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TITLE: The Role of Lifestyle Factors in Ovarian Cancer Prognosis

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14. ABSTRACT The primary aims of this study were to evaluate associations between ovarian cancer recurrence and physical activity, healthy diet, vitamin D exposure, smoking, and alcohol intake, and to estimate prevalence of participation in these lifestyle behaviors among ovarian cancer survivors. Recruitment was completed in February 2018, second interviews in June 2018, and medical chart review for outcomes in August 2018. An analysis of the prevalence of meeting physical activity recommendations and determinants of physical activity participation has been completed. We observed that 42% of survivors met physical activity guidelines of participating in 150 minutes/week of moderate activity. Most of the activity was from the housework domain. Among those who met guidelines, recreational activity was also important. The strongest determinant of meeting guidelines was being employed. Preliminary analyses between these lifestyle behaviors in relation to quality of life have commenced.						
15. SUBJECT TERMS <i>Lifestyle, post-diagnosis, recruitment rate, high grade ovarian cancer, recurrence, quality of life</i>						
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1. **INTRODUCTION:** This study addresses the research question of how we can improve the prognosis of ovarian cancer, but rather than focus on clinical features and tumor biology, which constitutes the bulk of research on ovarian cancer prognosis, we are focused on lifestyle factors that the patients themselves can take action on. In particular, exposures were assessed for the period following ovarian cancer treatment, when patients are in remission and may engage in new lifestyle behaviors that could improve their outcomes. There are essentially no published studies that have attempted to address this research question among patients who have traversed the course of diagnosis and treatment, to a state of remission. Our two study aims were:

Aim 1: To evaluate associations between ovarian cancer recurrence and of each of the following: (1) physical activity, (2) healthy diet, (3) vitamin D exposure, (4) smoking, and (5) alcohol intake.

Aim 2: To estimate the prevalence of participation in healthy post-diagnosis lifestyle behavior's in ovarian cancer patients.

In this study, we included women diagnosed with ovarian cancer at three Montreal hospital centers with specialized units in gynecologic oncology.

2. **KEYWORDS:**

Cohort, epidemiology, survivorship, lifestyle, diet, exercise, physical activity, vitamin D, smoking, alcohol, sun exposure, post-diagnosis exposure, recurrence

3. **ACCOMPLISHMENTS:**

What were the major goals of the project?

Aim 1. To evaluate associations between ovarian cancer recurrence and of each of the following: (1) physical activity, (2) healthy diet, (3) vitamin D exposure, (4) smoking, and (5) alcohol intake.			
Major Task 1.1: Study Preparations	Target date	% completion	Actual completion date
Prepare telephone interview documents, consent form	Oct 2015	100%	Oct 2015
Pre-test questions for flow/readability Finalize consent form	Oct 2015	100%	Oct 2015
Contract work to prepare computer assisted telephone interview data entry system commences	Oct 2015	100%	Mar 2016
Submit grant, questionnaire, consent form, etc. to local IRB	Oct 2015	100%	Aug 2015
Submit grant, questionnaire, consent form, etc. and local IRB approval to DoD HRPO	Oct 2015	100%	Nov 2015
Local hospital chart access approval	Oct 2015	100%	Nov 2015 to Mar 2016
Major Task 1.2: Recruitment and interviews	Target date	% completion	Actual completion date
Recruitment of target population #1; telephone interview and self-administered CDHQII	Months 4-18	100%	April 2017
Recruitment of target population #2; telephone interview and self-administered CDHQII	Months 4-30	100%	February 2018
Ongoing checks of telephone interview data; scanning of CDHQII	Months 1-30	100%	August 2018
189 CDHQIIs have been processed at Alberta Health Services	Month 31	100%	
<i>Milestone(s) achieved: Baseline interview of 105 women</i>		100%	<i>We recruited 112 women.</i>
Major Task 1.3: Review of Patient Pathology Reports/Charts for Remission Status	Target date	% completion	Actual completion date

Chart reviews; ongoing task with 3 months at end of recruitment to finalize and verify reviews	Months 1-33	100%	August 2018
<i>Milestone(s) Achieved: Determining eligibility to remain in statistical analysis</i>		100%	<i>Eligibility status has been confirmed for all 112 participants, with 110 finally remaining eligible.</i>
Major Task 1.4: Follow-up	Target date	% completion	Actual completion date
2 nd telephone interview and 2 nd self-administered CDHQII	Months 8-34	100%	June 2018
Ongoing follow-up of patient charts for outcome assessment (i.e. recurrence)	Months 12-36	100%	August 2018
<i>Milestone(s) Achieved: Second interview completed and outcome assessed for all women that will have confirmed remission</i>			<i>All participants who agreed have completed their 2nd interview; Outcome assessment was completed in August 2018.</i>
Major Task 1.5: Statistical Analyses, Manuscript preparation	Target date	% completion	Actual completion date
Analyses; preliminary analyses for programming to be completed by the end of recruitment; analyses updated with updated outcome assessment data	Months 25-36	100%	August 2018
Manuscript preparation; first drafts based on preliminary analyses with everything finalized after final analyses	Months 30-36	30%	We are continuing our work on this manuscript.
<i>Milestone(s) Achieved: One manuscript is planned for submission to Cancer Epidemiology, Biomarkers and Prevention or International Journal of Cancer</i>			<i>This will occur within the next year.</i>
Aim 2. To estimate the prevalence of participation in healthy post-diagnosis lifestyle behaviors in ovarian cancer patients.			
Major Task 2.1: Statistical Analyses, Manuscript preparation	Target date	% completion	Actual completion date
Major task 1.1 to 1.4 described above apply here	1-33	100%	August 2018
Analyses; preliminary analyses will commence after 24 months of recruitment, which will be finalized at the end of recruitment	25-33	100%	August 2018
Manuscript preparation; first drafts based on preliminary analyses with everything finalized after final analyses	30-36	75%	A first draft focused on physical activity has been prepared.
<i>Milestone(s) Achieved: One manuscript is planned for submission to JNCI or Clinical Epidemiology</i>			<i>This will occur within the next 6 months.</i>

What was accomplished under these goals?

Recruitment and data collection

During this third year, we identified 23 new candidate participants. Of the 23 candidate participants identified in year 3, all were eligible and we were able to reach each of them. 19 agreed to participate, for a participation rate of 82.6%.

To summarize the 24 months of recruitment over the three year project, we identified 162 candidate participants, of whom 137 were eligible and reachable. Of these eligible women, 112 agreed to participate for an overall participation rate of 82%. All 112 participants participated in the first interviews; 107 completed the diet questionnaire. 100 also participated in a second interview and completed a second diet questionnaire. All 112 participants have had their medical charts reviewed through to August 2018. Among these participants, we have identified 46 recurrent cases. We also noted that 2 people that were recruited did not meet their eligibility criteria because they were recurrent at the time of interview (this was not in their chart information until later). Thus, these women will not be included in the final statistical analyses.

Related to Aim 2, we have conducted an analysis of physical activity (PA) participation in our study population. PA participation in relation to ovarian cancer prognosis has been addressed in only 5 previous studies, with a suggestion of a benefit. However, none of the studies examined PA in the post-treatment period, which is a period during which lifestyle changes may be an avenue for survivors to consider. Because none of the studies examined post-treatment PA, we also don't know the prevalence of participation in PA post-treatment among survivors, nor what factors predict PA participation.

Using the data collected in this study, we determined the prevalence of PA participation 6 months post-treatment among the 112 ovarian cancer survivors, as well as determinants of participation. Please note that based on the final chart reviews, only 110 participants were eligible; these analyses will be re-done, however, the removal of 2 participants will not greatly affect the interpretations presented in this report.

PA participation was defined as “meeting guidelines” based on the recommendations made to cancer survivors, which is 150 minutes per week of moderate physical activity. When considering energy expenditure, in units of metabolic equivalents (METs), 150 minutes of activity per week can be translated to 600 MET-minutes per week. As mentioned, baseline was defined as 6 months after treatment completion. All participants were telephone-interviewed at this time to obtain information on sociodemographic and lifestyle characteristics. PA participation was collected using the International Physical Activity Questionnaire (IPAQ), which assesses PA participation over the last 7 days according to 4 domains of PA: occupational, transportation, recreational and household work. We estimated the overall prevalence of meeting guidelines with and without the inclusion of walking as a potential PA source. For the association between different potential PA determinants and meeting guidelines, we estimated prevalence ratios (PRs), with their respective 95% confidence intervals (CI), using a modified Poisson regression approach. Each determinant was analyzed separately with covariates selected based on their association with the potential determinant of interest.

Among the 112 participants, 42.0% (95% CI: 32.8-51.1%) met PA guidelines, while 37.5% (95% CI: 28.5-46.5%) did not participate in any moderate activity (Table 1). The remaining 20.5 percent that did not meet guidelines did participate in some activity, which was of lower intensity and/or did not reach at least 150 minutes per week. When walking was included in the calculation of PA participation, a higher proportion of the participants met guidelines (57.1% (95%CI 48.0-66.3%)).

Table 1. Prevalence of meeting physical activity guidelines in the HPROQ study

	Meeting PA guidelines	Frequency	Percent (95% CI)
Without walking included ¹	No moderate activity ² (Did not meet guidelines)	42	37.5% (28.5-46.5%)
	Between 0-600 METs (Did not meet guidelines)	23	20.5% (13.1-28.0%)
	600 METs or more (Met guidelines)	47	42.0% (32.8-51.1%)
With walking included ³	Not meeting PA guidelines (<600 METs)	48	42.9% (33.7-52.0%)
	Meeting PA guidelines (≥600 METs)	64	57.1% (48.0-66.3%)

1 Walking is not included in the definition of 150 minutes of moderate, which is equivalent to 600 MET-minutes

2 These women did not participate in any PA at a moderate intensity level (but potentially participated in lower intensity activities)

3 Walking is included in the definition of 150 minutes of moderate

When considering domain of PA, participants were most active in housework-related PA, with 47.6% of all PA participation attributed to this domain, followed by recreational PA, occupational PA and transportation PA (Table 2). Among those who met guidelines, recreational PA was a more important domain. Among those who did not meet guidelines, occupational PA was not an important source of PA.

Table 2. Percentage of PA participation according to domain of PA

PA Domain	All participants (n=112)	Participants who met guidelines (n=47)	Participants who did not meet guidelines (n=65)
Occupational	11.0%	15.8%	0.5%
Transportation	7.8%	5.2%	13.6%
Housework	47.6%	39.9%	64.4%
Recreational	33.6%	39.1%	21.4%

There were no statistically significant associations between any of the potential determinants of PA that we examined and meeting PA guidelines (Table 3). The strongest PR observed was for current employment, which suggested that women who were currently employed had a prevalence of meeting PA guidelines that was 1.49 times than women who were unemployed (PR=1.49; 95% CI: 0.87-2.55). Strong PRs, though also not statistically significant, were also observed for relationship status, ethnicity, past oral contraceptive use, menopausal status and type of chemotherapy. In particular, the PRs suggested that the probability of meeting PA guidelines at baseline was increased if one was in a relationship, French Canadian ethnicity, had previously used oral contraceptives, was premenopausal, or had received neoadjuvant chemotherapy.

Table 3. PRs (95% CIs) for the association between potential determinants and meeting PA guidelines

Potential determinant	N	PR _{crude} (95% CI)	PR _{adjusted} (95% CI)	Adjustment covariates
Age				Education, hysterectomy, past hormone use, job status, ethnicity, menopausal status, age
Per 5 years	112	0.88 (0.75-1.04)	0.92 (0.77-1.11)	
Smoking (pack-years)				Age, BMI, education, ethnicity
Per standard deviation (=18)	112	0.97 (0.72-1.31)	0.91 (0.66-1.26)	
BMI (kg/m²)				Age, education, past hormone use, smoking
≤25.9	52	Ref.	Ref.	
25-29.9	30	0.90 (0.53-1.54)	0.85 (0.51-1.41)	
≥30	30	0.90 (0.53-1.54)	0.87 (0.48-1.56)	
Highest Attained Education				Age, BMI, job status, smoking, menopausal status, stage
≤High school	45	Ref.	Ref.	
Post-secondary	67	1.08 (0.69-1.70)	0.93 (0.56-1.55)	
Partner Status				Age, stage
Relationship	77	Ref.	Ref.	
Single	35	0.59 (0.34-1.05)	0.66 (0.38-1.18)	
Undergone Hysterectomy				Age, ethnicity, chemo
Yes	100	Ref.	Ref.	
No	12	0.99 (0.49-2.01)	0.99 (0.50-1.96)	
Past oral contraceptive use				Age, job status, ethnicity
Yes	82	Ref.	Ref.	
No	30	0.48 (0.24-0.95)	0.61 (0.30-1.23)	
Past Hormone Use				Age, BMI, menopausal status
No	70	Ref.	Ref.	
Yes	42	1.13 (0.73-1.75)	1.35 (0.83-2.18)	
Parity (full-term births)				Age, stage, chemo
Nulliparous	25	Ref.	Ref.	
1	28	1.16 (0.62-2.17)	1.09 (0.59-2.01)	
≥2	59	1.02 (0.57-1.80)	0.99 (0.55-1.78)	
Job Status				Age, education, past OC use, menopausal status
Unemployed	60	Ref.	Ref.	
Employed on sick leave	22	1.29 (0.69-2.41)	1.05 (0.56-1.99)	
Employed	30	2.00 (1.26-3.17)	1.49 (0.87-2.55)	
Ethnicity				Age, hysterectomy, past OC use, menopausal status
French Canadian	77	Ref.	Ref.	
Others/Mixed	35	0.59 (0.34-1.05)	0.66 (0.38-1.16)	

Potential determinant	N	PR _{crude} (95% CI)	PR _{adjusted} (95% CI)	Adjustment covariates
Menopausal Status^b				
Postmenopausal	94	Ref.	Ref.	Age, education, past hormone use, job status
Premenopausal	17	1.69 (1.09-2.61)	1.45 (0.82-2.54)	
Stage of Cancer^c				
Stage III/IV	78	Ref.	Ref.	Age, education, partner status, parity, chemo
Stage I/II	32	1.14 (0.73-1.80)	1.23 (0.64-2.38)	
Type of chemotherapy				
Neoadjuvant	52	Ref.	Ref.	Age, hysterectomy, parity, stage
Adjuvant only	60	0.83 (0.54-1.28)	0.70 (0.35-1.20)	

We also examined the cross-sectional relationship between meeting PA guidelines and quality of life as measured using the questionnaires, (1) the Functional Assessment of Cancer Therapy - ovarian cancer (FACT-O) and (2) the Hospital Anxiety and Depression Scale (HADS). The FACT-O provides an overall, multidimensional index of physical, functional, social and emotional well-being in addition to ovarian cancer specific outcomes, while the HADS provides a measure of symptoms of anxiety and depression. Though not statistically significant, we observed that women who met PA guidelines had higher FACT-O scores than those who did not meet guidelines ($\beta=2.2$, 95% CI: -4.8-9.2); the difference of 2.2 was not what is considered clinically meaningful (i.e. at least 8). We observed that women who met PA guidelines were more likely to report symptom of anxiety compared to those that did not meet guidelines, however, they were less likely to report symptoms of depression (Table 4).

Table 4. Association between meeting PA guidelines and quality of life

HADS outcome	Odds ratio (95% CI)
Anxiety symptoms: Yes vs. no	1.67 (0.72-3.84) ¹
Depression symptoms: Yes vs. no	0.30 (0.06-1.55) ²

1 adjusted for age and ethnicity

2 adjusted for age and partner status

Related to aim 1, we have conducted preliminary analyses of prospective associations between lifestyle factors at baseline and quality of life at the second interview. Aim 1 relates to the outcome of recurrence, however, because the quality of life data was already available, we started on these analyses first. We have analyzed body mass index (BMI), diet (based on the healthy eating index (HEI)), meeting PA guidelines based on recreational PA and a history of smoking, in relation to quality of life based on the FACT-O and the HADS (anxiety only, thus far).

We observed one statistically significant association, which indicated that women who were obese at baseline had a significantly lower FACT-O score at interview than those that were normal weight at baseline (Table 5). When looking at the change in FACT-O score from interviews 1 to 2, both women who were overweight and obese at baseline experienced a marginally significant lowering of quality of life, based on the FACT-O score, compared to women that were of normal weight at baseline.

Similarly, associations with diet (HEI), recreational PA and smoking history were not statistically significant. The observed regression coefficients suggested that those who had a better diet and had never smoked had a better quality of life, based on the FACT-O. On the other hand, those who met recreational PA guidelines at baseline had a lower FACT-O score at interview and experienced a lower quality of life from interview 1 to 2 which was of greater magnitude than those that did not meeting guidelines.

Table 5. Associations between baseline lifestyle factors and FACT-O score at interview 2 as well as change in FACT-O score from interview 1 to 2

Lifestyle (at baseline)	FACT-O score at interview 2			FACT-O change from interview 1 to 2		
	Mean (SD)	β^1	p-value	Mean (SD)	β^1	p-value
BMI						
Normal Weight (n=41)	121.2 (14.0)	ref	ref	1.51 (10.5)	ref	ref
Overweight (n=28)	119.0 (15.3)	-2.13	0.57	-4.39 (12.3)	-5.67	0.10
Obese (n=26)	106.5 (17.7)	-14.60	0.0003	-1.28 (16.3)	-6.29	0.09
HEI (continuous)	116.5 (16.5)	0.19	0.30	-0.99 (12.9)	0.22	0.14
Recreational PA						
Does not meet guidelines (n=72)	116.7 (16.4)	ref	ref	-0.34 (11.2)	ref	Ref
Meets guidelines (n=23)	116.1 (17.2)	-3.22	0.43	-3.04 (17.3)	-4.14	0.19
Smoking history						
Never smoked (n=43)	118.46 (18.0)	ref	ref	-0.47 (12.1)	ref	ref
Ever smoked (n=52)	114.90 (15.1)	-0.82	0.82	-1.43 (13.7)	-0.94	0.76

¹ regression coefficient adjusted for covariates, which differ across the different models and which were selected based on having changed the less adjusted regression coefficient by at least 5%

When examining quality of life based on the HADs, of which we have only examined anxiety so far, we observed odds ratios suggesting that the odds of having anxiety at interview 2 was increased among those that were obese at baseline (vs. normal weight) and who did not meet recreational PA guidelines (Table 6). On the other hand, being overweight at baseline (vs. normal weight) reduced the odds of anxiety at interview 2. Smoking history was not strongly associated with anxiety. For diet, those in the highest tertile (vs. the lowest tertile) of the healthy eating index at baseline had lower anxiety while those in the middle tertile had higher anxiety compared to those in the lowest tertile.

Table 6. Associations between baseline lifestyle factors and anxiety at interview 2, based on the HADS

Lifestyle (at baseline)	No anxiety, n	Anxiety, n	OR (95% CI)
BMI			
Normal	29	12	Ref
Overweight	22	6	0.49 (0.11 – 2.05)
Obese	14	12	1.41 (0.40 – 4.99)
HEI			
<65.3	16	13	Ref
65.3 to <73.4	19	13	1.51 (0.35 – 3.81)
73.4+	28	4	0.30 (0.07 – 1.30)
Recreational PA			
Does not meet guidelines	47	25	ref
Meets guidelines	18	5	0.74 (0.19 – 2.83)
Smoking history			
Never smoked	29	14	ref
Ever smoked	36	16	0.83 (0.31 – 2.24)

Summary:

Based on the recommended guidelines of 150 minutes of moderate PA per week for cancer populations, 42.0% (95% CI: 32.8-51.1%) of the study population was meeting this PA guideline (excluding walking) 6 months after treatment completion. The largest source of PA was from housework-related PA, with 47.6% of all PA participation from this domain. None of the potential determinants under consideration were statistically significantly associated with meeting PA guidelines but many of the characteristics under consideration trended in the direction that was hypothesized. In particular, those determinants suggestively associated with meeting PA guidelines were being currently employed, having previously used oral contraceptives, being in a relationship, being premenopausal and having received neoadjuvant chemotherapy.

This cross-sectional analysis of baseline data did not provide evidence of a significant difference in quality of life between women who met and did not meet PA guidelines 6 months after completing treatment. Nonetheless, the findings suggested that women who met PA guidelines had a mean FACT-O score that was greater than women who did not meet PA guidelines. Women who met PA guidelines were more likely to report symptoms of anxiety compared to women who did not meet PA guidelines, however, were less likely to report depressive symptoms.

In preliminary analyses of prospective associations between lifestyle factors and quality of life, the results suggested that being obese 6 months post-treatment was associated with a poorer quality of life 4 months later. Having a better diet quality and having never smoked was also suggestively associated with improved quality of life. Only the findings for body weight was statistically significant.

What opportunities for training and professional development has the project provided?

Nothing to report.

How were the results disseminated to communities of interest?

Anita Koushik was invited to present the state of research on lifestyle and prognosis among ovarian cancer survivors on two occasions, as listed below. Both of these events was organized by Ovarian Cancer Canada, the national group dedicated to supporting people affected by ovarian cancer, including patients, survivors, their families and their caregivers. Thus, the audience at these events primarily reflected community members, more so than researchers. At both events, very preliminary results from this study were presented.

May 2018: Lifestyle and prognosis among ovarian cancer survivors. Ovarian Cancer Canada Survivorship Forum: A day for women living with ovarian cancer and their families. Edmonton, AB.

November 2018: Le rôle du mode de vie sur le pronostic. Journée-conférence sur le cancer de l'ovaire. Montréal, Québec.

What do you plan to do during the next reporting period to accomplish the goals?

Nothing to report.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

This study has been the first on ovarian cancer to collect data on lifestyle factors in the post-treatment period. In particular, we have this data at approximately the same time post-treatment for all women that participated. Thus, our prevalence estimates as well as associations observed will not be biased from having a large variation in the definition of ovarian cancer survivor. Our publications will be more informative than that currently is available.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. **CHANGES/PROBLEMS:**

Changes in approach and reasons for change

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

Problems/delays encountered during the reporting period:

We had to increase the recruitment period and was thus granted a 12-month extension without funds.

Actions or plans to resolve problem

Nothing to report.

Changes that had a significant impact on expenditures

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals.

Nothing to report.

Significant changes in use of biohazards and/or select agent

Nothing to report.

6. **PRODUCTS:**

Publications, conference papers, and presentations

Journal publications

Nothing to report.

Books or other non-periodical, one-time publications

Nothing to report.

Other publications, conference papers, and presentations

Chow C, Richardon H, Arseneau J, Gilbert L, Lau S, Samouëlian V, Koushik A. Physical Activity in Ovarian Cancer Survivors: Prevalence and Predictors of Participation. 9th Canadian Conference on Ovarian Cancer Research, Edmonton, Alberta, May 26-29, 2018.

Website(s) or other Internet site(s)

Nothing to report.

Technologies or techniques

Nothing to report.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**What individuals have worked on the project?**

Anita Koushik, no change
 Nancy Faraj, no change
 Samia, no change
 Julie Lacaille, see below

Name:	<i>Julie Lacaille</i>
Project Role:	<i>Study Coordinator</i>
Researcher Identifier:	n/a
Nearest person month worked:	6.6
Contribution to Project:	<i>Ms. Lacaille's work on reviewing patient charts to follow up for outcomes became more prominent in this last year of the study. She was also involved in database management and cleaning so that we could begin preliminary analyses. Thus, her time contribution increased in this last year.</i>
Funding Support:	<i>This award</i>

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

Organization Name: McGill University Hospital Centre

Location of Organization: Montreal, Quebec

Partner's contribution to the project

Financial support: None

In-kind support: Partner makes computers available to project staff

Facilities: Project staff use the partner's facilities to review partner's patient charts

Collaboration: Partner's staff work with project staff on obtaining patient charts

Personnel exchanges: No

Other: None

Organization Name: Jewish General Hospital

Location of Organization: Montreal, Quebec

Partner's contribution to the project

Financial support: None

In-kind support: Partner makes computers available to project staff

Facilities: Project staff use the partner's facilities to review partner's patient charts

Collaboration: Partner's staff work with project staff on obtaining patient charts

Personnel exchanges: Project staff keep partner's staff up to date on patients recruited

Other: None

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS

Not applicable

QUAD CHARTS

Not applicable

9. APPENDICES:

Nothing to report