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 histopathologcal grade.

- Point out that whilst PROSIGNA shows promise, more research is needed to assess its effectiveness.

Explaining Participation in OPTIMA

- Use a **diagram** to talk through the OPTIMA study arms. The diagram will help patients to follow the possible treatment outcomes that may arise from participating in the study. Either draw it as you are explaining or use the diagram in the Patient Information Leaflet. The points below can be a helpful way of simplifying this explanation:

    1. All patients approached about OPTIMA will be randomly assigned to Group 1 or Group 2. This means they have an equal chance of going into either group.
    2. Group 1: patients receive chemotherapy. Hormone therapy starts once chemotherapy is complete.
    3. Group 2: the removed tumour is tested. If the test result is a high score, the patient receives chemotherapy and then hormone therapy. If the test score is low, they start hormone therapy.

- Patients need to understand that they will be randomly allocated to Group 1 or Group 2. Explain that randomisation is a method for producing groups that are as equivalent as possible, with the only difference being whether chemotherapy is determined by the Prosigna Test or not. This process allows patient outcomes to be compared fairly and for the trial results to be credible.
- Explain that where a patient is allocated to chemotherapy, neither the clinical team nor patient will know if they were assigned to Group 1 or 2. The only exception to this, is if the patient is allocated hormone therapy; in which case it is clear that their tumour was tested. The **diagram** will help to clarify this.

What to do if patients say they would prefer chemotherapy or not to have chemotherapy…

Often preferences appear stronger than they are - patients are often looking for information and reassurance. Asking patients to explain their reasons can expose misunderstandings. Try the following:

1. **Explore:** Gently ask why they have a preference by saying something like **"Can you tell me a little bit more about why you feel that way"**, or **"Is there anything about [non-preferred treatment] that concerns you?"**
2. **Address:** Once you know their reasons for a preference, you can address misinterpretations and provide accurate information to ensure the patient is fully informed before they decide to participate or not.

Tip: When you hear a preference, it is helpful to reply first with "**OK**" to acknowledge the patient's reason, and then say "**But…**" to indicate there is alternative, clearer, information that you can provide them with. You could also say "**Another way of looking at it is…"**, or "**We should also bear in mind that …."**

P: My mum had chemotherapy, so I want the same as her.
S: **OK**, that was your mum's experience. **But** you're a different person and you may or may not benefit from chemotherapy. We now know that there are different types of breast cancer, and not all tumours will respond to chemotherapy.

Closing

- Let the patient know that as their clinician, you are happy for them to be allocated to either Group (chemotherapy or test-determined treatment).
- If the patient feels unsure what to do about treatment (having received the necessary information), this is a sign that they understand the study, and rationale for this research. This is a good opportunity to ask for their thoughts on taking part in the study. Check they would be willing to have chemotherapy as current practice or have treatment determined by the Prosigna test result.

"It sounds to me like you may be open to OPTIMA. I think you would do well being in either patient group and so the study could be a good option for you.

- Be sure to check that the patient understands that they have the right to withdraw at any point without giving any reason, and that doing so will not affect their treatment.
- Invite the patient to consider participation over the next 24hrs or so and arrange for the patient to return to clinic to relay their decision.