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Résumé

Le rôle de l'infirmière d'essai clinique dans le processus d'obtention du consentement éclairé

Franca Cantini et Carolyn Ells

Cette étude descriptive visait à recueillir de l'information sur le rôle que jouent les infirmières d'essai clinique dans le processus d'obtention du consentement éclairé. On a fait remplir un questionnaire auto-administré de 50 éléments à 95 infirmières employées dans des hôpitaux affiliés à l'Université McGill à Montréal, Québec, Canada, qui participaient à un projet de recherche clinique dont le chercheur principal était un médecin et les sujets des adultes compétents. Les infirmières étaient toutes membres de l'association provinciale des infirmières. L'analyse révèle que les infirmières d'essai clinique jouent un rôle important dans l'obtention du consentement éclairé et qu'elles vivent des conflits d'intérêts et des dilemmes d'ordre éthique dans l'exercice de ce rôle. L'étude confirme la nécessité d'élaborer des lignes directrices précises en matière de pratique et d'éthique pour guider les infirmières en recherche clinique, ainsi que des programmes de formation.

Mots clés : consentement éclairé, essai clinique, infirmière, éthique

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The Role of the Clinical Trial Nurse in the Informed Consent Process

Franca Cantini and Carolyn Ells

The purpose of this descriptive study was to elicit information about the current practice of clinical trial nurses in the informed consent process. A 50-item self-administered anonymous questionnaire was completed by a sample of 95 nurses from hospitals affiliated with McGill University in Montreal, Quebec, Canada, who were members of a clinical trial research team whose principal investigator was a physician and whose research participants were competent adults. The nurses were all members of the provincial nurses' association. Clinical trial nurses were found to have an important role in the informed consent process and to experience conflict of interest and other ethical dilemmas as members of clinical trial research teams. There is a need to develop specific practical and ethical guidelines for nurses involved with clinical trial research and to develop educational programs for nurses working in clinical research.

Keywords: Informed consent, clinical trial, nurse, ethics, research ethics

Introduction

The extent of today's involvement of nurses in the informed consent (IC) process in research is unclear. In the Canadian province of Quebec, as documented by Deschamps et al. (1995), nurses are the professional group most commonly called upon to collaborate with a principal investigator (PI), usually a physician, in clinical trial research. But not only is there no official, standard title for these nurses — among the many variations are research assistant, research nurse, study coordinator, study nurse, nurse coordinator, and clinical trial nurse (CTN) — there is also a lack of practical guidelines issued by professional nursing organizations such as the Ordre des Infirmières et Infirmiers du Québec (OIIQ) for defining the role and responsibilities of these nurses.

The literature reveals that nurses are actively participating as members of research teams in the clinical setting (Arrigo, Gall, Delogne, & Molin, 1994; Barrett, 2002; Berry, Dodd, Hinds, & Ferrell, 1996; Davis, Chandros Hull, Grady, Wilfond, & Henderson, 2002; Di Giulio et al., 1996; Ehrenberger & Aikin, 2003; Ehrenberger & Lillington, 2004; Lynch, 1988; McLean, 1996; Mueller, 2001; Papakonstantinou et al., 1997; Sadler, Lantz, Fullerton, & Dault, 1999). However, the lack of guidelines, policies, and job descriptions for CTNs (Davis, 1989; Davis et al.; Johnson, 1986), and the participation of CTNs in clinical trials for which they are not the PI

of the study (Berry et al.; Mueller), has wrought confusion as to the functions and ethical obligations of these nurses. For instance, CTNs experience conflict between their loyalty to the investigator, their responsibilities to the sponsoring for-profit companies, and their primary responsibility to serve the interests of the study participants. This has caused CTNs to question their duty and their moral obligations. It has been suggested that ethical dilemmas and conflicts of interest experienced by CTNs are sometimes related to the fact that the PI is a physician (Davis, 1989; Johnson).

The literature contains sparse empirical data on the number of nurses participating in the IC process and the level of their participation. Nevertheless, the activities of CTNs as described by several authors reveal that it is common practice for PIs to delegate responsibility for obtaining IC partially or totally to CTNs (Arrigo et al., 1994; Berry et al., 1996; Davis, 1989; Davis, 1988; Deschamps et al., 1995; Lynch, 1988; McLean, 1996; Ocker & Pawlik Plank, 2000; Sadler et al., 1999). But the real nature of CTNs' role in the IC process remains unclear, as do the conflicts of interest and ethical dilemmas that attend the nurses' participation in the IC process.

In reporting on their 1994 quantitative study, Arrigo and colleagues describe CTNs' involvement in the IC process as providing information to the patient (73%) and participating in obtaining IC (56%). However, these investigators do not provide much information regarding the nature of the nurses' participation in the IC process, nor do they identify the point at which the nurses become involved in the IC process. Further, they do not address or identify ethical dilemmas or conflicts of interest encountered by CTNs related to the IC process.

More recent studies have begun to provide specific details about the roles of CTNs in the IC process. Ocker and Pawlik Plank (2000) evaluate the role of CTNs through literature review, analyses of job description, and discussions with CTNs. Their research reveals that CTNs may assess the knowledge and concerns of potential participants and their families about clinical trials at the beginning of and during the IC process. In addition, CTNs assess the potential participants' and families' understanding of information given about the research as well as education (mainly disclosure of information) associated with the IC process. This can include assessing potential participants' ability to read and comprehend the information given and helping them to understand "the randomization and registration process, the treatment goals of the study, the study requirements, the alternatives to the research study, and the potential benefits, side effects, or complications of the treatment protocol." For the health professionals involved in the study, job descriptions were drawn up and these distinguished the roles of CTNs in a

combined oncology research and clinical setting from the roles of the other team members. The authors report that CTNs were more satisfied with their jobs after receiving a job description (which included their role in the IC process) because of the clarity about role accountability and responsibility and the legitimacy that the job description lent to their role.

In 2004, Ehrenberger and Lillington published a study on the development of a reliable and valid measurement tool to delineate the role of CTNs (Ehrenberger & Lillington, 2004). They include the IC process as one of eight distinct CTN roles. According to the authors, CTNs "explain the study to the potential subject using the basic elements of informed consent (e.g., purpose, benefits, risks)" and "assess the potential subject's understanding of the consent form information." Note that for this measurement tool disclosing information about the research is not called "education" or "reinforcement" but is squarely classified as a CTN responsibility integral to the IC process. The authors also specify a role for CTNs in identifying and supporting discussion of ethical issues related to research.

Some agencies (Canadian Nurses Association, 2002; International Council of Nurses, 2000; Ordre des Infirmières et Infirmiers du Québec [OIIQ], 2005) have developed and published codes of ethics as well as ethical guidelines regarding nurses' behaviours in their various roles. However, these codes and guidelines do not address important areas of ethical concern for CTNs participating in the IC process. (We will return to this topic in the Discussion.) More information is needed if clear boundaries are to be drawn and if practical and ethical guidelines are to be developed.

A descriptive study was designed in order to gather information about current practices in Canadian settings, with a view to developing ethical guidelines for nursing practice and eventually developing standard educational programs for nurses working in clinical research.

Ethical Framework and Concepts

Professional nursing codes of ethics were used as frameworks guiding this study, since they express the profession's ethical ideals regarding the moral behaviour of its members (Yeo & Moorhouse, 1996). For example, the *Code of Ethics for Registered Nurses* (Canadian Nurses Association, 2002) sets out the ethical behaviours expected of nurses and addresses nurses' obligation to use their knowledge and skills for the benefit of others, to minimize harm, to respect client autonomy, and to provide fair and just care for their clients.

These codes of ethics reflect major nursing goals (e.g., health and well-being, health promotion and protection, relief of suffering) and do not deem them subservient to the goals of other professions or parties. Similarly, they reflect the eight principles/values that are central to ethical nursing practice in Canada: safe, competent, and ethical care; health and well-being; choice; dignity; confidentiality; justice; accountability; and quality practice environments (Canadian Nursing Association, 2002). At the foundation of several of these values are more general ethical principles described in the work of Beauchamp and Childress (2001) — respect for autonomy, non-maleficence, beneficence, and distributive justice — which are common to most if not all health professions.

Although the dominance of the principle/value of respect for autonomy, along with a conception of autonomy that is strongly individualistic, has received scholarly criticism, the health professions continue to support and give considerable importance to respect for patient/participant autonomy in health care and research, particularly as a moral foundation for IC. Health professionals, including nurses, tend to interpret "respect for autonomy" as the obligation of professionals to communicate information, to assess and ensure comprehension of that information, to assess and ensure the voluntary choice/participation of the patient/participant, and to provide adequate time for decision-making (Beauchamp & Childress, 2001).

Key Concepts

With a study questionnaire designed to measure five key concepts, we sought both to determine the role of the CTN in the IC process and to probe for ethical issues that might arise. The first three concepts correspond to key elements of IC that are reflected in nursing codes of ethics and thus potentially come under the purview of the role of CTNs in the IC process. The first concept, *disclosure of information,* refers to information relevant to the decision whether to participate in the research (e.g., purpose of the research, the risks and benefits of participation, alternatives to participation). The second, *comprehension of information,* refers to the (potential) participant's understanding of the information disclosed during the IC process. The third concept, *voluntary participation,* refers to the freedom to decide whether to take part in the research unimpeded by coercion or manipulation, as well as the freedom to withdraw from participation at any time during the research process without prejudice.

The latter concepts seek to identify ethical challenges for CTNs related to their role in the IC process. Following Jameton (1984), the fourth concept, *ethical dilemma,* is typically divided into three categories: ethical/moral uncertainty (about what principles/values apply or what

they mean), ethical/moral conflict (when an applicable principle/value leads to conflicting courses of action), and ethical/moral distress (when a law, policy, or power relationship prevents one from taking a course of action that is warranted). For CTNs involved in the IC process, ethical dilemmas can arise from factors that negatively affect disclosure of information, (potential) participants' comprehension of information, or voluntary participation. They can arise from the lack of a clear job description, lack of clear policies and guidelines about their role, lack of adequate information about the study, or lack of sufficient information or education about the IC process. They can also arise from conflict of interest. This can be considered a subcategory of ethical dilemma, but for the purpose of our research we highlight it as a distinct concept. *Conflict of interest* refers to a situation in which two or more interests are at stake and suggest conflicting courses of action. It has the potential to compromise objectivity in the execution of one's responsibilities. Such interests can be financial, professional, personal, educational, or a combination of these and other interests. For example, CTNs may have interests in ensuring the well-being of research participants, in serving the aims of the research, and in meeting the expectations of their employers, with each interest calling for a different course of action.

Study Objectives

The study had two objectives: to describe the role of Quebec CTNs in an IC process in which the PI is a physician, and to explore conflicts of interest and ethical dilemmas encountered by nurses in fulfilling that role. The study population was limited to nurses working in collaboration with a physician as the PI, the purpose being to validate the results of earlier studies (Davis, 1989; Johnson, 1986) suggesting that dilemmas and conflicts experienced by CTNs are related to the fact that the PI is a physician.

The research questions were the following. 1. *What is the role of the CTN in the IC process vis-à-vis three distinct aspects: disclosing information, assessing the participant's comprehension of the process, and ensuring the patient's voluntary participation in the clinical trial?* 2. *What are the types and frequency of conflicts of interest and ethical dilemmas encountered by CTNs participating in the IC process?*

Methodology

Because of the limited data available regarding the role of the CTNs in the IC process, we chose a descriptive study design. Feasibility served to limit the target population and the sampling procedure.

Sample

The target population consisted of all registered nurses working in clinical trial settings, with a physician as PI, at four McGill University-affiliated hospitals: the Sir Mortimer B. Davis Jewish General Hospital, the Montreal General Hospital, the Royal Victoria Hospital, and St. Mary's Hospital. To be included in the study, the participant had to be a practising nurse (validated by membership in the OIIQ) and be a member of a clinical trial research team for which the PI was a physician and whose research participants were competent adults able to read and understand English.

Sampling Procedure

Because no registries or records identifying CTNs' names or workplaces were available, we used a convenience-type networking procedure to identify potential participants. We identified and contacted key nurses working in clinical trial settings through the Research Ethics Office Coordinators Network, a body familiar with the research being conducted in the relevant hospitals and the nurses working in clinical trial settings. These nurses in turn suggested other nurses, and the networking snowballed until no additional CTNs were identified. All identified CTNs were invited to take part in the research. They were told about the study aims, what participation would entail, possible risks and benefits, their rights and freedoms regarding the decision whether to participate, and how their anonymity would be protected. Interested parties were given a questionnaire, an accompanying explanatory letter, and a self-addressed envelope. They were instructed to complete the questionnaire and return it via internal mail using the self-addressed envelope. Four weeks after the initial contact, thank you/reminder letters were sent to all potential participants along with a second information sheet, questionnaire, and self-addressed envelope.

Questionnaire[1]

We developed our 50-item self-administered questionnaire based on the available literature (Medical Research Council, Natural Sciences and Engineering Research Council, & Social Sciences and Humanities Research Council [MRC, NSERC, & SSHRC], 1998; World Medical Association, 2004). Two questions were taken from the validated questionnaire used by Arrigo and colleagues (1994). Two thirds of the questions were close-ended, mainly Likert-type (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always) or Likert-scale (1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree). We included some

[1]For a copy of the questionnaire, contact Franca Cantini: fcantini@lab.jgh.mcgill.ca.

yes/no questions and some items asking participants to select a response from among alternatives. A third of the questions were open-ended, whereby participants could elaborate on their responses. The questionnaire was piloted to three experts in the field in order to test its reliability and face validity. Once comments from this initial pilot were incorporated into the questionnaire, the revised version was piloted to four CTNs working in various institutions and varying in age and in years of experience. As determined by the second pilot, the questionnaire required approximately 15 minutes to complete and met the objectives in terms of information sought.

Variables and Measures

Five concepts (disclosure of information, comprehension, voluntariness, conflict of interest, and ethical dilemmas) were studied. Specific questionnaire items were used to measure these study variables.

Analysis

We used SPSS and Van Kaam's (1966) method to analyze data from descriptions of respondents' "lived experiences."

Ethical Considerations

The aims, risks, and benefits of the research were disclosed to potential participants, as were the voluntary nature of participation and the means used to ensure confidentiality. In terms of ensuring anonymity, the questionnaires were unlinkable and untraceable to specific participants. The project was approved by the research ethics committees at the Université de Montréal, McGill University, and each of the four hospitals.

Results

Demographics

A total of 95 nurses met the inclusion criteria and were invited to participate in the study. Of the 95 questionnaires distributed, 60 were returned (63.2% response rate); the second mailing netted five more questionnaires, for a total of 65 respondents (68.5% response rate). The respondents, who ranged in age from 25 to 60 years (*mean* = 39.5 years; *SD* = 7.9), had an average of 5.1 years' experience in the clinical trial setting (*SD* = 4.7). For the majority of respondents, the highest level of nursing education was a bachelor's degree (44.6%), followed by a college diploma (35.4%), an undergraduate certificate in nursing (13.8%), and a master's degree (6.2%). Twenty-three of the 65 respondents (35%) indicated that their highest level of education was in a field other than nursing:

community health (19%), business administration/management (14.2%), health sciences (14.2%).

The results show that the majority of respondents (66.2%) received some education in research ethics, whether during nursing studies (26.2%), during on-the-job training (20%), or after completing nursing studies but before assuming their current position (6.2%). Of the nine respondents who received training under more than one of the above categories, six received training both during their nursing studies and on the job, one received training during nursing studies and also prior to assuming the position, and one received training prior to assuming the position as well as on the job. Only one participant received training at all three points: during nursing studies, after completion of studies, and on the job.

In terms of amount of training received during their nursing studies, seven respondents reported receiving 45 hours or more, seven reported levels between 12 and 30 hours, and six reported levels between 2 and 6 hours. All those who received training before assuming their position but after completing nursing studies did so via a 45-hour undergraduate course. Lastly, for those trained on the job, 40% reported training of between 6 and 24 hours. On-the-job training was provided by the nurse being replaced (42.9%), the PI (28.5%), or the sponsoring company (28.5%). Of the respondents, 33.8% had not received any form of research ethics education at the start of their job in the clinical research setting. Although eight respondents (12.3%) had since received some research ethics education, 14 (21.5%) were practising in the field with little if any formal training or education in research ethics.

Less than half of the respondents (27, or 41.5%) reported having a job description. Of these, only 12 knew who had drawn it up. Seven nurses said they had written their own job description, while three specified that the PI had written it. One participant named both the sponsoring company and the institution as authors of his/her job description. With regard to their current title, 32.3% of respondents used the title "research coordinator," 32.3% "research nurse" and 30.8% "study coordinator." Less frequently employed were the titles "clinical trial nurse" (13.8%), "study nurse" (6.2%), and "research study coordinator" (4.6%); 15.4% of respondents reported using two or more titles interchangeably.

Role of the CTN in the Informed Consent Process

Point of involvement in IC process. A large percentage of respondents (75%) described being involved in the IC process before, during, and after the securing of IC. However, eight respondents reported being involved only before the securing of IC, four only before and during the securing of IC, and three only after the securing of IC; 97% of respon-

dents indicated that they did not perceive IC as simply the formality of a signature.

Disclosure of information. Almost all respondents (96.9%) reported that they participated in securing IC. All respondents indicated that they participated in providing information about the research to the participant; 98.5% provided participant and family education. In supplying greater detail about providing information to research participants, 56 respondents (86.2%) claimed that they did so often, six (9.2%) sometimes, two (3%) rarely, and one (1.5%) always. The majority of respondents indicated that the provision of information to research participants was a collaborative effort shared by the nurse and the PI. Shared explanations included: the purpose of the study (74.5%), the risks involved (67.3%), the potential benefits (69.1%), and the alternatives available (65.5%).

Comprehension of information. Just over half of the respondents (56%) said it was the responsibility of both the PI and the CTN to assess the participants' comprehension of the study and the information provided prior to the securing of consent. Twenty-two respondents (40%) said that this task was solely the responsibility of the CTN and one that it was solely the responsibility of the PI. Only one respondent said that no one assessed the participants' comprehension. Almost all respondents (95.4%) reported that their responsibility included answering participants' questions. In addition, respondents indicated that they were involved always (48.2%), often (30.4%), or sometimes (16.1%) in assessing the participants' comprehension of the options available.

Voluntary participation. The majority of CTNs (92.3%) reported assessing whether the participants took part in the research voluntarily (without undue pressure). Of these, 72.3% responded that they always, 12.3% often, and 7.7% sometimes assessed voluntary participation. Only a small percentage reported never (2.4%) or rarely (5.3%) assessing whether the participants truly volunteered (without undue pressure) to take part.

Almost all the respondents (93.8%) reported verifying the participants' willingness to continue taking part throughout the study (even after having signed the consent form). Forty-five indicated verifying always (69.2%), nine often (13.8%), and seven sometimes (10.8%).

Conflicts of Interest and Ethical Dilemmas

Conflicts of interest. Twenty-eight respondents (43%) reported never experiencing conflict of interest related to their role in the IC process. Of the 37 nurses who reported experiencing conflict of interest between their obligations to the participants and to the research project (56%), the frequency of occurrence varied (rarely = 29.2%, sometimes = 26.2%,

often = 1.5%), as did the conflict type. Only 21 respondents went on to describe the conflict.

After using Van Kaam's (1966) method for analyzing data from descriptions of the respondents' "lived experiences," we ranked the reported conflicts of interest in descending order according to frequency of occurrence: participants lacking full comprehension of the implications or purposes of the study (10 respondents); alternatives not offered to patients (4 respondents); respondents asked to approach potential participants at inappropriate times (when patients were vulnerable or seriously ill) (3 respondents); patients refused to read consent form because they trusted the physician investigator (2 respondents); patients unaware of voluntary nature of participation (1 respondent); and PI insistence on enrolling patients in the study even though they did not meet eligibility criteria (1 respondent). In effect, professional conflict of interest was the most frequently reported type of conflict, inasmuch as 38 nurses had experienced a situation in which patients appeared not to understand the implications of their participation but still signed the consent form (occurring rarely = 30.8%, sometimes = 24.6%, often = 3.1%).

Ethical dilemmas. Approximately two thirds of respondents (42) reported experiencing ethical dilemmas as a result of their role in the IC process. According to these respondents, ethical dilemmas were usually caused by a lack of clear policies and guidelines regarding nurses' role in the IC process (27%), the fact that their employer was also the PI of the study (23.8%), or the lack of a job description (22.3%). Insufficient information and education were the least identified causes of ethical dilemmas.

Respondents indicated that they always (92.3%) or often (6.2%) had access to the research protocol, and 95.4% reported reading the protocol. As well, the majority of respondents (67.7%) had their questions about protocol answered by the PI (often = 18.5%, sometimes = 11.7%); only one respondent reported never receiving answers from the PI. With regard to education, 35.4% of the respondents rated their knowledge of the IC process as excellent, 38.5% as very good, 21.7% as good, and 4.6% as poor. Nevertheless, half of the respondents (50.8%) reported needing more education to properly fulfil their role in the IC process. More specifically, 30.8% said they needed education in legal obligations and implications with regard to obtaining consent as well as liability issues regarding the CTN's role in the IC process, while 20% said they needed more education in the IC process generally.

Correlational Analyses

Correlational analyses were performed to determine the existence of a relationship between the key concepts (conflicts of interest, ethical

dilemmas) and continuous variables (age, years of experience, amount of research ethics training received). In addition, a *t* test was used to compare the mean score of two groups (Table 1) — those with and without a job description — in order to determine whether this variable influenced the experience of conflicts and ethical dilemmas.

As evidenced in Table 2 by Pearson's correlation tests, years of experience and number of hours of research ethics training had a significant effect on the perceived experience of conflict of interest. This finding suggests that those with more research ethics education and more years of experience in the field have an increased tendency to report conflict. This may be the very reason for the low prevalence of conflict among the study population. Most respondents had little if any research ethics education and little CTN experience. One can therefore postulate that research ethics education and years of experience sensitize the CTN to potential conflicts and dilemmas and render them better able to identify and report any such instances. With regard to the other variables, such as job description, the tests revealed no significant relationships (Table 2).

Table 1 ***Mean Score of Two Groups, Those With and Without a Job Description***

	Conflict of Interest			***p***	**Ethical Dilemma**			***p***
Job description	*n*	*Mean*	*SD*	0.278	*n*	*Mean*	*SD*	0.320
Yes	26	7.5	2.5		27	11.4	3.8	
No	37	6.8	2.6		35	10.4	3.7	

Table 2 ***Pearson's Correlation Between Key Concepts and Age, Years of Experience, and Research Ethics Training***

	Conflict of Interest	**Ethical Dilemma**
Age	0.16	-0.08
Years of experience *Mean* = 5.1 *SD* = 4.7	0.32*	-0.21
Hours of training in research ethics	0.262*	0.177

* Significant at 0.05 (2-tailed).

Discussion

Role of the CTN in the IC Process

The results of this descriptive study demonstrate that a large majority of CTNs in the study population are actively involved in ensuring disclosure of information, comprehension, and voluntariness in the informed consent process, and that they are meeting their professional obligations in this regard. The analyses indicate that the role of the CTN in the IC process is that of resource person (providing information as required, assessing participants' comprehension), watchdog (ensuring that coercion and manipulation tactics are not employed), and advocate (ensuring that participants' rights are respected). Finally, the results indicate that it is common practice for CTNs to fulfil their role in the IC process in collaboration with the principal investigator. Nevertheless, one third of the respondents were delegated complete responsibility for disclosing information, two thirds had responsibility for assessing participants' comprehension, and almost all had responsibility for assessing voluntary participation. Thus CTNs perceive themselves as playing a central role in the IC process — and this with little or no educational preparation. They are therefore placed in a position where they must engage in self-learning and implement national and international guidelines (e.g., Gouvernement du Québec, 1998; Health Canada, 1997; MRC, NSERC, & SSHRC, 1998) governing the practice of research. In other words, the lack of educational preparation and lack of specific nursing guidelines create a situation in which CTNs are expected to take a proactive stance and familiarize themselves with regulations and guidelines governing research in order to fulfil their professional role. The guidelines available to them are of limited help when it comes to defining the role of CTNs in the IC process. These CTNs are pioneering the role of the nurse in the IC process, but in so doing find themselves in vulnerable situations, confronted with conflicts of interest and ethical dilemmas. Given this situation, should CTNs exercise caution, or should they simply decline to take part in the IC process?

The role of the nurse in the IC process has long been a controversial one (Davis, 1989). There are two existing paradigms. One argues that the PI is responsible for obtaining the IC and that this is a personal duty that cannot be delegated (Smith, 2000; World Medical Association, 2004). The other asserts that while IC is indeed the PI's responsibility, the nurse has an ethical duty and/or moral responsibility to ensure that the participant understands the IC process (Berry et al., 1996; Canadian Nurses Association, 2002; Cassidy & Macfarlane, 1991; Davis, 1989; Johnson, 1986; Lynch, 1988; McLean, 1996; Sadler et al., 1999). Some go so far as to declare that the nurse, whether or not entrusted with this responsi-

bility, is at least as responsible as the physician for obtaining IC and has an obligation to provide information to the potential participant, in collaboration with the physician (Berry et al.; Cisar & Bell, 1995; Sadler et al.).

As prescribed by the values enshrined in the *Code of Ethics for Nurses* (Canadian Nurses Association, 2002), the obligations of the professional nurse include truthful disclosure of information, assessment of clients' understanding with regard to their care — providing information as required — and, finally, ensuring that coercion and manipulative tactics are not employed in the securing of consent. As well, the International Council of Nurses (1996) *Ethical Guidelines for Nursing Research* state that all nurses have an ethical responsibility and duty to protect their patients, whether research participants or not. Finally, in order to minimize undue influence, when the research participant is also in a relationship of dependency with the investigator, such as a patient/physician relationship, caution is warranted (Smith, 2000). The Medical Research Council of Canada (1987) suggests that in order to minimize the potential for conflict of interest, it is prudent for PIs to delegate the securing of IC to other health professionals, especially if the PI is also the treating physician. Given the above, one could argue that nurses do indeed have a professional and moral duty to ensure that research participants have provided IC, regardless of whether the responsibility for obtaining it is delegated to the CTN. So, given the controversy and our results, should the responsibility for obtaining IC be delegated to the CTN?

According to Lynch (1988), because nurses receive education in the principles of client teaching, communication, and interpersonal relationships, coupled with the fact that they are the professional group with the closest and most frequent contact with research participants, they are ideally positioned to be delegated responsibility for the IC process. Conversely, McLean (1996) offers a word of caution to nurses who take on the role of obtaining consent for research purposes. McLean asserts that prudence is called for and that responsibility for securing IC should not be assumed unless the nurse is at the very least knowledgeable about and familiar with the research protocol, the condition being investigated, the screening criteria and process, any risks and potential benefits, and relevant legal and ethical issues. Furthermore, McLean recommends that nurses become familiar with the proper procedures for delegating medical functions to nurses and with institutional policies and procedures governing the IC process. Analysts such as Lynch and McLean underline the importance of research ethics education, for CTNs cannot become sensitized to the legal and ethical implications of such a role without being properly educated.

With regard to lack of education, 35.4% of respondents rated their knowledge of the IC process as excellent, while only 4.6% rated it as poor. Nevertheless, half of the respondents cited a need for more education in the IC process, identifying legal obligations and implications for CTNs regarding IC and the IC process as areas of weakness. The desire for education among CTNs about their role is also supported in the recent literature (Davis et al., 2002; Ehrenberger & Aikin, 2003).

Education and Policy

It would seem appropriate for the nursing curricula to include research ethics courses. Also critical is the need for standardized, perhaps even mandatory, minimal training for CTNs. Such training should include education in ethical issues common to their role. Only one third of respondents had received training in research ethics, provided by either the PI, the nurse leaving the position, or the sponsoring company. It is unacceptable for nursing to leave it up to other disciplines to define the role and standards of the CTN through education and job description.

Furthermore, it is essential that guidelines be developed in order to provide a framework on which CTNs can base their practice and clear boundaries regarding their role in the IC process. This would serve to address the conflict and dilemmas described by the respondents. It is also essential for the proper conduct of research, adhering to the highest level of ethical and professional standards. The lack of guidelines and clear policies was the most common cause of ethical dilemmas described by the respondents. Other causes of ethical dilemmas included the PI of a study also being the employer of the CTN (23.8%) and the lack of a job description (22.3%), both of which situations could be addressed in guidelines or policies in order to minimize the ethical difficulties confronting CTNs.

With regard to conflict of interest, more than half of the respondents reported experiencing conflict between their obligations to the participants and their duty to ensure the successful completion of the study. The cause of such conflict was most commonly reported as organizational, with the PI being the employer of the CTN. This situation results in other professions and for-profit companies defining and guiding nursing practice with regard to CTNs. In the absence of guidelines and policies on the role of CTNs, either the employer (usually the PI) draws up (or has the sponsor draw up) a job description governing the practice of the employee (CTN) or no job description is drawn up at all. All of these scenarios are unacceptable. The nursing profession should intervene and develop educational programs as well as policies and guidelines in order to address the vulnerable situations described in this study.

Revised Professional Code of Ethics in Quebec

In Quebec, the *Code of Ethics of Nurses* was amended by the OIIQ and adopted by the government in June 2005 (OIIQ, 2005). The amended code addresses some of the issues identified in this study, namely consent issues (i.e., nurses must ensure disclosure of information, comprehension of information, and voluntary participation) and conflict-of-interest issues (i.e., nurses must advise an appropriate authority, such as a research ethics committee, of any conduct that appears to run counter to scientific and ethical norms). The amended code is a step in the right direction, as it provides practical guidelines with regard to the role of the CTN in the IC process.

Methodological Limitations

The convenience non-random sample, which included only practising nurses working with a physician PI at a McGill-affiliated hospital, affects the external validity of the study and limits the generalizability of the results. This limitation resulted from a lack of financial and human resources.

With regard to the questionnaire, it was noted that the results obtained in certain areas were not well dispersed. This limitation could not have been anticipated, as no empirical data giving an idea of the prevalence of the concepts being studied were available at the time. In addition, the questionnaire falls short with respect to exploring the collaborative role described by the sample regarding disclosure of information and comprehension. Also unexplored was the means by which the nurse assesses the participants' comprehension and voluntary participation. These shortcomings are related to the fact that the level of participation and involvement of the CTN in the IC process was unclear at the time when the questionnaire was developed.

Conclusion

The results of this study point to the need for standard ethical and practical guidelines with respect to the role of the CTN in the IC process. This void is responsible for these nurses' experience of conflicts of interest and ethical dilemmas. Furthermore, the results of this study suggest the need for standardization of educational preparation and training in this setting.

One can argue that CTNs who collaborate as members of research teams in clinical trials are not participating in research that serves to advance nursing knowledge and that this could be the reason for the lack of guidelines and recognition by the nursing profession. However, we believe that this thinking must change and that it is indeed beginning to

change. The recent revision of the nursing code of ethics in Quebec is a step in the right direction.

The empirical data collected in this study confirm what has been reported elsewhere: CTNs play a critical role in the IC process in Quebec and are experiencing conflicts of interest and ethical dilemmas. In order to serve the interests of the public as well as of nurses themselves, nursing educators and the nursing profession must recognize this fact and continue to develop educational programs for nurses who are involved in research as well as guidelines governing the practice of CTNs.

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