Omissions and misunderstandings in Phase 1 trial discussions

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Background: Effective communication about Phase 1 and Phase 2 trials is arguably more difficult than Phase 3 as it demands a complex amalgam of advanced skills, balancing honesty about likely therapeutic gains versus risks and managing the many emotions evoked. Studies reveal that many patients have limited understanding of the primary research aims, unrealistic expectations about benefits and risks, a questionable appreciation of their right to abstain/withdraw, and little knowledge about alternatives to P1 trial participation.

We report data from a CRUK funded study incorporating triangular analyses of doctors, patients and researchers' views of P1 consultations.

Sample & Method: Between August 2007 and December 2008, 17 clinicians and 52 patients from 5 UK cancer centres in Glasgow, London, Southampton and Oxford participated in the study and consented to recording of their Phase 1 trial consultations.

Following each consultation, researchers conducted semi-structured exit interviews with patients probing understanding of the trial, perceived risks & expectations. Patients completed 3 questionnaires measuring optimism, distress and reasons for trial entry (poster A60).

After consultations oncologists also completed a checklist indicating areas of information they felt they had covered e.g. whether or not unknown side effects were discussed, the voluntary nature of the trial, other treatment options etc.

Oncologists (n=17): 7/17 were consultants with more clinical trial experience than SpRs, including being principal investigators. Most (14/17) had received some communication skills training. The median and mean number of consultations per month per clinician was 3 (range 1-8).

Patients (n=52)

sex (M/F)	24 (46%) /28 (54%)
age mean (sd)	58.1yrs (10.59)
previous P2/P3 trial exp	26 (50%)
Cancer sites	
colorectal/breast/melanoma	37 (72%)
gynae/urological/other	15 (28%)

Analysis: Independent researchers coded the consultations to identify whether 8 key elements of information had been discussed i.e. prognosis, aim of trial, lack of medical benefit, symptom control, voluntary nature, right to withdraw, extra effort & unknown side effects.

Observed levels of agreement using Bangdiwala plots were analysed for each consultation between oncologist/coder, oncologist/patient, patient/coder pairs. Bangdiwala plots are divided into 4 main rectangles. The edges of the black boxes, which are located within larger shaded rectangles along the diagonal, are the number of equal answers given by any dyad for a specific key element. Edges of the larger shaded rectangles represent the maximum possible agreement. Thus, larger black boxes indicate better agreement.

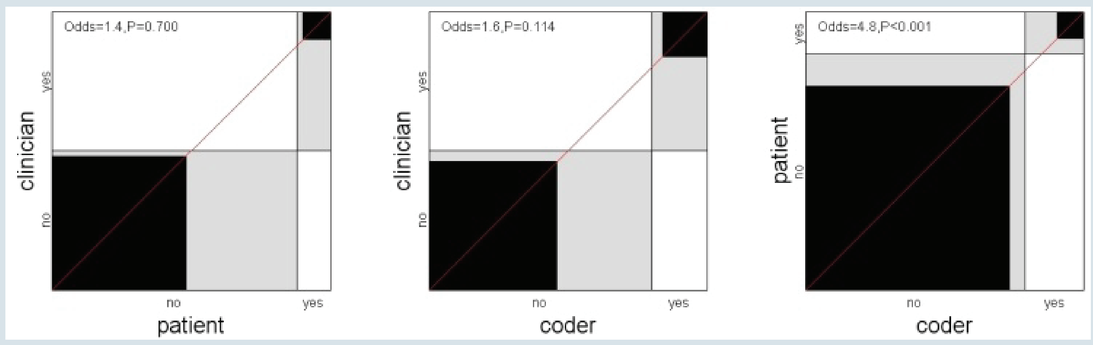
As an example the results for 3 of the key elements are shown in figures A, B & C.

Acknowledgements: All the patients, clinicians, clinic staff and researchers Louise Parlour & John Anderson. Cancer Research UK funded the project.

Reference: What oncologists believe they said and what patients believe they heard: an analysis of Phase 1 trial discussions in press with J Clin Oncology (2010)

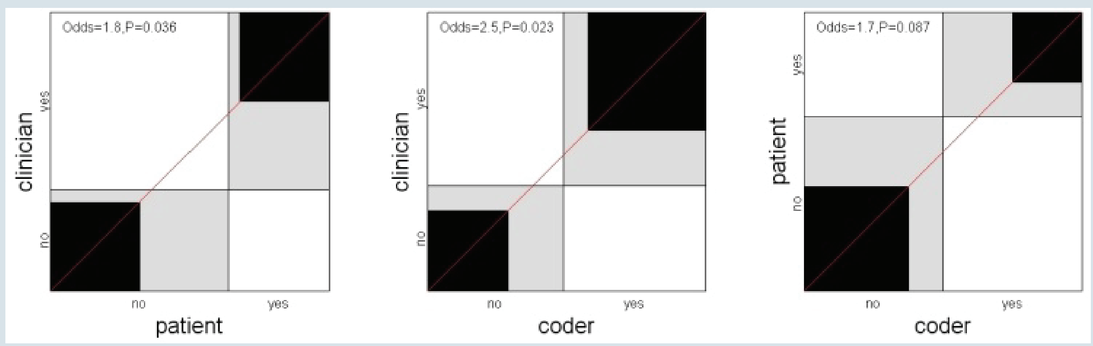
Results: Bangdiwala Observer Agreement Plots

(A) Prognosis



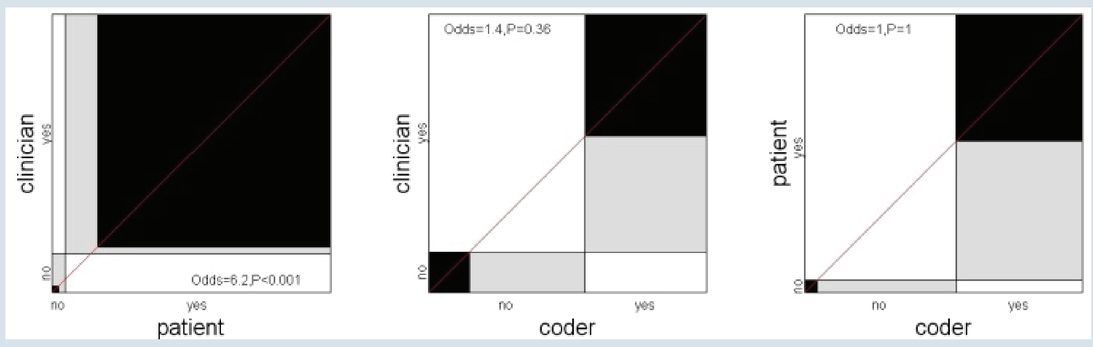
Discussion of prognosis was a frequent omission, with patients and coders significantly more likely to agree that oncologists had not discussed it (Odds=4.8, P<0.001).

(B) Symptomatic care/ other treatment plans



In contrast, coders and oncologists were more likely to agree that alternate care plans to P1 trial entry had been explained (Odds=2.5; P=0.023).

(C) Voluntary nature explained



Whereas patients and clinicians agreed voluntary nature was discussed (Odds 6.2; P<0.001). The clinician was more likely to report explaining voluntary nature of the trial if the patient had been under his/her care before (P=0.0009).

Conclusion: Full results will be available shortly (JCO in press) but in several key areas, information was either missing or had been explained but interpreted incorrectly by patients. Without a clear appreciation of likely prognosis and explicit discussion about good quality palliative care, patients cannot provide informed consent to Phase 1 trials.

Although some patients were aware that the P1 trial was unlikely to benefit them personally, many saw trial entry as the only option.

A modular training programme to help communication about early phase trials has been developed and evaluated.