

# Clinical Trials: The Patients' View

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**This article will cover clinical trials from a patient perspective. The views in this paper are my own, but I hope will resonate with others.**

Taking part in clinical trials and research is something I feel strongly about, although in my own case I was never asked to join in a trial. I don't know if this is because there was nothing suitable at the time or if my clinicians did not feel able to approach me or that I was able to make the decision.

Reflecting on this now I believe that as upset and scared as I was at the start of my treatment if I had been approached and asked if I was interested in taking part in a trial and given good information and time to consider I very much believe I would have said yes. I think the same can be said for most patients.

It is a time of a great deal of fear, but as one starts treatment and starts to find out about options and pathways this is also a time that patients need to feel involved in the process.

One part of having cancer is a feeling that one is no longer in control of events, if joining a trial is explained clearly this can give the patient a positive event in an otherwise negative period. It also gives back a bit of control. As the patient can feel empowered that although something bad is happening, something good for someone else might be the result.

When asked to give this talk I felt I should look into what has been discussed in the past. In my professional life I am an Information Scientist, so the first thing I did was a literature search. In a very short space of time I found dozens of studies, academic papers and surveys done over a great many years. Reading through the papers and abstracts I came to two main conclusions.

The first was that most of the studies assess the situation from the clinicians' perspective and not the patients. Perhaps more work needs to be done with patient organisations. A European survey in 2008 looked at the level of participation of patient organisations in trials and research. Over 200 organisations from 30 countries were surveyed. Over 65% of the organisations had some involvement in trials, but only 37% had given advice or assistance on the content of informed consent forms and had taken part in the reviewing of patient information leaflets. The general conclusion was that more patient involvement was needed.

The second conclusion is the most obvious in that they all realised that INFORMATION AND THE WAY IT IS DELIVERED IS KEY TO SUCCESS.

It is not only WHAT you tell the patient, but also HOW you tell it. Don't make assumptions about a patients understanding, readiness or willingness to take part. Patients are increasingly well informed and some are not as fragile as you may think.

Saying that, language is also important and any information given should be carefully balanced and not include too much medical jargon and especially acronyms which seem very popular in the medical world. It should be sufficiently detailed to inform and involve the patient.

The main area for concern with clinicians, in my opinion, seems to be when to approach a patient as often it is necessary for the trial to recruit as near as possible to diagnosis. I believe some clinicians are very protective of their patients and perhaps do not encourage the researchers to speak to patients too soon as it may be too much to take on board. There is no evidence that this is the case for all patients, so the challenge is not only to get the timing right, but to choose the right patients.

After the initial shock of receiving a diagnosis the subsequent consultations are all geared to what will happen next and giving the patient information on her pathway. This would seem to be the time to include invitations to join a trial. All the patient literature from Breast Cancer Care and others mention that this might happen, but it needs to be done correctly. The majority of patients want to know exactly what is happening to them and with good information the patient will start to feel that they have a real say in the process and this can only be for the good. I have also heard from other patient groups that approaching patients on the day of diagnosis is perfectly acceptable if done in the right way.

Information is the key point in all this. Many patients may ask about trials and will be upset if the clinicians don't have all the facts to hand. If trust is lost between patient and clinician nothing will be achieved. In the US there is an interactive database of all trials that can be searched by patients to see what is available to them according to their diagnosis and their locality. Perhaps this is something that could be done in the UK.

In my research I read a report of a piece of work done in Australia using a decision aid. This was for the IBIS II trial and the initial results of using the aid were very positive. More work is being done on this, but it certainly seemed a good model. The users of the aid felt that it worked on a number of levels, firstly to help them understand the complexities of trials and what it would mean to them and secondly as an aide memoire for later on when they wanted to refresh themselves. I obtained a copy of the decision aid used and was very impressed with the information and the way it was displayed.

Another good idea I came across is a question prompt list given to patients to help them discuss the issues with their clinician and to give them the right information to make an informed choice about joining a trial. There is a lot of information to take in at the time of diagnosis and perhaps one reason for recruitment difficulties could be that the patient is not given the time and resources to absorb all the information and feel comfortable about asking the right questions. The prompt list makes the patient focus on the subject and can help prepare for the consultation which should be a conversation and not just a delivery of information. The prompt list also gives the patient something to look at later to clarify things and recall the discussion.

The other area which suffers from similar issues to trial recruitment is obtaining permission to use tissue obtained from biopsies and surgery in research.

Again nothing was said to me after surgery if my breast tissue could be held for research. In my own situation chemotherapy was so successful that scans at the end could not detect any tumours, but it was still felt that because of my original diagnosis I should have a mastectomy as to quote my surgeon "it had been there". To me it seems that further research on my tissue in the lab may have shown that the chemo had in fact cleared the cancer. This may have helped in work to reduce radical surgery for others in the future.

I do not know of a patient who would not agree with a request that their tissue be used in research. To think that the material is thrown away or stored and not recorded in any useful way is a terrible waste and should not happen. The European survey I mentioned earlier also looked at patient organisations involvement in biobanks. This seems pretty limited over most of Europe at the moment and is another issue that needs to be improved. I know that the Breast Cancer Campaign Tissue Bank Project does have patient input, so we are on the first step.

I belong to an independent patient advocate group – Independent Cancer Patients' Voice – we would very much like to help with trial recruitment and put a patient's view to the patients. In all cases when trials are discussed within patient groups the majority are very positive about wanting to participate and feel more involved in all aspects of their care and treatment. We realise that patient involvement is critical in cancer research and our wish is to help in any way we can. With this in mind we are aiming to put together a small leaflet which might be of use when speaking to patients about joining a trial or allowing their tissue to be used.

My final point is to say that patients want to be included in decisions, so please when appropriate 'just ask'.

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