Canadian Journal of Nursing Research, 2002, Vol. 34, No. 1, 131–142

Double Agency in Clinical Research

Marie Edwards and Karen Chalmers

L'intérêt actuel pour la pratique infirmière fondée sur les résultats cliniques et scientifiques force parfois les infirmières à assumer simultanément deux fonctions auprès des mêmes personnes, c'est-à-dire les rôles de chercheuse et de prestataire de soins. Puisque la relation entre infirmière et patient repose sur la confiance, ce double rôle peut être une source de problèmes à la fois réels et apparents. Le présent article aborde les questions découlant de cette situation dans la recherche avec des êtres humains, particulièrement en ce qui a trait au recrutement et au consentement éclairé, à la cueillette des renseignements et au désistement des patients. Il propose en outre des stratégies visant à prévenir et à contenir les problèmes liés au double rôle, en s'inspirant des lignes de conduite établies dans les codes de déontologie et dans l'*Énoncé de politique des trois conseils : éthique de la recherche avec des êtres humains*.

The current focus on evidence-based practice in nursing may result in nurses playing 2 roles concurrently — that is, acting as researcher and caregiver at the same time and with the same people. Given the fiduciary nature of the patient-caregiver relationship, this double agency can give rise to problems, both real and perceived. In this paper, the issues associated with assuming dual roles in research with humans will be examined, particularly in relation to recruitment and informed consent, data collection, and participant withdrawal from a study. In addition, strategies to prevent or minimize problems related to double agency are identified, with attention to the guidance provided by professional codes of ethics and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.

Nursing's mandate for evidence-based practice is challenging the profession to systematically evaluate clinical practices. Much of this focus is on direct nursing interventions, often with ill, institutionalized patients. At the same time, more nurses are receiving master's level education and are encouraged by their employing agencies and professional organizations to mount or participate in research on nursing outcomes. Given nurses' clinical role, issues of double agency can arise. Double agency refers to fulfilling two roles concurrently — for example, acting as researcher and caregiver at the same time and with the same

---

Marie Edwards, RN, MN, is a PhD student, University of Toronto, Ontario, Canada, and Lecturer, Faculty of Nursing, Helen Glass Centre for Nursing, University of Manitoba, Winnipeg, Canada. Karen Chalmers, RN, BScN, MSc(A), PhD, is Associate Professor, Faculty of Nursing, University of Manitoba.

people (Levine, 1992). While assuming dual roles can result in benefits for both the study participants and science, it can also cause problems, both real and perceived, with significant consequences. If nursing is to achieve its research mandate, greater awareness of double agency is paramount. The purpose of this paper is to examine issues related to double agency in research with humans and to make recommendations for preventing or minimizing problems with dual roles.

The Caregiver-Patient Relationship

To understand the problems associated with double agency, it is necessary to first understand the nature of the relationship between patients and their caregivers. The patient-clinician relationship is a fiduciary one. It is defined by Lemmens and Singer (1998) as a relationship "between unequals in which the more powerful party...is entrusted to protect the best interest or well-being of the less powerful party" (p. 961). There are two key aspects to this relationship: (1) it is based on a power differential, with the patient, who not uncommonly is ill and in need of assistance, occupying the more vulnerable position; and (2) it is founded on trust.

Out of any fiduciary relationship arise obligations, particularly on the part of the more powerful party, to show "undivided loyalty and commitment, unqualified by any element of clandestine self-interest or any competing loyalty" (Irvine, 1995, p. 216). It is not that clinicians ought never to have other interests, but, as expressed by Bloche (1999), "the more powerful the message of fidelity conveyed within a clinical relationship, the more compelling a social purpose should be to justify departure from the ethic of undivided loyalty" (p. 273). One need only read the Canadian Nurses Association ([CNA], 1997) *Code of Ethics for Registered Nurses* to see that nurses' primary loyalty is to the people under their care and their primary interest is the well-being of these people. This interest is rooted in the ethical principles of beneficence, involving the promotion of the welfare of others, and non-maleficence, involving the prevention of harm (Yeo & Molke, 1996).

Researchers, too, are concerned for the well-being of those individuals who participate in their studies. But researchers are likely to have additional interests: the discovery of knowledge; the application of that knowledge in the care of future patients; the maintenance of good relationships with funding bodies, including private sources like industry; and self-interests, including career advancement (Cattorini & Mordacci, 1993; Pellegrino, 1992). If the researcher is at the same time a caregiver, these other interests have the potential to influence, or at least to be per-

ceived as influencing, the caregiver's professional judgement regarding the primary interest of patient well-being. This places the caregiver in a situation of a real or perceived conflict of interest (Lemmens & Singer, 1998).

Problems Associated With Double Agency

Three areas of a research study may be particularly problematic for the person who acts simultaneously as caregiver and researcher with a group of patients: (1) the recruitment and informed consent process, (2) the data-collection process, and (3) participant withdrawal from the study. In these three areas the primary interest of patient well-being may be negatively influenced by the interests of science. The goal of the recruitment phase is the enrolment of an adequate — usually predetermined — number of informed participants. Since adherence to study time lines is important, recruitment must proceed in a timely manner. This can lead to problems when the researcher is also a caregiver. For example, in order to ensure an adequate sample size, a researcher may exert pressure, subtle or otherwise, on his or her own patients to consent to participate. Given the power of the researcher/caregiver and the vulnerability of the patient, some patients may be reluctant to decline for fear of jeopardizing the patient-caregiver relationship and, by extension, their future care (Levine, 1992; Moreno, Caplan, Root Wolpe, & the members of the Project on Informed Consent, Human Research Ethics Group, 1998; Orb, Eisenhauer, & Wynaden, 2001; Pellegrino, 1992). It is also possible that the researcher/caregiver in such a situation will take advantage of the "therapeutic misconception," described by Miller, Rosenstein, and DeRenzo (1998) as "the tendency of patient volunteers to believe that the research procedures that they undergo were designed for their benefit" (p. 1450). The members of the United States Project on Informed Consent, Human Research Ethics Group, have suggested that the language used on consent forms may actually encourage "an illusion of therapeutic benefit, whether intentionally or not" (Moreno et al., p. 1954).

A second potential problem area for the researcher/caregiver is the data-collection process. Various authors have found that ethical and role conflict can occur when nurses engage in research that involves direct interaction with respondents, such as interviews or field research (Archbold, 1986; Lipson, 1984, 1991; Lowes, 1996; May, 1979, 1991; Namei, O'Brien King, Byrne, & Profitt, 1993; Orb et al., 2001). For example, in the course of a research interview a patient-participant may seek information or advice regarding personal health status or care

from the nurse collecting the data. If the data collector is not in a direct clinical relationship with the participant, this is not a double-agency issue as defined here, but it can result in the nurse experiencing role conflict. It is also possible that a situation will arise during data collection wherein intervention and referral are necessary for the well-being of the participant. Orb et al. provide the example of a researcher interviewing victims of violence and triggering painful memories in the participants, resulting in participant distress. In this situation, the researcher must decide whether "to continue with the interview and gain more insight about the topic under study or to stop the interview and give advice or refer the participant to an appropriate treatment or counselling service" (p. 94). If the interviewer is both the participant's caregiver, with all the duties this entails, and the researcher, the primary interest of patient well-being might be unduly influenced (or might be perceived to be unduly influenced) by secondary interests associated with the need for complete data.

Problems can also develop around the withdrawal of participants from a study. Faced with competing interests, a researcher/caregiver may struggle with his or her obligation to ensure that participants receive the best care possible and come to the least harm possible, and as a result may delay withdrawing a participant when evidence of harm emerges. Such a situation can prove particularly complicated if the study is double-blind (Pellegrino, 1992). When is it appropriate to break the code to minimize harm? Compounding this problem is the fact that the participant, who ought to have the right to withdraw from the study at any time, may not feel free to withdraw without prejudice (Levine, 1992).

Perhaps the most worrisome consequence of real or perceived conflict of interest with double agency is the erosion of participants' trust in their caregivers (Lemmens & Singer, 1998). This can occur if participants believe their best interests are no longer the priority or if they question the motives of the researchers. Given that trust is the foundation of both the patient-caregiver relationship and the researcher-participant relationship, this is a serious concern. It is essential that the research community protect public trust. If that trust is eroded, it is quite possible that people will no longer participate in research and that the public will no longer support funding of research projects (Hanna, 2000). The advice Paul Ramsey offered researchers three decades ago still holds true today: "Act always so as not to abuse trust; act always so as to exhibit faithfulness to deserve and inspire trust" (Ramsey, 1970, p. 8).

Existing Guidance

When considering acting as caregiver and researcher with the same group of people, the researcher should seek guidance from the chair of the research ethics board or from some other knowledgeable person. Such feedback may assist the researcher in thinking through the ethical issues and structuring the research proposal. The CNA (1994) document *Ethical Guidelines for Nurses in Research Involving Human Participants* contains minimal discussion of the double-agency problem. Investigators are informed that the best interests of the participants ought to be their prime concern and are encouraged to disclose any areas of potential conflict of interest to a research ethics board. In the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Medical Research Council of Canada [MRC], Natural Sciences and Engineering Research Council of Canada [NSERC], & Social Sciences and Humanities Research Council of Canada [SSHRC], 1998), researchers are reminded of the ethical duties that govern potential or actual conflicts of interest for the clinician who also assumes the role of researcher (Section 2, Article 2.4). In order to preserve the trust relationship, researchers who do assume a dual role are advised to disclose this fact to study participants and to separate their role as researcher from their role as therapist, caregiver, teacher, advisor, or consultant throughout the entire research project, particularly during the process of recruitment and when securing informed consent. Conflict of interest matters are further elaborated on in Section 4 of the Tri-Council document. While these guidelines provide some direction to researchers and research ethics boards, the investigator is given no specific guidance in planning the proposal or dealing with the review process.

Recommendations

Strategies to prevent or minimize problems related to double agency will now be identified. Some of the recommendations that follow are made from a fairly strong position of consensus in the research ethics literature and research community. Others are raised more tentatively and will require ongoing discussion and debate as policies in research ethics evolve. The recommendations are directed to the key stakeholders in the research process: research ethics boards, researchers and their collaborators, research project employees, research administration offices, the patient ombudsman, funders, and educational institutions.

Research Ethics Boards

Research ethics boards (REBs) have a critical role to play in uncovering and preventing double-agency problems and in educating the research

community regarding this issue. This role cannot be fully realized, however, without a well-informed and knowledgeable review panel. This might appear self-evident, but REBs may have insufficient budgetary and other resources to provide a full orientation to members on this as well as numerous other ethical issues. Most members may be selected for their specialized knowledge in substantive research areas, with few having had formal training in ethics. During busy meetings in which numerous protocols must be reviewed, there is little time for in-service education and self-study on ethical issues. Inadequate preparation for the role can result in a lack of recognition of double-agency problems or conflict among the membership concerning their gravity. We recommend initial and ongoing education of REB members.

Research ethics boards also have a responsibility to their research community, such as by educating researcher-practitioners in double-agency concerns. It is not clear how this issue is best addressed (e.g., workshops, one-on-one consultation with the REB chair, the provision of literature with REB forms), but there is no doubt that resource implications must be considered.

Considerable attention must be paid to the REB process to ensure that potential and actual conflicts are made transparent and resolved. The question arises: Does the REB have the policies and procedures to address and resolve conflict of interest issues? The usual process when such concerns arise in an REB is the "to-ing and fro-ing" of applications between the researcher and the committee. Concerns are raised by the REB and some changes may be made by the researcher, but the central issues are not addressed. Some of these difficulties are exacerbated by vague or imprecise REB review forms. The written forms should be structured to elicit the needed information, with the inclusion of specific questions regarding power relationships (e.g., whether or not the researcher is in a position of power in relation to potential participants), practitioner and researcher roles, and project funding sources.

It is important that REB members see evidence that the researcher has sensitively considered power and trust issues when developing the proposal. If this information is not transparent or is incomplete, the committee may not have confidence in the researcher's ability to fully understand double-agency issues. An additional potential area of conflict is the source of research funding (Parascandola, 2001). Both the Canadian Medical Association (1996) and the Canadian Nurses Association (1994), as well as the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (MRC, NSERC, & SSHRC, 1998),

recommend that the source of funding for research be disclosed to the REB.

Finally, REBs require considerable resources to do their job effectively. These include release time for members from their other duties (especially the chair of the committee), adequate secretarial support, and budgets sufficient to host educational sessions.

Researchers and Their Collaborators

Researchers themselves are the most critical component of the double-agency debate. The importance of the trust relationship between the caregiver and the patient is central to the avoidance of any actual or perceived conflict of interest. It would appear self-evident that prevention of conflict is the most obvious course of action. The researcher should ask two central questions: Are there other places where I could recruit participants, besides from among the patients, students, and employees associated with my work? If there are other accessible sites, is there any rationale for not using them? These are different questions from: Will it be more inconvenient for me to recruit elsewhere?

If there are no other accessible sites, the researcher should carefully think through the power and trust issues as the proposal is being developed. The REB chair may be an important consultative source during this process. If the researcher concludes that he or she must function as a dual agent, he or she should provide the REB with evidence that there has been careful thought and attention to the concerns of double agency and evidence as to how potential or real conflicts will be managed throughout the research. Central to this discussion is consideration of the question: How do I create a climate, throughout the research process, in which the needs of patients (or others) are paramount?

This ought to entail recruitment through a third party (i.e., research coordinator, research nurse). Merely hiring a staff member to recruit and to secure consent is insufficient to ensure the prevention of harm. The researcher must develop policies and practices that will enable the research staff to function as neutral agents. Staff members are never fully in a position of neutrality when they are directly supervised by the researcher. Power differences must be recognized and handled sensitively, so that pressure to meet recruitment targets does not interfere with the process of free and fully informed consent. If it is not possible to recruit participants from another patient pool, the data should be collected by a third party (i.e., a person other than the clinician who is in a direct relationship with the patients). To minimize role conflict, clear

boundaries should be established around the research interview. If questions regarding a participant's care or health status arise during the interview, the participant should be informed that the researcher will return to this subject after the interview. At the completion of the interview, the data collector ought to respond to the participant's questions in a general rather than specific way and refer the participant to the appropriate health-care provider.

A growing concern is the issue of clinicians and others who are involved in research outside of universities and institutions and not linked to an institution's REB review process. This is an issue in pharmaceutical trials and other industry research. We recommend that practitioners, at the very least, ask for a copy of the industry REB's approval and consult with the research office of the employing institution.

When the practitioner and researcher roles are not fully separate, we endorse Shimm and Spece's (1991) recommendation that potential subjects be informed of the funding source, amount, and mechanism (i.e., block or capitation funding, directly to the researcher or through the research office of the institution). This should apply even in the case of third-party recruitment and data collection.

Central to all of the above recommendations is the integrity of the researcher. It will never be possible for REBs, research administration offices, or other bodies to fully regulate the research process. In the end, each researcher must be aware of and sensitive to the issues when acting in a dual role.

Research Project Employees

Nurses are frequently hired by researchers to recruit participants, gather data, and manage research projects. It is important that research employees be educated in the various components of their role. This entails an understanding of their professional responsibilities and knowledge of the codes of ethics that guide their practice. For example, nurses in Canada should be familiar with the CNA (1994) document *Ethical Guidelines for Nurses in Research Involving Human Participants.* They should also understand the guiding principles of recruitment and informed consent and be alert to their questionable neutrality in relation to recruitment and retention of subjects.

Research employees will need advisement on dealing with participants who seek specific advice on their personal care or health status or who require some form of intervention or referral. We suggest that they also be given access to administrative support and REB support as

needed if they identify ethical concerns that, from their perspective, are not successfully resolved by the research team.

Research Administration Offices

Research administration offices have an important role to fulfil in the prevention, early detection, and monitoring of problems of double agency. The research office of a university or other institution is responsible for establishing and/or approving policies for REBs. In order for the REBs to function effectively, they must have sufficient resources for reviews, education of researchers, and other supports. We see a major function of the research administration office as advocating for adequate supports from the senior administrative structure. Research administration also has a key role to play in the monitoring of research proposals, particularly in the case of studies involving double agency.

Another area of responsibility for the research office is managing or overseeing funds related to recruitment expenses. We do not support "finder fees" (direct payment to clinicians who enrol their patients). However, there are legitimate costs involved in enrolling patients in studies. The budget for such expenses should be transparent and subject to review.

Institutions also need to recognize the complexity of linkages with the private sector and assist in developing and communicating policies and procedures that ensure the appropriate handling of double-agency issues.

Patient Ombudsman

A patient ombudsman or some other designate should be available for all patients/participants in studies. Research participants need access to the name and telephone number of a neutral person or body to vet any questions, concerns, or complaints concerning subtle pressures to enrol in or remain in a study, particularly when the participant's caregiver is the researcher. This information should be communicated in the materials given to the participant at the time of recruitment.

Institutional Sponsors

The reductions in public-sector funding for research during the past decade have caused university and institutional researchers to seek funds elsewhere. Indeed many institutions, especially universities, are encouraging these linkages. We must all become sensitive to the seduc-

tive power that research funding holds for researcher-practitioners and institutions alike. The threat of "institutional hubris" (Pellegrino, 1992, p. 364) is a powerful force in encouraging researchers to strive for prestigious grants. With such systemic pressure, researchers may lose sight of potential harms.

Educational Institutions

The major focus in research training is theoretical and methodological. We recommend that adequate attention be given to the ethical components of research, particularly issues related to conflict of interest, power and coercion, and trust. The focus of ethics education in undergraduate programs is, appropriately, the client. It is important, however, that students be exposed to ethical issues in research at the undergraduate level. This knowledge base can then be expanded in graduate education as research training increases.

Summary

In order to ensure the protection of research participants, all parties involved in the research process need to understand the potential conflicts surrounding double agency. With greater clarity of the issues, researchers, REBs, and administrators will be more sensitive to the problems associated with dual roles in research and better able to identify strategies to prevent such problems from arising. Central to the above discussion and recommendations is the basic integrity of the researcher. It will never be possible for REBs, offices of research administration, or other bodies to fully regulate the research process. In the end, each researcher must be aware of and sensitive to the issues when acting in a dual role.

References

Archbold, P. (1986). Ethical issues in qualitative research. In W. C. Chenitz & J. Swanson (Eds.), *From practice to grounded theory: Qualitative research in nursing* (pp. 155–163). Menlo Park, CA: Addison-Wesley.

Bloche, M. G. (1999). Clinical loyalties and social purposes of medicine. *Journal of the American Medical Association, 281*(3), 268–274.

Canadian Medical Association. (1996). Code of ethics. In F. Baylis, J. Downie, & K. Dewhirst (Eds.), *Codes of ethics: Ethics codes, standards, and guidelines for professionals working in a health care setting in Canada* (2nd ed., pp. 44–47). Toronto: Department of Bioethics, Hospital for Sick Children.

Canadian Nurses Association. (1994). *Ethical guidelines for nurses in research involving human participants.* Ottawa: Author.

Canadian Nurses Association. (1997). *Code of ethics for registered nurses.* Ottawa: Author.

Cattorini, P., & Mordacci, R. (1993). The physician as caregiver and researcher. *Thyroidology, 5,* 73–76.

Hanna, K. (2000). Research ethics: Reports, scandals, calls for change. *Hastings Center Report, 30*(6), 6.

Irvine, J. (1995). The physician's other duties: Good faith, loyalty, and confidentiality. In B. Sneiderman, J. Irvine, & P. Osborne, *Canadian medical law. An introduction for physicians, nurses, and other health care professionals* (2nd ed., pp. 211–235). Toronto: Carswell.

Lemmens, T., & Singer, P. (1998). Bioethics for clinicians: 17. Conflict of interest in research, education and patient care. *Canadian Medical Association Journal, 159*(8), 960–965.

Levine, R. (1992). Clinical trials and physicians as double agents. *Yale Journal of Biology and Medicine, 65,* 65–74.

Lipson, J. (1984). Combining researcher, clinical and personal roles: Enrichment or confusion? *Human Organization, 43*(4), 348–352.

Lipson, J. (1991). The use of self in ethnographic research. In J. Morse (Ed.), *Qualitative nursing research: A contemporary dialogue* (Rev. ed., pp. 73–89). Newbury Park, CA: Sage.

Lowes, L. (1996). Paediatric nursing and research ethics: Is there a conflict? *Journal of Clinical Nursing, 5,* 91–97.

May, K. (1979). The nurse as researcher: Impediment to informed consent? *Nursing Outlook, 27*(1), 36–39.

May, K. (1991). Interview techniques in qualitative research: Concerns and challenges. In J. Morse (Ed.), *Qualitative nursing research: A contemporary dialogue* (Rev. ed., pp. 188–201). Newbury Park, CA: Sage.

Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada. (1998). *Tri-council policy statement: Ethical conduct for research involving humans.* Ottawa: Public Works and Government Services Canada.

Miller, F., Rosenstein, D., & DeRenzo, E. (1998). Professional integrity in clinical research. *Journal of the American Medical Association, 280*(16), 1449–1454.

Moreno, J., Caplan, A., Root Wolpe, P., & the members of the Project on Informed Consent, Human Research Ethics Group. (1998). Updating protections for human subjects involved in research. *Journal of the American Medical Association, 280*(22), 1951–1958.

Namei, S., O'Brien King, M., Byrne, M., & Profitt, C. (1993). The ethics of role conflict in research. *Journal of Neuroscience Nursing, 25*(5), 326–330.

Orb, A., Eisenhauer, L., & Wynaden, D. (2001). Ethics in qualitative research. *Journal of Nursing Scholarship, 33*(1), 93–96.

Parascandola, M. (2001). Conflicts of interest — the clinical researcher's dilemma. *Research Practitioner, 2*(1), 1–10.

Pellegrino, E. (1992). Beneficence, scientific autonomy, and self-interest: Ethical dilemmas in clinical research. *Cambridge Quarterly of Healthcare Ethics, 4,* 361–369.

Ramsey, P. (1970). *The patient as person.* New Haven, CT: Yale University Press.

Shimm, D., & Spece, R. (1991). Industry reimbursement for entering patients into clinical trials: Legal and ethical issues. *Annals of Internal Medicine, 115,* 148–151.

Yeo, M., & Molke, T. (1996). Beneficence. In M. Yeo & A. Moorhouse (Eds.), *Concepts and cases in nursing ethics* (2nd ed., pp. 57–88). Peterborough, ON: Broadview.

Authors' Note

Support for the first author was received from the Canadian Health Services Research Foundation and through a Doctoral Fellowship from the Social Sciences and Humanities Research Council of Canada.

Portions of this paper were presented at the conference "The Long and Winding Road: Research Ethics — The Basics and Beyond," held in Winnipeg, Manitoba, on September 17–18, 1999.