Institution: University of Sussex

Unit of Assessment: UoA 4 Psychology

Title of case study: Overcoming barriers to clinical trial recruitment in cancer with educational interventions

1. Summary of the impact

Research on professionals' discussions about clinical trials of cancer therapy has identified the major barriers to patient recruitment to clinical trials. This research was used to create an educational intervention to improve patient experiences and willingness to participate in a variety of clinical trials worldwide, resulting in increased participation in prostate, colorectal, renal and breast-cancer trials. It also involved educating members of UK cancer teams to the best ways to approach, communicate and maximise trial planning.

2. Underpinning research

In the late 1990s, Jenkins and her colleagues recorded actual doctor–patient discussions about recruitment to randomised clinical trials. The results revealed that the majority of doctors did not describe randomisation and had idiosyncratic ways of explaining different aspects of trial recruitment. In addition, several surveys revealed that patients had positive attitudes towards clinical trials, but found the concept of randomisation off-putting and wanted to be given as much information as possible about their disease, the available treatments and the side-effects.

Following Jenkins' arrival at Sussex in 2001, she and her colleagues conducted further studies to ascertain which descriptions of randomised trials were preferred by patients with cancer and why [see Section 3, R1]. Patients' preferences were compared with the descriptions used the most frequently by clinicians during consultations. The results revealed that the description 'tossing a coin' was used very frequently by clinicians and was commonly found in patient-information leaflets. However, this analogy was greatly disliked by both patients and members of the public. A follow-on survey showed that patients' preference was for statements that gave sense and meaning to randomisation, and did not use the word 'chance' or an analogy for chance [R2].

This research led to the development of a training programme, *Discussing Randomised Clinical Trials of Cancer Therapy,* involving educational DVDs and handbooks. This programme was evaluated in a before–after trial and was shown to significantly enhance communication skills [R3]. After further research into patients' understanding of early-phase trials [R4], the team developed and produced a set of modules to help with these difficult discussions.

Further research into the attitudes of patients and members of the cancer teams towards clinical trials, in collaboration with Wales Cancer Research Network (NISCHR), was conducted This was used to develop the team training workshop, *Teams Talking Trials*, which was evaluated in an RCT and was found to significantly improve team members' involvement in trials, their confidence in communicating about trials and their awareness of several aspects of trials management. This workshop is now widely used by cancer teams having difficulty with recruiting patients for trials [see Section 4].

3. References to the research

R1 Jenkins, V., Leach, L., Fallowfield, L.J., Nicholls, K. and Newsham, A. (2002) 'Describing randomisation: patients' and the public's preferences compared with clinicians' practices', *British Journal of Cancer*, 87(8): 854–858.

R2 Jenkins, V., Fallowfield, L. and Cox, A. (2005) 'The preferences of 600 patients for different descriptions of randomisation', *British Journal of Cancer*, 92(5): 807–810.

R3 Jenkins, V., Fallowfield, L.J., Solis-Trapala, I., Langridge, C. and Farewell, V. (2005) 'Discussing randomised clinical trials of cancer therapy: evaluation of a Cancer Research UK training programme', *British Medical Journal*, 333(7488): 400.

R4 Jenkins, V., Solis-Trapala, I., Langridge, C., Catt, S., Talbot, D.C. and Fallowfield, L.J. (2011) 'What oncologists believe they said and what patients believe they heard: an analysis of Phase 1 Trial discussions', *Journal of Clinical Oncology*, 29(1): 61–68.

Outputs can be supplied by the University on request.

Relevant funding

Work supporting this impact was funded by seven grants from agencies such as:

- Cancer Research Campaign / Cancer Research UK;
- AstraZeneca Pharmaceuticals;
- Roche UK; and
- Medical Research Council

Total value > £4m.

4. Details of the impact

The research has had an impact on the improvement of recruitment to successful clinical trials in two ways:

- the research has been developed into material for *training courses* for cancer health professionals with national and international reach;
- the research has been used to support *specific recruitment programmes* for difficult trials including prostate, renal, breast and haematological cancers.

Training courses

Over 200 facilitators from the UK, the USA and Canada have been trained to conduct courses using the communication about clinical-trials educational materials. These training courses have been adopted by the English National Cancer Research Network (NCRN) and Welsh National Institute for Social Care and Health Research Clinical Research Centre (NISCHR) [see Section 5, C1, C2].

In Wales, 221 participants attended one of 25 'Talking about clinical trials' training courses between 2007 and 2012. Feedback from the courses was extremely positive, with participants indicating that it has changed their practice: 'Given me greater understanding of the importance of the research nurse role'; 'Importance of effective communication and how it can affect trial outcome'. These courses are conducted every two months in the three Welsh regions [C2].

The 32 NCRN Local Research Networks regions in England conducted 31 courses with 329 staff members between 2010–2012, again obtaining very positive participant feedback [C1]. As a result, there was a fivefold increase in the recruitment of cancer patients to NCRN portfolio studies between 2001 and 2011, although an exact number attributable to the training alone cannot be specified. Data for 2010/11 show that over 50,000 cancer patients are now recruited into studies across the UK each year.

In 2006, Jenkins and Fallowfield were awarded the British Oncology Association (BOA) Excellence in Oncology Award for Best Professional Education Initiative for these educational and training materials.

Specific recruitment programmes

A specific request was received from the Medical Research Council (MRC) for help to increase recruitment to a prostate cancer trial (RADICALS) that was in difficulty. An easy-to-navigate patient information DVD, split into different sections that explained the trial – randomisation, uncertainty about treatments and side-effects of each arm, plus a question-and-answer session – was produced. These were the RADICALS (Radiotherapy timing comparison and hormonal duration comparison patient information) DVDs. These DVDs were given to eligible trial patients to watch so that they received consistent, clear information about the trial before deciding whether or not to participate. Feedback from the MRC showed that, on average, centres were recruiting 14 patients per month before the DVDs were distributed in January 2010. Since the use of the DVDs was introduced, centres have been recruiting, on average, 37 patients per month – see the report from the Radicals Trial Manager, MRC Clinical Trials Unit, London 2011 in [C3].

The popularity and success of the RADICALS DVDs has led to similar DVDs becoming an integral part of applications for many hard-to-recruit-to trial protocols, including ones for ductal carcinoma *in situ* (DCIS) breast, colorectal, renal and prostate cancer trials. For example, the PulMICC clinical trial randomises patients to either surgical removal of pulmonary metastases or active surveillance [C4]. Production of a patient information DVD for the LORIS trial (Low Risk DCIS) (Health Technology Assessment) is currently underway and communication training sessions will be held to help medical staff to explain the trial to women diagnosed with low or low/intermediate DCIS [C5]. Patient information and staff training DVDs are also a core feature of two International Preference Trials of herceptin treatment for DCIS, sponsored by Hoffman La Roche (PrefHer Cohort 1 and Cohort 2). The DVDs were translated into eight languages for use with staff recruiting 400 patients to the study [C6].

The team training work has been highlighted by the pharmaceutical industry (Roche UK), which has commissioned Jenkins' group since 2011 to work with breast and haematological cancer teams across the UK experiencing low patient-recruitment numbers. These have been a success and six-month follow up has shown changes in several areas, including an increased enthusiasm for trials, and of the recruitment of patients and teams [C7].

In Vancouver, Canada, the Breast Cancer Agency facilitates the course to their medical staff; the training DVDs were also dubbed for use in Germany.

5. Sources to corroborate the impact

C1 Letter from NCRN education centre.

C2 Email correspondence and feedback forms from NISCHR.

C3 MRC CTU (2010) 'Important changes to the RADICALS trial!', 5 March 2010, see http://www.ctu.mrc.ac.uk/news_and_press_releases/news_archive/important_changes_to_radicals.aspx. This states:

> There has been an important change to the RADICALS trial. The two randomisations in the trial have been uncoupled and can now be considered to be completely separate in version 3.0 of the protocol.
>
> Patients who have had a radical prostatectomy in the past five months can take part in RADICALS RT, looking at early versus deferred post-op RT. Only if and when they are definitely going to get post-op RT do they need to know about RADICALS HD, looking at RT +/- hormones.

> Eligibility for RADICALS RT is for men with any risk factor for recurrence (i.e. Gleason 7-10, **or** pT3, **or** margin +ve, **or** presenting PSA>10 **or** any combination). In other words, most men who have a radical prostatectomy are eligible for the RT Timing Randomisation.

This is an important change and should make recruitment to the RT question much simpler for patients and clinicians. In addition, there is now a DVD for patients to take away and find out more about the trial. They can also find the same video on YouTube (search RADICALStrial).

C4 *PulMiCC* – Royal Brompton & Harefield NHS Foundation Trust: www.rbht.nhs.uk/PulMiCC/ http://www.rbht.nhs.uk/research/cteu/projects/respiratory-disease/pulmicc/patient-info/ (this link shows one of the DVDs produced by Jenkins' group for recruitment to a Pulmonary Metastasectomy in Colorectal Cancer trial).

C5 Fallowfield, L.J., Franci, A., Catt, S., Mackenzie, M. and Jenkins, V. (2012) 'Time for a low-risk DCIS trial: harnessing public and patient involvement', *The Lancet Oncology*, 13(12): 1183–1185.

C6 Pivot, X., Gligorov, J., Müller, V., Barrett-Lee, P., Verma, S., Knoop, A., Curigliono, G., Semiglazov, V., López-Vivanco, G., Jenkins, V., Scotto, N., Osborne, S. and Fallowfield, L. (2013) 'Patient preference for subcutaneous administration of trastuzumab in HER-2 positive early breast cancer: results of the international randomised PrefHer study', *The Lancet Oncology*, 14(10): 962–970.

C7 Fallowfield, L., Langridge, C. and Jenkins, V. (2012) 'Communication skills training for breast cancer teams talking about trials', *The Breast*, (accepted for publication), pdf available for audit & email from Associate Head of Medical Affairs (Oncology), Roche.

Testimonials – available for audit

> One of the really important things we've found out about the DVDs is that it hasn't just helped the patients to understand the trial, but it has also helped some clinicians to understand the trial and use the DVDs as a guide on how to present the trial to their patients (MRC trial organiser – CM).
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> Our recruitment has improved since the DVD was given to patients; I do not mind saying maybe I was not good enough (Oncologist).
>
> I felt the course was beneficial in this way. I feel as if attending a workshop such as this would be of benefit for every new trial we open. In this way, we could all be certain of each other's roles and the pathway of the trial and all be confident we knew the arms of the trials and how best to approach this with the patient (Surgeon).
>
> Although I was rather hesitant in how much value this day would provide us and also dreading the role play (!) I have found this workshop very useful – particularly to have this opportunity to discuss all the complex issues with all the core members of the MDT. Actors were particularly valuable in addressing the many issues of this trial, but very helpful to look at ways of solving some of these problems (Specialist breast-care nurse).