

**FINAL REPORT**  
**Nova Scotia Health Research Foundation**

***TOWARDS A NEW MODEL OF CARE DELIVERY FOR  
LUNG CANCER PATIENTS AND THEIR FAMILIES***  
**(File# PSO - Project 2004 - 4005)**

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Capital Health/QEII Cancer Care Program



## Investigating Team and Partners

This study was planned and conducted with continuous support and collaboration among researchers from Dalhousie University, the Capital Health Cancer Care program, Cancer Care Nova Scotia, tertiary and primary care clinicians, and administrators of the Capital Health Cancer Care program. The principal investigators, **Lorna Butler**, PhD, Professor Dalhousie University School of Nursing and **Murali Rajaraman**, MD, Assistant Professor Dalhousie University Faculty of Medicine and Radiation Oncologist, Capital Health Cancer Care program, had the privilege to work with the following individuals:

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## ABSTRACT

Lung cancer was the leading type of cancer-related deaths in Nova Scotia between 1995 -1999. Sadly, the disease usually progresses rapidly with less than 10% of patients surviving five years and the majority of deaths occurring within one year of diagnosis (Cancer Care Nova Scotia, 2002). It is increasingly being recognized that traditional models of post treatment care of disease surveillance and detection of recurrence do not provide the opportunity for comprehensive care and support, and may result in patients spending precious time on lengthy hospital visits during periods of stable disease. This situation underscores the need to be proactive in considering alternate models of post treatment care that will be both sustainable and provide a safe, supportive, and coordinated service for this patient population.

The purpose of this pilot study was to test the feasibility of conducting a randomized trial comparing the effectiveness and expense of an alternative model of nurse led post treatment care of lung cancer patients and their families with the standard system of cancer clinic post treatment care. The main objective was to pilot test and evaluate the processes and data collection tools to be used to measure outcomes in a larger randomized study to determine whether nurse led post treatment care of individuals with lung cancer is an acceptable alternative to the existing system of clinic post treatment care. The pilot randomized controlled trial involved 12 post treatment lung cancer patients and their designated family members receiving care in the Capital Health cancer clinic. Patients in the control group received post treatment care in the cancer clinic according to standard practice. Patients in the experimental group received nurse led post treatment care. This study was comprised of two elements; a quantitative component and a qualitative component. The outcomes of the quantitative component of the study consisted of: 1) determining the accrual rate for this patient population; 2) assessing the study procedures; 3) assessing the questionnaire completion rate; 4) determining the frequency of significant clinical events; and 5) adherence to the study protocol. The qualitative component of the study was concerned with determining the aspects of the new model of care that healthcare providers identify as important domains to be measured in a future study. Instruments that were tested included those used to measure patient health related quality of life, patient and family members' levels of psychosocial distress, patient, family and providers' levels of satisfaction, and direct costs to the health care system and indirect costs to the patient.

The results of the research indicated that the patient eligibility criteria and method of nurse led follow-up chosen for this study would not support the conduct of a large randomized controlled trial. This pilot study provided the evidence needed to re-design the trial for a larger study.

## Introduction

Nova Scotia has the highest rates of lung cancer in Canada with approximately 800 new cases diagnosed each year (Cancer Care Nova Scotia, 2002). According to the Surveillance and Epidemiology Unit of Cancer Care Nova Scotia, lung cancer was the leading type of cancer-related deaths in the province between 1995-1999, accounting for 33% of cancer deaths in males and 23% of cancer deaths in females. Sadly, the disease usually progresses rapidly with less than 10% of patients surviving five years and the majority of deaths occurring within one year of diagnosis (Cancer Care Nova Scotia, 2003). Treatment options for lung cancer patients include combinations of surgery, radiotherapy, and chemotherapy, but for the majority, who present with advanced disease, curative treatment is unavailable.

Given the poor prognosis and lack of effective therapies presently available, it is evident that early intervention towards maximizing quality of life and managing the advanced stage symptoms for these patients is critical. Despite such circumstances, patients continue to routinely attend busy hospital outpatient post treatment cancer clinics where the emphasis of care is on disease surveillance and detection of recurrence or metastatic spread. It is increasingly being recognized that such traditional models of post treatment care do not provide the opportunity for comprehensive care and support. For patients with advanced stage lung cancer, ongoing post treatment care in the cancer clinic setting may promote unnecessary and time-consuming visits to hospital during periods of stable disease, when time is precious.

If the current trends of increasing cancer incidence continue, Nova Scotia can expect a 42% increase of cancer cases by 2010 relative to 1999 rates with a significant increase attributable to lung cancer (Cancer Care Nova Scotia, 2003). With an aging population and projected increases in the incidence and prevalence of cancer, an ever-increasing burden is being placed upon the health care system and our communities. In response to this situation, there is a growing understanding of the need for continuity in cancer care across the continuum to achieve optimal cost, clinical efficiency and patient, family and provider satisfaction. This situation underscores the need to be proactive in considering alternate models of post treatment care that will be both sustainable and provide a safe, supportive, and coordinated service for this patient population. The purpose of this project was to conduct a pilot study to test and evaluate the processes and data collection tools for a potential larger randomized trial. The aim of a larger study will be to determine whether an alternate model of

nurse led post treatment care of lung cancer patients is an acceptable alternative to standard post treatment care. This pilot study has provided information that suggests that aspects of the nurse led model of post treatment care of lung cancer patients and the patient eligibility criteria need to be modified before a larger randomized trial can be undertaken.

### **Summary of Activities to Date Compared to Proposed Timeline**

Despite carefully developed patient eligibility criteria, the acuity of the lung cancer patients was much higher than anticipated and resulted in a slower rate of accrual than originally projected. To a lesser degree, the accrual rate was also affected by the fact that the nurse led model of post treatment care involved a major shift in thinking on the part of physicians and patients. As a consequence, we were not able to accrue the 30 participants originally projected. The accrual rate also impacted our ability to undertake the focus groups at the original time proposed and limited the number of health care providers we could invite to participate.

### **Report of Achievements and Results**

#### **Quantitative Component**

***Identification and Selection of Potential Study Participants.*** A systematic and effective approach to identifying potential study participants was employed and included use of the OPIS registration system as well as a cross check with the nurses and physicians in the Cancer Centre. The process of asking patients to identify a primary family support and subsequently approaching them to participate in the study was also effective. The patient eligibility criteria were carefully developed with information gained from both expert clinicians and existing research literature. Out of a total 151 post treatment lung cancer patients, 31 met the study eligibility criteria. Of the 31 eligible patients, 23 were approached to participate. The reasons given for the other 8 not being approached were; 4 were missed, 2 moved out of province and 2 were not approached due to physician preference. Of the 23 who were approached, 14 agreed to participate and the other 9 were too “overwhelmed” to take part, preferred to stay with their oncologist or be followed in their home community, went on another trial or died. Of the 120 who did not meet the eligibility criteria, the majority were for reasons of disease progression, other medical issues, had exceeded the 3 month post treatment deadline, had less than a 3 month life expectancy or had plans for additional

treatment. The following factors were felt to be responsible for not being able to accrue a greater number of patients in this study; the heterogeneity and high acuity of the lung cancer patient population, the strict eligibility criteria, the scope of practice of the nurse in the nurse-led model and, to a lesser degree, the comfort level of some physicians and patients in accepting the nurse-led approach to follow-up. This provided important information relative to the design of this type of study.

**Participants.** A total of 14 patients and 9 designated family members were accrued to the study. Two of these patients were withdrawn from the study immediately post accrual; one for further treatment and the other due to death. Overall, 12 patients and 7 designated family members participated in this study. The randomization procedure selected for this study was successful in allocating participants to either the control or experimental group. Six patients and 4 family members were randomized to the standard model of post treatment care (control group) and 6 patients and 3 family members were randomized to the nurse-led model of post treatment care (experimental group). Of the 6 patients in the control group, 5 were male and 1 was female and all 4 family members were male. In the experimental group, 2 patients were male and 4 were female; 1 family member was male and 2 female. Fifty-eight percent of all family members were spouses of the patients and the remaining 42% were children, cousins or friends. All patients were 61-years of age or older and the family members were 41 years of age and over. Fifty percent of patients and 84% of family members had completed high school. The majority of patients were retired and 72% of all family members were employed. Over 80% of all participants lived within 60 kilometers of the clinic and 86% of the family members resided with the patient. Ninety-two percent of patients were within one year of diagnosis and described experiencing combined symptoms of pain and fatigue or “other” symptoms. Eighty-six percent of family members indicated that they attended a support group.

**Questionnaire Completion Rate.** Of the patients accrued, all completed time one (baseline) questionnaires fully and on time; however, in both the control and experimental groups two patients in each did not complete the time two (3 month) questionnaires as a result of deterioration in health status. Similarly, all family members completed time one questionnaires fully and on time but in both groups one family member in each did not

complete the time two questionnaires. Although the numbers are small it does represent approximately a 70% completion rate.

***Psychometric Properties of the Selected Instruments.*** The questionnaires used to measure patients' health related quality of life (EORTC QLQ-C30 and Lung Module), patients' and family members' psychological distress (Hospital Anxiety and Depression Scale-HADS), satisfaction with care (modified EORTC QLQ-SAT32 and FAMCARE), and costs associated with health service utilization (Health and Social Service Utilization questionnaire) are all well established tools and have been shown to be reliable and valid measures in cancer clinical trials. The EORTC QLQ-C30 and Lung Module and the HADS were administered at two time points (baseline and 3 months). The scores were compared using non-parametric test of paired data and Wilcoxon Signed Ranks Test. No significant differences were found over time for either experimentals or controls. Similarly, due to the small sample size there was insufficient power to achieve statistical significance between experimental and control scores from satisfaction with care and health and social service utilization measures.

***Frequency of Significant Clinical Events.*** This study helped us to determine the rate of significant clinical events (SCE) and the procedures for adjudicating the timely management of these events. The identification of the SCE's were based on current practices of the Thoracic Cancer Site Team and the existing literature. To determine whether a SCE occurred, the research assistant conducted a retrospective review of all patient charts at the completion of the study. The research assistant prepared a case summary for each SCE using an established form. There were two SCE's in the control group and three in the experimental group. A panel of two clinicians/researchers reviewed each case summary according to pre-set criteria to ascertain whether it was a preventable or an unpreventable SCE. There were two differences in classification which the panel discussed and an agreement was reached. This approach was used successfully as it has been in previous work (Grinfeld & Levine, 1996).

***Adherence to the Study Protocol.*** The accrual rate of patients and family members as well as the questionnaire completion rates indicate the study protocol was acceptable to the lung cancer patient and family member population. In addition, the physicians and nurses involved in the pilot stayed committed to the protocol throughout the study. It is believed that the

clinicians' adherence to the study protocol was a direct result of their involvement in the design and implementation of the nurse led model of follow-up as well as ongoing communication and significant education regarding the new model. This is a significant finding of the pilot and critical to the success of this type of study.

### **Qualitative Component**

Two focus groups were conducted to determine the aspects of the new model of care that healthcare providers identify as important domains to be measured in a larger study.

**Participants.** There were 9 participants in the first round of focus groups including 2 family physicians, 1 radiation oncologist, 3 oncology nurses, 2 palliative care nurses and 1 palliative care physician. During the second round of focus groups 5 new participants attended (1 surgical oncologist, 2 medical oncologists, and 2 radiation oncologists). Eight participants were male and 6 were female. Their clinical experiences were in the out-patient cancer clinics, in hospital, in private community offices, and in patients' homes. They had been in clinical practice a minimum of 5 years to a maximum of 30 years. Most had cared for 1 or 2 patients in the new model and a small number had cared for 5 or more.

**Results.** Using a focus group question guide the health care providers were probed for their views on how the models differed in terms of: access for patients and families to health care providers, coordination of care, satisfaction of patients and families, satisfaction of health care providers, perceptions of integration of care, reduction and prevention of symptoms, anxiety and stress on patients and families. The participants were also provided an opportunity to comment on any other areas on which they thought the new model had an impact. Qualitative comments from the focus groups provided valuable insight into providers' perceptions and experiences of the new model of post treatment care. These were examined using a content analysis and data reduction technique that enables identification of frequently occurring patterns or themes. The resulting themes can provide direction for the development of key qualitative questions to be used in a larger randomized trial.

### **Summary of Main Conclusions**

This pilot study helped to identify the impediments to accrual and the substantial paradigm shift and lengthy educative component required in introducing an alternative care delivery system. In many cases there was only a short period of time when lung cancer

patients were well during their follow-up care. This high level of acuity and the limits of the scope of practice of the staff R.N. in the nurse led model to address more medically complex patients meant that only a small and stable subset of the lung cancer patient population could be served in this model. That is not to say that the nurse led model is not benefiting this smaller number of patients through a more holistic approach to care but it does raise the issue of the economic feasibility of maintaining such a clinic as it is currently configured in a resource constrained environment. It would seem that for this patient population, the nurse undertaking follow-up care would have to demonstrate that they could safely monitor signs of progressive disease and initiate further investigations and treatment as necessary or determine which patients could be managed palliatively and make the appropriate referral. This may be in contrast to other patient populations studied in relation to nurse-led care who may remain stable for longer periods.

With respect to the data collection procedures, a larger sample size would be required to allow meaningful analysis of the quantitative data. However, conclusions can be drawn about the acceptability of the forms and compliance of participants using them. In general, most participants completed the majority of their questionnaires while they were in the study. This may be an indication of their ease of use or that these were a highly motivated group of patients and family members, eager to please the study team. Lastly, of the 23 patients approached to participate in the study only 2 refused on the basis of wanting to be followed up by their oncologist or in their home community. This suggests that patients are willing to have the management of their follow-up care transferred to a nurse specialist.

### **Recommendations for Follow-up**

Although the pilot study attempted to test a model that uses an existing highly skilled staff nurse resource, the study results are consistent with other literature that demonstrates the need for an advanced practice nurse role with high acuity patient populations such as lung cancer. However, the pilot study provided information to suggest that the pilot model may be transferable to other patient populations where the patient acuity is not as high.

## **Summary of what differences the project has made or can make to the health of Nova Scotians**

There are significant human resource demands on cancer care services in Nova Scotia; a situation that is only increasing. A project of this nature assists in creating an environment for exploring alternate approaches to service delivery that can better meet the full spectrum of needs of patients and their families. Nurse led care initiatives can be used to reconfigure the context of care to help meet the increasing demand for services and such initiatives have great potential throughout health care.

## **Summary of Dissemination Activities (completed and anticipated)**

The research team recently returned to the Capital Health Thoracic Cancer Site Team and key administrative personnel to present the findings of this study. All individuals who participated in the development of the nurse led model of post treatment care and in the research will be provided with a detailed report of the completed project. The insights regarding the development, implementation and evaluation of an alternate model of follow-up care for lung cancer patients and their families gained through this research have significance beyond this particular patient population and health care context. The lessons learned will be presented to members of the Capital Health Cancer Care program and Cancer Care Nova Scotia, published in a clinically based, peer reviewed journal and presented at the International Cancer Nursing Conference in Toronto in September, 2006.

## **Summary of how NSHRF has assisted in your development as a health researcher, and your future plans for participation in health research.**

The investment of a large multidisciplinary team of clinicians, administrators, educators and researchers in the conduct of this study was extraordinary and such support is not usually experienced by researchers. The high level of engagement and inclusiveness that was maintained throughout the study was a result of the initiative being driven by the practice setting rather than by the independent researcher; a valuable lesson for future research projects.

## **Authorized Current Financial Statements (attached)**

## PROJECT FACT SHEET – GENERAL

<b>Project Title</b>	Towards a New Model of Care Delivery for Lung Cancer Patients and Their Families
<b>Grant Sector</b>	Health Services
<b>Completion Date</b>	February 28, 2006
<b>Principal Investigators</b>	Lorna Butler, PhD, Associate Professor, Dalhousie University, School of Nursing and Murali Rajaraman, MD, Assistant Professor Dalhousie University Faculty of Medicine and Radiation Oncologist, Capital Health Cancer Care program
<b>Site of Research</b>	QEII Cancer Centre
<b>District Health Authority</b>	Capital District Health Authority
<b>Policy Implications</b>	This pilot study demonstrated support for a nurse led model of care and the potential success of such a model with the implementation of an Advanced Practice Nurse role. Such a model would contribute to the appropriate utilization of health human resources.
<b>Abstract</b>	<p>The purpose of this pilot study was to test the feasibility of conducting a larger randomized trial comparing the effectiveness and expense of an alternative model of nurse led post treatment care of lung cancer patients and their families with the standard system of cancer clinic follow-up. The pilot study involved 12 post treatment lung cancer patients and their designated family members receiving care in the QEII cancer clinic. Patients in the control group received post treatment care in the cancer clinic according to standard practice. Patients in the experimental group received nurse led post treatment care. This study was comprised of a quantitative component and a qualitative component. The outcomes of the quantitative component of the study consisted of testing and evaluating the processes and data collection tools to be used to measure quantitative outcomes in a larger randomized study. The qualitative component of the study was concerned with determining the aspects of the new model of care that healthcare providers identify as important domains to be measured. Instruments that were tested included those used to measure patient health related quality of life, patient and family members' levels of psychosocial distress, patient,</p>

family and providers' levels of satisfaction, and direct costs to the health care system and indirect costs to the patient.

## **Key Findings**

- Impediments to accrual included heterogeneity and acuity of patient population, eligibility criteria, and current configuration of nurse led model
- To support the conduct of a larger randomized controlled trial there is a need to expand the patient eligibility criteria and method of nurse led follow-up chosen for this study.
- Patients are willing to have the management of their follow-up care transferred to a nurse specialist.
- Tools and data collection procedures could be used in a larger randomized trial
- Focus group results provided direction for the development of key qualitative questions to be used in a larger randomized trial
- The pilot study acknowledges the substantial and lengthy educative component required in introducing an alternative delivery system.

## **Project Partners**

None

## **Future Implications**

Implementation of alternative models of care delivery for cancer patients and their families.

## **NSHRF Contribution**

\$49,787.88

## **Other Funding Partners**

Canadian Nurses Foundation

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## PROJECT FACT SHEET – POLICY

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