



# The Research Connection

The Psychosocial & Nursing Advisory Board to  
the New Jersey Commission on Cancer Research

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The Joint Psychosocial & Nursing Advisory Group to the NJCCR was appointed to advise the Commission of special research needs pertaining to nursing, psychology, sociology, and related disciplines for the purpose of addressing gaps in vital areas of cancer research and cancer care in New Jersey.

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## Historical Perspectives on Clinical Trials

by  
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The history of clinical trials dates back as far as 250 years ago, beginning with comparative investigations to treat scurvy, as well as other nutritional disorders and the prevention of infectious diseases. During the 1800's, comparative studies were conducted to examine the effects of various drugs and vaccines for the prevention and treatment of smallpox, cholera, and diphtheria. Recognizing the value of medical research in improving the public health of the nation, in 1887, the federal government established the National Institutes of Health, which provided research funding for disease prevention, detection, and treatment (Breslin, 2000).

(continued on page 2)

### IN THIS ISSUE

|           |                                                                            |   |
|-----------|----------------------------------------------------------------------------|---|
| Article 1 | Historical Perspectives on Clinical Trials                                 | 1 |
| Article 2 | Medical Decision Making                                                    | 3 |
| Article 3 | Challenges to Cancer Clinical Trial Recruitment and Minority Participation | 6 |

The first documented clinical trial in the United States in 1931 involved a randomized, control study evaluating the efficacy of a gold compound (Sanocrysin) for the treatment of pulmonary tuberculosis. In this study, patients were not informed of treatment differences between the experimental and control group. Infectious disease research predominated during the 1900's, and with time, clinical trials developed greater scientific rigor in methodology. In 1948, the British Medical Council designed a clinical trial involving the use of streptomycin in the treatment of tuberculosis. This study represented a significant advancement in research methodology, as the design included the essential elements of objective quantitative research: control, homogeneous sampling, constancy in data collection, randomization, and ethical guidelines. While research designs and data analysis have become more sophisticated, the fundamental principles of experimental designs remain today.

Funding for cancer research as well as training was made available in 1937 when President Franklin D. Roosevelt signed the National Cancer Act, establishing the National Cancer Institute (NCI) as a division of NIH. In the mid 1950's, NCI began funding cooperative oncology groups to increase enrollment in clinical trials. By 1958, 17 clinical cooperative groups had formed and were testing new neoplastic agents from the NCI drug development program (Cheson, 1991, p.235). The National Cancer Act of 1971 facilitated increased funding for oncology research as well as promoted the development of training programs, facilities, and public-education services (Jenkins & Hubbard, 1991). Exposure to the medical atrocities of World War II resulted in attention to ethical principles in the conduct of medical research. The Nuremberg Code of 1947 served as the initial foundation of ethical conduct in clinical research, followed by the Declaration of Helsinki, which was adopted by the World Medical Association in 1968. The Belmont Report of 1978, consisting of the three ethical principles of beneficence (above all, do no harm), respect for persons, and justice, as well as the establishment of Institutional Review Boards still presides today in the provision of regulations guiding research sponsored by the federal government.

Most of the clinical trials in the early 1970's were conducted at NCI approved Comprehensive Cancer Centers that received grants from NCI. However, these centers provided cancer treatment for only 20% of the population faced with cancer, as the remaining 80% of individuals with cancer were being treated in their own communities by their local oncologists (Cheson, 1991). Outreach programs with funding for community oncologists were then developed to increase accrual of patients into available NCI trials.

In 1976, NCI's Division of Cancer Treatment established the Cooperative Group Outreach Program (CGOP), enabling community physicians to affiliate with a cooperative group to provide patient access to cooperative group clinical trials. In 1983, the Community Clinical Oncology Program (CCOP) was established and funded by NCI's Division of Cancer Prevention and Control, providing different funding sources, accrual requirements, affiliation policies, and clinical trials focusing on treatment, as well as prevention and early detection (Breslin, 2000). In 1988, NCI established the High Priority Clinical Trials Program which increased accrual by setting phase III cooperative group trials as a high priority in cancer research.

Numerous cooperative groups exist within the United States, allowing greater numbers of investigations, as well as increased accrual of patients and ultimately, improved outcomes. Of these cooperative groups, several focus on the provision of care to children with cancer, with the result that in the early 1990's, more than 80% of children with cancer were entered into clinical trials, as compared to only 20% of potentially eligible patients being entered into clinical trials (Cheson, 1991). While many children benefited tremendously with dramatic survival rates, women, due to the potential teratogenic effects on the developing fetus, were excluded from clinical trials in 1977, in large part because of the phase I clinical trials of thalidomide. In 1990, NCI created the Office of Research on Women's Health, and the NIH Revitalization Act in 1993 mandated that women be included in all NIH sponsored clinical trials.

Throughout the course of 250 years, significant gains in scientific knowledge and improved health outcomes have been the end result of clinical trials. In many different types of cancers, the use of clinical trials and the widespread use of advanced research findings have led to the dramatic increases in cure rates witnessed today. It is the continued and increased conduct of our present sophisticated clinical trials that will provide improved health care advances in the management of cancer care in the future.

*Due to space limitations, references for this article are not listed but are available by contacting the NJCCR at 609-631-4747 or ([njccr@doh.state.nj.us](mailto:njccr@doh.state.nj.us)).*

## Medical Decision Making

by

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### Historical Overview

The role of patients in medical decision making has shifted over the last fifty years from a passive “sick” role with doctors who guided them in a paternalistic style to a more active role which involves mutual participation with physicians. Numerous historical factors have contributed to this change in medical consumerism.

In the 1950’s, patient education became a focus in healthcare with the main driving force being prepaid health plan providers who recognized that informed self care of patients would reduce their long term costs. In 1964, the American Hospital Association began to standardize the requirements for patient education which led to the passage of the federal Patients Bill of Rights. As medical technology advanced and physicians were able to keep patients alive longer, decision-making for the incapacitated became a focal point in 1973 with the Karen Anne Quinlan case. In the 1980’s and 1990’s, many states passed laws mandating that doctors discuss all surgical options with their breast cancer patients. Finally in 1990, Congress passed the Self-Determination Act which was designed to make patients better informed about many of their

rights regarding treatment decisions. It underscores the role and importance of patient participation in healthcare decisions by clearly identifying the parameters of their decision-making authority. It also requires hospitals to give patients information on state laws regarding advance directives.

Juxtaposed with these events during the 1960’s and 1970’s, public attitudes also changed toward the role of patients in regard to medical decision making. Influenced by the many advocacy movements occurring at that time (civil rights, womens rights, gay rights, AIDS, anti-war, etc.), people began identifying and asserting themselves as “consumers” of both their conventional and complementary health care. This led patients to seek more information and more accountability from a profession that had previously been seen as beyond reproach (Runfola & Levine, 2006).

### Overall Concepts of Medical Decision Making

Three models of physician-patient relationship regarding medical decision making have been identified: a) physician as agent; b) informed decision making; and c) shared decision making. They vary by the amount of decisional authority which is conferred to or assumed by patients (Emmanuel & Emmanuel, 1992; Gafni, Charles & Whelan, 1998; Quill & Brody, 1996).

#### a) Physician as agent

In this model, the doctor assumes the role of expert advisor, incorporating the values of the patient when making a treatment recommendation. The doctor has control over the decision making process and there is limited patient participation or autonomy (O’Connor, 1989; Sutherland et al, 1989).

#### b) Informed decision making

Informed decision making highlights the patient as a medical self advocate. While the doctor’s technical expertise is recognized, his/her role is to provide thorough information to patients to enable them to make decisions consistent with their values. The doctor neither advocates nor advises but rather assumes that patients can

understand the information they are given, can articulate their preferences and can successfully make a fully informed decision (Gattellari, 2001).

The term “informed decision making” as opposed to “informed consent” has become more commonly used in research literature (Charles, Gafni & Whelan, 1997; Feste & Anderson, 1995) to reflect a shift from focusing solely on legal and ethical concerns to include both information disclosure and patient participation (Gattellari, 2002).

### c) Shared decision making

This model is a balanced approach which advocates an equal sharing between doctors and patients in the decision making process. Information and preferences must be communicated fully by all parties in order to reach a mutually acceptable treatment decision (Gattellari, 2001). Doctors who utilize this type of participatory decision making may be more successful in achieving patient compliance with treatment regimens (Kaplan, 1996). This behavior encourages patients to ask questions, elicit treatment options, express opinions and state preferences about treatment on an ongoing basis. Patients who feel that they have participated in decision making also appear to have measurably better health outcomes than patients who are less involved (Kaplan et al, 1989; Greenfield et al, 1988; Greenfield et al, 1985; Barry et al, 1988; Rost et al, 1991). Some inherent challenges of this model are deficiencies in doctor communication skills (Ford, Fallowfield & Lewis, 1996) and patients' poor comprehension of information presented to them due to their own anxiety (Ley, Bradshaw & Kincey, 1973) or denial (Gattellari et al, 1999).

Research findings about the benefits of patient participation however are inconclusive with some studies even suggesting that patient participation may not be inherently beneficial. One hypothesis is that being an equal participant in decision making is more critical for patient well-being than actually being given a choice of treatments (Gattellari, 2001). Some studies even suggest that a considerable minority of patients prefers to relinquish decision making control (Butow et al, 1994; Degner & Sloan, 1992;

Sutherland et al, 1989) particularly if faced with increasingly distressing situations. Preferences for involvement in decision making also appear to shift as patients move along the continuum from wellness to illness (Beaver et al, 1996; Bilodeau & Degner, 1996; Degner et al, 1997). The cancer setting in particular usually involves healthcare providers and patients/families in more “uncertain, time-pressured and stressful conditions that implicate life and death” (Albrecht, 2003). Thus doctors are faced with on an ongoing basis with the challenge of maintaining good communication with their patients and should frequently reassess their patients' desired level of control throughout the disease process (Gattellari, 2001).

### Medical Decision Making in Clinical Trials

Patients who choose to enroll in clinical trials usually do so based on the recommendation of their physician however other factors also influence their decision. These factors include their age, their level of understanding of the clinical trial process, their perception of the physician's trustworthiness and the behaviors of their family members (Albrecht, 2003; Ellis, 2001). Communication also seems to have a significant mediating role influencing patient decision making. Communication provides the “lens” through which predisposing factors of the patient and family member, the characteristics of the physician, and the features of the protocol impact the patient's decision making, comfort with the decision and perceived therapeutic alliance with the doctor (Albrecht, 2003).

In one study, women who considered participating in clinical trials were younger, better educated, more likely to be in professional occupations and want an active role in treatment decision making. They also had a better understanding about the procedural aspects of clinical trials. Nonetheless, anxiety was identified as a contributing barrier to these women's attitudes toward trials. This study underscores the need for physicians to devote more attention to eliciting and addressing their patients' concerns and understanding about clinical trials (Ellis, 2001).

“For the provider, accruing patients to clinical trials is a communication task comprised of multiple and at times, conflicting goals, which includes providing the patient with the best care, enrolling patients in studies yet also maintaining a neutral position on the patient’s decision for scientific and ethical reasons.” The physician is expected to remain unbiased about which treatment is better so he/she cannot truly offer the patient expert scientific advice as to whether the standard of care or a clinical trial is preferable (Albrecht, 2003).

### **Benefits to Patients of Active Participation in Medical Decision Making**

The psychological benefits of control for patients are well known and include an increased sense of self-efficacy and enhanced coping. Patient involvement may help fulfill requirements for informed decision making and also serve to enhance the psychological status of patients (Gattellari, 2001).

A growing body of evidence indicates that believing one has control over outcomes in life plays an important role in maintaining and improving an individual’s health and sense of well-being. “Decision control” is a dimension of personal control which reflects a patient’s perception of how much control they have over health-related decisions. Patients with various chronic illnesses often experience better outcomes, i.e. faster recovery, less pain, better psychological adjustment, when they either participate in medical decision making or believe they have some control over their health-related decisions. Again, active participation, as exhibited by asking questions, offering opinions and expressing concerns enhance patients’ feeling of having control over treatment decisions (Street, 1986).

Patients’ need for autonomy may however be less than their need for clear and accurate information. One study of 150 newly diagnosed breast cancer patients indicated that 20% wanted an active role in their treatment decision, 28% preferred to share decision making and 52% wanted their doctor to decide their treatment for them. Again the importance is underscored for the

formation of a “therapeutic alliance” between the patient and doctor. This is typically characterized by the patient’s trust in the physician, cordiality, responsiveness and a sense of shared meaning (Albrecht, 2003).

*Is informed consent beneficial or “unnecessarily cruel”?*

Numerous studies have validated the value of informed consent and suggested that providing inadequate information may even heighten patients’ anxiety. It has also been suggested that patients do not just value information for its content but also for its role in promoting the development of a trusting relationship with their doctors. In addition, it appears that patients who are active rather than passive recipients of information seem to have greater comprehension of the information they are given (Gattellari, 2002).

*Can all competent patients fully benefit from informed consent?*

It remains a challenge for doctors to accurately assess patients’ level of understanding in regard to treatment decision making. When a patient does not fully acknowledge the gravity of their situation even when it is well explained to them, a clinician may have great difficulty judging whether the patient is not comprehending the information or whether the patient is exhibiting denial, a healthy adaptive response to an otherwise unacceptable situation (Mackillop, 1988).

### **Role of Nurses and Social Workers in Medical Decision Making**

Among the members of the clinical interdisciplinary team, both nurses and social workers play significant roles in helping patients work through their decision making process. In nurses’ professional code of ethics, there are numerous sections which elaborate this more fully. “Relationship to patients” refers to importance of planning health care “without prejudice” and that “such consideration does not suggest that the nurse necessarily agrees with or condone certain individual choices, but that the nurse respects the person as a person.” Right to self-determination”

refers to support throughout the decision-making process including the “provision of advice and support from knowledgeable nurses”. “Primacy of the patient’s interests” mentions that the nurse “strives to provide patients with opportunities to participate in planning care, assures that patients find the plans acceptable and supports the implementation of the plan.” “Collaboration” includes that nurses should work to assure that the relevant parties are involved and have a voice in decision-making about patient care issues.” “Protection of participants in research” mentions the nurse’s role in assuring that adequate informed consent is achieved (nursingworld.org/ethics/code/protected\_nwcoe303.htm#3.3).

Social workers are similarly well qualified to help patients negotiate their medical decision making process. In social workers’ professional code of ethics, the first three ethical responsibilities to clients listed are “commitment to clients, self-determination and informed consent” ([www.socialworkers.org](http://www.socialworkers.org)). These responsibilities lead social workers to utilize their highly trained listening skills to help patients explore the meaning of their choices, provide emotional support, employ cultural sensitivity and identify resources to overcome emotional, familial, practical and financial barriers to treatment. The social workers may help the patients evaluate their health decisions, the meaning of illness and treatment in their unique family context as well as teach cognitive behavioral techniques to facilitate anxiety reduction (Runfola & Levine, 2006). By playing the role of advocate, social workers can help patients to integrate their decision making as well as to educate their colleagues about the multiple dimensions on which decision making takes place for patients.

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## Challenges to Cancer Clinical Trial Recruitment and Minority Participation

By

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Clinical trials provide the foundation on which advances in cancer therapies are built. They are essential for identifying effective therapies. There is some evidence that suggests that about one-third (32%) of Americans would be willing to participate in cancer clinical trials (CCTs) if asked (Comis, Miller, Aldige, Krebs, & Stoval, 2003). Yet, relatively few eligible adults participate, 3 to 5% (Swanson & Ward, 1995).

Much of the existing CCT research is based on data collected from samples lacking racial and economic diversity (Institute of Medicine, 1999). Though researchers recognize the importance of having diverse clinical trial participants, barriers to recruitment exist at multiple levels (Institute of Medicine, 1999; Kressin, Meterko, & Wilson, 2000; Underwood, 2000).

Cultural, structural and psychological barriers for patients and providers have been well documented (Adams-Campbell et al., 2004; Baquet, Commiskey, Daniel Mullins, & Mishra, 2006; Ellington, Wahab, Sahami, Field, & Mooney, 2003; Fouad et al., 2000; Giuliano et al., 2000; Harris, Gorelick, Samuels, & Bempong, 1996; Institute of Medicine, 1999; Kressin et al., 2000; McCaskill-Stevens et al., 1999; Swanson & Ward, 1995; Underwood, 1995; Underwood, 2000). Barriers such as lack of accessible and affordable research trials (Fouad et al., 2000; Giuliano et al., 2000) as well as a patient’s inability to qualify for (Adams-Campbell et al., 2004) or comply with specified research protocols (McCaskill-Stevens et al., 1999) characterize common structural hurdles for patients, especially those who are medically underserved (Institute of Medicine, 1999). Patient fears and mistrust of the research community are also powerful cultural barriers (Fouad et al., 2000;

Giuliano et al., 2000; Institute of Medicine, 1999; Kaluzny et al., 1993; McCaskill-Stevens et al., 1999; Royal et al., 2000).

Although patient barriers are important, equally challenging physician barriers have received far less attention. Structural hurdles exist such as physicians' lack of awareness of available trials, problems with data management, and the absence of adequate physician compensation for time devoted to studies (McCaskill-Stevens et al., 1999; Swanson & Ward, 1995; Taylor, Margolese, & Soskolne, 1984). In addition, "cultural barriers" such as fear of losing patients and distrust of institutions conducting clinical trials exist among some providers (McCaskill-Stevens et al., 1999).

Research suggests that physician referral is one of the most effective means of recruiting patients onto CCTs (Royal et al., 2000; Siminoff, Zhang, Colabianchi, Sturm, & Shen, 2000). Yet, there are few studies that examine cancer care providers' knowledge about CCTs and attitudes toward minority participation in CCTs. In a 2001 study of NJ physicians (Hudson, Momperousse, & Leventhal, 2005) we conducted a survey of oncologists, primary care physicians and specialists (i.e., general surgeons and OB/GYNs) to examine local barriers to CCTs. We found that structural barriers such as insufficient resources and physician lack of awareness functioned as primary barriers for CCT recruitment and diversification as they had in other studies (McCaskill-Stevens et al., 1999; Royal et al., 2000; Siminoff et al., 2000; Swanson & Ward, 1995; Taylor et al., 1984; Weinberg, Cooper, Mejia, & Spiker, 2004). In addition, these barriers varied by physician specialty. For oncologists, paperwork involved in referring patients figured as the primary recruitment barrier. Primary care physicians and specialists, however, reported lack of awareness and information about available trials as primary barriers.

Physicians in our study also reported that cultural factors were important in their decisions to recruit African-American and Hispanic or Latino (AA/HL) patients to CCTs. Some physicians reported that their patients were concerned about receiving ineffective treatment and being treated like a "guinea pig." These concerns served as

important barriers to recruitment. Physicians practicing in hospitals that served large numbers of minority patients reported these perceptions more frequently than others. Although we do not know what information physicians' based their responses about their patient's fears on, (e.g., experiences with individual patients or experiences with a specific patient community), their responses indicate that this is an important topic that deserves further study.

Some physicians in our study were also concerned about whether their AA/HL patients were eligible for CCTs. There are a few studies (Kemeny et al., 2003; Kornblith et al., 2002; Weinberg et al., 2004) that indicate that physicians, regardless of specialty, function as gatekeepers for CCTs. Findings from our NJ study underscore the importance of examining and addressing interpersonal factors in the patient/physician relationship that may affect physician attitudes regarding their patients and CCT eligibility. It is not clear from the physicians surveyed whether their concerns about eligibility for AA/HL patients were due to their experience with patients' comorbidities, beliefs around health literacy, protocol compliance, or some combination of these factors. Careful research is needed to examine the individual and collective impact of these factors on physician identification and recruitment of minority patients for CCTs.

Understanding barriers to minority recruitment for CCT research is an important and necessary first step to ameliorating the problem. CCT barriers are multifaceted. They operate on a variety of levels in both clinical and non clinical (i.e., community) settings. Given the complexity, breadth and synergistic nature of CCT barriers, effective solutions may require that intervention researchers stretch traditional research and evaluation paradigms to find effective barrier management strategies. This is a burgeoning area of study that is in great need of further development.

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