Discussing Early Phase Trials: Evaluation of a Cancer Research UK Educational Training Program

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1. Background:

Communicating well with patients and their families about early phase cancer trials presents many challenges. Studies examining the informed consent process show deficiencies including failures to check understanding about prognosis, a lack of clarity about the experimental nature of trials and inadequate discussion of palliative care options.[1] We report results from the evaluation of an educational initiative modelled around a previously successful method of enhancing discussions about randomised clinical trials between clinicians and their patients.[2]

2. Educational training program:

The content was developed in close collaboration with experienced oncologists and research nurses and from original evidence based research[1] of recordings of real Phase 1 and 2 interviews.

3. The 5 modules:

i) P1 trial of a standard drug plus a new agent; it illustrates some of the communication demands when dealing with a distressed younger man with metastatic malignant melanoma.

ii) P1 monoclonal antibody trial discussion between an oncologist and a metastatic colorectal cancer patient which provides useful examples of ways to explain trial aims.

iii) End of active treatment interview between an oncologist and a woman with metastatic breast cancer and her husband. Module demonstrates difficulty of handling relatives who see palliative care as giving up.

iv) P1 dose escalation trial discussed with the same couple seen in module iii) highlighting the uncomfortable situation when patients fail the trial screening tests.

3. Continued

v) P2 trial with a non-small cell lung cancer patient and his wife. Module initiates group discussion on how to encourage positivity about outcome whilst staying realistic.

4. Workshop content:

The workshop lasted 8 hours, split over 2 half days. It comprised a mix of didactic presentations of relevant data plus facilitated group discussion about the scenarios in each module. During the workshop, participants were encouraged to consider ways to:

- structure P1 & 2 trial discussions efficiently
- give prognostic information &/or check understanding
- describe the aims of the experimental trial
- mention the risk of unknown side effects
- describe extra effort involved with trial participation
- discuss symptomatic /palliative care alongside putative trial entry

5. Hypotheses:

Post workshop participants would display: **a)** increased competence & **b)** increased confidence when discussing early phase trials

6. Methods:

47 healthcare professionals (17 clinicians, 29 nurses and 1 network manager) participated in the evaluation. Prior to and following the workshop, participants conducted P1 or P2 trial interviews with simulated patients which were audio taped.
Participants were permitted to use patient information sheets and aids that they would employ in clinic. Different actors were involved at each interview to enhance authenticity but the trial remained constant.

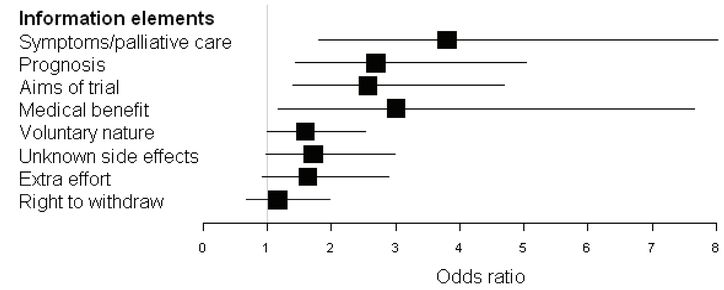
7. Assessments:

Objective:

a) Two experienced researchers using clearly defined criteria content coded audiotapes
b) Simulated patients' assessments using a checklist.

Subjective: Participants' self rated confidence about 15 items using visual analogue scale

8. Objective Results: Odds ratios of improved scores for coded audiotapes



Odds ratios of improved scores for simulated patients' assessments:

Area	OR	95%CI	P Value
Symptomatic/palliative care	2.11	1.27-3.48	0.004
Time to consider trial entry	6.11	1.56-23.9	0.009
Voluntary nature	3.67	1.28-10.5	0.015
Opportunity to ask questions	2.88	1.03-8.03	0.044
Unknown side effects	1.58	0.99-2.51	0.057
Used clear language	3.24	0.78-13.4	0.106
Sensitive to my concerns	2.61	0.79-8.64	0.115
Trusted physician/nurse	2.34	0.66-8.29	0.186
Understood aims of the trial	1.60	0.79-3.24	0.194
Extra effort on my part	0.64	0.27-1.51	0.305
Right to withdraw	1.21	0.66-2.14	0.539
Felt listened to	1.25	0.49-3.20	0.639
Gave me all the information	1.07	0.52-2.22	0.853

9. Subjective Results:

Self confidence

Participants' scores increased significantly after the course across all areas probed (P<= 0.001) including discussion of different types of P1 trials, prognosis & symptomatic care. The intervention was valued highly and rated to be informative, interesting, useful and enjoyable.

10. Conclusion:

This short, intensive educational program changed communication skills and self efficacy of the majority of healthcare professionals, in ways likely to enhance ethically valid informed consent.

References:

1. Jenkins V, Solis- Trapala I et al. What oncologists believe they said and what patients believe they heard: an analysis of Phase 1 Trial discussions. JCO, 2011 vol. 29 no. 1 61-68
2. Jenkins V, Fallowfield L et al Discussing randomised clinical trials of cancer therapy: evaluation of a Cancer Research UK training programme. BMJ 2005; 330:400