

WHICH CLINICAL TRIAL ISSUES ARE OF THE GREATEST AND THE LEAST IMPORTANCE TO ONCOLOGY PHYSICIANS AND NURSES? IMPLICATIONS FOR FUTURE CLINICAL RESEARCH

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Abstract

Background: Clinical trials in cancer are available in nearly all patient treatment centers. Major cooperative groups, comprehensive cancer centers, CCOP programs, philanthropic institutions and biomedical corporations all sponsor trials which can differ greatly in the issues studied. Still, only a minority of patients enter into trials. Many factors limit trial entry, including: professional staff time, resources, and interest; funding; and patient interest and ability to participate.

Methods: We asked 65 oncology professionals to complete a brief survey assessing the importance of each of 10 issues in clinical trials. Each issue was evaluated on a 5-point categorical scale ranging from "very important" to "not important at all." 40 professionals completed the study (63% MDs, 32% RNs, 5% other). Median years in oncology = 17 (range 1 – 35); 42% women.

Results: In general, all professional groups gave similar ratings for 1) the most important issues in clinical trials (survival benefit, side-effect reduction, symptom relief); for 2) those issues in the mid-range of importance in trials (tumor response, informed shared decision making, cost-effectiveness); and 3) the lowest range (psychosocial aspects, patient education materials). Differences in ratings of those issues in the lowest range (the 4 lower categories on the 5-point scale) were found between MDs primarily in practice when contrasted with clinical research MDs. The table outlines the percent of MDs rating the issue as **not important** for clinical trials, by MD group.

Issue	Practice MDs (n = 16)	Clinical Research MDs (n=9)
Psychosocial Aspects	25%	55%
Informed Decision-Making	7%	45%
Patient Education Materials	21%	45%
Cost-Effectiveness	21%	33%

Conclusions: The large differences between the two MD groups, indicates that MDs entering the greatest number of patients into trials (those in clinical research) are less likely to be involved in trials investigating these issues. Thus, it may be more difficult to study these issues, even though the majority of practicing physicians rate these issues more highly for their patients. While this is a small survey, it indicates that strategies to overcome these identified barriers should be developed if research on these issues is to be accomplished effectively.

Background

- The position stated by the National Cancer Policy Board of the Institute of Medicine, National Research Council (USA) outlines that quality care for patients with cancer and their caregivers includes informed, shared decision making.
- Healthy People 2010* directly addresses personal choice and its impact on behavior and health.²
- A *New England Journal of Medicine* editorial discusses the practical consideration that costs will increasingly affect providers' decisions about patient care. Thus, unless decisions in which patients' values should be considered are identified and protected, these decisions will be greatly affected by external sources.³
- Informing patients of a cancer diagnosis and its prognosis is common practice in many societies today. While this information is necessary for patients and families, knowledge of the relative risks and values of differing treatment alternatives is not readily available. This leads to difficulties in quality decision making for many patients faced with crucial issues.
- Clinical trials in cancer are available in nearly all patient treatment centers.
- Major cooperative groups, comprehensive cancer centers, CCOP programs, philanthropic institutions and biomedical corporations all sponsor trials which can differ greatly in the issues studied. In that only a small minority of patients enter into trials, the willingness of investigators to study issues concerning decision making can further affect the ability to produce evidence upon which to base patient information and effective approaches.
- Many factors limit trial entry, including: professional staff time, resources, and interest; funding; and patient interest and ability to participate.
- With health professionals responsible for study recruitment, understanding their priorities in relation to research can help in gaining a sense of potential feasibility of proposed research and avoidance of conflicting resource priorities.

Objectives

- To determine health providers' opinions about issues of importance for oncology research.
- To gain a better understanding of how decision making is ranked as a topic for research priorities in cancer.

Methods

- For this descriptive study, a survey approach was used at a regional oncology meeting to determine health providers' opinions about the relative importance of research issues concerning cancer. Included among the issues was an assessment of research related to shared decision-making interventions. All survey information was obtained anonymously.
- The survey purpose was discussed briefly by one of the investigators prior to its circulation. Two questionnaires were distributed (a demographic form and the survey of issues). Additionally, a brief cover letter introduced the survey as a "Health Provider Priorities Survey for Cancer" and solicited help with the two forms. Completion of the survey took less than 10 minutes.
- Participants were informed that the information from this anonymous survey would be treated confidentially. All were informed that participation was entirely voluntary, that one could refuse to answer any question, and that a participant was free to discontinue completion of the forms at any time.

Participants

TABLE 1. Characteristics of Participating Health Professionals

Characteristic	N=40
Profession:	
Physician	63%
Nurse	32%
Other*	5%
Gender:	
Women	42%
Men	58%
Age	
< 40 years	28%
40 – 59 years	60%
≥ 60 years	12%
Years in Oncology	
Median	17
Range	1 – 35
Number of Publications (MDs):	
0 – 5	46%
6 – 19	21%
20 – 200+	33%

* Includes one pharmacist and one student

Instruments

- Demographic Form:** A brief 8-item demographic form addressed: age, gender, type of profession, certification status, years in the profession, years in oncology, number of publications, and number of publications related to cancer.
- Priorities Survey:** A two-part questionnaire (clinical trials; patient information) was used with each issue evaluated on a 5-point categorical scale ranging from "very important" to "not important at all" (see Table 2). We report on Part I, clinical trials issues, in this presentation.

TABLE 2. Health Provider Priorities Survey for Cancer

Instructions: We would very much appreciate your opinion and views on 10 aspects concerning the importance of different endpoints in clinical trials. Your participation is entirely voluntary and confidential. There are no right or wrong answers – it is your opinion that counts.

Because there are many issues that are meaningful, please indicate just HOW IMPORTANT you feel that each of the following is by selecting the response that most agrees with your opinion. The first question (in blue) is only an example.

Please CIRCLE your response concerning how important you feel that each of the following is:	- PART 1: Clinical Trials -				
Example Question: How important is the following in your clinical practice?	RESPONSE:				
The weather:	Very Important	Important	Only a little Important	Not very Important	Not Important At All
Actual question: In considering the priorities for enrolling patients into clinical trials, how important do you feel each of the following primary endpoints or major study objectives are:					
Tumor response:	Very Important	Important	Only a little Important	Not very Important	Not Important At All
Tumor related symptoms:	Very Important	Important	Only a little Important	Not very Important	Not Important At All
Overall survival:	Very Important	Important	Only a little Important	Not very Important	Not Important At All
Psychosocial aspects of cancer:	Very Important	Important	Only a little Important	Not very Important	Not Important At All
Informed shared decision-making:	Very Important	Important	Only a little Important	Not very Important	Not Important At All
Progression-free survival:	Very Important	Important	Only a little Important	Not very Important	Not Important At All
Testing patient information materials:	Very Important	Important	Only a little Important	Not very Important	Not Important At All
Cost-effectiveness and economic issues:	Very Important	Important	Only a little Important	Not very Important	Not Important At All
Effects of cancer on the family:	Very Important	Important	Only a little Important	Not very Important	Not Important At All
Treatment-related side effects:	Very Important	Important	Only a little Important	Not very Important	Not Important At All

Analysis and Scoring

- A total score was calculated. This was performed by weighting the categories (the greatest weight was given to the highest category ["very important" which is weighted by a factor X4; the next highest category "important" by a factor of 3, etc. through all five categories; the contributions from each category are then summed to make a total score]).
- The total scores are then adjusted (total score / 4) so that the range varies from a lowest possible score = 0 to a highest possible score = 100.

Results continued

- Both professional groups (physicians, nurses) gave similar ratings for:
 - the most important issues in clinical trials (survival benefit, side-effect reduction, symptom relief)
 - those issues in the mid-range of importance for trials (tumor response, informed shared decision making, cost-effectiveness)
 - the lowest range (psychosocial aspects, patient education materials).
- Although the order of ranking is somewhat different for nurses and physicians, nurses ranked psychosocial issues slightly higher than physicians. Specifically, they rated decision making higher than physicians.
- Differences in ratings of those issues in the *lowest range* (the 2 lower categories on the 5-point scale) were found by physician clinical setting between oncology physicians primarily in practice when contrasted with clinical research physicians who are more involved in the conduct of trials and the recruitment of patients for these trials, as seen in the tables below. Clinical research physicians ranked decision making and psychosocial issues as research foci lower than those in practice.

Table 3. Ranking of Importance of All 10 Items by Total Score* (By Profession)

Issues	Physicians (n = 25) [Rank]	Nurses (n = 13) [Rank]
Survival	98 [1]	92 [1]
Progression-Free Survival	87 [2]	87 [5]
Side Effects	86 [3]	88 [3]
Symptoms	84 [4]	85 [7]
Response	82 [5]	92 [1]
Decision Making	78 [6]	88 [3]
Psychosocial Needs	70 [7]	87 [5]
Effects on Family	68 [8]	85 [7]
Cost Effectiveness	67 [9]	67 [9]
Patient Education Materials	62 [10]	67 [9]

*Total Score (0=lowest possible, 100 = highest possible)

TABLE 4. Which Clinical Trial Issues Were Rated to be of the Least Importance to Physicians: Percent by Practice Setting*

Issue	Practice Physicians (n = 16)	Clinical Research Physicians (n = 9)
Psychosocial Aspects	25%	56%
Decision Making	6%	44%
Patient Education Materials	19%	44%
Cost-Effectiveness	19%	33%

* Higher percentages indicate that more physicians gave this issue a LOWER rating

Conclusions

- Understanding health professionals' research priorities can help in gaining a sense of potential feasibility of proposed research and avoidance of conflicting resource priorities.
- While this survey is relatively small, potential barriers for some research issues are suggested and some differences between health professionals (physicians and nurses) are noted.
- Large differences were found between the two groups of oncology physicians. These differences indicate that physicians entering the greatest number of patients into trials (those in clinical research) are less likely to be involved in recruiting patients into trials investigating several specific issues as outlined in the results tables. Thus, it may be more difficult to study issues in decision making, psychosocial concerns, cost and economic areas, and patient education materials even though the majority of practicing physicians rate these issues more highly for their patients.
- Further research should focus on strategies to overcome this identified barrier if patients are to be offered tested approaches to aid in making informed shared decisions and in the other elucidated areas. Such issues that were ranked at lower levels of importance will require new methods of study if research in these areas is to be accomplished effectively.
- Larger surveys and health care provider populations beyond a regional conference could be useful. It must be noted; however, the large differences outlined in this survey indicate that similar results may be found when comparing physician groups by their involvement in clinical research.
- Oncology research nurses perform major roles in clinical research. Larger surveys of these individuals are necessary in that they may be particularly important as principal investigators or as collaborators in new approaches to study these under-addressed issues.
- While it is not surprising that the highest rated research endpoint was on studies emphasizing survival, it is notable that quality of life issues were highly rated as well. Surveys of patients should be conducted on these issues in that confidence in making appropriate decisions is likely to contribute to both of these outcomes.
- In addition, the willingness of investigators to study issues concerning decision making can ultimately affect the ability to produce sound evidence-based results upon which to base patient information and effective approaches related to both survival and quality of life.

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