NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Multiple Technology Appraisal (MTA)

Intrabeam targeted intraoperative radiotherapy for the treatment of early or locally advanced breast cancer

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: Marcelle Clark

Name of your organisation: Freelance novelist, journalist and teacher

Are you (tick all that apply):

- a patient with the condition for which NICE is considering this technology?
- a carer of a patient with the condition for which NICE is considering this technology?
- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc)
- other? (please specify)

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. **Advantages**
(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

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Dramatically reduced timespan between diagnosis and end of treatment.
The difference this makes to physical condition and mental attitude is inestimable. I am told that the repeated hospital visits necessitated by EBRT seem endless, no matter how caring the staff.

Another result of the above is that one does not have time to feel like a 'breast cancer sufferer.' There is an immediate sense of well-being, Added to that is continuous good quality of life.

Precise targeting of tumour.
This gives confidence to the patient that there is no 'dancing in the dark.' The surgeon pinpoints exactly the (possibly tiny) spot to target with Intrabeam. . Certainly in my experience there were no side effects such as local tenderness, swelling, reduced range of movement or change in breast appearance. All of which I understand are regularly experienced after EBRT.

Other organs are spared the effects of radiation. It is now accepted that there is no level of radiation which does not adversely affect the heart. Following whole-breast radiation, non-breast cancer deaths or long term illness can be attributable to heart damage and other cancers, including of the lungs and oesophagus. With Intrabeam, the results of a major trial (The Lancet Nov.11.2013) showed that deaths from causes other than breast cancer were lower in the TARGIT trial group than in women who received standard radiotherapy – only 1.3% compared with 4.4%.

Intrabeam treatment can be repeated in the same breast if necessary. I understand that this is not possible with EBRT since breast tissue will not tolerate further radiation. I further understand that if breast cancer recurs, it may well do so in the same breast and even in the same quadrant. Intrabeam could then be used again. But if EBRT has already been used, mastectomy might be the only recourse.

Rapidity of Intrabeam delivery.
Because this is done immediately after the tumour is removed, there is vastly reduced risk of cancer cells repopulating. This detrimental process may take place in the time allowed for the wound to heal before EBRT. This may be many weeks. If chemotherapy is also used, as in more aggressive cancers, radiation may be delayed by six months.

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

1. The course of the condition is drastically curtailed with Intrabeam. So recovery is much faster. What is normally a prolonged illness becomes virtually a single episode. And then it's over, except for medication and check-ups.

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2. Certainly in my case there were no physical symptoms resulting from the use of Intrabeam. I merely had the results of the surgery – and those were minimal.

3 Pain was virtually non-existent. I really had none at any time – I did not even use the morphine on demand button on my robe.

4 No disability beyond taking care of the right arm for several weeks, not lifting weights, ironing etc. Certainly nothing permanent.

5 Mental health – excellent as a result of not worrying about my treatment.

6 My life-style is unaffected. My worklife is busier than it has ever been, our social life is far too busy.

7 My various employers do not even know I had breast cancer.

8. My family – husband and three adult children – are entirely aware of my health issues. But thanks to the speed and efficacy of Intrabeam, their anxiety for me is minimal: our family life is just as it was prior to my diagnosis. Maybe closer.
The same is true of friends. And my women friends, should they find themselves in my situation, would I think prefer intrabeam themselves.

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition? (continued)

2. **Disadvantages**
Please list any problems with or concerns you have about the technology.
Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse.
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

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I can think of no disadvantages. Intrabeam takes place while the patient is unconscious: no question of 'using' technology.
There are no side-effects, certainly not in my case. And I don't think for anyone.
Repeated travel for radiotherapy sessions is not required.
The effects of conventional radiotherapy - tiredness, inability to work, low mood or depression – are virtually non-existent with Intrabeam, certainly in my experience.
I have discussed these issues with other women at the breast clinic and I am not unusual – the enthusiasm for Intrabeam among patients is general.

A very real concern about the technology is availability. Financially, as things stand, Intrabeam is available to only a limited number of potential patients. I was lucky enough to have health insurance. Without that, Intrabeam would have been unaffordable for me. With conventional radiotherapy, I would have been adversely affected in many ways: physical, emotional, financial (loss of earnings.)

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

Every woman I have met who has had Intrabeam (I have had many conversations with them at the breast clinic) has been delighted. Women with breast cancer conventionally treated to whom I have talked have without exception wished they had known about it. In fact, I have to be very careful talking to such women. If someone has had traditional treatment, I do not want to suggest they could have done better elsewhere.

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

From everything I know and have read, at the present moment wider use of Intrabeam would benefit women of 45 and over with early breast cancer if they are suitable candidates physically.
Women living alone would I think find Intrabeam especially beneficial. (And there are a lot of older women who live alone.) Finding support for protracted care, or for hospital visits, may be problematic for them. Intrabeam reduces the need for both.

Patients in remote rural areas would in particular benefit from Intrabeam. For several years we lived in a Northamptonshire village, where eventually even the irregular local bus service was terminated. Any woman of limited means in such an area would inevitably ace real difficulty in making daily hospital visits for radiotherapy. Or the cost would be borne by local social services.
And I also understand that women living in really remote areas in parts of Scotland, for example, have to have mastectomies because repeated hospital visits for EBRT would be impossible and they cannot remain away from home for the length of time treatment would take.

I can think of no group who would not benefit from Intrabeam.

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Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

I know only about the alternatives I was offered by Guys' and St.Thomas' –first lumpectomy followed by five weeks of EBRT. Later in the same consultation a double mastectomy was proposed (I don't know what the locum breast consultant was going to suggest after that, I was beyond asking questions at that point.) It makes me feel depressed even to contemplate that I might have gone down either route.

So as far as I am concerned, Intrabeam is a godsend.

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:

- improvement in the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc.)

Answered at length under heading:

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:

- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at

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home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

I can think of no disadavantages arising from the use of Intrabeam

Equality and Diversity

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- Could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- Could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- Could lead to recommendations that have any adverse impact on people with a particular disability or disabilities

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts

I can think of no cases or groups who would not benefit immensely by the use of Intrabeam.

Research evidence on patient or carer views of the technology

If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

Not as far as I am concerned

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Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

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Availability of this technology to patients in the NHS

What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

It seems to me beyond question that Intrabeam **should** be available on the NHS.
The simplicity of Intrabeam for patients cannot be exaggerated. They and their carers must benefit because there is no prolonged treatment necessitating extensive nursing and repeated travel.
Patients would recover far sooner than with conventional treatment. Therefore they would require less hospital care; less help with physically demanding tasks at home, so less help from eg social services, friends, partners.
They would not require prolonged sickness leave from work.

The Southampton Report says that more training and equipment would be necessary if Intrabeam were introduced. But we know our ageing population will inevitably produce greatly increased numbers of breast cancer cases. This is already happening. We know that there is increasing pressure on the NHS to care for cancer sufferers generally, particularly older people. This is already a matter for concern.
So more staff must be trained, and more equipment will be needed, in any event.
Add to that the fact that many hospitals have increasingly old equipment in use.
The Southampton Report acknowledges that Intrabeam is cheaper. The machines are around £300,000 apiece. But because Intrabeam emits far less radiation 'scatter' they do not need a protective environment as do conventional radiotherapy machines. Running costs are half that of standard breast-radiation equipment. The single delivery method frees up staff and equipment.

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

Women who live alone and have to undergo conventional EBRT may have to make arrangements for long-term nursing help. They may well need help from friends or family to attend appointments and to do this for five weeks or so could present very real problems.

Older women may well be carers for partners – as I have been on occasion when my husband had for example heart surgery, and later a stroke. Such a woman undergoing longterm conventional breastcare treatment would be presented with a whole new set of problems for which she must find solutions. This could be both difficult and costly. Indirectly, it could cost cost the country more than the actual NHS costs, because social services would possibly be involved in providing carers in her place.

Are there groups of patients that have difficulties using the technology?

I cannot envisasge difficulties for any woman associated with Intrabeam.

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Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.

I believe that several hospitals around the country are already in the process of raising money to acquire their own Intrabeam machines – The Great Western Hospital in Swindon, Wiltshire, for example, where the surgeon Nathan Coombs is in charge. If individual hospitals are already moving to Intrabeam,and the NHS does not do so as a matter of policy, then once more a healthcare postcode lottery situation will be in place. Which is surely to be avoided if at all possible.