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Editorial

This is the inaugural issue of the new look for the *Canadian Journal of Cardiovascular Nursing*. We hope you like it. This is part of the CCCN's strategic plan to "go green". We have eliminated the paper envelope the journal previously came in and we have reduced the weight of the paper. Watch for other "green" initiatives.

We are pleased to bring you this issue with two original articles. In Wendy Young and colleagues' article, they discuss an innovative program for educating the community about heart disease. The impact of education entertainment has yet to be studied fully. Perhaps it will have a role in your educational programs. In the second article by Tina Pereza Rolls and Lynne Young, the lived experience of heart failure among older women is explored. Along with these articles, we also include our Clinical, Research and Did You Know Columns.

I wish to take this opportunity to thank my friend and colleague, Nicole Parent, for all of her work and contributions to the *CJCN* over the last four years. Nicole has stepped down as co-editor to pursue other career opportunities. I want to also welcome Dr. Martha Mackay to the CJCN Editorial Board. ♥

Wishing all of you the best in 2012,
Paula Price, PhD, RN
Editor

Call for Volunteers

The CJCN Editorial and CCCN National Research Committees are looking for volunteers to assist with translation of journal content and abstracts. Please contact Kathryn Cyr, CCCN Administrator, at **Kathryn@cccn.ca** for more information and to volunteer.

Thank You to our Recent Peer Reviewers and Volunteer Translators

We would like to express our sincere appreciation to our peer reviewers who assisted the associate editors by reviewing manuscripts for the *Canadian Journal of Cardiovascular Nursing* during 2010–2011.
Sanjy Lochan, RN, BSN, CCCN(C), Vancouver, BC
Martha Mackay, RN, PhD, Vancouver, BC
Suzette Turner, RN, ACNP, MScN, Toronto, ON

Thank you to the translators for this issue, who were:
Audrey Verville, RN, MSc, NP, Montreal, QC
Marie-Eve Leblanc, RN, MSc, Quebec, QC

Thank You!

This was the first year for the CCCN National AGM and Scientific Sessions Committee. Many thanks to the committee members for their dedicated work in making the Vancouver 2011 AGM and Scientific Session a success!

- Dorothy Morris, National Director Health Promotion & Advocacy (Victoria, BC)
- Nicole Parent, National Director Research (Montreal, QC)
- Elvessa Narvasa, Provincial Director, Quebec (Montreal, QC)
- Brenda Ridley, Provincial Director, Ontario (Toronto, ON)
- Sanjy Lochan, Provincial Director, British Columbia & Yukon (New Westminster, BC)
- Annemarie Kaan, Chair British Columbia & Yukon Professional Education Committee (Vancouver, BC)

Thank you, as well, to the CCCN members who volunteered to be moderators for the Scientific Sessions.

Marianne Beardsall	Karen Charron	Cleo Cyr	Sarah Desrosiers
Cindy Desson	Gerald MacDonald	Annemarie Kaan	Martha Mackay
Stephanie Macleod	June Macdonald	Susan McKenzie	Dorothy Morris
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Canadian Council of Cardiovascular Nurses

Conseil canadien des infirmières et infirmiers en soins cardiovasculaires

CCCN SCIENTIFIC SESSION CALL FOR ABSTRACTS in conjunction with the Canadian Cardiovascular Congress Toronto, Ontario, October 27–31, 2012

CCCN is announcing a Call for Abstracts related to any aspect of cardiovascular and/or cerebrovascular nursing for presentation at the Scientific Sessions of the Canadian Council of Cardiovascular Nurses in Toronto, Ontario, October 27–31, 2012.

Submissions are invited for presentation in English or French. Please indicate on the abstract form the language in which you would like to present. Abstracts are invited in **four** presentation options:

Workshop: Workshop presenters will offer an interactive discussion and analysis of a clinical topic or clinical practice issue in a forum lasting 50 to 60 minutes. The abstracts for the workshop sessions must meet the same criteria as the other submissions, and must outline the educational objectives, proposed content area and method of presentation (i.e., case study, multiple choice questions) for attendees to interact with one another and the presenters.

Oral: Paper presentations will be 15 minutes in length with five minutes for questions.

Poster: Posters will be displayed over two days of the CCCN conference. Presenters will be requested to be available at their poster location for 30 minutes on one of the two days. Poster presenters **may** be selected by the abstract review committee to present their poster in a moderated oral poster session.

Oral or poster: Submitter is willing to have their abstract considered by the abstract review committee for either an oral or poster format.

Submissions will be peer-reviewed in one of two broad categories: research and non-research. An abstract submission will be reviewed in the "research" category if it describes some aspect of an original piece of research, either as "completed research" or "research in progress".

The "non-research" category includes theoretical, clinical application, literature reviews, etc. (i.e., submissions that do not describe an original piece of research). Clinical topics are strongly encouraged.

Abstract submissions will be considered under one of the following themes: ACS/AMI, Stroke, Paediatrics and Congenital Heart Disease, Arrhythmia Management, Health Promotion, Nursing Education, Health Services, Patient Safety, Heart Failure/Transplant, Cardiac Surgery and Other.

Submission of an abstract constitutes a commitment by the author(s) to attend the meeting and present their abstract. All presenting authors must register for the meeting and are responsible for their own transportation and accommodation. Abstract grading will be performed by blind review and notification of acceptance or rejection of abstracts will be by email in May–June 2012.

Students are invited to submit their abstract to be considered for either an oral or poster presentation award at the CCCN Scientific Annual Meeting. Each award recognizes excellence in a clinical or research presentation. Successful candidates will be awarded a free membership and a certificate of achievement. To be eligible for either an oral or a poster presentation award:

1. The presentation has to be based on work completed as a student and related to the student's program of study.
2. The presentation must be made within a year of graduation.
3. The student must be either the lead or co-author, and also must be the presenting author at the CCCN National Scientific Session.
4. The student must be a current member of CCCN.

Please note, CCCN has an online submission process and all abstracts **must** be submitted on the CCCN website at **www.cccn.ca**. Online submission will open February 15, and submission deadline is April 1, 2012, at 2400 hours. For more information, visit **www.cccn.ca** or contact **info@cccn.ca**.

Please note: *Abstracts that have been previously presented at CCCN Scientific Sessions will not be accepted. Should an abstract be accepted for presentation at CCCN Scientific Sessions in Toronto, it may not be presented in duplicate at another national conference before or within three months following presentation at CCCN.* ♥

APPEL DE RÉSUMÉS POUR LES SÉANCES SCIENTIFIQUES DU CCIISC en conjonction avec le Congrès canadien sur la santé cardiovasculaire à Toronto, Ontario, du 27 au 31 octobre 2012

Canadian Council of Cardiovascular Nurses

Conseil canadien des infirmières et infirmiers en soins cardiovasculaires

Le Conseil canadien des infirmières et infirmiers en soins cardiovasculaires (CCIISC) lance un appel de résumés portant sur des aspects particuliers des soins cardiovasculaires, ou cérébrovasculaires, ou les deux, pour être présentés dans le cadre des Séances scientifiques du Congrès canadien sur la santé cardiovasculaire qui aura lieu à Toronto du 27 au 31 octobre 2012.

Vous pouvez proposer des résumés en vue des présentations en français ou en anglais. Veuillez indiquer sur le formulaire de proposition de résumé la langue dans laquelle vous aimeriez offrir votre présentation. Vous pouvez nous proposer un résumé pour les **quatre** options de présentation suivantes :

Présentation en atelier : Les présentatrices et présentateurs en atelier offriront une discussion et une analyse interactives d'un sujet clinique ou d'une question de pratique clinique dans un format de tribune d'une durée de 50 à 60 minutes. Les résumés proposés pour les séances d'atelier doivent respecter les mêmes critères que pour les autres propositions. Ils doivent énoncer les objectifs d'apprentissage, le contenu proposé et la méthode de présentation (étude de cas, questions à choix multiple) pour permettre aux participantes et aux participants d'interagir ensemble et avec les présentatrices et les présentateurs.

Présentation orale : La présentation orale du contenu sur papier devra durer 15 minutes, et elle sera suivie d'une période de questions et réponses de cinq minutes.

Présentation sur affiche : Les affiches seront exposées pendant deux jours à la conférence du CCIISC. Les présentatrices et les présentateurs devront être présents près de leur affiche pendant 30 minutes au cours de l'une ou l'autre des deux journées. Les présentatrices et les présentateurs sur affiche **peuvent** être choisis par le comité d'examen des résumés afin de présenter leur affiche dans une séance orale d'affiche qui sera animée.

Présentation orale ou sur affiche : La présentatrice ou le présentateur accepte que son résumé soit considéré par le comité d'examen des résumés afin d'être présenté en format oral ou sur affiche.

Les résumés proposés seront examinés par les pairs selon l'une des deux grandes catégories suivantes : « travail lié à la recherche » et « travail non lié à la recherche ». Un résumé proposé sera examiné dans la catégorie « travail lié à la recherche » s'il décrit un aspect d'un travail de recherche original, soit à titre de « travail de recherche achevé » ou de « travail de recherche en cours ».

La catégorie « travail non lié à la recherche » comprend les travaux théoriques, les travaux qui portent sur des applications cliniques, les analyses documentaires, etc. (c'est-à-dire qu'il ne s'agit pas de la description d'un travail de recherche original). Les sujets cliniques sont fortement encouragés.

Les résumés proposés seront considérés aussi selon l'un des thèmes suivants : Syndrome coronarien aigu (SCA) et Infarctus aigu du myocarde (IAM); Accident vasculaire cérébral; Pédiatrie et Cardiopathie congénitale; Gestion de l'arythmie; Promotion de la santé; Enseignement infirmier; Services de santé; Sécurité du patient; Insuffisance cardiaque et Transplantation; Chirurgie cardiaque; et autre.

Il est entendu que les auteures et auteurs qui proposent un résumé s'engagent à participer à la rencontre et à y faire une présentation de leur résumé. Toutes les auteures et tous les auteurs qui font une présentation doivent s'inscrire à la rencontre et sont responsables de leur déplacement et de leur hébergement. Les résumés proposés seront classés par examen aveugle et les avis d'acceptation ou de refus seront envoyés par courriel en mai ou en juin 2012.

Les étudiantes et les étudiants sont invités à proposer un résumé devant être présenté en format oral ou sur affiche pour être admissibles à un prix à la Réunion scientifique annuelle du CCIISC. Chaque prix reconnaît l'excellence d'une présentation clinique ou liée à la recherche. Les lauréates et les lauréats obtiendront une adhésion gratuite et un certificat de mérite. Critères d'admissibilité à un prix pour une présentation en format oral ou sur affiche :

1. La présentation doit être basée sur un travail achevé à titre d'étudiante ou d'étudiant et elle doit porter sur le programme d'études de l'étudiante ou de l'étudiant.
2. La présentation doit être faite dans l'année suivant l'obtention du diplôme.
3. L'étudiant(e) doit être l'auteur(e) principal(e) ou la co-auteure ou le co-auteur, et doit également faire la présentation à la Réunion scientifique annuelle du CCIISC.
4. L'étudiante ou l'étudiant doit être membre courant(e) du CCIISC.

Veuillez noter que le CCIISC utilise un processus de proposition en ligne et que tous les résumés **doivent** être proposés sur le site Web du CCIISC à **www.cccn.ca**. Le processus de proposition en ligne ouvrira le 15 février 2012, et la date limite de proposition sera le 1er avril 2012 à 24 h. Pour en savoir plus, allez à **www.cccn.ca** ou contactez **info@cccn.ca**.

Veuillez noter *que les résumés qui ont déjà été présentés aux Séances scientifiques du CCIISC ne seront pas acceptés. Advenant qu'un résumé soit accepté en vue d'une présentation aux Séances scientifiques du CCIISC à Toronto, il ne pourra pas être présenté en double à une autre conférence nationale avant sa présentation au séances du CCIISC, ou dans les trois mois qui suivront les séances du CCIISC.* ♥

HOLD THE DATE

Canadian Council of Cardiovascular Nurses

Conseil canadien des infirmières et infirmiers en soins cardiovasculaires

Canadian Council of Cardiovascular Nurses Annual Spring Nursing Conference

Update Your Cardiovascular Nursing Toolkit
Friday, May 2, 2012
Regina, Saskatchewan

This premiere annual CCCN conference is for nurses in urban, rural and remote settings, practising in acute care, community, or public health, in roles that span front-line to advanced practice, and any other health care professionals interested in updating their knowledge of cardiovascular disease prevention and management.

This conference will also provide education needed for nurses in either obtaining or retaining cardiovascular certification with the Canadian Nurses Association*.

Come knowing you will hear cardiovascular nursing experts speak on an array of clinically focused and practically based topics in keynote/plenary and breakout sessions. Leave knowing you are better equipped to address the needs of cardiovascular patients and their families.

** For more information on obtaining CNA national certification in CV Nursing, visit* **www.cna-aiic.ca**

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Congratulations to the CCCN 2011 Award Winners

Jacqueline Forman, Cardiovascular Nursing Clinical Excellence Award 2011

Claire Prentice, Cardiovascular Nursing Leadership Excellence Award 2011

Gina Colburne, Mae Gallant Cardiovascular Nursing Student Award 2011

Every year CCCN honours cardiovascular nurses with awards that celebrate nursing excellence. Awards are presented at the CCCN Annual General Meeting & Scientific Sessions. Deadline for application is August 31, 2012. For nomination guidelines and additional information, please visit our website at **www.cccn.ca**

Please consider nominating a nurse you feel exemplifies the best in cardiovascular nursing.

Student Oral and Poster Presenter Awards 2011
Catherine Goldie, Canadian Cardiovascular Congress 2011 Student Oral Presenter Award

Vanessa Spyropoulos, Canadian Cardiovascular Congress 2011 Student Oral Presenter Award

Kathryn Caldwell, Canadian Cardiovascular Congress 2011 Student Poster Presenter Award

The purpose of the student oral/poster presenter awards is to recognize excellence in clinical or research presentations based on work completed as a student and related to the student's program of study. The presentation must be made within a year of graduation and the student must be the lead or co-author, and the presenting author at the CCCN National Scientific Sessions.

CLINICAL COLUMN

Cardiac Rehabilitation: Patient Referral and Enrollment

Jennifer A.D. Price, RN, MScN, ACNP, CCN(C)

At the Canadian Cardiovascular Congress in October 2010, the Canadian Cardiovascular Society (CCS) and the Canadian Association of Cardiac Rehabilitation (CACR) joined together to deliver a position paper that synthesized the evidence and provided strategies to increase patient referral to and enrollment in cardiac rehabilitation (CR) programs. In this clinical column, I will provide an overview of CR and its benefits, the utilization of CR in Canada and a summary of the joint position paper.

Cardiovascular Disease

Heart disease and stroke are two of the three leading causes of death in Canada. In 2007, heart disease and stroke accounted for over 64,000 deaths in Canada (27% of the deaths in Canada). This statistic holds true for both men and women (Statistics Canada, 2010). In addition to being the leading cause of death, cardiovascular disease (CVD) accounted for almost 3 million hospitalizations in 2004 and costs the Canadian economy more than $22.2 billion every year in physician services, hospital costs, lost wages and decreased productivity. In 2007, 1.3 million Canadians reported having heart disease.

Cardiac Rehabilitation

What is cardiac rehabilitation? Cardiac rehabilitation is a supervised outpatient program designed to improve the health and well-being of people living with heart disease. CR programs use an interprofessional team to ensure optimal medical management, exercise training and risk factor modification. Education and self-management underpin all activity in a CR program. The team typically consists of physicians, nurses, dietitians, physiotherapists, exercise specialists and mental health professionals, with other professionals participating, as required.

The CACR has adopted the following definition of CR, "The enhancement and maintenance of cardiovascular health through individualized programs designed to optimize physical, psychological, social, vocational and emotional status (Stone, Arthur, & Suskin, 2009, p. 2). CR typically involves a long-term commitment from the participant, as programs can last from three months to more than a year. Participants may attend an on-site exercise program, one to two times weekly, or they may choose to exercise at home or in the community if medically stable. Those participants who exercise at home or in the community have regularly scheduled contacts with program personnel to discuss issues and document progress over the course of their program.

Benefits. CR has been shown to be an effective intervention for both men and women and is considered an essential component of care for all patients with CVD (American Heart Association, 1994; Stone et al., 2009). The effects of exercise-based CR have been investigated in numerous trials. Four meta-analyses of randomized controlled trials have consistently shown that participation in exercise-based CR improves mortality and morbidity outcomes (Jolliffe et al., 2000; Jolliffe et al., 2001; Oldridge, Guyatt, Fischer, & Rimm, 1988; Taylor et al., 2004). Following initial treatment of a cardiac condition, participation in CR further reduces mortality by approximately 25% (Stone et al., 2009; Taylor et al., 2004). In addition, CR program participants demonstrate improvements in physical functioning and risk factor profile, as well as decreased activity-related symptoms and disability (Jolliffe et al., 2009). A recent Cochrane Review designed to determine the effectiveness of home-based CR found this method of delivery equally effective when compared to centre-based CR (Dalal, Zawada, Jolly, Moxham, & Taylor, 2010; Taylor, Dalal, Jolly, Moxham, & Zawada, 2010).

The survival benefits in more recent trials continue to be of similar magnitude despite the added benefits of increasing pharmacological and revascularization therapies. Indeed, in a recent Canadian study, CR participation was associated with a 50% lower mortality rate compared to population-matched controls (Alter, Oh, & Chong, 2009). CR programs work, improving functional status and decreasing morbidity and mortality, whether delivered at home or in a CR centre. Getting cardiac patients to participate in CR is the key to improving a patient's health and well-being.

Utilization. While the benefits of CR are well substantiated and international clinical guidelines include referral to exercise-based CR for treatment of patients with CVD (Australia, 2010; Mosca et al., 2007; Mosca et al., 2011; Stone et al., 2009; Wenger, 1995) referral and attendance rates are low, and only a small proportion of eligible candidates complete a CR program. In 1999, King et al. found that only 28% of 1,245 eligible patients attended CR programs in a study in Western Canada. A more recent Canadian systematic clinical and economic review estimated only 10% of eligible patients participate in CR programs and called for interventions to improve utilization especially among women, the elderly, ethnic minorities, and patients at high risk of a second cardiac event (Brown, Noorani, Taylor, Stone, & Skidmore, 2003).

Several studies have reported reasons for under-utilization of CR programs, which include sociodemographic fac-

tors, physician recommendation and medical/psychological factors. Independent of these factors, lack of provider referral has been shown to be the largest predictor of non-enrollment (Cooper, Jackson, Weinman, & Horne, 2002; Jackson, Leclerc, Erskine, & Linden, 2005; Stone et al., 2009).

CACR and CCS Position Statement

The objective of the policy position was to synthesize the evidence and make recommendations concerning strategies that could increase patient enrollment in CR programs. The team conducted literature searches looking for studies that evaluated the impact of a referral strategy on CR enrollment. Fourteen studies were identified and evaluated and a meta-analysis was undertaken.

Five different referral strategies were identified and included usual care, systematic, liaison, systematic and liaison and other. Usual referral practice involves an individual physician making a decision to refer to CR, discussing this with the patient, finding a referral form and communicating with a specific CR program. This strategy is the least successful with enrollment rates ranging from 6% to 32% with an overall rate of 24% (95% CI 18–32%) (Grace et al., 2011). Liaison strategies involve one-on-one discussion at the patient's bedside concerning CR programs. These strategies were shown to be more successful with a 44% enrollment rate (95% CI 35–53%) (Grace et al., 2011). Systematic referral, or standing orders for CR referral is slightly more successful at 45% (95% CI 33–57%), but combining systematic and liaison referral improves enrollment to 66% (95% CI 54–77%) (Grace et al., 2011). The most successful strategies for referral were in the "other" category. Two studies reported on the use of a letter to the patient, one following a liaison referral and one following systematic referral resulting in 58% to 86% enrollment (73%, 95% CI 39–92%) (Grace et al., 2011). While the use of patient letters seems promising, the authors caution that the evidence is inconsistent and more research is required prior to implementing.

Recommendation. Based on the finding of the meta-analysis, the position statement suggests implementing systematic referral strategies, including a patient discussion at the bedside. The evidence to support the recommendation is rated as "strong." Using a systematic referral strategy in the in-patient setting will ensure that all patients with a cardiac diagnosis are actually referred to a CR program. This should include patients undergoing coronary artery bypass surgery, valve surgery or percutaneous coronary interventions, as well as patients diagnosed with myocardial ischemia, angina or heart failure. Adding the discussion with the patient at the bedside or post-procedure enhances the probability that the patient will actually enroll in a CR program.

Nurses are ideally positioned to have the discussion with the patients concerning CR program participation. They are already providing education and support to patients concerning their cardiac diagnosis. Discussing the benefits of CR, accessing programs, and assisting patients to identify and problem solve any potential barriers to participation is a natural extension of the care provided. Even before systematic referral is implemented, cardiac nurses can take a proactive role by initiating a discussion about CR programs. Helping cardiac patients get to CR programs will help restore their health, decreasing morbidity and mortality and improving quality of life. ♥

About the Author

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REFERENCES

Alter, D.A., Oh, P.I., & Chong, A. (2009). Relationship between cardiac rehabilitation and survival after acute cardiac hospitalization within a universal health care system. *European Journal of Cardiovascular Prevention and Rehabilitation, 16,* 102–113. doi:10.1097/HJR.0b013e328325d662

American Heart Association. (1994). Cardiac rehabilitation programs: A statement for healthcare professionals from the American Heart Association. *Circulation, 90,* 1602–1610.

Australia, N.H.F. (2010). *Secondary prevention of cardiovascular disease*. Retrieved from http://www.acra.net.au/images/news/Secondary_Prevention_of_CVD_Paper.pdf

Brown, A., Noorani, H., Taylor, R., Stone, J., & Skidmore, B. (2003). *A clinical and economic review of exercise-based cardiac rehabilitation programs for coronary artery disease.* Ottawa, ON: Canadian Coordinating Office for Health Technology Assessment.

Cooper, A.F., Jackson, G., Weinman, J., & Horne, R. (2002). Factors associated with cardiac rehabilitation attendance: A systematic review of the literature. *Clinical Rehabilitation, 16,* 541–552.

Dalal, H.M., Zawada, A., Jolly, K., Moxham, T., & Taylor, R.S. (2010). Home based versus centre based cardiac rehabilitation: Cochrane systematic review and meta-analysis. *British Medical Journal, 340,* b5631. doi:10.1136/bmj.b5631bmj.b5631

Grace, S.L., Chessex, C., Arthur, H., Chan, S., Cyr, C., Dafoe, W., … Suskin, N. (2011). Systematizing inpatient referral to cardiac rehabilitation 2010: Canadian association of cardiac rehabilitation and Canadian cardiovascular society joint position paper. *Journal of Cardiopulmonary Rehabilitation & Prevention, 31*(3), E1–E8. doi:10.1097/HCR.0b013e318219721f

Jackson, L., Leclerc, J., Erskine, Y., & Linden, W. (2005). Getting the most out of cardiac rehabilitation: A review of referral and adherence predictors. *Heart, 91,* 10–14.

Jolliffe, J.A., Rees, K., Taylor, R.S., Thompson, D., Oldridge, N., & Ebrahim, S. (2000). Exercise-based rehabilitation for coronary heart disease. *Cochrane Database of Systematic Review (4), CD001800.*

Jolliffe, J.A., Rees, K., Taylor, R.S., Thompson, D., Oldridge, N., & Ebrahim, S. (2001). Exercise-based rehabilitation for coronary heart disease. *Cochrane Database of Systematic Reviews 2000(4), CD001800.*

Jolliffe, J., Rees, K., Taylor, R., Thompson, M.A., Oldridge, N., & Ebrahim, S. (2009). Exercise-based rehabilitation for coronary heart disease. *Cochrane Database of Systematic Reviews 2001(1), CD001800.* doi:10.1002/14651858.CD001800

King, K.M., Humen, D.P., & Teo, K.K. (1999). Cardiac rehabilitation: The forgotten intervention. *Canadian Journal of Cardiology, 15,* 979–985.

Mosca, L., Banka, C.L., Benjamin, E.J., Berra, K., Bushnell, C., Dolor, R.J., … Wenger, N.K. (2007). Evidence-based guidelines for cardiovascular disease prevention in women: 2007 update. *Circulation, 115*, 1481–1501. doi:10.1161/CIRCULATIONAHA.107.181546

Mosca, L., Benjamin, E.J., Berra, K., Bezanson, J.L., Dolor, R.J., Lloyd-Jones, D.M., … Wenger, N.K. (2011). Effectiveness-based guidelines for the prevention of cardiovascular disease in women—2011 update: A guideline from the American Heart Association. *Journal of the American College of Cardiology, 57*, 1404–1423. doi:10.1016/j.jacc.2011.02.005

Oldridge, N.B., Guyatt, G.H., Fischer, M.E., & Rimm, A.A. (1988). Cardiac rehabilitation after myocardial infarction. Combined experience of randomized clinical trials. *Journal of the American Medical Association, 260*, 945–950.

Statistics Canada. (2010, Nov. 30). *Leading causes of death in Canada, 2007*. Ottawa, ON: Author.

Stone, J., Arthur, H., & Suskin, N. (Eds.). (2009). *Canadian guidelines for cardiac rehabilitation and cardiovascular disease prevention: Translating knowledge to action* (3rd ed.). Winnipeg, Manitoba: Canadian Association of Cardiac Rehabilitation.

Taylor, R.S., Brown, A., Ebrahim, S., Jolliffe, J., Noorani, H., Rees, K., … Oldridge, N. (2004). Exercise-based rehabilitation for patients with coronary heart disease: Systematic review and meta-analysis of randomized controlled trials. *American Journal of Medicine, 116*, 682–692.

Taylor, R.S., Dalal, H., Jolly, K., Moxham, T., & Zawada, A. (2010). Home-based versus centre-based cardiac rehabilitation. *Cochrane Database Systematic Reviews, (1), CD007130*. doi:10.1002/14651858.CD007130.pub2

Wenger, N.K. (1995). Coronary heart disease in women. The high prevalence of coronary risk factors and the importance of prevention. *Journal of the Medical Association of Georgia, 84*, 323–328.

CHRONIQUE CLINIQUE

La réadaptation cardiaque : Référence et recrutement des patients

Jennifer A.D. Price, RN, MScN, ACNP, CCN(C)

Lors du Congrès canadien sur la santé cardiovasculaire en octobre 2010, la Société Canadienne de Cardiologie (SCC) et l'Association Canadienne de Réadaptation Cardiaque (ACRC) se sont réunis afin de présenter leur position dans un document synthétisant les évidences et les stratégies qui permettront à davantage de patients d'être référés et recrutés dans un programme de réadaptation cardiaque (RC). Dans cette chronique clinique je transmettrai une vue d'ensemble des programmes de RC et de leurs avantages, de l'utilisation des programmes de RC au Canada ainsi qu'un sommaire de l'énoncé de consensus.

Maladies cardiovasculaires

Au Canada, deux des trois principales causes de décès sont reliés aux maladies cardiaques et aux accidents vasculaires cérébraux. En 2007, ceux-ci ont causé plus de 64 000 décès au Canada (27 % des décès totaux au Canada). Ces statistiques concernent à la fois les hommes et les femmes (Statistics Canada, Released November 30, 2010). En plus d'être une cause majeure de décès, les maladies cardiovasculaires (MCV) ont occasionné environ 3 millions d'hospitalisations en 2004 et engendrés des dépenses annuelles de plus de 22,2 billions de dollars en frais de services médicaux, en frais d'hospitalisation, en perte salariale et en diminution de la productivité. En 2007, 1,3 million de Canadiens se sont identifiés comme étant atteints de maladie cardiaque.

Réadaptation cardiaque

Qu'est-ce que la réadaptation cardiaque? Destinée aux patients non-hospitalisés, la RC est insérée dans un programme structuré et supervisé et sert à améliorer la santé et le bien-être des personnes atteintes de maladies cardiaques. Les programmes de RC incluent une équipe interprofessionnelle afin d'assurer une gestion optimale des soins médicaux, favoriser l'exercice physique et modifier les facteurs de risque. L'éducation et l'auto-gestion sont des principes sous-jacents aux activités d'un programme de RC. L'équipe de soin comporte généralement des médecins, infirmières, diététistes, physiothérapeutes, kinésiologues (ou thérapeutes du sport), psychologues (ou spécialistes en santé mentale) et d'autres types de professionnels, si nécessaire.

L'ACRC a adopté la définition suivante pour décrire la RC « l'amélioration et le maintien de la santé cardiovasculaire grâce à un programme individualisé visant à optimiser l'état physique, psychologique, social, vocationnel et émotif » (Stone, Arthur, & Suskin, 2009, p. 2). La RC implique généralement un engagement du participant au programme pour une durée variant entre trois mois à plus d'un an. Les participants peuvent donc suivre un programme d'entraînement physique avec des exercices à faire dans un centre prévu à cet effet 1–2 fois par semaine ou encore ils peuvent choisir de faire leur entraînement à domicile ou dans la communauté si leur état médical le permet. Les participants qui font leurs exercices à la maison ou dans la communauté ont des contacts réguliers avec les responsables du programme de RC afin que ceux-ci puissent répondre à leurs questions et qu'ils puissent évaluer et documenter leur progression dans le programme de RC.

Avantages. La RC a été démontrée comme étant une intervention efficace autant pour les hommes que les femmes et est considérée comme étant une composante essentielle des soins pour tous les patients avec une MCV (American

Heart Association, 1994; Stone et al., 2009). Les effets des exercices du programme de RC ont été investigués dans plusieurs études. Quatre méta-analyses incluant des études contrôlées et randomisées font ressortir que la participation des patients aux exercices intégrés au programme de RC diminue la mortalité et la morbidité (Jolliffe et al., 2000; Jolliffe et al., 2001; Oldridge, Guyatt, Fischer, & Rimm, 1988; Taylor et al., 2004). La participation des patients ayant reçu un traitement initial pour leur condition cardiaque a réduit la mortalité subséquente de 25 % approximativement (Stone et al., 2009; Taylor et al., 2004). De plus, les participants à un programme de RC ont démontré une amélioration considérable de leur condition physique et de leurs facteurs de risque tout en diminuant les incapacités et les symptômes reliés à l'activité physique (Jolliffe et al., 2009). Une récente revue Cochrane destinée à déterminer l'efficacité d'un programme de RC poursuivi à domicile a fait ressortir que cette méthode est aussi efficace que si la RC est poursuivi dans un centre prévu à cet effet (Dalal, Zawada, Jolly, Moxham, & Taylor, 2010; Taylor, Dalal, Jolly, Moxham, & Zawada, 2010).

Les avantages du programme de RC présentés dans les études plus récentes sont aussi considérables que ceux des études précédentes malgré les avantages additionnels reliés à l'intensification des traitements pharmacologiques et des thérapies de revascularisation. En effet, dans une étude canadienne récente, une diminution du taux de mortalité de 50 % a été rapportée pour les participants à un programme de RC comparativement aux participants du groupe-contrôle (Alter, Oh, & Chong, 2009). Les programmes de RC sont efficaces puisqu'ils améliorent le statut fonctionnel et diminuent la mortalité et la morbidité, peu importe que la RC soit poursuivie à domicile ou dans un centre de RC. Faire participer les patients atteints de maladies cardiaques à un programme de RC est la clé pour améliorer leur santé et leur bien-être.

Utilisation. Tandis que les avantages de la RC sont bien d'emontrées et que les lignes directrices cliniques internationales indiquent l'importance de référer les patients atteints de MCV à participer à un programme de RC (Australia., 2010; Mosca et al., 2007; Mosca et al., 2011; Stone et al., 2009; Wenger, 1995), les taux de référence et de participation sont faibles et seulement une infime proportion des candidats éligibles complètent un programme de RC. En 1999, King et al. ont fait ressortir que seulement 28 % des 1 245 patients éligibles ont participé à une étude impliquant la RC dans l'Ouest canadien. Une récente revue de littérature systématique canadienne de type clinique et économique, a estimé que seulement 10 % des patients éligibles à un programme de RC y participent (Brown, Noorani, Taylor, Stone, & Skidmore, 2003). Les auteurs de la revue ont énoncé l'importance d'intervenir afin d'optimiser l'utilisation des services des programmes de RC auprès des patients et particulièrement auprès des femmes, des personnes âgées, des minorités ethniques et des patients à haut risque d'un second événement cardiaque.

Plusieurs études ont invoqué les raisons potentielles associées à une sous-utilisation des programmes de RC. Ces raisons portent sur des facteurs socio-économiques, les recommandations médicales et des facteurs médicaux/psychologiques. Indépendamment de ces facteurs, le manque de référence en provenance des fournisseurs de soins a été démontré comme étant le plus important prédicteur de non-recrutement (Cooper, Jackson, Weinman, & Horne, 2002; Jackson, Leclerc, Erskine, & Linden, 2005; Stone et al., 2009).

Position de l'ACRC et de la SCC

Les objectifs de l'énoncé de consensus ont été de synthétiser les évidences et émettre des recommandations en regard des meilleures stratégies à mettre en place pour améliorer le recrutement des patients dans un programme de RC. Les équipes ont donc réalisé une revue de littérature afin de trouver des études ayant comme objectif d'évaluer l'impact de stratégie de références dans des programmes de RC sur le recrutement des patients. Quatorze études ont été identifiées et évaluées et une méta-analyse a été réalisée.

Cinq stratégies de référence ont été identifiées : usuelle, systématique, liaison, systématique et liaison, et autre. La référence usuelle implique que seul le médecin prend la décision de référer le patient en RC en discutant de cette possibilité avec lui, en remplissant un formulaire de référence et en l'acheminant à un programme de RC spécifique. Cette stratégie est la moins efficace dans le taux de recrutement, variant entre 6–32 % et un taux global de 24 % (95 % IC, 18–32 %) (Grace et al., 2011). La stratégie de référence avec liaison implique une discussion en « tête-à-tête » au chevet du patient en regard du programme de RC. Cette stratégie a été démontrée comme étant plus efficace que la précédente avec un taux de recrutement de 44 % (95 % CI 35–53 %) (Grace, et al., 2011). La référence systématique, ou lorsqu'une ordonnance permanente est impliquée pour la référence en RC, est à peine plus efficace avec 45 % (95 % CI 33–57 %) mais la combinaison de la stratégie systématique et de liaison améliorent le recrutement jusqu'à 66 % (95 % CI 54–77 %) (Grace, et al., 2011). Les stratégies les plus efficaces pour les références sont dans la catégorie « autre ». Deux études ont rapporté que l'utilisation de lettres aux patients, l'une suivant la référence avec la liaison et l'autre suivant la référence systématique, ont démontré des taux de recrutement variant entre 58–86 % (73 %, 95 % CI 39–92 %) (Grace, et al., 2011). Tandis que l'utilisation de lettres aux patients semble prometteuse, les auteurs recommandent d'être prudent à cet égard car les évidences doivent être soutenues par davantage de recherche avant de promouvoir son application sur le terrain.

Recommandation. Basée sur les découvertes provenant de cette méta-analyse, l'énoncé de position suggère d'appliquer les stratégies de référence systématique en y incluant la discussion au chevet du patient. Les évidences qui supportent

ces recommandations sont jugées très « fortes ». L'utilisation d'une stratégie misant sur la référence systématique des patients au programme de RC lors de leur hospitalisation permettra à tous ceux ayant un diagnostic de maladie cardiaque de bénéficier d'une référence et éventuellement d'un accès à un programme de RC. Les conditions cardiaques peuvent impliquer des patients ayant recours à des pontages cardiaques, des chirurgies valvulaires ou des angioplasties coronariennes transluminales percutanées autant que ceux ayant un diagnostic d'infarctus du myocarde ou de défaillance cardiaque. Que ce soit à son chevet ou suite à son intervention, prendre le temps de discuter du programme de RC avec le patient augmentera les chances de recrutement.

Les infirmières occupent un rôle important auprès des patients, ce qui fait d'elles des personnes idéales pour discuter avec eux de leur participation à un programme de RC. On reconnaît d'ores et déjà que les infirmières procurent de l'éducation et du soutien aux patients en regard de leur diagnostic de maladie cardiaque. Discuter des bienfaits de la RC et de l'accès aux programmes, fournir de l'assistance aux patients quand vient le temps d'identifier les problèmes à résoudre et les solutions associés pour lever les barrières à la participation au RC doit être considéré comme une extension naturelle des soins prodigués. Bien avant qu'une procédure de référence systématique soit mise en œuvre par les infirmières en cardiologie, celles-ci peuvent prendre de l'avance en adoptant un rôle proactif en initiant la discussion à propos des programmes de RC. Aider les patients atteints de maladies cardiaques à accéder à la RC améliorera leur bien-être et leur santé, et diminuera la mortalité et la morbidité trop souvent associées à leur condition. ♥

Auteure

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RÉFÉRENCES

Alter, D.A., Oh, P.I., & Chong, A. (2009). Relationship between cardiac rehabilitation and survival after acute cardiac hospitalization within a universal health care system. *European Journal of Cardiovascular Prevention and Rehabilitation, 16,* 102–113. doi:10.1097/HJR.0b013e328325d662

American Heart Association. (1994). Cardiac rehabilitation programs: A statement for healthcare professionals from the American Heart Association. *Circulation, 90*, 1602–1610.

Australia, N.H.F. (2010). *Secondary prevention of cardiovascular disease*. Retrieved from http://www.acra.net.au/images/news/Secondary_Prevention_of_CVD_Paper.pdf

Brown, A., Noorani, H., Taylor, R., Stone, J., & Skidmore, B. (2003). *A clinical and economic review of exercise-based cardiac rehabilitation programs for coronary artery disease.* Ottawa, ON: Canadian Coordinating Office for Health Technology Assessment.

Cooper, A.F., Jackson, G., Weinman, J., & Horne, R. (2002). Factors associated with cardiac rehabilitation attendance: A systematic review of the literature. *Clinical Rehabilitation, 16*, 541–552.

Dalal, H.M., Zawada, A., Jolly, K., Moxham, T., & Taylor, R.S. (2010). Home based versus centre based cardiac rehabilitation: Cochrane systematic review and meta-analysis. *British Medical Journal, 340*, b5631. doi:10.1136/bmj.b5631bmj.b5631

Grace, S.L., Chessex, C., Arthur, H., Chan, S., Cyr, C., Dafoe, W., … Suskin, N. (2011). Systematizing inpatient referral to cardiac rehabilitation 2010: Canadian association of cardiac rehabilitation and Canadian cardiovascular society joint position paper. *Journal of Cardiopulmonary Rehabilitation & Prevention, 31*(3), E1–E8. doi:10.1097/HCR.0b013e318219721f

Jackson, L., Leclerc, J., Erskine, Y., & Linden, W. (2005). Getting the most out of cardiac rehabilitation: A review of referral and adherence predictors. *Heart, 91*, 10–14.

Jolliffe, J.A., Rees, K., Taylor, R.S., Thompson, D., Oldridge, N., & Ebrahim, S. (2000). Exercise-based rehabilitation for coronary heart disease. *Cochrane Database of Systematic Review (4), CD001800.*

Jolliffe, J.A., Rees, K., Taylor, R.S., Thompson, D., Oldridge, N., & Ebrahim, S. (2001). Exercise-based rehabilitation for coronary heart disease. *Cochrane Database of Systematic Reviews 2000(4), CD001800.*

Jolliffe, J., Rees, K., Taylor, R., Thompson, M.A., Oldridge, N., & Ebrahim, S. (2009). Exercise-based rehabilitation for coronary heart disease. *Cochrane Database of Systematic Reviews 2001(1), CD001800.* doi:10.1002/14651858.CD001800

King, K.M., Humen, D.P., & Teo, K.K. (1999). Cardiac rehabilitation: The forgotten intervention. *Canadian Journal of Cardiology, 15,* 979–985.

Mosca, L., Banka, C.L., Benjamin, E.J., Berra, K., Bushnell, C., Dolor, R.J., … Wenger, N.K. (2007). Evidence-based guidelines for cardiovascular disease prevention in women: 2007 update. *Circulation, 115*, 1481–1501. doi:10.1161/CIRCULATIONAHA.107.181546

Mosca, L., Benjamin, E.J., Berra, K., Bezanson, J.L., Dolor, R.J., Lloyd-Jones, D.M., … Wenger, N.K. (2011). Effectiveness-based guidelines for the prevention of cardiovascular disease in women—2011 update: A guideline from the American Heart Association. *Journal of the American College of Cardiology, 57*, 1404–1423. doi:10.1016/j.jacc.2011.02.005

Oldridge, N.B., Guyatt, G.H., Fischer, M.E., & Rimm, A.A. (1988). Cardiac rehabilitation after myocardial infarction. Combined experience of randomized clinical trials. *Journal of the American Medical Association, 260*, 945–950.

Statistics Canada. (2010, Nov. 30). *Leading causes of death in Canada, 2007*. Ottawa, ON: Author.

Stone, J., Arthur, H., & Suskin, N. (Eds.). (2009). *Canadian guidelines for cardiac rehabilitation and cardiovascular disease prevention: Translating knowledge to action* (3rd ed.). Winnipeg, Manitoba: Canadian Association of Cardiac Rehabilitation.

Taylor, R.S., Brown, A., Ebrahim, S., Jolliffe, J., Noorani, H., Rees, K., … Oldridge, N. (2004). Exercise-based rehabilitation for patients with coronary heart disease: Systematic review and meta-analysis of randomized controlled trials. *American Journal of Medicine, 116*, 682–692.

Taylor, R.S., Dalal, H., Jolly, K., Moxham, T., & Zawada, A. (2010). Home-based versus centre-based cardiac rehabilitation. *Cochrane Database Systematic Reviews, (1), CD007130*. doi:10.1002/14651858.CD007130.pub2

Wenger, N.K. (1995). Coronary heart disease in women. The high prevalence of coronary risk factors and the importance of prevention. *Journal of the Medical Association of Georgia, 84*, 323–328.

Heart Truth Entertainment Education Event for Professional Women in Newfoundland and Labrador: An Exploratory Study

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Problem: *Entertainment education (EE) is under-studied.*

Methods: *The Heart Truth EE event for professional women brought entertainers to educate individuals about heart health. Pre- and post-event survey data from participants were supplemented by interview data.*

Findings: *Approximately one half of the respondents reported having relatives who had a myocardial infarction (MI) before age 65 years, or a male relative who had an MI or stroke before age 35 years, engaged in less than 30 minutes of activity per day, and reported being overweight or obese. During the post-survey at four months, we found that 64% of respondents made at least one change to improve their health.*

Conclusions: *Our results suggest that EE may be an effective way to promote heart health.*

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L'événement d'éducation de divertissement vérité du cœur pour les femmes professionnelles à Terre-Neuve et au Labrador : Une étude exploratrice

Problème : *L'Éducation de Divertissement (ÉD) est sous étudié.*

Méthode : *L'événement d'ÉD Vérité du Coeur pour les femmes professionnelles, amène les formateurs à enseigner la santé du cœur aux participantes. Les données des participantes recueillies avant et après l'événement sont un supplément à celles recueillies par les entrevues.*

Résultats : *Approximativement la moitié des répondantes rapportent avoir un parent ayant souffert d'un infarctus du myocarde (IM) avant l'âge de 65 ans, ou un parent de sexe masculin ayant souffert d'un IM ou d'un accident vasculo-cérébral avant l'âge de 35 ans, pratiquant moins de 30 minutes d'activité par jour, et reportant avoir un surplus de poids ou souffrant d'obésité. Durant la période post-sondage, à 4 mois, nous avons constaté que 64 % des répondantes ont réalisé au moins un changement pour améliorer leur santé.*

Conclusion : *Nos résultats suggèrent que le l'ÉD peut être un moyen efficace de promouvoir la santé cardiaque.*

Background and Literature Review

The burden of heart disease has shifted, now killing more women than men. In Canada, heart disease is the leading cause of death for women aged 55 years and older (Public Health Agency of Canada, 2009). Cardiovascular disease is linked to behavioural risk factors and genetic susceptibility. The situation for women stands to worsen as the number of Canadian women with non-modifiable risk factors (such as age, race/ethnicity and family history) increases. Furthermore, Canadian women are not reducing their modifiable risk factors for heart disease (such as smoking, high-fat diets, high blood cholesterol levels, overweight/obese, physical inactivity and hypertension) (Heart and Stroke Foundation of Canada, 1997).

Approximately one half of the future burden of heart disease could be eliminated with the introduction of population-based interventions designed to promote healthier diets and increase physical activity (Capewell, 2009). The Heart Truth Campaign (Heart & Stroke Foundation of Canada, 2002) aims to raise awareness among women of their risk of heart disease and stroke and provide them with the necessary tools to protect themselves. One of the ways in which the campaign has been raising awareness is through the annual

Heart Truth Fashion Show. At this event, celebrities and fashion designers partner with the Heart & Stroke Foundation of Canada (HSFC) to promote greater awareness and encourage heart health.

HSF of Newfoundland and Labrador (HSFNL) is an active participant in the national Heart Truth Campaign (See http://www.thehearttruth.ca/what_is_the_red_dres/ for additional information on the campaign). As part of the Heart & Stroke Foundation's Heart Truth Campaign, HSFNL launched an initiative for rural women titled "Heartbeats on-line" in which Jodine Kean, RN, Director, Health Promotion and Resuscitation, HSFNL, reported that, "Heartbeats help women take small steps that add up to big gains" (The Compass, 2009, para. 10) that include tips on smoking cessation, exercise, and healthy eating. During another presentation, Kean commented that "through lifestyle changes, people can reduce their risk of having a heart attack or stroke by up to 80 per cent" (The Charter, 2009, para. 6).

In the fall of 2009, an HSFNL planning committee was established to organize a Heart Truth event that would deliver health messages using entertainment education (EE) in an effort to deliver heart health education to professional women in an urban setting. NL has a rich history of passing on stories from generation to generation orally and HSFNL was interested in capitalizing on this strength by delivering heart truth messages using story-telling, music, theatre, and comedy. This use of entertainment is referred to as entertainment-education (EE). EE is defined as "the process of purposefully designing and implementing media messages to both entertain and educate, in order to increase audience members' knowledge about an educational issue, create favourable attitudes, shift social norms and change overt behaviour" (Singhal & Rogers, 1999, p. 9).

The Centers for Disease Control (CDC) recognizes that EE can be an effective strategy for promoting health. In May 2000, the CDC assembled an expert panel to identify EE research topics and identify any gaps (Centers for Disease Control, 2000). The CDC concluded that more research is needed to understand the effects of EE. We were interested in exploring the impact that EE may have on changing health-related behaviours in women.

The Heart Truth event organized by the HSFNL, "Listen to Your Heart", was a fun, entertainment-based, heart-healthy luncheon. Its goal was to educate women about their risk of heart disease and to encourage and motivate them to make at least one lasting lifestyle change to reduce their risk. On February 26, 2010, at the GEO Centre in St. John's, more than 150 people attended the event. The event started at 12 p.m. and concluded at 2 p.m. Women sat at tables and throughout the event shared heart healthy tips. The healthy lunch was provided by Red Oak Catering while entertainers Amy House, Kelly-Ann Evans and Sarah Small delivered life-changing messages through comedy and song. Krissy Holmes, a local TV celebrity, was master of ceremonies. Additional celebrities, and members of the research team, wore red designer dresses, previously used in the 2008 and 2009 Fashion Shows held in Toronto (pictures available on the NLCAHR website http://www.nlcahr.mun.ca/research/affinity/aging/heart.php). There were testimonials from two women who each told their stories about how heart disease affected them. The luncheon concluded with each model providing a tip on a manageable lifestyle change that women in the audience could make to reduce their risk of heart disease or stroke.

In February 2010, coinciding with the Heart Truth Campaign, our Memorial University research team, in partnership with the HSFNL, completed an exploratory study of the Heart Truth EE event for professional women in NL.

Objectives

The four objectives of our exploratory study were:

1. To examine the characteristics of women who participated in a Heart Truth EE event;
2. To determine if women who attended a Heart Truth EE event made at least one lifestyle change, as measured using pre-post survey data;
3. To determine the single most important change that women made after they had attended the Heart Truth EE event before, as measured using pre-post survey data;
4. To collect women's perceptions of the Heart Truth EE event and their suggestions for improvement, using a post-event survey and interviews.

Method

Design. This exploratory study used pre-event and four months post-event survey data supplemented by interview data.

Participants. All women who registered to attend the Heart Truth EE event (n = 85) were invited to complete an online pre-event survey pertaining to heart health and health behaviours. Forty-eight of the 85 women (56.4%) completed the initial survey. Four months after the event, we invited women who indicated a willingness to be contacted on follow-up (n = 41) to complete an online post-event survey and/or participate in a 15-minute post-event interview. Twenty-five women completed the post-event survey and four women participated in a post-event interview.

Instruments. The pre- and post-event surveys were comprised of questions from the Heart and Stroke Foundation's Heart Truth Quiz and a question published by Mosca et al. (2006) concerning self-efficacy, used with permission from the study author. A 15-minute audio-taped interview was completed and transcribed. No names appeared on the transcripts.

Ethics. The study was approved by Memorial University's Human Investigations Committee (HIC). Participation in the study was voluntary.

Data analysis. Quantitative data were analyzed using descriptive statistics. Themes from the qualitative data were identified using content analysis.

Results

Objective 1: To examine the characteristics of women who participated in a Heart Truth EE event.

The majority of women who participated in the Heart Truth EE event were between the ages of 40 and 60 years (81.3%). The majority indicated they were non-smokers (89.6%), consumed less than two drinks a day (95.7%), and ate high-fat foods less than once a week (65.2%). The majority of women reported not having high blood pressure (82.6%) or high cholesterol (71.7%). They indicated confidence in changing behaviours (95.7%) and in their abilities to perform tasks and activities needed to manage their health condition so as to reduce their need to see a doctor (56.5%). More than 40% reported having a relative who had a heart attack or stroke before age 65. Only approximately 50% reported: being of normal weight, knowing their body mass index (BMI) and engaging in 30 minutes of physical activity a day. Many reported they occasionally felt stressed or anxious (76.1%).

Objectives 2 and 3: To determine if women who attended a Heart Truth EE event made at least one lifestyle change, as measured using pre-post survey data, and determine the single most important change.

The majority of respondents to the follow-up survey (64.0%) described making at least one lifestyle change since the event. The most frequently reported changes included increased exercise and/or sports/physical activity, losing weight, and improving eating habits. An overview of follow-up data is outlined in Table 1.

Table 1: Overview of "Listen to Your Heart" follow-up data

	n = 25	%
Since attending the Listen to Your Heart Luncheon, did you do anything to improve your health?		
Yes	16	64.0
What is the single most important change you have made?		
Increased exercise and/or sports/physical activity	8	50.0
Lost weight	2	12.5
Changed diet and/or improved eating habits	2	12.5
Do you think there is anything (or anything else) you should do to improve your physical health?		
Yes	21	84.0
What is the most important thing?		
Start/increase exercise and/or sports/ physical activity	7	33.3
Change diet and/or improve eating habits	8	38.1
Quit smoking or reduce amount smoked	1	4.8
Drink less alcohol	2	9.5
Reduce stress level	2	9.5
Other	1	4.8
Is there anything stopping you from making this improvement?		
No	17	81.0
What is that?	4	
Lack of will power / self-discipline	1	25.0
Family responsibilities	1	25.0
Work schedule	1	25.0
Other	2	50.0
Is there anything (or anything further) you intend to do to improve your physical health in the next year?		
Yes	15	60.0
What is that?		
Start/increase exercise and/or sports/ physical activity	5	33.3
Lose weight	6	40.0
Change diet and/or improve eating habits	7	46.7
Quit smoking or reduce amount smoked	1	6.7
Drink less alcohol	2	13.3
Reduce stress level	3	20.0
Receive medical treatment	1	6.7
Take vitamins	2	13.3
Other	3	20.0

continued…

Objective 4: To collect women's perceptions of the Heart Truth EE event and their suggestions for improvement, using a post-event survey and interviews.

Women's perceptions of what worked well at the Heart Truth EE event and suggestions for improvement are presented below.

A. What worked well?

Three themes were identified under "What worked well": (1) messages about non-modifiable risk factors, (2) delivery of the messages that included testimonials and comedy, and (3) reinforcement.

Theme 1: Messages about non-modifiable risk factors

There were many statements made by respondents regarding the information delivered during the event on the non-modifiable risk factors for heart disease. Women who attended the event reported that the lifestyle changes they had attempted on their own were not always enough in avoiding heart disease, but that there were also genetic influences.

> *… everybody thinks that, you know, if you change your lifestyle and you do this, this, and this, then you certainly will lower your risk of heart disease, but that probably isn't enough… it's hereditary and although those particular individuals I know from knowing them look after themselves very, very well they still have high cholesterol…*

Women recognized that there were non-modifiable risk factors involved in the risk of developing heart disease and mentioned it was important to share that information with others.

> *… I think all women need to know not just the ones who have problems you know, because you can have a heart attack and not be overweight. You can have a heart attack and be very physically active, you know…*

Theme 2: Delivery of the messages that included testimonials and comedy

There were also many positive statements made by respondents about the way the messages were delivered. The testimonials provided by the women at the event were said to be very powerful. Listening to the stories of others worked well for them and they could relate to the way the information was provided.

> *"… for that type of event… you certainly didn't need a lecture… the ladies who gave the stories about what happened to them… it always helps to know there are others who are going through the same thing…."*

The personal stories motivated women to consider healthy behaviours.

> *"… hearing the stories of women who have had heart disease and whose lives were threatened made a huge impact and motivated us to be healthy and prevent heart attacks from occurring…."*

Comments made by the women suggest that storytelling is an effective way to deliver messages.

> *"… certainly the testimonials were very powerful… the way she sort of presented her storyline it made you think… people learn from other people's stories because they can readily relate more so… it sort of sends home a stronger message to the everyday person because then they can sort of relate it to their own lives and probably hit a chord…"*

> *"… hearing the stories of women who have had heart disease and whose lives were threatened made a huge impact and motivated us to be healthy and prevent heart attacks from occurring…"*

There were many quotes about the presentation of health information using comedy. *"… I thought it was a good mixture of entertaining, light-hearted event and this very serious side of heart disease… the serious side of it was brought out in a not too heavy way…."*

Theme 3: Reinforcement

Reinforcement of heart information was a strong theme identified in the transcripts. Women mentioned that the event helped them to become more determined to continue to take the time to focus on their health.

> *"… attending that luncheon—everything made me more determined to move forward and take care of myself… I had been neglecting myself for a long time…."*

They found that the event provided an opportunity to consider their health a priority.

> *"… good opportunity for all of us to take the time to focus on ourselves and our own health—to put priority on taking care of ourselves…."*

The women reported that messages received from the Heart Truth luncheon reaffirmed the changes women had made in reducing the risks of heart disease.

> *"… attending the luncheon just reinforced for me in a positive way what I was doing was correct… it just reaffirmed for me what I was doing was appropriate for my own health…."*

Women stated they thought they had done what they could in order to reduce the risks.

> *"… I can't think of any more changes that I can make… diet or exercise or lifestyle or stress… it [the event] reinforced that I have made all of the smaller changes that I think are possible…."*

B. Suggestions for improvements

Three themes were identified by the women related to improvements that could be made: cost, collaborative care, and public education. Cost related to improvements for future events. Collaborative care and public education related to improvements in general.

Theme 1: Cost

Women reported only one area for possible improvement to future events: cost. The cost factor associated with the event was mentioned by some as a possible deterrent to women being able to attend the event.

"… the cost factor may have potentially prevented women from attending...."

… in my opinion that was a lot of money for one night [sic, event was a luncheon] for one person… I could afford to go, but there are a lot of women in this province who wouldn't put out $50 to go—not only would they not put it out, but they can't put it out. They don't have the money to go out for that. So the cost of the night might be a factor to consider…

Theme 2: Collaborative care

The women had many comments on ways the delivery of care could be improved. We labelled this theme collaborative care. Threaded throughout many of the women's comments was the role of health care professionals in heart health education. Nurses were seen as playing a significant role.

"… somebody like a nurse would be able to go into it in more detail and answer questions for people who can't interpret the sheet [diagnostic test results]… it is so useful to have somebody like patient consultants or a nurse practitioner…."

Women also reported that nutritionists could play a role.

… I would have appreciated if the nutritionist… if they could just do a handout that would say this is what your luncheon contains today—this is how much fibre is in your lunch, how much fibre was in the soup, how much fat, how many calories, because our goal is to learn to eat better and take care of ourselves… to teach us how to analyze the food and know what we're doing…

Theme 3: Public education

Respondents commented on the need for public education to increase public awareness of heart health. The following quote is a good example.

"… the public aspect of education would probably be the one that needs to be boosted… things like the whole campaign about stroke on television… and maybe those symptoms of heart disease are not as obvious I don't think… it's not emphasized quite as much as the stroke aspect… "

Women suggested making information readily available and visible through written materials such as brochures and posters.

"… if there were some brochures—I know I saw an ad on TV yesterday I think it was talking about if someone is having a stroke… if I had a brochure I would probably read it from time to time… "

"… you could have a huge poster that would display various aspects… you'd get a large number of the population looking at it and not only females, but I think you'd get males looking at it too and then sort of maybe even questioning or maybe helping some of their female partners or even questioning their own heart health for that matter… reinforcing the importance of heart health… "

Discussion

In this exploratory study we found that most women who participated in a Heart Truth EE event in St. John's, NL, reported that they were above age 40, were non-smokers, drank less than two drinks per day, avoided high-salt foods, and were confident that they could successfully change their behaviour. Approximately half of the respondents also reported that they had a relative who had a heart attack before age 65 or a male relative who had a heart attack or stroke before age 35, engaged in less than 30 minutes of exercise per day, and were overweight or obese but did not know their BMI. At follow-up we found that 64% of respondents did at least make one change to improve their health after attending the Listen to Your Heart luncheon. The single most frequent change made by respondents was increased exercise and/or sports/physical activity.

Women tended to make very positive comments about the testimonials that addressed non-modifiable risk factors and about the reinforcing nature of the event. Women suggested that the event could be improved by lowering the cost. They also commented that care to women could be improved by increasing the availability of nurse practitioners to educate individuals and by increasing public awareness of heart disease and women.

The strength of our exploratory study is the collection of quantitative data before and after an event that used innovative entertainment-education and the collection of qualitative data through an open-ended question in the survey and interview data. Our results are consistent with the previously cited literature indicating that EE can lead to changes in behaviour. Our exploratory study has some limitations. First, our study lacked a comparison group. However, national tracking data collected by Harris/Decima indicated that 17% of women who had heard of the Heart Truth Campaign reported that they had made a change to their lifestyle (Bobbi Wood, personal communication, March 23, 2011). Our results suggest that, compared to the campaign, the campaign plus EE led to more women making changes. Second, the women who attended this event were very confident that they could change their behaviour. EE may not be as effective with less confident women.

Nursing Implications

The Canadian Nurses Association (CNA) has outlined the important educational and advocacy role that nurses can play in cardiovascular disease (Canadian Nurses Association, 2005). With individual patients, nurses can use their skills in health education to help patients develop skills to

manage their heart disease. Nurses within communities, CNA noted, should play a role in ensuring that appropriate services are available. If services are unavailable, nurses should advocate for increased investment in chronic disease management services.

Some comments made by the participants of the HSFNL Heart Truth EE event are consistent with the CNA's comments. Participants stated that there are opportunities for staff nurses to play important roles as educators, navigators, and as advocates in promoting heart health. Staff nurses could increase the knowledge and skills of individuals to identify and manage risk factors for heart disease. These actions by staff nurses would increase individuals' capacity for self-management of cardiac disease. In turn, if staff nurses were to use teachable moments to increase self-efficacy for cardiac disease, morbidity and mortality and the burden on the health care system would be reduced.

Other comments suggest that the CNA may want to augment its backgrounder on *Chronic Disease and Nursing* with a discussion of the role of nurses in addressing non-modifiable risk factors. The CNA backgrounder does not address the important role nurses can play in helping individuals who have a genetic predisposition to cardiac disease. The data from the pre-event survey indicate that almost 42% of respondents appear to be genetically at risk for heart disease. We conclude that nurses have a role as navigators to assist individuals in seeking and obtaining appropriate medical help, beyond providing education on lifestyle modifications.

Implications for Future Research

Self-management training has been shown to improve blood pressure (Katch & Mead, 2010). Nevertheless, self-management education appears to not reach everybody, which leads us to consider alternatives building on our EE research reported here. EE's potential has not been explored systematically in either developed or developing countries (Centers for Disease Control, 2000). The CDC assembled an expert panel to identify priority EE research topics, and it was determined that there is an important research gap concerning the effects of EE. Our future research will help address this research gap. We have received funding to develop an EE intervention for individuals 45 years and older with uncontrolled hypertension. We will develop and pilot test the intervention, and then apply to conduct a randomized controlled trial (RCT). Our objective will be to determine whether individuals exposed to EE are able to reduce blood pressure more than those receiving usual care and by how much. Our future research could lead to sustainable initiatives that empower individuals with cardiovascular disease and improve their quality of life. ♥

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REFERENCES

Capewell, S. (2009). Trends in cardiovascular disease: Are we winning the war? *Canadian Medical Association Journal, 180*, 1285–1286.

Centers for Disease Control. (2000). *Setting a research agenda for entertainment-education.* Retrieved from http://www.cdc.gov/healthmarketing/PDF/eersrcha.pdf

Canadian Nurses Association. (2005). *Chronic disease and nursing: A summary of the issues.* Retrieved from http://www.cna-nurses.ca/cna/documents/pdf/publications/bg3_chronic_disease_and_nursing_e.pdf.

Heart and Stroke Foundation of Canada. (1997). Women, heart disease and stroke in Canada: Issues and options. Retrieved from http://www.med.mun.ca/chhdbc/pdf/womanhrt.pdf

Heart & Stroke Foundation of Canada (2002). *The heart truth campaign.* Retrieved from http://www.theheartttruth.ca/the_campaign/

Heart and Stroke Foundation of Canada. (2008). *The heart truth quiz.* Retrieved from http://www.theheartttruth.ca/heart_truth_quiz/

Katch, H., & Mead, H. (2010). The role of self-efficacy in cardiovascular disease self-management: A review of effective programs. *Patient Intelligence, 2*(1), 33–44.

Mosca, L., Mochari, H.l., Christian, A., Berra, K., Taubert, K., Mills, T., … Simpson, S.L. (2006). National study of women's awareness, preventative action, and barriers to cardiovascular health. *Circulation, 113,* 525–534.

Public Health Agency of Canada. (2009). *Are women at risk for heart disease?* Retrieved from http://www.phac-aspc.gc.ca/cd-mc/cvd-mcv/women-femmes_01-eng.php

Singhal, A., & Rogers, E.M. (1999). *Entertainment-education: A communication strategy for social change.* Mahwah, NJ: Erlbaum.

The Compass (2009). *One in three Canadian women die of heart disease.* Retrieved from http://www.cbncompass.ca/section/2009-01-20/article-1500219/One-in-three-Canadian-women-die-of-heart-disease/1

The Charter (2009). *Heart health awareness raised.* Retrieved from http://www.thecharter.ca/section/2009-04-20/article-1493910/Heart-health-awareness-raised/1

Disrupting the Biomedical Discourse: Older Women's Lived Experiences with Heart Failure: A Feminist Review of the Literature

Tina Pereza Rolls, RN, BScN, MN, and Lynne E. Young, RN, PhD

To understand heart failure from older women's perspectives, a systematic review of the literature on older women's lived experiences with heart failure was conducted from a feminist perspective. The review and analysis of the literature on the experiences of older women living with heart failure was based on Hall and Steven's (1991) three basic principles of feminism. To make the transition from feminist principles to feminist praxis, six questions formulated by Bunting (1997) were applied when reviewing and analyzing the literature. Four journal articles were found to be relevant for this literature review. All four articles benefited women; valued women's experiences, ideas, and needs; recognized the structural, interpersonal, and ideological conditions that oppress women; and included a portrayal of women's strengths. Two out of four of the articles represented an awareness of human diversity; none of the journal articles stated a commitment to social change.

There is a paucity of literature on older women's lived experiences with heart failure. Historically, men have been the model subjects of cardiovascular disease; men's experiences have been privileged and are regarded as the normative frame of reference with women constantly compared to men. Using feminist principles to critically review research on women's experiences of cardiovascular disease, such as in this review of older women's experiences of heart failure, brings to the surface unique issues relevant to knowledge generation. Reviewing the literature from a feminist perspective disrupts the androcentric biomedical discourse on heart failure. Further, generating new understandings of heart failure from the perspectives of older women contributes to nursing knowledge, practice, and research.

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Perturbation du discours biomédical : Les expériences vécues des femmes plus âgées souffrant d'insuffisance cardiaque : Une revue de la littérature féministe

Résumé

Pour comprendre l'insuffisance cardiaque de la perspective des femmes plus âgées, une revue systématique de la littérature chez les expériences vécues des femmes plus âgées souffrant d'insuffisance cardiaque a été conduit via une perspective féministe. La revue et l'analyse de la littérature concernant l'expérience des femmes plus âgées vivant avec l'insuffisance cardiaque sont basées sur les trois principes de bases du féminisme de Hall et Steeven (1991). Pour faire la transition des principes féministes à la pratique féministe, six questions élaborées par Bunting (1997) ont été appliquées lors de la révision et de l'analyse de la littérature. Quatre articles de journaux ont été retenus pour cette revue de la littérature. Tous ces articles ont profité aux femmes, estimant leurs expériences, leurs idées et leurs besoins; reconnaissant leurs conditions structurelles, interpersonnelles et idéologiques qui les oppressent; et incluant un portrait de leurs forces. Deux des quatre articles représentent une conscientisation de la diversité humaine; aucun article relatait un engagement vers le changement social.

Il y a un manque dans la littérature concernant l'expérience vécue des femmes plus âgées souffrant d'insuffisance cardiaque. Historiquement, les hommes ont été le sujet modèle pour les maladies cardiovasculaires; l'expérience des hommes a été privilégié et sont vu comme le cadre de référence normatif où les femmes sont constamment comparées avec les hommes. En utilisant les principes féministes pour réviser de façon critique les études concernant l'expérience vécue des femmes souffrant de maladies cardiovasculaires, tel que cette revue sur l'expérience vécue des femmes plus âgées souffrant d'insuffisance cardiaque, amène des points uniques pertinents pour la génération de nouvelles connaissances. Réviser la littérature de la perspective de féministe perturbe le discours biomédical androcentrique sur l'insuffisance cardiaque. Dans le futur, générer de nouvelles compréhensions sur l'insuffisance cardiaque dans une perspective de femmes plus âgées contribue au savoir infirmier, à la pratique et à la recherche.

Background to Older Women's Experiences of Heart Failure

Canada's aging population. The demographics in Canada are changing. The Canadian population is aging with one in seven Canadians aged 65 or older, 56% of whom are women (Minister of Public Works and Government Services Canada, 2002; Statistics Canada, 2007). Heart failure accounted for about 4,300 deaths of those older than 65 in Canada in 2006 with 63% of those deaths occurring in women (Statistics Canada, 2010), a number higher than would be expected given the demographics of this population. Heart failure is a condition that seriously affects one's quality of life and lon-

gevity, and one that is more likely to occur in women than men (Gary & Davis, 2008). Nurses are well positioned to support women with heart failure to live as healthily and as long as possible. Thus, cardiovascular nurses will benefit from knowledge about heart failure to support their practice with older women. An important source of nursing knowledge relevant to caring for women in heart failure is knowledge of women's lived experiences (Jacobs, 2001). The purpose of this paper is to use feminist principles to guide a critical review of the research on women's lived experiences of heart failure from the perspective of women themselves, a decidedly feminist perspective on research (Im, 2010). Reviewing the literature from a feminist perspective disrupts the androcentric biomedical discourse on heart failure (Perry, 1994).

Feminism and knowledge for nursing. Harding (1987) defines feminist research as being done for women and from the perspective of women's experiences. Furthermore, Harding contends that women's experiences are pluralistic—in other words, there is no universal "women's experience" for women's lives have never been shaped exclusively by gender. Hall and Stevens (1991) note that women's interpretations, values, interests, and actions are vast and vary according to sexual orientation, class, race, ethnicity, education, age, and national origin. Moreover, Hall and Stevens posit that the intent of feminist inquiry is not only to describe and interpret phenomena of women's lives, but also to raise consciousness and bring about changes in the interests of the women studied. While studying women is not a novel concept, studying women from the perspective of their own experiences, as understood by the women themselves, is distinctive (Bunting & Campbell, 1990; MacPherson, 1983; O'Donnell, Condell, & Begley, 2004). To this end, Parker and McFarlane (1991) assert that feminist research is grounded in women's experiences.

Understanding women's experiences from their own perspective provides nursing with valuable knowledge that contributes to what and how nurses know in order to be authentically present with, and respect, women (Jacobs, 2001). A feminist perspective resonates with us personally and professionally. As a respectful approach, it is reflective of our way of knowing and being. Coming to understand others' experiences enables us to come to understand our own experiences and knowledge, as women, and our own experiences and knowledge, as nurses. Thus, we use feminist principles to guide a critical review of the literature on women's lived experiences of heart failure to appraise this body of research relevant to advancing knowledge development for women. An explanation of a feminist perspective from a historical and current context will now be provided.

Historical and current context of a feminist perspective. Hall and Stevens (1991) claim that generating knowledge from a feminist perspective is distinguished by several characteristics. First, research questions reflect the concerns of a particular group of women; second, the purpose of feminist research is to benefit the women being researched rather than the researcher; third, the researcher's history, assumptions, motives, interests, and interpretations are explicit in the process; and, fourth, the multiple realities of women are recognized, valued, and connected to the larger political, social, and economic environments. Im (2010) contends that there are characteristics that all feminist perspectives have in common. These characteristics include placing an importance on women's lived experiences at the centre of the study and considering women's diverse situations and contexts; examining theory, practice, and action that are problematic to the social justice for women; viewing gender as a major factor that interacts with other considerations such as race and class to structure relationships; objecting dualism; striving toward narrowing the distances between the observer and the object of the study; and, rejecting uni-causal, hierarchical approaches.

In 1991, Hall and Stevens identified and articulated three basic principles of feminism:

1. A valuing of women and a validation of women's experiences, ideas, and needs;
2. A recognition of the existence of ideological, structural, and interpersonal conditions that oppress women; and
3. A desire to bring about social change of oppressive constraints through criticisms and political actions (p. 17).

Gaining an awareness of the historical context, characteristics, principles, and criteria of feminism informed our understanding of a feminist perspective. In turn, this raised our consciousness and influenced our lens, as we engaged in the literature review.

Transition from Feminist Principles to Feminist Praxis

To make the transition from feminist principles to feminist praxis, the practical and specific application of feminist principles to a critique (McCormick & Bunting, 2002), six questions were applied when reviewing and analyzing the literature. The six questions were formulated by Bunting (1997) from a synthesis of characteristics identified from nursing's feminist literature:

1. Does the research report have a stated or strongly implied purpose of benefiting women?
2. Is there evidence of valuing women and women's experiences, ideas, and needs?
3. Is there an expressed or implied recognition of the structural, interpersonal, and ideological conditions that oppress women?
4. Is there evidence of commitment to social change?
5. Is there a representation of statement of awareness of human diversity?
6. Does the report include a portrayal of women's strengths? (p. 526).

McCormick and Bunting (2002) assert that research studies that do not claim to be feminist should not be judged by feminist standards. Thus, in respect to the authors of the four journal articles, and in concert with McCormick and Bunting's paper, the intent of the literature review is not to criticize these readings for not being feminist, nor is it a critique of the quality of the research study. Rather, the feminist aspects of the researcher's perspective on studies on the experience of women with heart failure are examined. Bunting (1997) observes that many nurses researching women may have, consciously or unconsciously, used a feminist perspective in their studies without an explicit statement.

Searching for and reviewing the literature. The electronic database, Cumulative Index to Nursing and Allied Health Literature (CINAHL) was used to identify and locate literature for review. Key words for searching the literature included heart failure, adults, older adults, women, experience, qualitative, phenomenology, hermeneutics, and narratives. The criteria for reviewing journal articles included articles written in English, women as the study's sole participants, and use of a qualitative methodology. The exclusion criteria were journal articles not in English (Barremo, Bruce, Salander, & Sundin, 2008), men as the sole participants (Nordgren, Asp, & Fagerberg, 2007), men included as study participants (Costello & Boblin, 2004; Ekman, Ehnfors, & Norberg, 2000; Evangelisa, Kagawa-Singer, & Dracup, 2001; Galvao, 2005; Rodriguez, Appelt, Switzer, Sonel, & Arnold, 2008; Stromberg & Martensson, 2003; Stull, Starling, Hass, & Young, 1999; Yu, Lee, Kwong, Thompson, & Woo, 2007), women not identified as study participants (Albert, 2007; Zambroski, 2003), the methodology was quantitative and/or based on epidemiology, pathophysiology, and treatment (Halm & Penque, 2000; O'Mahony, Sim, Ho, Steward, Buchalter, & Burr, 2003; Richardson & Rocks, 2001; Tandon, Hankins, & Le Jemtel, 2002), and if a concept in addition to heart failure was also in the article (Brännström, Ekman, Norberg, Boman, & Strandberg, 2006; Dougherty, Pyper, Au, Levy, & Sullivan, 2007; Falk, Granger, Swedberg, & Ekman, 2007; Gary, 2006; Hägglund, Boman, & Lundman, 2008). The aim of the research of the four relevant readings along with the methodology, participant sample, setting, procedures, findings, and researcher's statement of limitations will now be provided.

When searching for literature on the lived experiences of older women with heart failure, we found four articles to be relevant for this literature review: Ekman & Skott, 2005; Ekman, Skott, & Norberg, 2001; Martensson, Karlsson, & Fridlund, 1998; Rhodes & Bowles, 2002. We read and reviewed each article several times. Once the abstract was read, the article was read in its entirety for content. Following, we reviewed the aim, setting, participants, methodology, procedures, findings, and limitations for each individual article. Subsequently, we applied the aforementioned six questions that addressed the feminist aspects of the researcher's perspective on these journal articles when we reviewed and analyzed the literature.

Examination of Feminist Aspects of the Researcher's Perspective on Studies on the Experience of Women with Heart Failure

The first article is by Ekman and Skott (2005). The aim of their research was to "develop clinical knowledge applying hermeneutic phenomenology to gain an understanding of how it is to live with heart failure from a daily life perspective" (Ekman & Skott, p. 251). Hermeneutic phenomenology is a method used by the researcher to come to an understanding of the meaning of the text using an interpretative approach (Patton, 2002; Schwandt, 2001). In this study, an interview was conducted with one 62-year-old woman; the setting of the research was not disclosed by the researchers. However, the researchers state that the woman was a participant in a prior research project dealing with the experience of people living with heart failure and was being treated in a heart failure outpatient clinic for approximately one year at the time of the study. The purpose of Ekman and Skott's research was to garner a greater understanding of living with heart failure by interpreting the woman's narrative of this experience. The woman was asked to talk about her experiences of living with heart failure. The story flowed smoothly, uninterrupted by questions or comments from the researchers. This story was tape-recorded and then transcribed verbatim. The researchers interpreted the textual account of the woman's experience using Ricoeur's (1991) five-step approach to an interpretative analysis: "(1) general or naïve reading, (2) distancing, (3) examination of discourses, (4) conjectures and questions, and (5) reflection on the whole" (p. 253). The researchers identified an overarching theme as "struggling to comprehend medical information" (p. 254). The researchers did not identify limitations of their study.

The second article is written by Ekman et al. (2001). The aim of this research, in which hermeneutic phenomenology was the method applied, was to obtain a deeper "understanding of the lived experience of being an elderly woman with heart failure" (Ekman et al., 2001, p. 60). Data were gathered during an interview with a 79-year-old woman. When asked about her illness, the woman talked about her experience during two occasions uninterrupted by the researcher. The first narrative took place in the woman's two-room apartment and the second narrative occurred a year later in a nursing home to which she had relocated. Both accounts were tape-recorded, transcribed verbatim, and interpreted using Ricoeur's (1991) five-step analysis. The researchers identified the overarching themes of "being at home" and threats to this "being at home." The researchers did not identify limitations to their study.

The third article is by Mårtensson et al. (1998). The aim of their research, using phenomenography as method, was "to describe how female patients with heart failure conceive their situation" (Mårtensson et al., 1998, p. 1216) from a nurse's perspective. Phenomenographic research examines phenomena as they are conceived and increases awareness of the ways a particular phenomenon may be experienced (Åkerlind, 2005).

Semi-structured interviews were conducted with participants. The interview questions reflected the perspective of holistic nursing and, as a guided interview process, involved asking questions that interrupted the flow of the women's narratives. Twelve women between the ages of 65 and 83 years participated in the interviews: eight attended elementary school and four attended college, five were married and seven were widowed, and five were housewives, four were unskilled workers, and three were skilled workers. To document the degree of the physical limitation and severity of heart failure, the New York Heart Association [NYHA] functional classification was used. The NYHA is classed from I to IV and is defined as NYHA I: no symptoms, NYHA II: symptoms with ordinary activity, NYHA III: symptoms with less than ordinary activity, and NYHA IV: symptoms at rest or with any minimal activity (Arnold et al., 2006). The women were NYHA II to IV. The interview questions were based on nursing's theory holistic perspective and, thus, focused on five domains: biophysical, sociocultural, emotional, intellectual, and spiritual-existential (Sarvimäki & Stembock-Hult, 1993).

The setting for the interviews was the woman's home except one interview that was held in the visitor's room in the hospital. The interviews were transcribed verbatim; analysis began by reading each transcript repeatedly until saturation was reached and similarities and differences were grouped into patterns. The researchers do not cite the author whose method they used. A final pattern emerged and resulted in five categories: feeling content, feeling a sense of support, feeling a sense of limitation, feeling anxiety, and feeling powerless. The researchers noted that a limitation of their study was that their results could not be generalized. However, qualitative research, of which phenomenography is a part, is concerned with fleshing out meanings and respecting multiple realities, not generalizability (Polit & Beck, 2004).

The fourth article is by Rhodes and Bowles (2002). The aim of their research, using Husserl's (1970) descriptive phenomenology, was "to examine and describe the experience of living with NYHA Stage II heart failure from the perspective of women living with it" (Rhodes & Bowles, p. 441). The intent behind Husserl's descriptive phenomenology is to "describe the meaning of an experience from the perspective of those who have had that experience" (Rhodes & Bowles, p. 443). Four semistructured interviews were conducted with five women aged 60, 78, 81, and 90 years old and were diagnosed with NYHA Stage II heart failure. The number of interviews was determined by whether or not new information continued to emerge with each additional interview. The women decided on the setting of the interviews, with most choosing to be interviewed at home. One interview took place in a quiet corner of a senior centre. The researchers noted that the setting of the interview allowed the researchers a "glimpse" of the woman's living environment. The interviews were transcribed verbatim and transcripts were analyzed using Colaizzi's (1978) seven steps: "(1) reading and re-reading the data to gather a sense of the whole, (2) extraction of significant statements and phrases related to heart failure, (3) drawing meanings from the phrases and statements, (4) clustering these meanings into themes, (5) using themes to develop as complete a description as possible of the experience of living with heart failure, (6) forming a statement of identification from this description, and (7) verifying this description with the participants in the study (Rhodes & Bowles, p. 444).

Four themes emerged from the data analysis: acknowledging losses in their lives, accepting the losses, changing their lives, and deepening relationships, with subthemes for each main theme delineated and described. The authors note the similarities between their findings and the findings of the study reviewed above by Mårtensson et al. (1998) relative to the first three themes of the Mårtensson et al. study. The researchers identified that a limitation of their study was that their sample size was small. However, with qualitative research, of which Husserl's (1970) descriptive phenomenology is a part, the sample is almost always small (Polit & Beck, 2004). According to Polit and Beck (2004), sample size should be determined based on the informational needs of the research. Thus, a guiding principle in sampling is data saturation—sampling to the point at which no new information is acquired and redundancy is attained.

Ekman and Skott (2005), Ekman et al. (2001), Mårtensson et al. (1998), and Rhodes and Bowles (2002) were unanimous in the purpose of their studies: to gain an understanding of what it is like for older women to live with heart failure. None of the articles, however, claimed to have been conducted within a feminist framework. The first two criteria developed from nursing's feminist literature (McCormick & Bunting, 2002) were met in all four articles. Ekman and Skott (2005) developed clinical knowledge through the use of narrative analysis; the authors used the term "her" and "she" to indicate that the knowledge developed was from research on a woman with heart failure. Ekman et al. (2001) used the woman's name and the term "patient" interchangeably while Mårtensson et al. (1998) and Rhodes and Bowles (2002) used the term "women," "female patients," and "patients" throughout. The significance of this use of language is because the women were explicitly being identified as being women and that the research was on and about the women themselves. Interviews were used as their research method in all four studies. Thus, the women's experiences, ideas, and needs were directly and explicitly sought. Ekman and Skott and Ekman et al. asked the women to describe their experiences of living with heart failure and, each time, the narrative flowed without prompting or questioning. Mårtensson et al. had an interview guide, based on the holistic domains of nursing theory on the biophysical, sociocultural, emotional, intellectual, and spiritual-existential domains. Rhodes and Bowles also had an interview guide, though the interview questions were not disclosed in the articles. Further, the interviews in all four studies were undertaken where the women spent most of their time.

The research questions and methodology implemented by all of the researchers are appropriate. All four researchers used a genre of phenomenology, an approach to research in which health research strives to bring forward the essence of the lived experience of a health-related phenomenon. Ekman and Skott (2005) and Ekman et al. (2001) used hermeneutic phenomenology as the method for their research. Ekman and Skott drew from the experience of a woman living with heart failure. The authors noted that the purpose of the interpretation of the narrative was "to develop clinical knowledge and to gain a deeper understanding of how it is to live with heart failure from a daily life perspective" (Ekman & Skott, p. 251). The authors asserted that knowledge about the illness experience of a patient is needed. The authors advocated that the meanings from the narratives could be used in everyday practice as clinical tools.

Ekman et al. (2001) strived toward a deeper understanding of the meaning of the lived experience of being an older woman with chronic heart failure. The authors observed that research concerning older people is based strongly on a biomedical orientation while knowledge of how this population experiences their disease and care that they receive are limited. The authors asserted that becoming informed of this population's illness perspective gives important detail to the knowledge that is necessary to render good care.

Mårtensson et al. (1998) used phenomenography in their research. The women described their experiences of living with heart failure by stating how they conceived their own situation. The researchers listed a variety of nursing interventions that focus on the women's experiences with heart failure. The nursing interventions included encouraging the women to express their feelings by creating a safe and supportive environment, helping the women set goals and expectations, and increasing the women's and their family's knowledge of heart failure with a focus on self-care.

Rhodes and Bowles (2002) employed Husserl's (1970) descriptive phenomenology as the research design and provided a clear background to their research question. The authors stated that they bracketed their beliefs and assumptions derived from experience and the literature and recorded these before the interviews began; identifying and suspending assumptions are key components to Husserl's methodology.

The third criterion developed from nursing's feminist literature, that there is an expressed or implied recognition of the structural, interpersonal, and ideological conditions that oppress women (McCormick & Bunting, 2002), is met by all four articles. Ekman and Skott (2005) stated they "had a feeling that the narrator had considerable hardship in her daily life" (p. 253). The authors also noted that different voices were present in the woman's narrative: the voice of the "lifeworld" (p. 253)—that being the voice of the life experiences of the woman and her everyday concerns—and the voice of medicine—or medical science, which is the dominant discourse. As a dominant discourse, medicine would highlight the pathology, management, and treatment of heart failure and this may oppress women by denying women's voice and their experiences with heart failure.

Ekman et al. (2001) identified that the interpretation of being ill with heart failure is made from many different perspectives: from the woman herself and from her caregivers and doctors. As the woman becomes more dependent on others, she has had to leave her home. Different dimensions of "being at home" and threats to this "being at home" were expressed. As a result, the woman experiences a "homelessness" (p. 64) in her own body and a "homelessness" (p. 64) in her relations with her caregivers. Furthermore, the woman experiences homelessness in spite of, and as a result of being in institutional care. The woman's caregivers and physicians, along with the woman having to leave home, are examples of ideological and structural conditions that oppress women. The woman's experience of heart failure is different than the physician's view of the woman's experience of living with heart failure. The women in the Mårtensson et al. (1998) study described a sense of limitation, anxiousness, powerlessness and guilt, for they were unable to fulfill role expectations at work, at home, and in social settings. Moreover, the authors identified that hospitals and general health care routines subject people, in general, to feelings of powerlessness. These authors, too, show that ideological and structural conditions oppress women. Rhodes and Bowles (2002) noted that the women in their study expressed concerns about maintaining control. This threat came from different sources, ranging from loss of control due to physical symptoms to emotional control to financial constraints of being on a fixed income, as retirees. Interpersonal conditions that oppress women were addressed in this article.

The fourth criterion developed from nursing's feminist literature, evidence of commitment to social change (McCormick & Bunting, 2002), is not met in any of the four articles. Ekman and Skott (2005) referred to an article by Mishler (1984) and noted the inclination to transform the patient's life into a medical problem is also a part of a larger, more general social process. The authors did not elaborate on this statement or state how this may lead to social change. Ekman et al. (2001) asserted that the woman experiences "placelessness" (p. 64) in the organization of care and this is reflected in the "placelessness" (p. 64) of her illness experiences. "To deny a patient (a woman) [sic] this place, or to promote a system that does not permit a place for patients, as whole persons, threatens the patient's identity… as well by conveying that there is no place for reflection upon the experience of illness" (Ekman et al., p. 64). However, the authors did not make recommendations from their findings. Mårtensson et al. (1998) provided suggestions as to what nurses can do to intervene and break the cycle of women who feel limited and powerless. Alas, the women were not asked what they needed in order to break this cycle. Rhodes and Bowles (2002) wrote that women drew on inner resources of great strength and courage in order to find contentment in their lives. "They dis-

cover ways to create productive lives and deeply meaningful relationships, within the boundaries imposed by HF (heart failure) [sic]" (Rhodes & Bowles, p. 448). Again, there is no discussion as to how to facilitate women living within the boundaries imposed by heart failure, while still creating productive and meaningful lives.

The fifth criterion developed from nursing's feminist literature, some awareness of human diversity (McCormick & Bunting, 2002), is met by Mårtensson et al. (1998) and Rhodes and Bowles (2002). Mårtensson et al. interviewed 12 women between the ages of 65 and 83 years old; eight attended elementary school and four attended college. With regard to marital status, five women were married and seven women were widowed. With regards to socioeconomic status, five women were housewives, four were unskilled workers, and three women were skilled workers. Rhodes and Bowles interviewed five women aged 60, 78, 81, 84, and 90, and all were Caucasian; no further demographics were disclosed. Ekman and Skott (2005) and Ekman et al. (2001) interviewed one woman each aged 62 and 79 respectively. However, there were no additional characteristics of the women revealed.

The sixth criterion developed from nursing's feminist literature, a portrayal of women's strengths (McCormick & Bunting, 2002), is met in all four articles. Ekman and Skott (2005) noted that the woman experiences conflict when attempting to incorporate her personal experience and her medical diagnosis. While the woman cannot fully incorporate the medical explanation into her own understanding, she does not completely reject the explanation. Rather, she adds her own experiences to the explanation and does not accept being identified according to a medical diagnosis. Ekman et al. (2001) realized that as the woman became more ill with heart failure, she expressed a loss of courage, power, and self-confidence. However, the researchers realized that these losses were not the sole results of the illness; rather, these losses were compounded by the woman's experience in institutional care. Thus, there are personal contexts and social contexts to consider. Mårtensson et al. (1998) recognized that while the women expressed feelings of limitation, anxiety, and powerlessness, they also experienced feelings of contentment and a sense of support. The researchers recommended nursing interventions to facilitate the women in obtaining a more hopeful perspective by encouraging them to verbalize their feelings and concern, therefore facilitating women in acquiring a greater sense of control, competence, and self-esteem. Mårtensson and colleagues delineated what nurses need to do to help women achieve a sense of control: encouraging a hopeful outlook and plan for self-care based on the assessment of the women's self-identified need for support and information. Further, these authors stated that the nurse could contribute to the woman's safety and sense of security by increasing the quantity and quality of family support. Rhodes and Bowles (2002) observed that heart failure affects every aspect of the women's lives and, yet, the women were able to draw on inner resources of strength and courage. The themes that the researchers identified were acknowledging losses in their lives, accepting those losses, changing their lives, and deepening their relationships. So, in spite of losses experienced as a result of having heart failure, the women were able to positively change their lives by creating more productive and more deeply meaningful relationships.

Recommendations for Future Research and Practice

We would use a feminist perspective to guide our research on experience of older women living with heart failure and disrupt the androcentric biomedical discourse. We would also apply the feminist principles identified by Hall and Stevens (1991). Our research would address the six questions identified from nursing's feminist literature (Bunting, 1997). We would also uphold the eight criteria of feminist research as summarized by Duffy (1985):

1. The principal investigator is a woman.
2. Feminist methodology is used (defined as a research approach characterized by one or more of the following: interaction between the researcher and subject, a non-hierarchical relation between the researcher and the subject, an expression of feelings, and a concern for values).
3. The study has the potential to help the subjects, as well as researchers.
4. The research is focused on the experiences of the woman (defined as having to do with how a woman lives through the topic of the research).
5. The purpose of the investigation is to study women (not nurses, patients, etc. [sic]).
6. The word "feminist" [sic] of "feminism" [sic] is used in the report.
7. Bibliographic references to feminist literature are included.
8. Non-sexist language is used (p. 341).

There are six recommendations that we would follow in our feminist research. Our first recommendation is that we would identify our research as having a feminist perspective; we would include the term "feminist" in the title of our research paper, as well as use and make reference to feminist literature. Our second recommendation is that we would engage in a non-hierarchical relationship with our research participants by valuing the women's experiences, values, ideas, and needs; we would strive to recruit a diverse group of women with various values and interests to sexual orientation, class, race, ethnicity, education, age, and national origin. Women who participate in our research will be identified as "research participants." Our research question, "what is the lived experience of older women with heart failure" would drive the research method. Accordingly, we would use phenomenology with a feminist perspective; the intent of phenomenology is to understand an experience as it is understood by those who are living with it (Cohen, Kahn,

& Steeves, 2000). Interviews would be held in a place where the women feel safe and spend most of their time. We would listen to the women's experiences, ideas, and needs.

Our research would benefit each research participant by drawing on the experiences of being a woman living with heart failure, without privileging her diagnosis and chronic illness. Thus, our third recommendation is that each woman would be given the time and space to share the experiences she chooses to reveal, as well as withhold any information—again, as she chooses. Her experiences would be listened to and acknowledged as heard at the time of the interview. It is essential that each woman's voice be heard and acknowledged, as well as affirmed. As a fourth recommendation, and in concert with the feminist perspective and phenomenology approach, we would articulate our history, assumptions, motives, and interests, and make our interpretations explicit in the research process. Our fifth recommendation for feminist research is to identify the social, historical, cultural, political, and economical contexts that oppress women, locating specific sources of oppression in overarching general social constructions.

Our sixth recommendation is to be mindful of how we translate the results of research findings. Our intent would be to raise the consciousness of professional health care providers, the general public, and women with heart failure. Parker and McFarlane (1991) identified that dissemination and utilization of research findings are political endeavours. Our research would state any need for changes in the social, political, and health policies and practices that affect women and call for political activism. We would make the research findings accessible to women and professional health care providers using strategies for women such as summaries written in plain language, posters with illustrations of the findings placed in key locations, such as out-patient clinics, blog postings, and so on, and for health care providers, presentations at professional conferences, and scholarly papers. Enabling access to research findings is an important first step in the knowledge translation process, and a key step when using research to catalyze social change.

Recommendations for Nursing Practice

Reviewing and analyzing the literature from a feminist perspective enabled us a greater understanding of women's experiences from their own perspective. Based on our reading and reflections on the four studies that we have reviewed, we recommend five approaches to nursing practice with older women with heart failure. First, we would seek out the woman's voice, actively listen to her, and demonstrate presence and mindfulness in an attempt to view her experiences from her perspective rather than from our perspectives. Second, we would give the woman time and space to articulate her experiences, ideas, and needs. Third, we would strive to create a safe and caring environment for her to enable her to reflect on her experiences, strengths, and relationships. We would foster hope, facilitate in the planning of her self-care, and support her family by providing them with information and frequently contacting them. Our fifth recommendation is to identify the biomedical discourse counterbalancing or disrupting it through the process of acknowledging and appreciating the complex contexts of women's lives. We suggest that by implementing these recommendations in practice, this would change the experience that older women with heart failure have when being cared for by nurses.

Conclusion

We carried out a systematic review of the literature that explored older women's experiences with heart failure and critiqued the articles for approaches that align with key feminist principles. Of the four articles that were retrieved that met the criteria for inclusion, all articles exemplified most of the principles of feminist research. However, no articles met the criterion of a commitment to social change. We conclude the paper with recommendations for research and practice with older women living with heart failure. These recommendations have potential to disrupt the dominant biomedical discourse by shifting the centre of research and practice from biomedicine to women's lives, as they are lived. ♥

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REFERENCES

Åkerlind, G.S. (2005). Variation and commonality in phenomenographic research methods. *Higher Education Research & Development, 24*, 321–334.

Albert, N.M. (2007). Heart failure with preserved systolic function. Giving well-deserved attention to the "other" heart failure. *Critical Care Nursing Quarterly, 30*, 287–296.

Arnold, J.M. O., Liu, P., Demers, C., Dorian, P., Giannetti, N., Haddad, H., … White, M. (2006). Canadian Cardiovascular Society consensus conference recommendations on heart failure 2006: Diagnosis and management. *Canadian Journal of Cardiology, 22*, 23–45.

Barremo, A., Bruce, E., Salander, M., & Sundin, K. (2008). Personers upplevelse av att leva med kronisk hjärtsvikt – systematisk litteraturstudie

[Person's experiences of living with congestive heart failure – A systematic literature review]. *Sykepleievitenskap Omvādmadsforskning [Nursing Science], 28*, 34–38.

Brännström, M., Ekman, I., Norberg, A., Boman, K., & Strandberg, G. (2006). Living with severe chronic heart failure in palliative advanced home care. *European Journal of Cardiovascular Nursing, 5,* 295–302.

Bunting, S.M. (1997). Applying a feminist analysis model to selected nursing studies of women with HIV. *Issues in Mental Health Nursing, 18*, 523–537.

Bunting, S., & Campbell, J.C. (1990). Feminism and nursing: Historical perspectives. *Advances in Nursing Science, 12*, 11–24.

Cohen, M.A., Kahn, D.L., & Steeves, R.H. (2000). *Hermeneutic phenomenological research: A practical guide for nurse researchers*. Thousand Oaks: Sage.

Colaizzi, P. (1978). Psychological research as the phenomenologist views it. In R. Valle & M. King (Eds.), *Existential-phenomenological alternatives for psychology* (pp. 48–71). New York: Oxford University Press.

Costello, J., & Boblin, S. (2004). What is the experience of men and women with congestive heart failure? *Canadian Journal of Cardiovascular Nursing, 14*(3), 9–20.

Dougherty, C.M., Pyper, G.P., Au, D.H., Levy, W.C., & Sullivan, M.D. (2007). *Drifting in a shrinking future: Living with advanced heart failure.* Journal of Cardiovascular Nursing, 22, 480–487.

Duffy, M.E. (1985). A critique of research: A feminist perspective. *Health Care for Women International, 6*, 341–352.

Ekman, I., Ehnfors, M., & Norberg, A. (2000). The meaning of living with severe chronic heart failure as narrated by elderly people. *Scandinavian Journal of Caring Sciences, 14,* 130–136.

Ekman, I., & Skott, C. (2005). Developing clinical knowledge through a narrative-based method of interpretation. *European Journal of Cardiovascular Nursing, 4,* 251–256.

Ekman, I., Skott, C., & Norberg, A. (2001). A place of one's own. The meaning of lived experience as narrated by an elderly women with severe chronic heart failure. A case-study. *Scandinavian Journal of Caring Science, 15,* 60–65.

Evangelisa, L.S., Kagawa-Singer, M., & Dracup, K. (2001). Gender differences in health perceptions and meaning in persons living with heart failure. *Heart & Lung, 30,* 167–176.

Falk, K., Granger, B.B., Swedberg, K., & Ekman, I. (2007). Breaking the vicious circle of fatigue in patients with chronic heart failure. *Qualitative Health Research, 17*, 1020–1027.

Galvao, M. (2005). Reshaping our perception of the typical hospitalized heart failure patient. A gender analysis of data from the ADHERE heart failure registry. *Journal of Cardiovascular Nursing, 20*, 442–450.

Gary, R. (2006). Self-care practices in women with diastolic heart failure. *Heart & Lung, 35,* 9–19.

Gary, R., & Davis, L. (2008). Diastolic heart failure. *Heart & Lung, 37,* 405–416.

Hägglund, L., Boman, K., & Lundman, B. (2008). The experience of fatigue among elderly women with chronic heart failure. *European Journal of Cardiovascular Nursing, 7,* 290–295.

Hall, J.M., & Stevens, P.E. (1991). Rigor in feminist research. *Advances in Nursing Science, 13,* 16–29.

Halm, M.A., & Penque, S. (2000). Heart failure in women. *Progress in Cardiovascular Nursing, 15,* 121–133.

Harding, S.G. (1987). Introduction: Is there a feminist model. In S.G. Harding (Ed.), *Feminism and methodology* (pp. 1–14). Bloomington, IN: Indiana University Press.

Husserl, E. (1970). *The crisis of European sciences and transcendental phenomenology: An introduction to phenomenological philosophy.* Evanston, IL: Northwestern University Press.

Im, E.O. (2010). Current trends in feminist nursing research. *Nursing Outlook, 58v ,* 87–96.

Jacobs, B.B. (2001). Respect for human dignity: A central phenomenon to philosophically unite nursing theory and practice through consilience of knowledge. *Advances in Nursing Science, 24,* 17–35.

MacPherson, K.I. (1983). Feminist methods: A new paradigm for nursing research. *Advances in Nursing Science, 5*, 17–25.

McCormick, K.M., & Bunting, S.M. (2002). Application of feminist theory in nursing research: The case of women and cardiovascular disease. *Health Care for Women International, 23,* 820–834.

Mårtensson, J., Karlsson, J.E., & Fridlund, B. (1998). Female patients with congestive heart failure: How they conceive their life situation. *Journal of Advanced Nursing, 28*, 1216–1224.

Minister of Public Works and Government Services Canada. (2002). *Canada's aging population.* Ottawa: Author.

Mishler, E.G.(1984). *The discourse of medicine: Dialectics of medical interviews.* Norwood, NJ: Ablex Publishing Corporation.

Nordgren, L., Asp, M., & Fagerberg, I. (2007). Living with moderate-severe chronic heart failure as a middle-aged person. *Qualitative Health Research, 17*, 4–13.

O'Donnell, S., Condell, S., & Begley, C.M. (2004). 'Add women & stir' – The biomedical approach to cardiac research! *European Journal of Cardiovascular Nursing, 3*, 119–127.

O'Mahony, M.S., Sim, M.F.V., Ho, S.F., Steward, J.A., Buchalter, M., & Burr, M. (2003). Diastolic heart failure in older adults. *Age and Ageing, 32*, 519–524.

Parker, B., & McFarlane, J. (1991). Feminist theory and nursing: An empowerment model for research. *Advances in Nursing Science, 13*, 59–67.

Patton, M.Q. (2002). *Qualitative research & evaluation methods* (3rd ed.). Thousand Oaks, CA: Sage.

Perry, P.A. (1994). Feminist empiricism as a method of inquiry in nursing. *Western Journal of Nursing Research, 16*, 480–494.

Polit, D.F., & Beck, C.T. (2004). *Nursing research: Principles and methods* (7th ed.). Philadelphia, PA: Lippincott Williamson & Wilkins.

Rhodes, D.L., & Bowles, C.L. (2002). Heart failure and its impact on older women's lives. *Journal of Advanced Nursing, 39*, 441–449.

Richardson, L.G., & Rocks, M. (2001). Women and heart failure. *Heart & Lung, 30*, 87–97.

Ricoeur, P. (1991). Life in quest of narrative. In D. Wood (Ed.), *On Paul Ricoeur: Narrative and interpretation* (pp. 20–34). New York: Routledge.

Rodriguez, K.L., Appelt, C.J., Switzer, G E., Sonel, A.F., & Arnold, R.M. (2008). "They diagnosed bad heart": A qualitative exploration of patients' knowledge about and experiences with heart failure. *Heart & Lung, 37*, 257–265.

Sarvimäki, A., & Stembock-Hult, B. (1993). *Caring: An introduction to health care from a humanistic perspective.* Stockholm: Almquist & Wisksell.

Schwandt, T.A. (2001). *Dictionary of qualitative inquiry* (2nd ed.). Thousand Oaks, CA: Sage.

Statistics Canada. (2007). *Portrait of the Canadian population in 2006, by age and sex, 2006 census.* Statistics Canada Catalogue no. 97-55-XWE2006001. Retrieved from http://www.statcan.ca/Daily/English/070717/d070717a.htm

Statistics Canada. (2010). *CANSIM results.* Retrieved from http://cansim2.statcan.gc.ca/cgi-win/cnsmcgi.pgm

Strömberg, A., & Mårtensson, J. (2003). Gender differences in patients with heart failure. *European Journal of Cardiovascular Nursing, 2,* 7–18.

Stull, D.E., Starling, R., Haas, G., & Young, J.B. (1999). Becoming a patient with heart failure. *Heart & Lung, 28*, 284–292.

Tandon, S., Hankins, S.R., & Le Jemtel, T.H. (2002). Clinical profile of chronic heart failure in elderly women. T*he American Journal of Geriatric Cardiology, 11*, 318–323.

Yu, D.S.F., Lee, D.T.F., Kwong, A.N.T., Thompson, D.R., & Woo, J. (2007). Living with chronic heart failure: A review of qualitative studies of older people. *Journal of Advanced Nursing, 61*, 474–483.

Zambroski, C.H. (2003). Qualitative analysis of living with heart failure. *Heart & Lung, 32*, 32–40.

RESEARCH COLUMN

Informed Consent in Research: An Overview for Nurses

D. Banner, RN, PhD, and L. Zimmer, RN, PhD

Nurses are assuming greater involvement in research and require a good understanding of the ethical principles and processes that underpin research. An individual's right to self-determination and autonomy is a core consideration in research. Informed consent is the process through which an individual voluntarily agrees to an intervention, treatment or participation in research following consideration of the associated risks and benefits. Informed consent processes are an everyday part of nursing practice. However, gaining and supporting patients to give informed consent for research is complex and requires skill.

A nurse may be involved in the informed consent process either directly, as a researcher or member of a research team, or indirectly, as a caregiver advocating for and supporting patients considering participation in a study. It is important that nurses understand the ethical principles for obtaining a valid informed consent in research. This includes the clear and accurate disclosure of information, assessment of decisional capacity and the promotion of voluntarism. Understanding and responding to these issues and criteria are important in maintaining client safety, dignity and respect and are essential to the development of high-quality, ethically sound research that improves health outcomes.

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Cardiovascular disease is a global concern and a major cause of morbidity and mortality in Canadians (Heart and Stroke Foundation, 2011). As the prevalence of heart disease and its associated co-morbidities and risk factors, such as diabetes and obesity, continue to rise, the need for high-quality and relevant research has never been greater.

Nurses have a professional responsibility to be research active and are assuming greater involvement in research (Canadian Nurses Association, 2008). These roles include being members or leaders of research teams, facilitators of clinical research projects, and members of research ethics committees. Additionally, nurses have indirect involvement through their role as caregivers to patients enrolled in research studies and as active consumers of research evidence (Banner & Grant, 2011). Through such activities, nurses are able to contribute and respond to a growing body of evidence that may help improve the health outcomes of those with cardiovascular disease. Informed consent processes are an everyday part of nursing practice. However, gaining and supporting patients to give informed consent for research is complex and requires skill (Croudass, Hughes, Phillips, & Tye, 2008; Rosse & Krebs, 1999).

Informed consent is the process through which an individual voluntarily agrees to take part in a research study following consideration of the associated procedures, risks and benefits (Parahoo, 2006). A nurse may be involved in the informed consent process either directly, as a researcher, or indirectly, as a caregiver advocating for and supporting patients considering participation in a study. In this research column, we will discuss ethical practice, the key elements required for gaining valid informed consent, and the roles of nurses in the informed consent process.

Research Ethics

Research is guided by ethical principles that protect human rights. These principles include the right to self-determination and autonomy, beneficence, non-maleficence, justice, veracity and confidentiality (Beauchamp & Childress, 2008; Lobiondo-Wood & Haber, 2009). Ethical practice in research is underpinned by a number of codes, guidelines and legislation, such as the Declaration of Helsinki (World Medical Association, 2008). Many of these codes emerged following the atrocities of the Nazi experiments on imprisoned Jewish people during World War II (Lifton, 1986). Table 1 outlines the key research ethics codes and guidelines for health research with human participants.

The application of ethical principles starts at the onset of study design and continues beyond the completion of the study to include the dissemination and application of the research findings. It applies to research that involves healthy or patient populations, regardless of the type of research, and works to support the development of ethically sound, high-quality research (Thompson, 2003). Overseeing ethical practice in research is a

Table 1: Key ethical codes

World Medical Association Declaration of Helsinki	**http://www.wma.net/en/30publications/10policies/b3/**
Belmont report	**http://ohsr.od.nih.gov/guidelines/belmont.html**
Nuremberg Code	**http://ohsr.od.nih.gov/guidelines/nuremberg.html**
National Institutes of Health: Research Involving Human Subjects (USA)	**http://grants.nih.gov/grants/policy/hs/index.htm**
Interagency Advisory Panel on Research Ethics: CIHR, NSERC, SSHRC (Canada)	**http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/**

core function of the research ethics committee. Research ethics committees comprise interdisciplinary health care professionals, ethicists, lay members, and representatives of relevant stakeholder groups. They provide an independent examination of a proposed study to ensure that the rights of the individual and responsibilities of the researcher are clearly laid out (Douglas, 2007). Promoting autonomy through the application of appropriate informed consent processes is an essential part of this.

Informed Consent

Informed consent is "based on both a legal doctrine and an ethical principle of respect for an individual's right to sufficient information to make decisions about care, treatment and involvement in research" (Canadian Nurses Association, 2008, p. 26). A valid informed consent process should come before any data collection or study procedures. There are a few extenuating circumstances where informed consent may not be required. These include situations where an immediate threat to the individual's health and well-being exists, where there is no standard of care, and where there is the potential for direct benefit to the patient (Canadian Institutes of Health Research [CIHR] et al., 2010). Examples of this may include research that investigates novel treatments during unexpected cardiac arrest or life-threatening emergencies. In such instances, the researcher is required to justify these decisions to the research ethics committee prior to commencing the research study (CIHR et al., 2010).

The informed consent process is complex and "should not be seen as an exercise in bureaucratic form filling, but as an essential part of the trial [research] requiring time, insight, and communication skills" (Wager & Tooley, 1995, p. 734). As in all nursing practice, a client-centred approach is paramount. Providing information and obtaining informed consent is no exception. For this reason, it is important to consider the individual participants who are being recruited into a study. There are three elements of informed consent that a researcher must be cognizant of; these are disclosure of information, decisional capacity and voluntarism (Dimsdale, 2006; Roberts, 2002).

Table 2: Content of participant information sheet

- Title of the research project
- Name and affiliation of the researcher
- Purpose of the study
- How and why individual was selected for inclusion
- Expectations and procedures (including alternatives, additional clinic visits or tests) involved
- Potential risks and benefits
- Duration of participation
- Who is funding the research
- Confidentiality and anonymity
- Who will have access to the study data and how will it be managed, stored and used
- Freedom to withdraw from the study without an explanation being sought or cessation of necessary care and treatment
- How to contact the research team or make a complaint
- Compensation (if any) or incurred expenses

Disclosure of Information

Prospective participants should be provided with comprehensive information about a research study and understand that participation is voluntary. A participant information sheet or pamphlet is usually provided for this purpose. In the case of complex procedures, a diagram or flow chart may be used to promote understanding (Croudass et al., 2008).

Participant information sheets. An information sheet is usually devised by the research team to help prospective participants understand the study and to assist them in their decision of whether to participate. Participant information sheets should use appropriate language and provide prospective participants with adequate information to enable them to make an informed decision (Wager & Tooley, 1995). Matching the literacy level of the information sheet with that of the participant population is also important to promote comprehension. The Flesch Kincaid Readability Test is a useful tool for gauging the reading level of such documents (Paasch-Orlow, Taylor & Brancati, 2003). Table 2 outlines the key areas that should be covered by an information sheet.

A paper copy of the participant information sheet is typically provided to participants. However, more recently, novel approaches to providing information on research and confirming consent, such as the use of computers, online tools and mobile telephones, are emerging to assist in the information-giving process (Gulbrandsen & Jensen, 2010; Jimison, Sher, Appleyard, & LeVernois, 1998).

Giving information. Information sheets are one way to support the individual to make an informed choice. These are particularly important in patient populations, as power relationships, dependency in a clinical setting, and a desire to please health care providers may mean that full consideration regarding participation is not given (Wager & Tooley, 1995). However, the written components of this information process should not replace discussions about the research. It is also essential that adequate opportunities for questions be provided both prior to and during the research study. The person undertaking the consent procedure should provide a verbal overview of the information contained in the patient information sheet, answer questions, or provide appropriate interpretation of information that best meets the needs of the individual (Dimsdale, 2006).

Written information and consent may be appropriate modes of communication for many individuals. However, for some this approach is inappropriate. For those who are illiterate or hearing or sight impaired, alternate forms of communication and recording of voluntary consent must be considered. In cases where a participant cannot read, it is the responsibility of the researcher or designate to communicate the details of the information to the participant with the same clarity and detail that is

included on a written information sheet. Likewise, if a language barrier exists, accurate interpretation is necessary. Translation may be provided by a friend, intermediary or appointed translator, although this should be with the permission of the prospective participant. In such situations, every effort should be made to maintain confidentiality (Wager & Tooley, 1995).

When providing information on a study, the researcher should approach a prospective participant in an unhurried way and provide ample time for consideration and questions. Ideally, a prospective participant should be provided with 24 hours to consider their involvement and be given the opportunity to discuss the study with friends, family members or other health care professionals if required (Behrendt, Golz, Roesler, Bertz, & Wunsch, 2010). It may also be necessary to revisit this process in situations where the patient's circumstances or research procedures may have changed significantly over the course of the study (CIHR et al., 2010).

The information and discussion process should be documented fully by the researcher or research assistant. A statement signed or initialed by the participant stating that he or she has read and understood the information, and has had an opportunity to ask questions, may also be a part of documentation of the information disclosure process. A copy of this statement should be given to the participant along with a copy of the information sheet (CIHR et al., 2010).

Decisional Capacity

Decisional capacity reflects an individual's ability to understand the information and the potential consequences of participation (Ocker & Plank, 2000; Roberts, 2002). For patients enrolling in a clinical trial, this also requires a good understanding of their own health condition, as well as gaining understanding of the key research procedures such as randomization or use of a placebo. One mechanism for researchers to test comprehension is to ask individuals to give an account of the study procedures in their own words (Wager & Tooley, 1995).

Assessing the decisional capacity of individuals can be difficult and may be challenging in populations such as children, those with cognitive impairment or psychiatric illness, and patients who are critically or terminally ill (Brahams, 1993; Fulford & Howse, 1993; Shield & Baum, 1994). In turn, the ability to comprehend information may change throughout the duration of a study in response to an altered clinical status. For example, participants may experience a change in decision-making capacity immediately following cardiac surgery due to the effects of medications (such as analgesia or sedation) or complications such as stroke or post-pump delirium (intensive care syndrome). Decision-making capacity should, therefore, be an ongoing consideration and the inclusion of an appointed third party advocate may be useful (Appelbaum, 2007; Appelbaum & Grisso, 1988; CIHR et al., 2010). In situations where decision-making competence is questioned, a psychiatric evaluation or legal assessment may need to be made (Appelbaum, 2007).

Voluntarism

Voluntarism is a central aspect of informed consent. It is closely tied to decisional capacity and is based on the ability of the individual to act with free will (Roberts, 2002). Populations where voluntarism is compromised should be considered vulnerable. While these vulnerable populations require special consideration, they also should not be unfairly excluded from participating in potentially beneficial research or equally be inappropriately involved because of ease of access and recruitment (CIHR et al., 2010).

There are many factors that can affect voluntarism. These include factors relating to development, illness, psychology, culture and environment (Canadian Nurses Association, 2008; Roberts, 2002).

Developmental factors. Developmental factors relate to the intellectual or cognitive abilities of the individual. An individual's decision-making ability may be affected by development stage (childhood) or the presence of a learning difficulty (Roberts, 2002). For instance, young children are not considered able to make an informed decision and, in such situations, an authorized third party such as a parent or guardian is involved (CIHR et al., 2010). In such cases, depending on the intellectual ability of the individual, assent may be obtained before proxy consent is given. Assent is defined as an individual's agreement to research participation or treatment based on an explanation of what is going to happen or be done, and the risks and benefits involved, in language appropriate to the individual's developmental level or intellectual capacity. This is followed by the individual's agreement to participate (assent), or disagreement (dissent) (Bray, 2007; CIHR et al., 2010; Kimberley, Hoehn, Feudtner, Nelson, & Schreiner, 2011). Assent or dissent may be given verbally or in writing.

Illness-related factors. Illnesses, such as psychiatric disorders, terminal illness or degenerative conditions like Alzheimer's disease, can affect an individual's decision-making ability. In addition, critical illness, such as complications following acute myocardial infarction, nearly always diminishes informed decision-making and can create significant challenges for the researcher (Thompson, 2003). The researcher may need to assess the nature of these illness-related factors and consider the involvement of an authorized third party (CIHR et al., 2010).

Psychological factors. There are many psychological issues that may impact on an individual's self-determination. These can include past experiences of health care interactions, as well as experiences of abuse or institutionalization. In addition, impairment due to substances, either prescribed or recreational, may affect an individual's clarity of thinking and decision-making capacity. It is therefore important that researchers are aware of any psychological issues that may affect voluntarism and undertake research that is ethically sensitive (CIHR et al., 2010).

Cultural factors. When undertaking research with persons of different cultures, it is important to consider potential differences in power relations or language that may inadvertently

affect an individual's ability to freely consent. In some cultures, there may be different worldviews, unique histories, or knowledge systems that underpin understandings of research and informed consent. For example, when undertaking research with First Nations communities, including gaining informed consent, there may be additional protocols and necessary preliminary community engagement that researchers should observe and respect before seeking voluntary consent of individuals. The tri-council policy statement on ethical conduct for research provides clear guidelines around undertaking research with First Nations communities (CIHR et al., 2010).

Environmental factors. Some environments may affect an individual's ability to make a free and informed decision. An example of this is the health care setting where the researcher is also the patient's physician, nurse or direct caregiver. In such situations, a patient may feel obliged to participate in a study to please the health care provider or may have concerns that non-participation may adversely affect his or her care (CIHR, 2010). It is important that careful consideration of these potential conflicts is given to ensure that patients do not feel manipulated or coerced into participating in a research study. These situations may require additional steps in the recruitment process (CIHR et al., 2010). This may include the use of other members of staff, such as research nurses or assistants, to lead the initial consent process.

The Role of Nurses in Informed Consent

Nurses may assume many different levels of involvement with informed consent procedures, including a direct or indirect role in the research.

Nurses directly involved in research and implementing informed consent procedures. For nurses new to research, undertaking the informed consent process can seem daunting. Some nurses may experience tensions between their clinical and research roles, for example, when discussing risks associated with a research study they may inadvertently take a reassuring role and, as a result, may discourage the individual from fully considering the potential risks. Likewise, clinical research nurses may experience a sense of split loyalties. On one hand, they are part of the research team and may feel pressured to recruit a specific number of participants within a given time period in order to meet the expectations of the primary investigators. Yet, on the other hand, they are nurses first and foremost and carry a professional obligation to the patient. In addition, as advocates, nurses are obligated to answer questions, discuss the matter with family members, if requested, and provide the potential participant adequate decision-making time (Campbell, 1999). It is important that nurses who are directly involved in the informed consent process gain the necessary knowledge and skills to balance these role tensions in order to promote ethically sound practice.

The Canadian Nurses Association Code of Ethics (Canadian Nurses Association, 2008) provides a clear definition of informed consent and incorporates this concept through the code for registered nursing practice. Despite this, nurses working as research nurses, or as research assistants may require additional education or training. There are many ways that nurses may gain access to this, including training provided as part of graduate studies or a clinical research study, or through formal instruction or tutorials such as those available on the tri-council policy statement website that provides an orientation to the ethical requirements of research with humans, including consent (http://www.pre.ethics.gc.ca/english/tutorial/). In addition, mentorship may provide an effective avenue for skill development and confidence building (Croudass et al., 2008; Winter, Lavender, & Blesing, 2011). This may include observing experienced researchers, honing skills through role-play, or undertaking initial consent procedures with a supervisor.

Nurses indirectly involved in informed consent procedures. Nurses often come across research in their everyday practice and are playing an increasingly important role in supporting patients and their decision-making (Dimsdale, 2006). In the case of clinical research studies, nurses at the bedside may be responsible for administering an aspect of the treatment under investigation, such as an allocated medication in a pharmaceutical trial or caring for patients following an intervention. Therefore, it is important to know about any research studies in which your patients may be involved. In particular, being aware of medications being used, potential interactions, complications or restrictions that may be required.

In many research studies, a witness is required during the informed consent process. The purpose of the witness is to ensure that the patients' rights are respected and that sufficient information is given without coercion or intimidation (Wager & Tooley, 1995). Nurses may be present when information is being given to a patient and may be required to witness the informed consent process. In practice, a nurse may be involved in the overall process or may step in at the end to act as a witness to the signature. The role of the nurse as witness is not well defined, although by acting as a witness it is assumed that the nurse is present during the discussions and is satisfied that factors relating to disclosure, decision-making and voluntarism have been addressed appropriately (Gordon & Borglund, 2000).

In some situations, a nurse may need to advocate for the patient by judging his or her level of understanding, facilitating communication needs (such as larger print documents), and supporting the patient to ask questions or refuse participation (Wager & Tooley, 1995). In other cases, a nurse may need to intervene during the process, for example, by deterring researchers if a patient is temporarily unable to make a considered judgment, such as following opioid analgesia.

The presence of a witness is particularly important when undertaking research with vulnerable populations. For example, those in long-term care facilities may require additional support during the consent process due to the effects of institutionalization on an individual's ability for self-determination through learned helplessness, dependence or low self-esteem (Brahams, 1993; Fitten, 1993; Fulford & Howse, 1993; Wager & Tooley, 1995).

Conclusion

Nurses are assuming greater involvement in research and require a good understanding of the ethical principles and processes that underpin research. An individual's right to self-determination and autonomy is central to this. Informed consent is the process through which an individual voluntarily agrees to an intervention, treatment or participation in research following a consideration of the associated risks and benefits (Canadian Nurses Association, 2008; Parahoo, 2006).

Nurses may be involved in the informed consent process either directly, as a researcher or member of a research team, or indirectly, as a caregiver advocating for and supporting patients considering participation in a study. It is important that nurses understand the ethical principles for obtaining a valid informed consent in research. This includes the clear and accurate disclosure of information, assessment of decisional capacity and the promotion of voluntarism. Understanding and responding to these issues and criteria is important in maintaining client safety, dignity and respect and is essential to the development of high-quality, ethically sound research that improves health outcomes. ♥

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REFERENCES

Appelbaum, P.S. (2007). Clinical practice. Assessment of patients' competence to consent to treatment. *New England Journal of Medicine, 357,* 1834–1840.

Appelbaum, P.S., & Grisso, T. (1988). Assessing patients' capacities to consent to treatment. *The New England Journal of Medicine, 319*, 1635–1638.

Banner, D., & Grant, L.G. (2011). Getting involved in research. *Canadian Journal of Cardiovascular Nursing, 21*(1), 31–39.

Beauchamp, T.L., & Childress, J.F. (2008). *Principles of biomedical ethics* (6th ed.). Oxford: Oxford University Press.

Behrendt, C., Golz, T., Roesler, C., Bertz, H., & Wunsch, A. (2010). What do our patients understand about their trial participation? Assessing patients' understanding of their informed consent consultation about randomized clinical trials. *Journal of Medical Ethics, 37*, 74–80. doi:10.1136/jme.2010.035485

Brahams, D. (1993). Consent to research in presence of incapacity. [Article]. *Lancet, 341,* 1143.

Bray, L. (2007). Developing an activity to aid informed assent when interviewing children and young people. *Journal of Research in Nursing, 12*, 447–457. doi:10.1177/1744987107078876

Campbell, T. (1999). Patient-focused care: Primary responsibilities of research nurses. *British Journal of Nursing, 7*, 1405–1409.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada. (2010). *Tri-council policy statement: Ethical conduct of research involving humans.* CIHR Retrieved from http://www.pre.ethics.gc.ca/eng/resources-ressources/news-nouvelles/nr-cp/2010-12-07/

Canadian Nurses Association. (2008). *Code of ethics for registered nurses*. Ottawa: Author.

Croudass, A., Hughes, C., Phillips, H., & Tye, K. (2008). An approach to obtaining informed consent from patients with cancer. *Nursing Standard, 22*(30), 35–38.

Dimsdale, A.W. (2006). Playing your part in a clinical trial. *Nursing, 36*(7), 22–23.

Douglas, T.M. (2007). Ethics committees and the legality of research. *Journal of Medical Ethics, 33*, 732–736.

Fitten, L.J. (1993). The ethics of conducting research with older psychiatric patients. *International Journal of Geriatric Psychiatry, 8*(1), 33-39.

Fulford, K.W., & Howse, K. (1993). Ethics of research with psychiatric patients: Principles, problems and the primary responsibilities of researchers. *Journal of Medical Ethics, 19*(2), 85–91.

Gordon, S., & Borglund, S. (2000). When your patient is enrolled in a research study. *Home Healthcare Nurse, 18*, 660–665.

Gulbrandsen, P., & Jensen, B.F. (2010). Post-recruitment confirmation of informed consent by SMS. *Journal of Medical Ethics, 36*(2), 126–128. doi:10.1136/jme.2009.033456

Heart and Stroke Foundation. (2011) *Statistics*. Retrieved from http://www.heartandstroke.com/site/c.ikIQLcMWJtE/b.3483991/k.34A8/Statistics.htm

Jimison, H.B., Sher, P.P., Appleyard, R., & LeVernois, Y. (1998). The use of multimedia in the informed consent process. *Journal of the American Medical Informatics Association, 5*, 245–256.

Kimberly, M.B., Hoehn, S.K., Feudtner, C., Nelson, R.M., & Schreiner, M. (2011). Variation in standards of research compensation and child assent practices: A comparison of 69 institutional review board–approved informed permission and assent forms for 3 multicenter pediatric clinical trials. *Pediatrics, 117*, 1706–1711. doi:10.1542/peds.2005-1233

Lifton, R.J. (1986). *The Nazi doctors, medical killing & the psychology of genocide*. New York: Basic Books.

Lobiondo-Wood, G., & Haber, J. (2009). *Nursing research in Canada: Methods and critical appraisal for evidence-based practice.* Toronto, ON: Elsevier.

Ocker, B.M., & Plank, D.M.P. (2000). The research nurse role in a clinic-based oncology research setting. *Cancer Nursing, 23*, 286–294.

Paasch-Orlow, M.K., Taylor, H.A., & Brancati, F.L. (2003). Readability standards for informed-consent forms as compared with actual readability. *New England Journal of Medicine, 348*, 721–726.

Parahoo, K. (2006). *Nursing research: Principles, process and issues* (2nd ed.). Basingstoke: Palgrave Macmillan.

Roberts, L.W. (2002). Informed consent and the capacity for voluntarism. *American Journal of Psychiatry, 159*, 705–712.

Rosse, P.A., & Krebs, L.U. (1999). The nurse's role in the informed consent process. *Seminars in Oncology Nursing, 15*, 116–123.

Shield, J.P., & Baum, J.D. (1994). Children's consent to treatment. *British Medical Journal (Clinical Research Ed.), 308,* 1182–1183.

Thompson, J. (2003). Ethical challenges of informed consent in prehospital research: Pedagogical tools and methods. *Canadian Journal of Emergency Medicine, 5*(2), 108–114.

Wager, E., & Tooley, P.J.H. (1995). Get patients' consent to enter clinical trials. *British Medical Journal, 311*, 734–737.

Winter, H., Lavender, V., & Blesing, C. (2011). Developing a nurse-led clinic for patients enrolled in clinical trials. *Cancer Nursing Practice, 10*(3), 20–24.

World Medical Association. (2008). *Declaration of Helsinki: Ethical principles for medical research involving human subjects.* Helsinki: Author.

Aperçu du consentement éclairé en matière de recherche pour les infirmières et infirmiers

D. Banner, IA, Ph. D. et L. Zimmer, IA, Ph. D.

Les infirmières et infirmiers participent plus à la recherche et doivent bien comprendre les principes éthiques et les processus qui sous-tendent la recherche. Le droit individuel à l'auto-détermination et à l'autonomie constitue une considération essentielle en recherche. Le consentement éclairé est le processus en vertu duquel une personne accepte volontairement de subir une intervention, de suivre un traitement ou de participer à de la recherche après avoir considéré les risques et les avantages associés. Les processus de consentement éclairé sont un aspect de la pratique quotidienne des soins infirmiers. Mais convaincre les patient(e)s de participer à la recherche en donnant leur consentement éclairé et les soutenir dans cette démarche est un processus complexe qui exige des aptitudes particulières.

L'infirmière ou l'infirmier peut faire partie du processus de consentement éclairé de deux façons, soit directement, à titre de chercheur(e) ou de membre d'une équipe de recherche, soit indirectement, à titre de personne soignante qui défend les intérêts des patient(e)s qui envisagent de participer à une étude et qui les soutient dans leur démarche. Il est important que les infirmières et infirmiers comprennent les principes éthiques de l'obtention d'un consentement éclairé valide de participer à la recherche. Cela comprend la divulgation claire et exacte de l'information, l'évaluation de la capacité décisionnelle et la promotion du volontarisme. Il est important de comprendre ces questions et ces critères et d'y répondre pour maintenir la sécurité, la dignité et le respect du (de la) patient(e). Ce sont des aspects essentiels au développement de la recherche de qualité élevée et conforme à l'éthique, qui améliore les résultats de santé.

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Mots clés : *recherche, éthique, consentement éclairé, infirmières et infirmiers, profession infirmière, volontarisme*

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Les maladies cardiovasculaires sont un problème mondial et une cause majeure de morbidité et de mortalité chez les Canadiens et les Canadiennes (Heart and Stroke Foundation, 2011). Étant donné que la fréquence des maladies du coeur et des co-morbidités et facteurs de risque qui leur sont associés, comme le diabète et l'obésité, continue d'augmenter, le besoin de recherche pertinente de haute qualité n'a jamais été aussi élevé.

Les infirmières et infirmiers ont la responsabilité professionnelle de se préoccuper de la recherche et y participent plus (Association des infirmières et infirmiers du Canada, 2008), notamment à titre de membres ou de leaders d'équipes de recherche, de facilitatrices et de facilitateurs de projets de recherche clinique et de membres de comités d'éthique de la recherche. En outre, les infirmières et infirmiers participent indirectement à la recherche à titre de personne soignantes des patient(e)s inscrit(e)s dans les études de recherche et par leur consommation active des données de recherche (Banner & Grant, 2011). Ces activités leur permettent de contribuer et de répondre à un corpus croissant de données qui peut améliorer les résultats de santé des personnes atteintes de maladies cardiovasculaires. Les processus de consentement éclairé sont un aspect de la pratique quotidienne des soins infirmiers; mais convaincre les patient(e)s de participer à la recherche en donnant leur consentement éclairé et les soutenir dans cette démarche est un processus complexe qui exige des aptitudes particulières (Croudass, Hughes, Phillips, & Tye, 2008; Rosse & Krebs, 1999).

Le consentement éclairé est le processus en vertu duquel une personne accepte volontairement de participer à une étude de recherche après avoir considéré les procédures, les risques et les avantages associés (Parahoo, 2006). L'infirmière ou l'infirmier peut faire partie du processus de consentement éclairé de deux façons, soit directement, à titre de chercheur(e), soit indirectement, à titre de personne soignante qui défend les intérêts des patient(e)s qui envisagent de participer à une étude et qui les soutient dans leur démarche. La présente Chronique Recherche examine la pratique éthique, les éléments clés requis pour obtenir un consentement éclairé valide, et les rôles des infirmières et infirmiers dans le processus de consentement éclairé.

Éthique de la recherche

La recherche est guidée par les principes éthiques qui protègent les droits de la personne. Ce sont notamment les droits à l'auto-détermination et à l'autonomie, à la bienfaisance, à la non-malfaisance, à la justice, à la véracité et à la confidentialité (Beauchamp & Childress, 2008; Lobiondo-Wood & Haber, 2009). La pratique éthique dans la recherche est étayée par des codes, des lignes directrices et des lois, comme la Déclaration d'Helsinki (Association Médicale Mondiale, 2008). Un grand nombre de ces codes ont pris naissance à la suite des atrocités des expérimentations des nazis sur les prisonniers juifs au cours de la Seconde Guerre mondiale (Lifton, 1986). Le Tableau 1 énonce les principaux codes d'éthique de la recherche et les grandes lignes directrices sur la recherche en santé avec des êtres humains.

L'application des principes éthiques commence dès le début de la conception de l'étude et se poursuit au-delà de l'achèvement de celle-ci afin d'inclure la diffusion et l'application des résultats de la recherche. Cela s'applique à la recherche sur les populations de personnes en santé ou de patient(e)s, peu importe le type de recherche, dans le but d'étayer l'élaboration de la recherche éthique de haute qualité (Thompson, 2003). La surveillance de la pratique éthique dans la recherche est une fonction principale des comités d'éthique de la recherche. Les comités d'éthique de la recherche sont formés de professionnels de la santé de toutes les disciplines, d'éthiciens, de profanes et de représentants de groupes d'intéressés pertinents. Ils examinent de façon indépendante une étude proposée pour s'assurer que les droits des personnes et les responsabilités des chercheur(e)s sont clairement énoncés (Douglas, 2007). La promotion de l'autonomie par l'application des processus appropriés de consentement éclairé est un élément essentiel de la démarche.

Consentement éclairé

Le consentement éclairé est « basé à la fois sur une doctrine juridique et sur un principe éthique de respect du droit d'une personne à avoir suffisamment d'information pour prendre des décisions sur ses soins, ses traitements et sa participation à la recherche » [traduction] (Association des infirmières et infirmiers du Canada, 2008, p. 26). La collecte de données ou l'application des procédures de l'étude doit être précédée d'un processus de consentement éclairé valide. Il existe quelques circonstances atténuantes où le consentement éclairé peut ne pas être requis. Il s'agit notamment de situations où il existe une menace immédiate envers la santé et le bien-être de la personne, lorsqu'il n'existe pas de norme de soin, et lorsqu'il existe un potentiel d'avantage direct pour le (la) patient(e) (Instituts de recherche en santé du Canada, [IRSC] et al., 2010). Il peut s'agir entre autres de recherche sur de nouveaux traitements en cas d'arrêt cardiaque imprévu ou d'urgences graves qui mettent la vie en danger. En pareil cas, les chercheur(e)s sont tenus de justifier ces décisions devant le comité d'éthique de la recherche avant d'entreprendre l'étude de recherche (IRSC et al., 2010).

Le processus de consentement éclairé est complexe et « ne doit pas être considéré comme une simple formalité démocratique, mais comme un volet essentiel de l'étude [la recherche] qui exige du temps, de la perspicacité et des habiletés de communication » [traduction] (Wager & Tooley, 1995, p. 734). Comme dans toute la pratique infirmière, l'approche axée sur le (la) client(e) est capitale. Fournir de l'information et obtenir un consentement éclairé ne fait pas exception. Il est donc important de considérer les personnes recrutées à titre individuel pour participer à une étude. Les trois éléments du consentement éclairé dont les chercheur(e)s doivent être au courant sont la divulgation de l'information, la capacité décisionnelle et le volontarisme (Dimsdale, 2006; Roberts, 2002).

Divulgation de l'information

Il faut fournir de l'information exhaustive sur l'étude de recherche aux participant(e)s potentiel(le)s et leur faire comprendre que leur participation est volontaire. On leur fournit habituellement un feuillet d'information ou une brochure à cette fin. Dans le cas de procédures complexes, on peut utiliser un diagramme pour favoriser la compréhension (Croudass et al., 2008).

Feuillets d'information à l'intention des participant(e)s. L'équipe de recherche conçoit habituellement un feuillet d'information pour aider les participant(e)s éventuel(le)s à comprendre l'étude et faciliter leur décision d'y partici-

Tableau 1 : Grands codes d'éthique

Déclaration d'Helsinki de L'AMM—Principes éthiques applicables à la recherche médicale impliquant des êtres humains	**www.wma.net/fr/30publications/10policies/b3/index.html**
Belmont report	**http://ohsr.od.nih.gov/guidelines/belmont.html**
Code de Nuremberg	**http://www.frsq.gouv.qc.ca/fr/ethique/pdfs_ethique/nuremberg_f.pdf**
National Institutes of Health—Research Involving Human Subjects (USA)	**http://grants.nih.gov/grants/policy/hs/index.htm**
Groupe consultatif interagences en éthique de la recherche— IRSC, CRSNG, CRSH (Canada)	**www.ger.ethique.gc.ca/fra/policy-politique/initiatives/tcps2-eptc2/Default/**

per ou non. Ces feuillets d'information doivent être rédigés dans un langage qui convient et fournir suffisamment d'information aux participant(e)s éventuel(le)s pour leur permettre de prendre une décision éclairée (Wager & Tooley, 1995). Il est également important que le niveau d'alphabétisation du feuillet d'information concorde avec celui de la population participante pour promouvoir la compréhension. La formule de lisibilité de Flesch-Kincaid est un outil utile pour évaluer le niveau de lecture de tels documents (Paasch-Orlow, Taylor & Brancati, 2003). Le Tableau 2 énonce les aspects clés qu'un feuillet d'information devrait couvrir.

On fournit habituellement aux participant(e)s une copie papier du feuillet d'information à leur intention. On voit toutefois émerger de nouvelles approches pour fournir l'information sur la recherche et le consentement éclairé, comme l'utilisation d'ordinateurs, d'outils en ligne et de téléphones intelligents (Gulbrandsen & Jensen, 2010; Jimison, Sher, Appleyard, & LeVernois, 1998).

Donner de l'information. Les feuillets d'information sont une façon de soutenir la personne afin de l'aider à faire un choix éclairé. Ils sont particulièrement importants dans les populations de patient(e)s, parce que les rapports de force, la dépendance envers le contexte clinique, et le désir de plaire aux fournisseur(e)s des soins de santé peuvent faire en sorte que la décision de participer ne soit pas considérée entièrement (Wager & Tooley, 1995). Mais la partie écrite de ce processus d'information ne doit pas remplacer les discussions sur la recherche. Il est également essentiel d'offrir la possibilité adéquate de poser des questions avant l'étude de recherche et au cours de celle-ci. La personne qui entreprend le processus de consentement doit fournir un aperçu oral de l'information contenue sur le feuillet d'information à l'intention du (de la) patient(e), répondre aux questions ou fournir une interprétation convenable de l'information qui répond le mieux aux besoins de la personne à qui elle est destinée (Dimsdale, 2006).

Tableau 2 : Contenu du feuillet d'information du (de la) participant(e)

- Titre du projet de recherche
- Nom et affiliation du (de la) chercheur(e)
- Objectif de l'étude
- Comment et pourquoi la personne a été choisie pour en faire partie
- Attentes et procédures (y compris les solutions de remplacement, les visites additionnelles à la clinique ou les tests)
- Risques et avantages potentiels
- Durée de la participation
- Qui finance la recherche
- Confidentialité et anonymat
- Qui aura accès aux données de l'étude, comment elles seront gérées, entreposées et utilisées
- Liberté de se retirer de l'étude sans explication requise ou cessation des soins et du traitement nécessaires
- Comment communiquer avec l'équipe de recherche ou présenter une plainte
- Indemnisation (s'il y a lieu) des dépenses engagées

L'information écrite et le consentement peuvent être des modes appropriés de communication pour beaucoup de personnes, mais la démarche ne convient pas nécessairement à tout le monde. Pour les analphabètes ou les personnes malentendantes ou malvoyantes, il faut envisager d'autres formes de communication et d'obtention du consentement volontaire. Quand un(e) participant(e) ne peut pas lire, les chercheur(e)s ou les personnes désignées ont la responsabilité de lui communiquer les détails de l'information aussi clairement et de façon aussi détaillée que ce qui est inscrit sur un feuillet d'information. De même, s'il existe un obstacle linguistique, il est nécessaire de fournir une interprétation exacte. La traduction peut être fournie par un(e) ami(e), un(e) intermédiaire ou un traducteur ou une traductrice désigné(e), mais avec la permission du (de la) participant(e) potentiel(le). En pareils cas, il faut faire tous les efforts pour maintenir la confidentialité (Wager & Tooley, 1995).

Quand ils fournissent de l'information au sujet d'une étude, les chercheur(e)s doivent approcher le (la) participant(e) éventuel(le) sans aller trop vite et en lui fournissant amplement de temps pour considérer ce qui est proposé et poser des questions. Idéalement, un(e) participant(e) éventuel(le) doit avoir 24 heures pour considérer sa participation et pouvoir discuter de l'étude avec ses ami(e)s, les membres de sa famille ou d'autres professionnels de la santé si nécessaire (Behrendt, Golz, Roesler, Bertz, & Wunsch, 2010). Il peut également s'avérer nécessaire de revoir ce processus quand les circonstances du (de la) patient(e) ou les procédures de recherche peuvent avoir changé de façon importante durant le déroulement de l'étude (IRSC et al., 2010).

L'information et le processus de discussion doivent être documentés exhaustivement par les chercheur(e)s ou leurs adjoint(e)s à la recherche. Une déclaration signée ou paraphée par le (la) participant(e) indiquant que la personne a lu et compris l'information, et a eu la possibilité de poser des questions, peut également faire partie de la documentation du processus de divulgation de l'information. Une copie de cette déclaration doit être remise au (à la) participant(e) avec une copie du feuillet d'information (IRSC et al., 2010).

Capacité décisionnelle

La capacité décisionnelle reflète la capacité de la personne à comprendre l'information et les conséquences potentielles de la participation (Ocker & Plank, 2000; Roberts, 2002). Pour les patient(e)s qui acceptent de faire partie d'un essai clinique, cela exige également une bonne

compréhension de leur propre état de santé et l'appréhension des principales procédures de recherche, comme la randomisation, ou l'utilisation d'un placébo. L'un des mécanismes à la disposition des chercheur(e)s pour tester la compréhension est de demander aux personnes de décrire les procédures de l'étude dans leurs propres mots (Wager & Tooley, 1995).

Il peut être assez difficile d'évaluer la capacité décisionnelle de populations comme les enfants, les personnes qui ont des déficiences cognitives ou des maladies psychiatriques, et les patient(e)s qui sont en phase terminale ou dans un état critique (Brahams, 1993; Fulford & Howse, 1993; Shield & Baum, 1994). Sans compter que la transformation de l'état clinique au cours de la durée de l'étude peut influencer la capacité de comprendre l'information. La capacité décisionnelle des participant(e)s peut changer par exemple immédiatement après une chirurgie cardiaque, en raison des effets des médicaments (comme l'analgésie ou la sédation), ou de complications comme un accident vasculaire cérébral ou le délire chez les patient(e)s qui ont été traité(e)s au moyen d'une pompe cardiaque (délirium des soins intensifs). On doit donc tenir compte sans cesse de la capacité décisionnelle, et l'inclusion d'un tiers jouant le rôle de défenseur des intérêts du (de la) patient(e) peut être utile (Appelbaum, 2007; Appelbaum & Grisso, 1988; IRSC et al., 2010). Dans les situations où la capacité décisionnelle est mise en doute, une évaluation psychiatrique ou juridique peut s'avérer nécessaire (Appelbaum, 2007).

Volontarisme

Le volontarisme est un aspect central du consentement éclairé. Il est lié étroitement à la capacité décisionnelle et basé sur la capacité de la personne d'agir de son propre gré (Roberts, 2002). Les populations où le volontarisme est compromis doivent être considérées vulnérables. Si ces populations vulnérables exigent une considération spéciale, il ne faut pas non plus qu'elles soient exclues injustement de la participation à des recherches susceptibles d'apporter certains bénéfices ou bien, du même souffle, qu'elles y participent de façon inappropriée à cause de la facilité de les approcher et de les recruter (IRSC et al., 2010).

Beaucoup de facteurs peuvent influer sur le volontarisme, entre autres des facteurs relatifs au développement, à la maladie, à la psychologie, à la culture et à l'environnement (Association des infirmières et infirmiers du Canada, 2008; Roberts, 2002).

Facteurs de développement. Les facteurs de développement ont trait aux capacités intellectuelles ou cognitives de la personne. La capacité décisionnelle d'une personne peut être affectée par le stade de développement (l'enfance) ou par la présence d'une difficulté d'apprentissage (Roberts, 2002). Par exemple, les jeunes enfants ne sont pas considérés aptes à prendre une décision éclairée et, dans de telles situations, un tiers autorisé, comme un parent ou un tuteur, participe à la décision (IRSC et al., 2010). Dans de tels cas, selon la capacité intellectuelle de la personne, l'assentiment peut être obtenu avant que le consentement par procuration soit donné. L'assentiment est défini comme l'accord d'une personne à participer à de la recherche ou à un traitement sur la base d'une explication de ce qui va se produire ou de ce qui sera fait, et aussi des risques et des avantages que cela comporte, dans un langage approprié au niveau de développement ou à la capacité intellectuelle de la personne. Cela est suivi de l'accord de la personne à participer (assentiment), ou de son désaccord (dissentiment) (Bray, 2007; IRSC et al., 2010; Kimberley, Hoehn, Feudtner, Nelson & Schreiner, 2011). L'assentiment ou le dissentiment peut être donné verbalement ou par écrit.

Facteurs liés à la maladie. Les maladies peuvent affecter la capacité décisionnelle d'une personne, comme des troubles psychiatriques, des maladies terminales ou des conditions de dégénérescence comme la maladie d'Alzheimer. De plus, des maladies graves, comme des complications à la suite d'un infarctus aigu du myocarde, diminuent presque invariablement la capacité de prendre des décisions éclairées et peuvent rendre la situation compliquée pour les chercheur(e)s (Thompson, 2003). Les chercheur(e)s peuvent devoir évaluer la nature de ces facteurs liés à la maladie et envisager la participation d'un tiers autorisé (IRSC et al., 2010).

Facteurs psychologiques. Beaucoup de facteurs psychologiques peuvent influencer l'auto-détermination d'une personne. Il peut s'agir notamment d'expériences antérieures d'interactions en matière de soins de santé, ou encore d'expériences d'abus est d'institutionnalisation. De plus, l'affaiblissement des facultés par des drogues, prescrites ou récréatives, peut affecter la clarté de réflexion d'une personne et sa capacité décisionnelle. Il est donc important que les chercheur(e)s soient conscients de tous les problèmes psychologiques qui peuvent affecter le volontarisme et qu'ils fassent de la recherche sensible sur le plan éthique (IRSC et al., 2010).

Facteurs culturels. En faisant de la recherche avec des personnes de cultures différentes, il est important de tenir compte des différences potentielles en matière de relations de pouvoir ou de langue qui peuvent affecter par inadvertance la capacité de consentement libre d'une personne. Certaines cultures peuvent avoir des perspectives différentes sur le monde, des histoires particulières ou des systèmes de connaissances qui sous-tendent la compréhension de la recherche et du consentement éclairé. Par exemple, la recherche avec les personnes des Premières nations, y compris les démarches d'obtention du consentement éclairé, peuvent nécessiter l'application de protocoles additionnels et requérir un engagement communautaire préliminaire dont les chercheur(e)s doivent tenir compte et qu'ils doivent respecter avant de demander le consentement volontaire des per-

sonnes. L'Énoncé de politique des trois Conseils : Éthique de la recherche avec des êtres humains contient des lignes directrices claires sur la recherche avec les membres des Premières nations (IRSC et al., 2010).

Facteurs environnementaux. Certains environnements peuvent affecter la capacité d'une personne à prendre une décision libre et éclairée. C'est le cas par exemple d'un établissement de santé où le chercheur(e) est également le médecin du (de la) patiente, son infirmière ou infirmier ou sa personne soignante directe. Dans de telles situations, un(e) patient(e) peut se sentir obligé(e) de participer à une étude pour plaire au fournisseur de soins ou craindre que le fait de ne pas participer pourrait nuire aux soins qui lui sont dispensés (IRSC, 2010). Il est important d'envisager soigneusement ces conflits potentiels pour s'assurer que les patient(e)s ne sentent pas manipulés ou obligés de participer à une étude de recherche. Ces situations peuvent nécessiter des étapes additionnelles dans le processus de recrutement(IRSC et al., 2010). Cela peut inclure le recours à d'autres membres du personnel, comme des infirmières ou infirmiers de recherche, ou des assistant(e)s de recherche, pour mener le processus initial de consentement.

Le rôle des infirmières et infirmiers dans le consentement éclairé. Les infirmières et infirmiers peuvent assumer divers niveaux de participation au processus de consentement éclairé, y compris un rôle direct ou indirect dans la recherche.

Infirmières et infirmiers qui participent directement à la recherche et qui appliquent le processus de consentement éclairé. Pour les infirmières et infirmiers qui n'ont jamais participé à de la recherche, le processus de consentement éclairé peut apparaître comme une lourde tâche. Des infirmières et infirmiers peuvent avoir de la difficulté à concilier la dimension clinique et l'aspect recherche de leur rôle. Ainsi, le fait d'afficher involontairement une attitude rassurante dans la discussion des risques associés à une étude de recherche peut avoir pour effet de dissuader le (la) patient(e) d'envisager pleinement les risques potentiels de la recherche. De même, les infirmières et infirmiers de recherche peuvent se sentir en conflit de loyauté. Le fait d'une part d'être membre de l'équipe de recherche peut créer une pression pour recruter un nombre précis de participant(e)s au cours d'une période donnée afin de répondre aux attentes des chercheur(e)s principaux. Par ailleurs, le fait d'être d'abord et avant tout une infirmière ou un infirmier leur confère une obligation professionnelle envers le (la) patient(e). En plus, à titre de défenseur(e)s des intérêts des patient(e)s, les infirmières et infirmiers sont tenus de répondre aux questions, de discuter de la situation avec les membres de la famille, si on leur demande, et de fournir suffisamment de temps aux participant(e)s potentiel(le)s pour prendre leur décision (Campbell, 1999). Il est important que les infirmières et infirmiers qui participent directement au processus de consentement éclairé acquièrent les connaissances et les capacités nécessaires pour équilibrer ces tensions entre leurs différents rôles pour promouvoir une pratique éthique.

Le Code de déontologie des infirmières et infirmiers (Édition du centenaire 2008) de l'Association des infirmières et infirmiers du Canada définition clairement le consentement éclairé et intègre ce concept dans le code de la pratique infirmière autorisée. Malgré cela, les infirmières et infirmiers de recherche, ou qui sont assistant(e)s de recherche, peuvent avoir besoin d'éducation ou de formation additionnelle. Les infirmières et infirmiers peuvent y avoir accès de bien des façons, incluant la formation dispensée dans les études supérieures ou en participant à une étude de recherche clinique, ou par l'enseignement officiel ou au moyen de didacticiels comme ceux qui sont disponibles sur le site Web de L'Énoncé de politique des trois Conseils qui offre une orientation concernant les exigences éthiques de la recherche avec des êtres humains, y compris le consentement éclairé (http://www.pre.ethics.gc.ca/english/tutorial/) [Note du traducteur : ce lien mène à un site unilingue anglais où l'on apprend que le didacticiel dont il y est question est désuet et non recommandé; le site contient néanmoins un lien vers un autre site (en anglais), dont l'adresse du site équivalent en français est http://www.ger.ethique.gc.ca/fra/education/tutorial-didacticiel/]. De plus, le mentorat peut être un véhicule efficace pour développer ses capacités et bâtir sa confiance(Croudass et al., 2008; Winter, Lavender, & Blesing, 2011). On peut observer des chercheur(e)s expérimenté(e)s, peaufiner ses capacités dans des jeux de rôle ou appliquer un processus de consentement éclairé initial avec un(e) supérieur(e).

Infirmières et infirmiers qui participent directement au processus de consentement éclairé. Les infirmières et infirmiers sont souvent en contact avec la recherche dans leur pratique quotidienne et jouent un rôle de plus en plus important de soutien des patient(e)s dans leur cheminement décisionnel (Dimsdale, 2006). Dans le cas des études de recherche clinique, les infirmières et infirmiers au chevet des patient(e)s peuvent être responsables de l'administration d'un aspect du traitement visé par la recherche, comme la prise d'un médicament particulier dans un essai pharmaceutique ou les soins aux patient(e)s à la suite d'une intervention. Il est donc important pour elles et pour eux d'être au courant des études de recherche dont leurs patient(e)s font peut-être partie. Il faut connaître en particulier les médicaments qui sont utilisés, les interactions potentielles, les complications, et les restrictions qui peuvent être nécessaires.

Beaucoup d'études de recherche exigent la présence d'un témoin au cours du processus de consentement éclairé. La présence du témoin a pour objet d'assurer que les droits du (de la) patient(e) sont respectés et qu'on lui donne suffisamment d'information sans coercition ni intimidation (Wager & Tooley, 1995). Les patient(e)s peuvent être informé(e)s

en présence des infirmières et infirmiers, qui peuvent être tenu(e)s de faire office de témoin du processus de consentement éclairé. En pratique, une infirmière ou un infirmier peut participer à l'ensemble du processus, ou y arriver à la fin, à titre de témoin de la signature. Le rôle de témoin de l'infirmière ou de l'infirmier n'est pas bien défini, mais on s'attend à ce qu'à titre de témoin, elles et ils soient présent(e)s au cours des discussions et soient satisfait(e)s que les facteurs relatifs à la divulgation, à la décision et au volontarisme ont été traités convenablement (Gordon & Borglund, 2000).

Il arrive dans certains cas qu'une infirmière ou un infirmier doive défendre les intérêts du (de la) patient(e) en évaluant son niveau de compréhension, en facilitant ses besoins de communication (par exemple en fournissant des documents imprimés en plus gros caractères) et en le ou la soutenant dans les questions qu'il ou qu'elle désirer poser ou dans son refus de participer (Wager & Tooley, 1995). Dans d'autres cas, il faut parfois intervenir au cours du processus, par exemple en freinant parfois les chercheur(e)s si un(e) patient(e) est temporairement incapable de juger de façon éclairée, notamment après une analgésie opiacée.

La présence d'un témoin est particulièrement importante dans la recherche auprès des populations vulnérables. Par exemple, les patient(e)s en établissements de soins de longue durée peuvent avoir besoin de soutien additionnel au cours du processus de consentement, en raison des effets de l'institutionnalisation sur la capacité d'auto-détermination de la personne qui engendrent l'impuissance acquise, la dépendance ou la faible estime de soi (Brahams, 1993; Fitten, 1993; Fulford & Howse, 1993; Wager & Tooley, 1995).

Conclusion

Les infirmières et infirmiers participent plus à la recherche et doivent bien comprendre les principes éthiques et les processus qui sous-tendent la recherche. Le droit de la personne à l'auto-détermination et à l'autonomie est un aspect central de cela. Le consentement éclairé est le processus en vertu duquel une personne accepte volontairement de subir une intervention, de suivre un traitement ou de participer à de la recherche après avoir considéré les risques et les avantages associés (Association des infirmières et infirmiers du Canada, 2008; Parahoo, 2006).

L'infirmière ou l'infirmier peut faire partie du processus de consentement éclairé de deux façons, soit directement, à titre de chercheur(e) ou de membre d'une équipe de recherche, soit indirectement, à titre de personne soignante qui défend les intérêts des patient(e)s qui envisagent de participer à une étude et qui les soutient dans leur démarche. Il est important que les infirmières et infirmiers comprennent les principes éthiques de l'obtention d'un consentement éclairé valide de participer à la recherche. Cela comprend la divulgation claire et exacte de l'information, l'évaluation de la capacité décisionnelle et la promotion du volontarisme. Il est important de comprendre ces questions et ces critères et d'y répondre pour maintenir la sécurité, la dignité et le respect du (de la) patient(e). Ce sont des aspects essentiels au développement de la recherche de qualité élevée et conforme à l'éthique, qui améliore les résultats de santé. ♥

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RÉFÉRENCES

Appelbaum, P.S. (2007). Clinical practice. Assessment of patients' competence to consent to treatment. *New England Journal of Medicine, 357*, 1834–1840.

Appelbaum, P.S., & Grisso, T. (1988). Assessing patients' capacities to consent to treatment. *The New England Journal of Medicine, 319,* 1635–1638.

Association des infirmières et infirmiers du Canada. (2008). *Code de déontologie des infirmières et infirmiers*. Ottawa : Auteure.

Association Médicale Mondiale. (2008). *Déclaration d'Helsinki: Principes éthiques applicables à la recherche médicale impliquant des êtres humains*. Helsinki : Auteure.

Banner, D., & Grant, L.G. (2011). Getting involved in research. *Canadian Journal of Cardiovascular Nursing, 21*(1), 31–39.

Beauchamp, T.L., & Childress, J.F. (2008). *Principles of biomedical ethics* (6th ed.). Oxford: Oxford University Press.

Behrendt, C., Golz, T., Roesler, C., Bertz, H., & Wunsch, A. (2010). What do our patients understand about their trial participation? Assessing patients' understanding of their informed consent consultation about randomized clinical trials. *Journal of Medical Ethics, 37*, 74–80. doi: 10.1136/jme.2010.035485

Brahams, D. (1993). Consent to research in presence of incapacity. [Article]. *Lancet, 341*, 1143.

Bray, L. (2007). Developing an activity to aid informed assent when interviewing children and young people. *Journal of Research in Nursing, 12,* 447–457. doi:10.1177/1744987107078876

Campbell, T. (1999). Patient-focused care: Primary responsibilities of research nurses. *British Journal of Nursing, 7*, 1405–1409.

Conseil de recherches en sciences humaines du Canada (CRSH), le Conseil de recherches en sciences naturelles et en génie du Canada (CRSNG) et les Instituts de recherche en santé du Canada (IRSC) (2010). *Énoncé de politique des trois Conseils : Éthique de la recherche avec des êtres humains – ou « EPTC 2 »*. *IRSC*. Données extraites de http://www.ger.ethique.gc.ca/fra/resources-ressources/news-nouvelles/nr-cp/2010-12-07/

Croudass, A., Hughes, C., Phillips, H., & Tye, K. (2008). An approach to obtaining informed consent from patients with cancer. *Nursing Standard, 22*(30), 35–38.

Dimsdale, A.W. (2006). Playing your part in a clinical trial. *Nursing, 36*(7), 22–23.

Douglas, T.M. (2007). Ethics committees and the legality of research. *Journal of Medical Ethics, 33*, 732–736.

Fitten, L.J. (1993). The ethics of conducting research with older psychiatric patients. *International Journal of Geriatric Psychiatry, 8*(1), 33–39.

Fulford, K.W., & Howse, K. (1993). Ethics of research with psychiatric patients: Principles, problems and the primary responsibilities of researchers. *Journal of Medical Ethics, 19*(2), 85–91.

Gordon, S., & Borglund, S. (2000). When your patient is enrolled in a research study. *Home Healthcare Nurse, 18*, 660–665.

Gulbrandsen, P., & Jensen, B.F. (2010). Post-recruitment confirmation of informed consent by SMS. *Journal of Medical Ethics, 36*(2), 126–128. doi: 10.1136/jme.2009.033456

Heart and Stroke Foundation. (2011) *Statistics*. Retrieved from http://www.heartandstroke.com/site/c.ikIQLcMWJtE/b.3483991/k.34A8/Statistics.htm

Jimison, H.B., Sher, P.P., Appleyard, R., & LeVernois, Y. (1998). The use of multimedia in the informed consent process. *Journal of the American Medical Informatics Association, 5*, 245–256.

Kimberly, M.B., Hoehn, S.K., Feudtner, C., Nelson, R.M., & Schreiner, M. (2011). Variation in standards of research compensation and child assent practices: A comparison of 69 institutional review board–approved informed permission and assent forms for 3 multicenter pediatric clinical trials. *Pediatrics, 117*, 1706–1711. doi:10.1542/peds.2005-1233

Lifton, R.J. (1986). *The Nazi doctors, medical killing & the psychology of genocide*. New York: Basic Books.

Lobiondo-Wood, G., & Haber, J. (2009). *Nursing research in Canada: Methods and critical appraisal for evidence-based practice.* Toronto, ON: Elsevier.

Ocker, B.M., & Plank, D.M.P. (2000). The research nurse role in a clinic-based oncology research setting. *Cancer Nursing, 23*, 286–294.

Paasch-Orlow, M.K., Taylor, H.A., & Brancati, F.L. (2003). Readability standards for informed-consent forms as compared with actual readability. *New England Journal of Medicine, 348*, 721–726.

Parahoo, K. (2006). *Nursing research: Principles, process and issues* (2nd ed.). Basingstoke: Palgrave Macmillan.

Roberts, L.W. (2002). Informed consent and the capacity for voluntarism. *American Journal of Psychiatry, 159*, 705–712.

Rosse, P.A., & Krebs, L.U. (1999). The nurse's role in the informed consent process. *Seminars in Oncology Nursing, 15*, 116–123.

Shield, J.P., & Baum, J.D. (1994). Children's consent to treatment. *British Medical Journal (Clinical Research Ed.), 308*, 1182–1183.

Thompson, J. (2003). Ethical challenges of informed consent in prehospital research: Pedagogical tools and methods. *Canadian Journal of Emergency Medicine, 5*(2), 108–114.

Wager, E., & Tooley, P.J.H. (1995). Get patients' consent to enter clinical trials. *British Medical Journal, 311*, 734–737.

Winter, H., Lavender, V., & Blesing, C. (2011). Developing a nurse-led clinic for patients enrolled in clinical trials. *Cancer Nursing Practice, 10*(3), 20–24.

DID YOU KNOW...

The Canadian Cardiovascular Society 2010 Atrial Fibrillation Guidelines (Cairns, 2010) Recommend the Use of Dabigatran over Warfarin for Stroke Prevention in Non-Valvular Atrial Fibrillation?

Elizabeth Hodgson, RN, MSc, NP

The purpose of this column is to discuss the use of dabigatran (Pradax) (Boehringer Ingelheim, 2010) as an oral anticoagulant (OAC) for stroke prevention in atrial fibrillation (AF) based on the results of the RE-LY trial (Connolly et al., 2009), the advantages, disadvantages, limitations, and the precautions that cardiovascular nurses should consider when administering and teaching patients about dabigatran.

Atrial fibrillation (AF) is the most common arrhythmia experienced by Canadians, prompting thousands of emergency department visits each year. The etiology of AF is diverse, occurring as a primary electrical disturbance and as a consequence of structural heart disease, ischemia and heart failure. AF is the most common complication following open heart surgery, resulting in increased morbidity and lengthened hospital stays. The presentation of AF is as diverse as its etiology with some patients debilitated with paroxysms of tachycardia and others with no symptoms before the development of heart failure due to tachycardia-induced cardiomyopathy. Management of AF is aimed at control of symptoms and improved quality of life rather than necessarily restoration of sinus rhythm. Researchers have demonstrated that there is no advantage of rhythm control over rate control to either quality of life or mortality, (Cairns et al., 2010). More definitive, invasive procedures such as AV nodal ablation or surgical ablation are reserved for those few patients who cannot tolerate their symptoms. No mortality benefit has been demonstrated with these procedures (Cairns et al., 2010).

The greatest risk to mortality and morbidity associated with AF is stroke. Stroke occurs at a rate of 4.5% per year, associated with death or permanent disability in more than half. The risk of stroke rises to over 20% when risk factors such as age, heart failure, diabetes, hypertension and previous stroke are considered (Cairns et al., 2010). Risk of stroke associated with AF has been managed with Aspirin and vitamin K antagonists, which can reduce the risk by 64% (Cairns et al., 2010). The decision to employ an OAC for stroke prevention should be made on an individual patient basis and should be made objectively using a scoring system such as CHADS, and the risk of bleeding complications should similarly be evaluated using the HAS-BLED score (Cairns et al., 2010).

Previously the only OAC available was the vitamin K antagonist warfarin. While warfarin is effective in reducing stroke risk, it is not without side effects and limitations as a therapy. Increased risk of bleeding, with major bleeding requiring transfusion or causing organ damage such as hemorrhagic stroke is the worst side effect. This can be reduced by close monitoring of the international normalized ratio (INR) to the therapeutic range of 2 to 3. Maintaining therapeutic INR is not easy to accomplish, however, since metabolism of warfarin is affected by various foods and medications affected by liver metabolism, including antibiotics and antiarrythmic drugs including amiodarone. Dietary restrictions and the need for regular and, at times frequent, blood testing to monitor INR can have a negative effect on quality of life and can actually be impossible in rural or remote parts of the country.

Dabigatran is a new OAC that is a direct, competitive inhibitor of thrombin. Thrombin converts fibrinogen to fibrin in the clotting cascade. Administered as the pro-drug dabigatran-etexilate, it is rapidly converted by non-specific esterases in the serum and liver to the active drug. Dabigatran has an absolute bioavailability of only 6.5% with 80% of the active drug excreted by the kidneys and a serum half- life of 12 to 15 hours (Connolly et al., 2009). Dabigratran, therefore, requires twice-daily dosing. Approved in Canada in two dosages 150 mg and 110 mg, the 150 mg dose was shown by the RE-LY trial to be superior to warfarin in preventing stroke in atrial fibrillation. The 110 mg dose was non-inferior to warfarin and is recommended for the elderly and those with renal insufficiency (Cairns et al., 2010). Unlike warfarin there is no blood test for efficacy of dabigatran although monitoring serum levels of dabigatran in the elderly and in renal insufficiency or measuring thrombin time has been suggested (Nainggolan, 2011).

While the RE-LY trial (Connolly et al., 2009) demonstrated that dabigatran was superior to warfarin in stroke prevention, was associated with less intracranial bleeding, and overall did not cause more major bleeding or death, dabigatran has also been associated with serious side effects. Dabigatran was associated with more major and even fatal gastrointestinal (GI) bleeding (Connolly et al.,

2009). Anecdotal reports of serious GI bleeding, especially in the elderly (Nainggolan, 2011) have raised concerns about the safety of dabigatran in the frail elderly and those with impaired renal function. Dyspepsia was identified as an important side effect resulting in discontinuation of the drug in 21% of subjects over two years (Callaghan, 2011; Connolly et al., 2009). Discontinuation of dabigatran without switching to warfarin leaves those patients with increased risk of stroke. Like warfarin, dabigatran should be discontinued prior to invasive procedures associated with increased bleeding risk. The actual time off dabigatrin pre-procedure should be determined on an individual basis and should consider renal function, since impaired renal clearance results in higher serum concentrations and longer therapeutic half-life (Callaghan, 2011). Dabigatran should be stopped one to two days pre-procedure and resumed two to four days after (Callaghan, 2011).

Dabigatrin is excreted by the kidneys and, therefore, should not be used in renal failure with creatinine clearance of less than 30 ml/min. The 110 mg dose is recommended for the elderly and those with renal insufficiency (Cairns et al., 2010) and renal function should be carefully monitored. Another concern that arose from the RE-LY trial (Connolly et al., 2009) was a small increase in the incidence of myocardial infarction seen with both doses of dabigatran. The cause of this is not apparent but, as a result, the Canadian Cardiovascular Society (CCS) recommendations (Cairns et al., 2010) support warfarin for those at risk of coronary events.

The RE-LY trial researchers (Connolly et al., 2009) demonstrated the superiority of dabigatran over warfarin in stroke prevention in patients with non-valvular atrial fibrillation. At present, sufficient research has not been completed to support recommending the use of dabigatran for patients with valvular heart disease, prosthetic valves requiring anticoagulation, or in the case of intra-ventricular or atrial thrombi (Cairns et al., 2010). Warfarin remains the OAC of choice for these patients.

Finally, the cost of dabigatran therapy has been raised as a concern. An analysis of quality-adjusted-life-years between warfarin and dabigatran, based on CHADS scores, concluded that for patients at low risk of stroke, warfarin was more cost-effective but, if the risk of stroke was greater, dabigatran became more cost-effective (Black, 2011). The actual cost of warfarin tablets is much less than dabigatran.

Warfarin is taken only once daily while dabigatran requires twice-daily dosing and, at present, dabigatran is not covered by all provincial drug plans or even all private insurance companies. This means that many patients would have to cover the cost of dabigatran out of pocket and this is not possible in many cases.

In summary, dabigatran is a new OAC that has been shown by the RE-LY trial to be superior to warfarin for stroke prophylaxis at the 150 mg dose and is non-inferior to warfarin at the 110 mg dose (recommended for use in the elderly and with renal insufficiency). Dabigatran is recommended by the CCS in the 2010 AF guidelines for use with non-valvular AF, but not for use with valvular disease, prosthetic valves or with mural thrombi.

Advantages of dabigatran over warfarin include superior stroke prevention without increased incidence of major bleeding or death, no requirement for blood testing to determine efficacy, no food interactions, and fewer drug interactions affecting efficacy.

Disadvantages or concerns with dabigatran include increased incidence of GI bleeding with the 150 mg dose, dyspepsia, inconvenience of twice-daily dosing, contraindication in renal failure, caution in the elderly and with renal insufficiency, increased incidence of MI suggesting that it should not be used in patients with coronary ischemia, and cost making it unaffordable for many.

Despite these concerns, many patients are asking if they can use dabigatran rather than warfarin to avoid the necessity of frequent blood work and food restrictions, and are willing to meet the cost of the drug. Cardiovascular clinicians must weigh the risks and benefits of this new OAC for each patient based on current knowledge and wait for more research and experience with dabigatran to extend its application to a broader group of patients requiring anticoagulation. ♥

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REFERENCES

Black, H.R. (2011). *Dabigatran—A good new drug, but when is it cost-effective?* Retrieved from http://www.medscape.com/viewarticle/737000

Boehringer Ingelheim. (2010). *Information for people with atrial fibrillation who have been prescribed "Pradax"*. Burlington, ON: Author.

Cairns, J.A., Connolly, S., McMurtry, S., Stephenson, M., Talajic, M., & The CCS Atrial Fibrillation Guidelines Group. (2010). Canadian Cardiovascular Society atrial fibrillation guidelines 2010: Prevention of stroke and systemic thromboembolism in atrial fibrillation and flutter. *Canadian Journal of Cardiology, 27*, 74–90.

Callaghan, M. (2011). *D is for … New drugs in the management of patients with atrial fibrillation.* Powerpoint presentation at the 16th Annual Atlantic Cardiovascular Conference. Halifax, NS.

Connolly, S.J., Ezekowitz, M.D., Yusuf, S., & the RE-LY Steering Committee and Investigators. (2009). Dabigatran versus warfarin in patients with atrial fibrillation. *New England Journal of Medicine, 361*, 1139–1151.

Nainggolan, L. (2011). *Caution needed with dabigatran in the elderly.* Retrieved from http://www.theheart.org/article/1260157.do?utm

LE SAVIEZ-VOUS?

Les lignes directrices 2010 de la Société canadienne de cardiologie en matière de fibrillation auriculaire (Cairns, 2010) recommandent l'usage du dabigatran par rapport à warfarine pour la prévention de l'accident vasculaire cérébral (AVC) chez les patients qui présentent une fibrillation auriculaire non valvulaire

Elizabeth Hodgson, IA, MSc, IP

La présente chronique examine l'usage du dabigatran (Pradax) (Boehringer Ingelheim, 2010) comme anticoagulant oral (AO) pour la prévention de l'accident vasculaire cérébral chez les patients qui présentent une fibrillation auriculaire (FA), sur la base des résultats de l'étude RE-LY(Connolly et al., 2009). La chronique précise également les avantages, les désavantages, les restrictions et les précautions que les infirmières et infirmiers en soins cardiovasculaires doivent prendre en considération en ce qui a trait à l'administration du dabigatran et dans la communication d'information sur ce médicament aux patients.

La fibrillation auriculaire (FA) est l'arythmie la plus commune chez les Canadiens et les Canadiennes, source de milliers de visites dans les services d'urgence chaque année. L'étiologie de l'AF est diversifiée. Elle se traduit principalement par des perturbations électriques et apparaît également comme conséquence de cardiopathies structurelles, d'ischémie et d'insuffisance cardiaque. La fibrillation auriculaire est la complication la plus commune à la suite d'une chirurgie à cœur ouvert; elle augmente la morbidité et prolonge la durée des séjours à l'hôpital. Elle se manifeste de façon aussi diversifiée que son étiologie; certains patients sont débilités par des paroxysmes de tachycardie, tandis que d'autres ne présentent pas de symptômes avant de développer une insuffisance cardiaque en raison d'une cardiomyopathie favorisée par la tachycardie. La gestion de la fibrillation auriculaire vise le contrôle des symptômes et l'amélioration de la qualité de vie plutôt que de restaurer nécessairement le rythme sinusal. Les chercheurs ont démontré que le contrôle du rythme cardiaque ne présente pas plus d'avantages que le contrôle de la fréquence cardiaque en ce qui a trait à la qualité de vie ou à la mortalité (Cairns et al., 2010). Plus définitives, les procédures invasives comme l'ablation du noeud auriculoventriculaire (AV) ou l'ablation chirurgicale sont réservées aux quelques patients qui ne peuvent pas tolérer leurs symptômes. Aucun avantage en ce qui a trait à la réduction de la mortalité n'a été démontré avec ces procédures (Cairns et al., 2010).

Le plus grand risque de mortalité et de morbidité associé à la fibrillation auriculaire est l'accident vasculaire cérébral (AVC). L'AVC, qui se produit au rythme de 4,5 % par année, est associé au décès ou à l'invalidité permanente dans plus de la moitié des cas. Le risque d'AVC augmente à plus de 20 % quand des facteurs de risque comme l'âge, l'insuffisance cardiaque, le diabète, l'hypertension et un AVC antérieur sont pris en considération (Cairns et al., 2010). Le risque d'AVC associé à la fibrillation auriculaire a été géré avec de l'aspirine et des antagonistes de la vitamine K, qui peuvent réduire le risque de 64 % (Cairns et al., 2010). La décision d'utiliser un anticoagulant oral pour la prévention de l'AVC doit être prise en fonction de chaque patient. Elle doit être objective, en utilisant par exemple un système de stratification du risque comme le système CHADS. Il faut évaluer de façon similaire le risque de complications hémorragiques, au moyen du score HAS-BLED (Cairns et al., 2010).

Auparavant, le seul anticoagulant oral disponible était la warfarine, antagoniste de la vitamine K. Bien qu'elle soit efficace pour prévenir le risque d'AVC, la warfarine est une thérapie qui n'est pas sans effets secondaires et sans restrictions. Le risque accru d'hémorragie, et d'une hémorragie majeure nécessitant une transfusion ou endommageant des organes, comme un accident vasculaire cérébral hémorragique, est le pire de ces effets secondaires. On peut réduire ce risque en contrôlant attentivement le rapport international normalisé (RIN) afin de le maintenir dans la marge thérapeutique cible de 2,0 à 3,0. Il n'est toutefois pas aisé de maintenir le RIN dans la marge thérapeutique cible, parce que le métabolisme de la warfarine est affecté par diverses interactions alimentaires et médicamenteuses, par le métabolisme hépatique, et aussi par les antibiotiques et les antiarythmisants, notamment l'amiodarone. Les restrictions alimentaires, et la nécessité d'analyses sanguines régulières, et parfois fréquentes, pour surveiller le RIN, peuvent avoir un effet négatif sur la qualité de vie, et même parfois s'avérer impossible à mettre en œuvre dans les régions rurales ou éloignées du pays.

Le dabigatran est un nouvel anticoagulant oral qui est un inhibiteur direct et compétitif de la thrombine. La thrombine convertit le fibrinogène en fibrine dans la cascade de la coagulation. Administré sous la forme de la pro-drogue dabigatran-etexilate, le dabigatran est rapidement converti en forme active par des estérases non spécifiques présentes dans le sérum et le foie. Le dabigatran a une biodisponibilité absolue de seulement 6,5 % avec 80 % de sa forme active excrétée par les reins et une demi-vie sérique de 12 à 15 heures (Connolly et al., 2009). Il doit donc être administré deux fois par jour. Il est approuvé au Canada en deux doses de 150 mg et de 110 mg, et l'étude RE-LY a démontré que la dose de 150 mg était supérieure à la warfarine pour prévenir l'AVC en présence de fibrillation auriculaire. La dose de 110 mg était non inférieure à la warfarine et est recommandée pour les personnes âgées et les personnes atteintes d'insuffisance rénale (Cairns et al., 2010). Contrairement à la warfarine, l'évaluation de l'efficacité du dabigatran n'est pas effectuée au moyen d'une analyse sanguine, bien qu'il ait été suggéré, dans le cas des personnes âgées et des personnes atteintes d'insuffisance rénale, de surveiller les niveaux sériques du dabigatran ou de mesurer le temps de thrombine (Nainggolan, 2011).

Bien que l'étude RE-LY (Connolly et al., 2009) ait démontré que le dabigatran était supérieur à la warfarine pour la prévention de l'AVC, qu'il était associé à moins d'hémorragies intracrâniennes et qu'il n'a pas causé plus d'hémorragies majeures ou de mortalité en général, le dabigatran a également été associé à des effets secondaires sérieux. Il a été relié à plus d'hémorragies gastro-intestinales majeures et même fatales (Connolly et al., 2009). Les rapports anecdotiques d'hémorragie gastro-instestinale sérieuse, particulièrement chez les personnes âgées (Nainggolan, 2011), ont soulevé des inquiétudes au sujet de la sécurité du dabigatran chez les personnes âgées fragiles et les personnes dont la fonction rénale est altérée. La dyspepsie ayant été identifiée comme un effet secondaire important, et a entraîné le retrait du médicament chez 21 % des sujets en deux ans (Callaghan, 2011; Connolly et al., 2009). Le retrait du dabigatran sans le remplacer par la warfarine laisse ces patients à risque accru d'AVC. Comme dans le cas de la warfarine, il faut interrompre l'administration du dabigatran avant les procédures invasives associées à des risques accrus d'hémorragie. Le moment réel choisi pour interrompre l'administration du dabigatran avant l'intervention doit être déterminé sur une base individuelle et en prenant en considération la fonction rénale, parce que l'altération de la clairance rénale produit des concentrations sériques plus élevées et prolonge la demi-vie thérapeutique du médicament (Callaghan, 2011). L'administration du dabigatran doit être interrompue un ou deux jours avant l'intervention et reprendre dans les deux à quatre jours suivant l'intervention (Callaghan, 2011).

Le dabigatran étant excrété par les reins, il faut donc éviter de l'utiliser chez les personnes atteintes d'une défaillance rénale et dont la clairance de la créatinine est inférieure à 30 ml/min. La dose de 110 mg est recommandée pour les personnes âgées et les personnes atteintes d'insuffisance rénale (Cairns et al., 2010), et la fonction rénale doit être surveillée de près. L'étude RE-LY (Connolly et al., 2009) a également mis en lumière une autre préoccupation, soit une légère augmentation de l'incidence de l'infarctus du myocarde constatée avec les deux doses de dabigatran. Bien que la cause n'en soit pas apparente, il en résulte que la Société canadienne de cardiologie (SCC) appuie dans ses recommandations (Cairns et al., 2010) l'utilisation de la warfarine pour les personnes qui présentent un risque d'événement coronarien.

Les chercheurs de l'étude RE-LY (Connolly et al., 2009) ont démontré la supériorité du dabigatran par rapport à la warfarine dans la prévention de l'AVC chez les patients qui présentent une fibrillation auriculaire non valvulaire. Il n'y a pas suffisamment de recherche achevée à l'heure actuelle pour étayer une recommandation d'utiliser le dabigatran pour les patients qui présentent une cardiopathie valvulaire, qui portent des prothèses valvulaires nécessitant l'utilisation d'anticoagulants, ou qui présentent un thrombus intraventriculaire ou auriculaire (Cairns et al., 2010). La warfarine demeure l'anticoagulant oral de choix pour ces patients.

Finalement, le coût du traitement avec le dabigatran est une préoccupation qui a été soulevée. Une analyse des années de vie pondérées par la qualité dans le cas de la warfarine et dans celui du dabigatran, sur la base des scores CHADS, a conclu que la warfarine était plus rentable pour les patients à faible risque d'AVC, mais que le dabigatran devenait plus rentable si le risque d'AVC était plus élevé (Black, 2011). Le coût réel des comprimés de warfarine est beaucoup moins élevé que pour le dabigatran. La warfarine est prise seulement une fois par jour, tandis qu'il faut prendre le dabigatran deux fois par jour. En outre, à l'heure actuelle, le dabigatran n'est pas couvert par tous les régimes provinciaux d'assurance-médicaments, ni même par toutes les compagnies d'assurances privées. Cela signifie que beaucoup de patients devraient assumer eux-mêmes le coût du dabigatran, et cela n'est pas possible dans bien des cas.

En résumé, le dabigatran est un nouvel anticoagulant oral dont l'étude RE-LY a démontré qu'il était supérieur à la warfarine pour le traitement prophylactique de l'AVC à la dose de 150 mg, et non inférieur à la warfarine à la dose de 110 mg (recommandée pour les personnes âgées et les personnes atteintes d'insuffisance rénale). La Société canadienne de cardiologie recommande, dans les lignes directrices 2010 en matière de fibrillation auriculaire, l'usage du dabigatran chez les patients présentant une fibrillation auriculaire non valvulaire, mais non chez les patients qui présentent une cardiopathie vasculaire, qui portent des prothèses valvulaires ou qui présentent un thrombus mural. Le dabigatran est supérieur à la warfarine notamment pour la prévention de l'AVC

sans incidence accrue d'hémorragie majeure ou de mortalité, parce qu'il n'exige pas d'analyse sanguine pour en déterminer l'efficacité, parce qu'il n'est pas associé à des interactions alimentaires, et parce qu'il est associé à moins d'interactions médicamenteuses nuisant à son efficacité.

Les désavantages du dabigatran ou les inquiétudes qui y sont associées sont notamment l'incidence accrue d'hémorragie gastro-intestinale avec la dose de 150 mg, la dyspepsie, l'inconvénient de l'administration de deux doses quotidiennes, la contre-indication dans les cas d'insuffisance rénale, la prudence qu'il exige dans le cas des personnes âgées et des personnes ayant une insuffisance rénale, l'incidence accrue d'infarctus du myocarde (IM) qui laisse croire qu'il ne doit pas être utilisé chez les patients qui présentent une ischémie coronarienne, et son coût inabordable pour beaucoup de patients.

Malgré ces préoccupations, beaucoup de patients veulent savoir s'ils peuvent prendre du dabigatran plutôt que de la warfarine pour éviter l'obligation d'analyses sanguines fréquentes et les restrictions alimentaires, et ils sont prêts à payer le prix du médicament. Les cliniciens en santé cardiovasculaire doivent mesurer les risques et les avantages de ce nouvel anticoagulant oral pour chaque patient sur la base de l'état actuel des connaissances, et ils doivent attendre qu'il existe plus de recherche sur le dabigatran et plus d'expérience avec ce médicament pour en étendre l'application à un groupe plus large de patients qui ont besoin d'anticoagulation. ♥

Au sujet de l'auteure

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REFERENCES

Black, H.R. (2011). *Dabigatran—A good new drug, but when is it cost-effective?* Données extraites de http://www.medscape.com/viewarticle/737000

Boehringer Ingelheim. (2010). *Information for people with atrial fibrillation who have been prescribed "Pradax"*. Burlington, ON : Auteur.

Cairns, J.A., Connolly, S., McMurtry, S., Stephenson, M., Talajic, M., et le groupe de travail de la Société canadienne de cardiologie sur les lignes directrices en matière de fibrillation auriculaire. (2010). Les lignes directrices de la Société canadienne de cardiologie en matière de fibrillation auriculaire 2010 : prévention des AVC et de la thromboembolie systémique en matière de fibrillation auriculaire et de « flutter ». *Journal canadien de cardiologie, 27*, 74–90 (en anglais seulement).

Callaghan, M. (2011). *D is for … New drugs in the management of patients with atrial fibrillation.* Présentation PowerPoint à la 16e Conférence annuelle du Canada atlantique cardiovasculaire—Halifax, Nouvelle-Écosse.

Connolly, S.J., Ezekowitz, M.D., Yusuf, S., & the RE-LY Steering Committee and Investigators. (2009). Dabigatran versus warfarin in patients with atrial fibrillation. *New England Journal of Medicine, 361*, 1139–1151.

Nainggolan, L. (2011). *Caution needed with dabigatran in the elderly.* Retrieved from http://www.theheart.org/article/1260157.do?utm

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Les manuscrits doivent être tapés à double interligne, dans une police couramment employée pour les lettres. Les marges latérales doivent être de 2,5 cm. La longueur maximale permise est de 20 pages, ce qui comprend les tableaux, les figures, les illustrations et les références. (Les graphiques équivalent à la moitié d'une page ou à une page complète, selon la taille prévue lors de la publication.)

Style du texte : le style de présentation du manuscrit doit être conforme au style décrit dans l'American Psychological Association's (APA) Publication Manual (6th ed.).

Le style doit être conforme aux lignes directrices du manuel de publication de l'APA en ce qui concerne la grammaire, la ponctuation, le langage impartial, les références et les citations. Il y a cependant deux exceptions à l'emploi des règles de l'APA : l'orthographe devrait être conforme à l'usage canadien courant, le cas échéant, et le résumé ne doit pas dépasser 150 mots.

Tableaux, graphiques et illustrations : ils doivent être préparés selon les lignes directrices du manuel de publication de l'APA. Chacun des tableaux, figures et illustrations doit être présenté sur une feuille distincte et être numéroté selon son ordre d'apparition dans le texte (p. ex. figure 1). Les illustrations doivent être produites par ordinateur ou dessinées de manière professionnelle. Les photographies doivent être présentées sous forme de duplicata dans le manuscrit soumis, et non montées.

Liste des références : la RCSC utilise une liste de références (par opposition à une bibliographie); la raison en est précisée dans le manuel de publication de l'APA.

Page de titre

Veuillez inclure une page de titre précisant le titre de l'article ainsi que les noms, les titres professionnels et les affiliations de chacun des auteur(e)s. Précisez à qui la correspondance doit être adressée, en prenant soin de donner le numéro de téléphone, le numéro de télécopieur et l'adresse électronique de cette personne.

Indiquez sur la page de titre quatre ou cinq mots clés tirés de la liste des sujets contenus dans la base de données CINAHL.

Remerciements

Les noms des autres personnes qui ont contribué à l'ouvrage et l'information sur l'aide financière obtenue pour conduire les travaux de recherche décrits dans le manuscrit doivent apparaître dans la section des remerciements.

Processus d'examen

Les manuscrits des articles originaux sont évalués de façon anonyme par des pairs qui jugent de leur mérite et de leur clarté. Si les pairs recommandent des révisions du contenu avant la publication, le manuscrit sera envoyé à l'auteur(e) en précisant une date limite pour retourner le manuscrit révisé par courriel.

L'échéancier prévu de réponse aux manuscrits soumis est huit semaines.

Révisions éditoriales

Les articles qui sont acceptés sont sujets à une révision éditoriale.

Droits d'auteur

Il est entendu que si l'article est publié, la *Revue canadienne des soins cardiovasculaire* détiendra les droits exclusifs pour l'article, y compris le contenu de l'article et tout ce qui a trait à sa reproduction et à sa vente.

Consultez la présentation PowerPoint pour vous aider avec les règles de formatage du manuel de publication, qui se trouve sur la page Web de la RCSC à **http://www.cccn.ca/info/cjcn.cfm**