

Obtaining informed consent for clinical pain research: patients' concerns and information needs.

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Abstract:

Investigators who conduct clinical pain research are required to obtain voluntary informed consent from patients. However, little is known about what information patients expect when they decide whether to enroll in such studies. It is important that investigators understand these information-needs so they can effectively and clearly describe the research risks and potential benefits that matter to potential subjects. By understanding these needs for information, investigators may also be better able to anticipate patients' concerns and to recruit subjects more efficiently. This study was designed to define information needs that patients have when they decide whether to participate in clinical pain research. This paper describes these information needs, and identifies clinical and demographic variables associated with specific needs.

Comments:

Strengths/uniqueness: This paper describes in a "structured" way observations which are usually anecdotally reported by research personnel working with patients. These observations are thought-provoking for investigators who are sensitive to patients' concerns/needs as well as willing to conduct worthwhile research studies. The research process followed by investigators appeared appropriate.

Weaknesses: Data from qualitative studies are by definition not generalizable. The relevance of these results should be further investigated by incorporating this information in assessment tools (i.e. questionnaires) which could be administered to a wider and more representative sample. The latter type of study could also allow for more robust statistics. Furthermore a clearer feed-back could be provided to Health Research Ethics Committees in order to appropriately modify their guidelines to prepare an informed consent form. At the present the quality and amount of information provided to patients in the latter is quite standard and strictly codified.

Relevance for Palliative Care: A similar type of research should be conducted with terminally ill patients, in order to define issues that are more pertinent to this population. The above-mentioned "anecdotal" experience of clinical research nurses should be better documented in palliative care.