%)	125 (30%)	37 (28%)	123 (28%)	370 (23%)	141 (24%)	71 (23%)
Unsure	0 (0%)	0 (0%)	0 (0%)	3 (0.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%

Did your GP advise you that breast pain is not a symptom of breast cancer?

ariable	CoCH $N = 47^{T}$	DBTH (Bassetlaw) $N = 46^{7}$	RFL $N = 8^{T}$
Yes	40 (85%)	30 (65%)	6 (75%)
No	7 (15%)	16 (35%)	2 (25%)
Unsure	0 (0%)	0 (0%)	0 (0%)

Appendix 10. Cost Summary (Year 1)

Cost Line	UHDB/ CRHFT	LLR PCL	ULH	NUH	кдн	NLAG	YSTH	NWA	ESNEFT	ENH	DBTH	ELHT	STНК	UHDB (S.Staff)
Set-up Costs														
Laptop	£780	-	1	£2,487	-	£2,800	-	£2,380	£1,982	£1,018	£4,485	£7,000	£900	-
Phones	£140	-	-	-	-	-	-	-	£224	-	£492.20	-	-	-
Miscellaneous	£30	-	£4,000	£26	-	£250	-	£6,000	-	6,552	£346	£5,000	-	-
Training	-	-	£3,000	-	-	-	-	£7,195	£2,937	£66.89	£1,235	-	-	-
Admin														
Band 2 Admin	-	-	-	-	-	-	-	-	-	-	-	-	-	£5,118
Band 3 Admin	£27,729	-	£31,686	£12,674	£6,337	£2,535	£12,674	£25,349	£25,349	-	£15,843	-	-	£8,925
Band 4 Coordinator	-	-	-	-	-	-	-	-	-	£14,177	-	-	£35,443	-
Band 3 Healthcare Assistant	-	-	-	-	-	£3,169	-	-	-	-	-	£3,169	-	-
Clinical Staff														
Band 7 Specialist Nurse	-	-	£24,727	£12,364	-		£24,727	£30,909	£24,727	-	-	-	-	-
Band 7 Physician Associate	-	=	-	=	-	-	-	-	-	-	-	£12,364	-	-
Band 6 Nurse Practitioner	-	=	ı	=	-	-	-	-	-	ı	£25,099	-	-	-
Band 8a Specialist Nurse	£30,823	-	-	-	£14,556	-	-	-	-	-	-	£14,556		£8,018
Band 7 Advanced Nurse Practitioner	-	-	-	-	-	£6,182	-	-	-	-	-	-	-	-
Band 8a Advanced Nurse Practitioner	-	-	-	-	-	-	-	-	-	-	-	-	£14,556	-
Breast Physician	-	-	-	-	-	-	-	-	-	£25,536	£24,412	-	-	-
Consultant	£8,266	-	-	-	-	£13,440	-	-	-	-	-	-	-	£1,600
Tariff														
Tariff	-	£33,600	-	-		-	-	-	-	-	-	-	_	-
Additional Run Co	osts													
Estate	-	-	£5,000	£7,540	-	£3,600	-	-	£3,004	£2,600	-	-	-	-
FaHRAS	£24,336	£16,224	£16,224	£8,112	£24,336	£16,843	£8,112	£6,760	£16,224	£7,800	£16,000	£4,050	£16,224	£6,084
Total Costs	£92,104	£49,824	£84,638	£43,203	£45,229	£48,819	£45,513	£78,593	£74,447	£57,750	£87,913	£46,138	£67,123	£29,745





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or email us at:

info@edgehealth.co.uk