



Healthcare
Improvement
Scotland

SHTG
Advice on health
technologies

Patient Organisation Submission Form

Subject of SHTG Assessment

Tumour profiling tests to guide chemotherapy decisions in early breast cancer

Name of patient organisation

Breast Cancer Now

Health/medical conditions represented

Early breast cancer

Contact name for this submission

Supplied to SHTG

Role of contact person

Supplied to SHTG

Postal address

Supplied to SHTG

Phone

Supplied to SHTG

Email

Supplied to SHTG

Website

breastcancernow.org

Date of submission

6th June 2023

Please complete the SHTG Declaration of Interest form.

Please complete this form using the accompanying guide and do not include patient identifiable information.

Accessible Language: Where not specifically required for scientific/technical explanation, please use plain language, explaining acronyms and other non-lay terms.

Please note that the information submitted on this form will be held by the SHTG secretariat in accordance with Healthcare Improvement Scotland's [policies](#). This information may be published on the SHTG website or disclosed to third parties in accordance with the Freedom of Information (Scotland) Act 2002 (FOISA).

1. Tell us about the sources you used to gather information for this submission. (See page 6 of guidance.)

Breast Cancer Now has significant experience in patient submissions. We utilise our various networks of people affected by breast cancer, including our Helpline, online Forum and breast cancer services to gather information about patient experience and views of various medicines. In this instance we were able to capture the stories of three breast cancer patients, two of whom had tumour profiling tests (Prosigna and Oncotype DX).

2. What is the health condition and how does it affect the day-to-day lives of patients and their carers? (See page 7 of guidance.)

In Scotland, every year around 4,800 people (4,800 women and 30 men) are diagnosed with breast cancer. That's around 94 people every week.

The specific type of breast cancer under consideration here is ER-positive, HER2-negative, early-stage breast cancer (stages I or II) who are lymph node negative and positive.

Treatment for primary breast cancer is usually a combination of surgery, radiotherapy and chemotherapy. Up to 80% of breast cancers are oestrogen receptor positive (ER+). Patients with hormone-receptor positive breast cancer will receive endocrine (hormone therapy). Research suggests that patients' experience of hormone therapy side effects can affect adherence and, in some cases, result in treatment discontinuation. Some patients will also have adjuvant chemotherapy which can be associated with additional side effects, such as nausea, neutropenia and hair loss.

A diagnosis of breast cancer can be devastating for the patient and the people close to them. Breast cancer survival is improving and has doubled in the last 40 years in the UK, due to improvements in treatment and care, earlier detection through screening and a focus on targets, including faster diagnosis.

Despite these improvements there is still concern about the impact disease will have on the body, the side effects of treatment and whether the cancer will return. Patients also report high levels of stress and anxiety, and many find life after breast cancer to be challenging.

“The shock was tremendous. I hadn’t felt ill or felt any lumps. For me, all I had noticed was dimpling in my left breast and nothing had shown on either mammogram or ultrasound. It was only as a result of biopsies that it was confirmed I had lobular breast cancer ER+ HER2-. None of this meant anything to me and the 3 weeks following diagnosis which were filled with various diagnostics (MRI/Tomosynthesis) were a mental battle which had me fearing a death sentence and feeling very lonely.”

Risk of recurrence can be particularly distressing. “The constant worry about a recurrence or developing a secondary is also an ongoing issue. Dealing with the constant thoughts of ‘will I be around for that’ or ‘is there any point in paying into a pension’ is definitely on my mind a lot.”

Having to take time out of work and family responsibilities is common, as people attend hospital appointments and recover from the side effects of drug and other therapies “I am self-employed and the news that I had breast cancer and that it had spread to my lymph nodes was both terrifying and devastating for me. I decided to give up work straight away as felt I couldn’t work and go through my treatment at the same time. It was a very difficult time for me both financially and emotionally.”

Patients and their carers report that the side effects of treatment can be as devastating as the disease itself. In the words of one patient, “The main issue I have day to day is the medication I take to reduce a recurrence. In my case this is a monthly zoladex injection and a daily exemestane tablet. The muscles aches and joint pain can sometimes be unbearable. I’m 33 years old and some days feel 100!”

Chemotherapy can be viewed with trepidation because of the side effects which can include, feeling sick, loss of appetite, losing weight, increased risk of getting an infection and hair loss.

One person commented: “Until I started chemotherapy I actually still felt well. I recovered well from surgery, but chemo is so much more systemic, and the loss of my hair was a notice to the world that I had cancer. I felt like I was no longer “normal” and was very fatigued. At times, I could hardly walk the length of myself.”

3. What do patients and carers want from the health technology? (See page 8 of guidance.)

The health technology being considered here are tumour profiling tests, specifically Oncotype DX, MammaPrint, EndoPredict, Prosigna. Tumour profiling tests are designed to provide information on the activity of genes within tumour samples from people with early breast cancer who are lymph node negative and positive.

The results of the tests provide a risk profile of an individual's breast cancer which can be combined with other clinical risk factors that are routinely assessed, such as nodal status and tumour size, to better predict the risk of disease recurrence in the future. Some tests may also predict the benefit a patient may receive from chemotherapy.

The availability of tumour profiling tests is an opportunity to provide a more personalised treatment approach; identifying people who have a high risk of recurrence and are more likely to benefit from chemotherapy, as well as identifying those who are more low risk and where chemotherapy can be safely omitted. Whether or not chemotherapy is needed can often be one of the top concerns for patients and having more information to inform discussions and provide reassurance can be an important step forward.

Tumour profiling tests can provide some 'certainty' and reassurance. A patient said: "I believe the benefits are that it allows clinicians and patients to make more informed decisions regarding treatment options and in particular whether chemotherapy is going to be beneficial."

Another highlighted how the test results can ease worry and concern, saying: "I think it helps people who get a low score to not worry as much and also not have treatment they don't need and for people who score high I feel it allows them to take any action necessary to reduce their reoccurrence risk."

It is important to remember that waiting for test results can also be anxiety inducing for people. Therefore, it is essential that people be given their results in a timely manner.

For someone who wasn't offered a tumour profiling test, her oncologist used NHS Predict, a concern remains that she, if she'd had access to the tests, she could have avoided chemotherapy ("...the worst part of my treatment). ". I question whether I needed to go through chemo and whether it has actually made any difference. I have since found out that lobular cancer tends to respond less to chemo than other cancer types (not always but in general terms). I have questioned why I didn't get oncotype testing and was told I didn't qualify due to the size of my tumour (12.5cm)."

A 30-year-old patient told us that she felt the tests were particularly important for younger women: "I was very happy to have access to the test so I could have the full information

about my cancer and could make an informed decision about my treatment. The majority of treatments and medications are tested on and discussed around older people. I realise the older age groups make up the majority of cases but not all. Younger people should have tailed access to treatment and the test I had on my tumor meant I was treated in a specific way for me.”

4. What difference did the health technology make to the lives of patients that have used it? (Leave blank if you didn't make contact with anyone who had experience of the health technology.) (See page 9 of guidance.)

Patients we spoke to suggested that benefits include reassurance and confidence about their treatment plan - whether chemotherapy is the most effective and appropriate treatment or whether they can safely avoid having chemotherapy. It is important that patients have a clear understanding of the role of the test within wider decision-making.

Tumour profiling tests can make a significant difference to patients, knowing that the decision about treatment is personalised and providing assurance that everything that can be done, has been done, to prevent recurrence and reduce the time under treatment.

The quantification of risk in a single score can help people understand the complexity of risk assessment. “I think it helps people who get a low score to not worry as much and also not have treatment they don't need and for people who score high I feel it allows them to take any action necessary to reduce their reoccurrence risk.”

Test results gave this person a sense that they had taken every step to prevent the cancer returning. “I felt it put my mind at rest as to whether it was highly likely it would come back or not. I do take comfort in the fact I didn't get a high score on the test and also had all treatments I could have to stop it from coming back.”

In this specific case, it was decided that chemotherapy was not the most appropriate treatment. “Results took a couple of weeks to come back, and I was told I could go straight to radiotherapy. I have never regretted my decision to join the trial. The only “nuisance” was

that I was prescribed the zoladex injection for 3 years. If I had seen the needle before joining the trial, I might have changed my mind! I was elated that my treatment time had been dramatically reduced by not needing chemotherapy.”

5. Additional information you believe would be helpful for SHTG to consider. (See page 9 of guidance.)

Where tumour profiling is made available for people with ER-positive, HER2-negative, early-stage breast cancer who are lymph node negative and positive, test results should be turned around in a timely manner and that patients understand the possible turnaround times.

6. Please summarise the key points of your submission in up to 5 statements. (See page 9 of guidance.)

A diagnosis of breast cancer can be devastating for the patient and the people close to them. Breast cancer survival is improving and has doubled in the last 40 years in the UK, due to improvements in treatment and care, earlier detection through screening and a focus on targets, including faster diagnosis. However, there is still concern about the impact disease will have on the body, the side effects of treatment and whether the cancer will return. Patients also report high levels of stress and anxiety, and many find life after breast cancer to be challenging.

Tumour profiling tests can provide some 'certainty' and reassurance for patients. The results of the tests can allow clinicians to better predict the risk of recurrence and identify those who may not benefit from adjuvant chemotherapy.

Chemotherapy can be viewed with particular concern because of the side effects which can include, feeling sick, loss of appetite, losing weight, increased risk of getting an infection and hair loss.

Tumour profile testing can be seen as positive for patients because their treatment can be 'personalised'. Tumour profiling can make a significant difference to patients in terms of providing assurance that the treatment provided to them is most effective and appropriate.

7. Please give us details of anyone outside your organisation that had a role in preparing your submission. (See page 10 of guidance.)

8. Do you consent for your submission to be posted on the SHTG website? (See page 10 of guidance.)

Yes

No

Thank you for completing this form. It will be given to SHTG members to inform their development of an Advice Statement for this technology.

Please return the form to:

his.shtg@nhs.scot