Patient recruitment: what have we learnt from the Qualitative Recruitment Study

Carmel Conefrey, University of Bristol

OPTIMA Investigator Meeting

21 June 2022

Patient recruitment: what have we learnt from the Qualitative Recruitment Study to help with the final leg of recruitment?

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The Qualitative Recruitment Study

QuinteT
Qualitative research Integrated within Trials

Understand recruitment issues as the RCT's underway

Implement changes, to optimise recruitment

Journal List › Trials › v.17; 2016 › PMC4898358

Trials

BMC

Trials. 2016; 17: 283.

PMCID: PMC4898358

Published online 2016 Jun 8. doi: 10.1186/s13063-016-1391-4

PMID: 27278130

Optimising recruitment and informed consent in randomised controlled trials: the development and implementation of the Quintet Recruitment Intervention (QRI)

Jenny L. Donovan, Leila Rooshenas, Marcus Jepson, Daisy Elliott, Julia Wade, Kerry Avery, Nicola Mills, Caroline Wilson, Sangeetha Paramasivan, and Jane M. Blazeby

Author information · Article notes · Copyright and License information Disclaimer

Trials

Donovan et al. Trials. 2016; 17: 283.
https://tinyurl.com/**yy5lnqdc**

Understanding recruitment obstacles

QRS data & analysis

Interviews with healthcare professionals & patients

Analysis of monthly screening log data

Audio-recordings of Dr / patient consultations

Review of Study material

Applying learning to ongoing recruitment

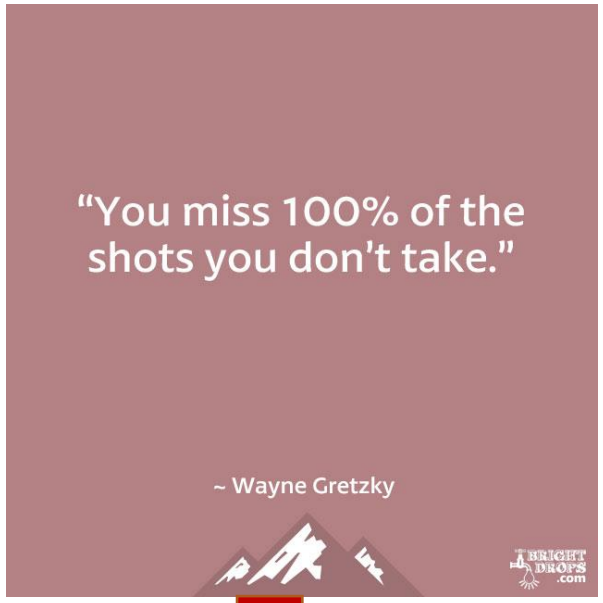
The screening process

Preparing patients for a discussion about OPTIMA

The value of engaging with patient preferences

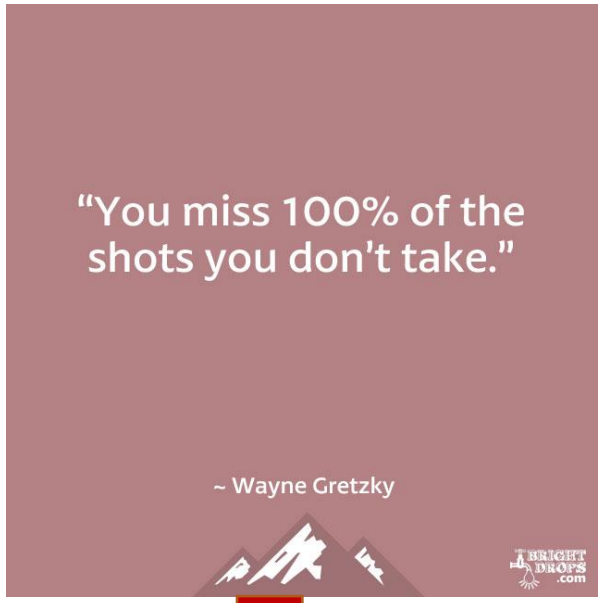
The Screening Process

Screening, identifying as eligible and approaching patients



100% of patients who
Are **NOT identified as eligible**
are **NOT approached**
are **NOT randomised**

Screening, identifying as eligible and approaching patients



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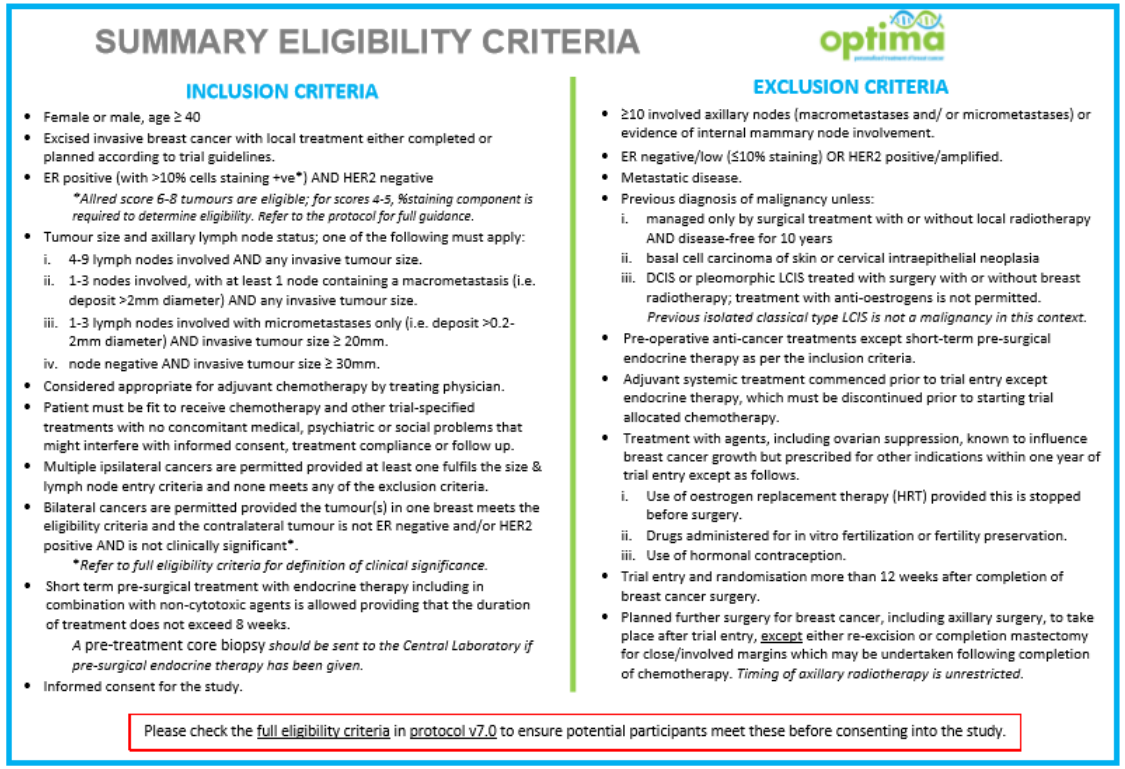
Reviewing your recruitment process:

1. Is your MDT set up to identify all eligible OPTIMA patients?
2. Are all members of the MDT familiar with OPTIMA?
3. Once flagged as eligible, are patients easily identifiable to health care practitioners?

Resources to support screening



SUMMARY ELIGIBILITY CRITERIA

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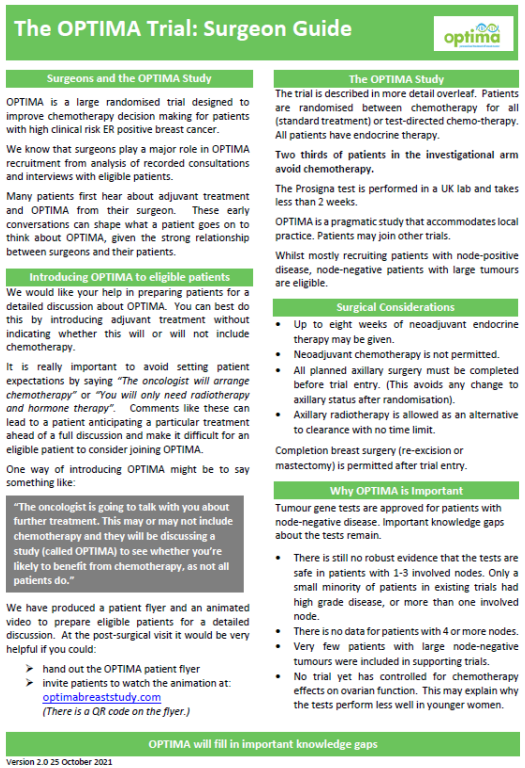
INCLUSION CRITERIA

- Female or male, age ≥ 40
- Excised invasive breast cancer with local treatment either completed or planned according to trial guidelines.
- ER positive (with >10% cells staining +ve*) AND HER2 negative
  **All red score 6-8 tumours are eligible; for scores 4-5, %staining component is required to determine eligibility. Refer to the protocol for full guidance.*
- Tumour size and axillary lymph node status; one of the following must apply:
  i. 4-9 lymph nodes involved AND any invasive tumour size.
  ii. 1-3 nodes involved, with at least 1 node containing a macrometastasis (i.e. deposit >2mm diameter) AND any invasive tumour size.
  iii. 1-3 lymph nodes involved with micrometastases only (i.e. deposit >0.2-2mm diameter) AND invasive tumour size ≥ 20mm.
  iv. node negative AND invasive tumour size ≥ 30mm.
- Considered appropriate for adjuvant chemotherapy by treating physician.
- Patient must be fit to receive chemotherapy and other trial-specified treatments with no concomitant medical, psychiatric or social problems that might interfere with informed consent, treatment compliance or follow up.
- Multiple ipsilateral cancers are permitted provided at least one fulfils the size & lymph node entry criteria and none meets any of the exclusion criteria.
- Bilateral cancers are permitted provided the tumour(s) in one breast meets the eligibility criteria and the contralateral tumour is not ER negative and/or HER2 positive AND is not clinically significant*.
  **Refer to full eligibility criteria for definition of clinical significance.*
- Short term pre-surgical treatment with endocrine therapy including in combination with non-cytotoxic agents is allowed providing that the duration of treatment does not exceed 8 weeks.
  A pre-treatment core biopsy *should be sent to the Central Laboratory if pre-surgical endocrine therapy has been given.*
- Informed consent for the study.

EXCLUSION CRITERIA

- ≥10 involved axillary nodes (macrometastases and/ or micrometastases) or evidence of internal mammary node involvement.
- ER negative/low (≤10% staining) OR HER2 positive/amplified.
- Metastatic disease.
- Previous diagnosis of malignancy unless:
  i. managed only by surgical treatment with or without local radiotherapy AND disease-free for 10 years
  ii. basal cell carcinoma of skin or cervical intraepithelial neoplasia
  iii. DCIS or pleomorphic LCIS treated with surgery with or without breast radiotherapy; treatment with anti-oestrogens is not permitted.
  Previous isolated classical type LCIS is not a malignancy in this context.
- Pre-operative anti-cancer treatments except short-term pre-surgical endocrine therapy as per the inclusion criteria.
- Adjuvant systemic treatment commenced prior to trial entry except endocrine therapy, which must be discontinued prior to starting trial allocated chemotherapy.
- Treatment with agents, including ovarian suppression, known to influence breast cancer growth but prescribed for other indications within one year of trial entry except as follows.
  i. Use of oestrogen replacement therapy (HRT) provided this is stopped before surgery.
  ii. Drugs administered for in vitro fertilization or fertility preservation.
  iii. Use of hormonal contraception.
- Trial entry and randomisation more than 12 weeks after completion of breast cancer surgery.
- Planned further surgery for breast cancer, including axillary surgery, to take place after trial entry, except either re-excision or completion mastectomy for close/involved margins which may be undertaken following completion of chemotherapy. *Timing of axillary radiotherapy is unrestricted.*

Please check the full eligibility criteria in protocol v7.0 to ensure potential participants meet these before consenting into the study.



The OPTIMA Trial: Surgeon Guide

optima

Surgeons and the OPTIMA Study

OPTIMA is a large randomised trial designed to improve chemotherapy decision making for patients with high clinical risk ER positive breast cancer.

We know that surgeons play a major role in OPTIMA recruitment from analysis of recorded consultations and interviews with eligible patients.

Many patients first hear about adjuvant treatment and OPTIMA from their surgeon. These early conversations can shape what a patient goes on to think about OPTIMA, given the strong relationship between surgeons and their patients.

Introducing OPTIMA to eligible patients

We would like your help in preparing patients for a detailed discussion about OPTIMA. You can best do this by introducing adjuvant treatment without indicating whether this will or will not include chemotherapy.

It is really important to avoid setting patient expectations by saying *"The oncologist will arrange chemotherapy"* or *"You will only need radiotherapy and hormone therapy"*. Comments like these can lead to a patient anticipating a particular treatment ahead of a full discussion and make it difficult for an eligible patient to consider joining OPTIMA.

One way of introducing OPTIMA might be to say something like:

"The oncologist is going to talk with you about further treatment. This may or may not include chemotherapy and they will be discussing a study (called OPTIMA) to see whether you're likely to benefit from chemotherapy, as not all patients do."

We have produced a patient flyer and an animated video to prepare eligible patients for a detailed discussion. At the post-surgical visit it would be very helpful if you could:

- hand out the OPTIMA patient flyer
- invite patients to watch the animation at: optimabreaststudy.com
  (There is a QR code on the flyer.)

The OPTIMA Study

The trial is described in more detail overleaf. Patients are randomised between chemotherapy for all (standard treatment) or test-directed chemo-therapy. All patients have endocrine therapy.

Two thirds of patients in the investigational arm avoid chemotherapy.

The Prosigna test is performed in a UK lab and takes less than 2 weeks.

OPTIMA is a pragmatic study that accommodates local practice. Patients may join other trials.

Whilst mostly recruiting patients with node-positive disease, node-negative patients with large tumours are eligible.

Surgical Considerations

- Up to eight weeks of neoadjuvant endocrine therapy may be given.
- Neoadjuvant chemotherapy is not permitted.
- All planned axillary surgery must be completed before trial entry. (This avoids any change to axillary status after randomisation).
- Axillary radiotherapy is allowed as an alternative to clearance with no time limit.

Completion breast surgery (re-excision or mastectomy) is permitted after trial entry.

Why OPTIMA is Important

Tumour gene tests are approved for patients with node-negative disease. Important knowledge gaps about the tests remain.

- There is still no robust evidence that the tests are safe in patients with 1-3 involved nodes. Only a small minority of patients in existing trials had high grade disease, or more than one involved node.
- There is no data for patients with 4 or more nodes.
- Very few patients with large node-negative tumours were included in supporting trials.
- No trial yet has controlled for chemotherapy effects on ovarian function. This may explain why the tests perform less well in younger women.

OPTIMA will fill in important knowledge gaps

Version 2.0 25 October 2021

Preparing patients for a discussion about OPTIMA

Early treatment indications set expectations

So, this **is a case of chemotherapy**. They told me I'd have to take nine months off work, which I was very devastated about. But, hey ho, **I've adjusted to that.** (Consultation)

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Yeah, so that – then [after operation] they said 'we're just going to give you radiotherapy'… and I was thankful for that actually. (Interview)

Preparing patients to discuss OPTIMA?

Every medical person that I'd spoken to, even the Macmillan nurses had **coaxed me** on this journey to needing chemotherapy, this was the next stage. Surgery was the easy bit. You were going to need chemotherapy for four to five months. It was a bit like a **bombshell** when I sat in that room for that **chemotherapy appointment** to get it all under way, to be told I might not need it. **I think I panicked**. I just thought, "Well I'm going to die then because you're not going to give it to me. (Interview)

Surgeons

Radiographers

Breast Nurse Specialists

Clinic nurses

Mammographers

Cancer Support workers

Oncologists

Research Nurses

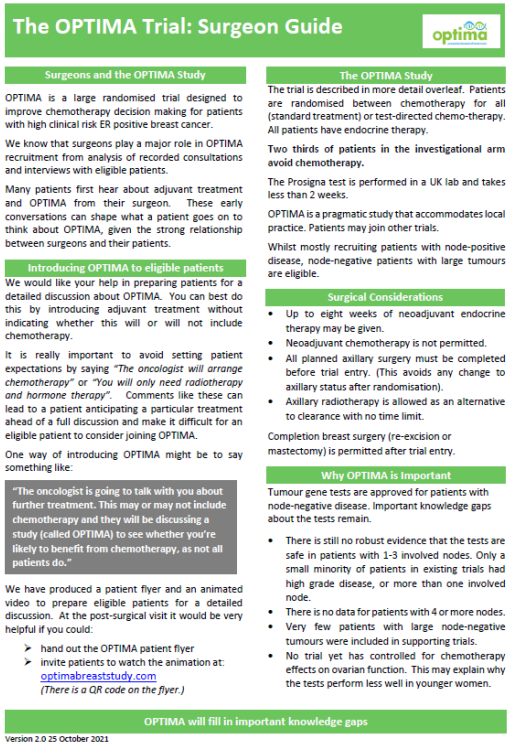
Ask your colleagues to prepare patients for a discussion about OPTIMA

“The oncologist is going to talk with you about further treatment. This may or may not include chemotherapy and they will be discussing a study (called OPTIMA) to see whether you’re likely to benefit from chemotherapy, as not all patients do.”

“The oncologist will arrange chemotherapy”

“You will only need radiotherapy and hormone therapy”.

Resources to support colleagues become familiar with OPTIMA



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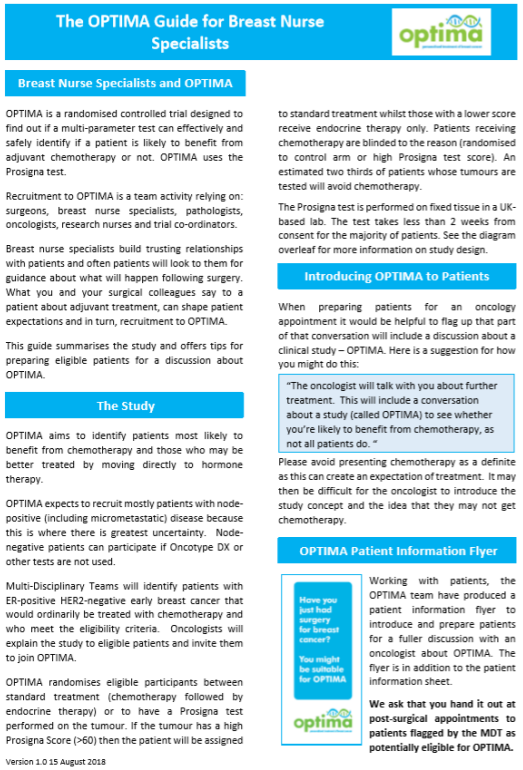
Version 2.0 25 October 2021



The OPTIMA Guide for Breast Nurse Specialists

Breast Nurse Specialists and OPTIMA

OPTIMA is a randomised controlled trial designed to find out if a multi-parameter test can effectively and safely identify if a patient is likely to benefit from adjuvant chemotherapy or not. OPTIMA uses the Prosigna test.

Recruitment to OPTIMA is a team activity relying on: surgeons, breast nurse specialists, pathologists, oncologists, research nurses and trial co-ordinators.

Breast nurse specialists build trusting relationships with patients and often patients will look to them for guidance about what will happen following surgery. What you and your surgical colleagues say to a patient about adjuvant treatment, can shape patient expectations and in turn, recruitment to OPTIMA.

This guide summarises the study and offers tips for preparing eligible patients for a discussion about OPTIMA.

The Study

OPTIMA aims to identify patients most likely to benefit from chemotherapy and those who may be better treated by moving directly to hormone therapy.

OPTIMA expects to recruit mostly patients with node-positive (including micrometastatic) disease because this is where there is greatest uncertainty. Node-negative patients can participate if Oncotype DX or other tests are not used.

Multi-Disciplinary Teams will identify patients with ER-positive HER2-negative early breast cancer that would ordinarily be treated with chemotherapy and who meet the eligibility criteria. Oncologists will explain the study to eligible patients and invite them to join OPTIMA.

OPTIMA randomises eligible participants between standard treatment (chemotherapy followed by endocrine therapy) or to have a Prosigna test performed on the tumour. If the tumour has a high Prosigna Score (>60) then the patient will be assigned to standard treatment whilst those with a lower score receive endocrine therapy only. Patients receiving chemotherapy are blinded to the reason (randomised to control arm or high Prosigna test score). An estimated two thirds of patients whose tumours are tested will avoid chemotherapy.

The Prosigna test is performed on fixed tissue in a UK-based lab. The test takes less than 2 weeks from consent for the majority of patients. See the diagram overleaf for more information on study design.

Introducing OPTIMA to Patients

When preparing patients for an oncology appointment it would be helpful to flag up that part of that conversation will include a discussion about a clinical study – OPTIMA. Here is a suggestion for how you might do this:

"The oncologist will talk with you about further treatment. This will include a conversation about a study (called OPTIMA) to see whether you're likely to benefit from chemotherapy, as not all patients do. "

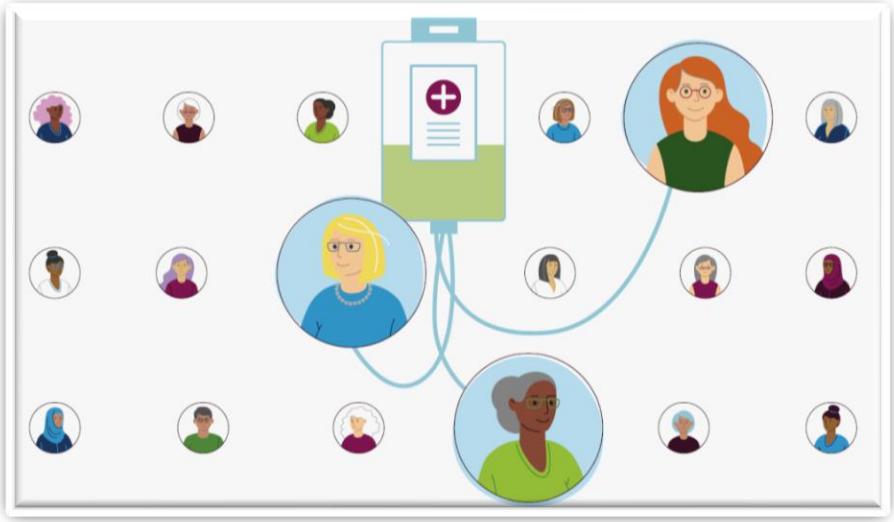
Please avoid presenting chemotherapy as a definite as this can create an expectation of treatment. It may then be difficult for the oncologist to introduce the study concept and the idea that they may not get chemotherapy.

OPTIMA Patient Information Flyer

Working with patients, the OPTIMA team have produced a patient information flyer to introduce and prepare patients for a fuller discussion with an oncologist about OPTIMA. The flyer is in addition to the patient information sheet.

We ask that you hand it out at post-surgical appointments to patients flagged by the MDT as potentially eligible for OPTIMA.

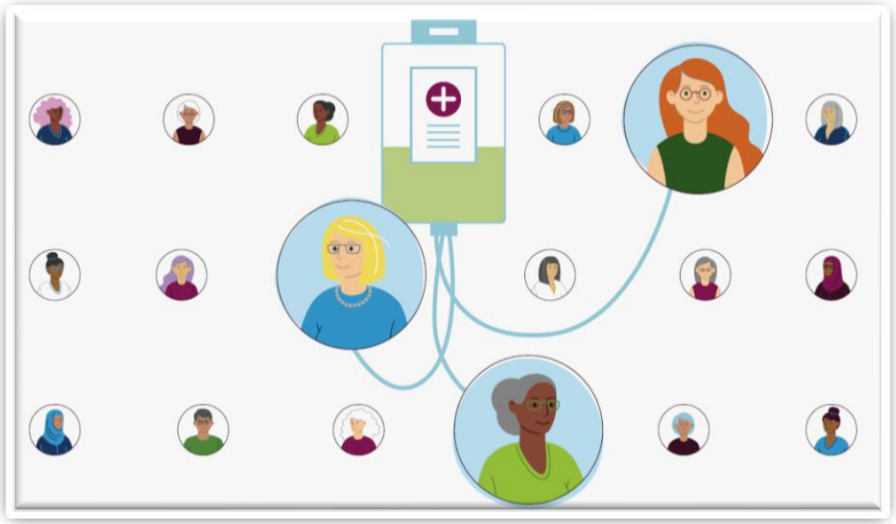
Version 1.0 15 August 2018



OPTIMA Animation

www.optimabreaststudy.com

Resources to introduce patients to OPTIMA



OPTIMA Animation

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The value of engaging with patient preferences

Engaging with patient preferences gives you the opportunity to:

- address misunderstandings
- fill in information gaps
- acknowledge and potentially overcome concerns

Misunderstanding about how treatment allocations determined

So, I understood that, even if you went on the trial, you could be on a placebo as such. Do you know what I mean? You could just not go on the chemotherapy, **but it's not because the OPTIMA test said that**. It's just you wouldn't go on it, or you would (Interview)

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So she [surgeon] said, well, they will decide what treatment you have and some people don't get any treatment, but some people do… It was just, sort of, said as, yeah **you go into a trial and you're either treated or you're not**… I sort of I said 'what do you mean at random' and, you know, well they just pick people. You know, it's just like, **kind of, like a lottery**. You just pick. And what treatment you get will depend on, you know, what they decide. (Interview)

Engaging with a preference

Talk about chemotherapy what's involved and possible short and long-term side effects.

A little later in the consultation when the patient is asked their thoughts ….

Pat: It's a 50/50 chance though.

To reveal a misunderstanding or gap in information

Engaging creates the opportunity to …

Pat:	It's a 50/50 chance though.
Con:	Well no, it's your only way of missing out on the chemotherapy in the most intelligent way, because this gives you a chance of being asked not to have chemotherapy within the study, having had a test done that must have said, "We don't think you need it."

…..address a misunderstanding or gap in information

Engaging creates the opportunity to …

Pat: **My only concern is, I'm worried if I don't have chemo …I'm worried it will come back.**

Cons: You're worried you would miss out on something you should have – is that right?

Pat: **Mmm. I'm worried if I don't have chemo it will come back**

…acknowledge concerns, open up conversation,

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Cons: **I understand.** So I think the way we're looking at it, and the way the study is looking at it, is we're trying to only give chemotherapy at the times when we think it's going to make a difference. **The cancer could come back, whether you have chemotherapy or not.**

…acknowledge concerns, open up conversation, restore balance

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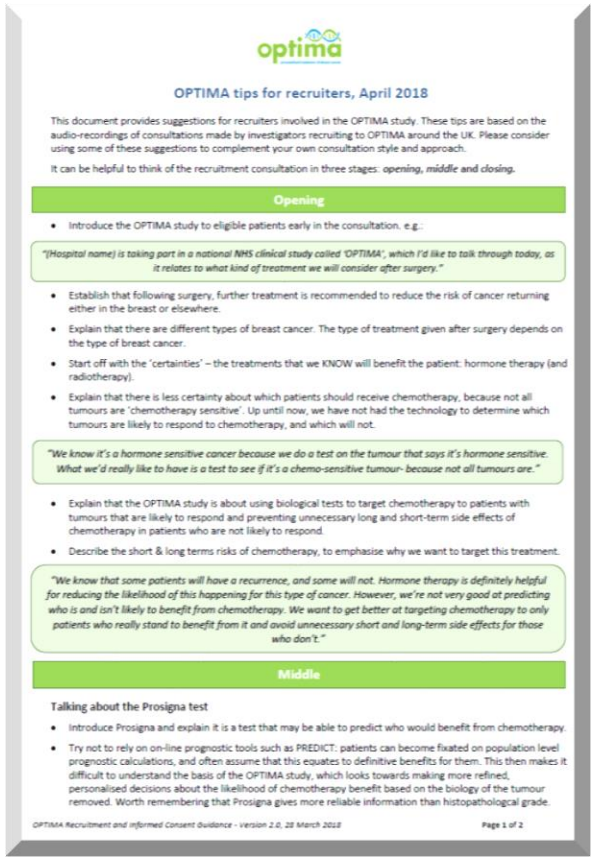
[Oncologist talks about how for some patients, better to move straight to hormone therapy, which is likely to benefit]

Pat: **Yes, I understand what you're saying, yes.**

…acknowledge concerns, open up conversation, restore balance

Resources to support recruiters engage with patient preferences



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OPTIMA tips for recruiters, April 2018

This document provides suggestions for recruiters involved in the OPTIMA study. These tips are based on the audio-recordings of consultations made by investigators recruiting to OPTIMA around the UK. Please consider using some of these suggestions to complement your own consultation style and approach.

It can be helpful to think of the recruitment consultation in three stages: ***opening, middle and closing.***

Opening

- Introduce the OPTIMA study to eligible patients early in the consultation, e.g.:

"(Hospital name) is taking part in a national NHS clinical study called 'OPTIMA', which I'd like to talk through today, as it relates to what kind of treatment we will consider after surgery."

- Establish that following surgery, further treatment is recommended to reduce the risk of cancer returning either in the breast or elsewhere.
- Explain that there are different types of breast cancer. The type of treatment given after surgery depends on the type of breast cancer.
- Start off with the 'certainties' – the treatments that we KNOW will benefit the patient: hormone therapy (and radiotherapy).
- Explain that there is less certainty about which patients should receive chemotherapy, because not all tumours are 'chemotherapy sensitive'. Up until now, we have not had the technology to determine which tumours are likely to respond to chemotherapy, and which will not.

"We know it's a hormone sensitive cancer because we do a test on the tumour that says it's hormone sensitive. What we'd really like to have is a test to see if it's a chemo-sensitive tumour- because not all tumours are."

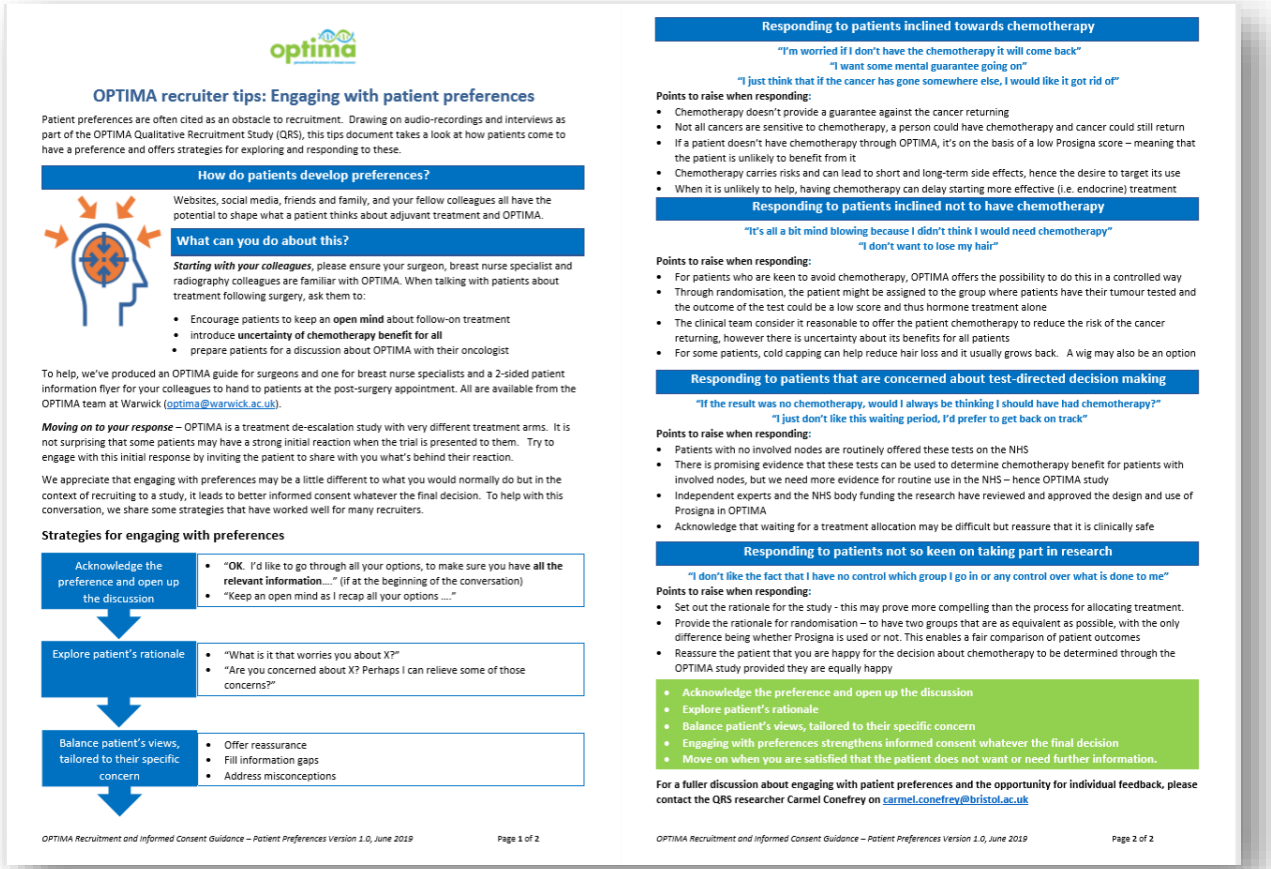
- Explain that the OPTIMA study is about using biological tests to target chemotherapy to patients with tumours that are likely to respond and preventing unnecessary long and short-term side effects of chemotherapy in patients who are not likely to respond.
- Describe the short & long terms risks of chemotherapy, to emphasise why we want to target this treatment.

"We know that some patients will have a recurrence, and some will not. Hormone therapy is definitely helpful for reducing the likelihood of this happening for this type of cancer. However, we're not very good at predicting who is and isn't likely to benefit from chemotherapy. We want to get better at targeting chemotherapy to only patients who really stand to benefit from it and avoid unnecessary short and long-term side effects for those who don't."

Middle

Talking about the Prosigna test

- Introduce Prosigna and explain it is a test that may be able to predict who would benefit from chemotherapy.
- Try not to rely on on-line prognostic tools such as PREDICT: patients can become fixated on population level prognostic calculations, and often assume that this equates to definitive benefits for them. This then makes it difficult to understand the basis of the OPTIMA study, which looks towards making more refined, personalised decisions about the likelihood of chemotherapy benefit based on the biology of the tumour removed. Worth remembering that Prosigna gives more reliable information than histopathological grade.



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OPTIMA recruiter tips: Engaging with patient preferences

Patient preferences are often cited as an obstacle to recruitment. Drawing on audio-recordings and interviews as part of the OPTIMA Qualitative Recruitment Study (QRS), this tips document takes a look at how patients come to have a preference and offers strategies for exploring and responding to these.

How do patients develop preferences?

Websites, social media, friends and family, and your fellow colleagues all have the potential to shape what a patient thinks about adjuvant treatment and OPTIMA.

What can you do about this?

Starting with your colleagues, please ensure your surgeon, breast nurse specialist and radiography colleagues are familiar with OPTIMA. When talking with patients about treatment following surgery, ask them to:

- Encourage patients to keep an **open mind** about follow-on treatment
- introduce **uncertainty of chemotherapy benefit for all**
- prepare patients for a discussion about OPTIMA with their oncologist

To help, we've produced an OPTIMA guide for surgeons and one for breast nurse specialists and a 2-sided patient information flyer for your colleagues to hand to patients at the post-surgery appointment. All are available from the OPTIMA team at Warwick (optima@warwick.ac.uk).

Moving on to your response – OPTIMA is a treatment de-escalation study with very different treatment arms. It is not surprising that some patients may have a strong initial reaction when the trial is presented to them. Try to engage with this initial response by inviting the patient to share with you what's behind their reaction.

We appreciate that engaging with preferences may be a little different to what you would normally do but in the context of recruiting to a study, it leads to better informed consent whatever the final decision. To help with this conversation, we share some strategies that have worked well for many recruiters.

Strategies for engaging with preferences

Acknowledge the preference and open up the discussion	• "**OK**. I'd like to go through all your options, to make sure you have **all the relevant information**…." (if at the beginning of the conversation) • "Keep an open mind as I recap all your options …."
Explore patient's rationale	• "What is it that worries you about X?" • "Are you concerned about X? Perhaps I can relieve some of those concerns?"
Balance patient's views, tailored to their specific concern	• Offer reassurance • Fill information gaps • Address misconceptions

Responding to patients inclined towards chemotherapy

"I'm worried if I don't have the chemotherapy it will come back"
"I want some mental guarantee going on"
"I just think that if the cancer has gone somewhere else, I would like it got rid of"

Points to raise when responding:

- Chemotherapy doesn't provide a guarantee against the cancer returning
- Not all cancers are sensitive to chemotherapy, a person could have chemotherapy and cancer could still return
- If a patient doesn't have chemotherapy through OPTIMA, it's on the basis of a low Prosigna score – meaning that the patient is unlikely to benefit from it
- Chemotherapy carries risks and can lead to short and long-term side effects, hence the desire to target its use
- When it is unlikely to help, having chemotherapy can delay starting more effective (i.e. endocrine) treatment

Responding to patients inclined not to have chemotherapy

"It's all a bit mind blowing because I didn't think I would need chemotherapy"
"I don't want to lose my hair"

Points to raise when responding:

- For patients who are keen to avoid chemotherapy, OPTIMA offers the possibility to do this in a controlled way
- Through randomisation, the patient might be assigned to the group where patients have their tumour tested and the outcome of the test could be a low score and thus hormone treatment alone
- The clinical team consider it reasonable to offer the patient chemotherapy to reduce the risk of the cancer returning, however there is uncertainty about its benefits for all patients
- For some patients, cold capping can help reduce hair loss and it usually grows back. A wig may also be an option

Responding to patients that are concerned about test-directed decision making

"If the result was no chemotherapy, would I always be thinking I should have had chemotherapy?"
"I just don't like this waiting period, I'd prefer to get back on track"

Points to raise when responding:

- Patients with no involved nodes are routinely offered these tests on the NHS
- There is promising evidence that these tests can be used to determine chemotherapy benefit for patients with involved nodes, but we need more evidence for routine use in the NHS – hence OPTIMA study
- Independent experts and the NHS body funding the research have reviewed and approved the design and use of Prosigna in OPTIMA
- Acknowledge that waiting for a treatment allocation may be difficult but reassure that it is clinically safe

Responding to patients not so keen on taking part in research

"I don't like the fact that I have no control which group I go in or any control over what is done to me"

Points to raise when responding:

- Set out the rationale for the study - this may prove more compelling than the process for allocating treatment.
- Provide the rationale for randomisation – to have two groups that are as equivalent as possible, with the only difference being whether Prosigna is used or not. This enables a fair comparison of patient outcomes
- Reassure the patient that you are happy for the decision about chemotherapy to be determined through the OPTIMA study provided they are equally happy

- **Acknowledge the preference and open up the discussion**
- **Explore patient's rationale**
- **Balance patient's views, tailored to their specific concern**
- **Engaging with preferences strengthens informed consent whatever the final decision**
- **Move on when you are satisfied that the patient does not want or need further information.**

For a fuller discussion about engaging with patient preferences and the opportunity for individual feedback, please contact the QRS researcher Carmel Conefrey on carmel.conefrey@bristol.ac.uk

www.optimabreaststudy.com

Reaching 4,500 patients……

- Actively screen for eligible patients, approach eligible patients and let the patient decide about OPTIMA
- Garner the interest and support of your surgical colleagues – OPTIMA needs their support
- Engage with patient preferences to enable patients to make an informed decision.

optima
personalised treatment of breast cancer

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Quintet
Qualitative research Integrated within Trials

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