PC-FACS AAHPM

Feature Editor: Amy P. Abernethy, MD, FAAHPM

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Summaries with Commentary

From PC-FACS Issue 110 – May 2, 2011

Oncologists Versus Patients on Phase 1 Trial Discussions

Background. Many patients do not understand research aims or benefits/risks of phase 1 trials, their right to abstain/withdraw from a trial, or alternatives to trial participation.[1] In discussions about phase 1 trials, does what oncologists think they said coincide with what patients think they heard?

Design and Participants. This observational study at five U.K. cancer centers compared (a) what oncologists said (via audiotape), (b) what areas oncologists believed they covered (self-report questionnaire), and (c) what patients recalled and understood (semistructured interview) in discussions about phase 1 trials. Audiotaped consultations were coded to identify information areas discussed; observed levels of agreement were analyzed for each consultation between oncologist-coder, oncologist-patient, and patient-coder pairs. Participating oncologists ($n = 17$) were 71% < 45 years old, 76% male, and 41% were current/previous principal investigator. Participating patients ($n = 52$) were mean age 58 years (SD 11), 46% male, and 50% had previous trial experience.

Results. Thirteen of 17 oncologists mentioned prognosis in < 50% of consultations; also in < 50% of consultations, 10 mentioned unknown adverse effects, nine mentioned the voluntary nature of participation, and 10 mentioned participants' right to withdraw. Best agreement on topics discussed was in establishing trial aims and participant burden. Although 50% of oncologists reported discussing prognosis in the consultation, 12% of patients and 20% of coders agreed that it had been mentioned (OR 4.8; $P < 0.001$). Coders (vs. patients) were more likely to agree with clinicians that other care or treatment plans (OR 2.5; $P = 0.02$), right to withdraw (OR 2.9; $P = 0.01$), and likelihood of medical benefit (OR 5.1, $P < 0.001$) were discussed.

Commentary. When conventional therapies prove ineffective, phase 1 trials are sometimes presented as an alternative to palliative care. There are many good reasons to participate in such trials, although expectation of cure or increased survival is generally not one of them. Nevertheless, most patients participate because of this "therapeutic misconception." By recording consent encounters and physicians' and patients' perceptions afterwards, this study showed that responsibility for this misconception lies with both parties. Oncologists infrequently checked for understanding of prognosis, and patients took advantage of this ambiguity to interpret what they heard in an overly optimistic light. Overcoming patients' "therapeutic optimism" may be difficult and not always desired. Yet, it can only be done by delivering a clear message about prognosis and checking for patient understanding.

Bottom Line. For patients to make truly informed decisions about phase 1 trials, they ought to be given the opportunity to receive unambiguous information about prognosis.

Reviewer. James A. Tulsky, MD, Duke University and VA Medical Centers, Durham, NC.

Source. Jenkins V, Solis-Trapala I, Langridge C, et al. What oncologists believe they said and what patients believe they heard: an analysis of phase I trial discussions. J Clin Oncol 2011;29(1): 61–68.

Reference

1. Cox AC, Fallowfield LJ, Jenkins VA. Communication and informed consent in phase 1 trials: a review of the literature. Support Care Cancer 2006;14:303–309.

Disclosure of Terminal Illness to Patients and Families in Islamic Countries

Background. The presence of 1.57 billion Muslims worldwide creates a need for knowledge of, sensitivity to, and competence in Islamic medical ethics in other cultures. What codes of medical ethics related to disclosure of terminal illness exist in Islamic countries?

Design and Participants. This was a media search of Google and PubMed in April 2008 and July 2009, supplemented by a hand search of reference lists in identified articles. The search used multiple terms related to codes of medical ethics and disclosure of terminal illness and included documents written in Arabic, English, and French.

Results. Codes for 14 Islamic countries were located. Fifty-seven percent of the codes were

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