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The Process of Clinical Trials: A Model for Successful Clinical Trial Participation

Cecile A. Lengacher, RN, PhD, Lois L. Gonzalez, PhD, ARNP, Rosemary Giuliano, ARNP, MSN, Mary P. Bennett, DNSc, RN, Charles E. Cox, MD, and Douglas S. Reintgen, MD

Purpose/Objectives: To present barriers and strategies related to successful clinical trial participation and integrate them into a model for successful trial participation.

Data Sources: The proposed model was developed based on a literature review related to clinical trial participation, review of empirical studies related to clinical trials, and experiences with subject participation.

Data Synthesis: Successful clinical trial participation depends on study design, participant factors, issues related to ethnic diversity, the informed consent process, and physician factors.

Conclusions: Clinical trial participation is critical for all disciplines. However, nurses either are researchers or co-investigators with physicians on clinical trials, and it is critical for them to understand specific barriers and success strategies for patient participation. Future studies need to be conducted related to participation in nursing clinical trial research. These study results will facilitate successful nursing clinical trials.

Implications for Nursing Practice: This model can be used in implementation of clinical trials across disciplines prior to and during enrollment of patients into studies.

Key Points . . .

- ➤ Successful clinical trial participation can be increased when barriers and issues are identified.
- ➤ Success in overcoming barriers related to subject recruitment, retention, and compliance could result in decreased costs and increase the power of the study.
- ➤ Successful clinical trials depend on study design, participant factors, issues related to ethnic diversity, the informed consent process, and physician factors.
- ➤ The model for successful participation identifies strategies that can be used across disciplines by nurses and healthcare providers to facilitate successful accrual and increased satisfaction of patients, nurses, and physicians.

Recruitment and retention of participants to clinical trials is critical to the outcome and success of clinical trial research. Clinical trials in nursing research have become more prevalent in the past decade, particularly as more intervention-level studies are implemented (Burns & Grove, 1997). Clinical trials have provided validity to examinations of outcomes of nursing interventions for testing theory-based practice (Tyzenhouse, 1981; Woods, 1990).

Clinical trials in nursing fall into two categories—preventive and therapeutic (Talbot, 1995). Preventive trials examine the efficacy of a specific treatment in reducing risks associated with a disease. Therapeutic trials examine outcomes of specific interventions or treatments, such as symptom relief, risk reduction, or relapse prevention. The most common types of clinical trials are drug studies that test the efficacy of medications.

An advantage of clinical trials is that they establish a relationship between treatment and clinical outcomes. Clinical trials most often require randomization, which involves placement of subjects in groups on a random basis, giving every subject an equal chance of being assigned and eliminating selection bias (Polit & Hungler, 1999). This method helps reduce threats to internal and external validity (Talbot, 1995). Disadvantages of clinical trials include expense and ethical considerations related to treatments for which risks have not yet been documented (Talbot).

A number of factors may affect participation in clinical trials. Pilot studies are critical and usually required prior to the implementation of large clinical trials. The pilot study allows

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the opportunity to examine the intervention, methodology, instruments, and processes of subject enrollment. Funding agencies expect pilot data to anticipate and resolve issues, which will make the large clinical trial successful (Burns & Grove, 1997). Major issues in clinical trials often are related to recruitment, accrual, retention, and compliance/adherence of research subjects. Valid and reliable results from clinical trials require large samples, usually from multiple sites and multiple geographic locations. The costs of conducting clinical trials generally are covered by extramural funds.

Success in overcoming barriers related to subject recruitment, retention, and compliance/adherence decreases costs and increases the power of the study (Agras & Bradford, 1982; Hunninghake, Darby, & Probstfield, 1987; Tangrea, 1997). The purpose of this article is to address the barriers and issues related to successful clinical trials and to provide strategies for improving clinical trial participation. A model for successful trial participation has been developed that addresses barriers and strategies.

Model Development

The proposed Model for Clinical Trial Participation (see Figure 1) was developed based on a literature review and experiences with subject participation. Analysis and use of the model in implementation of clinical trials may be helpful in all research disciplines. The model identifies barriers and issues related to clinical trial participation, strategies that can be used

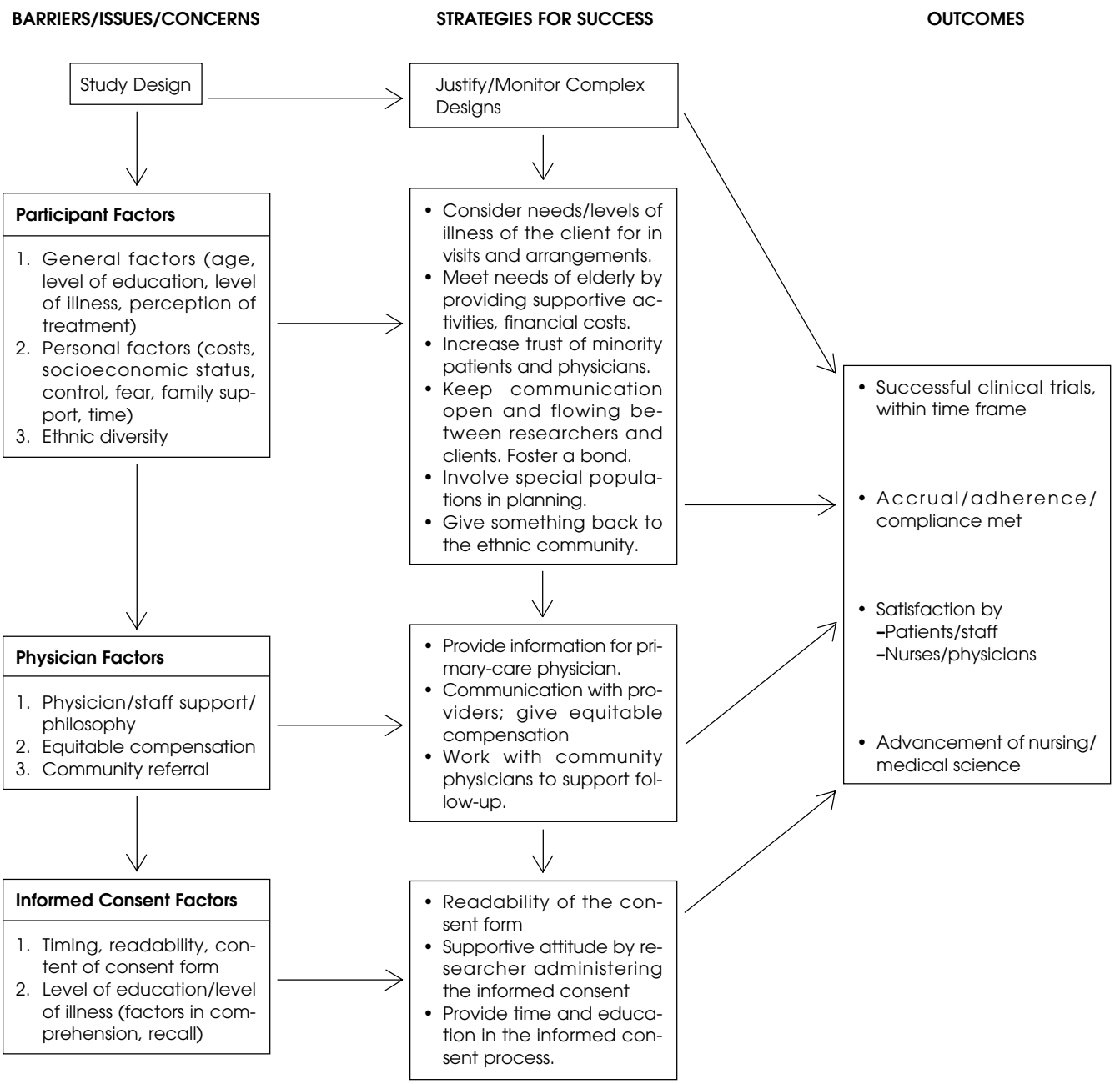

Figure 1. Model for Clinical Trial Participation

for success, and outcomes for successful clinical trials. A literature review indicated that successful clinical trials depend on certain key issues and factors: study design, participant factors, issues related to ethnic diversity, the informed consent process, and physician factors. Strategies for success are identified in the model to overcome these issues and concerns, and specific outcomes are identified. Healthcare providers across disciplines can use the model prior to and during enrollment of patients into studies.

Literature Review

A literature review revealed specific barriers and factors related to the success of clinical trials. The major barriers identified were study design, participant factors (i.e., general and personal issues related to special populations), the informed consent process, and physician factors.

Study Design

Study design has been identified as a major factor in the successful process of clinical trials. Clinical trials often are dictated by the intervention or agent and the endpoint being monitored. They most often are randomized and include an experimental group that receives the intervention and a control group that receives standard care. Patients who want more control and a greater role in their healthcare decisions are somewhat less likely to volunteer for clinical trials because of the nature of randomization to an intervention, which often is double-blind, with no feedback occurring until the trial is over (Winn, 1994). Patients who believe their needs should have a high priority may not agree with this. The very fact of being randomized may cause uncertainty with the process (Winn).

Because randomization frequently is a critical part of a clinical trial, the overall study design must include strategies to overcome patients' reluctance to participate in a randomized study. Clear explanation of the randomization process and the role of the control group is needed so patients do not feel that something has gone wrong if they do not receive the experimental treatment. In addition, offering patients who are randomized to the control group some benefit (e.g., being first to receive the experimental treatment following the study) also can help. For instance, in a randomized control study of the effects of massage on immune function, subjects who were randomized to the control group (no massage) were offered free massage therapy following the study (Bennett, Fletcher, Barnhart, Hudgins, & Sims, 2000).

Trials that have clear, simple goals and endpoints based on a defined rationale have a greater chance of success (Tangrea, 1997). Sometimes, researchers are tempted to include ancillary studies and additional interventions or collections of biologic specimens to test other hypotheses (Tangrea). This increased complexity can be a barrier to nurse, physician, and patient participation (Hjorth, Holmberg, Rodjer, Taube, & Westin, 1996; Mansour, 1994). A more complex design increases the requirement for a more complex infrastructure to carry out the study. If a need or desire to conduct multisite studies exists, the impact on the primary goals should be examined. Complex studies often have multiple inclusion or exclusion criteria that can limit patient eligibility. This can discourage nurses and physicians from enrolling patients into a study.

Participant Factors

General participant factors: Age, serious illness and comorbid conditions, level of education, and perception of benefits can influence successful trial participation.

A major risk factor for certain illnesses is age. Because of increased longevity, more people are developing serious illnesses. Potential barriers to clinical trial participation in older patients include history of prior malignancy, more frequent and serious comorbid conditions, presentation of an advanced stage, poor knowledge resulting from less education, and the perception that older patients are less likely to benefit from research (Trimble et al., 1994). Including older women, assessing for comorbid conditions, and identifying individuals to be targeted for special assistance programs that focus on adherence can assist with clinical trial participation (Buist et al., 2000). Older patients may lack financial, social, and logistic support for participation (Trimble et al.). Statistics show an increase in cancer in patients over age 65, yet participation in trials by those over age 65 is not common (Reis, Hankey, & Edwards, 1990; Yancik & Reis, 1994). A need exists to examine how age can affect participation in these trials.

Another problem is the lack of older female participants in clinical trials (Muss, 1996). In a current trial at a regional cancer institute, one factor that often is a problem for older women is transportation to the hospital to complete the protocol or interventions related to the trial. Often, older women do not drive, are not physically able to travel, or do not have a husband or family member to transport them. They also may lack access to or be uncomfortable using public transportation. In addition, if traveling to the hospital for participation in studies is costly, they may not be able to afford to return (Lengacher, 2000).

Oncologists had greater expectations of benefits from clinical trials than were found in the literature related to phase I trials (Daugherty et al., 1995). Participants' tendency to overestimate their chances of cure with a particular treatment or the potential benefits from enrollment (Kodish, Stocking, Ratain, Kohrman, & Siegler, 1992) is another issue. Often, patients' and physicians' expectations are similar, although therapeutic benefit is not guaranteed (Daugherty et al.). Patients with cancer and parents of children with cancer were found to have an expectation of benefit similar to their physicians (Lesko, Dermatis, Penman, & Holland, 1989).

Personal participant factors: Other barriers identified were costs to patients, control, altruism, fear of risk, desire for privacy, lack of family support, transportation, socioeconomic status, time off from work, extra procedures, or unwillingness to tolerate toxicity (Bevan, Chee, McGhee, & McInnes, 1993; Hudmon et al., 1996; Mattson, Curb, & McArdle, 1985; Novak, Seckman, & Stewart, 1977; Tangrea, Adrianza, & Helsel, 1992; Winn, 1994). In a study of patients' perceptions of participation in a phase I cancer trial, the barrier that was considered most difficult was problems with billing (patients were billed in error for participation). Only 22% of participants indicated that they would be willing to pay for participation in the study (Hudmon et al.). Related to costs and problems with accrual are transportation problems. Similar to the barriers for older female participants, cost and transportation are problems for accrual. Travel time, cost of travel, methods of transportation, and traveling with others can affect costs and trial enrollment (Hudmon et al.). These factors are especially critical for patients of lower economic status or those without insurance.

Studies also have found that a primary motivation correlated with participation is patients' altruism—their belief that they would be contributing to increasing medical knowledge (Bevan et al., 1993; Tangrea et al., 1992) or preventing others from getting cancer in the future (Hudmon et al., 1996). In addition, adherence and compliance issues occur with clinical trial participation. Careful screening for motivation and ability to participate is critical. Patients who have doubts should not be enrolled (Fleetwood, 1993). Adherence and compliance decline with a complex intervention over a long duration. Tailoring the regimen to the patients' lifestyles as much as possible is helpful (Tangrea, 1997).

Ethnically diverse patients: Another very critical issue is increasing the number of ethnically diverse patients involved in clinical trials. Typical clinical trial participants are white, have higher levels of education, are in the middle-to-upper socioeconomic class, and are male. Increased participation by women from diverse groups is an important goal. Identified barriers to minority participation are historical; economic; social and cultural issues; availability, affordability, accessibility, and acceptability of clinical trials for minorities (McCabe, Varricchio, & Padberg, 1994; Thomas, Pinto, Roach, & Vaughn, 1994); and research (Swanson & Ward, 1995).

Although African Americans have the highest age-adjusted incidence of cancer and mortality rates in the United States, they remain underrepresented in prevention and control studies (Paskett, DeGraffinreid, Tatum, & Margitic, 1996). Historical incidents perpetuate mistrust and fear among African Americans related to clinical research. This mistrust is not only a product of the patient population, but also of African American physicians who often fail to refer patients for clinical trials (McCaskil-Stevens et al., 1999). In a study of perceptions of African American women about participation in clinical trials, 29% felt that researchers did not care about them compared to 14% of white women surveyed. Only 28% of the African American women felt that the research was ethical (Mouton, Harris, Rovi, Solorzano, & Johnson, 1997).

Informed Consent

Many factors are related to informed consent. Level of education is a factor in comprehension and recall of information (Cassileth, Zupkis, Sutton-Smith, & March, 1980; Daugherty et al., 1995; Lawson & Adamson, 1995; Riecken & Ravich, 1982; Waggoner & Sherman, 1996). Serious illness adversely affects comprehension in both younger and older patients (Stanley, Guido, Staley, & Shortell, 1984).

According to Daugherty et al. (1995), level of education was a predictor of the ability of patients with cancer to recall the purpose of the trial. Although patients were able to understand information about the clinical trial, only one-third could remember the purpose. The reading level of the informed consent document can be critical (Meade, 1999). Other researchers found that patients with less than a high school education had a more difficult time recalling information about the trial and specific information in the consent form (Cassileth et al., 1980).

Patients' physiologic illnesses can have an accompanying psychological response that makes them less able or willing to understand the information obtained in the informed consent process (Taylor, 1999). Healthy volunteers were found to retain the most information compared to patients with serious illnesses (Schaeffer et al., 1996). Perception of the treatment and benefits affects participation. Patients with cancer may perceive enrollment in a research protocol as a last hope to receive effective treatment (Schaeffer et al.).

The Informed Consent Process

A number of informed consent process-centered factors have been identified: timing (when the discussion takes place), readability of the consent form, content of the consent form, and who assists the patient through the process (Taylor, 1999). Timing of approach to the trial has an impact on the patient's ability to make a decision (Meade & Howser, 1992). If approached at time of diagnosis, participants may be so stressed that they cannot make a decision. Approaching the patient two to four weeks after the initial diagnosis of breast cancer is less stressful. Patients become more interested when physicians introduce the study during the presentation of treatment options (Lengacher, 2000). If the researcher takes time to explain the trial during the consent process, decreased attrition from the trial may occur. Sometimes, the complexity and legal language can increase anxiety and decrease understanding. Providing complex information can lead to poor understanding and miscommunication (Meade, 1999). Studies have shown that understanding the average consent form requires at least a high school education (Baker & Taub, 1983; Grundner, 1980; Meade & Howser; Morrow, 1980). Continued examination related to how individuals perceive clinical trials is critical.

Physician Factors

Physician factors that can affect successful trial participation are physician and staff support, philosophy of the physician, equitable compensation, and community referrals. A major reason for inadequate accrual has been the decision of physicians not to enroll eligible patients (Benson et al., 1991; Winn, 1994). A study reported that the main reason reported for nonparticipation by patients was the advice received from the primary-care physician (Henzlova, Blackburn, Bradley, & Rogers, 1994). Medical oncologists identified inconvenience to patients, excessive physician time, and lack of support for follow-up as specific reasons for nonaccrual (Benson et al.). Some physicians do not like communicating uncertainty about the effectiveness of the treatment for fear of being construed as lacking knowledge regarding treatment and disease (Schain, 1994). A physician's philosophy about patient care can be a barrier (Schain). As indicated earlier, the complexity of the design also has been identified as a barrier to participation by physicians (Tangrea, 1997). Effective clinical investigators integrate the role of the primary-care provider with that of a research scientist (Taylor & Kelner, 1987). Lack of compensation to the physician for time spent evaluating patients prior to enrollment and absence of reimbursement of physicians' fees, laboratory fees, and diagnostic tests are other barriers (Mansour, 1994; Tangrea). Often, these costs are not covered by the government or insurance company (Tangrea).

Community physician referrals are influenced by the experiences, beliefs, and attitudes of the community physician. Community physicians first must be made aware of trials and then reassured that they will not lose control of or contact with patients (Mansour, 1994). Trust must be enhanced, particularly with minority patients and physicians. Community physicians should be given as much detail and information as possible related to the intervention protocol so they can assist

with the management of problems, particularly if patients live a distance from the hospital that is conducting the clinical trial (Tangrea, 1997).

Strategies for Success

Once the barriers are understood, strategies for overcoming them can be identified in order for accrual to be successful. Examination of successful programs and interventions related to clinical trials with widely diverse populations need to be examined. Communication with primary-care physicians and a caring attitude on the part of researchers is critical. Needs of the elderly will have to be considered and met because of the need to increase enrollment of the elderly in clinical trials.

A number of strategies for successful clinical trials can be implemented. Based on a literature review and as identified in the model, there should be justification for complex designs. This justification can be monitored by the principal investigator, the institutional review board, or the institution where the research is implemented. Knowledge of general and specific participant factors can assist researchers in developing strategies that will increase accrual, consider the needs of the elderly, and provide specific financial support for transportation.

Given, Keilman, Collins, and Given (1990) support the strategy of fostering a bond between participants and study personnel. Recognition can be given for participation—formal thank-you letters, handwritten notes from nurses or project managers during the study, and a verbal thank you after participation. Making contact with patients and accommodating their needs may be critical to participation. In addition, compensation for participation can assist the patient with indirect costs. If scheduling problems occur, the research team should assist patients in arranging times that are convenient for both. Several strategies have been identified to increase minority recruitment and retention. Fully defining the target population, involving members of the target population in planning efforts, taking the message to the target population, giving something back to the community, and providing education to the community during the informed consent process are critical for enrollment and adherence. Time, education, and a caring attitude during the informed consent process also are important. Communication among providers and providing information related to treatment and the clinical trial will improve attitudes of primary-care providers and follow-up care for patients. Frequent contacts with physicians and providers are important during a time when downsizing has been the standard (Motzer, Reynolds-Moseley, & Lewis, 1997). In addition, trials should be conducted in facilities that are viewed to be trustworthy and that will provide appropriate compensation to patients and physicians (Robinson, Ashley, & Haynes, 1996).

Future studies need to be conducted to examine the effects of strategies to overcome these common barriers to clinical trial accrual. Results of these studies will facilitate successful nursing-initiated clinical trials and multidisciplinary clinical trials.

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