

**Research**

Comprehensive hospice palliative care delivery and impact on end-of-life care, and family satisfaction with care in Sudbury, Ontario 2012-2015: A propensity score matched retrospective observational study using administrative data.

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20 **Declaration of Competing Interests:**

21 The authors declare no competing interests.  
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## Abstract

**Background:** Access to hospice palliative care may improve quality of life, reduce the use of aggressive end-of-life care, and facilitate death outside of an acute care hospital. The aim of this study was to examine the impact of an ambulatory hospice palliative care program in Greater Sudbury, Ontario on end-of-life care when compared with a matched control group of decedent residents.

**Methods:** This retrospective study included patients who received hospice palliative care at the Symptom Management Program (SMP) in Sudbury, Ontario during 2012-2015. Using linked administrative health records, we defined a propensity matched control group and derived previously defined variables associated with aggressive end-of-life care (chemotherapy received in the last 2 weeks of life, multiple emergency department visits, hospitalizations, or admission to an intensive care unit 30 days preceding death), or place of death. Family/caregiver satisfaction was measured 3 months after the patient's death using the FAMCARE questionnaire.

**Results:** 754 SMP patients were matched, and all covariates appeared balanced. Receiving HPC through SMP was protective for most measures of aggressive end-of-life care, (ARR 12.73, 95% CI 12.65-12.81 for "any") and death in an acute care setting (ARR 19.89, 95% CI 19.78-20.00). Satisfaction with care received within SMP was high (total score 85.72 +/- 11.11).

**Interpretation:** Provision of hospice palliative care through an ambulatory program decreased the use of aggressive end-of-life care, and reduced the number of deaths in acute care hospital, while providing a high level of caregiver satisfaction.

**Word Count:** 239

## Introduction

For cancer patients facing terminal illness, a hospice palliative care (HPC) approach is an important component of quality care and can offer many benefits to patients and their families including pain and symptom management, coordination of care, and improved quality of life<sup>1-4</sup>. Additionally, a hospice palliative care approach offers substantial benefits to the health system that includes the decreased use of potentially aggressive end-of-life care (EOLC)<sup>4</sup> which is costly to the health system<sup>5-7</sup> and is often not the wish of patients<sup>8</sup>.

The Symptom Management Program (SMP) at the Northeast Cancer Centre of Health Sciences North, established in 2011, is an ambulatory program that uses a HPC approach for cancer patients with terminal disease. Though not restrictive, the primary catchment area of the program includes residents within the Greater Sudbury and District region in Ontario, Canada. The primary purpose of this study was to determine the association between delivery of comprehensive HPC through the SMP and the use of potentially aggressive end-of-life care in the last month of life as well as place of death, when compared to a matched cohort of palliative decedents with cancer. A secondary objective was to assess family caregiver satisfaction with the advanced cancer care delivered through the SMP.

## Methods

### *Design and Setting*

We performed a retrospective study of palliative care decedents who were enrolled in the SMP. The SMP serves approximately 100-120 active patients per year, and receives about 350 referrals per year. The majority of SMP participants reside in Greater Sudbury or District. We defined our treatment group as all members of the SMP who were resident in Greater Sudbury and District, who had lived for at least 30 days from the primary diagnoses of cancer, and who

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3 died during the interval 2012-2015. Matched controls were defined from the group of decedent  
4 residents of Greater Sudbury and District who were diagnosed with cancer, had lived for at least  
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6 30 days from diagnoses until death, had died within 2012-2015, and who were not identified as  
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8 part of the SMP (n=1613). A flow diagram (Fig. 1) describes the data linkages.  
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### 13 *Data Sources*

14 Membership within the SMP cohort was defined from medical records held at the  
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16 Northeast Cancer Centre at Health Sciences North. We included records for SMP members from  
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18 2012-2015, as the SMP became operational in fiscal 2011. The cohort was shared with the  
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20 Institute for Clinical Evaluative Sciences (ICES) under the protection of a comprehensive data-  
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22 sharing agreement, and access to data was provided through the cd-Link program. At ICES,  
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24 SMP records were merged with administrative databases. The ICES data was used as the source  
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26 for all study outcomes. Databases used included the Registered Person's Database (RPDB),  
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28 Ontario Cancer Registry (OCR), Ontario Health Insurance Plan (OHIP), Canadian Institute for  
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30 Health Information (CIHI) National Ambulatory Care Reporting System (NACRS), and the CIHI  
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32 Discharge Abstract Database (DAD).  
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### 39 *Exposure*

40 Exposure to comprehensive HPC was assumed for all decedents identified as members of  
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42 the SMP.  
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### 46 *Outcomes*

47 Study outcomes were defined *a priori* using definitions and codes that have been  
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49 published using the same administrative data sources<sup>5, 9-11</sup>. Potentially aggressive end-of-life  
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51 care (EOLC) was defined as: (1) chemotherapy administered within 14 days of death; (2) more  
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53 than one emergency department (ED) visit within 30 days of death; (3) more than one  
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3 hospitalization within 30 days of death; or (4) at least one intensive care unit (ICU) admission  
4 within 30 days of death; a composite aggressive end-of-life care variable (“any”) EOLC was  
5 defined as at least one occurrence of (1)-(4). Death in an acute care hospital was defined as a  
6 discharge disposition of death in the CIHI dataset. Administrative codes used to derive  
7 outcomes can be found in online Appendix A.  
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12 In addition, a sample of family caregivers of SMP decedents completed the 20 item  
13 FAMCARE questionnaire <sup>12</sup> 3 months following decedent death as part of a program evaluation  
14 that measured perceived quality of care and satisfaction with advanced cancer care delivery.  
15 These data were available for inclusion in study.  
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### 25 *Covariables*

26 Covariables available for the study included: age group at death, sex, Charlson Index,  
27 duration of disease, cancer type, rurality, income quintile, and index year of death.  
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### 32 *Statistical Analyses*

33 Logistic regression was used to define propensity scores with treatment as the outcome  
34 and all covariates as independent measures (Table 1). Using greedy matching, the treatment  
35 group was matched to controls (1:1) using a caliper width <sup>13</sup>. The suggested initial width was  
36 0.20 times the standard deviation of the logit propensity scores <sup>14</sup>. However, we decreased the  
37 caliper width from 0.20 in increments of 0.05 until covariates were adequately balanced after  
38 matching (standardized difference  $d < 0.10$ ). The final caliper width used was 0.05 times the  
39 standard deviation of logit propensity scores. The matched cohort consisted of 754 pairs  
40 (n=1508). Standardized differences (d) were calculated for each covariate before and after  
41 matching. Propensity score matched data were analyzed for the effect of SMP membership on  
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3 each indicator using McNemar's test <sup>15</sup>. Proportions were then used to calculate absolute risk  
4 reduction (*ARR*), number needed to treat (*NNT*), and relative risk (*RR*).  
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8 For the subset of SMP family caregivers who completed the FAMCARE questionnaire,  
9 individual items were combined to calculate composite scales following recommendations by  
10 Kristjanson <sup>12</sup>. The 20 items that make up the FAMCARE scale were presented as 5-point Likert  
11 scales (Very Dissatisfied=1, Dissatisfied=2, Undecided=3, Satisfied=4, Very Satisfied=5).  
12 Composite scales were classified as: Information Giving (5 items), Physical Patient Care (7  
13 items), Psychosocial Care (4 items), and Availability of Care (4 items) subscales. All subscales  
14 were combined into a total score (20 items). Comparisons of FAMCARE scores were conducted  
15 using Wilcoxon tests. All statistical analyses were conducted using SAS v9.4 (SAS Institute,  
16 Cary, NC, USA).  
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### 29 *Ethics Approval*

30 This study was approved by the Health Sciences North Research Ethics Board (Study  
31 approval #16-030).  
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### 36 **Results**

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38 A total of 914 SMP decedents were identified, and were successfully merged within the  
39 ICES holdings. There were 1613 potential controls available from our data sources (Table 1).  
40 Prior to matching, most covariates appeared unbalanced; however the majority of SMP  
41 decedents were matched 754 (82.5%), and after matching covariates appeared adequately  
42 balanced (Table 1).  
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50 Within the matched cohort all study outcomes except use of chemotherapy were  
51 significantly lower in the group that received hospice palliative care through enrolment in SMP  
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3 (Table 2). The largest difference was observed for death in acute care, with an ARR of 19.89  
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5 (95% CI 19.78-20.00); NNT of 5.03 and RR of 0.55 (95% CI 0.47-0.64) (Table 2).  
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8 For the matched SMP family caregivers that completed quality of life measures, the total  
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10 FAMCARE score was  $85.72 \pm 11$  (mean  $\pm$  SD). Total and each composite scale score was rated  
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12 lower, often significantly, for those who received “any” aggressive EOLC care (Table 3). There  
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14 were no differences in the level of caregiver satisfaction by place of death.  
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### 18 **Interpretation**

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20 Our study provides 3 key findings: 1) Enrolment in the SMP was protective for most  
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22 measures of potentially aggressive end-of-life care for residents in Greater Sudbury and District.  
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24 The risk reduction occurs most notably in ICU admissions and suggests that provision of HPC  
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26 may avoid high resource costs associated with an intensive care admission. Others have  
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28 demonstrated that palliative care is one of the most common reasons for hospital admissions  
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30 among high-cost users in Ontario <sup>6</sup>; Cheung <sup>5</sup> reports Ontario cancer patients who receive  
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32 aggressive end-of-life care incur 43% higher costs than those managed non-aggressively.  
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39 2) Provision of HPC was protective for death in the acute care hospital setting. While admission  
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41 to acute care hospitals could be appropriate for cancer patients because of disease progression or  
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43 because of a need for optimal treatment <sup>16</sup> or caregiver respite, overuse may signal a potential  
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45 gap in palliative care services <sup>16, 17</sup>. The risk reduction of almost 20% in our study suggests that  
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47 the SMP can play an important role in avoiding death in acute care hospital setting for Sudbury  
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49 area cancer patients. In this area of Ontario, about 44% of the non-SMP decedents died in acute  
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51 care hospital, which is slightly higher than the 40% reported for all of Ontario <sup>18</sup>.  
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3 (3) Family caregiver satisfaction with advanced cancer care received through the SMP, assessed  
4 either as an overall total satisfaction score, or through individual scales, appeared high as others  
5 have reported<sup>19</sup>. There was no difference in satisfaction for caregivers of SMP members that died  
6 in acute care, which may indicate that these instances involved appropriate use of acute care  
7 resources. However, satisfaction was significantly lower for approximately 10% of SMP  
8 members who received “any” aggressive end-of-life care and this finding supports the sparse  
9 research that reports family caregiver assessed satisfaction with care combined with system level  
10 resource use<sup>8</sup>. While the proportion receiving any aggressive end-of-life care through the SMP  
11 is lower than the 22.5 % reported for all of Ontario<sup>5</sup>, exploration of factors such as timing of  
12 initial palliative care consultations, availability of care and type of information provision may  
13 allow the SMP to further improve service delivery.  
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### 30 **Limitations**

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32 Our study has limitations. Some variables that would have allowed us to better  
33 characterize our cohort, such as stage at cancer diagnoses and cause of death were not available  
34 for analyses, and therefore we assumed that all deaths in the SMP or non-SMP were due to  
35 palliative cancer. Additionally, while program membership defined comprehensive HPC  
36 exposure in our treatment group, we are less clear about the level of HPC exposure that may  
37 have occurred in controls. However, 90.45% of the non-SMP group had at least 1 palliative  
38 consultation code, slightly less than the 93.10% in the SMP group, when defined using a  
39 comprehensive palliative care definition from system-billing codes<sup>5</sup>. Also, estimates of death in  
40 an acute care hospital, and use of any aggressive end-of-life care in the non-SMP group are only  
41 marginally higher than the Ontario provincial estimates derived using these same administrative  
42 sources but containing decedent cancer cohort definition (44% vs 40% for death in an acute care  
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3 hospital <sup>16</sup>, and 25% vs 22.5% for aggressive EOLC). Conversely, if members of the non-SMP  
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5 group received comprehensive HPC through a family physician or group health teams, our ARR  
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7 estimate may be conservative. We had individual level family caregiver satisfaction levels for a  
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9 subgroup of our treatment group, and while that satisfaction was high, we are unclear about the  
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11 generalizability of the results to all members of the treatment group. Additionally, our system  
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13 level measures used administrative data, and we have no information about the appropriateness  
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15 or quality of the care received.  
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## 20 **Conclusion**

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22 Provision of HPC from the SMP has a number of positive benefits that include high  
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24 family satisfaction with care, decreased use of potentially aggressive end-of-life care, and  
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26 decreased occurrences of death in an acute care hospital. While the provision of comprehensive  
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28 palliative care is associated with many benefits, a better understanding of the full spectrum of  
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30 costs associated with the delivery of care at the level of the provider, the family, and the  
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32 community are needed.  
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**Table 1.** Frequencies, descriptive statistics, and standardized differences (*d*) of each covariate before and after propensity score matching in palliative patients who received hospice palliative care from the SMP and those who did not.

Covariate	Before Matching			After Matching		
	Non-SMP n = 1,613	SMP n = 914	<i>d</i>	Non-SMP n = 754	SMP n = 754	<i>d</i>
<b>Age Group – n (%)</b>			<b>0.58</b>			<b>0.08</b>
< 55	68 (4.22)	101 (11.05)		58 (7.69)	69 (9.15)	
55-64	180 (11.16)	204 (22.32)		131 (17.37)	145 (19.23)	
65-74	356 (22.07)	283 (30.96)		234 (31.03)	234 (31.03)	
75+	1,009 (62.55)	326 (35.67)		331 (43.90)	306 (40.58)	
<b>Sex – n (%)</b>			<b>0.05</b>			<b>0.00</b>
Male	926 (57.41)	504 (55.14)		431 (57.16)	431 (57.16)	
Female	687 (42.59)	410 (44.86)		323 (42.84)	323 (42.84)	
<b>Charlson Index – mean ±SD</b>	3.81 ±2.88	5.23 ±2.82	<b>0.51</b>	4.92 ±2.90	4.91 ±2.83	<b>0.01</b>
<b>Duration of Disease – mean ±SD</b>	6.79 ±6.35	3.45 ±4.39	<b>0.55</b>	3.48 ±4.23	3.79 ±4.64	<b>0.07</b>
<b>Cancer Type – n (%)</b>			<b>0.44</b>			<b>0.07</b>
Breast	142 (8.80)	59 (6.46)		49 (6.50)	48 (6.37)	
Lung	225 (13.95)	264 (28.88)		170 (22.55)	190 (25.20)	
Colorectal	232 (14.38)	96 (10.50)		87 (11.54)	88 (11.67)	
Prostate	253 (15.69)	67 (7.33)		64 (8.49)	65 (8.62)	
Other	761 (47.18)	428 (46.83)		384 (50.93)	363 (48.14)	
<b>Rural – n (%)</b>			<b>0.18</b>			<b>0.01</b>
No	1,397 (86.61)	842 (92.12)		687 (91.11)	688 (91.25)	
Yes	216 (13.39)	72 (7.88)		67 (8.89)	66 (8.75)	
<b>Income Quintile – n (%)</b>			<b>0.14</b>			<b>0.06</b>
1 (lowest)	443 (27.46)	208 (22.76)		165 (21.88)	185 (24.54)	
2	324 (20.09)	188 (20.57)		163 (21.62)	159 (21.09)	
3	269 (16.68)	185 (20.24)		149 (19.76)	143 (18.97)	
4	327 (20.27)	175 (19.15)		147 (19.50)	140 (18.57)	
5	250 (15.50)	158 (17.29)		130 (17.24)	127 (16.84)	
<b>Index Year – n (%)</b>			<b>0.15</b>			<b>0.02</b>
2012	407 (25.23)	190 (20.79)		166 (22.02)	165 (21.88)	
2013	436 (27.03)	232 (25.38)		210 (27.85)	203 (26.92)	
2014	397 (24.61)	228 (24.95)		183 (24.27)	188 (24.93)	
2015	373 (23.12)	264 (28.88)		195 (25.86)	198 (26.26)	

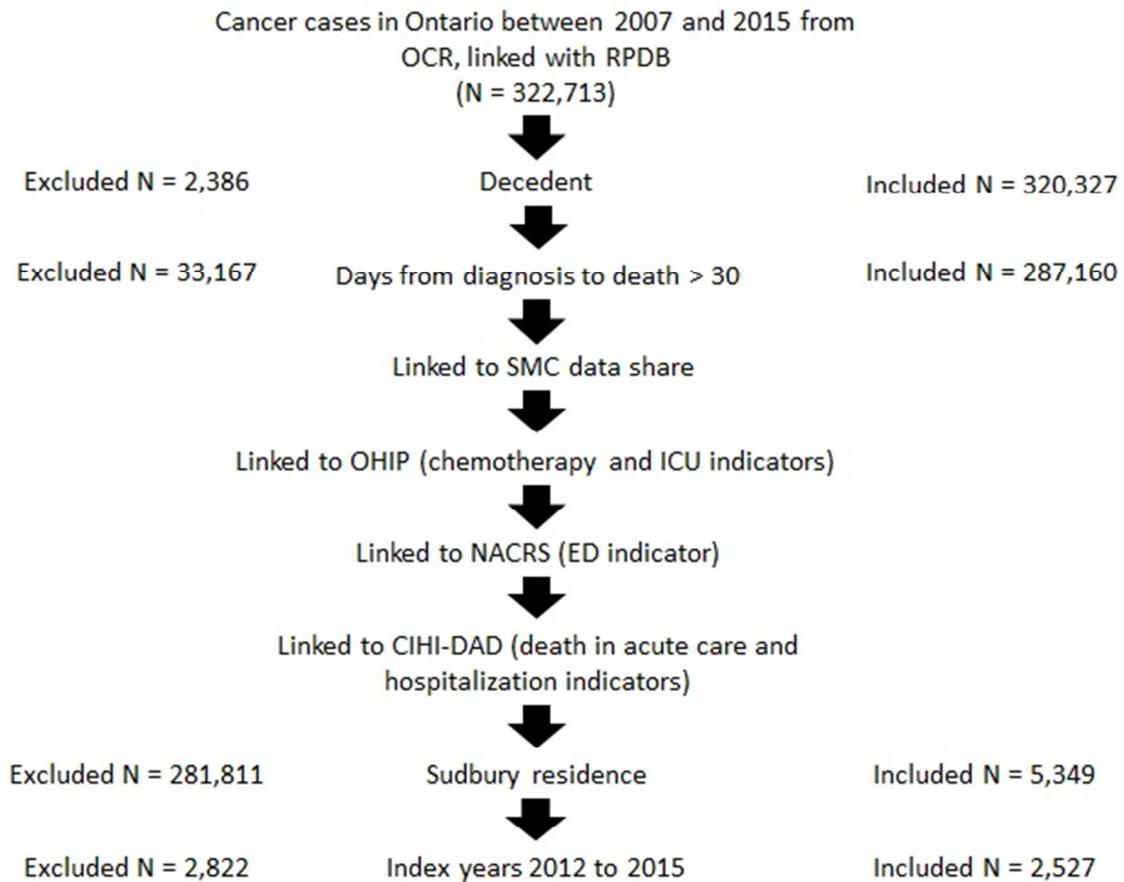
**Table 2.** Study outcomes of the use of aggressive end-of-life care in patients who participated in SMP and those with a palliative designation but did not receive HPC.

<b>Outcome</b>	<b>p*</b>	<b>SMP %</b>	<b>Non-SMP %</b>	<b>ARR (95% CI)</b>	<b>NNT (95% CI)</b>	<b>RR (95% CI)</b>
Hospitalization	0.04	4.77	7.56	2.79 (2.76-2.82)	35.84 (35.45-36.25)	0.63 (0.42-0.95)
Emergency Department	0.03	9.42	13.13	3.71 (3.66-3.76)	26.95 (26.57-27.35)	0.72 (0.53-0.97)
Chemotherapy	0.20	1.46	2.52	-	-	-
Intensive Care Unit	<0.001	1.06	12.20	11.14 (11.11-11.17)	8.98 (8.95-9.00)	0.09 (0.04-0.18)
Any end-of-life care	<0.001	12.47	25.20	12.73 (12.65-12.81)	7.86 (7.81-7.91)	0.50 (0.39-0.62)
Death in acute care	<0.001	24.14	44.03	19.89 (19.78-20.00)	5.03 (5.00-5.06)	0.55 (0.47-0.64)

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**Table 3.** Descriptive statistics and results for FAMCARE scales completed by family members of patients who received hospice palliative care treatment from SMP (n=96).

Scale (#items/score max)	Overall mean $\pm$ SD (n = 96)	Aggressive End-of-Life Care (Any) mean $\pm$ SD		<i>p</i> *	Death in Acute Care mean $\pm$ SD		<i>p</i> *
		No (n = 86)	Yes (n = 10)		No (n = 68)	Yes (n = 28)	
Total (20/100 max)	85.72 $\pm$ 11.11	86.50 $\pm$ 10.93	79.00 $\pm$ 10.94	0.03	85.22 $\pm$ 12.09	86.93 $\pm$ 8.32	0.80
Information Giving (5/25 max)	21.03 $\pm$ 3.39	21.26 $\pm$ 3.41	19.10 $\pm$ 2.60	0.02	20.88 $\pm$ 3.70	21.39 $\pm$ 2.50	0.95
Physical Patient Care (7/35)	29.98 $\pm$ 3.88	30.17 $\pm$ 3.84	28.30 $\pm$ 3.97	0.11	29.75 $\pm$ 4.18	30.54 $\pm$ 3.01	0.60
Psychosocial Care (4/20)	17.24 $\pm$ 2.43	17.41 $\pm$ 2.41	15.80 $\pm$ 2.15	0.04	17.25 $\pm$ 2.59	17.21 $\pm$ 2.03	0.69
Availability of Care (4/20)	17.47 $\pm$ 2.53	17.66 $\pm$ 2.40	15.80 $\pm$ 3.12	0.02	17.34 $\pm$ 2.80	17.79 $\pm$ 1.75	0.80



**Fig. 1.** Flow chart outlining data build including linkages

**Appendix A. Administrative Codes used to derive study outcomes.**

**A. International Classification of Diseases for Oncology Version 3 Cancer Topography Codes (used to identify cancer site)**

Breast	C500-C506, C508, C509
Lung	C340-C343, C348-C349
Colorectal	C180-C189, C199, C209
Prostate	C619
Other	C000-C006, C008-C009, C019-C024, C028-C031, C039-C041, C048-C052, C058-C062, C068-C069, C079-C081, C088-C091, C098-C103, C108-C113, C118-C119, C129-C132, C138-C140, C148, C150-C155, C158-C166, C168-C173, C178-C179, C210-C212, C218, C220-C221, C239-C241, C248-C254, C257-C260, C268-C269, C300-C301, C310-C313, C318-C323, C328-C329, C339, C379-C384, C390, C398-C403, C408, C410-C414, C418-C424, C440-C449, C470-C476, C478-C482, C488, C490-C496, C498, C499, C510-C512, C518-C519, C529-C531, C538-C543, C548-C549, C559, C569-C571, C573-C574, C577-C579, C589, C600-C602, C608-C609, C620-C621, C629, C631-C632, C637-C639, C649, C659, C669-C681, C688-C696, C698-C701, C709-C720, C723, C725, C728-C729, C739-C741, C749-C751, C753-C755, C758-C765, C767, C770-C775, C778-C779, C809

**B. Indicators of Aggressive End-of-Life Care**

Chemotherapy treatment received within the last 14 days before death (OHIP)	G281, G339, G345, G359, G381 days to service date <= 0 and > -15
Admission to an Intensive Care Unit (ICU) within the last 30 days before death (OHIP)	G400, G401, G402, G405, G406, G407, G557, G558, G559 days to service date <=0 and > -15
>1 Emergency Department (ED) visit within the last 30 days before death (NACRS)	Source = E days to registration date <=0 and > -31
>1 Hospitalization within the last 30 days before death (DAD)	Any code days to admission date <=0 and > -31
Death in Acute Care Hospital (DAD)	Discharge Disposition =7

**C. Palliative Designation**

Palliative Designation Codes  
 OHIP: A945, C945, K023, G512, K023, B998, C122, C123, C882, C982, W882, W982, W872, W972, K121, K700, K374, K735, A180, G511, G512  
 Home Care Database: service\_rpc=94 or 95  
 DAD: Z51.5

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	1 3
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed	4-6 7, 13 (Table 1)
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-6
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses	6-7 7 7, 13 (Table 1) n/a 6-7
<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	4-6; 7 n/a 16 (Fig. 1)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest	7, 13 (Table 1) 13 (Table 1)

		(c) Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	Report numbers of outcome events or summary measures over time	7-8, 14 (Table 2), 15 (Table 3)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	14 (Table 2) n/a 14 (Table 2)
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8, 15 (Table 3)
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	8-9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9-10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8-10
Generalisability	21	Discuss the generalisability (external validity) of the study results	10
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	2

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.