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# Attitudes Of Transplant Nurses Toward Clinical Trials

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# ATTITUDES OF TRANSPLANT NURSES TOWARD CLINICAL TRIALS

by

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A thesis

presented to Ryerson University

in partial fulfillment of the

requirements for the degree of

Master of Nursing

in the Program of

Master of Nursing

Toronto, Ontario, Canada, 2012

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Attitudes of Transplant Nurses toward Clinical Trials

Master of Nursing, 2012

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Master of Nursing: Leadership in Nursing Education

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Abstract

Nurses may have an important role in supporting patients' decision making about their participation in clinical trials. Nurses' views about clinical trials and patients' understanding of the clinical trial process may shape the role nurses play in these trials. Little is known about transplant nurses' attitudes and beliefs toward clinical trials. This quantitative study employed a survey method involving a convenience sample of transplant nurses (n=39) in an urban hospital in Southern Ontario to describe attitudes and beliefs of transplant nurses toward clinical trials. The results indicated that transplant nurses had positive attitudes and beliefs toward clinical trials. Specifically, outpatient coordinators and older nurses were more positive in their attitudes. Nurses perceived transplant patients were knowledgeable about clinical trials. The majority of nurses (85%) engaged in the conduct of clinical trials. Transplant nurses also suggested educational, administrative and financial support as beneficial to further enhance their participation in these trials.

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## Dedication

I dedicate my thesis to my parents, Taras and Olga, for their love, encouragement, support and inspiration. I also dedicate this thesis to my brother Yuriy and his family for their ongoing support and understanding. My dream could not have been realized without you.

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## **Chapter 1: Introduction**

### **Background**

Clinical trials are one of the most prominent methods to identify whether preventative or therapeutic medications or interventions are effective in humans (Grady & Edgerly, 2009). As a result of clinical research, transplantation is one such treatment that became a standard practice for various previously incurable diseases. In order to further improve the effectiveness of transplantation, clinical research is constantly undertaken. Nurses may have an important role to play in clinical trials including supporting patients' decision making about their participation in clinical trials. How nurses view clinical trials and patients' understanding of the clinical trial process may shape the role nurses play in clinical trials. Therefore, it is important to understand nurses' attitudes about clinical trials in general and nurses' beliefs about patients' understanding, knowledge and informational needs in relation to clinical trials.

Transplant nurses may be involved in all phases of clinical trials. Literature from oncology settings suggests that nurses may be primary investigators, research coordinators, direct caregivers, educators and/or patient advocates (Holaday & Mills, 2004; Yoder et al., 1997). Similar to nurses in oncology settings, transplant nurses maintain documentation, conduct patient assessments, administer investigational medications, manage side effects, and may also assist patients with informed consent. Transplant nurses may also educate patients about transplant clinical trials. Nurses may assist patients in a decision-making process pertaining to participation in a clinical trial by ensuring that adequate communication and informed consent take place between enrolling physicians or research nurses and patients regarding their investigational treatment regimens. Despite the potential for nurses to play a significant role in research, limited information is available about transplant nurses' attitudes and beliefs about clinical trials and factors influencing these attitudes and beliefs.

The role of nurses in supporting patients' decision making is of particular importance. Evidence indicates that the ease of understanding of information about clinical trials is an integral factor influencing patients' decisions about their involvement in clinical research (Lewellyn-Thomas, McGreal, & Thei, 1995). The National Cancer Institute (NCI) conducted a pilot study that examined the educational needs of patients contemplating participation in clinical trials (Nealon, Blumberg & Brown, 1985). Based on the findings, Nealon et al. (1985) concluded that patients at the time of enrolment found it very difficult to understand and retain information related to the clinical trial. These patients also reported having difficulty knowing what questions about the clinical trial to ask and, when they were ready to ask these questions, they preferred to ask nurses as opposed to doctors (Nealon et al., 1985). Thus, nurses may play an important role in providing information to patients about available options in clinical trials.

Nurses' attitudes toward clinical trials may shape their role in these research studies and may subsequently influence patients' decisions regarding participation in clinical trials. D'Amico (2007) suggested that nurses' attitudes toward clinical trials may affect their participation in these trials. Furthermore, Burnett et al. (2001) argued that attitudes of nurses toward clinical trials may influence patients' willingness to participate in clinical trials because nurses may provide information about clinical trials to patients and answer their questions pertaining to clinical trials. Thus, if a nurse holds a positive attitude toward a clinical trial, patients cared for by this nurse may be more likely to engage in this clinical trial. Finally, attitudes of nurses toward clinical trials may also reflect patients' views related to clinical trials. As compared to other healthcare professionals, nurses may be more aware of patients' attitudes toward clinical trials as a result of their interactions with patients (Burnett et al., 2001; Cheng et al., 2000). Therefore, it is of paramount importance to understand what nurses' attitudes toward clinical

trials are and what beliefs nurses hold about patients' understanding, knowledge and informational needs related to clinical trials.

Literature from oncology settings suggests various factors may influence nurses' attitudes toward clinical trials. These factors include age, gender, level of education, years of nursing experience, whether or not the nurse cares for patients who are contemplating enrolment or are currently enrolled in a clinical trial, the primary position of the nurse, and work setting (Burnett et al., 2001; D'Amico, 2007). No such literature from transplant settings is currently available. Therefore, the specific factors influencing transplant nurses' attitudes toward clinical trials are unknown.

Transplant nurses play an important role within clinical and research environments. Yet, little is known about transplant nurses' attitudes toward transplant clinical trials, nurses' beliefs about transplant patients' knowledge, understanding and informational needs related to clinical trials as well as factors that may influence nurses' beliefs and attitudes.

### **Statement of the Problem**

Nurses' beliefs about patients' knowledge pertaining to clinical trials may shape nurses' attitudes toward clinical trials and influence the extent to which nurses are involved in research activities. Furthermore, attitudes may influence how nurses interact with patients contemplating enrolment in or actually participating in clinical trials. The conduct of clinical trials is dependent on participation of transplant patients and nurses. Patients' decisions about participation in clinical trials might be influenced by their transplant nurses' attitudes about these trials. Transplant nurses' attitudes toward clinical trials and beliefs about patients' understanding of clinical trials have not been previously investigated. Hence, this study is a first step to explore transplant nurses' attitudes toward clinical trials and factors influencing their attitudes.



## **Purpose of the Study**

The overall purpose of this study is to build knowledge about attitudes of transplant nurses toward clinical trials. The specific objectives are to: 1) describe nurses' attitudes toward clinical trials, 2) identify transplant nurses' beliefs about patients' understanding, knowledge and informational needs related to the clinical trial process, and 3) examine factors that may influence transplant nurses' beliefs and attitudes. The factors include age, educational preparation, primary position, years of nursing experience, years of nursing experience in a transplant setting, and whether or not the nurse cares for patients currently enrolled in a clinical trial.

## **Significance of the Study**

Nurses are expected to provide safe, compassionate and ethical care to clients (Canadian Nursing Association [CNA], 2008). As outlined in the College of Nurses of Ontario (CNO) (2002) professional practice standards, nurses are responsible for safeguarding an ethical process of patients' involvement in research by ensuring a patient has all the information necessary to make an informed decision about his/her participation in a research study. Transplant nurses' attitudes may affect how they fulfil their role related to the research process. For instance, if a nurse has a negative attitude toward a clinical trial, she or he may be less likely to provide information about that clinical trial to patients and may even discourage patients from participation in that specific study. Furthermore, nurses' negative attitudes toward clinical trials can negatively influence nurses' intent to complete patient care activities required for a clinical trial such as collecting blood samples, administration of investigational treatments or completing study specific documentation. This is of concern because patients' safety could be compromised if research related activities are not undertaken appropriately. Because of importance of this kind

of clinical trial, the current study will contribute to closing a gap in knowledge regarding transplant nurses' attitudes toward clinical trials and is a first step towards better understanding of nurses' intent to perform or not to perform clinical trials related behaviours.

## **Chapter 2: Literature Review**

In this chapter, the analysis and synthesis of theoretical and empirical literature relevant to the main concepts of the study are provided. At the beginning of the chapter, a description of the literature search strategies is presented. Then the theoretical literature is reviewed to highlight the background and rationale for study concepts. The empirical literature pertinent to study concepts and relationships among them is synthesized.

### **Literature Search Strategies**

The literature search was conducted using CINAHL, ProQuest Nursing, ProQuest Dissertation/Thesis, Scholarportalinfo, PubMed, and Google Scholar databases. Key search terms used included nurses' attitudes, clinical research, clinical trials, healthcare providers' attitudes, patients' attitudes, research involvement and participation, combined with transplantation. The results were limited to English language and the primary focus was on the most recent 10 years (2000 – 2010). As a result of this search, no studies were found exploring transplant nurses' attitudes toward clinical trials in the area of transplantation. Therefore, the literature search strategies were expanded to include older than 10 years and those conducted in areas other than transplant. Only two quantitative studies investigating nurses' attitudes toward oncology clinical trials were found (Burnett et al., 2001; D'Amico, 2007). Therefore, this literature review primarily drew on findings from relevant research studies conducted predominantly in oncology settings as well as literature pertaining to attitudes of nurses toward research in general, and patients' and physicians' attitudes toward clinical trials to gain a better understanding of the topic.

## **Review of the Theoretical Literature**

The focus of this transplant study was on attitudes of transplant nurses toward clinical trials and nurses' beliefs about patient's knowledge, understanding and informational needs in relation to clinical trials. A review of the theoretical literature in nursing and other disciplines suggested that attitudes and beliefs are inter-related concepts. In the following sections, the important aspects related to attitudes and beliefs from the theoretical perspective are discussed.

### **Beliefs.**

Beliefs represent the information an individual has about a psychological object (e.g., events, issues, actions) (Fishbein & Ajzen, 1975). As it relates to the current study, the object is a clinical trial, which involves the evaluation of treatments in humans (Grady & Edgerly, 2009). People form their beliefs about objects by associating them with various characteristics and qualities (Fishbein & Ajzen, 2010). Over the period of peoples' lives, their experiences lead them to create different beliefs about various actions, issues and events. These beliefs may be shaped as a result of direct observation; they may be developed indirectly by receiving information from friends, teachers, the media, and other outside sources; and they also may be generated by an individual through the processes of inference. In the case of clinical trials, nurses' beliefs may be shaped by nurses' experiences with patients in clinical trials, and/or information about clinical trials received over the period of nurses' education. Some beliefs remain over time, some are forgotten and new beliefs are created. More specifically, Fishbein and Ajzen (2010) defined beliefs as "the subjective probability that an object has a certain attribute" (p. 96). In the current study, a belief could also be a perception, an opinion and/or a view.

### **Attitude.**

An attitude can be described as a disposition to respond favourably or unfavourably to a behaviour, person or an event (Fishbein & Ajzen, 2010). Fishbein and Ajzen (2010) further indicated that attitudes consist of beliefs that a person accumulates in the course of his or her life. These beliefs are based on an individual's experiences with different things, actions, and events as a result of his or her observations or inferences. Although an individual may hold a number of different beliefs, it is evident that only a few of them determine his or her attitude at any point in time. These beliefs have been referred to as salient (accessible) beliefs. Salient or accessible beliefs are spontaneously activated in the presence of an attitude object (actual or symbolic) without significant cognitive effort. Accordingly, attitudes are a person's salient (accessible) beliefs about the outcome of his or her action, experience of an event or experience related to the interaction with other individuals, whether this outcome or experience will be positive or negative. For example, if an individual has positive salient beliefs about the outcome of his/her actions or the experience of interactions with others, then it is believed that this individual has a positive attitude toward these actions or interactions; whereas, if an individual has negative beliefs toward the outcome of his or her actions or interactive experiences then this individual is said to have a negative attitude toward these actions or interactions (Fishbein & Ajzen, 2010). As it relates to the current study, if an individual believes that the outcome of clinical trials is favourable to their participants or participants' interactive experiences with research staff are positive, he or she is more likely to form a positive attitude toward these clinical trials; however, if a person believes that these clinical trials are harmful to their participants and interactive experiences with the staff are negative he or she is more likely to form a negative attitude toward these trials.

## **Attitude and Beliefs**

A number of terms have been used in the literature to represent an attitude and a belief including a perception, an opinion, and a view. For the purpose of the current study, an attitude and a belief are viewed as related concepts. An attitude is considered a sum of beliefs including any information an individual has about an object and evaluations of attributes of this object. Drawing on the work of Ajzen and Fishbein (1980) it is evident that “the more strongly a belief is held, and the more positive or negative the attribute evaluation, the greater is its expected contribution to the overall attitude” (p.100). As it relates to the current study a nurse may form beliefs that a clinical trial is a research study involving humans and follows a specific protocol that guides the conduct of this study. Furthermore, this person may associate attributes of a clinical trial such as its outcomes and interactive experiences of participants during the process of a clinical trial as being positive or negative. Positive or negative evaluations of an object may determine the overall attitude an individual forms. Hence, if an individual believes that research participants are well informed about the clinical trial process (e.g., about benefits and side effects of the investigational medication, participants’ right to withdraw from the study) this individual is more likely to form an attitude that will be positively oriented toward clinical trials; on the other hand, if an individual tends to believe that participants’ needs for information were not met, his or her attitude toward clinical trials will most likely be negative.

Positive or negative attitude toward an object (e.g., a behaviour) will determine the intention of an individual to perform or not to perform this behaviour. According to Fishbein and Ajzen (2010), intention is the best predictor of behaviour. Hence, people are believed to engage or not in a behaviour based on their intention to do so (Fishbein & Ajzen, 2010). As it relates to the current study, if transplant nurses have positive attitudes toward clinical trials in general they

are more likely to form an intention to participate in such trials. Hence, this intention might ultimately shape their actual engagement in clinical-trial related activities. However, negative attitudes of transplant nurses may influence an intention not to engage in such activities related to clinical trials.

### **Review of the Empirical Literature**

In this section the analysis and synthesis of empirical literature pertinent to nurses' attitudes toward clinical trials and nurses' beliefs about patients' understanding, knowledge and informational needs regarding clinical trials is presented. The literature review was based primarily on research studies conducted in oncology settings and included research related to nurses' attitudes toward research in general and factors impacting on nurses' attitudes. Patients' and physicians' views toward clinical trials are also discussed in this section as their views may potentially influence nurses' attitudes and beliefs toward clinical trials.

#### **Nurses' Attitudes toward Clinical Trials in Oncology**

The investigator found only two studies examining nurses' attitudes toward clinical trials. These studies were conducted in oncology settings in the United States (Burnett et al., 2001; D'Amico, 2007). Burnett et al. (2001) investigated nurses' attitudes toward clinical trials, nurses' beliefs about patients' understanding of clinical trials and their beliefs about factors influencing patients' participation in clinical trials. In this descriptive study, 400 nurses employed at a comprehensive cancer centre were invited to participate. A 59-item questionnaire measuring nurses' attitudes toward clinical trials and nurses' beliefs about patients' understanding of clinical trials was distributed to nurses. Two hundred-fifty nurses responded with an overall 60% response rate (Burnett et al., 2001).

Burnett et al. (2001) reported, that in general, nurses had positive attitudes toward clinical trials. Specifically, 96% of nurses indicated a belief that participation in clinical trials was essential to enhance standards of care. However, only 56% of the nurses believed that patients should be encouraged to participate in clinical trials. Whereas 93% of the nurses indicated that nurses respected patients' wishes, only 62% stated that physicians respected patients' wishes. Only 27% of nurses in intensive care (ICU) and bone marrow transplant (BMT) units compared to 78% of research nurses and 73% of outpatient nurses stated that physicians respected patients' wishes. Overall, 27% of nurses agreed with the statement "doctors put too much pressure on patients to participate in clinical trials". Specifically, nurses in ICU/BMT were most likely to express this concern (44% vs. 21% of other nurses). Only 2.6% of nurses agreed with the statement "nurses put too much pressure on patients to participate in clinical trials", although 11% of research nurses agreed with this statement. Overall, 24% of nurses, including 19% of research nurses, agreed with the statement "patients are often unaware that their treatment is part of a research protocol". Seventy-seven percent of nurses responded that they believed patients were frightened to ask questions (Burnett et al., 2001).

These findings suggest that the vast majority of nurses viewed patients' participation in clinical trials as important for future advances in care. However, nurses expressed concerns that patients may not be well informed about clinical trials in which they participate. Furthermore, nurses believed that healthcare practitioners (i.e. physicians and nurses), do not always respect patients' wishes and may even put pressure on patients to participate in clinical trials. The majority of nurses believed that patients are afraid to ask questions related to clinical trials. These beliefs may in fact have negative impact on the nurses' engagement in research studies involving patients because negative experiences with the conduct of clinical trials (e.g.,



suboptimal communication with patients and research staff at the time of enrolment) may negatively influence nurses' beliefs or attitudes toward clinical trials and subsequently their intention to participate in research-related activities.

Different attitudes and beliefs were evident in the sample included in Burnett et al.'s (2001) study. The findings showed that being a research nurse was associated with a positive attitude toward clinical trials. Work setting was also related to nurses' perceptions of patients' understanding of treatment. Specifically, nurses in ICU/BMT units as compared to nurses in outpatient and inpatient units and clinical research services were less likely to believe that patients understood the treatment plan or that their needs for information about the trial were met (Burnett et al., 2001). This could be related to the health condition of patients and the type of nurse-patient relationships established in these various settings. Patients are generally more ill in ICU/BMT settings and could be less likely to comprehend treatment related information as compared with patients on other in-patient units. Hence, nurses working in settings where patients' conditions may inhibit their ability to comprehend information, may form beliefs that patients' informational needs about clinical trials were not met and these patients may not understand their investigational treatment regimens. These findings may suggest that transplant nurses' attitudes toward clinical trials may vary depending on the patient population that nurses work with (e.g., patients in an acute care unit [ACU], a general ward or an outpatient clinic). Thus, transplant nurses' views about transplant patients' understanding of clinical trials could differ among the settings and the type of relationships nurses have with their patients.

More recently, D'Amico (2007) conducted a descriptive study, the Nationwide Survey of Oncology Nurses, that utilised a 26-item Nurses Attitude Survey (NAS) adapted from the study by Burnett et al. (2001). The main objectives of the study were to examine nurses' attitudes

toward cancer clinical trials and to identify nurses' beliefs about patients' understanding of the clinical trial process and desire for information about clinical trials, as well as nurses' perceptions about the reasons for patient participation in clinical research. One thousand questionnaires were mailed out to registered nurses, who were members of the Oncology Nursing Society (ONS), with an overall response rate of 30.1% (n=301). The researcher found that overall nurses had positive attitudes toward cancer clinical trials. Ninety-eight percent of respondents reported a belief that clinical trials are important in improving future standards of care. Seventy-five percent of nurses agreed that patients should be encouraged to participate in research studies. Almost all nurses (93%) agreed that nurses respected patients' wishes and approximately 83% of nurses stated that physicians respected patients' wishes. Furthermore, contrary to the findings reported by Burnett et al., in the study by D'Amico less than 10% of nurses indicated a belief that doctors put too much pressure on patients to participate in clinical trials. More than 80% of the nurses perceived that patients were well informed when they chose to participate in a clinical trial. Sixty-eight percent of nurses agreed with the statement "patients understand their prognosis and goals of therapy" and only 10% of nurses indicated, "patients are often unaware that their treatment is part of a research protocol" (D'Amico, 2007).

These findings suggest that nurses in both, D'Amico's and Burnett et al.'s studies, were positively oriented in their attitudes toward clinical trials. However, some differences were evident in results from both studies regarding nurses' beliefs about patients' understanding of the process involved in clinical trials. A possible explanation for such differences between D'Amico's and Burnett, et al.'s studies could be the timing when these studies were conducted. During the data collection period, in the D'Amico study, the National Cancer Institute (NCI) developed and advertised a Clinical Trials Education Series and the Oncology Nursing Society

(ONS) updated its position statement in relation to cancer research and cancer clinical trials (D'Amico, 2007). D'Amico suggested that views of oncology nurses who participated in his study could have been positively influenced by these initiatives. Finally, different samples were used in both studies. D'Amico surveyed a random sample of oncology nurses who were members of ONS in the US; whereas, Burnett et al.'s sample was from one comprehensive cancer centre. In addition, in the study conducted by D'Amico, a large portion of participants (n=93, 31%) had a master's degree, whereas in the study conducted by Burnett et al., 10% of participants reported master's degree as their highest level of education. These differences in the sample and setting characteristics could account for differences in the findings between the two studies.

Multiple regression analysis conducted by D'Amico (2007), showed several significant "predictors" (p. 112) of attitudes and beliefs. The primary position of nurses was an important predictor for attitudes toward clinical trials. Clinical trial nurses had more positive attitudes toward clinical trials compared to staff nurses, and nurses who worked in the corporate industry setting were more positive in their attitudes compared to BMTU/ICU nurses. It is a possibility that clinical trial nurses and nurses who work in corporate industry have personal positive views and previous positive experiences with patients in clinical trials. Their strong personal beliefs in the value of clinical trials and positive past experiences may have positively influenced their attitudes toward clinical trials.

In addition, nurses' primary position, years of experience in oncology, work setting and educational level were significant predictors of the perception of the amount of benefit a cancer therapy would need to offer to patients if it was to be included in clinical trials. Bedside nurses compared to nurses in other positions, and nurses with 10 or fewer years of experience in

oncology expected cancer therapy to have high potential effectiveness in order to be offered in a clinical trial. On the other hand, nurses with greater than 20 years of experience, nurses who reported that they worked in corporate industry settings and nurses with a master's or higher degree reported that cancer therapy with low expectations of effectiveness should be offered as part of a clinical trial (D'Amico, 2007). A possible explanation for this finding is that nurses with more years of experience have seen positive outcomes in patients participating in clinical trials, which offered investigational treatments with low potential for benefit. In addition, nurses with a graduate degree may have greater knowledge of positive results of such therapies for patients based on their educational preparation and research involvement. Nurses who work in corporate industry are often research nurses who are involved in planning studies and may have personal beliefs that trials of therapies with low potential for benefit overall contribute to the enhancement of treatments in the future.

The variable of whether or not nurses work with clinical trial patients was strongly associated with nurses' perception of patients' knowledge and understanding of clinical trials in the study by D'Amico (2007). Compared to nurses who did not work with clinical trials patients, nurses who did work with such patients perceived that patients understood their treatment goals, plan and prognosis, and that their wishes were respected by oncologists and nurses (D'Amico, 2007). This variable was also strongly associated with nurses' perceptions about informational needs of patients. Nurses who did not work with clinical trials patients believed that patients were willing to accept side effects, pay more attention to the benefits of the therapy as opposed to side effects, have their decisions influenced by their families and were frightened to ask questions (D'Amico, 2007). These findings suggest that nurses without direct experience with patients who participate in clinical trials have less knowledge about patient's understanding and

informational needs in relation to clinical trials and whether these needs were met. As a result, negative beliefs in relation to the process of patients' involvement in these studies may be formed by these nurses.

Burnett et al. (2001) and D'Amico (2007) investigated nurses' perceptions of patients' understanding of the clinical trial process. Both authors indicated that the majority of nurses believed that patients participate in clinical research with the expectation of cure and better symptom management as compared to the standard therapies. In both studies, most nurses believed that physicians respect patients' wishes; however, some nurses thought that doctors put too much pressure on patients to participate in clinical trials. Nurses who participated in the study by D'Amico were more likely to believe that patients are well informed when they choose to participate in a clinical trial as compared to nurses in the study by Burnett et al. Such a difference could possibly be related to the educational initiatives about clinical trials conducted during the period of D'Amico's study. As previously described, due to these initiatives nurses who participated in D'Amico's study could have been more aware about how patients were informed about clinical trials.

Overall, positive attitudes of nurses toward clinical trials were reported in the studies conducted by Burnett et al. (2001) and D'Amico (2007). However, some nurses in both studies had concerns regarding the process involved in clinical trials, specifically that patients' informational needs are not always met and patients may experience pressure from doctors and/or nurses to participate in clinical trials. Furthermore, Burnett et al. and D'Amico recommended replication of their studies with nurses from settings other than comprehensive cancer centres and suggested comparing the findings between groups of nurses in order to achieve a greater understanding about nurses' views of clinical trials. One such group of nurses

who work with patients enrolled in clinical trials is transplant nurses. Attitudes and beliefs of nurses toward transplant clinical trials have not been previously studied, and were investigated in the present study.

Several limitations pertaining to these two studies need to be highlighted. D'Amico (2007) used a mailed survey to obtain data from a national sample of oncology nurses. One limitation of such approach is a nonresponse bias (Burns & Grove, 2009). Only 301 (30%) nurses responded to the survey, which may not be representative of the 32,000 members of the ONS. Therefore, it is possible that non-responders would have different attitudes and beliefs as compared to responders. Nurses employed in research and corporate industry settings were also included in these oncology studies. This in fact may have biased the findings because these nurses work in the research area and may have very strong positive attitudes toward clinical trials (Burnett et al., 2001; D'Amico, 2007). During the period of D'Amico's study the Clinical Trials Education Series were implemented by NCI. A possible threat to internal validity in the form of history is present (Burns & Grove, 2009). As a result of this initiative, oncology nurses may have had a greater awareness of the importance of participation in clinical trials, which may have positively influenced their responses (D'Amico, 2007).

The two studies reviewed that investigated attitudes of nurses toward clinical trials were conducted in oncology settings. Hence, their findings may not be applicable to transplant nursing due to possible differences between oncology and organ transplant nursing settings. Research within transplantation is a relatively new endeavour as compared to clinical research in oncology. Furthermore, the number of nurses and patients in oncology settings is considerably higher than the population of nurses and patients in transplantation. Hence, more patients tend to participate in clinical trials and more nurses are exposed to clinical research in oncology settings,

which may shape differences in attitudes and beliefs in oncology compared to transplant nurses. In addition, both studies were conducted in the US, and may not be applicable to nursing settings in Canada because of overall existing differences between health care systems in these countries. Therefore, further research is required to be conducted within Canada, which focuses on nurses' attitudes toward clinical trials.

### **Patients' Understanding of the Purpose of Clinical Trials**

Nurses' beliefs about patients' understanding of the purpose of clinical trials may influence the type of attitudes nurses form toward clinical trials. Investigations of patients' understanding of the purpose of clinical trials have drawn attention of researchers in the last two decades. Daugherty et al. (1995) conducted a pilot study investigating cancer patients' (n=30) beliefs about Phase I clinical trials. Patients were asked open-ended questions about their decision to participate in phase I trials and about their understanding of the researchers' goals in the phase I clinical trials in which they were participating (e.g., "What is the purpose of a Phase I clinical trial?"). Patients decided to participate in a Phase I trial based on possible therapeutic benefit (85%), advice or trust of physicians (11%), and family pressures (4%). Ninety-three percent of patients said that they understood all (33%) or most (60%) of the information provided about the clinical trial; however, only 33% were able to reiterate the purpose of the trial in which they were participating. Daugherty et al. concluded that patients who participate in Phase I cancer clinical trials are highly motivated by the hope of possible therapeutic benefit. Oncology patients who may be involved in phase I trials seem to have a sufficient self-perceived knowledge of the risk of investigational agents. However, only a minority of patients appear to have an adequate understanding of the purpose of Phase I clinical trials (Daugherty et al., 1995).

Similar findings were reported by Meropol et al. (2003), who conducted a survey to describe and compare the perceptions of cancer patients and their physicians regarding Phase I clinical trials. The questionnaire was administered to patients who were offered Phase I trial participation, had accepted, but had not yet begun treatment (n= 328) and to each patients' physician (n=48). The questionnaires measured perceptions of potential benefit and harm from treatment (experimental and standard), relative value of quality and length of life, and perceived content of patient-physician consultations. Patients overall had high expectations regarding treatment outcomes where 60% expected benefit was from experimental therapy. Furthermore, patients expected a higher likelihood of both benefit and adverse reactions from treatment (experimental and standard) as compared to their physicians. Even though 95% of patients reported that quality of life was at least as important as length of life, only 28% indicated that changes in quality of life with treatment were discussed with their physicians. On the contrary, 73% of doctors reported that this topic was discussed. The authors concluded that these discrepancies in reports of consultation content, specifically given patients' stated values regarding quality of life, raised the possibility that communication in this context was suboptimal (Meropol et al., 2003). Suboptimal communication about clinical trials between patients and physicians in fact may affect how nurses feel about patients' understanding of the process involved in clinical trials. If nurses believe that such discrepancy in communication between a patient and a physician exists then they may form negative attitudes toward clinical trials. Negative attitudes of nurses may subsequently influence the role nurses play in the clinical trial process.

Significant differences between patients' and providers' expectations of benefit from investigational therapy have been reported in the literature. Cheng et al. (2000) conducted a pilot



study to investigate the expectations of oncology patients, physicians and research nurses regarding the potential benefits of and toxicities from experimental and standard therapies, and to determine the relationship of life quality to patients' perceptions regarding treatment options. A survey was administered to cancer patients ( $n = 30$ ), their physicians ( $n = 6$ ) and research nurses ( $n = 6$ ). Results of the survey showed that patients estimated a greater potential benefit for experimental therapy (60%) as compared to standard therapy (37%;  $p < .01$ ) and less potential for toxicity (30% vs. 46%,  $p = .01$ ). Furthermore, patients estimated higher potential benefits of experimental therapy (60%) compared to physicians (24%) and research nurses (30%). These findings indicate that patients' expectations of potential benefit from experimental therapy are significantly higher as compared to standard therapy and significantly higher than expectations of physicians and research nurses. These results raise questions about whether patients' expectations of investigational and standard therapies were realistic, and whether patients were well informed about benefits and side effects of investigational and standard therapies. Nurses' beliefs about how well patients are informed about clinical trials prior to their participation in these trials may shape nurses' attitudes toward clinical trials.

Limitations to the studies reviewed in this section that may have an impact on the generalizability of findings need to be highlighted. The study by Daugherty et al. (1995) was conducted more than 15 years ago in the US. Thus, these findings might not well reflect current situations in nursing and nursing research in Canada because of significant changes that have taken place in the profession and in research. Some of these changes are: the baccalaureate degree became a minimum requirement for entry to practice in 2005 (CNO, 2010) and more nurses have completed graduate degrees in nursing (master's and doctoral) in Canada (CNA,

2010). With more education nurses may be better informed about the conduct of clinical trials. Hence, currently nurses may have different beliefs about clinical trials.

In addition, the studies included small samples of nurses. These limitations suggest that there is a need for more current research in the area of clinical trials, specifically focusing on nurses' views about patients' understanding of the process involved in clinical trials because nurses' views may ultimately influence nurses' intention to engage in clinical trial activities and in particular patient recruitment.

### **Nurses' Attitudes toward Research in General**

Studies about attitudes of nurses toward research in general might shed light on how nurses view specific types of research such as clinical trials. Kerr, Woodruff and Kelly (2004) investigated the attitudes toward and engagement in research activities of registered nurses (RNs) employed within an acute metropolitan public hospital in Australia, questionnaires (n=260) were distributed with a total of 178 (68%) returned. Results of this study indicated that overall nurses have positive attitudes toward research. All nurses who participated in this study rated the importance of evidence for nursing practice and nursing research at 7-9 out of 10 (10 being the most important). Nurses' responses to questions related to whether all nurses need to participate in research, the importance that a participant's research activity should have for nursing promotion, and enthusiasm for future involvement in research were rated at 5-7 out of 10. It could be concluded that overall nurses highly appreciated the contributions of research to nursing in general; however, some of these nurses did not see the benefit of their own participation in research (Kerr et al., 2004). Whether a similar phenomenon is evident in transplant nurses' attitudes toward clinical trials needs to be examined, specifically, what are transplant nurses'

beliefs about the contribution of clinical research to nursing and what are their views about personal participation in implementing research?

Kuuppelomaki and Tuomi (2005) examined Finnish nurses' attitudes toward nursing research. Questionnaires were mailed out to 600 nurses with an overall response rate of 67% (n=400). The majority of Finnish nurses believed that nursing research was important to the development of nursing practice. Sixty five percent of nurses agreed with the statement "Nursing science is important to me personally" and 77% of nurses expressed interest in following the latest trends in advancements in the discipline. However, 55% felt that science remained distant to them and almost a half (48%) indicated that they believed that research is completely detached from the practice of nursing. Furthermore, almost a half of nurses (45%) believed that research findings rarely did little more than indicate the obvious, something they already knew. About 40% of nurses thought that the research findings reported had no real influence on nursing practice. Only 38% of nurses felt that doing research is an essential part of a nursing job. The authors concluded that, in general, nurses in this study held quite positive attitudes toward nursing research. More specifically attitudes were most positive when nursing research was assessed in more abstract terms without a direct link to nursing practice or nurses themselves (Kuuppelomaki & Tuomi, 2005). These findings suggest that nurses tend to distinguish between the role of research in the development of nursing science versus in the advancement of nursing practice. Nurses may be more likely to believe that outcomes of research are more positive for science than for practice. These results are similar to those reported in the study by Kerr et al. (2004).

It is evident from the studies discussed above that overall nurses have positive attitudes toward research in general. However, some degree of variability in their responses exists;

specifically, nurses' attitudes toward research in general appear to be quite positive when attitudes are evaluated in the context of nursing as a science and tend to be less positive when attitudes are assessed in relation to nursing practice or nurses themselves. As it pertains to clinical trials, these findings may suggest that nurses may view clinical trials more relevant to nursing science than nursing practice, possibly because the research evidence may suggest something already known to nurses in practice or this evidence may not be relevant to all nurses working in various nursing practice environments.

Several limitations need to be noted when interpreting these results. Kerr et al. (2004) stated that nurses with interest in research were more likely to respond to the survey, potentially biasing the results. Nurses who work mainly on the weekends did not participate in the study, and as a result, their opinions remain unknown (Kerr et al., 2004). The study by Kerr et al. was conducted in Australia. Nurses' attitudes toward research in Australia might be different from those in Canada; hence, generalization from these findings to the Canadian context should be done with caution. Kuuppelomaki and Tuomi (2004) purposefully selected the hospitals in Finland for their study. Healthcare settings and nurses' attitudes toward research might be different in Finland than those in Canada. Therefore, the examination of these attitudes and beliefs in a Canadian context is needed.

Several studies were found that did not specifically focus on attitudes toward research; however, these attitudes were reported as one component of their study. McCloskey (2008) utilised a mailed survey method to determine whether hospital nurses in the United States differed in their views on research utilisation (availability of research resources, attitude toward research, support, and research use) based upon selected socio-demographic characteristics (educational level, years of nursing experience and organisational position). Of the 2500

questionnaires distributed, a total of 270 (11%) were returned. Findings of this study showed overall positive attitudes of nurses' toward research. Statistically significant differences existed in nurses' views about research based on their level of education and position within the organisation. Nurses in management positions held more positive attitudes toward research than bedside nurses. In addition, nurses with a master's degree reported a more positive attitude toward research than nurses with baccalaureate and associate degrees or diplomas.

Similarly, Bonner, and Sando (2008) conducted a survey in Australia with the primary objective to determine knowledge, attitudes and use of research by nurses. Three hundred and forty-seven nurses completed the questionnaire with a response rate of 39%. The results of the study indicated that nurses in higher level positions such as Senior Nurse Managers, Nurse Unit Managers and Clinical Nurse Consultants, were more likely to have positive attitudes toward research as compared to registered and clinical nurses (Bonner & Sando, 2008). Findings from both studies suggest that nurses with more education (e.g., graduate) and in administrative positions tend to be more positive in their attitudes toward research in general compared to nurses with lower levels of education (e.g., baccalaureate, diploma) and in non-administrative positions. A possible explanation for these findings is that nurses with more years of education receive more information about the importance of research as compared to nurses with lower levels of education. In addition, nurses with a graduate degree and in administrative positions may have been involved in the conduct and planning of clinical research. Hence, these nurses might have previous experiences with research, which perhaps positively influenced their attitudes toward these research studies. As it relates to the current study, findings from the above studies suggest that nurses with more years of education may be more positively oriented in their attitudes toward clinical trials.

Several limitations need to be highlighted. McCloskey (2008) utilized a convenience sample of nurses drawn from a large magnet hospital. Magnet hospitals are health care institutions that were recognised by the American Nurses Credentialing Centre (ANCC) for high quality patient care, nursing excellence and innovations in professional practice (ANCC, 2012). Caution is indicated in generalizing the results of this study to other organizational settings. Large magnet hospitals offer a significant amount of support for the conduct of research, which may not be the same in other healthcare institutions. In the study conducted by Bonner and Sando (2008) participants were from hospital and community settings in rural areas only. Therefore, future research is required in these settings in urban areas.

### **Factors Related to Attitudes toward Research**

Attitudes of nurses toward research may play a significant role in influencing their engagement in research related activities. An exploration of factors related to attitudes toward research may help to better understand how these attitudes are shaped. A number of variables have been examined in the nursing literature as described next.

#### **Primary position and work setting.**

A number of studies examined differences in attitudes toward research based on primary position and type of workplace. D'Amico (2007) indicated that clinical trial nurses had more positive attitudes toward clinical trials compared to bedside nurses. Furthermore, oncology nurses from intensive care and bone marrow transplant units were less likely to have positive attitudes toward research as compared to other nurses (e.g., outpatient clinics, nurses working in corporate industry) (Burnett et al., 2001; D'Amico, 2007). In addition, McCloskey (2008) reported that nurses in management positions were more positively oriented in their attitudes toward research than bedside nurses. Similarly, Bonner and Sando (2008) found that nurses in

primary positions such as Senior Nurse Managers, Nurse Unit Managers and Clinical Nurse Consultants, had more positive attitudes toward research compared to registered and clinical nurses. These results suggest that nurses' attitudes toward research may vary depending on the primary position and type of their workplace. Specifically, research nurses, nurses in administrative positions and nurses who worked in outpatient clinics were more likely to have positive attitudes. On the other hand, bedside and ICU/BMT nurses reported negative attitudes toward clinical trials. As previously mentioned, such differences could possibly be related to the patient population these nurses work with (e.g., patients whose ability to understand clinical trial information was compromised or not) as well as, nurses being involved in planning and conduct of clinical trials (e.g., nurses in administrative positions). Whether similar phenomena exist in the transplant nursing setting was investigated in the current study.

#### **Educational level.**

Several studies have investigated differences in attitudes of nurses toward research based on their level of education. McCloskey (2008) found that nurses with a master's degree were more positively oriented toward research as compared to nurses with baccalaureate and associate degrees or diploma. Similarly, Bonner and Sando (2008) indicated that nurses, who had completed university courses on nursing research, were more likely to hold positive attitudes toward research and were more willing to undertake research than those nurses who did not have such educational preparation. Kuuppelomaki and Tuomi (2005) also found that nurses who received training in research were more likely to have positive attitudes toward research. Hence, these findings suggest that nurses with more education tend to have more positive attitudes toward research in general.

### **Age.**

Studies have been conducted to examine differences in nurses' attitudes toward research based on nurses' age. Burnett et al. (2001) found that nurses who were 40 years of age and older held a positive attitude toward clinical research. However, Kuuppelomaki and Tuomi (2005) and D'Amico (2007) found no statistically significant association between age and attitudes toward research. Nonsignificant findings in these studies could be related to the type of sample used. Specifically, in the D'Amico's study nurses on average were 40 years of age and older and in the Kuuppelomaki and Tuomi study the majority of nurses were older than 35 years. Therefore, fewer nurses less than 35 years old participated in both studies. Hence, findings from both studies could have been skewed due to minimal variability in age, and therefore showed no significant association between nurses' age and type of attitudes. Currently, the relationship between nurses' age and attitudes toward research remains inconclusive.

### **Years of nursing experience.**

Years of nursing experience has also been investigated as a potential factor influencing nurses' attitudes toward research. Kuuppelomaki and Tuomi (2005), and D'Amico (2007) found that the relationship between years of nursing experience and attitudes toward research was not statistically significant. This factor was examined in only two studies and requires further exploration. Whether years of nursing experience in transplant settings would be related to transplant nurses' attitudes toward research was investigated in the current study.

### **Nurses' previous involvement with patients participating in clinical trials.**

Nurses' previous involvement with patients participating in clinical trials has been investigated in one study. D'Amico (2007) found statistically significant associations between nurses' previous involvement with patients participating in clinical trials and nurses' perception



of patient knowledge and understanding of the treatment regimen and where clinical trials need to be conducted. The author reported that nurses who worked with patients enrolled in clinical trials perceived patients understand their treatment goals, plan and prognosis, and believed that patients' wishes are respected by oncology nurses and physicians. In addition, these nurses also believed that clinical trials should not be conducted only in oncology centres (D'Amico, 2007). No other studies investigated the association between this variable and nurses' attitudes and beliefs. The relationships among transplant nurses' previous experience with patients involved in clinical trials and their beliefs and attitudes toward clinical trials were investigated in the current study.

As evident in this literature review, factors such as primary position (e.g., senior management positions, clinical trials nurses), education (e.g., graduate degree, training in research) as well as work setting (e.g., outpatient clinics, corporate industry) were associated with nurses' attitudes toward clinical research. However, findings related to variables such as age and years of nursing experience were inconclusive. Thus, there is a need for more research to better understand factors influencing nurses' attitudes toward clinical trials because these factors may influence the attitudes nurses have toward clinical trials and may ultimately influence patients' and nurses' participation in these clinical trials.

### **Summary of the Literature Review**

The literature reviewed suggests that overall nurses held positive attitudes toward clinical trials and research in general. However, a degree of variability existed in nurses' specific beliefs about patients' knowledge, understanding and informational needs related to clinical trials. Some nurses felt that patients were not well informed about clinical trials in which they were asked to participate and also believed that patients may receive too much pressure from doctors and/or

nurses to be involved in these trials. Nurses' beliefs about patients' understanding of the process involved in clinical trials may positively or negatively influence nurses' attitudes toward clinical trials, the role nurses play in these research studies and how likely they are to endorse these studies in practice.

It is also important to mention that nurses in the studies reviewed tended to differentiate between the role of research in nursing science and in nursing practice. Specifically, nurses held more positive attitudes toward research supporting nursing science but less positive attitudes toward research related to practice. In addition, nurses' attitudes and beliefs are complex phenomena, which could be affected by various factors related to nurses' personal and professional life experiences, age and educational levels.

The knowledge gleaned from the reviewed literature suggests that transplant nurses may vary in their attitudes toward clinical trials and may have various beliefs about patients' knowledge, understanding and informational needs in relation to clinical trials. Furthermore, transplant nurses' attitudes and beliefs may differ depending on primary position, level of education, age and years of nursing experience.

In this literature review, the knowledge about nurses' beliefs and attitudes toward research in general and clinical trials primarily was drawn from the empirical evidence generated in the US, Australia and Europe, and predominantly in oncology settings. These findings may or may not well reflect the attitudes of nurses in other countries and settings including the area of organ transplantation in Canada. Furthermore, lack of literature in other than the oncology environment also suggests that attitudes of nurses have been largely uninvestigated. This study is an initial step in addressing the gap in knowledge related to nurses' attitudes and beliefs toward clinical trials in transplant settings.

### **Chapter 3: Theoretical Framework**

At the beginning of this section, the Theory of Reasoned Action (TRA) as proposed by Ajzen and Fishbein (1980) is presented including a description of the key concepts and the relationships among them. Then, the TRA as adapted to the study of transplant nurses' attitudes toward clinical trials is introduced and the conceptual and operational definitions of key variables are highlighted. Finally, the research questions that guided this study are outlined.

The TRA was chosen as a theoretical framework to guide this study because of its focus on attitudes and beliefs as predictors of behaviours, which is consistent with the research problem addressed in this study. In addition, the TRA has been previously used in investigation of attitudes in the area of transplantation (e.g., attitudes of the public about signing a donor card (Weber, Martin, & Corrigan, 2007), student attitudes regarding organ donation (Feeley, 2007), attitudes of nursing staff toward organ donation in Spain, (Zambudio, Martinez-Alarcon, Parrila, & Ramirez, 2009), attitudes of nurses toward pain assessment and management (Young, Horton, & Davidhizar, 2006), and renal transplant recipients' non-adherence with immunosuppressive medication (Schmid-Mohler, Pechula, Wuthrich, Denhaerynck, & De Geest, 2009)). In addition, the TRA was used as the framework in the study by D'Amico (2007) examining oncology nurses attitudes toward clinical trials. Results of these studies in general lend support to the propositions of the TRA model.

#### **Theory of Reasoned Action**

The Theory of Reasoned Action (TRA) originated from social psychology. One of the central topics of social psychology is the investigation of attitudes from various perspectives; the structure and function of attitudes, how attitudes can be changed, and how attitudes influence behaviour (Fishbein & Ajzen, 2010). The TRA attempts to understand and hence, predict human

behaviour by taking into consideration the concepts of intentions, attitudes toward the behaviour, personal beliefs about behaviour, subjective norms and perceived beliefs of others (Fishbein & Ajzen, 2010).

People are most likely to behave based on their intentions to engage in a particular behaviour (Fishbein & Ajzen, 2010). According to the TRA, a person's intention is an individual's readiness to engage in a behaviour. An intention is a function of several determinants, which are personal and social in nature. The personal factor is termed *attitude toward the behaviour*, which is defined as an individual's positive or negative evaluation of the outcome of performing the behaviour. It is an individual judgment of whether performing the behaviour is good or bad. The second determinant of intention is *subjective norm*, which is described as the individual's perception of the social pressure put on him or her to perform or not to perform the behaviour of interest. The third determinant is *control beliefs*, which are individual beliefs about personal or environmental factors that can facilitate or hinder attempts to engage in a behaviour. As a rule, individuals intend to engage in a behaviour when they evaluate it positively, when they believe that significant others think they should perform it and when these individuals believe they have control over performing this behaviour (Fishbein & Ajzen, 2010).

Attitudes are a function of beliefs about the object, in this case behaviour according to the TRA (Fishbein & Ajzen, 2010). A person may hold a number of beliefs or have a variety of information about an object of interest; however, only some of these beliefs will determine an individual's attitude. These beliefs have been termed salient or accessible beliefs. Salient beliefs are beliefs that are instantly activated in the presence of an object (actually or symbolically represented). Therefore, from the theoretical point of view, attitudes are based on the total set of

an individual's salient beliefs about an object. Generally, people believe that engagement in a given behaviour can result in both positive and negative consequences. The attitude toward the behaviour will correspond to the favourability or unfavourability of the total set of consequences; thus, each behaviour will be evaluated by the strength of an individual's belief that engaging in the behaviour will result in each of the consequences (Fishbein & Ajzen, 2010).

The investigation of subjective norms is beyond the scope of the current study; however, they are presented here for completeness in describing the theoretical perspective. Subjective norms are also a form of beliefs; however, these beliefs relate to the individual's beliefs that particular people who are often important to the person think he/she should perform or not perform the behaviour (Fishbein & Ajzen, 2010). The beliefs that underlie a person's perception of subjective norms are termed *normative beliefs*. As a rule, an individual who believes that most referents (or important others) think he or she should perform the behaviour will perceive a social pressure to do so. On the contrary, an individual who believes that important others think she or he should not perform the behaviour will have a subjective norm that exerts pressure on him or her to avoid performing the behaviour. Hence, the subjective norm may put pressure on an individual to perform or not to perform a given behaviour, regardless of the person's own attitude toward the behaviour under investigation (Fishbein & Ajzen, 2010).

The TRA considers various factors, such as socio-demographic variables, including age, social status, and social role as *external variables* (Fishbein & Ajzen, 2010). The external variables may influence the behavioural beliefs an individual holds. However, external variables do not directly influence the performance or non-performance of the actual behaviour. These variables do not constitute an integral part of the TRA. An external variable will affect behaviour

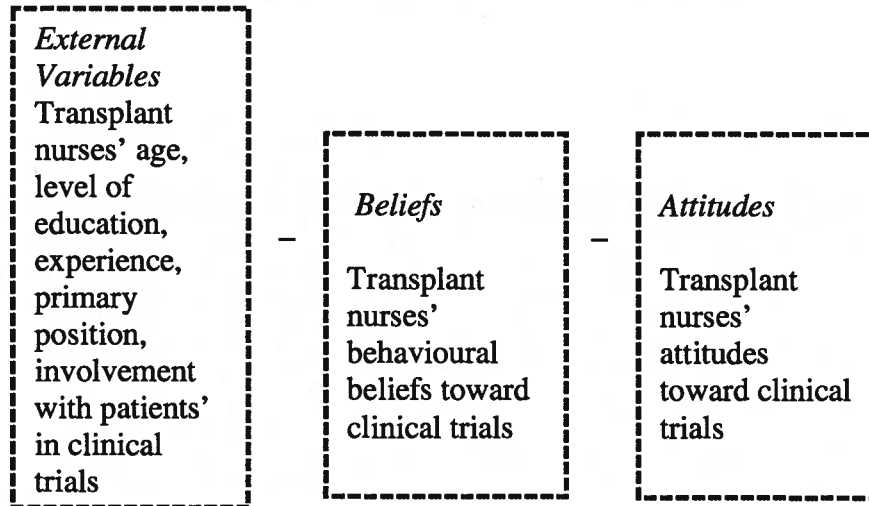
only to the degree it influences the determinants of that behaviour such as personal behavioural beliefs, perceived beliefs of others, and control beliefs.

### **The TRA as a Theoretical Framework in this Study**

Attitudes of transplant nurses toward clinical trials and transplant nurses' beliefs about patients' knowledge, understanding and informational needs in relation to clinical trials are the central concepts in this study. The examination of nurses' attitudes and beliefs is a first step in understanding intention and may ultimately help understand nurses' behaviours in relation to clinical trials. The investigation of nurses' intention and behaviours pertaining to clinical trials was outside of the scope of the current study because it was deemed important to first explore attitudes and beliefs that shape intention to engage in behaviours.

Transplant nurses' attitudes toward clinical trials and transplant nurses' beliefs about transplant patients' understanding, knowledge and informational needs regarding clinical trials were evaluated based on the concepts suggested by the TRA (transplant nurses' personal beliefs toward clinical trials and attitudes toward clinical trials) (see Figure 1). Consistent with the TRA, one would expect transplant nurses' intentions to engage in clinical trials related activities to be dependent on personal beliefs and attitudes. The personal salient beliefs of individual transplant nurses toward the outcome of clinical trials may determine their attitudes toward clinical trials. For example, if a transplant nurse believes that the outcome of clinical trials is likely to improve transplant patients' care, he or she is more likely to form a positive attitude toward clinical trials and if a transplant nurse believes that clinical trials will not contribute to enhancement of patient care he or she is more likely to form a negative attitude toward transplant clinical trials. Furthermore, the transplant nurses' beliefs about patients' being knowledgeable and well informed about clinical trials, and his or her beliefs that patients make voluntary

decisions to participate may also influence the overall attitudes of individual transplant nurses toward clinical trials, which may ultimately shape their intention.



*Figure 1. Study Framework adapted from the Theory of Reasoned Action from Predicting and changing behaviour: The reasoned action approach by M. Fishbein and I. Ajzen, (2010). New York, NY: Psychology Press.*

External variables, such as socio-demographic factors may also affect nurses' beliefs toward clinical trials according to the TRA (Fishbein & Ajzen, 2010). Some of these factors have been identified in other studies including nurses' primary positions, level of education, years of experience, age and previous involvement with patients participating in clinical trials as part of overall nurses' past experiences with clinical trials. The current transplant study evaluated the association of these factors with transplant nurses' attitudes and beliefs.

### **Definitions of Key Study Terms Used in the Current Study**

#### **Attitude.**

Conceptual definition: "The evaluation of an object, concept, or behaviour along a dimension of favour or disfavour, good or bad, like or dislike" (Fishbein & Ajzen, 2010; p.78).

Attitudes are comprised of the beliefs that people accumulate over their lifetimes (Ajzen & Fishbein, 1980).

**Operational definition:** In this research study, attitudes represent the evaluative beliefs transplant nurses have in relation to the importance of clinical trials for patient care in general. Attitudes were measured with items from the Attitudes toward Clinical Research (ATCR) subscale in the Transplant Nurses Attitude Survey (TNAS). The items elicit transplant nurses' level of agreement with statements that clinical research improves patient care and is important for future standards of care in transplantation. The TNAS was adapted from the NAS as modified by D'Amico (2007).

### **Belief.**

**Conceptual definition:** A belief represents the information an individual has about an object (Fishbein & Ajzen, 1975). People form their beliefs about an object by associating the object with various characteristics, qualities, and attributes (Fishbein & Ajzen, 2010). More specifically, Fishbein and Ajzen (2010) defined beliefs as "the subjective probability that an object has a certain attribute" (p. 96).

**Operational definition:** In this research study, a belief reflects the information transplant nurses have about how effective a research drug or experimental therapy should be before it is offered to patients, about patients' understanding, knowledge and informational needs in relation to clinical trials and about transplant care centres as a preferred location for the conduct of transplant clinical trials. Nurses' beliefs were measured with items from the Patients' Understanding and Knowledge (PUK), Roles and Location (RL), and Informational Needs of Patients (INP) subscales on the TNAS. These subscales inquire about nurses' level of agreement with statements that patients are well informed about clinical trials, patients are aware that their



treatment is part of a research protocol, and that clinical trials need to be conducted only in transplant care centres (Burnett et al., 2001; D'Amico, 2007).

### **Clinical trial.**

Conceptual definition:

“Clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate its effects on health outcomes. ... Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes and preventive care.” (WHO, 2011 para #2)

Clinical trials include phase I, II, III, IV (Grady & Edgerly, 2009). Phase I is conducted to examine an investigational treatment for the first time in a small sample (20-80 participants), establish a safe dose range and discover side effects. Phase II is undertaken to test investigational therapy in a larger sample (100-300) to observe its effects and further assess safety. Phase III involves a larger group of participants ( $\geq 1000$ ) to verify its effectiveness, observe side effects and compare it to standard therapies. Phase IV is conducted to gather additional information after the therapy has been approved (Grady & Edgerly, 2009).

Operational definition: A transplant clinical trial is identified as any study investigating a treatment for patients who have had a transplant. The clinical trial has a research protocol approved by the research ethics board and participants sign informed consent.

### **Primary position and setting.**

Conceptual definition: Primary position represents the nature of nurses' position within the organization, determined by the job title and type of responsibilities or functions assigned to them. It may include a staff nurse, who provides direct patient care on an inpatient unit; a

transplant outpatient coordinator who cares for transplant patients in outpatient clinics; nurses in administrative or educational positions who support transplant nurses; and advanced practice nurses who manage the care for patients in the inpatient units or outpatient clinics.

Operational definition: Nurses' self-report of their position, which may encompass staff nurse, nurse in administrative / educational position, or transplant outpatient coordinator / nurse practitioner (Demographic Information Form, Appendix A).

**Years of experience in transplant setting.**

Conceptual definition: The number of years a nurse has practiced nursing in a transplant setting.

Operational definition: Nurses' self-report of how long they have been practicing nursing in a transplant setting.

**Years of experience in nursing.**

Conceptual definition: The number of years a nurse has practiced nursing.

Operational definition: Nurses' self-report of how long they have been practicing nursing.

**Education.**

Conceptual definition: The highest level of education (nursing and/or non-nursing) a transplant nurse has obtained.

Operational definition: Nurses' self-report of their highest level of education.

**Age.**

Conceptual definition: Age is the number of years a person lives.

Operational definition: Nurses' self-report of their age measured in years.

**Involvement with clinical trial patients.**

Conceptual definition: Nurses' interactions with patients who participate in clinical trials.

**Operational definition:** Transplant nurses' self-report of whether they perform clinical trials-related activities and whether they have patients in their care who are participating in clinical trials. The clinical trials activities included familiarising themselves with the study protocol, administering investigational medications, managing side effects related to these medications, documenting their assessment and a patient's progress, answering patient's questions related to the clinical trial process and treatments / procedures, contacting investigators in relation to the study process, and collecting specimens as per study protocol.

### **Research Questions**

The following research questions guided this study:

1. What are transplant nurses' attitudes toward clinical trials?
2. What are transplant nurses' beliefs about patients' knowledge, understanding and informational needs in relation to clinical trials?
3. What are nurses' beliefs about where clinical research should be conducted and the role of transplant physicians and nurses in clinical trials?
4. What are nurses' beliefs about patients' decision-making process and desire for information in relation to clinical trial participation?
5. What factors do transplant nurses believe influence a patient's decision to participate in a transplant clinical trial?
6. What are transplant nurses' beliefs about how effective an experimental treatment should be before it is offered to patients?
7. To what extent are the socio-demographic variables of age, educational level, number of years in transplant area, whether or not the nurse actually works with patients enrolled in a clinical trial, primary position associated with attitudes and beliefs?

## **Chapter 4: Method**

In this chapter the study design is explained, followed by the description of the sample, including sample size and the setting where the data were collected. Procedures for data collection, the protection of human subjects and the data analysis plan are also elaborated. Information about the instrument used in the study is included in this chapter.

### **Design**

This quantitative study employed a descriptive, non-experimental design. Descriptive research focuses on exploring and describing phenomena of interest in real-life situations (Burns & Grove, 2009). This design is particularly useful for the generation of new knowledge on a topic, about which limited or no research has been previously conducted. Attitudes of transplant nurses toward clinical trials and factors associated with these attitudes have not previously been investigated. Thus, utilisation of a descriptive design is appropriate to address the overall purpose of this study.

This research study was conducted in naturally occurring settings, which is congruent with the descriptive design. Conducting a research study under real life circumstances has the benefit of examining a phenomenon as it naturally occurs, which increases the external validity of the study or the generalizability of the results to the target population (Burns & Grove, 2009). However, it may also pose threats to internal validity due to lack of control of external factors that may influence responses to measures (such as history, conditions under which the measures are completed). To minimize these threats, the researcher tracked events taking place at the same time this study was conducted and interpreted results of this study in the context of these events. The researcher asked nurses to complete the questionnaire at their earliest convenience and

encouraged nurses to do it within work settings in order to increase the likelihood that the nurses themselves would complete the survey.

### **Setting and Sample**

A convenience sample of all transplant nurses employed at the Multi Organ Transplant (MOT) department in a large tertiary care hospital in Southern Ontario was invited to participate in this study. Convenience sampling possesses strengths and limitations. Convenience samples are useful to obtain information in previously unexamined areas, are economical and accessible, and require less time to attain than random sampling methods (Burns & Grove, 2009). On the other hand, this sampling method has weaknesses due to its limited opportunities for researchers to control for biases (Burns & Grove, 2009). Thus, the investigator established specific criteria for subjects to be included/excluded from the study to control for possible confounds in socio-demographic characteristics of the sample.

The inclusion criterion for participation in this study was full time and part time employment in the inpatient units and outpatient clinics of the MOT. Staff nurses and advanced practice nurses were eligible to take part in the study. Nurses working through a nursing resource team (NRT), agency staff and nurses employed on casual basis were excluded from participation in this study. NRT, agency nurses and casual nurses work predominantly on other units (e.g. cardiology, medicine, nephrology units) and are not confined to the care of transplant patients. Work on other units could influence nurses' attitudes and beliefs toward clinical trials.

At the time the study was conducted, there were 123 nurses in the MOT department meeting the study inclusion criteria. The sample size in this study was determined based on the guideline that specifies the need to have 5 to 10 participants for each independent variable included in the analyses (Burns & Grove, 2009). There are six independent variables in this

study (e.g. age, years of experience as a nurse and as a nurse on the transplant unit, primary position, level of education and previous involvement with patients who participate in clinical trials). Therefore, a sample of 30 to 60 participants was targeted for this study. In order to maximize the sample size the researcher invited all nurses (total of 123 nurses) working in the MOT department to participate.

### **Recruitment.**

Several strategies were used to recruit nurses in the transplant unit. An announcement regarding this study was made by the researcher to the outpatient transplant nurses during the weekly staff meeting. In addition, an email announcement was sent to nurses on the inpatient unit by the nurse manager. The announcement contained information about the purpose of the study, when the study started, where the surveys were placed, and when and where to return the completed questionnaire. Flyers informing nurses about this study were also posted on the transplant units.

### **Ethics**

The researcher obtained approval from the Research Ethics Boards at the university and the health care institution where the study took place. All potential study participants were offered an information letter, which provided details about the study (Appendix B). Participation in this study was voluntary and all participants had the right to decline enrolment. Participants were asked to return the completed survey within two weeks in one of the allocated boxes situated on each unit (total of 4 boxes). Completion and return of the completed questionnaire by the participant indicated consent to participate (i.e. implied consent). Data collection was anonymous; thus participants did not indicate their names on the forms they completed for the study. The benefits of anonymous data collection are that participants might be more honest in

their responses because the responses cannot be linked to the individuals who completed the questionnaire, potentially reducing social desirability bias. The limitations to such an approach are that participants cannot withdraw from the study once their results are submitted and it is difficult to follow up with participants whose responses need some clarification. There was no harm known for taking part in this study. No personal incentives were offered to participants.

Data were saved in a locked file cabinet in the office at the researcher's home. Electronic coded data are kept on the investigator's computer and are password protected. All information will be destroyed by the investigator within 10 years post study completion as per the protocol at the institution where data were collected.

### **Instruments**

The nurses were asked to complete two instruments, the Socio-demographic Information Form and the Transplant Nurses' Attitude Survey (TNAS).

#### **Demographic Information Form (DIF).**

The form contained six questions inquiring about nurses' age, level of education, years of experience as an RN, years of experience as an RN in transplantation, primary position, and involvement with patients who participate in clinical trials. To answer the questions nurses checked the appropriate box or provided short answers. In addition, the nurses who checked "yes" to the question about involvement with transplant patients who participate in clinical trials were also asked to identify activities they usually perform as part of their involvement. These activities included familiarizing themselves with the study protocol, administering investigational medications, managing side effects related to these medications, documenting their assessment and patient progress, answering patients' questions related to the clinical trial

process and treatments / procedures, contacting investigators in relation to the study process, and collecting specimens as per study protocol.

### **Transplant Nurses' Attitude Survey (TNAS).**

The Transplant Nurses' Attitude Survey was adapted from an attitude survey developed for use with nurses in oncology settings (Burnett et al., 2001; D'Amico, 2007). The original instrument consisted of 59 items and was divided in four sections: section 1 - Clinical Research Using Patients as Research Subjects, section 2 - Patient Care and Patient Communication, section 3 - Nurses' Role in a Cancer Institute, and section 4 - About You (Burnett et al., 2001). The instrument contained two subscales, including subscale 1 - Nursing Attitudes Toward Benefit of Clinical Trials and subscale 2 - Nurses' Perceptions of Patients' Understanding of the Process Involved in Clinical Trials. Cronbach's alpha for subscale 1 was reported as 0.78 and for subscale 2 as 0.63 (Burnett et al., 2001).

D'Amico (2007) modified the survey developed by Burnett et al. (2001) to a 26-item questionnaire (Nurses Attitude Survey [NAS]) in the Nationwide Survey of Oncology Nurses. The researcher excluded Section 3 related to the nurses' role as it was beyond the scope of his study and administered Section 4 as a separate Socio-demographic Information Sheet (D'Amico, 2007). Therefore, the modified NAS focused on measuring oncology nurses' attitudes toward cancer clinical trials and nurses' perceptions of the understanding that patients have about the clinical trial process and the reasons for patient participation in clinical research. In the current study, the NAS as modified by D'Amico (2007) was adapted.

Content validity testing of the NAS was reported by D'Amico (2007). Eight master's prepared oncology nurses completed the instrument, as a part of a field test. It took fewer than 10 minutes to complete the questionnaire. They felt that the instrument assessed their opinions



about cancer clinical trials, including information pertaining to patients who participate in these trials. In the original instrument Item 1 stated “Conducting patient research is an important role of oncologists” and Item 9 “Doctors put too much pressure on patients to participate in clinical trials”. The nurses who reviewed the questionnaire suggested using similar language throughout the instrument. Thus, “doctor” was changed to “oncologist” in the entire instrument (D’Amico, 2007).

D’Amico (2007) mailed out 1000 surveys to a national sample of oncology nurses. The final sample included 301 returned questionnaires yielding a response rate of 30.1%. To examine the psychometric properties of the modified NAS, D’Amico conducted a factor analysis to determine how items on the questionnaire clustered together. Twenty four of the 26 items from the questionnaire were included in the analysis because items 14 and 15 were scored separately. Four subscales were identified after factor analysis: (1) Patient Understanding and Knowledge (PUK), (2) Attitudes toward Clinical Research (ATCR), (3) Roles and Location (RL), and (4) Information Needs of Patients (INP). Cronbach’s alpha for the PUK subscale was 0.74. For newly developed scales Cronbach’s alpha coefficient is considered acceptable at  $\geq 0.70$  (Burns & Grove, 2009) suggesting that this subscale had an acceptable level of internal consistency reliability. Cronbach’s alpha for the ATCR subscale was 0.66, for the RL subscale was 0.47 and for the INP subscale 0.56 indicating lower than the widely acceptable values (Burns & Grove, 2009). Reliability of the entire NAS, excluding two items, which are scored separately (items 14 and 15), was reported with Cronbach’s alpha at 0.72 (D’Amico, 2007), which is an acceptable level.

The construct evaluated by item 14 was nurses’ perceptions of motivations for patient participation in clinical research (D’Amico, 2007). This item listed 9 statements giving possible

reasons for patient participation in clinical trials and asked participants to indicate their agreement with each statement using a 5-point Likert scale. The Cronbach's alpha for this item was 0.68. Item 15 asked participants to indicate the percent chance that a research drug would produce a desired effect before it should be offered to patients.

In summary, there are 26 Items on the NAS as modified by D'Amico (2007), which were incorporated into four subscales (PUK, ATCR, RL and INP). All items (excluding Item 15) are evaluated according to a 5 point Likert scale, where nurses state their agreement or disagreement with each statement where 1= strongly disagree, 2= somewhat disagree, 3= neither, 4= somewhat agree, 5= strongly agree. A higher score indicates more positive nurses' attitudes and beliefs. Nine items (2, 9, 10, 13, 22, 23, 24, 25, and 26) are negatively worded and reverse scored.

In the current study the key variables were attitudes of transplant nurses toward transplant clinical trials and beliefs transplant nurses have about transplant patients' understanding, knowledge and informational needs in relation to transplant clinical trials. The variables were measured with the 26 items of the NAS (as modified by D'Amico, 2007). The NAS was designed for use in oncology settings, thus it was adapted for the purpose of the current study. The adaptation consisted of changing the following words: "oncology" was changed to "transplant", "oncologist" to "transplant physicians", "treatment for cancer" to "treatment for transplant", and "chemotherapy" to "immunosuppressive therapy" and the adapted measure was called Transplant Nurses' Attitudes Survey (TNAS) to reflect the population studied.

The ATCR subscale has eight items that ask about transplant nurses' attitudes regarding the importance of transplant clinical research in improving care for the patient involved in these trials, in enhancing overall standards of care in research hospitals in the future. One item also inquires about transplant nurses' preference to be part of clinical trials in case he/she needs a

transplant. Finally, one item evaluated nurses' opinion on whether or not patients need to be encouraged to participate in clinical trials.

The PUK subscale includes seven items that ask about transplant nurses' beliefs about patients being well informed when they choose to participate in a clinical trial, patients' understanding of their plan of care and prognoses, and whether patients' wishes regarding their treatment are respected by transplant physicians and nurses.

The RL subscale consists of four items. These items assess transplant nurses' beliefs about the transplant care centre as a preferred location for the conduct of clinical trials, and whether or not physicians and nurses overly pressure patients to participate in clinical trials.

The INP subscale includes five items evaluating transplant nurses' perceptions of the informational needs of patients. Specifically, these items ask about transplant nurses' beliefs regarding patients being more attentive to potential benefits of the therapy than side effects, whether patients accept side effects even for a small amount of benefit of this therapy, whether patients are afraid to ask questions and whether patients' decisions to participate in these trials are influenced by their family members.

Scoring was done as described by D'Amico (2007) to obtain total scores for the four subscales. The possible score for the ATCR subscale was 8 to 40, for the PUK subscale 7 to 35, for the RL subscale 4 to 20, and for the INP subscale 5 to 25.

Item 14 was used to evaluate nurses' beliefs about patients' motivation to participate in clinical trials. Similar to the NAS questionnaire (D'Amico, 2007), the item asks, "Patients participate in research because of ...," and there are nine sub-items, for example "wish for a cure", "wish for improved quality of life", and "hope for better medical care", which are ranked

on a five point Likert scale. The nine sub-items were ranked from highest to lowest according to the percentage of participants who selected “somewhat agree” or “strongly agree”.

Item 15 was used to assess transplant nurses’ beliefs about how effective a research drug or experimental therapy should be before it is offered to patients. Nurses were asked to indicate their opinion about the likelihood of a drug or a treatment being effective before it should be offered to patients.

Content validity of the adapted measure was examined prior to its use in the study. The TNAS was administered to three content clinical experts (one master’s and two baccalaureate prepared transplant nurses) to obtain their feedback related to comprehension and relevance of the measure’s content. The expert nurses who reviewed the tool were asked if the revised tool reflected transplant nurses’ views about transplant clinical trials and information about patients who participate in these trials. Furthermore, expert nurses were asked whether the measure’s content was easy to understand and if not, what their suggestions were to improve the clarity of the instrument. The expert nurses indicated that the questionnaire was easy to understand and follow, and reflected transplant nurses’ views about clinical trials. No changes to the questionnaire were suggested. These expert nurses were excluded from the final study sample.

Two open-ended questions were added to the questionnaire to give an opportunity for nurses to describe their opinions in relation to barriers and supports for participation in clinical trials. These questions were: “What are some barriers to your participation as a nurse in clinical trials?” and “What can be done (within the transplant unit) to enhance transplant nurses’ participation in clinical trials?”.

## **Data collection**

A survey method was utilised to collect data on the variables of interest study. The advantages of using a survey technique are that the data can be obtained over a short period of time and it is relatively inexpensive (Burns & Grove, 2009). However, a limitation of this approach is the low response rate (which can be as low as 30-35%) thus, requiring over-sampling in order to have sufficient sample size (Burns & Grove, 2009). In order to maximize response rate in the current study, the researcher implemented strategies to enhance participation of transplant nurses such as posters and e-mails to remind participants about the survey.

After informing potential participants about the study, a package containing a copy of the letter of information and the questionnaire (including the socio-demographic information form and the TNAS) were placed by the ward clerk and/or receptionist in the nurses' personal mail boxes or delivered to nurse practitioners' offices. The nurse manager on the outpatient unit and the patient care coordinator on the inpatient unit then sent an e-mail to all nurses indicating that the survey had been placed in their mail boxes. A week after the initial distribution, a follow up e-mail was sent to nurses reminding them to complete the survey if they had not already done so. Two weeks after the initial distribution of surveys the designated boxes for the return of completed forms were collected by the researcher.

## **Data Analysis**

All data were entered in the Statistical Package for the Social Sciences (SPSS) version 17. The data entered in the SPSS data base were crosschecked for accuracy against the participants' raw data. Data analysis was done in two steps; the first was preparatory and the second aimed at addressing the study questions. The preparatory step involved exploring the data for missing values and testing the reliability of the questionnaire.

### **Missing data.**

Missing data is an important issue in research. There are various approaches to address missing data including: replace missing values or delete cases with a large amount of missing data. For instance, Polit (2010) suggests evaluating for the pattern (whether one or more items were missed consistently or randomly) and extent of missing data (the percent of missing values). The statistical analysis of missing data in this study revealed that there were three different items left blank by three different respondents, comprising 2.6% missing values for each item. Therefore, the pattern was revealed as missing at random. Polit also asserts that case mean substitution is applicable for missing data when there is a missing value in a set of items that form a unidimensional scale. Furthermore, this approach works well when up to 30% of item values on a scale are missing (Shrive, Stuart, & Ghali, as cited in Polit, 2010). In accordance with case mean substitution the researcher replaced each missing value with the mean of the other items in the subscale for that individual. The assumption of case mean substitution is that individuals' responses are "internally consistent across similar questions" (Polit, 2010, p. 373).

### **Reliability testing.**

Reliability testing was performed by calculating a Cronbach's alpha coefficient for the four subscales used in this study. In addition, the mean and median values were analysed to assess the distribution of data (Burns & Grove, 2009). If the mean and median are the same then the sample distribution is considered symmetrical, as in the normal distribution. Normal data distribution - is an assumption that should be met prior to using parametric statistical tests (Burns & Grove, 2009).

### **Statistical analysis.**

Descriptive and inferential statistics were used to analyse the data. Frequency distributions were used to describe socio-demographic variables measured at the nominal and ordinal levels (e.g. level of education, primary position and involvement with patients who are enrolled or contemplate enrolment in clinical trials). Measures of central tendency (mean) and dispersion (SD) were used to analyse socio-demographic variables measured on an interval/ratio level (e.g. age, years of experience as an RN and as an RN in transplantation). The mean and median are appropriate measures of central tendency for interval/ratio level data and offer the most succinct representation of the location of data within the distribution of scores (Burns & Grove, 2009). As a measure of dispersion, standard deviation (SD), provides information about how individual scores deviate from the mean (Burns & Grove, 2009). In addition, descriptive statistics were conducted for the instrument subscales scores. Mean, median and SD were calculated for each subscale to demonstrate on average what the scores were and how they varied.

A data analytical approach similar to the one performed by D'Amico (2007) was applied to address research questions 1- 6. The mean scores obtained from the four subscales (ATCR, PUK, RL, INP) were analysed to answer questions 1 - 4. Descriptive statistics and frequencies were reported for item 14 to address question 5. The mean value indicated in item 15 was evaluated to answer question 6. Bivariate and multivariate statistics were used to answer research question 7, which addressed factors associated with attitudes and beliefs. Bivariate statistics were used to assess the relationship between one independent variable (IV) and one dependent variable (DV) at a time (Polit, 2010). Pearson's product moment correlation coefficient (Pearson's  $r$ ) was used to examine the nature and magnitude of the relationship between IVs

measured on interval/ratio level (age, years of experience as a RN and as a RN in transplantation) and each of the mean subscale scores as the DVs. In addition, a point-biserial correlation coefficient ( $r_{pb}$ ) was calculated for dichotomous nominal-level IVs (i.e. interaction with patients enrolled in clinical trials) and each of the mean subscale scores as the DVs. The independent variables, highest level of education and primary position, each consisted of three groups and were recategorised to represent these groups in a dichotomy. The variable assessing the highest level of education included baccalaureate, diploma and master's prepared nurses. The majority of the participants were baccalaureate prepared RNs (75%) and 25% of the sample included diploma and master's prepared RNs. Therefore, the selected dichotomous category was RNs with a bachelor degree versus others (diploma and master's educated RNs). In addition, the IV of primary position originally included staff nurses, outpatient coordinators /Nurse Practitioners and nurses in educational / administrative positions. No participants selected the option of RN in educational / administrative position. Therefore, two categories were used for analysis: staff RNs and outpatient coordinators/Nurse Practitioners.

Multivariate analysis was conducted to capture the influence of all IVs on each DV (Polit, 2010). Four separate multiple regression analyses were used to assess the relationship of socio-demographic variables (IVs) with attitudes and beliefs (DV) as measured with the four subscales (ATCR, PUK, RL, and INP) of the TNAS. Dummy variables were created for categorical IVs: "primary position", "highest level of education" and "nurses' interaction with patients participating in clinical trials" (Polit, 2010). Multiple regression allows a researcher to calculate the percentage of the variability in the DV explained by the IVs, by computing  $R^2$  (the coefficient of determination) (Polit & Beck, 2007). The most practical measure of the success of the model is  $R^2$  adjusted for sample size and number of IVs (Polit & Beck, 2007). A value of



adjusted  $R^2$  close to 1 is desirable because it indicates that approximately all the variability in the dependent variable is accounted for by the independent variables; thus, the IVs are considered good predictors of the DV. A low  $R^2$  shows that IVs are poor predictors of the DV and the variance in the model could be attributed to some other factors, which are unidentified. In nursing, an  $R^2$  of 0.40 is considered acceptable, which indicates that 40% of the variability in a DV can be explained by IVs identified in the model (Polit & Beck, 2007). The standardized regression coefficient ( $\beta$ ) was evaluated to determine how strongly each IV is associated with the DV (Polit, 2010).

The standard multiple regression approach in which all independent variables are simultaneously entered into the regression models was used in this study (Polit, 2010). This approach is appropriate when all independent variables are of equal significance to the research problem (Polit, 2010).

#### **Analysis of open-ended questions.**

The written responses of nurses to the two open-ended questions were transcribed and analysed using content analysis. Content analysis is an approach in which words or phrases are classified into categories based on their meaning and frequency of occurrence (Burns & Grove, 2007). Exhaustive and mutually exclusive categories need to be created so no data fall in-between the categories or are excluded because of the lack of a category (Graneheim & Lundman, 2004). In the current study, most of the comments provided by nurses were short or in point form. The investigator came up with a category list based on the review of these responses. The frequency of the occurrence of common responses within categories was reported. The identified categories were described by the researcher and exemplified with participants' quotes.

## **Chapter 5: Results**

This chapter presents the study results. The first section describes the response rate and the socio-demographic profile of study participants. The second section summarizes the nurses' involvement in research. The focus of the third section is on the study instruments, including the results of the reliability testing and exploratory data analysis. The fourth section presents the findings in relation to the research questions.

### **Sample**

#### **Response rate.**

A total of 123 research packages were distributed. Thirty-nine packages were returned yielding a 32% response rate, which was within the number targeted to meet study requirements for sample size.

#### **Socio-demographic profile.**

Socio-demographic characteristics of participants are reported in Table 1. Thirty-six participants indicated their age and three left the question unanswered. The age of the participants extended from 24 to 58 years with a mean of 35 years (SD=9.2). On average nurses reported 8.2 (SD 9.2) years of experience as an RN and 5.9 (SD 6.1) years as an RN in transplantation. The minimum number of years reported as an RN and as an RN in transplantation was 6 months. The maximum number of years as an RN was 38 years and as an RN in transplantation was 28 years.

Table 1

*Age and Number of years as an RN and as an RN in Transplantation (n = 36)*

| Variables  | Mean | Median | SD  |
|--|------|--------|-----|
| Age  | 35.3 | 34.5   | 9.3 |
| Experience as an RN (in years)                       | 8.2  | 5      | 9.3 |
| Experience as an RN in<br>Transplantation (in years) | 5.9  | 4      | 6.2 |

Thirty-seven participants indicated their highest level of education. The majority of participants (n=28, 76%) had a baccalaureate degree in nursing or another field; six (16%) nurses reported being diploma educated and three (8%) nurses had a graduate degree in nursing or another field. In relation to their primary position, the majority of participants were staff nurses (n= 32, 82%) and the remainder (n=7, 18%) were transplant outpatient coordinators / nurse practitioners.

***Nurses' involvement in research.***

Predominantly, the majority of nurses (n = 33, 85%) reported that they interact with patients enrolled in clinical trials. Nurses who interacted with patients in clinical trials indicated the activities that best described their involvement with these patients (Table 2). Most nurses described their involvement as collecting specimens as per study protocol (n=24, 73%) and administering investigational medications (n=22, 67%). The least frequently reported activity was familiarizing patients with study protocols (n=9, 27%).

Table 2

*Activities Performed by Participants Who Reported Interaction with Patients in Clinical Trials**(n=33)*

| Activity  | n  | %    |
|---|----|------|
| Collecting specimens as per study<br>protocol   | 24 | 72.7 |
| Administering investigational<br>medication   | 22 | 66.6 |
| Managing side effects related to these<br>Medications   | 18 | 54.5 |
| Documenting patients' assessment and<br>Progress  | 18 | 54.5 |
| Answering patients' questions related<br>to the clinical trial process, treatment<br>and/ or procedures | 11 | 33.3 |
| Contacting investigators in relation to<br>the study  | 10 | 30.3 |
| Familiarizing patients with the study<br>protocol   | 9  | 27.2 |

## Study Instrument

### Reliability testing.

Table 3 displays the descriptive statistics and the Cronbach's alpha coefficient computed for the subscales of the TNAS. Two subscales (ATCR and PUK) had adequate reliability for a newly adapted questionnaire (Cronbach's alpha coefficient  $\geq 0.70$ ) (Burns & Grove, 2009). The Cronbach's alpha for the RL and INP subscale was lower than the widely acceptable 0.70, which may be related to low variability in the scores of items in the respective subscales (Brown, 2002).

Table 3

#### *Descriptive Statistics for Subscales of the Transplant Nurses' Attitudes Survey (TNAS)*

| Subscale | Range of scores |         | Mean | Median | SD  | Skew  | Cronbach's $\alpha$ |
|----------|-----------------|---------|------|--------|-----|-------|---------------------|
|          | Possible        | Actual  |      |        |     |       |                     |
| ATCR     | 8 – 40          | 22 – 39 | 31   | 31     | 4.4 | .039  | 0.70                |
| PUK      | 7 – 35          | 17 – 35 | 26.6 | 27     | 3.9 | -.364 | 0.71                |
| RL       | 4 – 20          | 7 – 19  | 14.2 | 14     | 2.7 | -.950 | 0.63                |
| INP      | 5 – 25          | 5 – 18  | 12.2 | 12     | 2.8 | -.132 | 0.54                |

*Note.* SD=Standard Deviation; ATCR =Attitudes toward Clinical Research; PUK = Patients Understanding and Knowledge; RL = Roles and Locations; INP = Informational Needs of Patients.

### Findings Related to the Research Questions

Research Question 1 – What are transplant nurses' attitudes toward clinical trials? Nurses' attitudes were assessed by the ATCR subscale (Table 3). The mean was 31 (SD 4.4), indicating that on average transplant nurses had positive attitudes toward clinical trials. Nurses also believed that clinical research is essential for future improvements in care available to patients and hospitals that conduct clinical research have a better standard of care.

Research Question 2 - What are transplant nurses' beliefs about patients' knowledge, understanding and informational needs in relation to clinical trials? The PUK subscale was used to measure these beliefs (Table 3). The mean score was 26.6 (SD 3.9) indicating that, on average transplant nurses believed that patients are well informed about clinical trials and understand their treatment regimens.

Research Question 3 - What are nurses' beliefs about where clinical research should be conducted and the roles of transplant physicians and nurses in clinical trials? The RL subscale was used to measure nurses' views (Table 3). Items on the subscale were reverse coded so that higher scores reflect favourable views. The mean score was 14.2 (SD 2.7) suggesting that on average transplant nurses did not believe that clinical trial research should only be conducted in transplant research centres, and did not perceive that transplant physicians and nurses do put too much pressure on patients to participate in the clinical trials.

Research Question 4 - What are nurses' views about patients' decision-making process and desire for information in relation to clinical trial participation? The INP subscale was used to assess this variable (Table 3). The items on this subscale were reverse coded for consistency with the overall score trend on the TNAS. The mean score obtained in this sample was 12.2 (SD 2.8). Results indicate that these respondents somewhat agreed that patients are frightened to ask questions and patients' decisions about participation in clinical trials are influenced by family presence. In addition these nurses also believed that patients are somewhat willing to accept side effects for only a small benefit in therapy.

Research Question 5 - What factors do transplant nurses believe influence a patient's decision to participate in a transplant clinical trial? Nurses' beliefs were assessed with Item 14 on the TNAS (Table 4). There were nine possible responses. The most frequently selected response

was that patients participate in clinical trials because of hope for better medical care (90%), and the least frequently selected response was that there are no other options available for patients (14%).

Table 4

*Reason for Patients' Participation in Clinical Trials (n = 39)*

| Motivation  |    | Somewhat agree and |      |
|---|----|--------------------|------|
|   |    | Strongly agree (n) | %    |
| Hope for better medical care                      | 39 | 35                 | 89.8 |
| Wish to improve quality of life                   | 39 | 30                 | 76.9 |
| Wish for cure                                     | 39 | 29                 | 74.4 |
| Wish to help others                               | 39 | 26                 | 66.7 |
| Inability to accept death                         | 39 | 12                 | 30.8 |
| Pressure from transplant physician                | 39 | 11                 | 28.9 |
| Inability to accept that nothing else can be done | 39 | 9                  | 23.1 |
| Family wishes                                     | 39 | 6                  | 15.4 |
| No other options available                        | 39 | 5                  | 13.5 |

Research Question 6 - What are transplant nurses' beliefs about how effective a research drug or experimental therapy should be before it is offered to patients? This question was assessed with Item 15. On average transplant nurses believed that the experimental therapy or a drug should be at least 70% effective prior to being offered to patients (mean = 70%, SD 19.3; minimum 25% and maximum 100%).

Research Question 7 - To what extent are the socio-demographic variables of age, educational level, number of years working in transplant, whether or not the nurse actually works with patients enrolled in a clinical trial, and primary position associated with attitudes and beliefs toward clinical trials? Bivariate analyses were performed. Pearson's  $r$  was computed to examine the relationship between age, years of experience as an RN and as an RN in transplantation, and the attitudes and beliefs toward trials operationalized in the TNAS subscales. A Point biserial correlation coefficient was obtained for the association between the level of education, primary position, whether the nurse interacts with patients in clinical trials and the four TNAS subscales. Table 5 presents the obtained correlation coefficients. There were no statistically significant associations ( $p < .05$ ) between any socio-demographic factors and each of the TNAS subscales.



Table 5

*Correlations among Socio-Demographic Characteristics and Subscales of the Transplant Nurses' Attitudes Survey (TNAS)*

|  | TNAS Subscales           | ATCR | PUK  | RL   | INP  |
|--|--------------------------|------|------|------|------|
| Socio-Demographic Characteristics                        | Correlation Coefficients |      |      |      |      |
| Age (n=36)   |                          | .21  | .00  | -.15 | .09  |
| Nursing experience as an RN (n=37)                       |                          | .19  | .01  | .01  | .07  |
| Nursing experience as an RN in transplantation<br>(n=38) |                          | .14  | -.17 | -.06 | .05  |
| Baccalaureate prepared nurses (n=37)                     |                          | -.07 | -.04 | -.24 | -.16 |
| Staff Nurses (n=39)                                      |                          | -.19 | -.09 | -.11 | -.18 |
| Interact with patients in clinical trials (n=33)         |                          | -.02 | -.22 | .24  | -.02 |

*Note.* ATCR = Attitudes toward Clinical Research; PUK = Patients Understanding and Knowledge; RL = Roles and Locations; INP = Informational Needs of Patients.

Multivariate analysis was performed to determine the amount of variance in the TNAS subscales that could be attributed to the selected socio-demographic characteristics (age, level of education, years of experience as an RN and as an RN in transplantation, primary position and whether or not a nurse interacts with patients in clinical trials). Separate analysis was done for each of the four TNAS subscales.

The regression model for the nurses' attitudes toward clinical trials revealed that 4% of variance in the ATCR subscale could be attributed to the independent variables entered in the model. Analysis of the standardized regression coefficients for each IV showed that nurses' age and being an outpatient coordinator were strongly associated with nurses' attitudes toward

clinical trials (Table 6). Specifically, older nurses and those working as transplant outpatient coordinators had more positive attitudes.

Table 6

*Standardized Regression Coefficient for Attitudes toward Clinical Research (ATCR) subscale*

| Socio-Demographic Characteristics                 | $\beta$ | P    |
|---|---------|------|
| Age   | 0.79    | 0.05 |
| Nursing experience as an RN                       | -0.84   | 0.12 |
| Nursing experience as an RN in transplantation    | -0.63   | 0.14 |
| Do you interact with patients in clinical trials? | 0.17    | 0.37 |
| Diploma prepared nurses                           | -0.95   | 0.13 |
| Baccalaureate prepared nurses                     | -0.79   | 0.26 |
| Graduate degree in nursing                        | -0.09   | 0.83 |
| Outpatient coordinator                            | 0.77    | 0.05 |

The regression model for nurses' beliefs about patients' knowledge and understanding about clinical trials showed that 16% of variance in the PUK subscale could be explained by the independent variables entered in this model. Specifically, nursing experience in transplantation and being an outpatient coordinator were strongly associated with nurses' beliefs about patients' knowledge and understanding about clinical trials (Table 7). Thus, nurses with less experience in transplantation and nurses who worked as transplant outpatient coordinators were more likely to hold beliefs that transplant patients are knowledgeable about and understand the process involved in clinical trials.

Table 7

*Standardized Regression Coefficient for Patient Understanding and Knowledge (PUK) Subscale*

| Socio-Demographic Characteristics                 | $\beta$ | P    |
|---|---------|------|
| Age   | 0.62    | 0.09 |
| Nursing experience as an RN                       | -0.43   | 0.39 |
| Nursing experience as an RN in transplantation    | -0.96   | 0.02 |
| Do you interact with patients in clinical trials? | 0.07    | 0.69 |
| Diploma prepared nurses                           | -0.65   | 0.26 |
| Baccalaureate prepared nurses                     | -0.19   | 0.76 |
| Graduate degree in nursing                        | -0.07   | 0.87 |
| Outpatient coordinator                            | 0.81    | 0.02 |

The regression model for nurses' views about where clinical research should be conducted and the roles of transplant physicians and nurses in clinical trials revealed that only 1% of variance in the RL subscale's scores could be explained by the independent variables used in this model. None of the selected variables were statistically significantly associated with nurses' views about the location of clinical trials and roles of nurses and physicians in clinical trials (Table 8).

Table 8

*Standardized Regression Coefficient for Roles and Location (RL) subscale*

| Socio-Demographic Characteristics                 | $\beta$ | p    |
|---|---------|------|
| Age   | -0.54   | 0.18 |
| Nursing experience as an RN                       | 0.86    | 0.12 |
| Nursing experience as an RN in transplantation    | -0.30   | 0.49 |
| Do you interact with patients in clinical trials? | 0.08    | 0.65 |
| Diploma prepared nurses                           | 0.26    | 0.68 |
| Baccalaureate prepared nurses                     | 0.22    | 0.75 |
| Graduate degree in nursing                        | -0.19   | 0.64 |
| Outpatient coordinator                            | -0.01   | 0.97 |

The regression model for the nurses' beliefs about patients' decision making process and desire for information in relation to clinical trial participation showed that 12% of variance in the INP subscale could be attributed to the independent variables used in this model. Analysis of standardized regression coefficients showed that none of the selected independent variables had statistically significant association with the INP scores (Table 9).

Table 9

*Standardized Regression Coefficient for Information Needs of Patients (INP) subscale*

| Socio-Demographic Characteristics                 | $\beta$ | P    |
|---|---------|------|
| Age   | 0.33    | 0.44 |
| Nursing experience as RN                          | -0.47   | 0.43 |
| Nursing experience as an RN in transplantation    | -0.23   | 0.62 |
| Do you interact with patients in clinical trials? | 0.09    | 0.63 |
| Diploma prepared nurses                           | -0.63   | 0.35 |
| Baccalaureate prepared nurses                     | -0.43   | 0.57 |
| Graduate degree in nursing                        | -0.39   | 0.38 |
| Outpatient coordinator                            | 0.51    | 0.21 |

### **Additional findings.**

Twenty-nine nurses' provided written responses to the two open-ended questions. These responses were categorized by the researcher and are described below.

Open-ended question 1 - "What are some barriers to your participation as a nurse in clinical trials?" Table 10 summarizes nurses' responses to this question as categorized by the researcher.

Table 10

*Barriers to Participation in Clinical Trials (n=29)*

| Category  | n  | %    |
|---|----|------|
| Lack of training in and information about clinical trials | 15 | 51.7 |
| Lack of time  | 8  | 28.0 |
| Lack of opportunities to provide input                    | 2  | 6.8  |
| Lack of administrative support                            | 2  | 6.8  |
| Lack of financial support                                 | 1  | 3.4  |

About half of the nurses (n= 15) expressed that “Lack of training in and information about clinical trials” was a barrier to their participation in clinical trials. Nurses’ comments highlighted that nurses felt there was a *“lack of information on the unit regarding what trials are currently ongoing”* (Participant 31). In addition, participants reported that there was a lack of information about the purposes of the trials, how to properly administer investigational medications, and how to accurately monitor clinical trials’ patients. In general, participants felt they were not well prepared to participate in clinical trials as highlighted by the following comments:

*“There is not enough education for staff about the different trials for us to both properly administer and monitor them”* (Participant 32).

*“We do not understand the study well”* (Participant 17).

Furthermore, about one quarter (n=8) of the nurses specified “Lack of time” as a barrier to their participation in clinical trials. In particular, nurses’ workloads were emphasized as limiting their ability to be involved in clinical trials as reflected in this quote:

*“Most of us have a heavy patient workload. Therefore, clinical trials duties are not possible!!” (Participant 37).*

“Lack of administrative and financial support” was evident as a barrier in three nurses’ comments. Specifically, one participant thought that nurses’ involvement in clinical trials is *“not seen as important by nursing admin in this area”* (Participant 34).

A small number of nurses (n=2) also felt that their role in clinical trials was limited to the technical skills and their input was not sought, as indicated by the following comment:

*Nurses are not asked for our input. We only act as a technician in drawing blood and for administering medications. We are not informed of the nursing research/clinical trials”* (Participant13).

Finally, one nurse felt that “Lack of reimbursement” was a barrier to nurses’ involvement in clinical trials. The nurse stated that *“I am not paid to do that”* (Participant 27).

Open-ended question 2 - “What can be done (within the transplant unit) to enhance transplant nurses’ participation in clinical trials?” Table 11 summarizes strategies highlighted by nurses that could be used to enhance participation in clinical trials.

Table 11

*Interventions to Enhance Nurses Participation in Clinical Trials (n=29)*

| Category                     | n  | %    |
|------------------------------|----|------|
| Educational Strategies       | 21 | 72.4 |
| Additional Resources         | 6  | 21   |
| Incentives and Reimbursement | 3  | 10.3 |

Most nurses (n= 21) indicated that implementing “Educational strategies” such as in-services, seminars and posters with information about clinical trials would be important to enhance transplant nurses’ participation in clinical trials. The respondents explained that these

strategies would better prepare them for successful participation in the trials. These nurses would like to receive information about the goals and benefits of clinical trials, what patient population is eligible to participate, results of previous studies conducted and nurses' roles and responsibilities in clinical trials. The following nurses' responses highlight these suggestions:

*"More in-services explaining the goals, benefits of studies conducted, as well as examples of benefits from different studies already conducted"* (Participant 3).

*"Increase education surrounding current clinical trials affecting my patient population, share feedback from trials and outcomes of trials"* (Participant 36).

*"Clinical trial seminars for nurses and education"* (Participant 15).

Furthermore, some nurses felt that "Additional resources" and "Incentives" were essential in order to facilitate their participation in clinical trials. In particular, some transplant nurses would prefer to have a nurse from the clinical trials' department available on the unit to answer clinical trial related questions and phlebotomists to collect blood samples. Having allocated time for clinical research would also be helpful for nurses. Furthermore, receiving incentives and being reimbursed for participation in clinical trials were expressed by three nurses as potential supports. However, nurses did not comment on what specific incentives were needed.



## **Chapter 6: Discussion**

At the beginning of this chapter the representativeness of the sample is described. The key findings for each of the research questions are then discussed.

### **Representativeness of the Sample**

The sample socio-demographic characteristics were compared to the socio-demographic profile of RNs in both Ontario and Canada to assess representativeness of the sample. The College of Nurses of Ontario (CNO) (2010) and Canadian Nurses Association (CNA) (2010) documents do not report the socio-demographic data on transplant nurses. Therefore, the author used the available socio-demographic data on RNs in general. A recent publication by the CNO (2010) revealed that on average, nurses practicing in Ontario are 46.5 years old, whereas, the average age of nurses in Canada in 2008 was 45.1 years (CNA, 2010). The mean age of nurses who participated in this study was 35.3 years (SD 9.3), indicating that the study sample is slightly younger than nurses in Ontario and Canada. The reason for the younger age group in the transplant sample is unclear; however, it could be related to the fact that the institution in which the study was conducted is a university-affiliated hospital in an urban setting, which is an attractive work setting for recent graduates. In addition, the nature of the work and on-going innovations in transplantation may possibly be appealing to young nurses. It is also possible that some nurses decide to pursue further education (e.g., a graduate degree, various nursing certifications), which may require a change in an area of practice or employment status (e.g., part time, casual). Nurses who work on a casual basis were excluded from the current study.

Regarding the highest level of nurses' education in Ontario, 24% of nurses were diploma educated and 75% of nurses had a baccalaureate degree in nursing (CNO, 2010). In Canada, 62% of nurses had diploma in nursing, 35% of nurses had a baccalaureate degree and about 3%

possessed a graduate degree in nursing (CNA, 2010). The results of the current study revealed that 16% of nurses were diploma prepared, 76% of participants were baccalaureate prepared and about 8% had a graduate degree in nursing. It could be concluded that the sample of participants in this study is more closely representative of the nursing population in Ontario and less representative of nurses in Canada. A possible explanation could be that a baccalaureate degree has been an-entry-to-practice requirement for RNs in Ontario since 2005 (CNO, 2010); hence, more nurses tend to pursue their baccalaureate education and be employed in specialised acute care settings as compared to diploma prepared nurses.

The sample of the current study was compared to the accessible population, that is, all transplant nurses on the MOT department in the healthcare institution where this study was conducted. According to administrative data, the majority of transplant nurses in the participating unit have a baccalaureate degree, are in the early thirties or younger and have five or fewer years of experience as an RN in transplantation. Hence, this study sample was fairly representative of the accessible population with regard to these characteristics. It is evident that overall the socio-demographic characteristics of this sample were similar to those reported provincially. However, the extent to which the sample was representative of the target population, transplant nurses, in Ontario and Canada in terms of age, education level and primary position remains unknown.

### **Key Findings**

Overall transplant nurses expressed positive attitudes toward clinical trials. They believed that transplant patients participate in clinical trials with the hope for better medical care, are knowledgeable about clinical trials, understand their treatment regimens and want to be informed about clinical trials. Nurses also thought that transplant clinical trials did not need to be conducted only in transplant care centres and indicated that transplant physicians and nurses

do not to put pressure on patients to participate in these trials. Furthermore, nurses believed somewhat that transplant patients are afraid to ask questions regarding clinical trials and that these patients will accept side effects for only a small amount of benefit from these trials. Transplant nurses' expectation of the amount of benefit from treatment was high (70%), which means that nurses believe that the treatments should be highly effective before being offered to patients. Lack of education about clinical trials, lack of time, lack of reimbursement, and lack of support from administration and clinical trial staff were identified as barriers to nurses' participation in clinical trials. Finally, transplant nurses indicated that more information about clinical trials, as well as administrative and financial support are needed to enhance their involvement in these clinical trials.

This study was the first to explore the attitudes of transplant nurses toward clinical trials and transplant nurses' beliefs about patients' knowledge, understanding and informational needs in relation to clinical trials. Hence, no normative data from the area of transplantation exist against which to compare these findings. The results of this study were obtained based on the modified NAS questionnaire originally used in the oncology nurses' study by D'Amico (2007). Therefore, the findings derived from the current study's transplant sample were compared to the findings from D'Amico and within the context of data from oncology settings, and literature related to nurses' attitudes toward research in general.

#### **Nurses' attitudes toward clinical trials.**

Overall, transplant nurses held positive attitudes toward clinical trials as indicated by the mean score on the ATCR (M=31); similar results were reported by D'Amico (2007) (M=32). Burnett et al. (2001) also indicated that nurses in their study were positively oriented toward clinical trials. These findings suggest that nurses in the transplant area who participated in this

study, similar to nurses in oncology settings, believed that 1) clinical trials are essential for future improvements in care available to patients, 2) hospitals that conduct clinical research have a better standard of care, and 3) patients should be encouraged to participate in clinical trials. On the other hand, there is also a possibility that only transplant nurses who were positive in their attitudes toward clinical research responded to the questionnaire, suggesting a possible nonresponse bias, which means that nurses who did not respond to the questionnaire may not have such positive attitudes.

In this study, predominantly staff nurses on the inpatient unit responded to the questionnaire and less than 20% were outpatient transplant coordinators, which overall reflects the proportion of MOT nurses that are staff nurses versus transplant outpatient coordinators. Results of multiple regression revealed that being a transplant outpatient coordinator was associated with more positive attitudes as compared to inpatient nurses. In-patient nurses provide direct care to patients in more acute periods after transplantation and may be more likely to observe various complications due to experimental therapies as compared to transplant coordinators who care for stable patients with fewer complications overall. From the theoretical perspective personal negative or positive experiences with an object of interest may influence the type of attitude an individual forms toward this object (Ajzen & Fishbein, 1980). The extent to which experience shapes nurses' attitude should be further explored.

Others have reported differences in attitude according to the role nurses play in clinical settings. D'Amico (2007) reported that nurses who worked in corporate industry settings had more positive attitudes as compared to nurses in intensive care / bone marrow transplant units (ICU/BMTU), and in-patient medical-surgical oncology units. Furthermore, clinical trial nurses and nurses who reported "other" for primary position had more positive attitudes compared to

staff nurses (D'Amico, 2007). Burnett et al. (2001) also found that research nurses had significantly higher mean scores as compared to ICU/BMTU nurses, who had the lowest score on attitudes toward clinical trials. These findings suggest that as compared to bedside nurses, clinical trial or research nurses were more positive in their attitudes toward clinical trials, which was not surprising given the types of roles these nurses play. Strong personal beliefs in the value of clinical research, supportive nature of the research environment, motivated people with whom research nurses socialize, and previous positive experiences with the conduct of clinical research may shape positive attitudes toward clinical trials. Participants in the current study did not include nurses working in research roles and therefore, the attitudes and beliefs of transplant nurses working in these roles remain unknown.

Nurses' age was significantly associated with nurses' attitudes toward clinical trials. Specifically, older nurses were likely to have more positive attitudes than younger nurses. Burnett et al. (2001) also reported that older age (> 40 years) was a strong predictor of positive attitudes toward clinical trials. However, D'Amico (2007) indicated that age was not significantly related to attitudes. Of note, the majority of nurses in D'Amico's study were older than 40 years, indicating a possible skew in age distribution that could explain the non-significant association between attitudes toward clinical trials and age of nurses.

The relationship between age and attitudes toward clinical trials observed in the current study and the one done by Burnett et al., (2001) may be explained by other factors related to age that might also be associated with attitudes. In the current study, primary position, specifically transplant outpatient coordinator, was also associated with positive attitudes toward clinical trials. On average, outpatient coordinators were 45.6 years old as compared to the staff nurses, who were 31.4 years old. This may suggest possible collinearity between age and position or

correlation between these independent variables (Burns & Grove, 2009). Future research should identify the unique contribution of age and position to attitudes.

**Nurses' beliefs about patients' knowledge, understanding and informational needs.**

The results obtained in the current study in relation to transplant nurses' perceptions about patients' motivation to participate in clinical trials were compared with results from D'Amico's (2007) study conducted in an oncology setting.

Predominantly transplant nurses believed that patients participate in clinical trials because they hope for better medical care (90 %). In contrast, D'Amico (2007) reported that the majority of oncology nurses (93%) believed that patients participate in clinical trials with the hope for a cure for their cancer, which is similar to the findings reported by Daugherty et al. (1995), Meropol et al. (2003), Shutta and Burnett (2000), and Yoder et al. (1997), who investigated motivations of oncology patients for participation in clinical trials. Patients who participated in these studies indicated the primary reason for their participation was the wish for a cure. One of the possible explanations for the differences in findings between the transplant versus oncology settings could be that transplantation is not a cure but a treatment that requires a person to take on-going medications to prevent rejection of the transplanted organ (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2010). The focus of the investigational treatments in clinical trials is to enhance the effectiveness of these medications and minimize their side effects (University Health Network [UHN], 2010). On the other hand, in oncology settings life-prolonging treatments may not always be available to patients with advanced stages of cancer; hence, the focus of clinical trials is to find new treatments with the overall hope to cure cancer in the future (National Cancer Institute [NCI], 2008). These

differences in goals of the investigational therapy in the oncology and transplantation could have possibly influenced nurses' responses. These differences need to be investigated in the future.

Of note, 75% of transplant nurses also selected hope for a cure as a reason for transplant patients' participation in clinical trials. Since transplantation is not a cure but a long-term treatment, why transplant nurses selected this option remains unclear. Transplant nurses may view transplantation as a cure or as the only solution for an end stage organ disease. Hence, once the main cause of an individual detrimental condition is resolved transplant nurses may have considered that this individual was cured. However, the exact nurses' meaning of *cure* in the transplant setting needs to be further explored.

Nurses' views about where clinical research should be conducted were explored in the current study. The results showed that most nurses disagreed that clinical research should only be conducted in transplant centres. Similar findings were reported by D'Amico (2007).

Nurses' views about the roles of transplant physicians and nurses in clinical trials were explored in the current study. The findings revealed that transplant nurses believed that transplant physicians and nurses did not put too much pressure on patients to participate in clinical trials. D'Amico (2007) also reported that oncology nurses disagreed that oncology physicians and nurses put too much pressure on patients to participate in clinical trials. These findings suggest that nurses believe that patients' wishes to participate in clinical trials are respected by nurses and physicians in transplant and oncology settings.

Transplant nurses' beliefs about patients' knowledge, understanding, and informational needs in relation to clinical trials were evaluated in the current study. Overall, transplant nurses believed that patients are knowledgeable about clinical trials, understand their treatment regimens and want to be informed about clinical trials as measured by the PUK subscale.

Similarly, oncology nurses agreed with statements that oncology patients are well informed about clinical trials and understand their treatment regimens as reported by D'Amico (2007). Nurses' work experience and primary position may also influence nurses' beliefs about the conduct of clinical trials. Multiple regression analysis revealed that nurses who had less experience in transplantation and nurses with a primary position as outpatient coordinators tended to have more positive views about patients' knowledge and understanding about clinical trials. Outpatient coordinators, as previously described, provide care for more stable transplant patients and may have more allotted time to interact with these patients as compared to in-patient nurses. During this time outpatient coordinators may have more opportunities to explore transplant patients' understanding, knowledge and informational needs in relation to clinical trials. Hence, their positive experiences from such interactions with transplant patients might positively influence their beliefs about patients' knowledge and understanding of clinical trials. On the other hand, in-patient nurses care for more unstable patients, are more likely to observe patients' complications from treatments, and may have fewer opportunities to explore transplant patients' knowledge and understanding of clinical trials; as a result, they may form more negative views.

It is also possible that beliefs of in-patient nurses with less experience reflect overall positive views about the conduct of clinical trials, and about patients' optimal knowledge and understanding of clinical trials learned in their research courses. However, with more years of experience, in-patient nurses possibly shape different views based on their direct practice experience with patients who participate in clinical trials; specifically, if these experiences are negative in-patient nurses are likely to shape more negative views about clinical trials.



Transplant nurses' beliefs about patients' decision-making process and desire for information about clinical trial participation were investigated in the current study. Transplant nurses agreed somewhat that patients were afraid to ask questions, that patients' decisions in relation to therapy were influenced by their family members' presence, and that patients were willing to accept side effects even for a small amount of benefit in therapy. D'Amico (2007) reported similar results. It is well documented in the literature that when interacting with health care professionals, patients might feel intimidated to ask questions pertaining to their care in general (Jangland, Gunningber, & Carlsson, 2009; Mooney, Fitzsimons, & Richardson, 2007). In addition, family members' presence when discussing the care plan was identified as beneficial by patients in these studies because they could ask questions on patients' behalf and assist patients with making decisions pertaining to their care (Jangland et al., 2009; Mooney et al., 2007). These findings reflect patients' experiences with care in general hence, suggesting that patients might have similar experience when making decisions about their participation in clinical trials.

#### **Expectations of benefit.**

Transplant nurses' beliefs about how effective a research drug or experimental therapy should be before it is offered to patients were also investigated in this study. Overall, transplant nurses believed that an experimental drug should be at least 70% effective before being offered to patients. In the study conducted by D'Amico (2007), staff nurses, nurses with baccalaureate degrees, and nurses with less than 10 years of experience believed that an investigational therapy should be at least 50% effective. In addition, Burnett et al. (2001) found that in-patient nurses believed that a research drug should be at least 50% effective prior to being offered to patients in clinical trials. Studies investigating perceptions of the benefits of research treatments among patients with cancer demonstrated that patients had high expectations from clinical cancer

research. Meropol et al. (2003) reported that patients entering phase I clinical trials believed that their chance of benefit was at least 50%, which was similar to expectations of oncology nurses.

Transplant nurses' expectations of benefit from the experimental therapy were considerably higher than expectations of oncology nurses and patients, which could be influenced by the fact that positive outcomes were observed by transplant nurses with the standard immunosuppressive therapy already available to transplant patients. Hence, to achieve further improvements in treatments and better outcomes for patients, nurses may have believed that the expectation of benefit from the investigational therapies should be high. However, oncology nurses may have different experiences with oncology patients such as no treatment options available for cancer patients. These experiences may in fact influence oncology nurses' views about expectations of benefit from the investigational treatments in cancer settings. As suggested by the TRA, individual positive or negative experiences with an object of interest (i.e. clinical trials) may shape personal beliefs and a positive or negative attitude toward the object this individual forms (Ajzen & Fishbein, 1980). Specifically, oncology nurses' experience with patients in clinical trials (e.g. no treatment available to patients) may influence nurses' personal beliefs that medications even with a small amount of benefit need to be offered to oncology patients. On the other hand, in transplant nurses' experiences standard medications with good effects are usually available to transplant patients; hence, transplant nurses may form a belief that expectations of benefit from the investigational treatments need to be high before it is offered in a clinical trial.

### **Barriers and Supports**

Transplant nurses identified several barriers to nurses' participation in clinical research. Over half of transplant nurses in the current study felt that lack of training in and information

about transplant clinical trials limited their participation in these studies. No studies exploring nurses' knowledge about clinical trials were found by the author. However, the importance of nurses' knowledge about research in general was identified in the literature. Roxburgh (2005) reported that a deficit of knowledge about the research process and skills to undertake research were significant factors impeding nurses' research participation. Furthermore, Witzke et al. (2008) argued that nurses' lack of confidence in their knowledge and ability to conduct research were significant barriers to nurses' participation in research related activities. On the other hand, Titler et al. (2001) found that even though nurses reported high levels of knowledge and ability to perform research, their willingness to participate in research remained low. Based on these findings it could be concluded that training alone is not sufficient for nurses' participation in research related activities. Therefore, other factors need to be considered to understand nurses' willingness to actually participate in these studies. Some of these factors could be level of support and time available for involvement in research.

Lack of time to participate in research activities was identified in this study as a frequent barrier to transplant nurses' participation in clinical research. It is also well recognized in the literature that having not enough time hinders nurses' involvement in research related activities (Bjorkstrom & Hamkin, 2001; Kuuppelomaki & Tuomi, 2003; Lopez-Bushnell, 2002; Olade, 2003). Nurses play various roles in the health care environment; most importantly they provide direct care to patients. Direct care for patients who are enrolled in clinical trials often includes completion of patient care activities required by these studies. However, nurses frequently viewed these clinical trial related activities as additional to direct patient care; hence, they perceived having limited time to be involved in these activities. This in fact raises the questions of how clinical trials are introduced in the nursing environment, whether nurses are informed

about the purpose of clinical trials, and the importance of clinical trial task completion for participating patients.

Lack of administrative and financial support, and opportunities to provide input into the implementation of clinical trials on the transplant unit were identified by transplant nurses as aspects that limit their participation in clinical trials. Similarly, Roxburgh (2005), and Tanner and Hale (2002) reported that lack of managerial, staff and financial support were barriers to nurses' involvement in research studies. In relation to clinical trial research, Baer et al. (2011) reported that nurses are responsible for administering investigational agents and monitoring outcomes; however, they are usually not on the payroll of these clinical trials suggesting, that nurses' contribution to the conduct of clinical trials may not always be adequately reimbursed. In the current study 67% of nurses reported that they administered investigational treatments to patients, and about 55% managed patients' side effects related to these treatments and documented patient assessments and outcomes. In addition, one nurse pointed out that nurses were not reimbursed for their participation in these trials, further supporting the fact that nurses tend to view clinical trial related activities separately from their nursing tasks. It could be concluded that even though nurses play a significant role in clinical trials, their input in the conduct of clinical trials is not always sought or incorporated and they may not have much needed support systems. These considerations could influence nurses' perception of clinical trial activities as additional to their nursing role functions.

The majority of transplant nurses in this study emphasized that various educational strategies about the research studies being conducted on the unit (e.g., in-services, posters, seminars) would facilitate their participation in these studies. Baer et al. (2011) argued that education of nurses about current clinical trials (e.g., any special requirements associated with

the investigational agents, their potential adverse effects, and how to monitor patients) is essential to promote staff nurses' participation and their satisfaction with the conduct of clinical trials, and to maintain the quality of these trials. Engaging potential participants (e.g., nurses) in the decision- making process about clinical trials may contribute to the development of a clinical research culture on the unit (Baer et al., 2011). In addition, various resources to assist nurses with the conduct of clinical trials were deemed important by participants. In the present study, some transplant nurses suggested the need for a clinical trial nurse on the unit to answer clinical trial related questions, phlebotomists to collect samples, and reimbursement/ incentives to facilitate their involvement in clinical trials. Resources to support nurses in clinical trial participation and collaboration among research and non-research staff members may contribute to enhanced nurses' satisfaction with the conduct of clinical trials (Baer et al., 2011).

## Chapter 7: Summary, Implications and Conclusion

### Summary

Clinical trials are essential in identifying the effectiveness of preventative or therapeutic interventions in transplant settings. Nurses' roles in transplant clinical trials may include primary investigators, research coordinators, direct caregivers, educators and/or patient advocates. How nurses view clinical trials and patients' understanding of the clinical trial process may shape various roles nurses play in the clinical trials. Yet, there is a paucity of information about transplant nurses' attitudes about clinical trials in general, beliefs about patients' understanding, knowledge and informational needs in relation to clinical trials, and factors that may influence their attitudes and beliefs toward clinical trials. The current study begins to address this gap in the literature.

A convenience sample of 39 transplant nurses was recruited from one urban tertiary health care centre in Southern Ontario. The *Nurses' Attitudes Survey* (D'Amico, 2007) was modified to reflect the transplant setting and administered to nurses. Participants also answered two open-ended questions related to barriers and supports for the conduct of clinical trials.

Overall, study results indicated transplant nurses held positive attitudes toward clinical trials. Specifically, older nurses and nurses in the position of an outpatient coordinator tended to have more positive attitudes. The majority of participants reported involvement in clinical trials related activities, which predominantly included collecting study specimens and administering investigational medications. In general, nurses believed that transplant patients 1) participate in clinical trials because they hope for better medical care, and 2) are knowledgeable about clinical trials and understand their treatments. Nurses viewed that transplant clinical trials need to be conducted not only in transplant care centres. Participants also thought that research nurses and

physicians do not put pressure on patients to participate in clinical trials. Nurses with less experience in transplantation and outpatient coordinators had more positive views about patients' knowledge and understanding about clinical trials. Finally, transplant nurses believed that patients were afraid to ask questions about clinical trials and would accept side effects for even a small amount of benefit from the investigational therapy. Of note, transplant nurses believed that investigational therapy should be at least 70% effective before it is offered to patients.

Responses to the open-ended questions revealed that a perceived lack of training and information about clinical trials, and lack of time were major barriers for transplant nurses' participation in clinical trials. Hence, nurses believed that to enhance their participation in clinical trials, educational in-services or seminars about clinical trials, and additional resources (e.g., phlebotomists) were warranted.

### **Study Limitations**

There are some limitations inherent in the study. Even though the anticipated response rate was achieved, the sample size was relatively small. The small sample size could be attributed to a number of design factors. The length of the questionnaire and the time commitment of 15 minutes to complete it might have affected the response rate. The study requirements may have conflicted with nursing care demands (busy assignments) limiting nurses' time for research participation. It is also possible that the low response rate reflected nurses' low interest in the topic under study. The enrolment in the study started before the Easter holidays when fulltime staff were more likely to take vacations and time off work (more casual staff were employed who were not eligible). If this study were conducted at a different time, a higher response rate could possibly have been achieved. However, limited resources did not allow extending the enrolment time for this study. The Cronbach  $\alpha$  coefficient was lower than

the widely acceptable cutoff value for a new scale of  $\geq 70\%$  (Burns & Grove, 2009) for two subscales on the questionnaire. Hence random error of measurement might have been introduced which might have attenuated the correlation coefficients for these subscales (Burns & Grove, 2009). For these reason the study findings need to be interpreted with caution.

### **Implications**

In spite of these limitations, the study is among the first to begin to address transplant nurses' attitudes and beliefs toward clinical trials. The findings provide some preliminary evidence with implications for nursing practice, policy, research, theory and education.

#### **Implications for practice and policy.**

The findings suggest that transplant nurses have positive attitudes and beliefs toward clinical trials. Most participants were involved in clinical trial activities. However, they reported lack of training in and information about clinical trials. These findings suggest the incongruence between the roles that nurses say they are playing and their perception of preparation to fulfil their roles. Findings imply issues in how clinical trials are incorporated in nursing practice on the transplant unit and point to the need for a standardized approach to integrate clinical trials in practice. At the institutional level, guidelines are needed to facilitate integration of clinical trial studies into nursing practice, delineating how to introduce a new trial to nursing staff and to educate staff about the purpose of the trial and its requirements. Such guidelines would support nurses' meaningful participation in a particular trial.

This study's findings indicated that transplant nurses were engaged in clinical trials; however, they identified lack of time, and of administrative and financial support as barriers to their participation. Some participants suggested that additional resources such as availability of a clinical trial nurse on the unit to answer clinical trial related questions, phlebotomists to collect



samples, and reimbursement/ incentives were important to encourage their involvement in clinical trials.

A possible solution to address participants' concerns is introducing strategies to enhance collaboration among various professionals in the clinical trial process. A collaborative approach to the conduct of clinical trials, in which research tasks are appropriately delegated to involved staff, was emphasized by Baer et al. (2011). Collaboration among staff involved in the conduct of clinical trials and management of patient care activities in in- and outpatient settings may contribute to sharing of knowledge, streamlining procedures and ensuring that the clinical trial budget accurately reflects the needed personnel. No single individual can accomplish all tasks required for a clinical trial. Therefore, appropriate delegation of tasks by clinical research leaders (e.g., phlebotomists to collect study samples, availability of a clinical trial nurse to address questions/issues) could be put in place to achieve overall staff satisfaction with the conduct of clinical trials, quality outcomes of these trials, and optimal financial expenditure for these trials (Baer et al., 2011). In addition, collaborative multidisciplinary research rounds could be facilitated on the transplant unit. Finally, nursing administration may need to consider possible implications of caring for clinical trials patients on nurses' workloads and take this into account when planning for staffing patterns.

### **Implications for research.**

The current study findings provide preliminary evidence suggesting positive nurses' attitudes and beliefs about clinical trials. However, there is a need for further research to explore how nurses' attitudes toward clinical trials influence nurses' clinical trial-related behaviours. Findings in the current study suggest that the majority of transplant nurses engaged in clinical trials activities and that these activities were predominantly limited to administration of

investigational medications and collection of blood specimens. Activities such as managing side effects related to investigational medications and documenting patients' condition and progress were performed by approximately one half of transplant nurses. In addition, familiarizing patients with the study protocol and answering patients' questions about clinical trials were reported by fewer than 30% of transplant nurses. No literature is available about the transplant nurses' type and amount of responsibilities in clinical trials; specifically, what are the clinical trial organizers' expectations of transplant nurses in relation to clinical trials. In the future, research studies could focus on understanding expectations of nurses in clinical trials and what support nurses may need to better fulfil these expectations. This could possibly be achieved by conducting qualitative studies (e.g. focus groups and/or individual interviews) exploring common themes related to clinical trial organizers' and transplant nurses' views about nurses' roles in clinical trials and supports required to best accomplish these nursing roles.

The study sample was relatively homogenous in relation to transplant nurses' level of education. This may have limited the ability to detect significant association between nurses' education and attitudes and beliefs about clinical trials. A larger more diverse sample of nurses is needed to explore whether such relationships exist. One possible strategy to increase sample variability in future studies would be to recruit transplant nurses from multiple sites provincially and nationwide.

Transplant nurses in the present study believed that transplant patients participate in clinical trials because they hope for better medical care. These findings may suggest an inherent difference in nurses' experiences with and perspectives about clinical trials conducted in transplant as compared to oncology clinical programs. In future, qualitative studies exploring

nurses' perception of the purpose of transplant clinical trials are warranted because it may influence the role nurses play in these studies.

### **Implications for theory.**

The Theory of Reasoned Action (TRA) was used to guide the design of the current study. Nurses' personal beliefs or attitudes toward a behaviour were assessed. The assessment of normative (perceived beliefs of others) and control beliefs (perceived behavioural control) was beyond the scope of the current study. However, participating nurses commented on the lack of time, and of administrative, financial, and educational supports as barriers to their participation in transplant clinical trials, which might suggest that nurses believed that they had a lack of control in performing clinical trial-related activities. According to the TRA, people form control beliefs based on availability of or lack of various factors (e.g., knowledge, skills, time, resources) that may facilitate or impede the actual performance of behaviours (Fishbein & Ajzen, 2010). An in-depth investigation of the control transplant nurses have over performing their behaviours from the perspective of personal readiness to undertake clinical trials activities, availability of opportunities to engage in specific clinical trials and various support systems (e.g., education about clinical trials, peer mentorship) on the unit, and how these control beliefs influence their actual participation in clinical trials is warranted in future studies. If control beliefs present more impeding than enabling factors, individuals (e.g., transplant nurses) may be less likely to engage in actual performance of behaviours (Fishbein & Ajzen, 2010). Qualitative inquiry (e.g., focus groups and/or individual interviews) as well as quantitative descriptive studies could be undertaken to explore transplant nurses control beliefs.

Finally, according to the TRA, individual behavioural, normative and control beliefs predict a person's intent to perform or not perform a behaviour of interest (Fishbein & Ajzen,

2010). The current study was an initial step in exploring transplant nurses' attitudes and beliefs toward clinical trials with an ultimate goal to better understand nurses' clinical trials-related behaviours. The relative importance of behavioural, normative and control beliefs, the interrelationships between these beliefs and their influence on the nurses' behavioural intent, and actual performance of behaviours need to be investigated to better understand nurses' participation or non-participation in clinical trials. Quantitative studies (e.g., descriptive, correlational) could be designed to test the interrelationship among various types of beliefs and their influence on the performance of behaviours.

### **Implications for education.**

Nurses in the current study expressed the need for information about clinical trials in transplant settings. Specifically, transplant nurses recommended implementation of educational strategies (e.g., in-services, seminars, posters) about upcoming clinical trials to enhance their knowledge about research and expectations for their participation in trials. Witzke et al. (2008) suggested the importance of assessing nurses' knowledge of a study prior to developing an educational strategy or an educational program (e.g., a workshop, a course) that will best address nurses' research knowledge needs. Witzke et al. also recommended incorporating an overview of nursing research skills when orienting new nurses. Similar strategies could be implemented for transplant nurses. Namely, a workshop or a course for transplant nurses about clinical trials could be developed as well as a clinical trial skills review incorporated in the orientation of new nursing staff if they are expected to participate in clinical trials. Knowledge translation activities (e.g., in-services, multidisciplinary research rounds) to inform nurses about results of previous studies and share information about on-going clinical trials could also be implemented to enhance nurses' participation in clinical trials.

## **Conclusion**

The current study explored transplant nurses' attitudes and beliefs toward clinical trials and factors that might influence these attitudes and beliefs and examined barriers to transplant nurses' participation in clinical trials and supports needed to enhance transplant nurses' involvement in the clinical trials. No published studies have explored these aspects within transplant settings. The current study findings suggest that transplant nurses have positive attitudes and beliefs in relation to transplant clinical trials but they may require educational, administrative and financial support to enhance their participation in clinical trials.

### Demographic Information Form

Please answer the following questions by checking the appropriate box or filling in the blank. You are free to refuse to respond to any of the items on this form.

1. What is your age? \_\_\_\_\_ years old (*please insert a number*)
2. Indicate your highest level of education.
  - ☐ Diploma in nursing
  - ☐ Baccalaureate degree in nursing
  - ☐ Baccalaureate degree in another field
  - ☐ Graduate degree in nursing
  - ☐ Graduate degree in another field
3. Years of experience as RN ? \_\_\_\_\_
4. Years of experience as RN in transplantation? \_\_\_\_\_
5. Do you interact with patients who are enrolled in clinical trials?
  - ☐ Yes                      ☐ No

If "YES" please select all activities that would best describe your involvement with patients participating in clinical trials from the list below (please check all that apply):

- ☐ Familiarizing patient with the study protocol
- ☐ Administering investigational medications
- ☐ Managing side effects related to these medications
- ☐ Documenting patients' assessment and progress
- ☐ Answering patients' questions related to the clinical trial process and treatments / procedures

☐ Contacting investigators in relation to the study

☐ Collecting specimens as per study protocol

Other, (please list) \_\_\_\_\_

6. What is your primary position? (*Select one*)

☐ Staff nurse

☐ Nurse in administrative /educational position

☐ Transplant outpatient coordinator / nurse practitioner

**Invitation to Participate in a Research Study  
Consent Letter**

**Title: Attitudes of Transplant Nurses' toward Transplant Clinical Trials**

Dear Transplant Nurse;

You are invited to participate in a research study that examines transplant nurses' attitudes toward clinical trials and nurses' beliefs about transplant patients' understanding, knowledge and informational needs in relation to clinical trials. This study is being conducted by Olesya Kolisnyk as a part of her Masters' degree educational requirements. Her thesis supervisor is Dr. Heather Beanlands from the Daphne Cockwell School of Nursing at Ryerson University.

If you choose to participate you will be asked to complete the Demographic Information Form and Transplant Nurses' Attitude Survey. Your name will not be on the Demographic Information Form or Transplant Nurses' Attitude Survey and there will be no way to link your responses to you. It is anticipated that completing the Demographic Information Form and Transplant Nurses' Attitude Survey will take approximately fifteen minutes of your time. Once completed, you are asked to return these forms in one of the designated boxes in your area of practice labelled "Transplant Nurses' Attitudes Survey". Because responses are anonymous, withdrawal of your responses is not possible once your evaluations have been received. Responses will be stored in a locked file cabinet for ten years and then destroyed (shredded). Only the research team will have access to your responses and only grouped responses will be used and reported at professional nursing conferences and in professional nursing journals.

Your participation in this study is entirely voluntary and you may choose not to fill out the Demographic Information Form and Transplant Nurses' Attitude Survey. If you choose to participate, you are free to refuse to respond to any of the items on the Demographic Information Form and Transplant Nurses' Attitude Survey. Due to the anonymous nature of responses, the investigators will not know whether or not you choose to participate. Non-participation will in no way affect your future relationships and/or interactions with any person or institution involved in this study.

The investigators do not know of any harm that may arise from participating in this study. Your participation in this study will help investigators to understand transplant nurses' attitudes toward clinical trials.

If you would like to participate, please fill out the enclosed Demographic Information Form and Transplant Nurses' Attitude Survey, and once completed insert both in the envelop provided and return by placing the sealed envelope in one of the designated boxes on the unit. **Completion and return of the questionnaires implies your consent to participate in this study.** Please do not include any identifying information on any part of the Demographic Information Form and Transplant Nurses' Attitude Survey in order to ensure anonymity of your responses.

Should you require more information or have any questions, please contact Olesya Kolisnyk at [okostyuk@ryerson.ca](mailto:okostyuk@ryerson.ca) or Dr. Heather Beanlands (Thesis supervisor)  
Associate Professor, Program Director-Master of Nursing,  
Daphne Cockwell School of Nursing, Ryerson University, Toronto, Ont.  
tel: 416-979-5000 ext. 7972.

Should you have any questions about your rights as a study participant you may contact the Research Ethics Board at Ryerson University at: [rebchair@ryerson.ca](mailto:rebchair@ryerson.ca)

Nancy Walton, PhD  
Chair, Research Ethics Board  
Associate Professor  
Ryerson University POD 470B  
350 Victoria St, Toronto ,ON  
(416) 979-5000 ext 6300

THANK YOU FOR CONSIDERING THE INVITATION TO PARTICIPATE IN THIS RESEARCH.

Sincerely,  
Olesya Kolisnyk RN, MN(c)



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