



Implementation of home ‘finger-prick’ carcino-embryonic antigen testing for colorectal cancer follow-up – A pilot study of user acceptability



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ABSTRACT

Aim: Routine carcino-embryonic antigen blood testing is required after colorectal cancer resection, requiring face-to-face appointments. This has workforce implications, and impacts patients' lives. We assessed feasibility and acceptability of self-taken blood tests.

Methods: 50 colorectal cancer patients with experience of face-to-face phlebotomy surveillance agreed to self-testing finger-prick kits. Follow-up questionnaires assessed perspectives and preferences.

Results: 68% (50/74) of patients agreed to participate. 76% (38/50) successfully completed samples. 62% (29/47) felt it was no worse than their previous experience. Regarding future testing, 47% (22/47) preferred finger-prick testing. 19% (9/47) expressed no preference. This was unaffected by patient age. Qualitative assessment showed difficulties with pain, discomfort, and sample collection, but was more convenient and saved time for patients.

Conclusions: Many preferred finger-prick assessment, but some found it challenging, unnecessary or less preferable. This may reduce burden of follow-up blood tests but currently would only be acceptable to a limited patient cohort.

Introduction

Approximately 30,000 patients are diagnosed with colorectal cancer in England and Wales per annum. 20,000 will be treated with curative intent.¹ Following curative colorectal resection patients are followed up with the aim of identifying recurrence as early as possible, to improve the likelihood that the recurrence is resectable.² Current National Institute for Health and Care Excellence (NICE) guidance recommends that surveillance includes 6-monthly blood carcinoembryonic antigen (CEA) estimation for 3 years after treatment.² Patients are also followed-up with computed tomography (CT) imaging of the chest, abdomen and pelvis within three years of treatment completion, and British Society of Gastroenterology (BSG) guidance advises colonoscopy at one year and surveillance colonoscopy after 3 more years.³

CEA blood tests are typically taken through peripheral venepuncture, requiring face to face (F2F) contact between healthcare provider and patient. Locally, this service is most often provided at a patient's registered primary care facility, with samples couriered to the hospital

laboratory for analysis, and results followed up remotely by colorectal services. Anecdotally this has been associated with difficulties. Some patients report that their primary care service declines to facilitate bloods at the hospital's request citing concerns over funding of already over-stretched primary care resources, and concerns over responsibility for following-up results. Long waiting times for phlebotomy appointments can result in delays, and increased workload for secondary care services chasing up appointments or organising alternative testing. Patients may need to take time off work to attend a phlebotomy appointment. In recent years, national shortages of blood tubes have led to rationing of blood tests, with limits on ‘non-urgent’ tests.⁴ During the recent Covid pandemic, phlebotomy appointments resulted in increased contact between often clinically vulnerable patients and healthcare services, when they would normally have been discouraged from social interactions.

The 2021 NHS Long Term Plan stated that following cancer treatment, patients should move to follow-up pathways suiting their needs, termed personalised stratified follow-up pathways (PSFU).⁵ The NHS Long Term Plan also includes a drive towards redesigning services to

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avoid up to a third of F2F outpatient visits, saving patients' time and inconvenience, and freeing up staff for other tasks.

There has been a recent increase in private organisations advertising home-testing kits to consumers wishing to check a variety of biomarkers in their blood or sputum. These include postal kits with finger-prick sampling devices and blood tubes, which are then returned to accredited laboratories for testing,⁶ avoiding the need for appointment with a phlebotomist, or the involvement of a clinician in decision to test. Testable biomarkers include CEA and other tumour tissue markers, although CEA is not advertised or available to public purchase. In line with the NHS Long Term Plan, recent large scale regional pilot schemes have gained national media coverage for changing services such as NHS health checks into remote services, though concerns about whether this will be appropriate or acceptable for all patient groups have been raised by groups such as Age UK.⁷

This study aims to pilot the provision of CEA finger-prick blood testing as follow-up post curative colorectal cancer resection, and to assess feasibility and acceptability to colorectal cancer patients.

Methods

Patient selection

This study was carried out during the COVID pandemic with recruitment taking place between 18 January 2021 and 15 March 2021. All patients reviewed in colorectal cancer nurse specialist (CNS) clinics were assessed against the eligibility criteria. Eligible patients were those following curative colorectal cancer resection intended for active surveillance with CEA monitoring, with previous experience of CEA monitoring through primary care. Patients were ineligible if their underlying pathology was neuroendocrine tumours or appendiceal mucinous neoplasms, they were already involved in another trial requiring CEA monitoring or were unable to provide consent. Where patients declined recruitment, the reason was recorded. Consecutive eligible patients were offered participation in the study until 50 had been recruited. Recruited patients received a patient information leaflet and a follow-up telephone call to answer any questions, before verbally consenting to participation.

Testing protocol

Patient contact details were entered into a secure online database accessible to Medichecks. Home-testing finger-prick equipment was delivered via post with instructions. The test involves cleaning the skin, pricking the side of the finger with a sterile lancet and allowing a few drops of blood to collect into the test vial. A telephone helpline provided by Medichecks was available for support. Samples were returned using pre-paid envelopes directly to an accredited Medichecks laboratory for processing. Once available, CEA results were returned to the cancer nurse specialist team via the secure online database. Where patients were unable to take the sample despite instruction, they were instructed to have their blood test taken in primary care.

This small study was designed to address user acceptability rather than validate the CEA test itself. Prior to starting the project, all stakeholders agreed that any tests showing a new high CEA level would either be repeated using formal phlebotomy and/or further CT scans would be booked according to our existing protocols.

Questionnaire

Following return of results, patients were contacted by a CNS who went through the follow-up questionnaire [Addendum 1]. This utilised Likert-Type scales as well as free text questions to assess experience of testing. Patients were asked to directly compare their experience with previous phlebotomy. Questionnaire responses were stored securely on a

password-protected server. Once all responses were collected data were downloaded and analysed.

Data analysis

Data analysis and descriptive statistics were generated using *Microsoft Excel*. Free text responses were analysed and grouped according to recurrent themes for comparison. Two tailed t-tests were used to compare continuous variables. Categorical variables were compared using χ^2 tests.

Patient and public involvement

A patient representative with experience of colorectal cancer was involved in questionnaire design, including choice of outcome measures and co-designed the written patient information leaflets. All patients were fully consented for involvement and received written information about the study.

Results

Patient selection

Between 18 January 2021 and 15 March 2021, 74 eligible patients were identified from 163 appointments with CNS. 67.6% (50/74) agreed to participate. Of patients declining participation 13 were due GP blood tests for other reasons and wanted them taken together, 10 wanted blood tests at their primary care facility specifically, and one patient felt they would be unable to perform a finger-prick due to needle-phobia. Ineligible patients included 15 who had not previously had CEA blood tests taken, 12 who had had their CEA taken already prior to their clinic appointment, and two whose ongoing CEA monitoring was performed in conjunction with another clinical trial.

Four patients withdrew on receiving their finger-prick test kits and were not included in questionnaire follow-up. Seven patients were unable to obtain a sufficient sample for analysis using finger-prick testing. A further one patient reported their kit lost in transit after sampling. These eight patients subsequently underwent CEA testing at their primary care provider but were included in questionnaires and analysis (Fig. 1).

Patient demographics

Median age of the 38 successful patients who successfully achieved a finger-prick blood sample was 69 (range 33–85). Male: Female ratio was 1.4:1. Median age of the eight patients who were unsuccessful was 74 (range 51–80). Male: Female ratio was 1:1. Median age of the 28 patients who declined/withdrew was 66 (range 34–81). Male: Female ratio was 1.5:1. There was no statistically significant difference in the age of patients who were successful or unsuccessful in obtaining a finger-prick sample ($p = 0.74$).

Questionnaire completion

Questionnaires were undertaken with 46 patients. Due to a technical issue one unknown patient was asked the questionnaire twice hence 47 unique responses were received. As no two responses were identical in their feedback, and data were stored anonymously, a duplicate could not be identified and excluded.

Subjective preference

Asked to compare experience with previous blood sampling, 17% (8/47) responded that finger-prick sampling was 'better', and 10.6% (5/47) felt it was 'slightly better'. 29.8% (14/47) felt that finger-prick

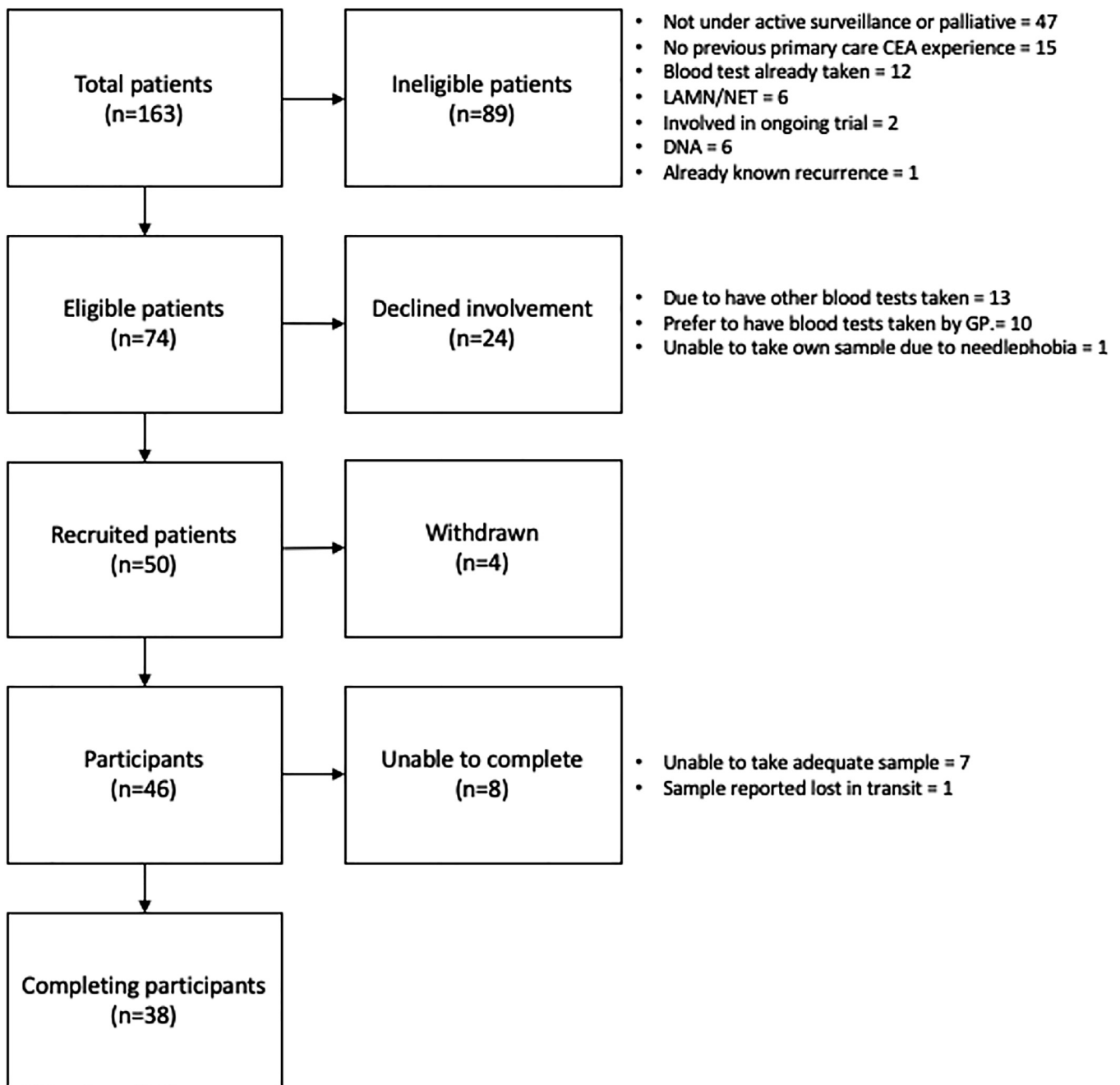


Fig. 1. Patient selection flowchart.

sampling was 'worse' and 8.5% (4/47) felt that it was 'slightly worse'. The remaining 34.0% (16/47) felt it was 'neither better nor worse' (Fig. 2).

Asked which form of testing patients would prefer during the COVID-19 pandemic, 53% (25/47) stated finger-prick testing, 19% (9/47) had no preference and 27% (13/47) preferred to revert to their previous blood sampling experience. 47% (22/47) of patients felt that 'after Covid' they would prefer finger-prick testing, 19% (9/47) would have no preference, and 34% (16/47) would prefer their previous experience (Fig. 3). There was no significant difference between patient preference with respects to Covid ($p = 0.78$). Most patients aged <65 preferred finger-prick assessments for future testing (10/16–63%), whereas in patients 65+ the greatest preference was to revert to F2F methods (13/31–42%). There was no statistically significant difference in preferences between age groups ($p = 0.22$).

Perspectives on testing

Most patients either 'agreed' (17/47) or 'strongly agreed' (9/47) that the finger-prick test was easier for them to do than to attend a F2F appointment (55.3%). Most also 'agreed' (22/47) or 'strongly agreed' (9/47) that the finger-prick test saved them time in their life (66.0%). More patients 'disagreed' (14/47) or 'strongly disagreed' (5/47) that they felt more comfortable with finger-prick testing than 'agreed' (12/47) or 'strongly agreed' (0/47) (Table 1).

Clarity of instruction

Most patients agreed (31/47) or strongly agreed (11/47) that instructions provided were clear (89.4%). 2.1% (1/47) neither agreed nor disagreed, and 8.5% (4/47) disagreed, whilst none strongly disagreed.

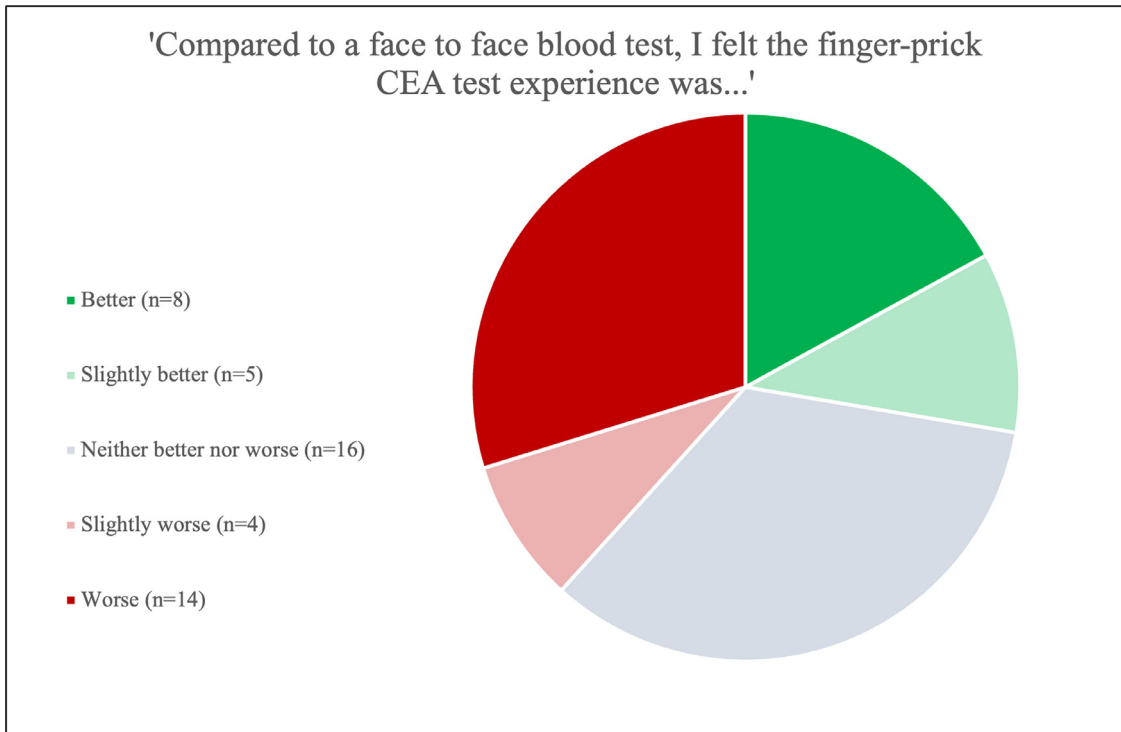


Fig. 2. Pie chart demonstrating subjective experience of finger-prick sampling versus previous experience.

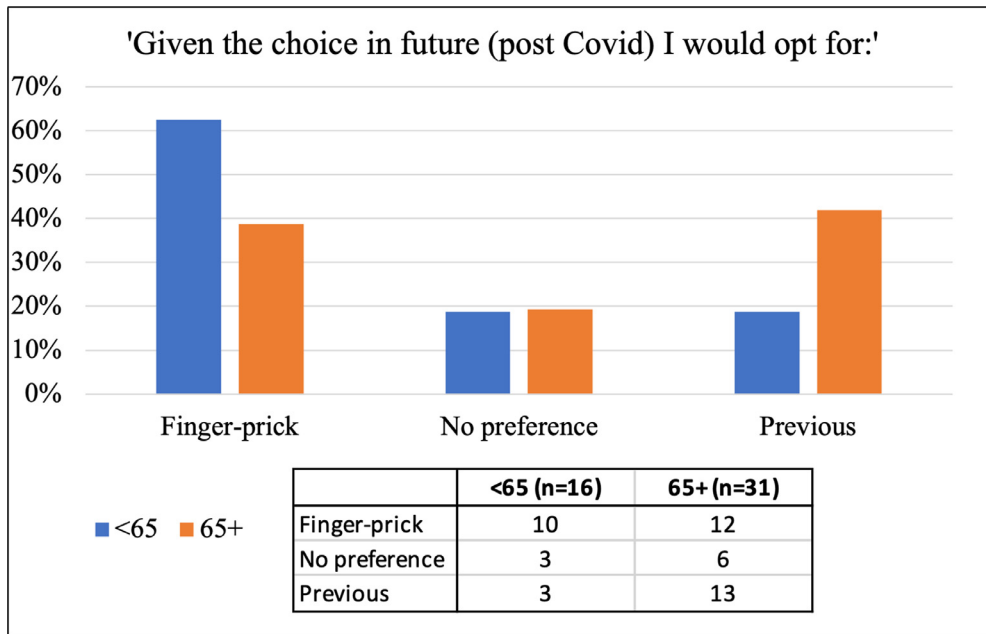


Fig. 3. Bar chart demonstrating different preferences for future CEA monitoring post-Covid.

8.5% (4/47) of patients utilised the available customer service team, with half (2/4) finding it helpful.

Qualitative analysis

Convenience was the benefit most frequently cited by respondents with 14/47 free text responses identifying it as a particular benefit. 11/47 respondents highlighted that the finger-prick test saved them time. 8/47 respondents identified the lack of travelling required, 4/47 respondents felt that not needing to take time off work was a benefit, 4/47 felt safer staying at home during the pandemic, 2/47 found it easier than getting a GP appointment, and a further 2/47 noted the benefit

in saved appointments for the health service. Only 8/47 respondents were unable to identify a benefit of finger-prick testing.

Most respondents (28/47) raised concern about the difficulty associated with taking a sample, following the instructions, taking enough blood and getting it into the right place. 6/47 were specifically concerned about the associated pain, and 3/47 felt they were uncertain about or not confident in the test. 11/47 respondents had no specific concerns regarding finger-prick tests. When asked what participants preferred about their previous blood sampling method, 11/47 felt it was easier, and 5/47 felt more reassured by, or had more faith in, a formal blood test. 10/47 noted that they preferred someone else taking their blood, and 10/47 also preferred having F2F contact with someone. 1/47

respondents reported their previous method was quicker, and 1/47 reported that their previous method was less painful. 10/47 respondents did not prefer anything about their previous method.

CEA values

Ten elevated CEA results were received from sampling (range 2.26–32.30 ng/mL). At the discretion of the CNS these were either repeated formally by phlebotomy in the first instance, or a CT scan was performed.

Discussion and conclusions

There was significant variability in patient perspectives, with 34% of patients expressing preference to continue with their previous method of blood sampling post pandemic. Only 68% of eligible patients agreed to participate in finger-prick testing. Together these values suggest that of eligible patients more than half (55%) would prefer not to have finger-prick testing. The largest barriers to acceptability related to how ‘comfortable’ patients felt taking their own samples, with many patients expressing concern about the process of taking their own blood. There were anxieties relating to doing the test incorrectly causing an inaccurate result. These anxieties were supported by the 8/50 patients who failed to achieve a result with the equipment supplied, and the 4/50 patients who changed their consent to participation upon receiving the testing kit. It is interesting that despite this, only 4/50 patients contacted the helpline provided, and 89% of patients felt that instructions provided were clear or very clear.

Following the Covid pandemic 47% of patients still preferred finger-prick testing. There was no significant difference between those aged below or above age 65, but the reported benefits of finger-prick testing such as convenience, saving time in life and avoiding time off work suggest that those in employment or with care-giving responsibilities may be more likely to benefit from finger-prick testing. Only a small proportion of patients (4/47) felt that avoiding contact with healthcare providers was a notable benefit during the Covid pandemic, and this was likely reflected in the non-significant difference between patient preferences for future testing during, and after, the Covid pandemic.

Our results are similar to other pilot studies conducted for patients with diabetes for HbA1c monitoring during the Covid pandemic, in which 67.9% of a cohort aged 19–81 preferred capillary HbA1c monitoring to peripheral venepuncture, and 52.8% feeling more in control of their condition, despite 25% finding the system difficult to use and 63.2% reporting difficult achieving an adequate sample.⁸ In a separate study of self-collected capillary blood screening for relatives of people with type 1 diabetes, in a young population aged 1–49 there was significant preference (82%) for home sampling versus peripheral venepuncture, with the greatest preference seen in the relatives of those under 18.⁹ This highlights the potential benefits not just to patient groups, but also relatives or carers who are also impacted by the need for clinic appointments, and who were not considered in our study. This population, relatives of people with type 1 diabetes, is also presumed to have higher baseline familiarity with capillary blood sampling. Further studies with larger sample sizes, as well as analysis of data regarding employment status, caring responsibilities and socio-economic status may help to further delineate those for whom finger-prick testing is most advantageous.

Patient populations such as ours differ demographically from the usual target audience of private companies offering blood tests such as ‘well man/woman’ screens to interested individuals. Though little public data exists, these consumers are presumed to be younger and less comorbid. They are also financially incentivised to get a result having paid for the testing kit, and as they have no alternative National Health Service (NHS) route by which to acquire results. The difficulties noted by our participants, with resultant decrease in acceptability, may reflect the different demographics and motivations.

Table 1
Patient perspectives on ease, timesaving and comfort of finger-prick testing.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total
The finger-prick CEA test was easier for me to do than attend an appointment for a blood test	12.8% (n = 6)	19.1% (n = 9)	12.8% (n = 6)	36.2% (n = 17)	19.1% (n = 9)	47
The finger-prick CEA test saved me time in my life	6.4% (n = 3)	23.4% (n = 11)	4.3% (n = 2)	46.8% (n = 22)	19.1% (n = 9)	47
I felt more comfortable with the finger-prick CEA test than a face to face appointment	10.6% (n = 5)	29.8% (n = 14)	34.0% (n = 16)	25.5% (n = 12)	0% (n = 0)	47

CEA = Carcino-embryonic antigen

Whilst our data suggests that for many a finger-prick test represents a less favourable alternative, this cannot necessarily be extrapolated to an unacceptable or unworkable alternative. Issues relating to confidence with ease of testing methods may improve with increasing familiarity with the process, and a limitation of this study is that it did not allow patients the opportunity to familiarise themselves with testing equipment prior to sample collection. Furthermore, there is an established 'normal' with F2F phlebotomy that may have resulted in the lack of confidence some patients had with the alternative finger-prick process. Whilst not fully explored, patients' lack of confidence in the testing process may arise from concern regarding smaller blood volume for testing, or worries that incorrect technique may result in spurious results. Thirteen patients declined to participate because they needed other blood tests at the same time, and this be a practical reason why formal phlebotomy could be preferable. In our study, elevated CEA results were either repeated formally by phlebotomy, or a CT scan was performed. Our study aimed to assess user acceptability of finger-prick testing rather than accuracy of test results but clinicians must also have confidence in the validity of results for the test to also be acceptable to service providers.

Approximately 20,000 colorectal cancer patients are treated with curative intent in England and Wales per annum,¹ resulting in a considerable burden upon healthcare resources monitoring CEA levels six monthly over 3 years.² There are many reasons for which routine blood test surveillance is predictably required, ranging from PSA surveillance in prostate cancer to monitoring for adverse medication effects such as Methotrexate.^{10,11} With the resultant burden on primary care resources, there is financial and work-force incentive to achieve a means of obtaining test results without relying upon F2F appointments, especially when only a single test is required.

CEA testing within our unit is monitored and coordinated by colorectal nurse specialists (CNS), who request the investigation, remind patients to organise phlebotomy, and contact patients if results are not obtained in a timely manner. The experience of our CNS colleagues during this study was that process delegation, with results fed directly back to the team, would be a significant time-saving measure, such that more time could be sent on tasks relevant to their specialised skillset. We have not undertaken a formal economic analysis but anticipate further savings to include primary care reception and phlebotomy time.

Clear benefits were seen in a large proportion of patients, but many patients did not find finger-prick testing preferable. In these groups, the benefits of finger-prick testing may favour the healthcare provider rather than the patient. Utility is likely to be restricted to selected patient groups until wider acceptability can be achieved. Future work should focus on identifying which patient groups are most likely to accept non-F2F blood testing so that tests can be rolled out to specific groups, in line with the NHS long term plan. Technology and testing equipment will need to improve such that the benefits to patients and healthcare systems of not having appointments, are not outweighed by the anxieties and difficulties of sampling. Further work regarding whether patient perception changes with repeated exposure to finger-prick blood tests may help to identify more groups of patients who could benefit from non-F2F blood testing. Ultimately, with increasing pressure on resources and the national drive towards remote monitoring, feasibility and technical considerations are likely to be more important factors to overcome than acceptability and patient wishes.

Conclusions

Whilst some patients prefer finger-prick CEA assessment, there are significant numbers for whom it is currently not preferable. Finger-prick

CEA testing may represent a strategy for reducing burden of follow-up blood tests on resources, but in the first instance this is likely to be limited to certain patient groups.

Ethics approval statement

Prior to project commencement a meeting was held with all stakeholders including the local Clinical Commissioning Group (CCG). They supported the project and agreed it did not need ethics committee approval as it is a service improvement project.

Declaration of competing interest

Equipment provided by Medicecks Ltd free of charge, who also were involved in study design. All survey results, interpretation and write-up performed independently.

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Evidence Summary/Literature Search: Use of patient conducted home blood testing (13 December 2022). UK: Sarah Rudd

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