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Access to Breast Cancer Assessment Clinics without GP Appointment: Final Report

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Definitions and Abbreviations

ARIMA: autoregressive integrated moving average

BIC: Bayesian Information Criterion

Cancer tracker: a member of the cancer services team that is specifically dedicated to supporting the pathway of cancer patients in the Board.

CCA: cost consequence analysis, an economic evaluation method that compares the costs and consequences of different options.

DNA: did not attend – when a patient misses their appointment, it is referred to as DNA.

GP: general practitioner

IQR: inter-quartile range, a measure of the spread of the data.

ISAT: intervention scalability assessment tool, a tool to assess the suitability of health interventions for scale-up.

ITS: interrupted time series, a statistical analysis method that evaluates the impact of an intervention by comparing data collected before and after the intervention.

MDT: multi-disciplinary team, a group of professionals from different clinical backgrounds who work together to plan and provide care for patients/service users.

MRI: magnetic resonance imaging, a non-invasive medical imaging technique.

NHS: national health service

NICE: national institute for health and care excellence, a non-departmental public body that produces clinical guidelines for the NHS and wider health and care system.

P: patient participant

Public contributor: a person unconnected to the organisations or staff involved, with recent lived experience of cancer.

S: staff participant

SCI Gateway: Scottish Care Information Gateway – a national system that integrates primary and secondary care systems, enabling primary care to make online referrals to secondary care services

SIMD: Scottish index of multiple deprivation, the Scottish Government’s official tool for identifying areas in Scotland of concentrations of deprivation.

TOC: theory of change, a way of explaining how an intervention or set of interventions is expected to lead to specific outcomes.

TrakCare: the healthcare information system used for electronic shared patient records.

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Contents

Lay summary	1
Scientific Abstract.....	2
1 Introduction/background.....	4
2 The improvement project	5
2.1 Key actors	5
2.2 Rationale for improvement project.....	6
2.3 Aims and objectives of the improvement project.....	7
2.4 Explanation of the improvement project	9
3 The evaluation of the improvement project.....	12
3.1 Design	12
3.2 Data collection.....	16
3.3 Data analysis.....	18
3.4 Health economic analysis	20
4 Findings of the improvement project	22
4.1 Participants.....	22
4.2 Results	26
4.3 What seems to work for whom?	42
4.4 What are the explanations for succeeding in improving the cancer diagnostic pathway? 46	
4.5 What are the explanations for not succeeding in improving the cancer diagnostic pathway?	48
5 Main lessons learned and implications for transition	49
5.1 Working towards diagnostic pathway improvements that could have impact	49
5.2 Working towards diagnostic pathway improvements that could be transferable across the UK	50
5.3 Methodological reflections	50
6 Reflections and key points	51
7 Recommendations	52
References.....	53
List of appendices	54
Appendix 1: Improvement project description, using TIDieR framework	55
Appendix 2: GP rapid access breast referral questionnaire	55
Appendix 3: Breast lump GP patient information leaflet.....	55
Appendix 4: IRAS protocol	55
Appendix 5: Technical Report: routine data analysis	55

Appendix 6: Technical Report: health economic analysis	55
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Table of figures

Figure 1: 'Current state' flow diagram, prior to improvement project (May 2023)	8
Figure 2: 'Future state' flow diagram, after implementation of improvement project (Aug 2023)	11
Figure 3: Theory of Change	15
Figure 4: Number of survey participants in each SIMD quintile (N=148)	24
Figure 5: Number of survey participants in each Urban Rural Classification (N=148)	25
Figure 6: Impact of Fast-track Pathway on Referral to First Attendance Times: ARIMA Interrupted Time Series Analysis (Model 1)	29
Figure 7: Impact of Fast-track Pathway on Referral to Diagnosis Times: ARIMA Interrupted Time Series Analysis (Model 2)	30
Figure 8: Probability of attending breast clinic over time for all comparator groups	37
Figure 9: Probability of attending breast clinic over time SIMD: comparing pre-Covid and implementation groups.....	38
Figure 10: Probability of attending breast clinic over time SIMD: comparing pre-implementation and implementation groups.....	38

Table of tables

Table 1: A summary of indicators for the project's evaluation	14
Table 2: Measures included in the routine datasets	17
Table 3: Summary table of participants	22
Table 4: Patient demographics across cohorts.....	23
Table 5: Distribution of patient SIMD quintile across cohorts.	23
Table 6: Summary of staff interview participants according to their role.....	26
Table 7: Days between referral, first appointment and diagnosis.	27
Table 8: Patients seen within 14 days.	27
Table 9: Number of patients diagnosed with cancer.....	28
Table 10: Tumour Size for Those Diagnosed with Cancer in Pre-Implementation and Implementation Cohorts.....	28
Table 11: Average costs per patient, implementation cohort compared with pre-Covid cohort	39
Table 12: Average costs per patient, implementation cohort compared with pre-implementation cohort.....	39
Table 13: Sensitivity analysis using different average imaging costs, pre-Covid comparator. Dominant (less costly) strategies shown in bold.....	41
Table 14: Sensitivity analysis using different average imaging costs, post-Covid comparator. Dominant (less costly) strategies shown in bold.....	41

Lay summary

Breast cancer is the most common cancer in women in Scotland. Finding breast cancer early is important for achieving better outcomes, including a higher chance of successful treatment and longer survival. To diagnose breast cancer, patients usually undergo a breast examination, scans, and other tests at a breast clinic. Currently, patients with a breast lump typically visit their GP first, who then refers them to a breast clinic. This process can delay diagnosis and create additional costs for patients and the health system.

A team of clinicians and researchers developed and tested a new fast-track referral process for patients with a breast lump in Forth Valley, Scotland. The aim was to reduce the time to diagnosis and enhance the patient experience. In the new process, when patients called their GP practice about a breast lump, receptionists asked three specific questions created by breast clinic clinicians. These questions determined whether the patient needed further assessment for breast cancer. If an assessment was necessary, the patient was offered a fast-track referral to the breast clinic, bypassing the need for a GP appointment.

With input from patients and other stakeholders, the team evaluated how well this new referral pathway worked and for whom. We compared data for those patients who had been fast-tracked, with those patients who had gone through the normal referral process, before the fast-track option was implemented. During the time of implementation, the team found that half the patients waited 12 days or less to be seen by a specialist at the breast clinic. This compares to half the patients waiting 8 days or less in the period before the project was started. This is likely due to changes in demand overall, and the numbers of patients from other Health Boards, who are also assessed in the Forth Valley Clinic. Very long delays were less common in the implementation period, however. Also, fast-tracked patients did not have to wait for a GP appointment (a potential additional wait of up to 3 weeks, depending on how GP practices triage breast lumps). Health outcomes were similar to the previous system, with the percentage of patients subsequently diagnosed with cancer, and tumour size for those diagnosed with cancer broadly the same. When referrals were monitored, no issues with inappropriate referrals were identified. The new process was less expensive, with the most obvious benefit being the GP appointments that were no longer needed. Feedback from patients and staff showed the process worked well and was easy to use, though practices had some differences in how they carried out training and procedures. Patients trusted the new system and liked going straight to the breast clinic.

In conclusion, the fast-track system in Forth Valley was a success. It reduced the need for GP appointments in the pathway, reduced costs (average differences per patient ranged from £15.81 to £41.68) and improved patient experiences. Other areas could consider adopting this model since it is simple, safe and efficient for both patients and GP staff.

Scientific Abstract

Background

Staff in NHS Forth Valley, in discussion with patients, wished to explore new ways of working to improve access to the breast assessment clinic for people in Forth Valley finding a breast lump. A fast-track model was designed, where general practice reception staff screened patients reporting a breast lump to identify their eligibility for direct referral. Reception staff completed the referral without the patient needing a GP appointment. The intention was to reduce delays and improve patient experience. The pathway was implemented in August 2023.

Objectives

To develop and implement a fast-track pathway in NHS Forth Valley for the direct referral of patients presenting at general practice with a breast lump to the cancer service breast assessment clinic. To evaluate both the implementation and the effectiveness of the new pathway, to support transition of evidence into mainstream practice.

Methods

A mixed methods hybrid effectiveness-implementation design, assessing a range of implementation, service and clinical outcomes as determined by the theory of change. To enable sufficient exploration of context and process, a naturalistic case study design was used. Data were collected and synthesized from patient records and routine health services data, bespoke surveys of general practice reception staff and patients, semi-structured interviews with staff and patients and observations and field notes. Interrupted time series analysis was used to evaluate the impact of the intervention on outcome variables. A cost consequence analysis was used to explore differences in costs and resources between the new pathway and the pre-intervention pathway. Reflective thematic analysis was used to analyse qualitative data.

Results

The routine data indicated that median time for fast-tracked patients to be seen in the clinic, and to receive a diagnosis (12 days and 13 days respectively), was slightly longer than for patients in the pre-implementation cohort (8 days and 7 days respectively), but shorter than for patients in the pre-Covid cohort (14 days and 14 days respectively). Compared with the pre-implementation (47 days) and pre-Covid cohorts (77 days), there was a reduction in extreme delays amongst the fast-tracked patients (27 days). Taken together, the interrupted time series analyses suggest that although underlying time-varying trends contributed to increasing waiting times in both the pre-implementation and implementation cohorts, the intervention appears to have begun mitigating these trends, resulting in reductions in referral times over time; however, this reduction was marginally non-significant. It was not possible to calculate the amount of time saved by not having to wait for and attend a primary care appointment, but it is estimated to be between one day and three weeks, depending on how individual GP practices triage breast lumps.

Clinical outcomes are similar to those in pre-implementation cohorts, as far as they are comparable. Cancer conversion rates were not significantly different across cohorts, and tumour staging appeared to be similar. The fast-track pathway was associated with lower costs per patient, though these were variable dependent on comparator used (£41.68 reduction when compared to Pre Covid and £15.81 for Post Covid). Data from the questionnaires and interviews showed that the process, with eliminated the need for a general practice appointment for most patients presenting to primary care with a breast lump, was acceptable and efficient for most patients, for GP administration staff, and for breast clinic staff; training and process activities varied between practices. Qualitative data highlighted that patients trusted the fast-track referral process and felt that in general it made sense to go direct to the breast clinic for assessment.

Conclusions

The fast-track access pathway to the breast assessment clinic, for patients presenting to general practice with a breast lump, was implemented successfully with desired outcomes in terms of creating both efficiencies (reducing the need for a general practice appointment) and positive patient experiences. The local implementation in Forth Valley has demonstrated that the clinician appointment in primary care prior to breast clinic referral for eligible patients can easily and safely be omitted, using a simple referral tool that GP receptionists can employ at first contact with relevant patients. The evaluation highlighted some important lessons for other areas that might want to consider adopting this pathway.

1 Introduction/background

Breast cancer is the most common cancer in women in Scotland, affecting one in nine women (Public Health Scotland, 2021, 2024). Of the approximately 4,500 people diagnosed with breast cancer in Scotland each year, approximately 25 of these are men (NHS Scotland, 2019). The incidence of breast cancer in Scotland is increasing over time (Mesa-Eguiagaray et al., 2022). Early detection of breast cancer is critical for improving patient outcomes, including increasing the likelihood of successful treatment and improving overall survival rates.

The standard of care for diagnosing breast cancer involves several steps including breast self-examination, clinical breast examination, imaging studies and biopsy. Primary care referrals for urgent suspicion of breast cancer consider lumps (in patients aged 30 years and over), nipple symptoms, skin changes and mastitis or breast inflammation that does not settle or recurs after one course of antibiotics. Clinical breast examination in Forth Valley is conducted within a one-stop breast assessment clinic, run by a team of advanced practitioners across the service (including consultant radiographers, surgical care practitioners and advanced nurse practitioners).

Referral to this clinic requires an initial assessment within a primary care setting by a general practitioner. People who call their general practice to report finding a breast lump may have to wait for a GP appointment (particularly where the demand for primary care appointments exceeds capacity) and face the additional cost/inconvenience of attending a general practice and being assessed prior to being referred to the clinic for specialist assessment.

In a retrospective cohort study of 14,259 patients diagnosed with cancer, GPs reported that 24% of patients had an avoidable delay to their diagnosis, with 49% attributed to delays within the primary care setting (Swann et al., 2020). Reasons for non-attendance at GP appointments, for those with symptoms of cancer, have been reported as difficulties with booking GP appointments and hesitation around intimate examinations (Jefferson et al., 2019). Reducing delays in diagnosis could lead to a higher rate of early-stage cancer detections and enhance patient survival outcomes (Allgar & Neal, 2005; Caplan, 2014; Sud et al., 2020). Meta-analytic evidence indicates that delays in the diagnosis and treatment of breast cancer, of as little as four weeks, contributes to increased incidence of mortality (Hanna et al., 2020). There are, therefore, both considerable opportunities and good incentives to reduce preventable delays. The Forth Valley clinic successfully sustains a balance in capacity and demand, resulting in short waiting times for the clinic assessment; they aim to see all referrals (suspicious of cancer, urgent and routine) within seven to ten days. The average number of annual referrals for urgent suspected cancer is 3,800. The team also provides mutual aid to several neighbouring health boards, seeing an additional 60 to 80 referrals per week. Following internal audits, feedback from patients, and discussions amongst clinicians and operational managers (including in general practice), an improvement project was conceived to streamline the process of referral to this assessment clinic.

Improvement projects like this are often not evaluated well because they are complex: they involve intervening within a complex adaptive system and often contain multiple interacting elements; there may not be a clear consensus on what constitutes a successful outcome; and there may be limited

resources or time available (Greenhalgh and Papoutsis 2019). However, evaluations are important for determining what worked well, what did not work well, and what changes can be made to improve the success of future projects.

Funding to refine, implement and evaluate the improvement project was sought and obtained from Cancer Research UK. Cancer Research UK's 'Test Evidence Transition' (TET) programme aims to accelerate the adoption of impactful innovations and reduce inequality in access to proven interventions. Through funding and fostering collaboration, TET provides spaces to explore and evaluate pathway innovations. The Fast-track Breast Lump Assessment project received funding through the first phase of the TET programme, and was a collaboration between NHS Forth Valley, NHS Golden Jubilee (Centre for Sustainable Delivery) and a multidisciplinary academic team at the University of Stirling. The project began on 1st May 2023.

2 The improvement project

2.1 Key actors

Cancer Research UK (CRUK) took an 'Active Commissioner' role (Hamilton-West et al., 2024); a key contact for CRUK (Dr Claire Sloan, Senior Researcher) worked closely with the project team throughout, supported by others in the Evidence and Implementation department, and members of an independent Steering Group and external peer reviewers.

The principal investigator, taking overall responsibility for the project at NHS Forth Valley, was Juliette Murray, Deputy Medical Director NHS Forth Valley. The chief investigator, taking overall responsibility for the research evaluation, and for overall conduct of the study, was Dr Erica Gadsby, an Associate Professor at University of Stirling. The team incorporated clinical and project management staff based at NHS Forth Valley, and multi-disciplinary research staff based at University of Stirling. The project was co-sponsored by the University of Stirling and the Centre for Sustainable Delivery, who jointly ensured proportionate, effective arrangements were in place to set up, run, finance, manage and report the research project.

The project was overseen and managed by a project management group, which included a wider team of academics at University of Stirling, a wider team of clinical staff from NHS Forth Valley and strategic managers at NHS Golden Jubilee. Also on this group were four public contributors recruited specifically for the two CRUK TET projects in Scotland. This group met five times during the project. Smaller working groups met more frequently in between these meetings, led by Juliette and/or Erica.

A project steering group was formed to provide guidance and strategic direction. This group included representatives of both study sponsors and the funder, as well as representatives of patient advocacy groups (Maggies and Breast Cancer Now). This group met online four times during the project and received regular progress reports.

In addition to taking part in the Project Management Group, the public contributors met regularly with the research team to provide lay perspectives of people with lived cancer experiences at the design and analysis stages. Their input has shaped the theory of change and data collection tools, ensuring

lay perspectives in the former, and appropriate language in the latter. They were involved in analysing qualitative data during the initial coding stage.

The early conception of the improvement project was informed by patients who were involved in discussions about the proposal. These were recruited via and hosted by the Maggie's Centre in Forth Valley. Maggie's are a nationwide charity that provides support and evidence to cancer patients and their families. Fifteen women with lived experience of breast cancer took part in the small group discussion. The focus was on their past and present experiences of breast lump detection and referral to diagnostic processes. This provided initial insights into the acceptability of the pathway and helped to clarify the focus of the data collection tools with patients.

2.2 Rationale for improvement project

Faster diagnosis for suspected cancer is a policy target across the UK (Healthcare Quality and Improvement Directorate, Scottish Government, 2023; NHS England, 2022). The first stage of the diagnostic pathway for patients not picked up through routine screening, usually involves presentation of concerns to primary care, in order to seek a referral for further assessment. Delays at this stage can be due to patients' concerns of burdening the health service, difficulties arranging and securing a GP appointment, and GPs taking a cautious approach with timings of referrals to avoid having referrals rejected (British Medical Association, 2024a). Primary care is under considerable pressure, with high vacancy rates, increasing numbers of patients and consequently ever-increasing workloads for GPs (British Medical Association, 2024b).

The improvement project was initially proposed in early 2022 by Juliette Murray, a Consultant General Surgeon (specialty, breast surgery) and the Deputy Medical Director for Acute Services at Forth Valley Royal Hospital. Following internal audits, feedback from patients, and discussions amongst clinicians and operational managers (including in general practice), a possible streamlining of the referral pathway for patients with a breast lump was imagined. Clinicians identified that General Practitioner (GP) assessment created a potential delay from patient presentation to referral to the breast clinic. It was suggested that this need for a GP appointment prior to referral to the NHS Forth Valley breast assessment clinic could potentially be removed for patients presenting with a breast lump, since they were almost certainly going to require referral to the breast clinic regardless of whether or not the examining clinician in primary care could feel the lump.

There were several drivers for this improvement project: ongoing improvements to meet national cancer diagnosis targets, a goal to reduce waiting times within secondary care, and the desire to ease ongoing pressures placed upon primary care services. NHS Forth Valley has a well-established breast clinic, successfully sustaining balance in capacity and demand, making this an ideal test bed for implementation. The streamlined referral pathway had the potential to reduce referral to assessment times and improve the patient experience. The rationale therefore was to capitalise on key opportunities to support the effective and efficient use of resources across the health care system, at the same time as delivering excellent patient experience.

2.3 Aims and objectives of the improvement project

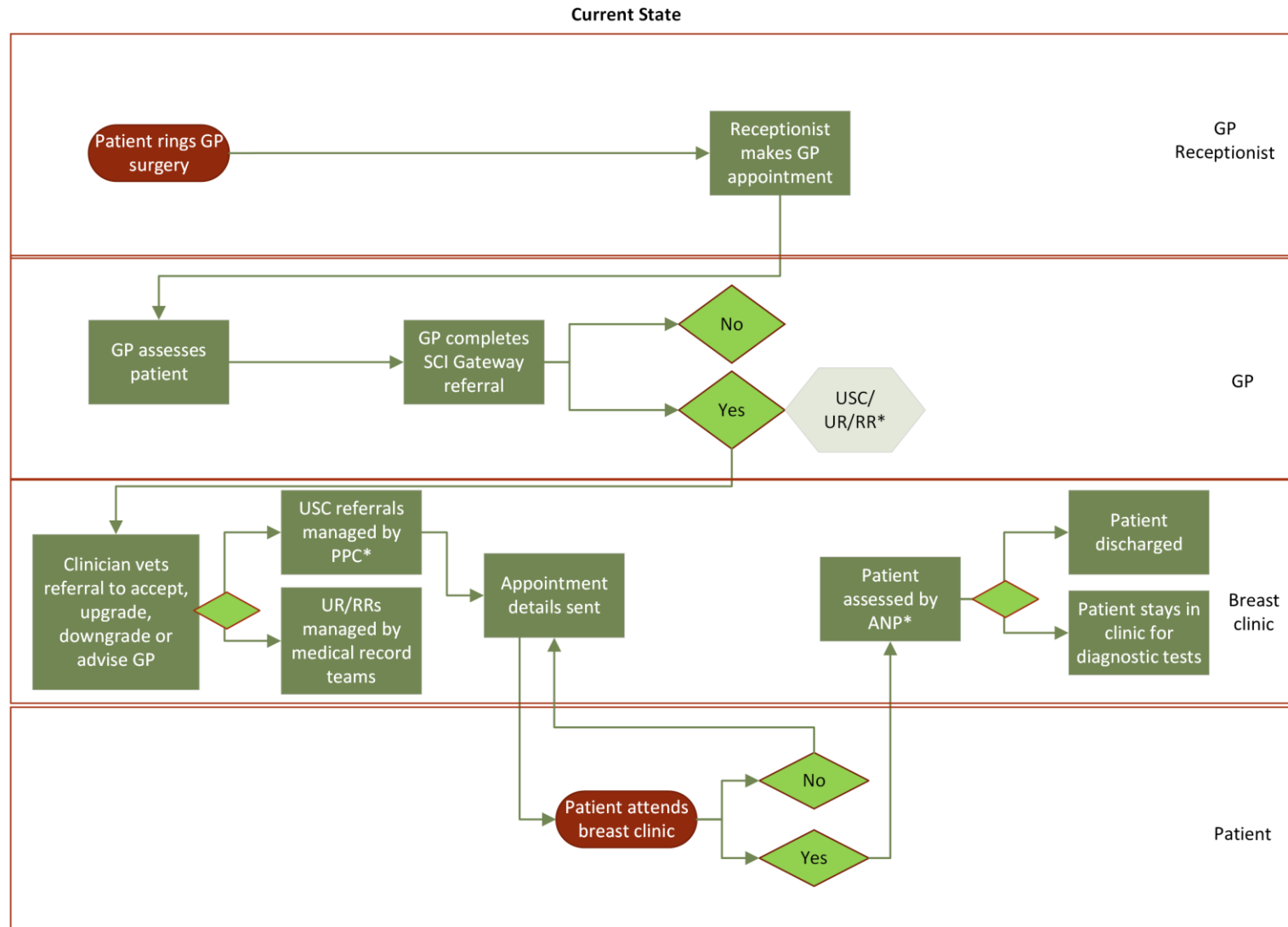
The project was designed to streamline the referral process for patients who identify a breast lump, utilising established services and staffing, and optimising available resources. This streamlined or 'fast-track' pathway is intended to complement other patient pathways, such as those for breast pain and breast abscesses.

The referral process for a breast lump prior to the improvement project is illustrated in Figure 1.

As Figure 1 shows, the GP was involved in assessing the patient presenting with a breast lump and completing a referral to the breast assessment clinic. The aim of the improvement project was to create a more efficient pathway that reduces any potential delays (and patient costs) associated with waiting for a GP appointment. The objectives were to:

1. Co-design a fast-track referral system for use by general practice receptionists.
2. Test and refine that fast-track referral system amongst the general practices in the NHS Forth Valley area.
3. Identify learning for scale up in other areas.

Figure 1: 'Current state' flow diagram, prior to improvement project (May 2023)



2.4 Explanation of the improvement project

The improvement project is described using a completed Template for Intervention Description and Replication (Appendix 1: Improvement project description, using TIDieR framework) (Hoffmann et al., 2014).

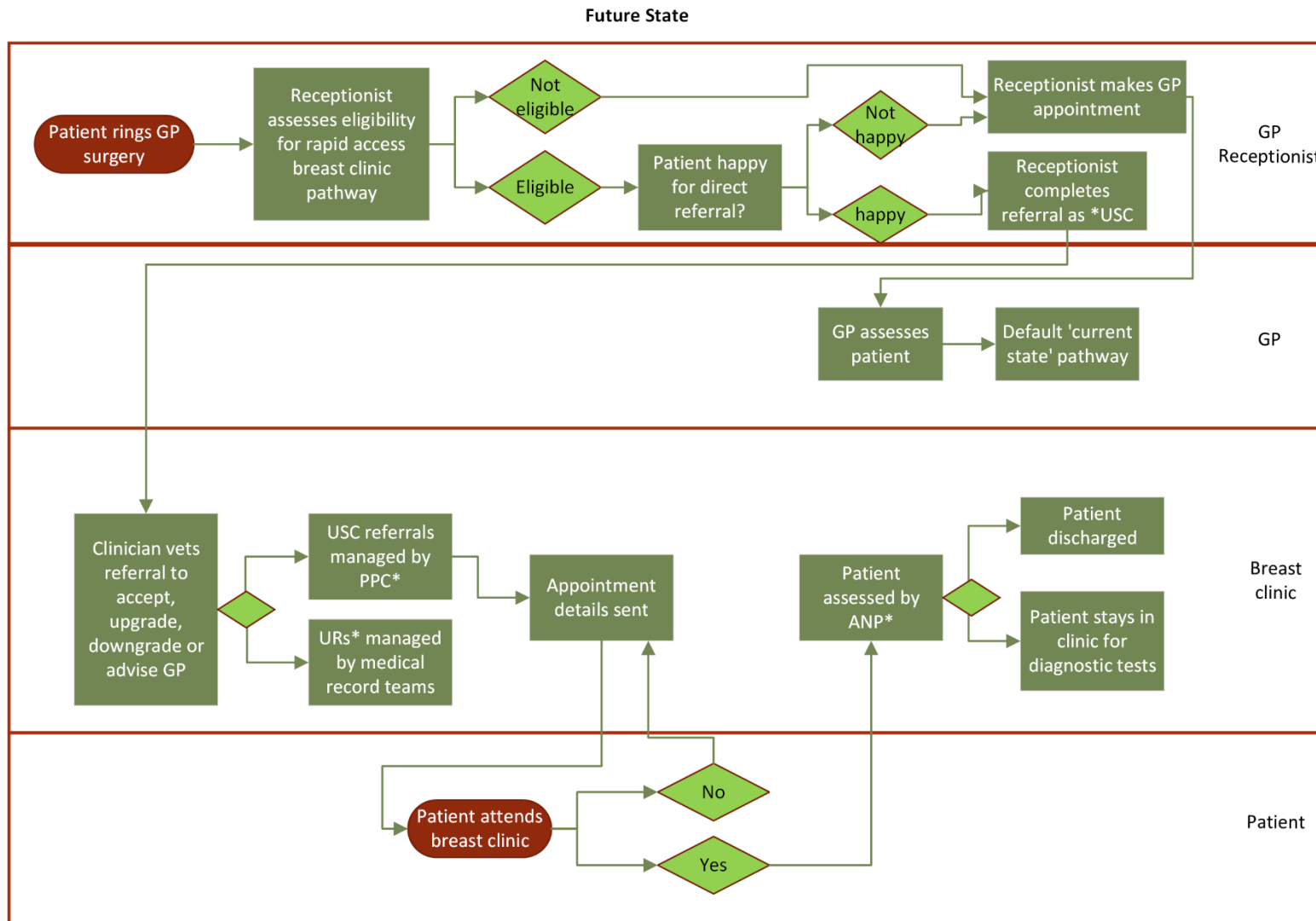
The improvement project entailed removing the need for a GP appointment prior to referrals to the NHS breast assessment clinic. Post implementation (from May 2023), patients aged 18 and over calling their general practice reporting symptoms of a breast lump were assessed by a receptionist for eligibility for a fast-track access breast clinic pathway, based on simple criteria (written by breast clinic clinicians) to rule out potential breast abscess or breast-feeding problems. The decision to refer patients to the breast clinic were then forwarded to a team member with access to the referral system (SCI (Scottish Care Information) Gateway). Thus, the patient no longer needed to wait for GP appointment availability, or travel to their GP practice for further examination. The receptionists were instructed to explain the fast-track option, and to offer the patient the choice of an appointment with a nurse or GP if they preferred. Key stages of the project included:

- 1) Initially the lead clinician/PI (Juliette Murray) met with the Forth Valley Lead Cancer GP to discuss the development and appropriateness of the new pathway. The pathway was then shared at GP sub-committees to gain feedback and explain new procedures for breast lump referrals.
- 2) The team identified a large GP practice and collaborated with the practice manager and reception team to develop referral protocols that aligned with the roles of receptionists and secretaries.
- 3) Bringing GP practices on board; the NHS Forth Valley and clinical teams identified and contacted 52 GP practices to explain the concept and rationale. Of those, 38 confirmed they would be happy to adopt the new pathway. Within six months, all 52 practices had agreed to implement the fast-track pathway.
- 4) Development by the breast clinic team of a screening tool to provide to GP practices to identify eligible patients for fast-track referral (Appendix 2: GP rapid access breast referral questionnaire).
- 5) Development by the breast clinic team of a patient information leaflet for GP practices to provide to patients, describing what to expect at the breast assessment clinic (Appendix 3: Breast lump GP patient information leaflet). This information was given verbally by receptionists while completing screening for the pathway, the leaflet was also designed to be sent by text message, email or provided in hard copy.
- 6) Ensuring access to the SCI Gateway referral system by the GP reception team, to enable them to submit direct referrals to the breast assessment clinic.
- 7) Implementing a new vetting outcome within TrakCare labelled as 'Urgent PPC Rapid Access Breast Appointment', which feeds into the appointment type 'New Urgent PPC breast'. This enabled all fast-track referrals (i.e. those that bypassed a GP appointment) to be tracked separately from other referral types.
- 8) Close working by the NHS Forth Valley team with GPs, practice managers and GP receptionists, to establish the new pathway. This consisted of a series of MS Teams meetings with each practice to describe the new pathway and to explain how to implement the screening and referral protocols.

- 9) Implementation of the new pathway within GP practices, in a phased approach, starting with five practices initially, then including an additional five practice each subsequent week, whilst monitoring impact on clinic workload.

The referral process after implementation of the improvement project is illustrated in Figure 2.

Figure 2: 'Future state' flow diagram, after implementation of improvement project (Aug 2023)



Abbreviations

USC = Urgent Suspected Cancer (>30 with a lump)

UR = Urgent Referral (<30 with a lump)

ANP = Advanced Nurse Practitioner (could also be consultant/junior doctor)

PPC = Patient Pathway Coordinator

3 The evaluation of the improvement project

3.1 Design

The research evaluation aimed to address the following questions:

1. Is the proposed intervention, to fast-track access for patients with a breast lump to a breast assessment clinic, effective on a small scale?
2. Does removing the initial GP consultation affect the process or outcomes of cancer diagnosis?
3. Is a fast-track model acceptable to referrers and patients, and are there any unintended consequences?
4. Might the intervention be successfully expanded across Scotland, while retaining effectiveness?
5. What impact is the intervention likely to have on earlier breast cancer diagnosis with a focus on reducing health inequalities?

Since we sought to understand a potential improvement within a complex system, we used a hybrid effectiveness-implementation design that assessed both the efficiency of the new pathway and its implementation strategy, in support of rapid translation (Curran et al., 2012).

The evaluation was theory-informed, using an explicit theory of change (TOC) developed at the outset by the project team, with input from patient representatives, clinicians and other stakeholders. The TOC is shown in Figure 3. It explains how the improvement project is expected to produce its results, outlining the mechanisms of change as well as the key assumptions that underpin the project's success. The TOC was used to identify indicators that were meaningful, feasible and appropriate for the project's evaluation. These are summarised in To enable sufficient exploration of context and process, a naturalistic case study design was used. This design is ideally suited to real-world, sustainable intervention development and evaluation where exposure to the intervention occurs in natural circumstances (Swanborn, 2010). Where appropriate, outcomes were assessed prior to and following the intervention. This design allowed for in-depth exploration of the intervention, its implementation, and the context in which it was implemented, drawing on data from multiple sources. This provided a rich understanding of the complexities of the intervention and helped to identify factors that influenced its effectiveness and implementation. It also helped to identify changes and developments over the implementation period.

Ethics approval for this study was granted by East of England – Cambridge East Research Ethics Committee (NHS Forth Valley, 23/EE/0168). Management approval was granted by NHS Forth Valley, on the basis of the favourable opinion from the Research Ethics Committee, and the Organisation Information Document site agreement.

Table 1.

To enable sufficient exploration of context and process, a naturalistic case study design was used. This design is ideally suited to real-world, sustainable intervention development and evaluation where exposure to the intervention occurs in natural circumstances (Swanborn, 2010). Where appropriate, outcomes were assessed prior to and following the intervention. This design allowed for in-depth exploration of the intervention, its implementation, and the context in which it was implemented, drawing on data from multiple sources. This provided a rich understanding of the complexities of the intervention and helped to identify factors that influenced its effectiveness and implementation. It also helped to identify changes and developments over the implementation period.

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Table 1: A summary of indicators for the project's evaluation

Outcomes, mechanisms and context	Indicators
Reduced cost to healthcare system	• Clinical effectiveness • Resource utilisation • Efficiency and flow
Increased capacity amongst GPs	• Number of fast-track referrals
Reduced time to diagnosis	• Timely diagnosis
Improved patient experience	• Acceptability/appropriateness • Access and equity • Patient safety • Anxiety
Reduced costs to patient	• Estimated costs saved
General practice setting	• Acceptability/appropriateness • Adoption • Feasibility • Fidelity • Sustainability
Breast clinic setting	• Acceptability/appropriateness of fast-track referrals • Number of fast-track referrals

3.1.1 Patient and public involvement

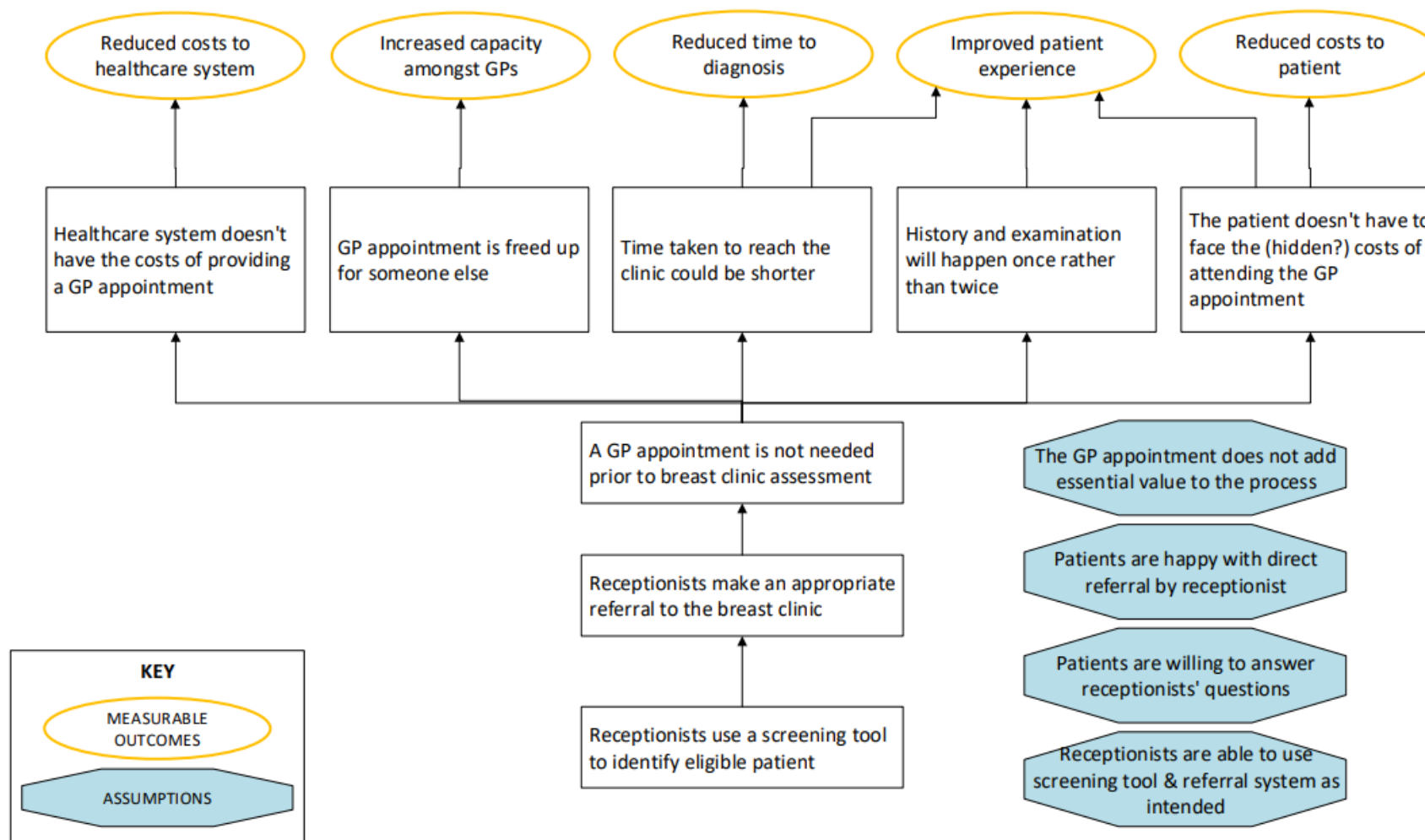
Four public contributors (three female, one male) with lived experience of a cancer diagnosis were recruited to support this study. In addition to taking part in the project management group, the public contributors have met regularly with the research team to provide lay perspectives at all stages. Their input helped to shape the theory of change and data collection tools, thus ensuring lay perspectives in the former, and appropriate language in the latter. To inform data analysis, they were involved in analysing qualitative data during the initial coding stage.

Some specific examples of the input from the public contributors are:

- Their feedback ensured that all questions in the interview guide and patient questionnaire were written in lay language and easily understandable by members of the public.
- Patient questionnaire was revised with additional open question to better capture patient experience and satisfaction.
- Draft TOC was adjusted to ensure language around patient experience was inclusive.
- Public contributors were co-authors of the protocol paper by providing lay perspectives into the draft.

The full protocol for the research evaluation is presented in Appendix 4: IRAS protocol.

Figure 3: Theory of Change



3.2 Data collection

3.2.1 *Routine quantitative data*

Routine quantitative data were collated by the project manager at NHS Forth Valley from SCI/Trakcare, with the support of an information analyst. All personal identifying information were removed, and the data were transferred to the research team for analysis in accordance with our data sharing agreement and data management plan.

Data were extracted/collated for 3 time periods:

- i. Pre-Covid: for a period of 3 months in a pre-pandemic period (in 2019), to analyse key measures in what might be considered a 'business as usual' environment.
- ii. Pre-implementation: for a period of 3 months immediately prior to implementation (May to August 2023), to analyse key measures immediately prior to the change in pathway (post-pandemic).
- iii. Implementation: for 9 months in phase 2 (August 2023 to April 2024), to analyse key measures following the change in pathway. This dataset included only those patients referred via the new pathway, excluding referrals for other reasons. Due to data governance policies (i.e., the Data Protection and Caldicott agreements), we were granted access solely to fast-track patient data, as they constituted the primary cohort for analyses.

Data included all NHS Forth Valley adult (18 years and over) patients newly referred to the breast clinic within the given time periods. Data for both pre-pandemic and pre-implementation cohorts was used to adjust for the continued impact of the pandemic upon service delivery. The measures included in the dataset are summarised in Table 2.

3.2.2 *Patient Survey Data*

All consenting patients referred to the breast assessment clinic during a 9-month period within the implementation phase were asked to complete a short online (anonymous) questionnaire, asking about their experience of the pathway *up to* arriving at the breast clinic. Participants were recruited in the clinic (by clinic staff), and facilitated to complete it while they waited, using a tablet specifically brought in for this purpose. A member of the breast clinic support staff aided the patient where required/requested, for example by reading out the questions, or by recording the answers for the patient. Patients wanting to complete the questionnaire at home were given a short information leaflet with the link to the survey, in the form of a short url and QR code.

Table 2: Measures included in the routine datasets

Measure	Detail
Patient age	
SIMD Quintile	Area deprivation
Referral date	
GP code	
Diagnostic clinic attendance date	
Mammography date	
Ultrasound date	
Core biopsy date	
Guided biopsy date	
Computed tomography (CT) date	
MRI date	
Bone scan date	
Diagnostic information	Includes diagnosis and staging at the time.
Diagnosis date	
Date of decision to treat	
Pathway defined outcome	
Diagnosis news date	

3.2.3 Patient Interview Data

A small subset of patients was invited to take part in a semi-structured telephone interview with an experienced member of the research team, lasting between 17 and 34 minutes (average = 27 minutes). These took place from April 2024 to July 2024. Interview guides were developed with input from stakeholders and public contributors and were informed by the analysis of the patient surveys.

Interview participants were recruited by the principal researcher and a member of the clinical team. Participants were invited to express their interest in taking part in an interview after completing the survey. The study team randomly selected participants from those who expressed interest. Patients who had attended the breast assessment clinic within the previous three months were included (n = 4; cancer diagnosis = 1). Additionally, to ensure a range of experiences were captured, particularly among those diagnosed with cancer following their assessment at the breast clinic, a member of the clinical team identified an additional five patients diagnosed with cancer to participate in an interview. Exclusion criteria were individuals currently undergoing radical treatment, those unable to give informed consent, or those with contraindications (e.g., symptoms or medical conditions) that might

cause difficulty or distress. The interviews were audio-recorded with permission, anonymised and transcribed by a professional transcription service.

3.2.4 Staff Survey Data

Key staff (receptionists, practice managers and GPs) in all participating general practices and staff in the Forth Valley breast clinic (patient pathway co-ordinators, clinicians and support staff) involved in the new pathway were invited to complete an online questionnaire in month 10 (31st January 2024 to 30th July 2024) to gather data related to implementation process.

3.2.5 Staff Interview Data

A purposive sample of staff involved in implementing the intervention (receptionists, practice managers, GP lead and breast assessment clinic staff) were interviewed [1st set: December 2023 to January 2024, 2nd set: May 2024]. Interview guides were developed with input from stakeholders and public contributors and were informed by the analysis of other data.

3.2.6 Project documentation and field notes

A range of other data such as meeting notes, action plans, team discussions, self-reports/audits by the implementation team and observations were collected throughout the study period to examine the implementation of the intervention. The collection of this data was facilitated by the participatory implementation process and close working of all relevant stakeholders. Data focused on assessing fidelity (in relation to the implementation plan) and adaptation, adoption and acceptability (particularly by different demographic groups and amongst different general practices), delivery settings and workforce, implementation infrastructure, and sustainability. Data collection and information sources were geared towards enabling us to answer the relevant questions posed in the Intervention Scalability Assessment Tool (ISAT) (Milat et al., 2020).

3.3 Data analysis

All data sources were analysed separately as one piece of a jigsaw, with each piece contributing to understanding of the whole phenomenon (Hancock et al., 2021).

3.3.1 Quantitative data analysis

Quantitative data was analysed within IBM SPSS v28 (IBM Corp, 2021). Interrupted Time Series (ITS) analysis, using ARIMA models, was employed to evaluate the impact of the intervention on the outcome variables (i.e., referral to first outpatient appointment, and referral to diagnosis). ARIMA is a robust time series method that accounts for temporal autocorrelation in longitudinal data, making it particularly suitable for assessing changes over time (Box et al., 2015; Kontopantelis et al., 2015; Lopez Bernal et al., 2017; Penfold & Zhang, 2013). In this analysis, the ARIMA framework allowed us to determine whether the intervention resulted in a statistically significant immediate level change and/or a change in trend beyond the underlying pre-intervention trajectory. A full explanation of the ARIMA modelling process is provided in Appendix 5: Technical Report: routine data analysis.

Data Preparation and Cleaning

The study population is described in section 4.1. Referral criteria for the breast clinic service changed over the course of the data set so inclusion criteria for the descriptive analyses and Interrupted Time Series Analysis (ITS) were adjusted per group to reflect this. To ensure consistency across cohorts (pre-Covid, pre-intervention, and intervention), case matching was performed based on age and referral type, aligned with national cancer referral guidelines. The data preparation and cleaning phase also involved applying inclusion criteria to address inconsistencies with adherence to the updated guidelines (e.g. in referral types and ages across the three cohorts), and removal of any patients referred from other health boards. Further details are provided in the appendix (Appendix 5: Technical Report: routine data analysis).

Prior to data cleaning there were a total of 1645 patients in the routine dataset, 175 of these were removed following procedures outlined above and detailed in the Technical Report. The final dataset for analysis included 1470 patients (≥ 18 years old) referred from 48 GP practices within the Forth Valley health board (pre-Covid = 438, pre-intervention = 643, intervention = 389).

Comparison Groups and Rationale for Excluding the Pre-Covid Cohort

The pre-Covid cohort was excluded because it does not reflect the current operational environment and exhibited greater historical variability in referral practices. The pre-implementation cohort, representing the system immediately prior to the intervention, was chosen as a more stable and temporally relevant comparator for assessing intervention effects. Further explanation can be found in the appendix (Appendix 5: Technical Report: routine data analysis).

3.3.2 Qualitative data analysis

Qualitative data were analysed within NVivo 20, following Braun and Clarke's (2021) approach to reflexive thematic analysis. Initial coding combined deductive coding, based on the TOC, and inductive coding, driven by the data. Coding was completed by two members of the research team (PT and MM) who met regularly to discuss the coding process. Regular meetings with other members of the research team offered additional space for reflection on analysis. Where appropriate, the public contributors were asked to inform aspects of analysis and interpretation through feedback and discussion. The research team shared with them initial coding of first patient and staff interviews for discussion. Their feedback furthered interpretation of data and identified new areas to explore during the following interviews.

3.3.3 Over-arching analysis

When the first stage of analysis was complete, data was then reduced to a series of thematic statements or summaries for each data source (Billings, 2004). The second stage of analysis involved pattern-matching across the data, seeking rival explanations, linking data to propositions (generated by our TOC), and building explanations. The propositions at the heart of the improvement project were:

1. The fast-track pathway will create efficiencies in the diagnostic process.

2. The fast-track pathway will have positive implications for patients' experience of the diagnostic process.

Organisational, behavioural and implementation theories were employed, alongside PPI input, to inform interpretation of data. Since the improvement project was unfolding in a complex environment with dynamic and unpredictable actions and interactions, we viewed the evaluation situation through the lens of systems thinking, looking beyond unanticipated consequences to being genuinely open to emergent outcomes.

3.4 Health economic analysis

The objectives of the economic analysis are linked to the measurable outcome "Reduced costs to healthcare system" outlined in the TOC (Figure 3) and are as follows:

- To identify and map key events on the patient pathway in line with the scope of the improvement project
- To identify and describe key resources and costs for each patient pathway
- To identify differences between the pre-intervention and post-intervention pathway descriptives such as time to event across the pathways
- To evaluate the cost consequence of the post-intervention pathway in comparison to pre-intervention and explore the robustness of these estimates.

The approach used for the project was a cost consequence analysis (CCA). The CCA was conducted using an economic model built with TreeAge Pro Healthcare and populated with patient level routine data from NHS Forth Valley and extant literature. A full explanation of the modelling is provided within the Technical Report (Appendix 6: Technical Report: health economic analysis).

A total of 1481 records were used for this analysis: 1466 who attended their appointment and 15 who did not attend (DNA). The comparator groups comprised participants referred to the breast clinic prior to the implementation date of the new pathway. In recognition of the potential variation to standard practice and patient flow resulting from the Covid-19 pandemic, two comparator groups were used: pre-Covid and pre-implementation. The perspective of the economic analysis was the health service (NHS Scotland).

For the model, the outcomes that were relevant to achieve the objectives of the CCA were:

- Diagnosis: confirmed cancer or not
- Did not Attend (DNA): the number of patients in each pathway who were referred to the breast clinic but did not attend at any time during the period of observation
- Resource use: which resources were required by each group on the pathways to enable costs calculation.

All outcomes were calculated using routine patient data supplied by NHS Forth Valley (see 3.2). Details of time to event data and rate calculation methods are provided in the Technical Report (Appendix 6: Technical Report: health economic analysis).

Resources relevant for consideration in this analysis were:

- GP appointment
- Breast clinic attendance
- Breast clinic imaging: this includes mammography, ultrasound scan (USS) and biopsy. The requirement for imaging is based on clinical presentation and is therefore variable amongst patients
- Further imaging: this includes imaging tests that may be carried out in addition to those at the breast clinic. Through discussion with the clinical team, these were identified as MRI (magnetic resonance imaging) and CT (computed tomography) scan. The requirement for further imaging is based on clinical presentation and is therefore also variable amongst patients.

For the pre-Covid and pre-intervention comparator groups, all patients were assumed to have attended a GP appointment prior to attendance at the breast clinic. Breast clinic attendance resource was still attributed to those patients who were DNA given that the appointment slot would still be made available and accrue associated costs. Routine data were used to calculate the number of patients who received each of the imaging modalities in all groups. These were combined with single test costs reported in the literature to calculate total and average imaging costs for each group. Where possible, costs for the Scottish NHS were used. All costs are reported in GBP (£) and adjusted using Bank of England CPI data for November 2024 where required.

The rationale for and description of the model used for analysis is provided in the Technical Report (Appendix 6: Technical Report: health economic analysis).

4 Findings of the improvement project

4.1 Participants

Within the 9-month implementation period, 393 patients attended the breast clinic following a fast-track referral from a general practice in Forth Valley (August 2023 to April 2024). Table 3 presents a summary of number of participants per data source.

Table 3: Summary table of participants

Source	Number of participants
Routine data	1470
Patient survey	155
Staff survey	58
Patient interviews	9
Staff interviews	8

Routine datasets

Data was provided for the three cohorts of interest: pre-Covid (n=438), pre-implementation (n=643), implementation (n=389) (

Table 4). Data for the first two cohorts each covered 3 months and data for the third cohort covered nine months of service. Broadly, these figures represent monthly patient numbers of 146, 214 and 130 respectively. The first two cohorts included women who attended the clinic with cancer indicators other than a lump and those with a lump. As the data contained referrals for reasons other than breast lumps, we performed case matching based on age and referral type, aligned with national cancer referral guidelines for patients symptomatic with breast lumps. This allowed us to gain a more accurate comparison across the three datasets.

The mean age of patients was similar in the first two cohorts (

Table 4), but the mean age for the implementation cohort was 7.4 years younger than the pre-implementation cohort. This is consistent with a reduction of the minimum age for the pathway.

Table 4: Patient demographics across cohorts

Measure	Cohort	N	Mean (SD)	Median (IQR)	Min	Max
Age (yrs)	Pre-Covid	438	50.71 (14.49)	49.0 (20)	18	90
	Pre-implementation	643	52.36 (16.01)	51.0 (24)	18	102
	Implementation	389	44.99 (15.0)	43.00 (20)	18	89
SIMD (quintiles)*	Pre-Covid	418	3.2 (1.38)	3.0 (2)	1	5
	Pre-implementation	614	3.18 (1.33)	3.0 (2)	1	5
	Implementation	375	3.06 (1.40)	3.0 (2)	1	5

Note. SIMD quintiles: 1 – most deprived to 5 – least deprived.

*n=63 record did not include SIMD quintile.

Since addressing health inequalities was a concern for the evaluation, the small reduction in mean SIMD quintile for the implementation cohort (0.12 points lower than the previous cohort) was investigated further, by comparing the SIMD quintiles. No significant differences were found using Chi-square test, but an apparent increased representation of 4.3% points in the most deprived group of patients (Table 5) could be investigated further. It may be that the fast-track pathway reduces barriers to care that disproportionately affects patients from the most deprived areas. Previous reports have indicated with women from the most socioeconomically deprived areas have had to attend their GP more times before referral for breast cancer, than women from the least deprived areas. These findings underscore the importance of innovations in cancer diagnostic pathways, which may yield additional benefits for disadvantaged patient groups.

Table 5: Distribution of patient SIMD quintile across cohorts.

		Cohort			Total
SIMD Quintile		Pre-covid N (%)	Pre-intervention N (%)	Intervention N (%)	N (%)
Most deprived	1	59 (14.1%)	77 (12.5%)	63 (16.8%)	199 (100%)
	2	84 (20.1%)	132 (21.5%)	81 (21.6%)	297 (100%)
	3	93 (22.2%)	142 (23.1%)	86 (22.9%)	321 (100%)
	4	80 (19.1%)	128 (20.8%)	60 (16.0%)	268 (100%)
Least deprived	5	102 (24.4%)	135 (22.0%)	85 (22.7%)	322 (100%)
Total		418	614	375	1407

Note. No statistically significant difference between cohorts (Chi-square).

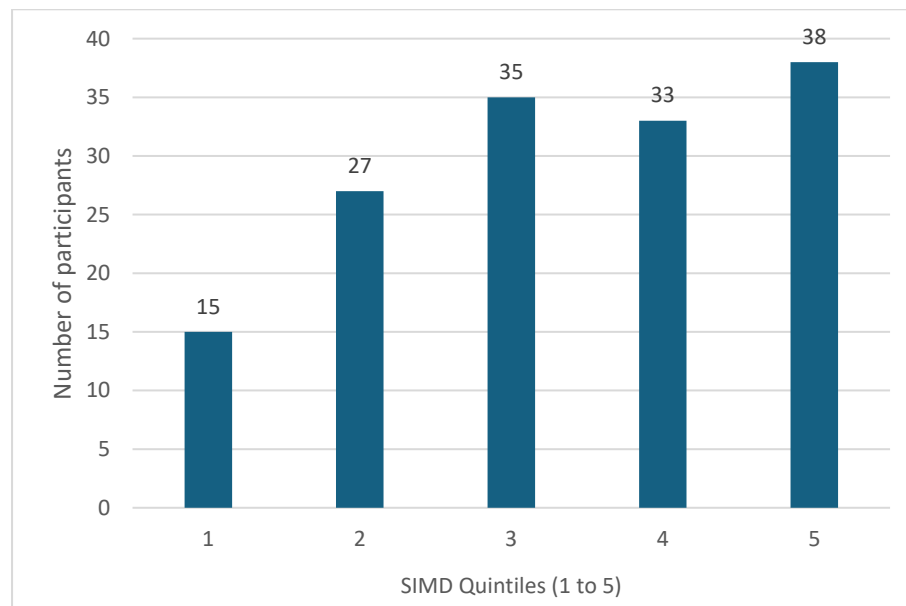
*n=63 record did not include SIMD quintile.

Patient survey

A total of 157 patients who were referred via the fast-track breast clinic pathway completed the patient survey from 12th December 2023 to 31st July 2024. During this period there were 386 referrals via the fast-track access pathway giving a response rate of 41%.

The final sample included 155 female participants with a mean age of 46 years ($SD = 13.7$; Missing = 5), of whom the majority were white ($N = 152$; Scottish/Irish/British/Welsh/English/ British, $N = 147$; Missing = 2). Participants reported their sexual orientation as heterosexual ($N = 143$; missing = 2; 1 participant did not disclose their sexual orientation), gay or lesbian ($N = 4$), bisexual ($N = 5$). Participants were referred from 43 different practices within the NHS Forth Valley health board. Participants were spread across the five SIMD (Scottish Index of Multiple Deprivation) quintiles as shown in Figure 4.

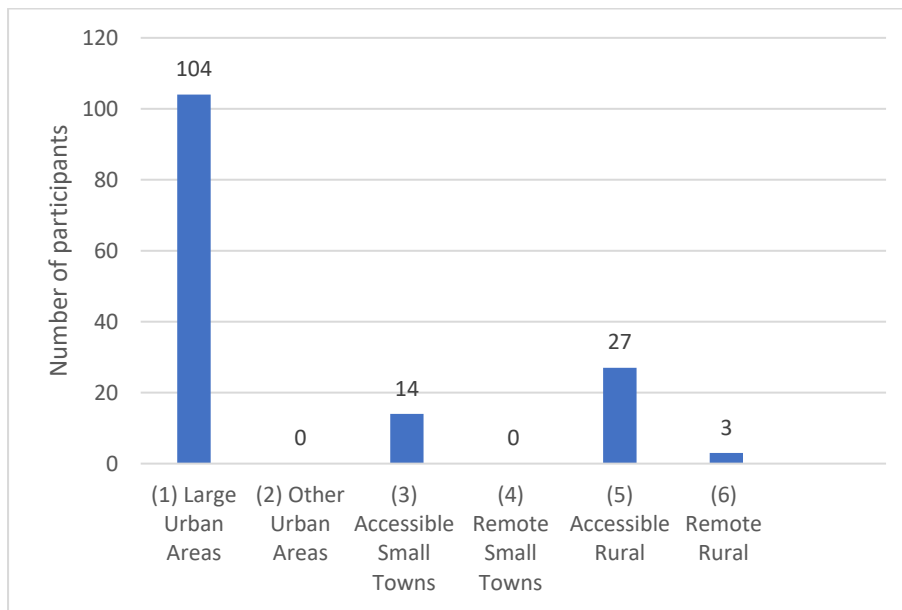
Figure 4: Number of survey participants in each SIMD quintile (N=148)



Note: seven participants did not provide a postcode and therefore no SIMD is reported.

Most survey participants were living in large urban areas, according to the Scottish Government Urban Rural Classification 2020 (see Figure 5).

Figure 5: Number of survey participants in each Urban Rural Classification (N=148)



Patient interviews

Semi-structured interviews were conducted with nine patients. Five of these had been diagnosed with cancer at the time of the interview, and four had not (though one had subsequently been diagnosed following lumpectomy). The ages of participants ranged from 37 to 75 (mean age = 54.7, mode = 55).

Staff survey

A total of 58 primary care staff who were involved in screening and referring patients via the fast-track breast clinic pathway completed the survey from 31st January 2024 to 30th July 2024. The final sample included 57 participants (after one exclusion due to quantity of missing data) from 24 different GP practices in Forth Valley. Since 52 GP practices in Forth Valley agreed to adopt the fast-track pathway, this represents a response rate of 46%. Participants identified their job role as a GP Receptionist (N = 25), Practice Manager (N = 12), GP Administrator (N = 10), GP Secretary (N = 9), or Practice Nurse (N = 1). Just under half (48.1%) of the survey respondents were responsible for screening patients, while just over half (51.9%) were responsible for both screening and submitting referrals.

Staff interviews

Semi-structured interviews were conducted with eight members of staff across primary and secondary care, and including clinicians and administrative/managerial staff (

Table 6). The shortest time in post for these participants was one year, and the longest 20 years.

Table 6: Summary of staff interview participants according to their role

Role	Role in new pathway	Number of participants
General practice receptionist	Screening and possibly referring patients	2
General practice manager	Supporting the implementation of the pathway in their practice and training practice staff	1
General Practitioner	Supporting the implementation of the pathway in their practice	1
Project manager (Hospital)	Set-up and overseeing implementation of improvement project	1
Consultant (Hospital)	Vetting and clinical assessment of fast-track access patients	1
Advanced practitioner (Hospital)	Clinical assessment of fast-track access patients. One was also lead clinician involved in set-up and overseeing implementation.	2

4.2 Results

One of the primary reasons for using a mixed-method case study approach in this research was to gain a holistic understanding of a complex and dynamic situation. Sections 4.3 to 4.5 integrate the results, focusing the narrative on central themes and relationships and presenting insights that emerged when the data was viewed as a cohesive whole. This section summarises the results of each dataset separately as a prelude to the integrated analysis.

4.2.1 Quantitative findings

The routine dataset

The key time points of interest in this evaluation were the number of days between referral and the first outpatient appointments and diagnosis. As an intranet was used to send referrals from the primary care practice to the breast service, the date that the referral was received was the same as the day it was sent. Across all three cohorts, we did not have access to data that captured the time from when a patient first contacted their GP to when the referral was received. This interval consists of two parts: (1) the time from the initial patient contact to the GP appointment, and (2) the time from the GP appointment to the submission of the referral.

Fieldwork, based on site visits to GP practices in Forth Valley, suggests that, for patients presenting with symptoms of a breast lump, the urgency of appointments varied considerably. Some patients received urgent, same-day appointments, whereas others waited up to three weeks for a routine appointment. Additionally, variations in referral procedures affected the time from the GP appointment to the submission of the referral. In some practices, GPs dictated their notes and referrals to a secretary, resulting in referrals that were sometimes delayed by up to a week. In contrast, other GPs reported completing the referrals themselves on the day of the patient's appointment. The fast-

track referral protocol implemented in the intervention cohort addresses these potential delays, potentially reducing the overall time to referral for this group.

The analysis is focussed upon the pre-implementation and implementation cohorts. It should be remembered that the pre-implementation cohort included women who were referred with non-lump indicators of cancer, as well as lumps, but data was not available to remove them from the analysis.

Table 7 shows that the median time for a woman on the fast-track pathway to attend her first appointment was four days longer than for the pre-implementation cohort. Both times were lower than for the pre-Covid cohort. Notably, the variation was much tighter for the implementation cohort compared with the pre-implementation, with a reduction of 20 days for the maximum time. There was also a drop in the numbers of patients seen within the target of 14 days, from 90.2% to 80.1% (Table 8). The analysis included records for all women, irrespective of whether they had not been able to attend earlier offers of an appointment. Analysis also does not account for the inclusion of multiple weekends, which may be influential over these short time periods.

The increase in time to first appointment was reflected in a six day increase in the median time to diagnosis (7 to 13 days) (Table 7), whilst also seeing a reduction in the extreme times from 104 days to 53 days.

Table 7: Days between referral, first appointment and diagnosis.

Measure	Cohort	N	Mean (SD)	Median (IQR)	Min	Max
Time from referral to first outpatient appointment (Days)	Pre-Covid	434	15.0 (10.95)	14.0 (8)	0	77
	Pre-Implementation	635	9.30 (5.57)	8.0 (5)	0	47
	Implementation	386	11.67 (4.09)	12.0 (5)	2	27
Time from referral to diagnosis (Days)	Pre-Covid	416	15.94 (12.50)	14 (9)	0	128
	Pre-implementation	624	8.94 (7.36)	7.0 (5)	0	104
	Implementation	375	12.78 (6.06)	13.0 (6)	2	53

Table 8: Patients seen within 14 days.

	Cohort	N (%)
Patients seen within 14 days	Pre-Covid	254 (58.5%)
	Pre-implementation	573 (90.2%)
	Implementation	309 (80.10%)

The percentage of patients who were subsequently diagnosed with cancer (the conversion rate) is an indicator of the specificity of a service, and so is of interest. There was a slight reduction (not significant) in the percentage, from 8.1% pre-implementation to 6.9% in implementation (Table 9).

Table 9: Number of patients diagnosed with cancer.

Diagnosis of cancer	Cohort			Total
	Pre-covid	Pre-intervention	Intervention	
Not Cancer	402	591	362	1355
% within Cohort	91.80%	91.90%	93.10%	
Cancer	36	52	27	115
% within Cohort	8.20%	8.10%	6.90%	
Total	438	643	389	1470

Note. No statistically significant difference between cohorts (Chi-square)

It is feasible that delays in diagnosis may allow tumours to progress, or that changes in the referral process may mean that cancers are missed. A descriptive overview of tumour size for the pre-implementation and implementation cohorts did not show any notable differences (Table 10). No statistical analyses were computed for the TNM T variable due to the low sample size in each TNM T category which would have violated the assumptions of Chi-square.

Table 10: Tumour Size for Those Diagnosed with Cancer in Pre-Implementation and Implementation Cohorts.

TNM T	Pre-Implementation		Implementation	
	Number in Cohort	% of Cohort	Number in Cohort	% of Cohort
No data	600	93.30%	368	94.60%
T1	13	2.10%	8	2.10%
T2	24	3.70%	10	2.60%
T3	3	0.50%	2	0.50%
T4	2	0.40%	0	0.00%
Tis*	0	0.00%	1	0.30%
TX**	1	0.20%	0	0.00%

*Tis – Cancer is in-situ only.

** TX - Could not be measured.

Interrupted Time Series Analysis

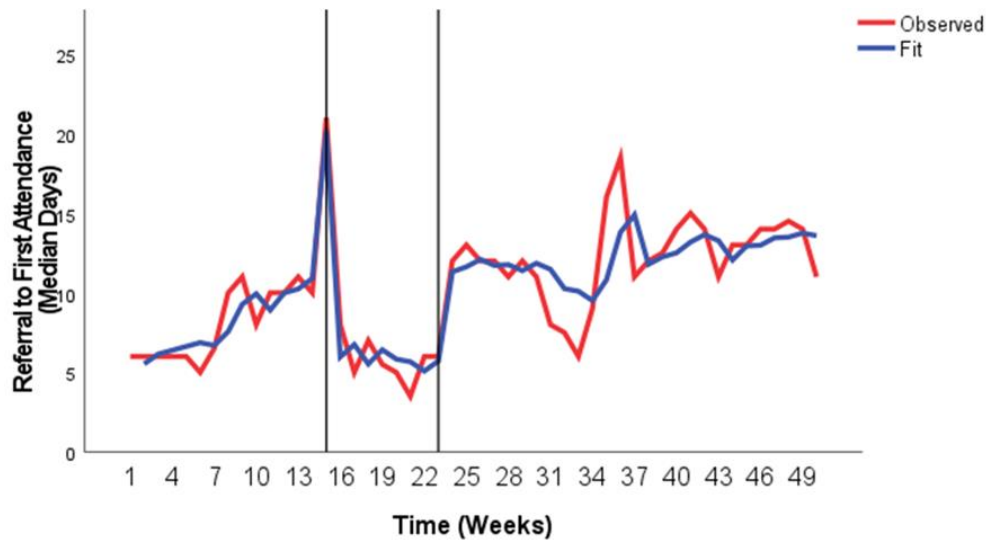
The days between referral and first appointment, and referral and diagnosis were modelled using the median values for all patients referred for each week. Interrupted time series was used to model patterns of change between the pre-implementation phase (14 weeks), a roll-out phase (8 weeks) and a full implementation phase (28 weeks).

Model 1 – Referral to first attendance time

For time to first appointment, the final model showed a good level of fit (normalised BIC = 2.01) and, notably, explained 77% of the variance in the length of time to first appointment. The plot (Figure 6) showed that time to first appointment was progressively increasing before the roll-out phase, with average weekly times of 7.4 days. The workload of the clinic, and thus the appointment waiting times, vary depending on a range of factors, including the extent of mutual aid offered to other Boards. However, the Forth Valley breast clinic sustains a balance in capacity and demand and all referrals are

generally seen within two weeks. The roll-out phase resulted in a reduced time to first appointment (5.4 median days); once full implementation was achieved this increased to 9.4 days, with an initial spike. The initial spike may be reflective of the time it takes for operational changes to take effect and the variation in demand upon the breast clinic service due to provision of mutual aid to other Boards.

Figure 6: Impact of Fast-track Pathway on Referral to First Attendance Times: ARIMA Interrupted Time Series Analysis (Model 1)

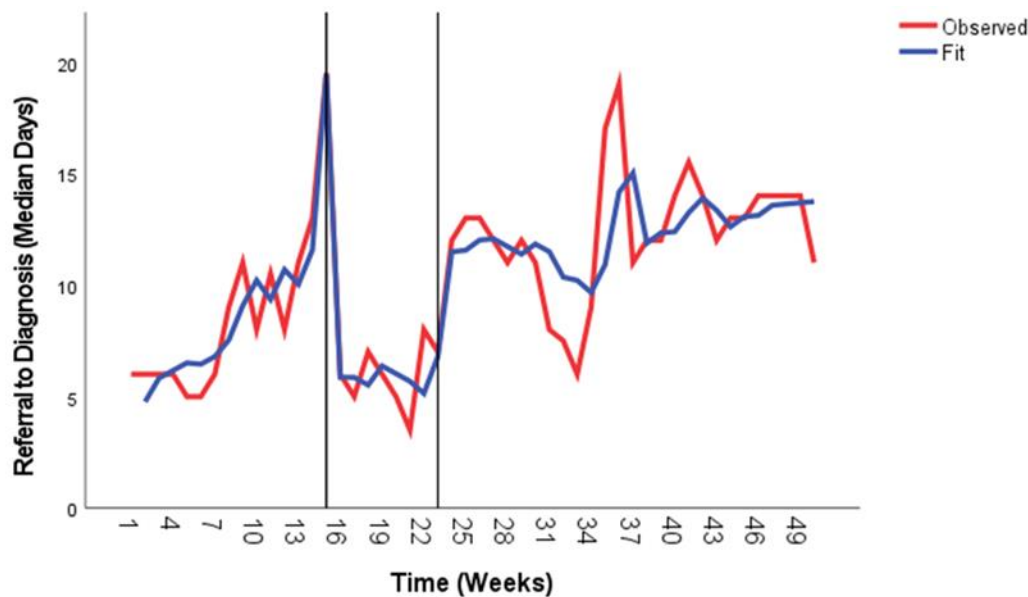


Note. 50-week series from pre-intervention to end of implementation. 1st X axis line for week 15 in the series is beginning of implementation rollout (2023 week 33); 2nd X axis line for week 23 in the series is the end of the 8-week rollout period (2023 week 41).

Model 2 – Referral to diagnosis time

The pattern for time to diagnosis was very similar as for time to be seen. The final model showed a good level of fit (normalised BIC=2.14) and explained 74% of the variance in the length of time to diagnosis. The plot (Figure 7) showed that the time to diagnosis was progressively increasing before the roll-out phase, with average weekly times of 7.0 days. The roll-out phase resulted in a reduced time to diagnosis (5.0 days); once full implementation was achieved this increased to 8.4 days, with an initial spike.

Figure 7: Impact of Fast-track Pathway on Referral to Diagnosis Times: ARIMA Interrupted Time Series Analysis (Model 2)



Note. 50-week series from pre-intervention to end of implementation. 1st X axis line for week 15 in the series is beginning of implementation rollout (2023 week 33); 2nd X axis line for week 23 in the series is the end of the 8-week rollout period (2023 week 41).

For both models, the analyses indicate that these changes were likely due to the intervention rather than exterior influences over the 50 weeks. Both models had included the variables age, SIMD, and number of cases each week, but these were not found to be significantly influential. Both patterns suggest that delays were increasing in the months before implementation. During the roll-out there were fewer practices referring patients into the service (five practices were added incrementally each week), with a smaller group of patients with a breast lump. This may have allowed the rapid access team to focus on the smaller group of patients and ensure more rapid pathways. As the full implementation began, there seemed to be a brief period of adjustment (potentially to developing clinic processes). Times to significant events (i.e., first attendance and diagnostic times) did increase over the implementation phase. A reduction in the weekly median towards the end of the full implementation phase showed a trend to reducing the time to both first appointment and diagnosis, but a longer analysis period would be needed to confirm this. Results do suggest that, had the pre-implementation trend for increasing waiting times continued over the next nine months (the implementation phase), waiting times would have likely been much longer; and that the implementation of the fast-track pathway helped to significantly reduce this trend.

The patient survey

The patient survey (N=155) indicated that the majority of respondents were asked by the GP receptionist about their health concern (89.7%), felt comfortable sharing this information with them (95.6%), and indicated that they would be happy to share it with their GP receptionist in the future (95.6%). Almost all (99.3%) respondents reported feeling happy to receive a direct referral to the breast clinic. However, 11 (7.7%) reported that in retrospect, they would have preferred to see their GP first.

Reasons for this varied but included concerns about ‘wasting’ a hospital appointment if it turned out not to be necessary, wanting to see the GP for ‘reassurance’ (that a lump was present), or a perception that their issue would have been dealt with quicker this way. Analysis revealed no statistically significant relationship between preference to see a GP prior to referral and SIMD quintile, rurality, age group, satisfaction with GP contact, sexuality, or anxiety. It should be noted, however, that the sample size is small.

The majority of respondents reported having enough information about their referral (81.3%) (seven participants could not remember), and that the quality of the information provided to them was very good or excellent (79.7%). A small number of respondents (7.7%) had an appointment with a GP/Doctor or a nurse prior to being referred. Of these, nine had a breast exam. The median time they reported waiting for this appointment was two days. Analyses revealed no statistically significant associations between have a GP appointment prior to referral and SIMD quintile, rurality, age group, satisfaction with GP contact, or anxiety. There was a weak association between reported sexuality and having a GP appointment prior to breast clinic referral; among the small number of participants who identified as gay, lesbian or bisexual, 30% reported having a GP appointment prior to the referral, compared to 6.3% of those who identified as heterosexual. However, caution is advised when interpreting these results due to small sample sizes within sub-groups.

Most respondents were satisfied or very satisfied with their experience of contacting their GP practice (85.1%) and with their care, from receiving their referral to arrival at the breast clinic (94.1%). Fewer than half of the respondents (45.1%) reported moderate to high levels of anxiety (score of 3+ on GAD-2) in the 2 weeks prior to their breast clinic appointment (Mean = 2.6). There were no statistically significant associations found between anxiety and either age group or SIMD quintile. The results demonstrated a distribution similar to that reported in the Scottish Health Survey (Scottish Government, 2024), indicating that: (1) younger women (18–54 years) have a higher proportion of clinically relevant anxiety compared to older women (≥ 55 years), and (2) women from the most deprived SIMD quintiles have a higher proportion of clinically relevant anxiety than those from the least deprived quintiles.

To summarise, most women in the survey found being referred directly by the receptionist to be acceptable, with a minority preferring to see their GP first. There were no strong indicators of health inequalities playing a part in the decision-making. There was no evidence that women on the fast-track access pathway experienced anxiety levels different than similar population levels of anxiety.

An additional consideration not captured within our data is the number of patients that may have contacted their GP practice or arranged an appointment through online portals (i.e., through Patient Access). We did not ask patients how they contacted their GP, and are therefore unable to provide a breakdown of the number of patients that accessed primary care services in person, via the phone, or through an online portal.

The staff survey

In the staff survey (N=58), over half (54.4%) of participants said they had received training to help them understand how to use the screening tool and submit referrals for the new fast-track pathway. In some

practices, instructions on the new pathway were informally delivered and may not have been considered as formal 'training' by respondents. Most respondents felt that they did not need further training to use the screening tool (75.0%) or to refer patients through SCI Gateway (75.0%). Of those responsible for both screening and submitting referrals (52%), the majority (95%) had access to SCI Gateway prior to adopting the new pathway. Of those who received training, only 25.8% of participants received training through protected training time, while 67.7% of participants received training through an additional session, and 6.5% through written instruction. Training was provided by practice managers (58.8%), a reception team member (26.5%), the breast clinic team (8.8%), a GP (2.9%) and one participant reported their training was provided by an unspecified other. The median reported training time was 15 minutes.

Most participants (68.4%) indicated that they "always" asked patients about their health concern before making a referral or arranging an appointment (not applicable = 12.3%). Most respondents felt comfortable making the decision to refer patients through the new pathway (92.7%), and felt they had enough information about the new pathway to discuss it with patients (91.1%).

One fifth (19.3%) of respondents reported completing referrals while speaking with the patient. Half (52.6%) completed referrals later on the same day, while a quarter (26.3%) sent referrals to another staff member to complete. The majority (93%) did not discuss referrals with a GP or practice nurse before completing the referral. Of those who did discuss the referrals, only one participant indicated that this may result in a patient following a different pathway.

Less than half of respondents (43.9%) provided patients with an information leaflet detailing what to expect when they attend the breast clinic (not applicable = 12.3%). Written information was used (either routinely or on request) to supplement the verbal information provided by reception teams about their referral and what to expect, which was delivered while speaking with them on the phone or in person. The patient survey indicated that 81.3% of patients reported having enough information, and not all patients felt the need to receive an additional information leaflet. Where they were provided, these leaflets were provided through email (62.5%), printed copy in person (45.8%), text message (33.3%), or printed copy via post (14.6%). (Note, since participants could select more than one option, the total percentage exceeds 100%.)

Three quarters of respondents (76.4%) indicated that speaking with patients about their breast concern did not take longer in the fast-track pathway than in the previous pathway.

To summarise, just over half of staff responding had received relevant training; most respondents felt that they did not need further training. Most staff involved in the referral process already had access to the SCI Gateway system and so this system was not new to them. Protected training time was not always offered, but brief training was provided through a variety of means. Most staff felt comfortable with the process, including independently discussing the process with patients. Fewer than half of staff provided patients with an information sheet (to supplement the verbal information they gave), and when they did this was through a range of media. Three quarters of staff had said that the fast-track process did not take them longer than referring via the GP.

4.2.2 *Qualitative findings – patient interviews*

The patient interviews (N=9) highlighted two overarching themes: ‘trusting the process’, and ‘cutting out the middleman’. Under the former, there were three sub-themes, and under the latter, there were two, as summarised below.

Trusting the process

The patient interview data revealed three sub-themes related to patients’ trust in and support of the fast-track referral process. The first theme was **communication and understanding of the referral**. Data highlighted that patients generally found the receptionists to be knowledgeable, helpful and courteous; they reportedly asked clear questions, explained the process and reassured the patients, as illustrated by these quotes:

“She was very empathetic, like her manner was beautiful ... and she went on to explain what happened about the rapid access, about they would refer me straightaway and I wouldn’t need to see the GP. She also clarified my understanding of it and ensured I was happy with it. I think if memory serves me, they were happy for me to go and see a GP if that would make me happier, which I thought was really good, until people are okay with it which of course I didn’t need, but some people might. So I was very impressed” (P4).

“She asked me three questions ... Then she said to me that’s your referral done, you’ll aim to be seen within two weeks” (P6).

“She just had said, if I remember correctly, that I didn’t have to, I could see the doctor if I preferred, but I didn’t have to and she could notify the breast clinic that I had discovered this and they would make all the arrangements. She was very, very nice about it and explained it very well” (P5).

Interviewees explained that people are generally used to receptionists asking information so they can be directed to the right person. Patients seemed comfortable to share confidential and medical information with the receptionist, and trusted them because they are general practice staff:

“Well obviously there’s like, you’re used to that, aren’t you, when you phone up, they’re going to ask you what it is that you’re phoning regarding, and obviously I know it’s confidential so therefore it’s, you know, they’re bound by confidentiality the same as everyone else that works in healthcare, so therefore, no, that didn’t bother me at all” (P9).

It was clear from the data that patients valued having practical information about the breast clinic appointment, to help them plan for it. Some also value having something in writing (not necessarily a letter) that confirms the key details of the appointment.

The second sub-theme related to trusting the process was **accountability and responsibility**. Data suggested that some patients feel that since diagnosing breast cancer is the responsibility of a breast specialist, it makes more sense to go straight to the breast clinic to be assessed. Since the nurse in the breast clinic is doing the job of breast assessment every day, some interviewees felt more reassured having concerns allayed by the nurse at the breast clinic, than by the GP. Some patients knew that a

diagnosis would require a mammogram or other diagnostic assessments, and that they require a secondary care referral to get that. Interviewees revealed some potential concerns, for example about the clinic getting too busy, or about the system not working smoothly. One interviewee expressed concern about receptionists making clinical decisions because they are not medically trained, so asked to speak to the nurse practitioner first:

“I spoke to a professional nurse practitioner rather than a receptionist. I don’t know how qualified the receptionists are, are they just people that can do admin, are they medically trained? So, the fact that I had spoken to a medically-trained person, that I know was medically trained, rather than it just being a receptionist and for her to say the right track is to go to Larbert, to the breast clinic, I was fine with that” (P2).

The third sub-theme was **empowering patients**. Interview data revealed that some women felt not just confident about going directly to the breast clinic, but also empowered; they reported feeling like they were being taken seriously since they felt they knew their own body, and knew when something was different or concerning:

“I didn’t feel I needed a GP appointment, I could feel the lump. I don’t need someone else to say it’s there, I know it’s there” (P6).

Cutting out the middleman

There were two sub-themes related to the perceived lack of need for the GP appointment. The first was **time and resources**. Patients were happy to save time and hassle by not attending a GP appointment. For some patients, this means not taking time off work, or being late for work, or negotiating shifts to attend an appointment. A GP appointment was potentially burdensome to family members as well as the patient.

“I don’t work local to where I live so it really mucks up my day entirely because I work eight o’clock to six o’clock in the west of the country, so it does change - It’s quite a pain, if I have to go to an appointment”. (P4)

“I had to get a bus to- The GP practice is in [Town name], and I’d have to get a bus or one of my daughters to give me a lift there, but I didn’t have to go so that was fine”. (P8)

Some patients recognised that general practice appointments were a precious commodity, and if they didn’t need an appointment to get their referral, then it was sensible *not* to use that resource, or to face any delay in waiting for it.

“It cut out the middleman because I don’t think my GP would have been able to do any more, my GP wouldn’t have been able to diagnose anything”. (P7)

“But actually, why not, if the chances are you’re going to be referred just cut the middleman out and get straight to the clinic where it can be all sorted in a day”. (P3)

“It just cut out the middleman, it cut out a GP who is uncomfortable with conversation sometimes and your hands are tied, it’s not them we need to see, we need a mammogram”. (P4)

“I thought, you know, miss out the middleman – for want of a better way of putting it – and just go straight through that rather than waste maybe a week to get the appointment with the doctor”. (P5)

The second sub-theme was **distress and anxiety**. Interviewees noted that they were keen to get a diagnosis quickly, since this implies quicker treatment and greater hope. Being ‘fast-tracked’ can make patients feel relieved and reassured. Data suggested that calling the general practice was sometimes the hardest step. To then hear that they don’t have to go in for an appointment (where they were anticipating having a physical examination), and that they will hear directly from the breast clinic was a relief.

“I made the call quite early in the morning expecting to have to go into the GP that day, and when I found out that didn’t have to happen, the whole day changed as it was going to be quite a hard day having to go, like as in just mentally going in. And then when I found, no, you don’t have to do that, they’ll contact you and you’ll go straight to the hospital, it was great”. (P3)

4.2.3 *Qualitative findings – staff interviews*

Interviews with staff (N=8) included staff perspectives in relation to patient acceptability that were in line with the data from patients themselves: that patients appeared very satisfied with the quick referral process.

Staff interviews suggested that GP appointments prior to referral offer limited added value. Breast clinic staff who participated in interviews perceived there to be no impact of the fast-track pathway on clinic workload, and perceived “the vast majority of the referrals [to] have been fairly appropriate” (S2, ANP) (as with GP referrals). Staff in the breast clinic said that they did not miss having notes from a GP, where patients have been fast-tracked, since they usually do a complete assessment themselves anyway.

Interviews with general practice staff provided additional information on how the referrals were being completed in different practices, and by whom. It was clear that the person who completes the referral might be the same person who speaks to the patient on the phone; this might depend on who has access to SCI Gateway. However, the interview data supported the staff survey data in demonstrating that the referral questions and process were straightforward and easy to incorporate into day-to-day practice. Reception staff felt reassured that patients will receive appropriate care, even if a fast-track referral isn’t made, since they would still be seen during a GP/ANP appointment.

General practice reception staff suggested they didn’t need much in the way of training to feel comfortable and confident in making the fast-track referrals. Short, digestible information, preferably presented verbally, with the opportunity to ask questions was generally sufficient to enable reception

staff to implement the change in practice. Staff members in the practice already familiar with the referral system were able to provide in-house help when others required it.

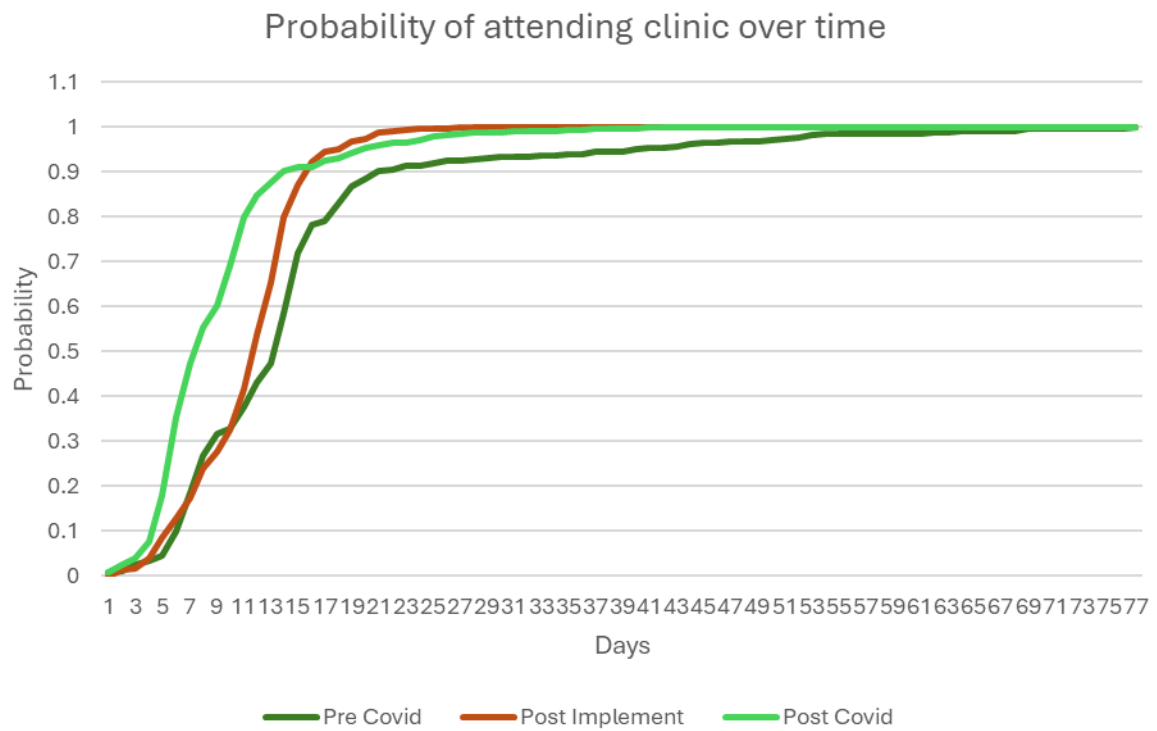
4.2.4 Health economic analysis findings

A summary of all model inputs is provided in Appendix 6: Technical Report: health economic analysis. Main results are presented in line with the objectives for the economic analysis outlined in section 3.4.

Economic modelling requires the calculation of probabilities of events (Briggs et al., 2006). Probabilities differ from rates in that they describe the “likelihood that an event will occur for a single individual in a given period” (Fleurence & Hollenbeak, 2007, p. 4) rather than rate, which describes the number of events over time. For the purposes of the current model, it is most appropriate to use probability, which looks at the likelihood of a patient attending clinic each day.

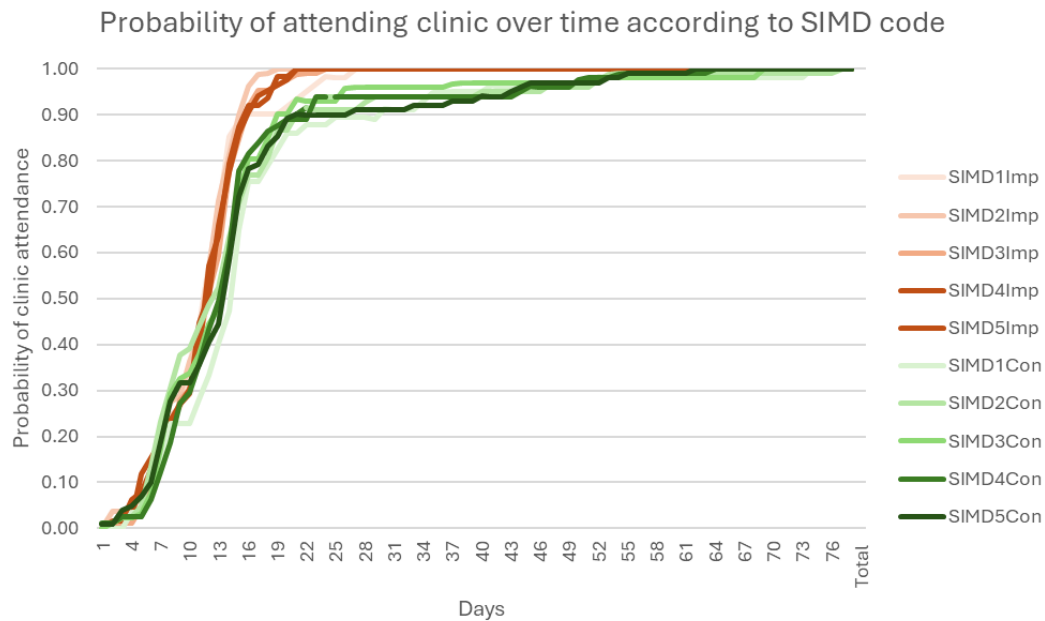
The probability of attending the breast clinic over time demonstrates that in the intervention group, all patients from the observational data set had completed the model pathway (from referral to end point of diagnosis/no cancer) by day 26 (n = 392). In the pre-Covid group (n = 434), this was day 77, and in pre-implementation (n = 636), day 47. The probability of attending clinic over time is summarised for all three groups in Figure 8. The figure suggests that the implementation group had higher attendance probability earlier when compared to the pre-Covid and pre-implementation groups. Pre-implementation, this trend is reversed however the total cohort achieved 100% attendance quicker in the implementation group overall. The practical implication of this finding is that, based on the routine observational data provided, there is a higher likelihood of future cohorts of eligible patients having a reduced time between referral and first clinic attendance compared to pre interventional change.

Figure 8: Probability of attending breast clinic over time for all comparator groups



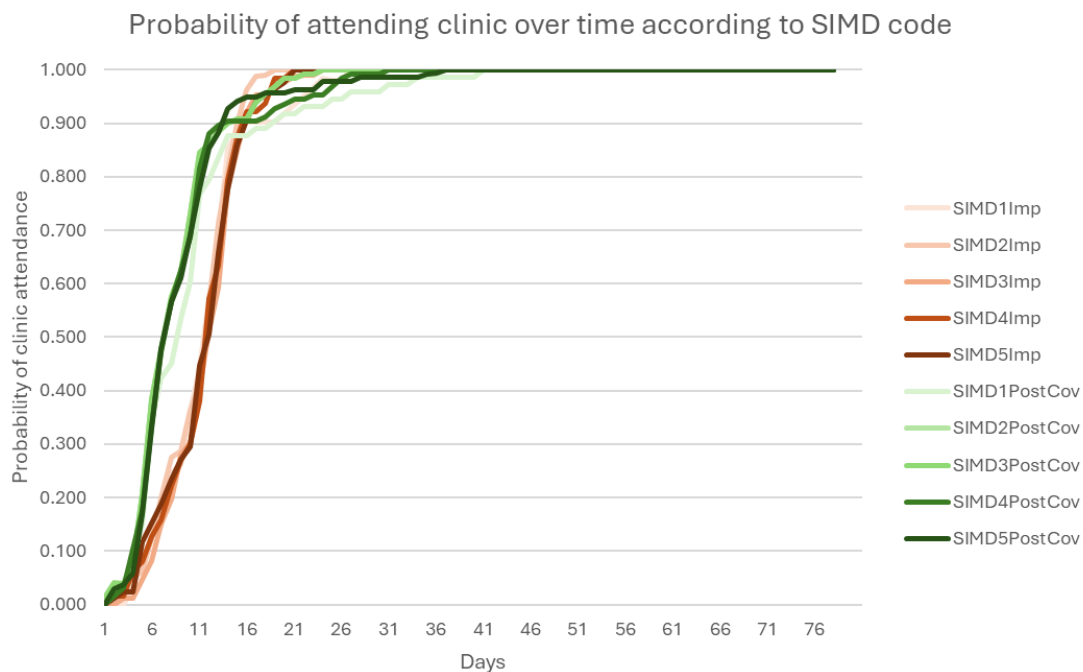
The probability of clinic attendance was also examined according to SIMD quintiles of the participants (SIMD 1 is the most deprived area and SIMD 5 is the least deprived area). The pre-Covid comparator is shown in Figure 9 and pre-implementation comparator in Figure 10. The same trend was noted as the overall group comparisons; no outliers according to SIMD were identified.

Figure 9: Probability of attending breast clinic over time SIMD: comparing pre-Covid and implementation groups



Note: Red lines ('Imp') = implementation cohort; Green lines ('Con') = pre-Covid cohort

Figure 10: Probability of attending breast clinic over time SIMD: comparing pre-implementation and implementation groups



Note: Red lines ('Imp') = implementation cohort; Green lines ('PostCov') = pre-implementation cohort

Resource use and costs

Average imaging costs for all groups were calculated and were found to be:

- for pre-Covid group (pre implementation), £158.18
- for pre-implementation group (post Covid), £133.33
- for implementation group, £122.85

A full breakdown is provided in Appendix 6: Technical Report: health economic analysis.

Base case results

For the base case, the model was run with 10,000 trials for each analysis with a half cycle correction applied for the first and final cycle. Average costs per patient on implementation and comparator pathways are shown in Table 11 and Table 12. In both cases, the intervention pathway was associated with lower costs, although the difference in costs differed across comparators. A difference of £41.68 per patient was found with the pre-Covid comparator, and £15.81 with the pre-intervention comparator. The source of these differences was explored through sensitivity analysis (see below). This finding does demonstrate the value of cost consequence analysis in this context in that only considering the reduction in costs due to a removal of a GP appointment would have overestimated the potential economic gains of the intervention.

Table 11: Average costs per patient, implementation cohort compared with pre-Covid cohort

	Pre-Covid	Implementation
Average cost per patient (£)	753.30	711.62
SD	79.98	90.63
95% CI	751.74 – 754.87	709.85 – 713.40

Table 12: Average costs per patient, implementation cohort compared with pre-implementation cohort

	Pre-intervention	Implementation
Average cost per patient (£)	736.38	720.57
SD	67.14	98.20
95% CI	735.07 – 737.70	718.85 – 722.50

Sensitivity analysis

The tornado diagram for the pre-Covid comparator group analysis demonstrates that the cost of clinic attendance was the most influential variable in the model result. However, further one-way sensitivity analysis over a range of costs for this variable demonstrates that there is no value for clinic costs which would change strategy dominance from the base case (intervention less costly).

The tornado diagram for the pre-intervention comparator group demonstrates that the cost of clinic attendance was also the most influential variable in the model result. Further one-way sensitivity analysis over a range of costs for this variable demonstrates that there is no value for clinic costs which

would change strategy dominance from the base case (intervention less costly). These findings are consistent with the pre-Covid comparator group.

The probability of requiring imaging in implementation and both comparator cohorts were similar (0.593 for pre-Covid, 0.579 for pre-implementation and 0.573 for implementation respectively, calculated from routine data) thereby demonstrating that this value is likely representative of the need for imaging in this patient population. Average costs associated with imaging were different and thus further sensitivity analysis was undertaken to explore how these impacted the overall model results.

Sensitivity analysis found that imaging costs would have to be very low in the comparator groups and very high in the implementation group for base case results to change. Full results are detailed in Appendix 6: Technical Report: health economic analysis.

To further explore the impact of imaging costs on the overall base case result favouring the implementation pathway, the model was re-run for a cohort of 10,000 trials using the same imaging costs for both groups. All other variables were held as per the base case. The results are summarised in Table 13 and Table 14. This analysis demonstrates that strategy dominance (intervention) is maintained using both pre-implementation comparators irrespective of imaging costs. This suggests that the lower patient pathway costs noted in the base case are not resultant from differences in imaging costs between the different groups.

Finally, probabilistic sensitivity analysis, which assigns a distribution of values rather than a single point estimate to allow for the quantification of the level of confidence of the model output, was undertaken. Gamma distributions were fitted around imaging costs using a 20% SD. Results favoured the intervention for 96.48% of the 10 000 draws of the PSA (average pathway costs per person £712.00 [95% CI 709.57 – 714.43] versus £753.84 [95% CI 751.40 – 756.28]) for the pre-Covid comparator group. Strategy dominance (Implementation pathway) was maintained with the Post Covid pre-implementation comparator group, although in a slightly lower 80.67% draws of the PSA (average pathway costs per person £732.65 [95% CI 732.33 - 732.97] versus £754.31 [95% CI 753.94 - 754.68]). These results indicate that for a cohort of 10 000 hypothetical patients, the post implementation pathway would be associated with lower costs 96.48% of the time when compared to the pre-Covid group and 80.76% of the time when compared to the pre- implementation group.

Economic analysis conclusions

The base case results indicate that regardless of which comparator is used, the average cost per patient of the implementation pathway was lower (pre-Covid £753.30 vs implementation £711.62 and pre-implementation £736.38 vs implementation £720.57) indicating a dominance of this pathway. Average cost differences in per patient pathway completion were greater using the pre-Covid comparator (£41.68 per patient) than the pre-implementation group (£15.81 per patient). The finding that lower per patient costs are associated with the implementation pathway was explored under a number of different scenarios. These included standardising imaging costs across all groups and exploring the impact of the main findings over a range of plausible values. The results of this analysis demonstrate that the main result favouring implementation consistently held, indicating the robustness of this finding.

Table 13: Sensitivity analysis using different average imaging costs, pre-Covid comparator. Dominant (less costly) strategies shown in bold.

	Pre Covid			Implementation		
	Base case	Imaging costs Average Comparator	Imaging costs Average Implement.	Base case	Imaging costs Average Comparator	Imaging costs Average Implement.
Average cost per patient (£)	753.30	753.75	733.53	711.62	739.68	713.37
SD	79.98	79.94	62.14	90.63	119.87	91.44
95% CI	751.74 – 754.87	752.19 – 755.32	732.31 – 734.75	709.85 – 713.40	737.33 – 742.03	711.58 – 715.16

Table 14: Sensitivity analysis using different average imaging costs, post-Covid comparator. Dominant (less costly) strategies shown in bold.

	Pre-Implementation			Implementation		
	Base case	Imaging costs Average Comparator	Imaging costs Average Implement.	Base case	Imaging costs Average Comparator	Imaging costs Average Implement.
Average cost per patient (£)	736.38	737.94	727.94	720.57	731.17	721.04
SD	67.14	67.34	102.39	98.20	62.01	97.82
95% CI	735.07 – 737.70	736.62 – 739.26	725.35 – 729.37	718.85 – 722.50	729.96 – 732.39	719.12 – 722.95

4.3 What seems to work for whom?

The project was designed to streamline the referral process for patients who identified a breast lump. The propositions at the heart of the improvement project were:

1. The fast-track pathway will create efficiencies in the diagnostic process.
2. The fast-track pathway will have positive implications for patients' experience of the diagnostic process.

4.3.1 Creating efficiencies

The fast-track pathway does appear to create efficiencies in the diagnostic process. The economic analysis found that the cost of the fast-track pathway was lower compared to both pre-intervention comparators. If we assume 8,000 breast clinic referrals each year (an estimate for NHS Forth Valley), we might estimate potential economic gains to be in the range of £126,480 to £333,440 per year. Whilst the routine data suggested a small increase (for the fast-tracked cohort) in the average number of days taken for patients to be seen and receive a diagnosis, there was a reduction in extreme delays. The staff survey and interviews confirmed that whilst the fast-track referral took a little bit of receptionist/secretary time, it did save at least one clinician appointment.

“Taking initial information and advising them of the referral maybe takes slightly longer than booking them in for an appointment with a clinician but cuts out need for an appointment.” (staff survey respondent ID58)

“We run a sort of blended way of working, so GPs have a morning session or an afternoon session of phone calls and then an afternoon or morning session of face-to-face appointments. If a patient booked in for a telephone call who didn't explain to us what that call is for, they then need seeing to investigate this lump, and all of a sudden that's not just one appointment it's two. So, there is a significant time saving for clinicians”. (S8, GP Practice Manager)

“In our practice, although we have ANPs [Advanced Nurse Practitioners], we still see a lot of breast lumps and things but it's definitely, it has freed up ANP appointments” (S5, GP Partner)

The advantages to general practices overall could be substantial when scaled up:

“When you think about it, there is approximately 8,000 patients per year referred to the breast service, 8,000 or 9,000 in Forth Valley, that's 8,000 or 9,000 patients they [general practices] do not have to see, for a one-on-one situation for the GP practices. So, it depends, you see for GGC [NHS Greater Glasgow & Clyde], you're probably talking maybe 25,000 patients. In Lanarkshire it's 12,000 patients per year. So that's very advantageous to the GP practice. And they don't have a lady coming in all agitated because she's got a breast lump, they don't have to see her. They don't have to spend 15 minutes to try to reassure, because you've referred directly to secondary care.” (S4, manager).

Over the three observational periods, the probability that all the patients in each cohort attended Clinic for the first time from point of referral was achieved quicker in the Post Implementation period (Day 26) than the Pre Covid (Day 77) and Post Covid (Day 47) comparator groups.

In qualitative data, staff and patients both perceived the process to be quicker. Time was a key factor for women who found a breast lump; the majority of survey respondents (62.2%) contacted their GP within one week of finding a lump. Waits for a GP appointment varied from practice to practice, and could sometimes depend on a patient's ability to fit an appointment into their work/home lives.

"So like before we had the pathway, obviously as I said, we would always try and see them that day but like half-past eight here sometimes we don't have any appointments or we do have appointments still and some of them are like, no, I can't come in that day, or I can't come in today, I can't come in tomorrow. Some of them are happy to take, like some of them are happy to take a week" (S3, GP receptionist).

"Well from a patient point of view, like obviously that cuts out like a lot of time, so therefore it is, you know, if it was a case of it ends up that it is breast cancer, that means that the treatment's going to get started sooner rather than later, which can only be beneficial" (P9).

General practice reception staff felt that any implications of the new pathway on their own workload were either negligible or insignificant. Staff interviews did not reveal any negative implications related to efficiencies or workload amongst secondary care staff. The majority (93%) of survey respondents (GP receptionists) reported that they did not need to discuss the referrals with a GP or nurse before completing them. In both the survey and the interviews, general practice reception staff reported feeling comfortable making the decision to refer patients through the fast-track pathway. One GP receptionist felt it was easier for the receptionist and the secretary to deal directly with a breast lump referral than for the GP to do so:

"It's easier for us as well. So, we just obviously do the questions and then the template and it goes to the secretaries. So, it's pretty much just answering questions and ticking boxes for us, and then I think the secretaries just do the referral and it goes away. So, I think it's a lot less, not work, but it's a lot less for us to do than the GPs. Like if they were to see someone, they would need to go through all the consultation and then the referral and waiting to hear back or- So I think it is, it's a lot easier for everybody actually" (S3, GP receptionist).

There did not appear to be any trade-offs in relation to clinical outcomes. This GP partner explained that for most women who present with a breast lump, GPs will simply refer them to the breast clinic anyway:

"It is very hard to say this is not breast cancer, and I, having personal experience, there are some which are very obviously breast cancer, but I think just feeling a lump it is impossible to say this is definitely a cyst, this is definitely not. So, the outcome is any woman you're going to refer, if they come in with a breast lump. So, you examine a woman, she says she has a breast lump, you refer. So, there's actually very little clinical addition that we're giving to that. We're not actually giving any clinical expertise, we're just acting almost as an admin role" (S5, GP Partner).

In some cases, patients speculated that the time saved by not having a GP appointment could have made a difference to their outcome:

“if I had to see a GP of course we’d have just done that, erm, but in hindsight that slows things up for me, I’ve got grade three breast cancer which is quite aggressive so, you know, in future down the line if it takes me three weeks to get a GP appointment and I’m three weeks later starting treatment, I don’t know how detrimental that is for me” (P6).

In both the pre- and post-implementation pathways, the referral criteria from primary care to the breast clinic as an urgent suspected cancer was the same for women aged 30 and over presenting with a breast lump: they were either referred by the reception staff (in the fast-track pathway) or by a clinician (in the previous pathway). However, since the new fast-track pathway did not include age as criteria, patients under the age of 30 were fast-track referred, and therefore able to receive a diagnosis (or reassurance), significantly quicker than via the previous pathway, which would not have categorised them as ‘urgent suspected cancer’. During the implementation phase of this project, there were 57 patients under the age of 30 who were fast-track referred (none with a cancer diagnosis). The mean time from referral to diagnosis for these patients was 12.13 days.

There was a concern voiced at the start of the project by staff involved in the secondary care breast clinic related to a possible increase in referrals to the breast clinic. However, this concern was quickly alleviated and not evidenced in the routine datasets. In the routine data, the pre-implementation cohort had average of 44 referrals each week, which is significantly more than the intervention cohort in which there was an average of 11 patients each week. The workload was perceived to be the same as before the improvement project was implemented.

“Well, my initial concerns were about the numbers of referrals that could have come through because of the easiness, how the patient could access this service ... I don’t think it has had a significant impact as I had expected ... I think the workload is pretty much the same” (S2, advanced practitioner).

“No, there’s been no change in capacity. The thing with us is we were meeting our targets, we were fully staffed at the time, but I think that was the worry that there was going to be more referrals; but from [Breast Coordinator] and from [Project Manager], there’s been no impact on the capacity. There’s been no more, so it’s quite, ... I was just quite surprised with that (S7, advanced practitioner).

Interviews with breast clinic staff indicated that the fast-track referral criteria were fit for purpose and led to appropriate referrals. Staff in the breast clinic reported that they did not miss having referral notes from a GP appointment, since they usually completed a full assessment themselves anyway.

In relation to quality of care, most patients responding to the survey (94.1%) were satisfied or very satisfied with their care, from receiving their referral to arrival at the breast clinic. This was supported by qualitative data in which most patients were very happy to be fast-tracked to the breast clinic and reported their experience in very positive ways.

“So, if, now, if I was to find another lump I could make the call when I was at work already because I know that it’s a referral process so again it will save me time and effort. So, fantastic” (P4).

“It kind of feels like you’re being listened to if you’re doing that [offering direct access], that they’re taking you seriously” ... “It was a great system and I think it’s, it put your mind at ease” (P1).

“As soon as they said we have a fast-track referral now where you just go straight, I was like, oh, this brilliant, this is such a good plan, because all those fears, I knew I was going to get in pretty soon and just go straight to the clinic” (P3)

“You know, the fact it was very quick, I had all the support I needed at the hospital. I’m absolutely not saying my GP wouldn’t have been a great help had I needed it, but I didn’t need it” (P7).

A small minority of patients would still rather speak to a health professional prior to a referral being made. In some cases, this could easily be a phone call with a nurse. One interviewee stated that she had asked to speak to a clinician prior to the fast-track referral being made. As she stated, she “was happier to speak to a health professional rather than just a receptionist” (P2). This could be due to a concern about non-medically trained staff apparently making clinical decisions. A clear explanation of the process was therefore important.

“So, the fact that I had spoken to a medically-trained person, that I know was medically trained, rather than it just being a receptionist and for her to say the right track is to go to the breast clinic, I was fine with that” (P2).

A potential downside of fast-track referral was suggested to be a lack of involvement of the patient’s GP in the process, which might affect continuity of care. A small proportion of the patients who responded to the survey (n=11; 7%) said that in hindsight, they would have preferred to see their GP first. However, their stated reasons did not relate to a negative experience on the fast-track pathway, and they reported the same level of satisfaction (very satisfied) on average as the rest of the participants.

4.3.2 Patient experience

Patient interviews suggested that benefits to patients included saving time and hassle associated with attending a GP appointment, not having to take time off or be late to work, or to negotiate shifts to attend a GP appointment, and not having to burden family members for transport. The survey confirmed that almost one third of patients in the sample would have had to take time off work to attend a general practice appointment, with 15% of these losing income as a result. One in ten would have had to arrange cover for caring responsibilities.

Data from the patient survey and interviews suggested that patients felt the fast-track ‘made sense’ to them for two key reasons: first, some patients expressed that they knew their own body, and they did not need to have confirmation from a GP that there was something different in their breast; second,

they knew that primary care is under considerable pressure, and they saw a GP appointment in this situation as largely unnecessary. Some patients had a good understanding of what was required to rule cancer in or out (i.e., imaging), and knew that this could not be provided in a general practice setting. So, they were generally keen to go straight to the breast clinic where they could get a definitive diagnosis more quickly. Although, on occasion, it was felt that going directly to clinic could create a sense of urgency and make patients nervous about the seriousness of their condition, this was not reflected in either the anxiety scores or the patient interview data.

4.4 What are the explanations for succeeding in improving the cancer diagnostic pathway?

Breast clinic staff, working with a project manager, invested considerable time prior to implementation to ensure all general practice staff were comfortable and confident in implementing the new pathway. Building good relationships between the general practice staff and the breast clinic staff at this early stage ensured any questions or concerns before and during implementation of the new pathway could be discussed and resolved. The Project Manager and ANP met with primary care teams through MS Teams meetings, telephone calls, and emails to provide *training* and offer support where needed. In the first 6 months of the implementation phase, email reminders of the referral protocols were sent out to all practices, along with a list of *Frequently Asked Questions* and responses. This was appreciated by the GP reception teams and helped to ensure referrals were appropriate and the teams were confident in screening and referring patients. Breast clinic staff were informed about the fast-track pathway through regular team meetings (e.g., Continuing Medical Education meetings), informal discussions, and regular email updates which provided an opportunity to discuss concerns and provide feedback.

Whilst there were some concerns amongst a minority of practices and amongst some breast clinic staff at the outset, a phased roll-out enabled a 'try it and see' approach. The majority (38/52) of practices were keen to be involved at the outset (by August). All other practices bar one subsequently agreed to implement (by November), and the final practice agreed to implement in December. The phased approach enabled concerns about potential increased workload in the breast clinic to be alleviated, and it enabled word to spread amongst the general practices, demonstrating that the new pathway could be implemented without problems.

"We gradually put the surgeries on, we didn't put them all on at the one time, there was like 52. So, we had like five and then five, just because we were afraid that we were going to get too many referrals all at once and it didn't happen at all" (S7, advanced practitioner).

Clinical and management teams at NHS Forth Valley closely monitored patient referrals throughout implementation. Meanwhile, breast clinic staff (the project manager and advanced nurse practitioner) met with GP managers to discuss the new pathway and to encourage all practices to adopt it.

The screening tool (referral criteria) was straightforward and easy to use in discussion with patients. Since it was short, it could be made clearly visible and to hand (for example, laminated at the desk). The tool was also fit for purpose in terms of generating appropriate referrals. It was clear from our data that patients reported a positive experience of the referral process and were happy to answer the

referral questions *because* the receptionists were ‘calm, clear, pleasant and professional’. It was important therefore that receptionists were clear, confident and well-informed. Reception staff felt they had enough information about the pathway to be able to discuss it with patients. It was helpful that the receptionist could reassure patients by always giving the option to speak to a clinician either on the phone or in person.

“I think having the laminated questionnaire at the desk as well, something that’s clearly visible, you didn’t need to go looking or try and memorise the criteria for this service, and it had the information leaflet next to it as well so staff were almost scripted essentially, as to the information they were providing which ensured the accuracy of it as well” (S8, GP practice manager).

The practices fitted the fast-track referral into their day-to-day practice in a way that worked best for them. Sometimes, receptionists completed the referral whilst on the phone to the patient; sometimes they completed them in batches later that same day (when they were less busy on the phones); sometimes they passed them to another staff member to complete. This meant that practices did not need to give receptionists access to and training on the SCI gateway referral system if they did not already have it. Streamlining the referral process for administrative staff (e.g., by embedding the screening tool in a clear way within SCI Gateway), helped to ensure consistent adoption.

“What I did ... was try to create some time where our staff were not attached to a reception desk or a phone, so actually if you need to wait until, so, you’ve spoken to a patient at 12 o’clock, if you need to wait until three, or half-past three when the phones get awful quieter to ask your colleague to take over the phone and reception, to give you 15 minutes to fire off the referral that you’ve spoken to that day, then we are happy to accommodate that for one another” (S8, SP practice manager).

“I could get a phone call, and we’ll go through the scenario where we get the form filled in and then we need to refer them, I can’t do that when I’m sitting on the phone and there’s 40 folk at the desk, so [Secretary] will do those ones for us. Or it’ll get handed to [Receptionist] when she comes in and she’ll do it because they always get done on the day. So, we’re not leaving anybody lingering if they need to get referred.” (S1 GP receptionist).

Breast clinic staff, supported by the project manager, made regular contact with GP practices to ensure continued engagement with the improvement project and to offer support where needed. This was done through emails (approximately once a month), phone calls (to follow up on queries), and other discussions with GP teams, which served as opportunities to gain feedback, answer questions, and talk about *how* practice teams were implementing the new pathway. For example, in the early implementation phase there was a practice manager that felt unsure about sending referrals through a cancer pathway and had sent a referral as routine instead. They contacted the ANP and Project Manager immediately to seek advice and the referral was amended. This worked well as the ANP and Project Manager had developed strong working relationships with the practice teams and offered an *open-door policy* in which they could be contacted when needed. GP staff gave eligible fast-track patients standardised information about their referral in advance of the breast clinic appointment.

Patient interviews highlighted that they valued this information to help them know what to expect and to help them plan. The staff survey revealed that this information was reaching patients in a variety of ways, via a written leaflet delivered in person or by post, by email or by text message. Where appointments were arranged quickly, there was a danger that information sent by post would not arrive before the appointment date. Some patients very clearly preferred receiving information in writing.

The new fast-track pathway was low risk because it required minimal additional workload and generally fitted well with existing processes for arranging patient appointments. The new pathway was consistent with an evolving way of working within general practice of signposting and triaging patients. Culturally, patients reported that they were used to being asked questions about their health condition by receptionists, so they could be directed to the most appropriate person. They generally trusted receptionists with this information because they are general practice staff. Receptionists also reported being used to taking on this 'care navigation' role and were generally comfortable with asking further questions and making decisions about what type of appointment was most suitable. The pathway was also low risk because if the patient opted not to be referred on the fast-track pathway, the 'default' pathway was to see or speak to a clinician first, which would not disadvantage them in any way.

4.5 What are the explanations for not succeeding in improving the cancer diagnostic pathway?

The improvement project was implemented almost exactly as intended, and with the anticipated outcomes. It was therefore not necessary to seek explanations for *not* succeeding in improving the cancer diagnostic pathway in this situation. The findings highlighted that an important aspect of ensuring the fast-track referral worked well was having reception staff who felt comfortable and confident in asking the referral questions and understood why they were asking them. Some of these staff, if they were putting the referral through, may be unfamiliar with SCI gateway. It was important, therefore, that they were trained and supported in implementing the new pathway. General practices can have very limited time available for staff training. The staff survey showed that some general practice admin staff preferred to learn by observing and by doing (and being observed) rather than by 'instruction by email'. Continued support from reception staff and sustained implementation could be harder to maintain when there is a high staff turnover.

It is important to consider some possible confounding factors affecting waiting times for clinics. In particular, the NHS Forth Valley breast clinic were providing mutual aid to patients from other Health Boards throughout the whole period, but at different rates depending on the requests they received for help. When the waiting times were longer, they were seeing 80-100 extra patients from other Health Boards, on top of their own referrals. This dropped at times, if the demand from other boards was reduced. During the last 4 years NHS Forth Valley have seen patients in their one stop clinics from NHS Lanarkshire, Tayside, Fife, Grampian, Shetland, Orkney, Western Isles, Borders and Highland. They felt it was important not to stop this mutual aid activity during the study period as it was providing an important service for patients who were having much longer waits in other Health Boards. However, it may have affected the fluctuating waiting times since there was significant variability in the number

of extra patients being seen. Although patients from other Health Boards were excluded from this study, they were being seen at the same one stop clinics, so there will have been an effect on overall waits.

5 Main lessons learned and implications for transition

5.1 Working towards diagnostic pathway improvements that could have impact

The NHS Forth Valley fast-track referral case study has highlighted that efficiencies can be achieved in diagnostic pathways where a clear potential for streamlining the process is identified, and where primary care and secondary care colleagues work together to design and implement the improvement. The key problem targeted by this improvement is unnecessary delays in cancer diagnostic pathways. This is a shared concern across all of the UK and can limit access to timely care, leading to delayed diagnoses and treatments, and disproportionately affecting vulnerable populations. When a primary care appointment is required in order to receive a secondary care referral for diagnostic assessment, this can create unnecessary delays.

Creating efficiencies in an over-burdened NHS is a key strategic priority. The intended outcome of the improvement project – to eliminate the need for a clinician appointment prior to referral for patients who identify a breast lump – will not solve GP pressures, but it is an example of reducing unnecessary workload so that GPs can focus on patient care. The key elements of this improvement project are simple: a screening tool for GP receptionists to use, and a method for supporting staff to embed the fast-track referral into their practice processes.

Our evaluation provides useful evidence to support the scale up of this improvement project, demonstrating that meaningful efficiencies can be gained, without detriment to quality of care, clinical outcomes or patient experience, and with potential economic gains in a reduction of patient pathway costs (from referral to first attendance). This is supplemented by a wider body of evidence that supports this improvement project's theory of change. For example, evidence highlights the importance of reducing both the duration of waiting for diagnostic results and the frequency of required appointments to alleviate stress and improve patient experience (Moore, 2018). Within general practice, the receptionist plays a pivotal role in the efficient functioning of healthcare services, acting as the first point of contact for patients. Their responsibilities extend beyond administrative tasks, encompassing care navigation to guide patients to the most appropriate services or healthcare professionals based on their needs. Moreover, the role of the receptionist is expanding to include more clinical responsibilities, such as triaging patients, administering repeat prescriptions, and managing referrals, with the aim of freeing up GP time (Litchfield et al., 2017).

Potential impact of introducing the new pathway in other Boards may depend on secondary care waiting times, and the secondary care clinic's capacity to respond to new fast-track referrals for suspicion of cancer on top of backlogs. The effort required to implement the improvement successfully (in terms of breast clinic staff actively engaging and working with general practice staff) may depend partly on the size of the Board, since larger boards will have a lot more general practices to work with.

5.2 Working towards diagnostic pathway improvements that could be transferable across the UK

Findings from this evaluation suggest that few changes to the improvement project are likely to be required for scale up. It contains few elements, around which there is relatively easy potential for local adaptation. For example, other Boards may wish to introduce a lower age limit that is higher than 18 years of age. Adaptations at the general practice level are also likely, for example in how they incorporate the fast-track referral process into their business as usual, and what information they distribute to patients and how. Our evaluation has demonstrated that such adaptations are feasible, and that they are unlikely to have any impact on the intended outcomes of the intervention. Moreover, it is feasible to monitor the implementation and outcomes of the new pathway at the level of the breast clinic.

The fast-track referral pathway has clear potential to appeal to general practices, given the opportunity it presents to reduce the number of clinician appointments required. However, adoption of the new fast-track referral pathway within general practices might depend on:

- Whether the practice is experiencing a 'steady state', or whether they are in a time of turbulence (e.g. related to significant staff changes).
- How many other innovations the general practice is being asked to adopt at the time.
- The practice's staff arrangements (how administrative tasks are handled, and by whom).
- Relationships with secondary care (breast clinic) staff; a pro-active breast clinic team that communicates well with general practice staff, that understands that different practices work in different ways, and that works together to resolve issues/concerns can facilitate adoption.
- The practice's perception of how much there is to gain (from a patient's perspective). If the practice already manages to make same-day appointments for patients, they may feel there is less to gain from the direct referral route.
- The practice's processes and computer systems; it may be easier to embed the new referral process in some systems than others.

The appeal to breast assessment clinics is less clear, and there may be concerns raised about subsequent increases in inappropriate referrals. However, this evaluation has shown that to ensure success, this project needs to be a collaboration between secondary care breast clinic teams and general practices. Therefore, leadership from breast clinic teams, and the support of a project manager to ensure successful communication, implementation and monitoring, is essential.

5.3 Methodological reflections

In the first phase of this project, we collaboratively developed a theory of change for the improvement, which helped us to refine our evaluation framework and data collection tools. We also conducted an evaluability assessment which was helpful in identifying the necessary data and resources required to conduct a meaningful evaluation. Identifying specific data for analysis relied upon an extensive conversation between NHS health care staff, NHS administration and analysts, and the University of Stirling evaluation team. A key challenge has been different understandings of what information about

data items is needed (e.g., metadata, such as the specific categories and data formats) which is made more difficult by governance preventing the University evaluation team seeing the original data in-situ. The purpose of this governance is to protect patients, but it can be a barrier to this type of evaluation. Another challenge has been limited access to some data because it is not in digital form, or because access requires gatekeeper permissions. These challenges are likely to affect other evaluations. One of the facilitators has been the responsiveness of NHS administration and analytical staff to specific data queries, despite their limited time capacity.

MM (the Researcher) regularly visited the breast clinic and engaged with clinical staff. For example, MM attended Continuing Medical Education meetings to present updates on the progress of the pathway and to gather valuable stakeholder feedback. These meetings provided an important opportunity for the breast clinic team to engage with the project, fostering a shared understanding of its goals and addressing any challenges collaboratively. By being actively involved in these discussions, the breast clinic team developed greater trust in the project and its aims, which helped to build confidence in the pathway's potential to deliver improved patient care.

6 Reflections and key points

KEY POINTS

- ✓ The fast-track referral is feasible and acceptable to clinical staff and patients.
- ✓ The new pathway saves at least one primary care clinical appointment for each referred patient.
- ✓ In NHS Forth Valley, where there are approximately 8,000 breast clinic referrals each year, the economic value of potential gains is estimated in the range between £126,480 and £333,440 per year.
- ✓ Having a fast-track referral, and avoiding the need for a primary care appointment, can be particularly valuable for those patients who find it harder to attend appointments (e.g., due to inflexible work, caring responsibilities, or unreliable or expensive transport). This has the potential to help address inequalities in access to healthcare.
- ✓ Removing the initial GP consultation does not affect the process or outcomes of cancer diagnosis.
- ✓ The impact of this new pathway on earlier breast cancer diagnosis will vary, for example, depending on how difficult patients would have found it to attend a GP appointment in their local area, and the relative demand/capacity in the breast clinic. There are indications that the fast-track referral system can reduce very long waits for outpatient appointments, and subsequently for a diagnosis.
- ✓ The intervention is suitable for rolling out across other Boards with minimal investment (see recommendations below).

The NHS Forth Valley fast-track access project successfully co-designed a fast-track referral system for use by general practice reception staff with patients reporting a breast lump. In testing and refining that fast-track referral system, the improvement was successfully implemented across 100% of the general practices in the Board area, proving it to be effective on a small scale. The evaluation found

that this fast-track access for patients with a breast lump was effective: it reduced costs to the local healthcare system, released clinician appointments in general practices, and resulted in timely diagnoses. Over 92% of patients received their diagnosis within the 28 days stipulated in NHS England's faster diagnosis standard, which is a standard that NHS Scotland also works towards (NHS England, 2022). The results of the routine data analyses suggest that, while underlying time-varying trends in the data were contributing to an increase in waiting times prior to implementation, the intervention appears to have started mitigating these trends, leading to reductions in referral times over time. While these effects were marginally not statistically significant, further data beyond the series captured in this analysis may have demonstrated beneficial effects for both time to first attendance and time to diagnosis. It is plausible that the volume of referrals from other health boards contributed to increased demand, potentially impacting referral times at the Forth Valley breast clinic and partially explaining the fluctuations in the underlying trend and the observed increases in waiting times.

The new pathway was acceptable to both the breast clinic setting and to general practices. Patients also reported positive experiences of the new pathway, which potentially saves at least a proportion of patients the time and cost of attending an unnecessary appointment.

This fast-track referral pathway has already been adopted as 'business as usual' in NHS Forth Valley. Clinicians in other NHS Boards have also shown interest in adopting it. To share the learning from this project, the team have presented early findings at the Scottish Cancer Conference and will be presenting full findings at the Cancer in Primary Care Research International Conference in April 2025. They will also present findings to the Scottish Primary Care Cancer Group, the cross-party group on cancer, the cancer performance delivery board, and to other groups as appropriate.

7 Recommendations

Based on the experience of NHS Forth Valley and the general practices that implemented this new fast-track pathway, we have noted the following recommendations to maximise the effectiveness and acceptability of the improvement project:

- a) Clinical leads from the secondary care breast clinic staff should be identified to champion/oversee this change. This might be a consultant, surgical care practitioner, or an advanced nurse practitioner who knows the work of the breast assessment clinic well. Identify some administrative/project management support for the clinical leads, who can help with liaising with general practices and monitoring implementation and data.
- b) Clinical leads need to have a good contextual understanding of their breast clinic services, to ensure they have capacity to meet demand of the fast-track referrals and can meet waiting times standards.
- c) Clinical leads might expect to take a couple of months to establish a good relationship between the secondary care team and general practices, working through local/regional general practice fora first. It is important to articulate the rationale, to highlight the potential gains (reduced GP appointments, excellent patient experience), and to alleviate concerns (patients find it acceptable and it has little to no impact on demand for breast clinic appointments or clinical outcomes).

- d) GPs and practice managers should identify the best way to integrate the process of making fast-track referrals into their usual practice, and who is best placed to complete the referrals (e.g., the receptionists answering the phones, or a secretary).
- e) Clinical leads, working with practice managers, should ensure that reception staff (all those who will be involved in making fast-track referrals) have the support and training to enable them to feel comfortable and confident in using the screening tool and completing the referrals.
- f) Practice managers should identify the best way to make the screening tool visible and easy to use – e.g., as a laminated copy on the desk, or integrated into the electronic referral system.
- g) Clinical leads should have regular (e.g., monthly) ongoing check-ins with participating practices to answer any questions and identify any issues.
- h) When speaking to eligible patients, receptionists should make it clear that they are still able to see a GP/nurse prior to clinic referral if that is their preference.
- i) All patients referred to the breast clinic should receive clear information about what to expect at their breast clinic appointment. This should be produced in a variety of formats. General practices should consider how to send this information quickly (e.g., via email), so that patients receive it before the clinic appointment (which might, depending on circumstances, be in just a few days).
- j) Clinical leads should ensure that clinic referral data is monitored on a routine basis to ensure fast-track referrals continue to be appropriate, and to ensure there are no implications for the workload of clinic staff.
- k) Clinical leads should feedback patient experiences of the referral process to general practice staff.

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List of appendices

Full documents are provided in a supplementary folder.

Appendix 1: Improvement project description, using TIDieR framework

Appendix 2: GP rapid access breast referral questionnaire

Appendix 3: Breast lump GP patient information leaflet

Appendix 4: IRAS protocol

Appendix 5: Technical Report: routine data analysis

Appendix 6: Technical Report: health economic analysis