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East Midlands Breast Pain Pathway: An Evaluation of Community Breast Pain Clinics Across the East Midlands Cancer Alliance

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ABSTRACT

Rationale: Research indicates that breast pain as the sole symptom has no association with breast cancer. However, patients with breast pain only are often referred onto urgent breast cancer diagnostic pathways, leading to unnecessary anxiety and overutilisation of secondary health care services. The novel community breast pain clinic (CBPC) service in the UK aims to improve patient care while providing system-wide improvements for patients with breast pain, patients who have ‘red flag’ symptoms, as well as being cost-effective.

Aim and Objectives: This study seeks to evaluate and assess the impact of the CBPC on patient care, experience, and healthcare system improvements.

Methods: Quantitative and qualitative analysis of CBPC was undertaken using data from CBPC based on a core data set designed by the programme team, secondary care follow-up data, Patient Reported Outcomes Measure (PROMs) data and family history data.

Results: The CBPC was well-received by patients with 98.5% recommending the service. Additionally, health economic analysis indicated a cost benefit ratio of 1.23 in year 1, indicating a positive return on investment. Breast cancer incidence within the cohort was estimated at 3.2 per 1000, in line with population estimates in the literature. For those with a breast cancer diagnosis, there is no evidence of care delays or missed diagnoses via the service.

Conclusion: The CBPC offers significant benefits in patient experience and value for money, with no evidence of reducing patient safety. The impacts of the clinics appear to be reproducible across all five centres in the East Midlands (a population of 5.5 million). Recommendations on further assessment on optimal staff mix and clinic cost mechanisms should be considered to maximise benefits.

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1 | Introduction

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 [1]. Research indicates that breast pain as the only symptom has no association with breast cancer [2–13]. National Health Service (NHS) England has also provided guidance that “breast pain as a sole symptom is rarely a presenting feature of breast cancer... 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” [14].

Similarly, the British Society of Breast Radiology (BSBR) has stated that “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.” [15].

Despite this, patients in the UK NHS are often unnecessarily referred onto the urgent suspected cancer pathway, adding anxiety for patients. Consequently, hospital trusts are setting up and increasing pressure on additional one-stop and out-of-hours clinics to manage the increasing demand [16].

Additionally, with each one-stop clinic appointment there is a high likelihood that diagnostic tests, such as mammograms and ultrasounds, are completed [16]. These services are under significant pressure from rising one-stop-clinic attendances, alongside major staff shortages within the breast imaging profession. In 2023, it was estimated that 12% of mammographic workforce posts were vacant and staffing has not increased in line with demand [17].

Given the BSBR's statement that the sole symptom of breast pain is not an indication for breast imaging, it is important that patients with breast pain only are appropriately managed to prevent unnecessary additional pressure on these services and also not to expose patients to unnecessary radiation.

There also presents an opportunity to identify patients with a family history of breast cancer within these cohorts. Studies have shown that patients presenting with breast pain have a higher-than-expected prevalence of family history of breast cancer when compared to the general population [3, 4, 6–8, 12, 13] with reported rates ranging from 15%–38%. Recognising a patient's family history of breast cancer is essential, as it enhances awareness about future risk and can promote appropriate screening and/or risk reducing strategies.

This becomes more crucial as primary care physicians often do not ask about or discuss family history of breast cancer and other risk factors with patients; one study reported that the percentage of patients having been asked about a family history of breast cancer and informed about breast cancer prevention issues was 35.1% and 26.4%, respectively [18]. This may be due to a lack of confidence among GPs at calculating risk of breast cancer or counselling on the risk of breast cancer. In one study, GPs were asked to state which of three groups they would place themselves – “not confident or a little confident”, “moderately confident” or “confident or very confident”. Of the GPs who reported themselves to be “not confident or a little confident”, 90% for calculating risk and 83% for counselling about risk of breast cancer [19].

Given the significant opportunity to optimise the management of patients with breast pain only, Community Breast Pain Clinics (CBPCs) have, with the support of the East Midlands Cancer Alliance (EMCA), been set up across the East Midlands, covering a population of approximately 5.5 million. This follows a pilot within Derbyshire (a population of ~1 million) which was set up under the governance of Joined Up Care Derbyshire (JUCD). This community breast pain pathway model has been endorsed by both the NHS England Getting It Right First Time (GIRFT) programme, referenced in the Faster Diagnosis Standards [14] and supported by the Association of Breast Surgery (ABS).

This audit aims to build the evidence of the impact of these clinics for women presenting to primary care with breast pain as their only symptom. It tested whether the CBPC model could be scaled up across the whole of EMCA with similar results to those seen in the Derbyshire pilot. The core questions it aimed to test were:

1. Does the CBPC model of care improve quality of care?
2. Is the CBPC model provide value for money (i.e. what does the cost-benefit analysis show)?
3. Is the CBPC model of care accepted by patients?

2 | Methods

2.1 | CBPCC Design

The Community Breast Pain Clinic (CBPC) is a novel service, and first in the UK, tackling the rising tide of symptomatic breast one-stop-clinic referrals. The CBPCs offer dedicated primary care/community specialist breast pain clinics following the East Midlands Breast Pain Pathway (EMBPP). These clinics aim to improve patient care and experience while simultaneously providing a system wide improvement (Primary, Secondary & Tertiary Care).

Clinics in Derbyshire opened in June 2021, followed by Leicestershire in January 2022, Lincolnshire in April 2022, then Nottinghamshire and Northamptonshire in September and November 2022, respectively (Appendix 1).

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. Experienced breast clinician (Advanced Nurse Practitioner, GP with Specialist Interest, Specialty Doctor, Consultant) confirms no clinical abnormality following examination and that the patient has no other symptoms; and
4. Family History Risk Assessment–triage according to NICE CG164 [20] referral guidelines for primary care.

The inclusion criteria are women aged 16 or over presenting to their GP with breast pain as their only symptom. Patients with

additional symptoms should not be referred to these clinics. The exclusion criteria for the clinics are a personal history of breast cancer (at increased breast cancer risk) and mammary implants (more likely to require imaging or a surgical opinion).

Familial breast cancer risk assessment was carried out according to NICE Guidelines (CG164) for Familial Breast Cancer in primary care [20]. This was done using the Family History Risk Assessment Software (FaHRAS) which is a risk assessment and patient management tool [21] along with the supporting, validated family history questionnaire (FHQ) to gather the family history (FH) information [22]. Further information is provided in Appendix 2.

There was prospective collection of a defined audit data set including: (i) core demographic data obtained via local hospital systems, (ii) CBPC outcome data collected on the day of attendance, (iii) risk assessment data following input to FaHRAS at the clinic, (iv) Patient Reported Outcome Measures (PROMs) by anonymised questionnaires and, (v) secondary care follow up data relating to subsequent one-stop-clinic attendance or cancer diagnosis. For the latter data, NHS numbers of all patients who attended the CBPC were run (a) against the one-stop-clinic attendance list for an appointment within 3 months of their CBPC visit and (b) against the hospital pathology database for a diagnosis of breast cancer within 12 months following the date of their original CBPC appointment to identify subsequent one-stop-clinic attendance within 3 months &/or breast cancer diagnosis within 12 months respectively. The case notes of each patient identified were reviewed by the clinical breast lead at the centre and the relevant data collected.

PROMs were collected via an anonymised paper questionnaire given to the patient at the end of their consultation as they were being checked out of the CBPC by admin staff, with a box at the clinic exit into which the patient could slip their completed questionnaire.

The full CBPC pathway and implementation schedule can be seen in Figure 1.

Each of the clinics deployed a different experienced breast clinician model. These are summarised in Table 1.

2.2 | Information Governance and Data Sharing

Each participating centre registered the audit locally, carried out a Data Processing Impact Assessment (DPIA) and signed a Data Sharing Agreement with Edge Health, the health care company which carried out the audit data analyses. The project used pseudonymised data (in line with the Information Commissioner's Office) received from participating Trusts. The Trusts provided CBPC data based on a core data set designed by the programme team, secondary care follow-up data, PROMS data and family history data. The core data set, secondary care data and family history data were linked together before analysis. National op-out was applied to the data shared with the exception of the PROMs data which was fully anonymised.

At the time of this evaluation, each clinic had been open for differing periods. All data from patients seen within the CBPC within the East Midlands audit start date, which for individual centres ran

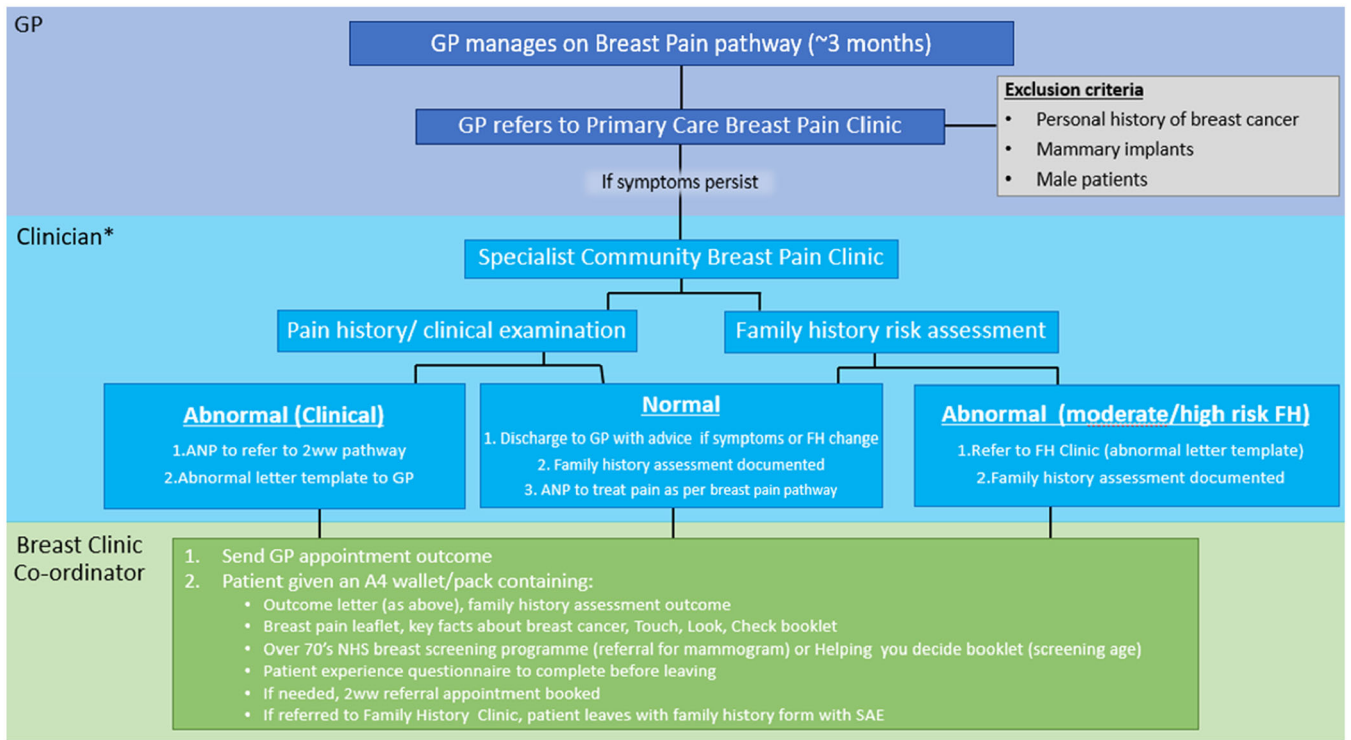


FIGURE 1 | Community Breast Pain Clinic–Breast Pain Pathway. *Clinician could be Advanced Nurse Practitioner, GP with Specialist Interest or Hospital Doctor.

from June 2021 to November 2022 (Appendix 1–Implementation Timeline) and 28th April 2023, has been included. Follow-up secondary care data was collected until the 9th June 2023. The data from Leicestershire only covers the final 6 months of the pilot.

2.3 | Analysis

2.3.1 | Audit Framework

This audit was prospectively designed using the NHS Triple Aim Framework. This was chosen as it is recommended by the NHS to effectively evaluate health-related interventions. It focuses the analysis on three aims: quality of care, cost effectiveness and patient experience.

2.3.2 | Quantitative Analysis

Quantitative analysis conducted during this audit used R Studio. Data from Trusts was loaded into R, linked (where possible) and cleaned before analysis.

2.3.3 | Cost Benefit Analysis Assumptions

A number of assumptions were used to undertake the cost benefit analysis, including:

- It is assumed that all attendances at a CBPC would have otherwise been referred onto an urgent suspected cancer pathway. On the foundation of this assumption, we use data from the pilots to estimate how many one-stop-clinic referrals were averted. Some patients who attend a CBPC are still later referred along an urgent suspected cancer pathway, which is accounted for in our estimates.
- Costs have also been assumed to be the same as year 1 (except for Derbyshire as these costs were known), less fixed costs. It is anticipated that some costs will rise in the second year of the pilot at some sites due to adaptations and learnings in the first year.
- To provide annual values, the number of attendances at a CBPC at each site has been scaled to 1 year. This has been done by using the average attendances for last full 3 months of the pilot as an indicator of potential attendances for any remaining months.
- For the analysis of year 2 costs and benefits, only staffing costs for the second year have been included. As Derbyshire

was in its second year at the time of the analysis, actual year 2 costs were used. For the remaining sites, the same staffing costs were rolled into year 2. Benefit calculation assumptions stayed the same in year 2.

3 | Results

3.1 | Descriptive Statistics of Population Utilising CBPCs

2,066 patients were seen in the CBPCs, of which 131 had signed the national opt-out. The data indicates that, of the remaining 1,935 attendances to CBPCs across the 5 pilot sites, the average age of patients attending the CBPCs during the pilot phase was 48 years (range 16–92) (Appendix 3). These patients, on average, had an Index of Multiple Deprivation (IMD) score of 6 (range 1–10). The highest IMD score, representing the least deprived areas, is 10, with 1 representing to most deprived areas. The distribution per 100,000 population, can be found in Appendix 4.

Additionally, the patients’ ethnicities have also been tracked (Table 2). This shows that 51% of the contacts at across the CBPCs reported being white, 4.7% Asian, 1.2% black and 0.9% mixed. Due to variable collection of ethnicity data, 42% of the contacts did not have their ethnicity recorded.

3.2 | Patient Follow-Up Recommendation

The patients are tracked through their pathways to determine the outcome of their CBPC visit. A table with a summary of the follow-up period can be found in Appendix 5.

This showed that, of the 1935 contacts through the CBPC during the pilot, 91% had no onward referral and 9% were

TABLE 2 | Descriptive statistics of patient ethnicity.

Variable Ethnicity	n 1935	n (%)
White		989 (51.1)
Unknown		813 (42)
Asian		91 (4.7)
Black		24 (1.2)
Mixed		18 (0.9)

TABLE 1 | Experienced Breast Clinician Model.

Centre	Experienced breast clinician model
Derbyshire	Advanced Nurse Practitioner (Breast Specialist)
Leicestershire	GP with Special Interest
Lincolnshire	Specialist Nurse
Northamptonshire	Advanced Nurse Practitioner (Breast Specialist)
Nottinghamshire	Advanced Nurse Practitioner (Breast Specialist)

referred on to the urgent suspected cancer pathway (Table 3). There is some variability between the percentages of each outcome in each area. The percentage discharged from the CBPC ranged from 96% at Derbyshire & Nottinghamshire, through 94% at Northamptonshire, 81% at Lincolnshire to 76% at Leicestershire.

The data collected also allows the analysis of appointments in secondary care, either as an outcome of onward referral from the CBPC, or through other routes, (e.g. indirectly via screening). Across all sites, of those patients seen within the CBPC, 162 were subsequently seen in secondary care within the defined time periods noted above – i.e., within 3 months for a visit to the one-stop-clinic and/or within 12 months for a diagnosis of breast cancer; 139 (7.2% of total CBPC attendances) of these 162 patients were referred directly from the clinic. There were then also 20 (1%) of patients as new referrals through their GP and 3 (0.2% of total CBPC attendances) patients referred via screening. There were 14 patients referred to secondary care following their CBPC attendance, who had not yet been seen within secondary care by the data lock for this report.

3.3 | Family History Risk Assessment

One of the features of the CBPC pathway is that patients were each offered an assessment of future breast cancer risk using the NICE CG164 guideline, which was facilitated using FaH-RAS software as described in the methods section.

The management recommendations from FaHRAS based on the NICE CG164 risk assessment can be defined as:

- **‘Near Population’ risk** - patient may have a relative with breast cancer but does not need further follow up.

- **Moderate or high risk** - patient has relatives with breast cancer and/or other relevant factors (including genetic mutations) and requires onward management in secondary or tertiary care.

The data shows that 1838/1935 (95%) attendances had a FaH-RAS recommendation provided during the pilot, while 97 (5%) patients did not. Of the 1838 patients, 10.6% were assessed as moderate or high risk (Table 4). 19.5% had at least one family member with a history of breast cancer, but not sufficient to place the current patient into an increased risk category. The remaining 69.9% had no family history of breast cancer meaning that, overall, 89.4% were deemed ‘near population’ risk.

3.4 | Patient Experiences

Throughout the pilot, patient experience has also been collected as part of a PROMS fully anonymised questionnaire which provided both quantitative and qualitative data. Since the PROMs were completely anonymised, it was not possible to apply the national op-out and so there are data from 2,066 PROMs returns.

Notably, the patients were asked how likely they would be to recommend this service to friends and family if they had troublesome breast pain (Figure 2a). This showed that 98.5% of patients were “extremely likely or likely” to recommend this service to friends and family. Full PROMS data can be found in Appendices 6–9.

3.5 | Qualitative PROMs

The final questions gave patients the option to respond about their feelings pre- and post-attendance at the CBPC in free-text.

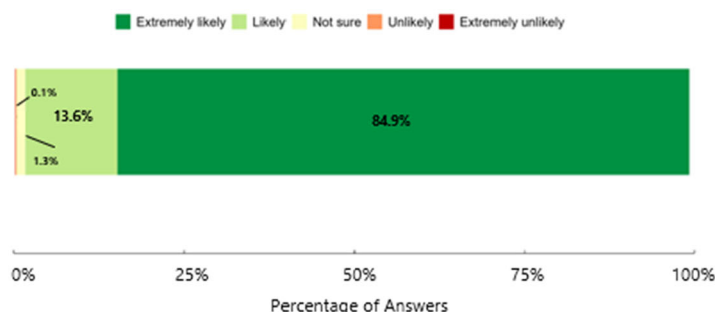
TABLE 3 | Descriptive statistics of patient outcomes.

Variable	Overall n = 1935	Derbyshire n = 1027	Leicestershire n = 212	Lincolnshire n = 337	Northamptonshire n = 244	Nottinghamshire n = 115
Clinic Outcome						
No Onward Referral	1759 (91)	984 (95.8)	160 (75.5)	275 (81.4)	230 (94.3)	110 (95.7)
Onward Referral to one-stop-clinic	176 (9)	43 (4.2)	52 (24.5)	62 (18.4)	14 (5.7)	5 (4.3)

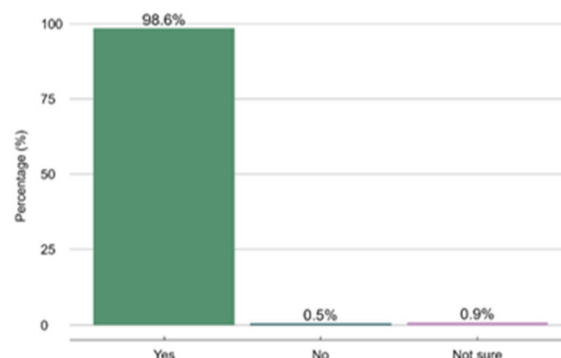
TABLE 4 | Summary of follow-up recommendations for patients.

Variable	Overall n = 1838	Derbyshire n = 1024	Leicestershire n = 203	Lincolnshire n = 317	Northamptonshire n = 190	Nottinghamshire n = 104
Follow-up recommendation						
Near population risk	1644 (89.4)	905 (88.4)	194 (95.6)	288 (90.9)	167 (87.9)	90 (86.5)
Moderate or high risk	194 (10.6)	119 (11.6)	9 (4.4)	29 (9.1)	23 (12.1)	14 (13.5)

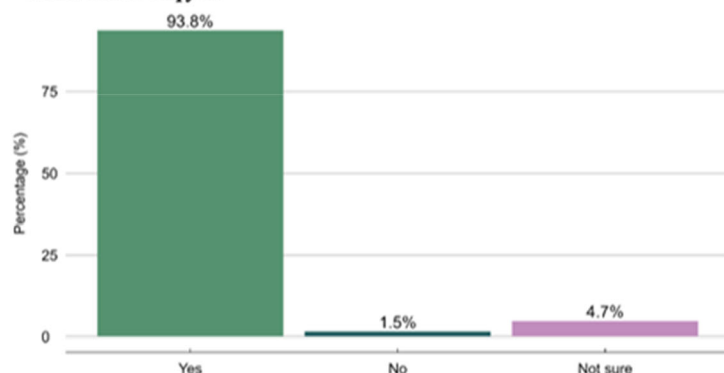
(a) *How likely are you to recommend this service to friends and family if they had troublesome breast pain?*



(b) *Did you find the breast pain advice you received helpful?*



(c) *Did you find the information regarding your personal risk of developing breast cancer helpful?*



(d) *Did you feel reassured by the breast pain advice you received?*

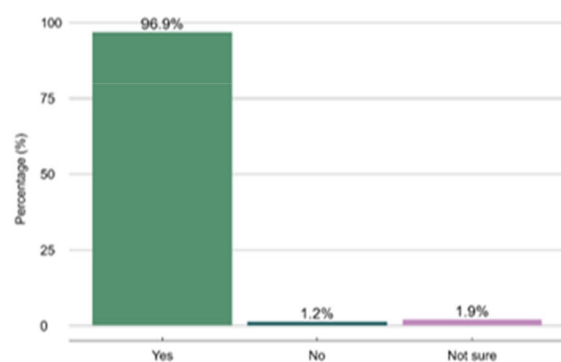


FIGURE 2 | PROMs responses.

Analysis of this free-text shows pre-attendance a high frequency of more negative emotions such as “apprehensive”, “concerned” and “scared” (Figure 3a). Analysis of post-attendance answers showed higher frequency of more positive emotions such as “happy”, “relaxed”, and “informed” (Figure 3b).

3.6 | Patient Safety

3.6.1 | Breast Cancer: Diagnoses & Incidence Rate

In the follow-up data collected to date, there have been 8 cancers diagnosed within 1 year of attendance at the CBPC. Table 5 shows where these were diagnosed. The total cancers include 2 patients who were ineligible for the CBPC, due to meeting one or more of the exclusion criteria - i.e., a personal history of prior breast cancer diagnosis.

For the cohort seen in CBPCs, 8/1901 patients have been diagnosed with breast cancer giving an incidence of 4.2 per 1000 (CI: 2.1–8.3 per 1000). However, as already noted, two patients who had been referred to the CBPC inappropriately because they had a personal history of cancer. If these patients are excluded, the prevalence estimate at the CBPC drops to 3.2 (CI: 1.4–6.9 per 1000).

The incidence in patients presenting with ‘breast pain only’ has been reported to be, on average, 4.6 per 1000 [2–13]. Therefore, the incidence at CBPC is below population incidence levels reported in the literature, looking just at patients eligible for the clinic.

At the point of this audit, only 33% of patients had a full 12-month follow-up. Of the 1,901 patients reported in this East Midlands audit we have looked at the patients on whom there is 12 months follow-up (621/1901): of these 3/621 patients were eligible for the CBPC and have been diagnosed with breast cancer giving an incidence of 4.8 per 1,000 (CI: 1.6–14.1).

3.6.2 | Additional Time Between CBPC and Subsequent One-Stop-Clinic Attendance

Across the pilot sites during the audit period, 8 cases of cancer were detected after attending a CBPC. There are a number of ways in which these cancers were identified.

3.6.3 | Onward Referrals to Breast Symptomatic One-Stop-Clinic

The data shows four patients subsequently diagnosed with breast cancer were referred onto the one-stop-clinic straight from their attendance at the CBPC. These occurred across three different Trusts. The median time from GP referral to CBPC attendance was 12 days. The median time between the CBPC referral and the referral to the one-stop-clinic was then 11.5 days. This does not constitute a clinically meaningful delay to care. This time period has been reported, since, without the CBPC referral route, these patients would have been directly referred onto the symptomatic breast cancer one-stop-clinic. Patients referred from

(a) *How did you feel before attending the CBPC?*



(b) *How did you feel after attending the CBPC?*

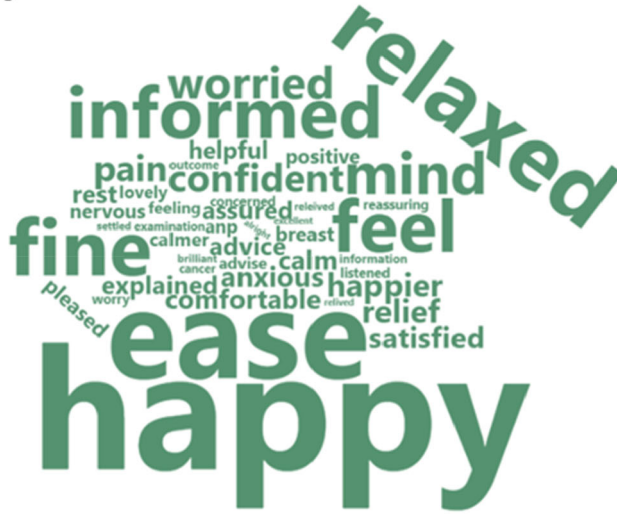


FIGURE 3 | Qualitative PROMs Word Clouds.

TABLE 5 | Cancer Diagnoses, by centre.

Centre	Total cancers
Derbyshire	6
Leicestershire	0
Lincolnshire	1
Northamptonshire	1
Nottinghamshire	0
Total	8

a CBPC are sent directly into a one-stop-clinic and are not sent as a new one-stop referral to the back of the line.

3.6.4 | Subsequent Referrals Through Asymptomatic Screening

This group of patients are those who were discharged from the CBPC and subsequently had cancer detected on mammographic screening. Examples of these include:

- 1 patient who was identified at their CBPC attendance as having missed their previous screening invite during Covid and was still eligible for NHS breast screening. They were only classified at 'population' risk of breast cancer but were advised to schedule a screen. This identified impalpable ductal carcinoma in situ in the ipsilateral breast cancer.
- Another patient was identified as moderate or high risk of breast cancer and was therefore advised by the CBPC clinic to schedule a mammogram. This identified an impalpable, invasive contralateral breast cancer.
- Another patient was identified as population risk of breast cancer and had a normal clinical assessment at the CBPC. They were signposted to NHS Breast Screening Programme for over 70 s. This identified impalpable contralateral invasive breast cancer.

3.6.5 | Subsequent Referrals by the GP

There was 1 patient who was initially discharged from the CBPC and later was referred by their GP onto a breast symptomatic one-stop-clinic. 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 one-stop-clinic referral. The patient also had a previous history of bilateral breast cancer and therefore did not fulfil the criteria for a CBPC attendance.

3.7 | Value for Money

3.7.1 | The Cost of the Pilot

Cost estimates, based on hospital Trust submissions, are provided in Table 6. For the purposes of this analysis, these estimates have been scaled to represent a full year of the clinic being open. This allows comparison between sites. Cost included both fixed costs (e.g. laptops, phones, training) and variable costs (e.g. staffing costs). A full cost breakdown can be found in Appendix 10.

3.7.2 | Quantified Benefits of the CBPCs

Through the redirection of patients to CBPC, patients no longer require an urgent cancer referral on the urgent suspected cancer pathway nor do they require additional diagnostic tests that normally accompany a referral along this pathway. Therefore, we can calculate this cost savings.

Firstly, by patients being seen in the CBPC and not referred down the urgent suspected cancer pathway, there is an avoided one-stop-clinic referral. In this cohort, 1773 patients were discharged from the CBPC and required no further care from secondary care. Using national tariff data for the cost of a one-stop-clinic appointment, this totals a saving of £378,409. This would rise to £786,924 by the end of year 2.

Alongside savings from the one-stop-clinic avoidance, there is also a saving associated with the reduction in diagnostic scans, namely, mammograms and ultrasounds. For mammograms, using the total number of anticipated attendances at a CBPC of 1987 in the first year of the pilot, there is a saving of £67,342. This uses an assumption from the secondary care audit which states that 0.64 mammograms are completed per one-stop-clinic referral. It also uses the reference cost which states a mammogram cost is £59.35 per scan (inflated using 21/22 healthcare inflation values – 22/23 values not yet available). This rises to £140,041 by the end of year 2.

For ultrasounds, prior research from a secondary care audit found there are 0.27 scans per one-stop-clinic attendance. We use the reference cost per scan, £59.99, inflated using 21/22 healthcare inflation values (22/23 values not yet available). Therefore, over the first year of the pilot there is anticipated to

be a saving of £28,714. This would rise to £59,712 by the end of year 2.

Therefore, in total, there is an anticipated saving of £474,465. This rises to £986,677 by the end of year 2.

3.7.3 | Cost-Benefit Analysis

This analysis then looks at the costs and benefit of a full first year pilot across the 5 trusts. Using the benefits quantified as part of this evaluation, the benefit to cost ratio is 1.23 in Year 1. Therefore, for each pound spent, the health system receives £1.23 in benefits. Both the cost benefit ratio (CBR) and net benefit from establishing the pilot CBPCs for each of the 5 centres are shown in Appendix 11. This combines the calculations of costs of patients going through the urgent suspected cancer pathway and costs of establishing the CBPC.

In year 2, we estimate prevented one-stop-clinic attendances using recent CBPC throughput data and the historic percentage of patients in CBPCs whose urgent suspected cancer pathway is prevented. Using the benefits quantified as part of this evaluation, the benefit to cost ratio is 1.24 in Year 2. Therefore, for each pound spent, the health system receives £1.24 in benefits. For most sites, the cost benefit ratio improved in year 2 as costs drop slightly but more patients are seen in a CBPC and therefore generate more benefits. As Derbyshire administrative costs increased in year 2 without a significant increase in patients seen, the cost benefit ratio for Derbyshire decreased.

4 | Discussion

This manuscript reports the expansion of the EMBPP across the East Midlands Cancer Alliance, covering a population of ~5.5 million. This follows the population-based feasibility study that was conducted in Derbyshire (~1 million population). The findings from this expanded pilot indicate that service provision in the community/primary care can provide improved patient care whilst freeing up resources in secondary care (staff, clinic costs, imaging resources) to provide better access for patients with red flag symptoms. The findings also suggest that the service addresses unmet need on an equitable basis in the early identification of those at increased familial breast cancer risk. This means that secondary care should benefit from the identification of patients at increased risk (moderate or high) who may be eligible for additional mammographic screening. Screening has been shown in randomised controlled trials to reduce breast cancer mortality in women between 50 and 70 years. Similarly, case-controlled cohort studies of younger women ranging from 35 to 49 years of age (e.g. FH01 & FH02)

TABLE 6 | Costs per year of the pilot, by Trust.

Centre	Derbyshire	Leicestershire	Lincolnshire	Nottinghamshire	Northamptonshire
Total	£102,343	£112,056	£77,509	£40,169	£52,670

have been shown to identify breast cancers at earlier stage and a reduction in breast cancer mortality too. Addressing this unmet need should also benefit tertiary care from an increased detection of high-risk families, which, in turn, should increase the detection of patients and families with identifiable genetic mutations (e.g. BRCA1 & 2) for which intervention by chemoprevention or surgery may be warranted, aiming to reduce the incidence of breast cancer in these patients.

Across all measures of patient experience, using both quantitative and qualitative measurements, patients attending the CBPCs rated their experience very highly. The anonymity of the patient questionnaire removed one potential bias that patients might be concerned their response could be linked to them personally, potentially affecting how they responded. The proximity to the end of their consultation could have introduced another potential bias – i.e. not identifying if a patient's satisfaction waned with time, particularly, if symptoms did not resolve. Providing questionnaires post-clinic (e.g. immediately on-line or after 3 months) also has the significant weakness that response rates are known to drop off markedly once patients leave an outpatient clinic. Even if questionnaires were requested immediately and at 3 months, because they were anonymised, it was felt with a marked drop off in return rate there would be no way of knowing if this was a select sub-group which replied after 3 months and if they had changed their opinions. It was therefore decided to use an objective assessment of patient satisfaction 3 months post-CBPC visit – that being the referral rate to the one-stop-clinic by their GP within 3 months of their CBPC visit. As reported in the results, there were only 20 patients (1%) referred by their GP to the one-stop-clinic within 3 months providing evidence that the excellent PROMS reported were maintained.

Alongside the patient experience, this paper reports on the health economics of these clinics for the first time. Across all clinics included within the East Midlands audit, the CBPC pilots were found to have a benefit ratio of 1.23 in Year 1 and 1.24 in Year 2. This was largely driven by a reduction in the referrals into the one-stop-clinic and the savings from the avoided appointment and associated mammogram and ultrasound scans. These savings will help drive down demand for these services, relieving pressures on the system. This aligns with the NHS Faster Diagnosis standards. The reduction in one-stop-clinic referrals from the patients with breast pain only, due to them now being seen in the CBPCs, frees up capacity for patients with 'red flag' symptoms to be seen more quickly, potentially leading to earlier cancer diagnoses.

Additionally, this report provides further assessment on safety of the CBPCs. The breast cancer incidence in this group should be equal to or less than the literature and expected population levels. The cancer incidence rate in the patient cohort attending CBPCs was lower than the population estimates in the literature. Initial estimates of breast cancer incidence among women attending CBPCs were estimated to be 3.2 (CI: 1.4–6.9 per 1000). The slightly lower incidence can be explained by the follow-up being less than 12 months for all patients. However, as noted, when only patients eligible for the CBPC and with 12 months follow-up (33% of the cohort (621/1901)) were included the incidence of breast cancer was 4.8 per 1000 (CI: 1.6-14.1). These

results with 12 months follow-up are supported by the breast cancer incidence from the Derbyshire pilot, the first area to implement the EMBPP; a recent update of their first 1000 patients with 12 months follow-up who fulfilled the inclusion/exclusion criteria was performed looking specifically at safety: the incidence of breast cancer was 4.8/1000 patients. Both this East Midlands audit and the updated Derbyshire pilot are virtually identical to the published literature.

Secondly, even in this 'low incidence' population, the majority of breast cancers are being detected as a result of attendance at the CBPC. So far in this audit period, 50% of cancers were detected through direct onward referral from the CBPC. Where this was not the case, three cancers were detected following signposting from the CBPC to the NHSBSP. Capiro and colleagues in a recent publication have suggested that women over 40 years presenting with breast pain should be referred for screening mammography [23]. This is essentially an "opportunistic" screen which is reflected by the fact that, as per the literature, half the cancers were found in the contralateral, non-concordant breast. The EMBPP was set up to focus on addressing the patients' presenting complaint – i.e., breast pain. It does support and encourage mammographic screening but on the basis that individual patients fall within breast screening programmes – i.e., patients are eligible for the NHSBSP by being over 47 years old or if younger are at increased risk due to other factors (eg familial or genetic). Like Capiro et al, the EMBPP has the advantage of focussing radiology resources (and thereby results in reducing costs) but also of clearly decoupling 'breast pain alone' from breast cancer. At the same time, the specialist clinic provides excellent patient satisfaction regarding the management of breast pain, as reflected in the PROMs, and also identifies and addresses unmet need through its familial risk assessment.

There was one case where a breast cancer was detected following a new referral to the one-stop-clinic through the patients GP. This cancer was mammographically occult even at the time of the one-stop-clinic referral and the patient should not have been eligible for the CBPC due to a prior breast cancer diagnosis. A Standard Operating Procedure (SOP) has been developed to try and prevent these patients from being referred to the CBPC in the first place – e.g., by making prior personal history of breast cancer a specified exclusion criteria on the referral–and secondly by triaging out any such referrals. The SOP also addresses where a GP doesn't mention the patient's personal history of breast cancer in their referral letter; any such patient seen at a CBPC is still automatically onward referred to a one-stop-clinic.

It is important to note that audits involving 17 centres in 9 different Cancer Alliances are still ongoing which will provide further evidence on safety from an even larger patient cohort yet all the data to date, both retrospective studies (i.e. published literature) and the prospective audits of the EMBPP (i.e. Derbyshire and now an East Midlands audit) provide a consistent and reassuring picture that patients presenting with breast pain only have a low incidence/risk of breast cancer.

Taken together, these findings support that the EMBPP model of care is reproducible. The reproducibility of these clinics is

further highlighted as these clinics all had subtle differences in the model of care. This flexibility was built within the design of the clinics. The clinics were required to be staffed by “an experienced clinician”, take patients with “breast pain only”, be set within primary or community care, adhere to the defined exclusion criteria and have the capability for family history risk assessment. The variation seen in the professional group of the experienced clinician (e.g. advanced nurse practitioner, GP with a special interest, etc) did not appear to have significant implications for either patient experience or the safety of the clinics. There was a variation in rates of onward referral to one-stop-clinics from the CBPC. It is difficult to investigate reasons for this based on five centres, but it is something that a ‘national’ audit which will report on many more centres and Cancer Alliances will look to address.

However, for the clinics to represent a high value for money, this paper reports that staffing models may be important. Across the different clinics, evaluated in this audit, a number of different staffing models have been utilised. For example, Leicestershire uses GPs with specialist interest and Nottinghamshire has a B7 Advanced Nurse Practitioner (Breast Specialist). Optimising these models will be important for the future development of these CBPCs both in terms of the costs associated with each clinic as well as the potential savings associated with prevented one-stop-clinic referrals. Initial analysis appears to suggest that the staffing of ANPs within the clinics could be optimal, with their average referral rate into one-stop-clinic sitting at approximately 5%. However, the number of centres with non-ANP models is too low to make such a definite conclusion at this stage. As the sample size for these datasets increase and the number of centres with these alternative models, further analysis will be performed to understand and recommend optimal staffing mix.

Finally, the paper analysed family history data for patients attending the CBPCs. One of the key requirements of the clinics is family risk assessment, in line with NICE CG164 referral guidelines for primary care. This data showed a 30.1% of women attending the CBPC during the audit had at least one family member with a history of breast cancer. Within this latter cohort of patients, 64.8% (i.e. around two thirds) are not at increased risk of breast cancer even though they have a family history. These women can be reassured regarding their risk which may help alleviate anxiety that may have contributed to their presentation with breast pain, and potentially lead to fewer future re-attendances.

All patients who are assessed as at increased risk of future breast cancer based on their objective risk assessment may be referred to the local Familial Cancer Services for advice and guidance. The services available will vary according to their individual level of risk and age group, but potentially can lead to access to early or additional breast screening, chemoprevention options, and/or genetic testing. Given this data is not routinely collected in primary care, our results indicate there is an unmet need where CBPCs do not exist, where patients at increased risk of breast cancer are potentially not being identified.

There are a number of key strengths to this audit. The pathway was prospectively defined, following the same protocol as pilot data previously published [16]. This included the four key principles (community or primary care-based clinics, staffed by an experienced

breast clinician, completion of a NICE CG164 [20] Family History Risk Assessment and a clinic for patients with breast pain only). Therefore, across multiple cancer sites within the East Midlands, the EMBPP was deployed which allowed consistent analysis across the participating sites in the region. Additionally, all data was independently analysed by an experienced external evaluator and included the analysis of both qualitative and quantitative data.

There are also some limitations of this audit. Firstly, at the point of this audit, we did not have a full 12-months follow-up for all patients. Additionally, one of the four key principles of the East Midlands Breast Pain Pathway is the clinic being staffed by an experienced breast clinician. This was left purposefully open to allow centres to staff their clinics with an “experienced clinician” in the most appropriate way for their local organisation. Although the model of care is reproducible, this introduces some variation in delivery across sites.

The health economic analysis relied on some assumptions. Firstly, the analysis relied on 2020/21 reference costs. Although this is a very close approximation for “true” costs to Trusts, there may be slight variations trust by trust which are not reflected here. The analysis also considers the costs and benefits of the clinics over 24-months. However, not all clinics have been open for 24-months at the point of the audit. Therefore, the analysis relies on scaled activity data.

The implementation of the EMBPP with the establishment of CBPCs have since been expanded to 17 sites nationally involving 9 Cancer Alliances and a ‘national’ audit is an integral part of this expanded implementation, which hopefully will confirm these findings extend outside of the East Midlands.

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We are grateful to patients 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.

Conflicts of Interest

Author	Declarations
Professor. John Robertson	As per East Midlands Cancer Alliance DOI
Dr. Thilan Bartholomeuz	As per East Midlands Cancer Alliance DOI
Veronica Rogers	No interests to declare.
Kevin Clifton	No interests to declare.
Michael Ellis	No interests to declare.
Lucy Pirkle	No interests to declare.
Denise Stafford	No interests to declare.
Mike Ryan	No interests to declare.
Dr. Mark Sibbering	As per East Midlands Cancer Alliance DOI

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Appendix 1
See Table [A1](#).

TABLE A1 | Implementation Timeline.

Phase	Date	Description	No. of clinics per week
1	June 2021	Implementation across Joined Up Care Derbyshire (University Hospital Derby and Burton and Chesterfield Royal Hospital)	3
2	January 2022	Implementation in Leicestershire	3
3	April 2022	Implementation in Lincolnshire	2
4	Sept 2022	Implementation in Nottinghamshire	1
5	Nov 2022	Implementation in Northamptonshire (Kettering General Hospital)	2

Appendix 2
FaHRAS protocol

The FHQ and guidance were sent out to the patient with their appointment letter to complete and bring to their appointment. This was inputted into the FaHRAS software which produced a management recommendation as per NICE Guidelines CG164 [20] harmonised to the local familial cancer referral pathways as well as producing clinical letter outputs for the case notes, the referring general practitioner and the patient. The FH data, the NICE CG164 risk assessment and the patient management outputs (e.g. letters) were all stored securely behind the NHS firewall and this electronic format facilitated inclusion of the FH data in the pathway evaluation.

In addition to receiving a clinical output letter detailing their risk assessment, patients were provided with an information pack about breast pain, including supplementary educational information, such as breast awareness leaflets, advice on NHSBSP screening for women between 50 and 70 years and advice to patients over 70 years on how to access breast screening if they wished to continue to attend. Patients were invited to submit anonymously a paper questionnaire to provide feedback on their CBPC attendance experience.

Appendix 3
See Table [A2](#).

TABLE A2 | Descriptive statistics of patient age and Index Multiple Deprivation (IMD) score.

Variable ¹	N	Statistic ²
Age at attendance	1,935	48 (16, 92)
IMD Score	1,918	6 (1, 10)
¹ Note: IMD: The Index of Multiple Deprivation, a measure of relative deprivation for small areas.		
² Median (Range)		

Appendix A4
See Figure [A1](#).

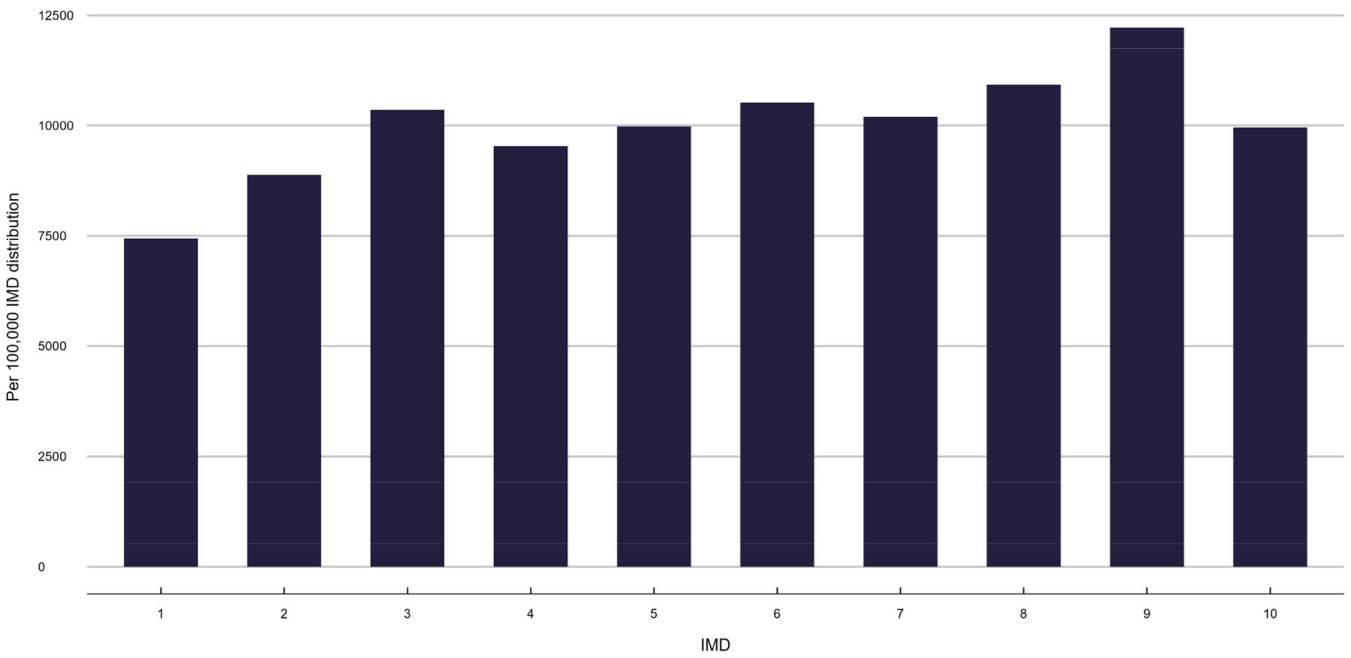


FIGURE A1 | Distribution of IMD score, standardised by 100,000 IMD population, for pilots to date.

Appendix A5
See Table [A3](#).

TABLE A3 | Follow-up data summary.

Follow-up period	N (%)
3-months	1797 (93%)
6-months	1294 (67%)
9-months	869 (45%)
12-months	639 (33%)

TABLE A4 | Summary of PROMs responses–patient experience in primary care.

Question	N	Statistic ¹
Did your GP advise you that breast pain is not a symptom of breast cancer?	2,066	1,568 (76%)
How many times have you seen your GP for this episode of breast pain prior to being referred to this clinic?	2,072	
1		1,297 (63%)
2		509 (25%)
3		160 (7.7%)
4		46 (2.2%)
5 or more		60 (2.9%)
Have you had any previous episodes of breast pain that required you to see your GP?	2,073	866 (42%)
¹ n (%)		

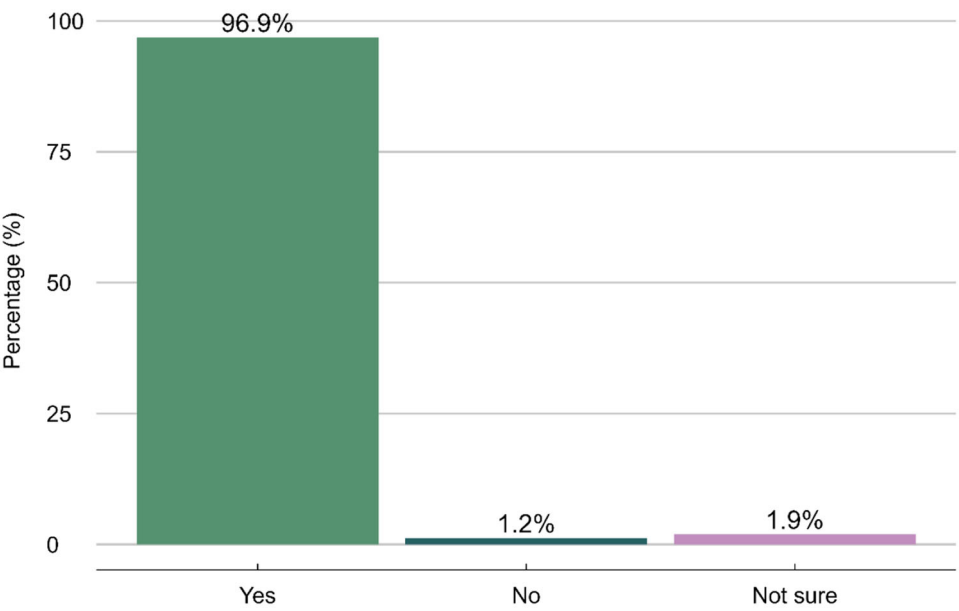


FIGURE A2 | Did you feel reassured by the breast pain advice you received?

Appendix 8
See Figure A3.

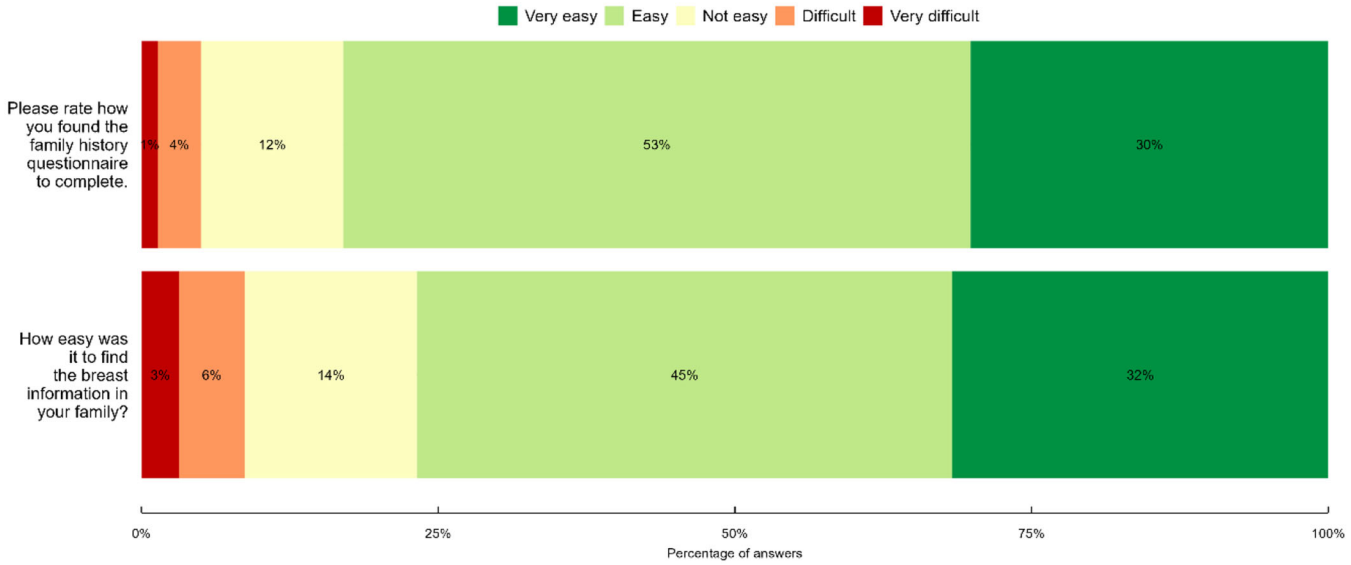


FIGURE A3 | Summary of PROMs responses–ease of use.

Appendix 9
See Table A5A.

TABLE A5A | Summary of PROMs responses by centre.

Question	Answer	Derbyshire	Leicestershire	Lincolnshire	Northamptonshire	Nottinghamshire
How likely are you to recommend this service to friends and family if they had troublesome breast pain?	Extremely Likely	82.6	81.7	93.2	93.0	76.4
Did you find the breast pain advice you received helpful?	Yes	94.7	95.3	99.7	98.7	100
Did you find the information regarding your personal risk of developing breast cancer helpful?	Yes	99.3	87.8	94.5	98.7	94.1
Did you feel reassured by the breast pain advice you received?	Yes	98.3	91.7	96	99.1	98.6

See Table A5B.

TABLE A5B | Costs per year of the pilot, by Trust.

Cost Line	Derbyshire	Leicestershire	Lincolnshire	Nottinghamshire	Northamptonshire
Laptop	£780	—	—	£2,487	—
Phones	£140	—	—	—	—
Miscellaneous	£30	—	£4,000	£26	—
Training	—	—	£3,000	—	—
Staff (B3 admin)	—	£25,320 (3 × 0.3 FTE)	£26,375 (1 FTE)	£10,550 (0.4 FTE)	£5,627 (0.2 FTE)
Staff (B7 SN)	—	—	£22,909 (2 × 0.2 FTE)	£11,455 (0.2 FTE)	—
Staff (B8a SN)	—	—	—	—	£22,707 (0.35 FTE)
Staff (ANP)	£60,000*	—	—	—	—
GP w special interest	—	£62,400 (cost per clinic)	—	—	—
Clinic Location	—	—	£5,000	£7,540	—
FaHRAS	£24,336	£24,336	£16,224	£8,112	£24,336
Total	£102,343	£112,056	£77,509	£40,169	£52,670

*Money left from Transformation budget given to a Trusts to backfill so the Trust could release ANP capacity to deliver the service. Costs for Year 2 include a B3 admin and an ANP totalling £140,752.

Appendix 10

See Table A6

TABLE A6 | Cost Benefit Analysis of Year 1 of the pilot.

Centre	Estimated total benefits from year 1	Estimated total costs from year 1	Cost benefit ratio	Net benefit
Derbyshire	£141,843	£102,343	1.39	£39,500
Leicestershire	£96,534	£112,056	0.86	—£15,522
Lincolnshire	£75,927	£77,509	0.98	—£1,581
Nottinghamshire	£84,478	£40,169	2.10	£44,308
Northamptonshire	£75,682	£52,670	1.44	£23,012
Total	£474,464	£384,747	1.23	£89,716

Appendix 11

See Table A7.

TABLE A7 | Cost Benefit Analysis at the end of Year 2 of the pilot.

Centre	Estimated total benefits after year 2	Estimated total costs after year 2	Cost benefit ratio	Net benefit
Derbyshire	£287,435	£243,095	1.18	£44,340
Leicestershire	£197,977	£224,113	0.88	—£26,136
Lincolnshire	£149,033	£148,017	1.01	£1,016
Nottinghamshire	£177,659	£77,826	2.28	£99,833
Northamptonshire	£174,573	£105,340	1.66	£69,232
Total	£986,677	£798,391	1.24	£188,286