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# Potential impact of population-based colorectal cancer screening in Canada

*William M Flanagan, Christel Le Petit, Jean-Marie Berthelot, Kathleen J White, B Ann Coombs and Elaine Jones-McLean*

## Abstract

*Randomized controlled trials (RCT) have shown the efficacy of screening for colorectal cancer (CRC) using the fecal occult blood test (FOBT) and follow-up with colonoscopy. We evaluated the potential impact of population-based screening with FOBT followed by colonoscopy in Canada: mortality reduction, cost-effectiveness and resource requirements. The microsimulation model POHEM was adapted to simulate CRC screening using Canadian data and RCT results about test sensitivity and specificity, participation, incidence, staging, progression, mortality and direct health care costs. In Canada, biennial screening of 67% of individuals aged 50 to 74 in the year 2000 resulted in an estimated 10-year CRC mortality reduction of 16.7%. The life expectancy of the cohort increased by 15 days on average, and the demand for colonoscopy rose by 15% in the first year. The estimated cost of screening was $112 million per year or $11,907 per life-year gained (discounted at 5%). Potential effectiveness would depend on reaching target participation rates and finding resources to meet the demand for FOBT and colonoscopy. This work was conducted in support of the National Committee on Colorectal Cancer Screening.*

***Key Words:*** *colorectal cancer screening, cost-effectiveness, FOBT, microsimulation, POHEM*

For readers interested in more information on colorectal cancer screening, Health Canada's *Technical Report for the National Committee on Colorectal Cancer Screening* and the National Committee on Colorectal Cancer Screening's *Recommendations for Population-based Colorectal Cancer Screening* can both be found on Health Canada's website at: <http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ncccs-cndcc/index.html>.

## Introduction

Colorectal cancer (CRC) is the second leading cause of cancer deaths after lung cancer in Canada in both sexes combined but ranks third after prostate cancer in men and breast cancer in women. It affects men and women almost equally with increasing incidence beginning at age 50. Although incidence and mortality rates have slowly declined over recent years, the absolute numbers have increased as a result of the aging of the population. In 2002, there were an estimated 17,600 new cases of CRC and 6,600 deaths due to CRC.[1] A chart review at the Ottawa Regional Cancer Centre demonstrated that over half of the colorectal cancers detected in Canada were estimated to be stage III or IV cancers with five-year survival rates of approximately 60% and 10% respectively[a]. Early detection through screening is expected to lead to better survival outcomes.

Health Canada established the National Committee on Colorectal Cancer Screening (NCCCS) in 1998 with a mandate to make recommendations on population-based CRC screening in Canada. Randomized controlled trials (RCTs) have shown the efficacy of CRC screening with fecal occult blood testing (FOBT) followed by colonoscopy for those with positive test outcomes.[3–5] Because real-life conditions are not necessarily captured in RCTs and the follow-up periods of the CRC trials were relatively short, the Population Health Model (POHEM) was used to evaluate the potential impact of population-based screening with FOBT followed by colonoscopy for colorectal cancer in Canada.

## Methods

The specification of the screening protocol was developed in close collaboration with the NCCCS. Screening with FOBT (Hemoccult II, nonrehydrated) followed by colonoscopy for those with positive results was chosen as the screening modality to model, since evidence of its efficacy has been reported in three RCTs: from Funen, Denmark;[3] Nottingham, UK;[4] and Minnesota, USA.[5]

The Funen trial was population-based and had a clearly documented recruitment strategy that could be reproduced in

[a] Canadian stage and survival estimates were derived from a chart review of 700 patients with a diagnosis of CRC in the hospital system in Ottawa, Canada, in 1991–1992 (national data unavailable). Survival rates are comparable to those obtained from SEER*Stat4.0.[2]

**Author References**

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POHEM to generate similar follow-up periods (10-year). We used it as the primary RCT to specify the screening model and used parameter estimates from the other trials where appropriate. The screening model was validated against the outcomes of the Funen trial before being applied to the Canadian setting.

## The Population Health Model (POHEM)

POHEM is a microsimulation tool developed by Statistics Canada to model various aspects of the health of Canadians and evaluate possible interventions.[6,7] It creates synthetic, longitudinal population samples, starting with the birth of each individual in the cohort, and dynamically simulates their aging, including exposures to risk factors, disease onset conditional on risks, treatment, case fatality and costs. POHEM estimates the characteristics of a population cohort by synthesizing a large sample of complete individual health and socioeconomic biographies based upon a myriad of detailed empirical observations.

POHEM includes detailed models of colorectal cancer, lung cancer, breast cancer, use of hormone replacement therapy, heart disease and fractures. It has been used to evaluate the impact of preventive tamoxifen in Canada,[8] interventions in lung cancer,[9] and the lifetime cost of breast cancer[10] and colorectal cancer.

A Canadian CRC model of incidence and progression had been completed and incorporated into POHEM in 2000. It included disease incidence by age, sex and site (colon or rectum); disease progression to local recurrence, metastasis and death; and treatment options and cost. Incidence data were obtained from the Canadian Cancer Registry (1995), and stage distribution and survival data were derived from a chart review conducted at the Ottawa Regional Cancer Centre. Treatment options and associated costs were obtained from hospital discharge abstracts, surveys of oncologists, billing data and numerous consultations. The CRC screening module was integrated with this base model.

## Simulating a screening program

Screening was simulated in POHEM to include the recruitment period; the target age of the population; screening frequency; participation in first and subsequent screens; FOBT sensitivity, specificity and sojourn time; FOBT outcomes; compliance with follow-up by colonoscopy; complications of colonoscopy; pre-clinical and interval cancer detection; and follow-up after polyp detection.

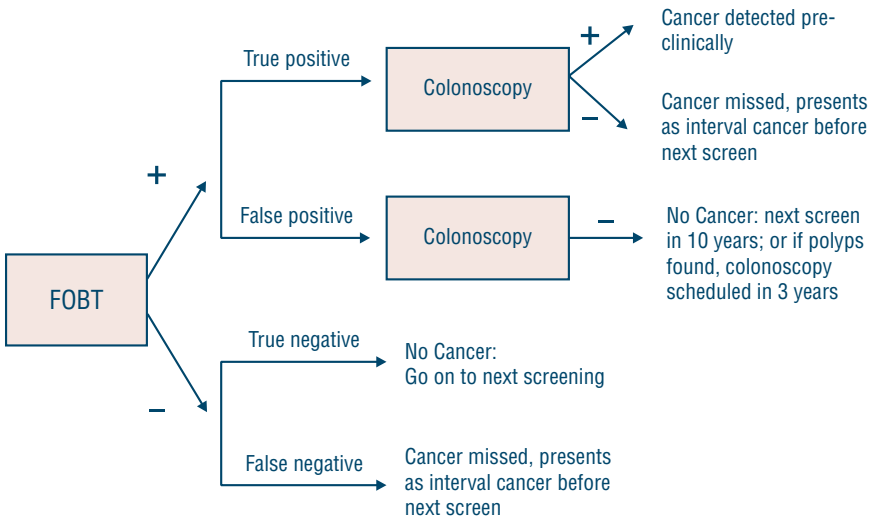
Simulated individuals within a targeted age range during the period of recruitment were eligible for FOBT screening, provided that they had no history of CRC. The recruitment period was either the year 2000 to generate a *fixed cohort* or the period 2000 to 2024 to generate a *dynamic* cohort. Fixed cohorts were used to simulate clinical trial conditions and to estimate the mortality reduction and cost-effectiveness of screening. Dynamic cohorts, which take into account the changing population structure, were used to determine the potential impact on resources, such as the volumes of FOBTs and colonoscopies that would be required in a population-based screening program.

Participation was simulated for first and subsequent invitations to FOBT screening and for follow-up with colonoscopy. Only individuals participating in the first screening round were re-invited. Participation in a subsequent round did not otherwise depend on participation in the previous round. Individuals not complying with follow-up by colonoscopy were no longer screened.

The recruitment strategy plays an important role in the overall participation rate and cost of a screening program. It was proposed that recruitment through media promotion, letters of invitation and visits to family physicians could achieve a 67% participation rate of the target population in Canada. It was estimated that those complying with screening would make an average of 1.5 visits to consult with physicians and to receive the FOBT test kit.

Outcomes of the FOBT, as shown in Figure 1, were simulated using the sensitivity and specificity estimates from the clinical trials. For simulated individuals identified in the microsimulation as having pre-clinical cancer, the sensitivity estimate was applied to assign a true positive or false negative outcome. A false negative outcome meant that the cancer was missed but would be detected clinically before the next screen as an interval cancer. For simulated individuals not having pre-clinical cancer at the time of screening, the specificity was applied to assign a true negative or false positive outcome. The presence of pre-clinical cancer potentially detectable by FOBT was simulated by calculating the probability of incidence of CRC within the next two years for biennial

**FIGURE 1**
**FOBT screening paths**



screening or within one year for annual screening.

Only cases with positive test results were offered further consultation with a gastroenterologist and follow-up investigation by colonoscopy. The colonoscopy was assumed to be 95% sensitive[11] and 100% specific in detecting CRC. Complications associated with colonoscopy were modeled for perforation (0.17%), hemorrhage (0.03%) and death (0.02%).[12] After a negative colonoscopy, participants were exempt from screening for 10 years provided that no polyps were found. When polyps were found (but no cancer), follow-up colonoscopies were performed at 3-, 5- and 10-year intervals according to guidelines[13,14] and expert opinion.

It was assumed that colonoscopy would detect polyps greater than 1 cm in diameter and that removal of polyps would have no impact on the incidence of CRC, consistent with findings in the Funen trial over the 10-year follow-up period. The prevalence of polyps greater than 1 cm was assumed to increase linearly from 3% at age 50 to 5% at age 70 to 5.5% at age 80.[15]

Stage was assigned according to how the cancer was detected (Table 1). The stage distribution for the Canadian reference (control) population was derived from a chart review at the Ottawa Regional Cancer Centre. The stage distribution for a hypothetically screened population in Canada was estimated by applying the relative stage shift observed in the RCTs to the Canadian reference stage distribution.

The improved stage distribution accounted for part, but not all, of the improved survival observed in the trials. Relative risks were applied to the survival of the reference group for cancers detected from the first screen (RR = 0.53), subsequent screen (RR = 0.62), in the interval (RR = 0.88) and in the non-participants (RR = 1.04).[16]

Costs related to CRC screening were difficult to estimate since a program does not exist in Canada. Table 2 shows the estimated cost of screening by component together with a higher cost option to take into account uncertainty. Treatment costs were included from the base CRC model. No indirect costs were modelled.

**TABLE 1**
**Estimated Canadian stage distributions according to how cancer was detected**

| Stage | No screening[a] (control) (%) | Biennial screening[b] Screen detected (%) | Biennial screening[b] Interval cancer (%) | Biennial screening[b] Non-participants (%) | Annual screening[c] (%) |
|---|---|---|---|---|---|
| I | 13 | 38 | 22 | 14 | 22 |
| II | 33 | 38 | 29 | 32 | 32 |
| III | 27 | 17 | 28 | 20 | 31 |
| IV | 27 | 7 | 21 | 34 | 15 |

[a] Derived from an Ottawa chart review
[b] Estimated from Funen trial observations
[c] Estimated from Minnesota trial observations

**TABLE 2**
**Estimated costs of screening program by component**

| Screening costs | Base cost ($) | High cost ($) |
|---|---|---|
| Head office, satellite and promotion[a] (per year) | 15,000,000 | 30,000,000 |
| Extra physician visits[b] (per FOBT) | 43.58 | 58.10 |
| FOBT kit[b] | 4.65 | 9.30 |
| Processing[c] (per FOBT) | 6.00 | 8.00 |
| Consultation[b] (per positive FOBT) | 123.70 | 161.10 |
| Colonoscopy[d] (per positive FOBT or follow-up to polyps) | 350.00 | 425.00 |
| Polypectomy[d] | 147.00 | 147.00 |

[a] Estimated from Cancer Care Ontario (2000) (unpublished report)
[b] Estimated from the Ontario Health Insurance Plan
[c] Based on quotes from private laboratories
[d] Estimated from Day Procedure Group cost lists (Manitoba Health Services and Alberta Standard Cost List for Health Economics Evaluations) and estimates from Prince Edward Island by NCCCS member Dr. Don Clark

The cost-effectiveness ratio was calculated as the incremental cost incurred divided by the incremental life-years saved due to screening. Cost-effectiveness ratios less than $40,000 per life-year saved are generally considered cost-effective.[17] Discounting for costs and life-years was performed at 0%, 3% and 5%. All costs were in Canadian dollars.

## *Simulating control and screen groups*

We used a sample of approximately 7 million to minimize the random error associated with the simulation. This sample consisted of two identical cohorts, a reference (control) cohort and a screen cohort. The life histories of individuals in the screen cohort were identical to those of the reference cohort until they became eligible for screening. The screen cohort was then subjected to the modelled screening protocol. The impact of screening was evaluated by comparing outcomes from the screened cohort with outcomes from the unscreened reference cohort. This approach was repeated for each screening scenario evaluated. The main outcomes of analysis were the reduction in mortality from CRC, life expectancy gains, cost-effectiveness and volumes of FOBTs and colonoscopies generated by screening.

**TABLE 3**
**Simulated scenarios of screening with FOBT Hemoccult II (nonrehydrated)**

| | Validation[a] | Canada | | | | |
|---|---|---|---|---|---|---|
| Frequency | Biennial | Biennial[b] | Annual | Biennial | Biennial | Biennial |
| Participation rate (%) | 67 | 67 | 67 | 50 | 67[d] | 100 |
| Re-screen rate (%) | 93 | 93 | 93 | 93 | 93 | 100 |
| Colonoscopy compliance (%) | 89 | 89 | 89 | 89 | 89 | 100 |
| Age group | 45-75 | 50-74 | 50-74 | 50-74 | 50-74 | 50-74 |
| Sensitivity (%) | 51 | 51 | 80.8[c] | 51 | 51 | 51 |
| Specificity (%) | 98 | 98 | 97.7[c] | 98 | 98 | 98 |

[a] Based on Funen trial results
[b] Canadian core scenario
[c] Based on Minnesota trial results
[d] Ramp-up scenario in which the target participation rate of 67% was reached over 5 years

### *Validation*

To validate the screening component of POHEM we used the characteristics of the Funen trial (Table 3) to reproduce the trial's observed mean mortality reduction. The stage distribution observed in the Funen trial was used to assign stage according to how the cancer was detected. The results were standardized to the age group and sex of the population structure of the Funen trial.

### *Canadian screening scenarios*

Table 3 shows the parameters chosen for each of the Canadian scenarios. Parameters for the Canadian core scenario were chosen to be as similar as possible to the conditions of the population-based Funen trial (i.e., the validation parameters), since the relation between trial participation patterns and observed mortality reduction may not extend to other participation rates. Thus, the core scenario was characterized by biennial screening, 67% participation in the first screen round, 93% participation in subsequent screening rounds, 89% compliance with follow-up by colonoscopy, an FOBT sensitivity of 51% and a specificity of 98%. To reflect the Canadian context, we used a target age range of 50 to 74, the estimated Canadian stage distributions and the Canadian population age structure.

The annual screening scenario for Canada used estimates of sensitivity and specificity observed in the Minnesota trial (for the subgroup of nonrehydrated FOBTs). To evaluate the impact of participation on mortality reduction and cost-effectiveness, participation in biennial screening was reduced from 67% to 50%. To study the impact on resources, participation was ramped up gradually to the target level of 67% over five years. Finally, to assess potential life expectancy gains, a cohort of eligible individuals aged 50 was simulated to participate fully in all aspects of biennial screening until age 74.

## Results

### *Validation*

The simulated validation scenario generated a mortality reduction of 17.9% (95% CI: 16.9%–18.9%). This was consistent with the mortality reduction in the Funen trial of 18% (95% confidence interval [CI]: 1%–32%) after 10 years of follow-up. The confidence intervals were tighter in our model because the sample was much larger (7 million versus 60,000). The validation increased our confidence in our simulation of the impact of CRC screening in Canada.

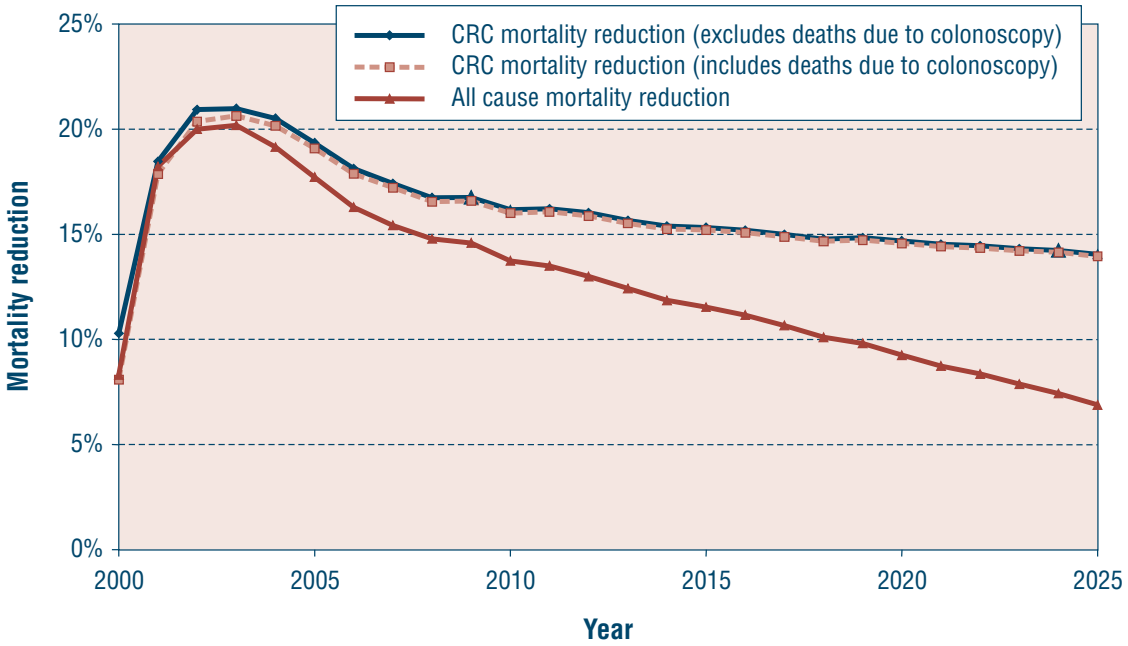
### *Mortality reduction and cost-effectiveness*

When biennial screening was simulated under the assumptions of the Canadian core scenario, there was an estimated 16.7% (95% CI: 15.8%–17.6%) reduction in the 10-year CRC mortality. This result was lower than observed in the Funen trial, reflecting a more restricted target age range. Figure 2 shows the projected change in mortality reduction over time. It peaked during the first few years of screening because of the high number of prevalent cases that could be detected and then steadily declined, since improved survival did not necessarily preclude mortality from CRC. In other words, death from CRC was postponed for some individuals. For the remaining individuals, the avoidance of CRC death was replaced by death from another cause at a later time, as illustrated by the lowest curve in Figure 2.

Deaths due to the complications of colonoscopy had minimal impact on the estimated mortality reduction: for every 178 CRC deaths avoided in the simulated cohort, one death due to complications was incurred. The overall impact on the cohort of the life-years gained and lost was reflected in an estimated life expectancy gain of 0.040 years (95% CI: 0.038–0.042) or 15 days (Table 4).

Similar trends in mortality reduction were observed for the other scenarios. After 10

**FIGURE 2**
**Estimated mortality reduction over time, Canadian core scenario, screened from 2000 to 2025**




Note: Based on a simulated cohort of eligible individuals aged 50–74 recruited in the year 2000 ($n$ = 7,001,322)

years of annual screening, CRC mortality was reduced by 26% and life expectancy increased by 0.065 years (24 days). When participation in biennial screening was reduced from 67% to 50%, the 10-year CRC mortality reduction dropped to 10.0% and the life expectancy gain dropped to 0.025 years (9 days). The 10-year CRC mortality reduction dropped by an additional 1.4% when the participation rate in subsequent screening rounds was reduced from 93% to 80% and compliance with colonoscopy was reduced from 89% to 80%.

The cost per life-year gained from biennial screening was $11,907, and this increased to $13,497 under annual screening (discounted at 5%). Both biennial and annual screening remained cost-effective under the high-cost sensitivity analysis. Biennial screening was less cost-effective ($15,688) when the participation rate was reduced from 67% to 50%.

Additional analyses were performed to evaluate the age at which to start and end screening. Using five-year increments, we evaluated start ages from 40 to 60 and end ages from 60 to 90. The increased cost of screening before age 50 was not war-

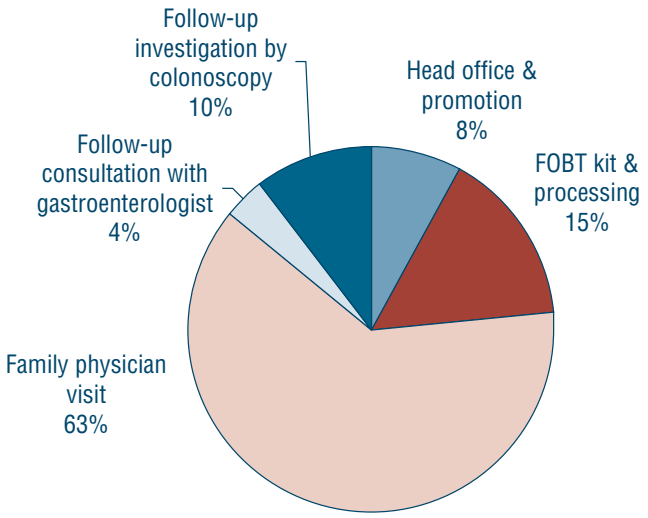
**TABLE 4**
**Mortality reduction and cost-effectiveness of biennial, annual and reduced participation screening scenarios (relative to no-screening option)**

| Participation | Biennial 67% | Annual 67% | Biennial 50% |
|---|---|---|---|
| **Mortality** | | | |
| 10-year CRC mortality reduction | 16.7% | 26.0% | 10.0% |
| 25-year CRC mortality reduction | 14.2% | 22.5% | 8.7% |
| CRC deaths avoided (lifetime) | 23,668 | 40,110 | 13,964 |
| Deaths from complications of colonoscopy | 133 | 265 | 106 |
| **Cost-effectiveness, no discounting** | | | |
| Years (days) of life saved for the cohort | 0.040 (15) | 0.065 (24) | 0.025 (9) |
| Cost per life-year gained | $6,202 | $7,129 | $8,262 |
| Cost per life-year gained, high cost option | $10,001 | $10,750 | $13,502 |
| **Cost-effectiveness, 5% discounting** | | | |
| Years (days) of life saved for the cohort | 0.016 (6) | 0.025 (9) | 0.009 (3) |
| Cost per life-year gained | $11,907 | $13,497 | $15,688 |
| Cost per life-year gained, high cost option | $18,445 | $19,893 | $24,635 |

Note: Based on a simulated cohort of eligible individuals aged 50-74 recruited in the year 2000 ($n$ = 7,001,322)

ranted, given the small gain in life expectancy, and screening after age 75 showed no significant gains in life expectancy. Starting to screen at age 50 and ending at age 74 was shown to be more cost-effective than starting later or ending earlier.

**FIGURE 3**
**Estimated average annual cost of biennial screening by component over 25 years of a simulated program**




Estimated average annual cost of FOBT screening: $112 million (discounted at 5%)

**TABLE 5**
**Impact on resources per year from biennial, annual and ramped-up screening (averaged over 25 years of screening program)**

| Participation | Biennial 67% | Annual 67% | Biennial 67%[a] |
|---|---|---|---|
| Number of FOBTs per year (million) | 2.8 | 4.9 | 2.6 |
| Number of colonoscopies | 55,845 | 111,654 | 51,632 |
| CRC incidence | 16,769 | 16,694 | 16,752 |
| Screen detected | 3,301 | 4,469 | 3,052 |
| Interval detected | 7,986 | 6,743 | 7,160 |
| Non-participants | 5,482 | 5,482 | 4,971 |
| Cost of screening per year ($ million) (discounted at 5%) | $112 | $194 | $100 |
| Screening as proportion of total cost | 23.6% | 35.1% | 21.5% |
| Reduction in treatment cost (lifetime) | 4.8% | 5.8% | 4.2% |

[a] Ramp-up scenario in which the target participation rate of 67% was reached over 5 years

Note: Based on a simulated cohort of eligible individuals aged 50–74 recruited from year 2000–2024

## Impact on resources

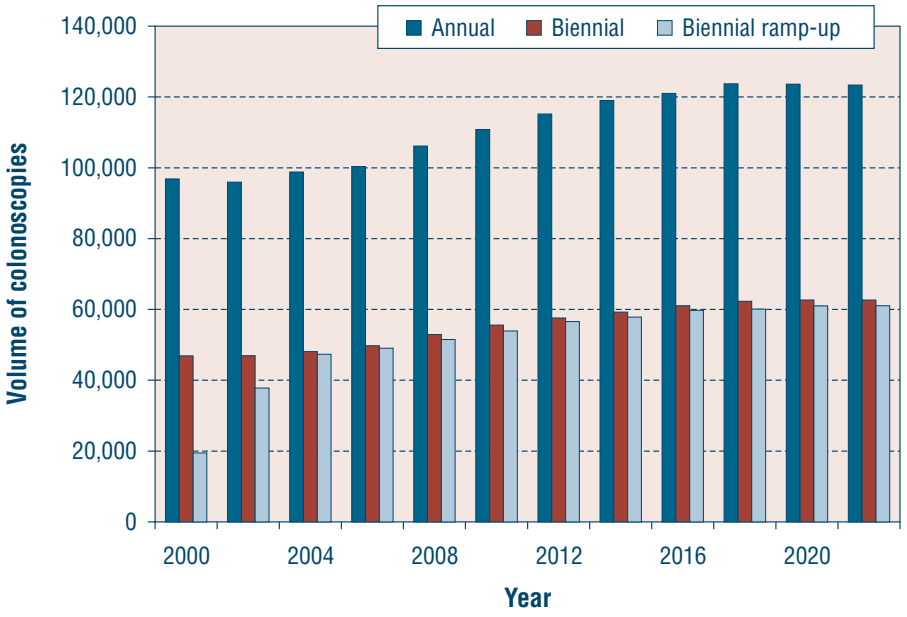
The impact on resources was evaluated by modelling the recruitment of all eligible individuals aged 50 to 74 to the screening program over the years 2000 to 2024. Biennial screening under the core scenario generated an estimated 2.8 million FOBTs and 55,845 colonoscopies per year on average (Table 5). The average cost of the screening program was $112 million per year over 25 years of screening (discounted at 5%). Physician visits accounted for 63% of this cost and overheads for 8% (Figure 3). The cost of screening represented almost one-quarter of the total cost of detecting and treating colorectal cancer. Early detection through screening reduced the cost of treatment by 4.8%.

Annual screening nearly doubled the demand on resources compared with biennial screening, as illustrated in Figure 4. The average number of FOBTs rose to 4.9 million per year, and the average number of colonoscopies increased to 111,654 per year. Also shown in Figure 4 is the phased-in demand for resources when the target participation rate of 67% was reached gradually over the first five years of the program (*ramp-up* scenario). The impact of the aging baby boomers was reflected in the increasing volume of colonoscopies projected over the 25 years of screening.

## Full participation

When a cohort of simulated individuals aged 50 who participated fully in all aspects of biennial screening until age 74 were followed until death, the cohort life expectancy increased by 0.10 years (37 days). An individual deemed to develop CRC within this cohort gained an estimated 1.75 years of life. The lifetime incidence of CRC rose slightly, by 0.5%, because screening detected cancer in some individuals who otherwise would have died from another cause before clinical detection. The lifetime mortality rate from CRC dropped from 3.0% to 2.3%. The probability of dying as a result of the complications of a colonoscopy was 0.005%; 0.043% suffered a perforation and 0.008% hemorrhaged as a result of the colonoscopy. Over the 25 years of screening, the

**FIGURE 4**
**Estimated annual volume of colonoscopies required for annual, biennial and biennial ramp-up screening scenarios for selected years**




probability of having a colonoscopy was 25%.

## Discussion

Screening for colorectal cancer with FOBT followed by colonoscopy for those with positive test results was cost-effective for the Canadian scenarios simulated relative to commonly accepted thresholds for health interventions.[7] However, the potential effectiveness of screening would greatly depend on reaching the targeted participation rate of 67%. To put this into perspective, participation rates in organized breast cancer screening programs in Canada in 1997–98 were well below the target of 70%, with estimates ranging from 12% to 55% across provinces after as much as 10 years of program implementation.[18] A pilot program is currently under way in Ontario that may help indicate attainable participation rates for CRC.[19]

As with participation rates, other model parameters, such as the sensitivity and specificity of the FOBT, have uncertainty associated with their estimates that we have not evaluated. Similarly, the model was constructed to reproduce the mean estimate of the mortality reduction but does not take into account the full uncertainty reported in the RCTs. Further analyses could be done to estimate the potential impact of this uncertainty.

A physician-based recruitment strategy will place additional burden on family physicians and may require additional doctors or other trained health care providers to meet the demand. Finding the resources to perform the increased number of colonoscopies may also be a challenge. According to simulation results, biennial screening would increase the demand for colonoscopies by 15% over current-use estimates (year 2000 estimates projected from 1995–96 Canadian Institute for Health Information estimates). Annual screening could double this demand. Given the potentially large number of colonoscopies and FOBTs that would be required in a fully operational screening program in Canada, issues of quality assurance become paramount,[20] especially since the potential for death from the complications of colonoscopy among otherwise healthy people raises ethical concerns.

There may also be ethical issues related to the impact of screening on quality of life. False positive FOBT results may increase anxiety in otherwise healthy individuals. Screening may adversely affect the quality of life, given that cancers are detected earlier. Patients live longer with knowledge of their disease and, further, the life-years gained may not be lived in perfect health. On the other hand, the life-years gained may be lived in less severe states of the disease, as suggested indirectly by the reduced cost of treatment in the simulated screening cohort.

Polyp removal was assumed to have no impact on the incidence of CRC, since none was observed over the 10 years of follow-up in the Funen trial. However, more recent results from 18 years of follow-up of the Minnesota trial showed lower than expected incidence rates of CRC,[21] as did an earlier analysis in the National Polyp Study,[22] suggesting a possible link with polyp removal. Consequently, our analysis may have underestimated the benefits of screening in this regard.

The estimates from this study were intended to be representative of Canada but may not reflect provincial variations. For instance, resource limitations may lead some jurisdictions to follow up a positive

FOBT result with barium enema instead of colonoscopy. Further analysis would be required to fully explore the potential impact of barium enema as an alternative follow-up procedure.

The current model is easily adapted to using various primary screening modalities but would require strong sources of evidence, such as RCTs, to obtain estimates of test efficacy. Regardless of the modality, acceptance by affected communities would remain critical for the feasibility and effectiveness of a program, as this analysis showed for FOBT.

This analysis provided evidence-based responses to address gaps in information identified by the National Committee on Colorectal Cancer Screening and was valuable in supporting the development of recommendations by the National Committee. It demonstrated the usefulness of modelling in the decision-making process.

## Acknowledgements

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# Colorectal cancer screening: A note of caution

*Gerry Hill and Patti Groome*

Persuasive arguments have been made for the introduction of screening for colorectal cancer[1–3]. However, some thought should be given to how such a program would be implemented, and its impact on the health care system. Mass screening creates an upsurge in diagnosed cases. If treatment resources remain unchanged a waiting list for treatment develops, and although the time from the inception of cancer to diagnosis is shortened, the time from diagnosis to treatment is increased. Since the aim of screening is to shorten the time from inception to treatment, the potential benefit of screening is reduced. It can be shown mathematically (see appendix) that unless treatment resources are increased, the overall time from inception to treatment remains the same, so that screening is ineffective. Even when the number of diagnosed cases returns to normal, the reduced effectiveness remains: once a queue develops it persists unless extra resources are provided to eliminate it.

There is empirical evidence to support this theory. In Quebec both the number of women per year diagnosed with breast cancer and the median waiting time from diagnosis to first surgery increased by 45 percent in the period 1992 to 1998,[4] increases attributed to mammography screening.[5] In Ontario the introduction of screening using prostate-specific antigen increased the number of men per year diagnosed with prostate cancer resulting in increases in waiting times for radical prostatectomy and radiotherapy.[6]

Since major increases in resources are unlikely in times of fiscal restraint, and even if funded would take some time to be achieved, the only way to avoid these bottlenecks is to introduce screening gradually, perhaps by selective screening based on risk factors.

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*(see appendix on next page)*

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## Appendix

Consider the following model of the diagnosis and treatment of cancer:

$$\xrightarrow{N} X \xrightarrow{d} Y \xrightarrow{s} \text{treatment}$$

Where

- $X$ = number of undiagnosed cases of cancer
- $Y$ = number of diagnosed, but untreated cases of cancer
- $N$ = number of new cases of cancer per year (assumed constant)
- $d$ = rate of diagnosis
- $s$ = rate of treatment

Before the onset of screening, with $d = d_o$ and $s = s_o$, the steady state values of X and Y, $X_0$ and $Y_0$ are:

$$X_0 = N/d_0, \quad Y_0 = d_0X_0/s_0 = N/s_0$$

The number of treatments per year $= s_0Y_0 = N$

The mean waiting time for diagnosis $w_x = X_0/N = 1/d_0$

The mean waiting time for treatment $w_y = Y_0/N = 1/s_0$

The total waiting time from inception to diagnosis $w_0 = (X_0 + Y_0)/N = 1/d_0 + 1/s_0$

Suppose that screening begins at time $t = 0$, increasing the rate of diagnosis to $d_1$ but the resources for treatment (assumed to be the same for for both methods of diagnosis) are not increased.

Then the differential equations for $X(t)$ = the number of undiagnosed cases, and $Y(t)$ = the number waiting for treatment at time t years after the onset of screening are:

$$dX(t)/dt = N - d_1X(t)$$

$$dY(t)/dt = d_1X(t) - N$$

with initial conditions $X(0) = X_0$, $Y(0) = Y_0$.

The solutions are:

$$X(t) = X_0\exp(-d_1t) + N[1 - \exp(-d_1t)]/d_1$$

$$Y(t) = Y_0 + N(1/d_0 - 1/d_1)[1 - \exp(-d_1t)]$$

As t increases $X(t)$ decreases from $X_0$ to a new steady state $X_1 = N/d_1 = X_0 - N(1/d_0 - 1/d_1)$, and $Y(t)$ increases to a new steady state $Y_1 = Y_0 + N(1/d_0 - 1/d_1)$.

Note that $w_1 = X_1 + Y_1 = X_0 + Y_0 = w_0$, so that the total waiting time is unchanged. Since the aim of screening is to reduce the time between inception and treatment, thus improving the prognosis, we have the following important corollary:

**If screening is implemented without increasing the resources for treatment then screening is ineffective.**

# Lifetime costs of colon and rectal cancer management in Canada

*Jean Maroun, Edward Ng, Jean-Marie Berthelot, Christel Le Petit, Simone Dahrouge, William M Flanagan, Hugh Walker and William K Evans*

## Abstract

*Colorectal cancer is the second leading cause of cancer-related mortality among Canadians. We derived the direct health care costs associated with the lifetime management of an estimated 16,856 patients with a diagnosis of colon and rectal cancer in Canada in 2000. Information on diagnostic approaches, treatment algorithms, follow-up and care at disease progression was obtained from various databases and was integrated into Statistics Canada's Population Health Model (POHEM) to estimate lifetime costs. The average lifetime cost (in Canadian dollars) of managing patients with colorectal cancer ranged from $20,319 per case for TNM stage I colon cancer to $39,182 per case for stage III rectal cancer. The total lifetime treatment cost for the cohort of patients in 2000 was estimated to be over $333 million for colon and $187 million for rectal cancer. Hospitalization represented 65% and 61% of the lifetime costs of colon and rectal cancer respectively. Disease costing models can be important policy-relevant tools to assist in resource allocation. Our results highlight the importance of performing preoperative tests and staging in an ambulatory care setting, where possible, to achieve optimal cost efficiencies. Similarly, terminal care might be delivered more efficiently in the home environment or in palliative care units.*

***Key words:*** *colorectal cancer; costing model; direct care costs; lifetime cost; micro-simulation*

## Introduction

As we begin the 21st century, the Canadian health care system is experiencing serious fiscal constraints. Costly technological advances and an aging population are creating daunting challenges for health care. To ensure the best health outcomes, health policy decision-makers need to set priorities for resource allocation. Economic studies of the burden of illness can make a valuable contribution to policy development. Such studies can estimate the present and future cost impact of diseases on society and can also be used as a benchmark against which the cost-effectiveness of new medical treatments or prevention programs can be evaluated.[1]

In 2002, colorectal cancer (CRC) was the third most common malignancy affecting Canadian men and women and the second leading cause of cancer-related death. Invasive CRC was diagnosed in an estimated 17,600 Canadians in 2002, and more than 6,600 individuals were expected to die from this disease in the same year.[2] A comprehensive model of the management of CRC by site (colon and rectum) was developed and incorporated into Statistics Canada's Population Health Model (POHEM)[3,4] to estimate the total lifetime direct cost of treating the cohort of patients with CRC* in 2000.

## Methods

To build the economic model incorporating all phases of CRC and their management required data from a number of databases (see Appendices A and B for the main sources and their use). The main source of data on clinical management came from a retrospective review of 700 charts of patients whose CRC was diagnosed in 1991–92 in the Ottawa hospital system (the Ottawa Chart Review). This review provided data on demographic characteristics of patients, staging work-up, treatment (surgery, chemotherapy and radiotherapy) and outcome information.

The management of CRC was categorized into three periods: initial treatment, treatment of local recurrence and management of metastasis. The initial treatment period captured information from diagnosis, the treatment phase and the well-patient follow-up phase (stages I–III). This period ended at five years, and patients were considered cured if they remained disease free. The local recurrence period captured information from that diagnosis, a three-month initial treatment phase and up to five years of active care, unless metastasis was docu-

* Since cancer of the anus is managed differently from colon and rectal cancer, anal cancer data were excluded from POHEM.

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mented. The metastasis period (which includes those whose cancer was initially diagnosed as stage IV) captured information from that diagnosis, a six-month initial treatment phase, and up to five years of active care. Death can occur at any point in these periods, and the three months before any CRC-related death were considered as a period of terminal care.

The stage at the time of primary surgical treatment is the most important determinant of prognosis. Disease progression was modelled from the Ottawa Chart Review for each stage and site at diagnosis, on the basis of the TNM classification.[5] For patients with stage I, II or III cancer, the three transitions modelled were diagnosis to local recurrence, to distant recurrence (or metastasis) and to death. Once a local recurrence had occurred, the only transitions modelled were to metastasis or to death. For those with metastatic disease at diagnosis (including stage IV), the only transition modelled was to death.

The Ottawa Chart Review was also used to estimate the type and frequency of treatment procedures by stage and disease site for each period. However, in light of the recent emergence of new chemotherapy drugs for the treatment of CRC, a Canada-wide survey of oncologists was conducted in 1998 to re-evaluate the proportion of patients receiving chemotherapy (and/or radiotherapy) and the type of chemotherapy selected.[6] These survey data replaced the Ottawa Chart Review data for all chemotherapy treatment information at initial diagnosis. The duration of surgery-related hospitalization at initial treatment (as well as at progression) was estimated using Statistics Canada's national person-oriented information (POI) database of hospital discharges[7] for each type of surgery identified by the Ottawa Chart Review. All hospital admissions up to 30 days before and 60 days after the admission date for surgery were included as a proxy for any hospitalization for preoperative tests and procedures as well as readmissions due to surgical complications.

The Canadian Cancer Registry (CCR)[8] and population estimates from Statistics Canada[9] were used to estimate age-sex specific incidence rates of colon and rectal cancer in Canada. At the time of analysis, the only reliable data available were for 1995, and therefore these data were used as a proxy for the Canadian situation in 2000. Survival was modelled with a piece-wise Weibull function[4] using the Lifetest procedure from SAS.[10]

## Cost assessment

Unless otherwise noted, all costs were determined in 1998 Canadian dollars. The economic analysis was carried out from the perspective of the government as payer in a universal health care system and did not take into account indirect costs such as lost income. The principal source of cost information on physician fees, procedures, laboratory tests and CRC-related surgeries was the 1998 Ontario Health Insurance Plan (OHIP)[†].[11] The unit cost components for the major items are presented in Appendix C.

To cost specific items (e.g., surgical procedures) for which more than one type of procedure could be used, the cost associated with the procedure was derived by summing the products of the cost, from OHIP, of each type of procedure multiplied by the proportion of its use according to the treatment algorithm derived from the Ottawa Chart Review. Similarly, the overall cost of a specific item was derived by multiplying the average weighted cost of that item by the proportion of the population using that resource. For example, the weighted cost of chemotherapy for stage III colon cancer ($4,120) was derived by multiplying the average weighted cost of chemotherapy for that population ($4,709) by the estimated proportion receiving it (87.5%).

## The Population Health Model (POHEM)

POHEM is a framework for organizing health information as well as a micro-simulation model to estimate disease progression, treatment consequences and lifetime cost in a large population. While estimates of this lifetime cost can be derived crudely in cell-based macro-simulation models, more detailed macro-modeling tends to explode the number of cells required and render this approach impractical. By contrast, micro-simulation models use relatively simple random processes to build complex synthetic life paths drawn from distributions of empirical data. The model is not inherently limited in the level of detail that can be included – only, rather, by the availability of clinically relevant descriptions of disease processes and the data required to model them.

Practically, POHEM simulates and synthesizes a sample of individual health and socio-economic life histories to re-create the age-sex and tumour stage distribution of the year 2000 cohort of new CRC patients in Canada. Each synthetic individual is aged and subjected probabilistically to demographic events, disease onset and progression, and use of health care resources, based on incidence, treatment and disease progression incorporated in POHEM. Whether, for a simulated individual, colon or rectal cancer develops is determined by a random number process as a function of the estimated probability of incidence. On the basis of the stage distribution by site, each individual with a diagnosis of CRC in the simulated population is randomly assigned a stage at diagnosis. The stage determines the treatment modalities according to the derived initial treatment algorithms for both colon cancer and rectal cancer. Disease progression and outcomes are determined by comparing random numbers with the derived survival function. The distribution of recurrence and treatment are also incorporated to estimate costs over time. The simulation sample size of 32 million individuals ensures that the Monte Carlo error is small relative to the model outputs of interest.

## Sensitivity analysis

"Discounting" takes into consideration the fact that future costs and benefits need to

[†] A commissioned study conducted by the Canadian Institute of Health Information concluded that OHIP reimbursements closely approximated average provincial costs in Canada. While this study was on the costs of breast cancer treatment, it is reasonable to assume that Ontario costs would also be close to the provincial average for colorectal cancer.

**TABLE 1**
**Summary of colon and rectal cancer disease progression based on POHEM**

| Disease site | Stage at diagnosis | Number with diagnosis (2000) | Percentage developing local recurrence[a] | Percentage developing metastatic disease[a] | Percentage dying of CRC[b] within 5 years | Percentage dying of CRC[b] | Average number of years alive after diagnosis |
|---|---|---|---|---|---|---|---|
| Colon | I | 988 (9%) | 9.0 | 17.5 | 12.5 | 20.4 | 12.9 |
| | II | 3,966 (35%) | 14.0 | 23.7 | 22.6 | 28.8 | 10.7 |
| | III | 2,970 (26%) | 9.7 | 31.3 | 34.3 | 41.4 | 9.2 |
| | IV | 3,506 (31%) | N/A | 100.0 | 93.9 | 94.4 | 1.2 |
| | All Stages | 11,430 (100%) | 8.2 | 48.6 | 46.7 | 51.6 | 7.6 |
| Rectal | I | 1,243 (23%) | 29.1 | 23.5 | 18.7 | 33.8 | 11.1 |
| | II | 1,592 (29%) | 9.5 | 45.2 | 36.9 | 45.5 | 9.3 |
| | III | 1,581 (29%) | 9.4 | 52.1 | 53.2 | 62.3 | 6.8 |
| | IV | 1,010 (19%) | N/A | 100.0 | 94.9 | 95.2 | 1.2 |
| | All Stages | 5,426 (100%) | 12.2 | 52.5 | 48.4 | 57.0 | 7.4 |

[a]Estimates over the lifetime of CRC patients
[b]CRC = colorectal cancer

be reduced or discounted, as the present value of today's dollars is greater than the present value of future dollars. Sensitivity analyses using yearly discount rates of 0%, 3% and 5% were carried out.

## Results

### Disease incidence, stage and survival

Table 1 provides a summary of disease evolution in patients with colon and rectal cancer based on POHEM. The overall expected number of years lived was 7.6 for colon and 7.4 for rectal cancer. The risk of local recurrence did not increase with stage of disease at diagnosis. However, there was a strong positive relation between stage and the risk of metastatic disease as well as the risk of disease-specific death, and an inverse relation between stage and survival duration. Overall, 52% and 57% of colon and rectal cancer patients respectively die of their cancer over a lifetime, and the majority of deaths occur within five years.

### Estimated costs of initial treatment period

All patients with cancer diagnosed at stages I to III were treated with surgery[‡]. Adjuvant chemotherapy was given to 19% and 88% of patients with colon cancer stages II and III respectively. The use of radiotherapy was limited to patients with rectal cancer. Combination chemotherapy and radiotherapy was given to 60% and 81% of patients with rectal cancer stages II and III respectively. Active care was given to 70% and 83% of patients with stage IV colon and rectal cancer respectively.

Table 2 shows that the average costs associated with the diagnosis and the treatment phases of the initial treatment period for stages I to IV colon and rectal cancer ranged between $11,598 and $19,742; 53% to 86% of these costs were attributable to hospitalization. For stage IV, 30% to 33% of the cost was attributable to first and second line chemotherapy. The cost of diagnosis and staging was minor in comparison, ranging between $375 and $568.

Well-patient follow-up practice is dependent on stage. The total annual follow-up cost per person decreased over time, from approximately $400 in year one to $150 in year five with an overall lifetime average of $615 to $908 for stages I to III (results partially shown in Table 3).

### Estimated costs of the local recurrence and metastatic phases

Table 2 shows the estimated cost of disease management for local recurrence and for metastatic disease from POHEM. The average cost of diagnosing and treating local recurrence was $6,611 for colon and $6,708 for rectal cancer patients. Hospitalization accounted for 69% and 56% of these costs for colon and rectal cancer respectively. In fact, a sizeable proportion of the patients with local recurrence (56% for colon and 68% for rectal cancer) did not undergo surgical resection at recurrence, and thus the hospitalization cost was less than that in the initial treatment phase of stages I to IV. For patients with colon cancer, less than 20% received radiotherapy or chemotherapy at the time of recurrence. However, 53% of rectal cancer patients received radiotherapy, and 12% received chemo-

[‡] Treatment algorithms are available upon request.

**TABLE 2**
**Average per patient cost of initial treatment for colon and rectal cancers by stage/state and component (1998 Cdn $)**

| Component | Stage I | | Stage II | | Stage III | | Stage IV | | Local recurrence | | Distant recurrence | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Site** | **Colon** | **Rectal** | **Colon** | **Rectal** | **Colon** | **Rectal** | **Colon** | **Rectal** | **Colon** | **Rectal** | **Colon** | **Rectal** |
| Diagnosis and staging | 375 (3%) | 411 (3%) | 453 (4%) | 462 (2%) | 443 (3%) | 447 (2%) | 519 (3%) | 568 (3%) | 477 (7%) | 407 (7%) | 563 (7%) | 510 (6%) |
| Surgery | 1,248 (11%) | 1,457 (12%) | 1,259 (10%) | 1,562 (9%) | 1,251 (8%) | 1,580 (8%) | 1,040 (7%) | 1,082 (6%) | 563 (9%) | 319 (5%) | 419 (5%) | 419 (5%) |
| Hospital | 9,976 (86%) | 10,097 (82%) | 10,005 (80%) | 11,040 (62%) | 10,092 (63%) | 10,617 (54%) | 9,188 (58%) | 9,054 (53%) | 4,581 (69%) | 3,758 (56%) | 3,662 (44%) | 3,662 (45%) |
| Radiotherapy | – | 310 (3%) | – | 2,330 (13%) | – | 3,820 (19%) | – | 1,235 (7%) | 299 (5%) | 1,729 (26%) | 204 (2%) | 204 (2%) |
| Chemotherapy (1st line) | – | – | 857 (7%) | 2,347 (13%) | 4,120 (26%) | 3,278 (17%) | 2,817 (18%) | 2,817 (16%) | 691 (10%) | 494 (7%) | 1,864 (23%) | 1,864 (23%) |
| Chemotherapy (2nd line) | – | – | – | – | – | – | 2,334 (15%) | 2,334 (14%) | – | – | 1,545 (19%) | 1,545 (19%) |
| **Total** | 11,598 (100%) | 12,275 (100%) | 12,574 (100%) | 17,741 (100%) | 15,907 (100%) | 19,742 (100%) | 15,899 (100%) | 17,090 (100%) | 6,611 (100%) | 6,708 (100%) | 8,257 (100%) | 8,204 (100%) |

N.B. Numbers may not add up to the total because of rounding.

therapy. The costs of diagnosis and staging for local recurrence were once again minor in comparison, ranging between $407 and $477 per patient.

The corresponding estimated costs associated with metastatic disease were higher (about $8,200), and hospitalization represented approximately 45% of these costs. The majority of patients did not have surgery (65%), and only 9% had radiotherapy. The mainstay of treatment at metastasis was chemotherapy. Based on the Ottawa chart review, 46% received first line chemotherapy, and less than 20% of them went on to receive second line therapy. While the chemotherapy cost for second line therapy was $19,314 per person, only 8% received this treatment, and thus the weighted cost was about $1,550. The chemotherapy practice survey showed that new and/or experimental regimens, such as irinotecan, are often used, and are costly. In addition, with the emerging new effective combinations, a larger proportion of patients are being treated in today's practice.

### *Estimated lifetime costs of CRC care in Canada*

Table 3 shows the POHEM results for the individual components of the lifetime costs of providing care to 16,856 patients with CRC in 2000. It also shows that the total lifetime cost of treatment for all patients with colon and rectal cancer (stages I to IV) was over $333 million and $187 million respectively. By phase of illness, almost 80% of these costs were for initial treatment or were incurred during the terminal care phase. Initial treatment accounted for 49% of the total cost of colon cancer, followed by terminal care (28%), mainly as a result of the large amount of hospitalization in these two phases. The figures for rectal cancer were similar. The average cost per case for all stages of colon and rectal cancer was $29,110 and $34,475 respectively and ranged from a low of $20,319 for patients with stage I colon cancer to a high of $39,182 for those with stage III rectal cancer.

Figure 1 presents the cost components for all stages of colon and rectal cancer by intervention and shows that, as expected, hospitalization represented a high proportion of the total cost, at 65% and 61% of the lifetime costs of care delivery for colon and rectal cancer respectively. Since most of the cost of treatment was incurred within the first five years from the base year of 2000, discounting had little impact on the total lifetime cost of treating colorectal cancer in Canada. The corresponding total cost of treatment for colon and rectal cancer respectively was $325 million and $182 million at a 3% discount rate, and $319 million and $178 million at a 5% discount rate.

## Discussion

This article describes the lifetime cost of care for Canadian patients with a diagnosis of CRC. It is the result of collaboration between Statistics Canada, the Ottawa Regional Cancer Centre, Queen's University and Cancer Care Ontario. Estimates of the lifetime costs of lung and breast cancer have been previously reported.[12–15]

Appropriate data are crucial in performing a disease burden study. The CRC model has been developed using a number of

**TABLE 3**
**Average and total lifetime costs ($000) of disease management of colon and rectal cancer by stage at presentation and components (1998 Cdn $)**

| Site | Cost component | Stage I $ (%) | Stage II $ (%) | Stage III $ (%) | Stage IV $ (%) | Average of all stages $ (%) |
|---|---|---|---|---|---|---|
| **Colon** | Initial treatment[a] | 11,599 (57%) | 12,574 (51%) | 15,906 (53%) | 15,898 (44%) | 14,375 (49%) |
| | Well-patient follow-up | 908 (4%) | 807 (3%) | 731 (2%) | 0 (0%) | 548 (2%) |
| | Local recurrence treatment | 597 (3%) | 927 (4%) | 641 (2%) | 0 (0%) | 540 (2%) |
| | Active care | 1,376 (7%) | 2,108 (9%) | 1,548 (5%) | 0 (0%) | 1,253 (4%) |
| | Metastases treatment | 1,448 (7%) | 1,954 (8%) | 2,583 (9%) | 0 (0%) | 1,474 (5%) |
| | Active care | 1,107 (5%) | 1,573 (6%) | 2,062 (7%) | 4,750 (13%) | 2,634 (9%) |
| | Terminal care[b] | 3,283 (16%) | 4,641 (19%) | 6,662 (22%) | 15,193 (42%) | 8,285 (28%) |
| | Average lifetime cost/patient | 20,319 (100%) | 24,584 (100%) | 30,132 (100%) | 35,841 (100%) | 29,110 (100%) |
| | No. of patients | 988 (9%) | 3,966 (35%) | 2,970 (26%) | 3,506 (31%) | 11,430 (100%) |
| | Total lifetime cost for all patients | 20,075 (6%) | 97,501 (29%) | 89,492 (27%) | 125,659 (38%) | 332,726 (100%) |
| **Rectal** | Initial treatment[a] | 12,275 (45%) | 17,741 (53%) | 19,742 (50%) | 17,090 (46%) | 16,951 (49%) |
| | Well-patient follow-up | 842 (3%) | 736 (2%) | 615 (2%) | 0 (0%) | 588 (2%) |
| | Local recurrence treatment | 1,953 (7%) | 637 (2%) | 632 (2%) | 0 (0%) | 818 (2%) |
| | Active care | 3,850 (14%) | 1,232 (4%) | 1,288 (3%) | 0 (0%) | 1,619 (5%) |
| | Metastases treatment | 1,932 (7%) | 3,797 (11%) | 4,275 (11%) | 0 (0%) | 2,776 (8%) |
| | Active care | 1,222 (4%) | 2,300 (7%) | 2,602 (7%) | 4,522 (12%) | 2,555 (7%) |
| | Terminal care[b] | 5,432 (20%) | 7,324 (22%) | 10,029 (26%) | 15,327 (41%) | 9,169 (27%) |
| | Average lifetime cost/patient | 27,505 (100%) | 33,678 (100%) | 39,182 (100%) | 36,939 (100%) | 34,475 (100%) |
| | No. of patients | 1,243 (23%) | 1,592 (29%) | 1,581 (29%) | 1,010 (19%) | 5,426 (100%) |
| | Total lifetime cost for all patients | 34,189 (18%) | 53,615 (29%) | 61,947 (33%) | 37,309 (20%) | 187,060 (100%) |

[a] The POHEM simulated result for total initial treatment cost is slightly different from the total cost shown in Table 2 because of the probabilistic nature of simulation.

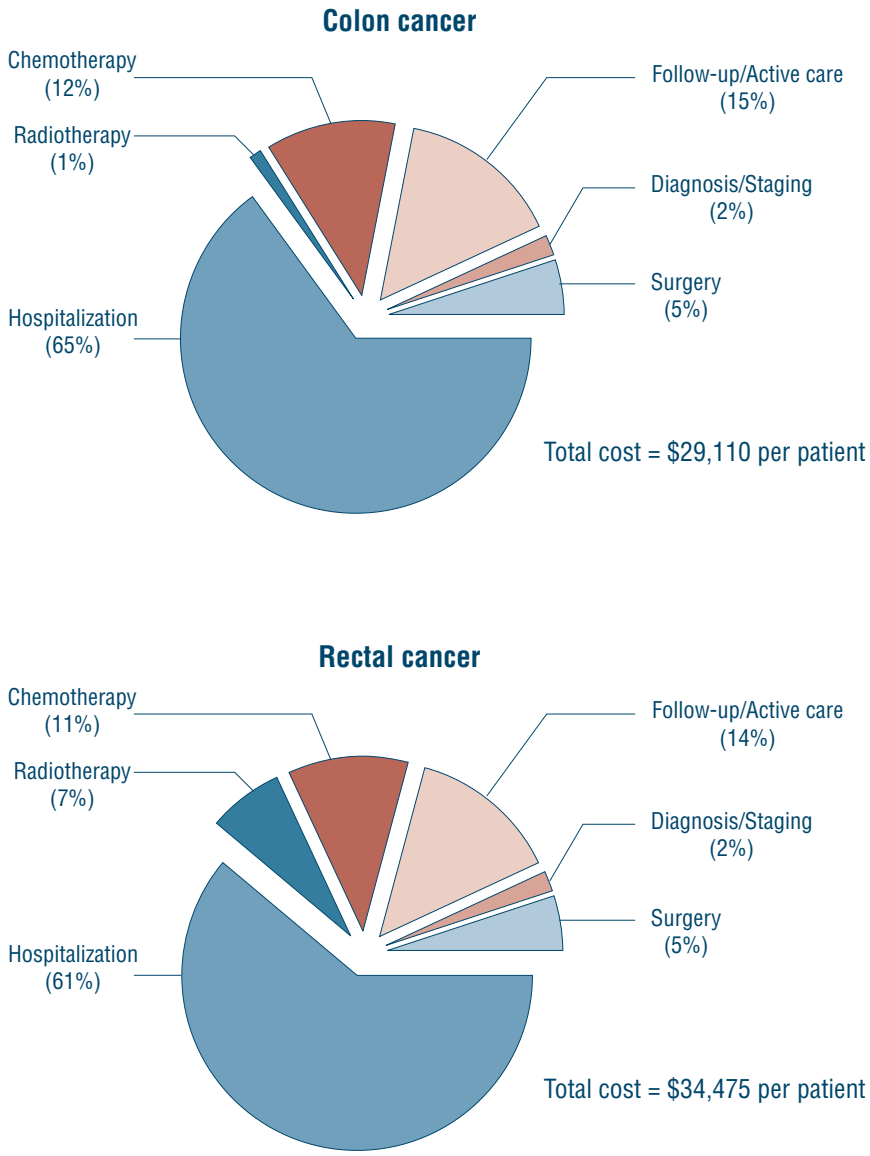
b Terminal care refers to costs in the last 3 months of life

Numbers may not add up because of rounding.

Canada-wide databases, such as Statistics Canada's person-oriented hospital discharge database and the Canadian Cancer Registry. Where national data were not available, provincial and regional data were used – for example, the Manitoba database[16] for follow-up patterns after CRC treatment and the Ottawa Chart Review for disease progression and treatment algorithms. Efforts were made to obtain the most up-to-date information. For instance, where existing data on chemotherapy became outdated because of the availability of new drugs, results from a survey of oncologists provided information on the most recent chemotherapy treatment. National initiatives to integrate data on cancer patients and to develop data definitions will hopefully facilitate future data collection.

Our results are similar to those obtained with the lung and breast cancer models. Hospitalization represented 65% and 61% of the lifetime cost of care delivery in colon and rectal cancer, as compared with 76% and 63% for lung and breast cancer. Initial treatment at diagnosis represented 49% of the costs for both colon and rectal cancer, as compared with 53% and 34% for lung and breast cancer. Similarly, terminal care represented 29% and 26% for colon and rectal cancer, as compared with 39% and 27% for the other two sites. These results highlight the importance of performing preoperative tests and staging in an ambulatory care setting, where possible, to achieve optimal cost efficiencies. Similarly, terminal care might be delivered

**FIGURE 1**
**Distribution of per patient lifetime costs of colon and rectal cancer by intervention – all stages**




more efficiently in the home environment or in palliative care units.

Chemotherapy costs have been refined to include the effects of toxicity and overhead costs. In the future, a comprehensive analysis of the cost of chemotherapy delivery should include out-of-pocket and other costs to patients and care givers. Finally, the chemotherapy costs are most likely underestimates in view of the recent development of effective agents such as irinotecan and oxaliplatin.[17] However, since the chemotherapy cost is only about 12% of the total cost of CRC treatment, this difficulty in capturing current chemotherapy practice patterns will not have a significant impact on lifetime cost.

The data from our model cannot be compared directly with data from other countries. Variation in costs may be due to differences in survivorship, treatment approaches, the nature of the health care systems and the patient populations included in the analyses[§].

We compared our results with two US studies by Taplin[18] and by Brown,[19] and our hospital costs with a study in Nova Scotia.[20] While there is agreement that the management of CRC can be divided into initial therapy, continuing care and terminal care, comparison is difficult because of the differences in the definitions of these phases. For example, in our model, initial treatment included the first three months after diagnosis, whereas both Taplin and Brown used the first six months instead. Similarly, we defined terminal care as the last three months of life, whereas Taplin and Brown defined it as six and 12 months.

Brown, using the claims payment information from the SEER-Medicare data in the US, estimated the cost during the initial, continuing and terminal phases of CRC (in $US) to be $18,100 (52.0%), $1,500 (4.3%) and $15,200 (43.7%) respectively. On the basis of enrolment during 1990 and 1991 in the Group Health Cooperative in Washington State, Taplin's estimates for colon cancer only were 52.7%, 4.6% and 42.6% of the total cost for initial, continuing and terminal care respectively. All three studies showed that initial care represented almost half the costs. However, our proportions for continuing care (24%) and terminal care (27%) varied considerably from those reported by Brown and Taplin, possibly because of the difference in definition.

The Nova Scotia study used administrative data to estimate the hospital costs incurred by a population-based cohort of CRC cases up to three years after diagnosis. The length of stay and the hospital-specific per diem rates were used as the measures of resource use. Our study used the Statistics Canada POI data, the resource intensity weight of CIHI[21] and an intensive provincial

§ Notwithstanding the cautious remark on international comparison, the Canadian costs were found to be lower than the U.S. costs. For example, although the average cost of treating patients with colon cancer as estimated by Taplin[18] was US$28,396, our Canadian estimate was CDN$29,110. We have compared colorectal cancer mortality by stage using the Ottawa Chart Review and the SEER data set from the United States to validate our survival data externally, and the result will be reported in another article in progress.

costing project[22] to estimate the hospital length of stay and per diem respectively. Similar to our findings, the cost of managing CRC in the Nova Scotia study was "significantly less for cases with local spread, highest in the six months around the time of diagnosis and in the final six months of life". However, we consider our estimates to be more realistic, as the Nova Scotia cost did not take into consideration the intensity of care provided during the hospital stay.

Overall, our study shows that the total lifetime cost of treatment for patients with colon and rectal cancer in Canada was over $333 million and $187 million respectively. Sensitivity analysis could have been conducted to examine whether the results were influenced by the estimates or assumptions used. However, given that the total cost of hospitalization, the major cost contributor to the management of CRC, was derived from a national database (POI) as well as from intensive costing projects as mentioned earlier, we felt that the data were sufficiently valid and robust.

In our study, we used the Ottawa Chart Review stage distribution of colon and rectal cancer at diagnosis, assuming that this reflected the situation across Canada. In verifying this assumption, we found that the Ottawa Chart Review distribution was comparable to that of the Manitoba database for stages I and II. However, as the Manitoba database contained more cases with missing information, the decision was made to use the Ottawa Chart Review distribution.

Regarding the survival analysis, some medical experts may consider our five-year survival of 65% for stage III colon cancer to be too high. This result may be due to the small sample and the specific patient characteristics of the Ottawa Chart Review. We do not think that it has a significant impact on the overall lifetime cost estimation. In a sensitivity analysis, we used rectal stage III as a substitute for colon stage III to arrive at a more acceptable survivorship. The overall cost implication of such a change is a mere 3% in the total lifetime cost of treating CRC.

The weighted average costs associated with the diagnosis, staging and initial treatment of CRC showed a gradient of increasing costs for stages I, II and III as well as higher costs for rectal cancer. This was due to an increased use of new and expensive chemotherapy for the more advanced stages as well as the use of radiotherapy for stages II and III rectal cancer. Hospitalization costs, while a major contributor to the total cost, were similar across most stages. For rectal cancer, costs associated with stage IV cancer were lower than those associated with stage III, because of the lower surgical rate and the lower use of radiotherapy.

Finally, the study was carried out from the perspective of the health care system and therefore incorporated only the direct costs associated with CRC management. It did not consider the costs of other comorbidities and did not include additional costs, such as lost productivity or wages, the costs of home care, prostheses, travel and accommodation, or the costs of caregivers in the home.

In conclusion, disease costing models such as the POHEM CRC model are important policy-relevant tools to assist in resource allocation. This model can guide the analysis of initiatives to optimize the costs of caring for patients with CRC and the evaluation of new management strategies for colon and rectal cancer. It has recently been used to assess the cost-effectiveness of a potential population-based screening program in Canada (see the article by Flanagan, Le Petit, Berthelot et al. in this issue).

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## APPENDIX A
## Summary of major data sources[a]

| Code | Data source | Description |
|---|---|---|
| 1 | Canadian Cancer Registry, 1995 | Contains Canada-wide data on the incidence of cancer and is maintained by the Health Statistics Division of Statistics Canada (see Statistics Canada[8]) |
| 2 | 1995 population estimates | Estimates of the Canadian population routinely derived by the Demography Division of Statistics Canada (see Statistics Canada[9]) |
| 3 | Ottawa Chart Review – 1991-92 | A retrospective chart review of 700 charts of patients with a diagnosis of colon and rectal cancer in 1991 and 1992 in the Ottawa hospital system |
| 4 | Manitoba Medical Services Foundation and Manitoba Cancer Treatment and Research Foundation (MCTRF) – 1990 | The Manitoba database is a uniquely linked database set up by the Manitoba Cancer Treatment and Research Foundation and the Manitoba Medical Services Foundation. It contains all cases of various cancers, including colorectal cancer diagnosed in 1990 and all their contacts with the Manitoba health care system (see Sloan[16]) |
| 5 | Survey of oncologists – 1998 | This Canada-wide survey of oncologists was conducted in 1998 to determine current chemotherapy practice patterns for patients with stages II and III and metastatic colon and rectal cancer. The target population of the survey was physicians who treated CRC. The membership lists of the Canadian Oncology Society and the Canadian Association of Medical Radiation Oncologists were used (1,165 physicians) as our sampling frame, regardless of whether they treated CRC (see Ng[6]) |
| 6 | National Person-oriented Database of Hospital Discharges – 1998 | This database of hospital discharges maintained by Statistics Canada contains person-oriented information (POI) that includes hospital separations from April 1995 to March 1997 (see Statistics Canada[7]) |
| 7 | Study by Earle and Grunfeld[b] | Empirical derivation of the standards of care for the follow-up of well patients with colorectal cancer after potentially curative treatment |
| 8 | Ontario Health Insurance Plan (OHIP) – 1998 | The Ontario Fee Schedule of benefits paid by the Ontario Ministry of Health, under the *Health Insurance Act*, 1998 (see Ontario Ministry of Health[11]) |
| 9 | Study by Earle et al., 1997[23] | Estimation of the cost of radiotherapy at an Ontario regional cancer centre |
| 10 | Chemotherapy costs study – ongoing | Chemotherapy costs – drug administration and facility overhead costs estimated by Dr. Maroun of the Ottawa Regional Cancer Centre in 1998 in an on-going collaboration with Dr. Hugh Walker of Queen's University. |
| 11 | National Surgical Adjuvant Breast and Bowel Project (NSABP) | Reports on the clinical investigation of adjuvant treatment of breast and colorectal cancer conducted in the U.S. and in Canada |
| 12 | The Resource Intensity Weights study – 1996 | Conducted by the Canadian Institute of Health Informíation on the cost of surgery-related hospital resource utilization by case mix grouping (see CIHI, 1996) |
| 13 | Ontario Case Cost Project – 1998 | This project uses standardized methodology to collect patient-level data to examine the cost incurred in 13 Ontario hospitals between 1996 and 1997 (see OCCP[21]) |

[a] Most data sources referred to in the article are already included in the references.

[b] Earle C, Grunfeld E, Coyle D, et al. Empirically derived standards of care for the follow-up of colorectal cancer patients after potentially curative treatment: practices attitudes and costs. Submitted to *Cancer Prevention and Control*.

## APPENDIX B
## List of main data requirements and sources

| Data required | Data sources (see Appendix A for dataset code) |
|---|---|
| **Disease epidemiology** | |
| Incidence of colon and rectal cancer | 1 |
| Population count | 2 |
| Stage at diagnosis | 3 |
| **Clinical information** | |
| Standard diagnostic work-up[a] | 3, 4[b] |
| Therapeutic algorithms at initial diagnosis | |
| Surgery | 3 |
| Chemotherapy | 5 |
| Radiotherapy | 4, 5 |
| Hospital length of stay | 6 |
| Follow-up after initial treatment[c] | 4, 7 |
| Diagnosis of disease at recurrence | 3 |
| Treatment algorithms at recurrence | |
| Surgery | 3 |
| Chemotherapy | 3 |
| Radiotherapy | 3 |
| Diagnosis of disease at metastasis | 3 |
| Treatment algorithms at metastasis | |
| Surgery | 3 |
| Chemotherapy | 5 |
| Radiotherapy | 3 |
| Active and terminal care | 3, 4, 6 |
| Survival data | 3 |
| **Cost assessment** | |
| Fees for physicians' services, diagnostic and surgical tests and procedures | 8 |
| Radiotherapy costs | 9 |
| Chemotherapy costs – drugs and administration | 10, 11 |
| Hospital per diem rates by case mix groups | 12 |
| Hospital per diem rate for active and terminal care | 13 |
| Monthly costs of active care | 4, 13 |
| Terminal care costs | 4, 13 |

[a] For the frequency and type of utilization of diagnostic procedures for each period, the average of the Ottawa Chart Review and Manitoba database results were used.

[b] The cost of the fecal occult blood test was obtained from MDS Nordion, a biomedical company based in Ottawa, Ontario.

[c] Well-patient follow-up pattern was not captured in the Ottawa Chart Review. It was derived from a Manitoba database that contains three years of follow-up data. This was supplemented by a survey of oncologists on their management of stage III colorectal cancer patients, which contained information on five-year patterns.

## APPENDIX C
### Main components of disease management for cost evaluation

| Components of disease management | Specific elements of disease management |
|---|---|
| Diagnostic assessment | Family physician assessment and re-assessment, gastrointestinal consultation |
| | Diagnostic procedures such as colonoscopy, proctosigmoidoscopy, biopsy and stool examination for occult blood |
| Staging | Biochemistry tests, complete blood counts, computed tomography (CT) scan and chest radiography |
| Surgery | Preoperative: surgical consultation, anesthesia consultation, electrocardiography, blood work |
| | Surgery: surgical procedure, surgical assistant, anesthetist |
| Hospitalization | In-hospital physician assessment<br>Per-diem cost |
| Chemotherapy | Drug delivery costs: drugs, nursing, pharmacy |
| | Chemotherapy Treatment Unit personnel costs: nursing, pharmacy, other clerical |
| | Space and administration overhead: ambulatory facility, lodge utilization |
| Radiotherapy | Consultation, partial assessment |
| | Treatment: dose and fractions, complete blood count |
| | Boost: dose and fractions, partial assessment, complete blood count |
| Follow-up | Physician assessments, complete blood count, biochemistry tests, abdominal ultrasound and CT scan as well as specific procedures such as colonoscopy or stool examination for occult blood. |
| Active care | Hospitalization, inpatient and outpatient medical services, and treatment with radiotherapy or chemotherapy |
| Terminal care | Same as active care |

# Which cancer clinical trials should be considered for economic evaluation? Selection criteria from the National Cancer Institute of Canada's Working Group on Economic Analysis

*William K Evans, Douglas Coyle, Amiram Gafni, Hugh Walker and the National Cancer Institute of Canada Clinical Trials Group Working Group on Economic Analysis*

## Abstract

*Rising health care costs, expensive new health care technologies and increasing patient expectations are placing huge pressures on the publicly funded health care system in Canada. As a result, policy makers need information on the cost and cost-effectiveness of new therapies in addition to their clinical benefits. In response to this need, the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) established a Working Group on Economic Analysis (WGEA) to provide advice on the economic evaluation of new cancer therapies. This article describes the WGEA's recommendations on which trials should be considered for concurrent analysis of economic, as well as related issues, such as the number of patients required for an economic analysis within a prospective clinical trial and the selection of participating centres. The recommendations in this document are meant to be pragmatic, as the WGEA recognizes that both the research funds and human resource capacity for this type of research in Canada are limited. These recommendations are currently guiding priority setting with regard to trials for economic evaluation in NCIC trials. Examples of how these recommendations have been applied to actual trials are presented.*

***Key Words:*** *clinical trials; cost; economic evaluation*

## Introduction

Rising health care costs, expensive new health care technologies and rising patient expectations are all creating pressure on provincial governments, as the principal payer in the Canadian universal access health care system.[1] Cancer contributes significantly to this health care burden, and its impact can be expected to increase as the population ages and as new diagnostic and therapeutic approaches emerge. In 1998, the economic burden of cancer care in Canada was estimated to be $14.2 billion, direct costs accounting for $2.46 billion and indirect costs for $11.76 billion.[2]

Decision-makers within government and agencies managing health care resources increasingly need information on the cost as well as the benefits of new interventions. However, there have been relatively few economic analyses of medical interventions to assist decision-makers in allocating resources for cancer treatments or any other health care interventions.[3–5] In 1998, the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) established a Working Group on Economic Analysis (WGEA) in response to the need to provide economic data on new cancer therapies. This article describes the WGEA's recommendations on which trials should be considered for concurrent analysis of economic and related issues, such as the number of patients required for an economic analysis within a prospective clinical trial and the selection of participating centres. It does not attempt to describe how to conduct an economic evaluation. Readers are directed to resources such as the Guidelines for Economic Evaluation of Pharmaceuticals from the Canadian Coordinating Office for Health Technology Assessment.[6]

## The role of economic evaluations

Economic analysis may assist in the choice of one therapeutic intervention over another or help to estimate the total impact of a new therapy on a health system. For these reasons, some government regulatory bodies require economic analyses as part of new drug submissions from the

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**TABLE 1**
**Potential outcomes of an economic analysis**

| | Decreased effectiveness | Improved effectiveness |
|---|---|---|
| **Decreased cost** | Need to determine whether cost savings are worth decreased effectiveness | Cost-effective |
| **Increased cost** | Not cost-effective | Need to determine whether increased effectiveness worth increased cost |

pharmaceutical industry;[7–9] but cost is just one of a number of factors to be considered in determining the value of a new diagnostic or treatment approach. The clinical benefits of the therapy are the most important consideration and include outcomes such as improved survival, delayed tumour progression, reduced toxicity and improved quality of life. As well, the decision-maker's personal values and specific notions of equity influence the decision-making process.[10]

Economic analyses are of greatest benefit when there is a comparison of both the incremental benefit and the incremental cost. There are four possible outcomes that can occur when benefits and costs are measured concurrently (Table 1).

a) Improved outcome and decreased cost. This type of strategy is referred to as a dominant strategy and, in principle, should always be adopted.

b) Improved outcome and increased cost. There is a clinical advantage but an incremental cost over the current standard treatment.

c) Poorer outcome and decreased cost. There is a decrease in the clinical benefit but savings to the health care system.

d) Poorer outcome and increased cost. With a worse clinical outcome and increased costs, such therapies should not be adopted.

In the context of a clinical trial, resource utilization data and measures of health state preference can be collected prospectively with the same rigour as the clinical data, enabling sophisticated analyses to be done that will stand up to scientific scrutiny.

The resource utilization data (cost) and clinical outcome data can be analyzed to provide an estimate of the cost-effectiveness or cost-utility of the therapeutic intervention. For example, in a cost-effectiveness analysis, the primary outcome measure is most commonly the cost of an additional life year gained.[11] As survival differences are often small in cancer trials, measures of disease and treatment-related morbidity are important in deciding about the value of a new therapy. In a cost-utility analysis, information is collected on the health state(s) experienced by the patients during treatment, using methods such the Standard Gamble or the Time Trade Off, and is incorporated into the analysis. This provides a measure of the quality of the life gained through the treatment intervention. Cost-utility is usually expressed as the incremental cost per quality-adjusted life year gained (QALY).[12]

There is no sharp definition of what constitutes a cost-effective treatment intervention. The figure of $50,000 (US) per QALY is commonly used to describe a level of expenditure that is believed to be acceptable to society. This is based on the level of cost-effectiveness of hemodialysis when the Congress of the United States voted on its coverage under Medicare. In Canada, Laupacis et al. have suggested that less than $20,000 per QALY should be considered cost-effective and between $20,000 and 40,000 per QALY should be considered moderately cost-effective.[13] As the authors acknowledge, these boundaries are arbitrary but are felt to reflect the "gut feeling" about the cost-effectiveness of new technologies.[14]

## Factors limiting the conduct of economic evaluations

Although the inclusion of an economic evaluation alongside a clinical trial adds value, it also adds to the burden and cost of conducting the trial.[11] This burden includes the cost of collecting additional data on the resources used to provide treatment, descriptions of the quality of life, and the health state preferences of patients. Data collection may require extraction of information from source documents, interviews of patients and the use of patient diaries. In the early stages of adding economic analyses to clinical trials, clinical research assistants need to be trained and an infrastructure for data collection and analysis developed. The limited availability of research funds to support health services research and the small number of health economists interested in cancer in Canada are important limiting factors to the conduct of economic analysis alongside clinical trials.

Finally to have economic information of value from a Canadian perspective, the clinical trial must have resource utilization data on a sufficient number of Canadian patients. This requirement may become an increasingly important barrier to economic evaluations as more trials are conducted as international cooperative group studies with only a small number of Canadian patients.

In determining whether an economic analysis should be performed alongside a clinical trial, the incremental burden of performing the economic analysis must be weighed against other alternative methods of addressing the economic question. If the burden of data collection on investigators and patients is too high, this could jeopardize the recruitment of patients and affect the completeness and quality of the clinical trial data collected. For these reasons, it is necessary to have a practical approach to determining which cancer trials should have economic evaluations together with clear criteria for selecting the most appropriate clinical trials for economic evaluation.

## Selecting appropriate clinical trials for economic evaluation

Some clinical trial designs are not suitable to answer economic questions.[11] Trials must be at least partly pragmatic and relate to actual clinical practice if they are to have an economic analysis.[15] The NCIC's WGEA recommends that at least one of the following criteria be met before an economic analysis is undertaken alongside an NCIC CTG clinical trial.

1. ***The new intervention is anticipated to have only a modest therapeutic benefit in a potentially large population.***

An example of such a trial is the randomized trial of anastrozole versus tamoxifen in postmenopausal women with early breast cancer.[16] After a median follow-up of 47 months, anastrozole provided approximately a 2% ($p = 0.03$) absolute risk reduction in disease-free survival. Given the large number of patients who are potentially eligible to receive this treatment, an economic evaluation would be informative to policy makers. A large incremental cost might not justify the modest benefits.

2. ***The new therapy is potentially very costly.***

If the treatment intervention is known to be very expensive and is expected to be used frequently enough to produce a large aggregate cost, then an economic evaluation alongside a clinical trial may be helpful in determining whether the new treatment is sufficiently cost-effective to warrant adoption. An example would be the use of high dose interleukin-2 (IL-2) in patients with stage IV melanoma. The requirement for hospitalization to manage the substantial treatment-related toxic effects and the high cost of IL-2 are important cost drivers.[17] In addition, the clinical benefit is small, yielding only a low rate of tumour regression. These factors are compelling reasons for undertaking an economic analysis in a trial of IL-2 in melanoma, in order to inform a policy decision about whether to fund the intervention.

It should be noted that an economic analysis is unlikely to be required to evaluate a high-cost but infrequently used therapy. Similarly, a high-cost but highly effective treatment (the treatment cures a high proportion of patients) is unlikely to require an economic analysis.

3. ***There is a high degree of uncertainty about the economic impact of the treatment of interest.***

A new treatment may appear to produce health benefits but be associated with significant side effects or other impacts that make it uncertain whether the net economic impact is positive or negative. In this situation, the economic analysis should ideally take the form of a cost-utility study, because this is the best way to capture the impact of side effects on the economic profile of a new treatment. The evaluation of chemotherapy regimens in advanced non small-cell lung cancer is a good example. There are multiple regimens, which are comparable in terms of tumour response and overall survival but unique in their side effect profile. Patient utilities, (information on the health states experienced by the patients) captured during a comparative trial would enable the determination of the cost per QALY gained relative to the current standard.

4. ***An economic evaluation associated with equivalence trials may yield information of importance in the determination of routine practice.***

In the case of an equivalence trial, the economic evaluation has the potential to yield important information when considered from different perspectives, including that of the patient, the provider, the government or society as a whole. Side effects, ease of administration and cost then become the major parameters that guide policy development.

A recent example is the use of zoledronic acid as an alternative to pamidronate for the prevention of skeletal related events (SREs) in advanced breast cancer and multiple myeloma.[18] A clinical trial demonstrated that zoledronic acid is equivalent to pamidronate in the prevention of SREs, but zoledronic acid can be infused over 15 to 30 minutes as compared with two to four hours for pamidronate. However, zoledronic acid is approximately twice the cost of pamidronate. From the perspective of the government as payer, an economic evaluation would be of value to determine whether the increased cost of the zoledronic acid is offset by reduced treatment administration costs. An economic evaluation from the patient perspective may show reduced out-of-pocket expenses as a result of reduced parking and care provider costs. Full economic data and data collected prospectively on patient preferences would be of value to policy makers in this situation.

5. ***Economic data will assist future economic evaluations of new therapies.***

For some studies, adding an economic analysis in the form of a cost-of-illness study or estimating the cost of side effects will provide resource utilization data and cost information that can be used in future studies, including modeling studies. Resource utilization data captured in the course of conducting a trial that failed to yield a significant therapeutic benefit may still be useful for future studies.

These five criteria are now used to assess new NCIC CTG trials for the appropriateness of an economic analysis. More than one criterion may apply to a particular trial.

## When not to do economic analyses

Given the need to set priorities for the use of funds for economic analysis, it may not be worthwhile to do an economic analysis in a number of clinical circumstances, such as when an expensive therapy works very well in a small number of patients.[19] The use of cisplatin for testicular cancer is a good example. Although cisplatin was very expensive when first introduced, it greatly increased the cure rate for patients with metastatic testicular cancer. Similarly, some therapies differ in cost only marginally and have similar clinical outcomes in common diseases. An economic evaluation may also be unsuitable if the sample size in the clinical trial is not large enough to capture sufficient resource and cost variables or if the

length of clinical follow-up is inadequate for the economic evaluation. Furthermore, the primary clinical endpoints may not be suitable effectiveness measures for economic evaluation. For example, in a clinical trial of cancer therapy, local tumour control may be the primary outcome of interest. However, for an economic evaluation, length of survival would be a more appropriate outcome measure.

## Selecting the sample size for economic analysis

The sample size for a clinical trial is normally determined by the number of patients required to answer the clinical question(s). However, once the need for an economic analysis has been established, it is important to determine the required sample size for the economic component, as that sample size will determine the ability to precisely measure the economic outcomes of interest.

It is impossible to make general statements as to whether the sample size for an economic evaluation should be less than, equal to or more than the sample size for the clinical question, as this will vary from study to study. However, the following considerations go into the design of the economic component of the clinical trial.

1. For cost minimization studies, sample size relates to the ability to precisely measure the cost difference between the two therapies of interest. A quantitatively important cost difference could be determined in advance, and the necessary sample size calculated according to standard methods. However, what constitutes a quantitatively important cost difference is unclear. Furthermore, the need to demonstrate statistical significance in economic studies has been questioned, especially as it is clinical efficacy that has to be proven.[20]

2. In cost-effectiveness and cost-utility analyses, the outcome of interest is a ratio of two differences. There are no generally recognized methods for determining the statistical significance of such ratios and, again, the relevance of this practice has been questioned.[21,22] Estimating sample size calculations requires agreement on the definition of the maximum acceptable cost per outcome gained. Decision-makers have understandably shown reluctance to determine such limits.

Therefore, there are important methodological and practical difficulties in determining the sample size required when conducting an economic analysis alongside a clinical trial. To estimate sample size according to a standard frequentist approach requires estimates of the costs, benefits and the quality of life of the control therapy and the expected benefits of the new therapy. In reality, however, this information is not usually available at the time the trial is being designed and, if it were available, there might be an argument that a full economic analysis was not necessary and that a modeling study would be sufficient.[22] Recently, Bayesian approaches have been suggested for determining sample size, although they also rely on the availability of the same information on cost, benefit and quality of life.[21]

From the research perspective, the ideal situation would be to have the optimal sample size to answer both the economic and clinical questions. However, there are two specific concerns that may require the economic analysis to be based on a smaller sample size.[22]

First, there may be an additional burden on patients who participate in the economic analysis if they are required to keep diaries or complete measures of quality of life. Investigators may be hesitant to enroll some patients in studies requiring this increased level of participation.

Second, there may be an increased burden of data collection on the participating centres. To ensure that the clinical trial gets started smoothly, it may be useful to delay the implementation of data capture for the economic component of the trial until the procedures for recruitment of patients to the clinical trial are running smoothly. In a current trial of regional radiation therapy in early breast cancer conducted by the NCIC, a reduced sample size for the economic component was accepted, which allowed accrual to the economic component to be delayed until the trial was well under way.

Therefore, consideration of sample size in clinical trials with an economic analysis must balance pragmatic, ethical and scientific considerations. When the additional burden of participating in the economic study is low from the perspective of both the patient and the participating centre, the sample size should be equal to that required to answer the clinical question in the trial. When the burden of conducting the economic component of the study is of concern, sample size should relate to the degree of precision that can be obtained with a reduced sample size. Given these issues, sensitivity analyses should always be considered more important than statistical analysis.

## Selecting centres for economic analysis

It is generally assumed that there is a large variation in the costs of care between treatment centres participating in multicentre economic evaluations. The costs of goods and services (unit costs) are likely to vary from one institution to another and from one geographical location to another because of different supply contracts, salaries and other factors.[23] Variations may also arise in the resources used in the treatment of patients at centres because of different clinical practices.[24] Multicentre clinical trials are typically undertaken in order to recruit sufficient patient numbers to answer a clinically important question, and data are pooled from across centres on the assumption that the clinical effects of the intervention are generalizable to all centres in the study. It is not clear, however, whether economic data collected from a number of diverse settings with different cost structures can be pooled in the same way. Therefore, it is necessary to consider how centres are selected for cost estimation.

A common approach is to pool the efficacy and resource utilization data from all patients from all of the centres but to choose one centre to obtain the unit cost estimates. The choice of the centre is typically made on the basis of convenience. The extent to which unit costs from the one

centre are applicable to the unit costs of all participating centres (i.e., internal applicability) or to all centres where the intervention would typically take place (i.e., external applicability) is not clear and is usually ignored. For internal applicability, unit costs should ideally be obtained from all participating centres. However, the lack of standardized and credible cost information systems at most health care facilities means that this approach is not feasible. The following factors and options should be considered when selecting a sample of centres for unit cost estimation.

The first consideration is that the capture of resource utilization data has a cost associated with it. Therefore, the amount of funding available for the study will determine how many centres can be involved in the collection of the data. The second factor to be considered is the method of sampling centres for unit cost information. It could be a systematic approach (i.e., by geographical area, centre size) or a method involving random selection. This consideration may be influenced by the extent of subanalysis that is considered desirable. For example, if there is a need to describe the extent of geographical variation in costs, institutions from different geographical areas will need to be selected. A further consideration is the availability of good costing data and the ease of access to this cost information. The availability of an institutional costing framework is a powerful determinant of whether a centre is included in the sampling frame. If there is interest in reporting external applicability, a centre could be chosen that is not a participant in the study.

The choice of which centres are selected for unit cost estimation and how these centres are stratified for analysis in a multicentre trial can have a significant impact on the results of the cost analysis. There is currently not enough information to guide decisions on which sampling strategy is optimal, but the strategy is likely to vary depending on the goals(s) of the study.

## Case studies

To illustrate the application of the guidelines presented in this paper, clinical trials that have been considered by the WGEA are presented. The first of these was a large multicentre study, which compared trastuzumab and placebo taken for one or two years by women with HER-2 positive primary breast cancers who had completed adjuvant chemotherapy. Given the high acquisition cost of trastuzumab, the large number of potentially eligible patients and the long duration of use of the drug in the event of a positive trial, the impact on the Canadian health care budget was anticipated to be large. Therefore, application of the current guidelines dictated that an economic analysis be conducted alongside this clinical trial. Resource utilization data would need to be collected from large representative cancer centres throughout Canada. Unit costs would need to be obtained from one centre and sensitivity analysis used to evaluate the impact of regional variations in unit costs.

A second trial considered by the WGEA was a study involving women who had undergone mastectomy for stage II breast cancer and were at risk of recurrence because of axillary lymph node involvement. The intervention in the experimental arm of the trial was radiotherapy, and the outcome of interest was its impact on overall survival. A review of the status of the trial revealed that patient accrual was slow, and this was compromising the ability of the trial to test the primary hypothesis in a timely manner. The nature of the intervention lent itself to computer modeling techniques for the economic evaluation. In this case, the WGEA recommended that an economic evaluation alongside the clinical trial not be undertaken.

The third clinical trial that the WGEA considered for an economic evaluation was a randomized placebo-controlled trial of adjuvant therapy with ZD-1839 (Iressa®) in patients with non small-cell lung cancer (NSCLC) who had undergone a complete surgical resection. Patients were to be randomly assigned to receive one year of adjuvant ZD-1839 or placebo. The main outcomes for this trial were disease recurrence rates and overall survival. There is evidence from two Phase II trials (IDEAL 1 and 2) that ZD-1839 (250 mg/day) can palliate patients with NSCLC refractory to chemotherapy.[25,26] Since the adjuvant use of this agent in lung cancer would affect a large population and be administered for a long duration, an economic analysis to determine the incremental cost per life year gained was felt to be necessary. This economic analysis would be highly valued by health policy makers as it would allow the cost of ZD-1839 per life year gained to be compared with other anticancer therapies currently being used in Canada.

In summary, three clinical trials considered by the NCIC's WGEA have been presented to illustrate how the proposed guidelines for the selection and design of economic evaluations in association with NCIC CTG clinical trials have been applied.

## Conclusions

Economic analyses alongside NCIC CTG randomized controlled trials are of increasing importance in the face of a proliferation of new treatment approaches for cancer and concerns about the sustainability of the publicly funded health care system in Canada. Given the current availability of resources, we have suggested a practical approach to determining which trials are appropriate for economic analysis. This article also provides guidance on the issues of sample size and the selection of centres for participation in the capture of resource utilization and unit cost data. However, it does not address the practical issues that relate to the conduct of these analyses within a given trial.

Currently the NCIC CTG has established a process whereby the WGEA reviews trials brought forward from the Disease Site Groups through their liaison representatives to the WGEA. If a trial is felt to meet the criteria discussed here and the NCIC CTG approves of the scientific merit of the clinical trial, the WGEA identifies a health economist to work with the principal investigators. Together, they identify the economic endpoints of the study, independent of the clinical endpoints, and the data elements needed to undertake the economic analysis.

As concerns over budgetary restrictions in the Canadian health care system increase, the need to demonstrate the value for money of new and more costly technologies is paramount. Given this new reality,

the NCIC CTG's approach to economic evaluations and clinical trials will provide Canadian data that will help to inform decisions on the efficient allocation of scarce health resources.

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# Cause-deleted health-adjusted life expectancy of Canadians with selected chronic conditions

*Douglas G Manuel, Wei Luo, Anne-Marie Ugnat and Yang Mao*

## Abstract

*Health-adjusted life expectancy (HALE) is life expectancy weighted or adjusted for the level of health-related quality of life (HRQOL). Cause-deleted probabilities of dying were derived using the cause-eliminated life table technique and death data from vital statistics for Canada in 1998/99. Life expectancy for men and women in Canada was 76.0 and 81.5 years respectively; HALE was 67.9 years for men and 71.1 years for women. Cancer represented the greatest burden of disease in the population, and eliminating it would increase men's life expectancy to 79.6 years and women's to 85.1 years. HALE would rise to 70.7 years for men and 73.6 for women. The gain in life expectancy would be very small if osteoarthritis were eliminated, but there would be an overall gain in HALE of approximately 1.0 years for men and 2.5 years for women. HALE estimated for chronic conditions using a utility-based measure of HRQOL from population health surveys should be regarded as a valuable component of population health surveillance.*

***Key words:*** *burden of disease; health-adjusted life expectancy; health expectancy; health-related quality of life; health status; health utility index; life expectancy; morbidity*

## Introduction

In countries with high life expectancy, such as Canada, mortality is being delayed until older ages, and chronic diseases are causing illness and disability among those surviving.[1] To evaluate the likely effects of health interventions, it is important to capture two dimensions of health: quantity of life (mortality) and health-related quality of life (HRQOL) (morbidity). Summary measures of population health, which take into account both mortality and morbidity, are described as two major classes of measures: positive measures of health expectancy,[2,3] and measures of health gaps such as healthy life years[4] or disability-adjusted life years (DALYs).[5] Health expectancy, which is the focus of this study, estimates overall life expectancy or life years lived adjusted according to the amount of time spent in less than perfect health or with disability.[6]

The burden of specific conditions in a population can be estimated using either DALYs or cause-deleted health expectancy. Cause-deleted health expectancy estimates the increase in health expectancy if a specific cause did not exist in a population. It is calculated by removing both the deaths and the reduction in HRQOL attributable to a specific condition from the overall or all-cause mortality and HRQOL. The difference between cause-deleted health expectancy and current Canadian overall health expectancy is the "gap" in health resulting from the elimination of a condition – meaning that health expectancy is expressed as a health gap measure when reported as the difference between a reference (current Canadian) and potential health expectancy.

In this study, we estimate cause-deleted health-adjusted life expectancy (HALE) for a number of chronic conditions in Canada for the period 1998/99. HALE refers to a health expectancy that is estimated using a utility-based measure of HRQOL. Utility-based measures assign a utility or value to the level of HRQOL, thereby making it easier to compare conditions with different HRQOL or mortality impact. We chose to estimate cause-deleted HALE over DALYs for three reasons. First, Canada has a relatively unique opportunity to estimate cause-deleted HALE with the availability of Statistics Canada population health surveys. Since 1994, the National Population Health Survey and the more recent Canadian Community Health Surveys collect information on both self-reported chronic conditions and HRQOL. These data allow for (ongoing) prevalence-based HRQOL assessment of chronic conditions. It is uncommon for population health surveys in other countries to include a utility-based measure of HRQOL, which is needed for HALE estimation.[7]

Second, health expectancy measures, like life expectancy, are expressed in intuitive terms – years of life or health – and, therefore, are helpful in describing the burden of disease to a wide audience.

Finally, changes in health expectancy compared with life expectancy can be used to describe whether there is a "compression or expansion of morbidity". In the 1980s,

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Fries coined this term to describe this changing pattern of disease.[8] He argued that an improvement in lifestyle would not only reduce death rates but would also slow the development of chronic diseases. This delayed onset, in turn, would lead to an increase in the proportion of life lived in a healthy state, or what he called "a compression of morbidity." Other authors have not been convinced by Fries's arguments, instead taking the view that increased medical care would lead to an "expansion of morbidity" because of an increase in survival without a change in the progression towards disability among the survivors.[1,9,10]

## Methods

### Data sources

The Canadian Mortality Database was used to calculate the age-specific death rates, survival probabilities and life table estimates of life and health expectancy for the entire Canadian population in 1998/99.[11,12] Age-specific mortality estimates were calculated using adjusted Census population estimates from Statistics Canada.[13]

Data on health status and chronic conditions were derived from the 1998/99 National Population and Health Survey (NPHS 1998/99). The survey collected both cross-sectional and longitudinal data on household residents in all provinces (except people on Indian reserves, Canadian Forces bases and some remote areas in Quebec and Ontario) in 1998/99. There were two components to the interview, which was a computer-assisted telephone interview. The general component collected limited information on all members of the household who were 12 years and older; the health component, which is the component used in this study, was administered to one randomly selected member from each survey household for additional in-depth health information.

For the first cycle (1994/95), a sample of approximately 20,000 households was drawn from the Labour Force Survey sampling frame. For Cycle 3 (1998/99), this frame was used to select an additional sample of recent immigrants and young children, thus ensuring that the data represent the 1998/99 Canadian population. The overall response rate was 88.2% at the household level. The response rate for the randomly selected respondents in these households was 98.5%.[14]

**TABLE 1**
**Disease groups**

| Disease | Mortality definition: ICD9 code | Chronic condition definition: variable name from NPHS 1998/99 |
|---|---|---|
| All causes | 001–999 | |
| Ischemic heart disease | 410–414 | heart disease (ccc8_1l) |
| Stroke | 430–438 | stroke (ccc8_1o) |
| All cancers | 140–208 | cancer (ccc8_1m) |
| Lung cancer | 162 | cancer (ccc8_1m) |
| Colorectal cancer | 153, 154, 159.0 | cancer (ccc8_1m) |
| Female breast cancer | 174 | cancer (ccc8_1m) |
| Melanoma | 172 | cancer (ccc8_1m) |
| Diabetes | 250 | diabetes (ccc8_1j) |
| COPD (chronic obstructive pulmonary disease) | 490–492, 496 | chronic bronchitis or emphysema (ccc8_1h) |
| Osteoarthritis | 715 | arthritis or rheumatism (ccc8_1d) |
| Mental disorders | 290–310 | depression scale (mhc8dpp) |

### Variable definition and classification

**Defining conditions:** Disease groups for mortality statistics were defined using the ICD9 code for the most responsible underlying condition on the death certificate (see Table 1). Disease prevalence was estimated using the NPHS 1998/99 response for self-reported chronic conditions. This question asked respondents whether a health professional had ever diagnosed any of 24 chronic conditions. The presence of mental conditions was estimated using questions from the Composite International Diagnostic Interview (CIDI). Respondents were classified as having a mental condition if their CIDI score was 0.90 or higher, indicating that they had a high level of psychological distress.[15]

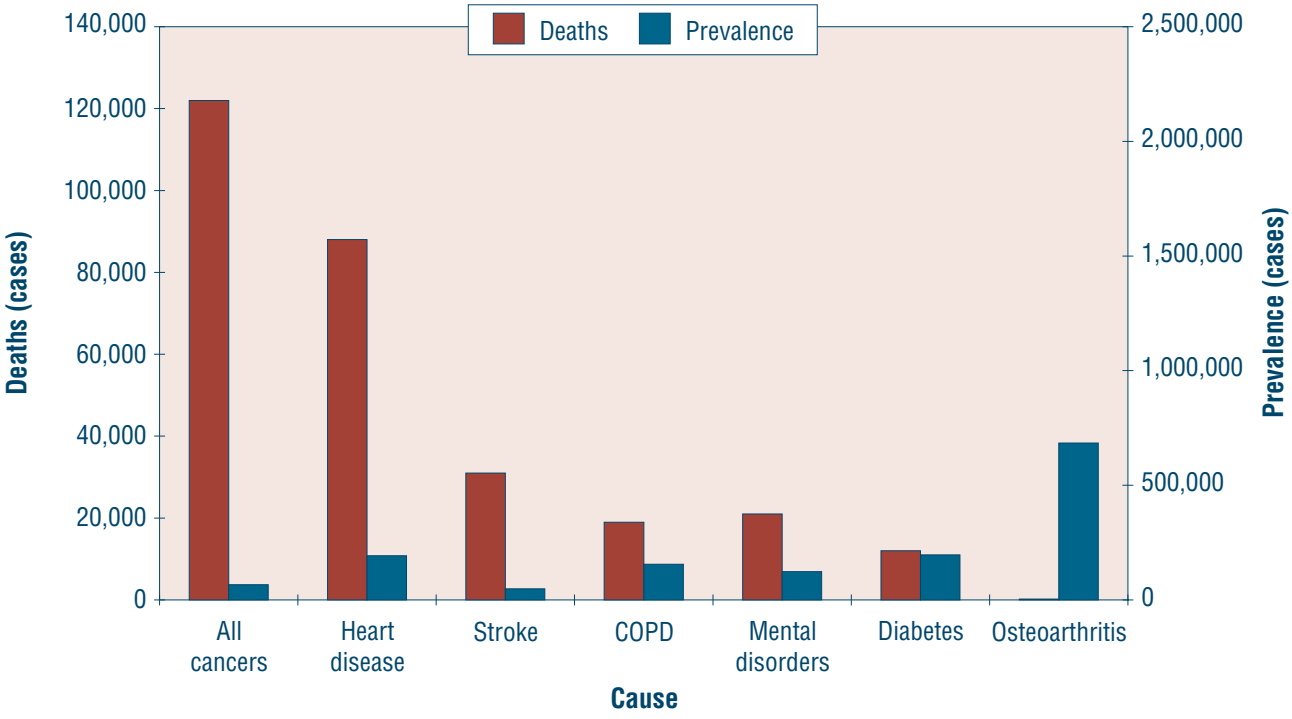
**Health-related quality of life measure (HRQOL):** The HRQOL measure used to calculate HALE in this study was the Health Utilities Index (HUI3). The HUI3 is a utility-based, multi-attribute health classification system that estimates a summary value of individual health in which 0.0 = "dead" and 1.0 = "perfect health" (states worse than death are also possible), based on preference scores for different health states.[16] Each respondent answered questions pertaining to eight attributes of functional health: vision, hearing, speech, mobility, dexterity, emotional state, cognition and level of pain and discomfort. Each attribute has from four to six possible levels, ranging from unrestricted to a highly disabled state (see Torrance[17] for a description of health states). The eight attributes were then combined using preference scores from the mark III version according to the following multi-attribute utility function, where u is a HUI3 attribute:[18,19]

$$u = 1.371 * (u1 * u2 * u3 * u4 * u5 * u6 * u7 * u8) - 0.371$$

### Analysis methods

**Life table analysis:** Chiang's[20] method was used to calculate period life tables for 1998/99 for men and women in 20 standard age groups ( < 1, 1–4, 5–9,…, 90 + years),

**FIGURE 1**
**Number of deaths and prevalence, chronic conditions, Canada 1998–1999**




**Data sources:** Health Indicators 1999, Statistics Canada; 1996-97 Ontario Health Survey

except for an adaptation for the final age group.[21] Cause-deleted life expectancy was calculated by subtracting the condition-deleted mortality rates from the overall mortality rates in the life table.[22]

HALE was calculated by means of a modified Sullivan method.[23] Sullivan used a period life table and the prevalence of disability to estimate the number of life years lived free of disability. After calculating life tables for each sex, we estimated HALE by weighting the years of life lived according to the age- and sex-specific mean HUI3 values. The cause-deleted mean HUI3 values were used to calculate cause-deleted HALE. Statistical error for life expectancy and health expectancy was calculated according to the method of Chiang and Mathers.[20,24] An example of the life tables used in this study are available in Microsoft Excel (http://www.ices.on.ca).

**Cause-deleted HRQOL estimates:** The cause-deleted methodology is based on the assumption that when a particular disease or condition is removed from the population, the pattern of morbidity and mortality in those without the disease/condition generalizes to the entire population.[25,26]

Cause-deleted mean HUI3 estimates were calculated in a manner similar to that of the cause-deleted mortality rates.[25] People with specific conditions were removed from the NPHS sample, and the mean HUI3 was estimated for each age-sex group. As the NPHS contains HUI3 scores for those over 12 years of age, the Canadian HUI3 estimates for age 12–15 were used for each of the age groups below 15 years old.

## Results

Figure 1 illustrates the number of deaths and estimated prevalence (cases) for the various conditions in Canada in 1998/99 (total population 29.5 million). As expected, cancer and ischemic heart disease were responsible for the greatest number of deaths, although the number of prevalent cases was quite low. On the other hand, arthritis had the highest number of prevalent cases but resulted in few deaths. If one were to consider only the number of people affected by a condition, arthritis would have had the greatest population health impact.

The effect of a condition on HRQOL varied from one condition to another (Table 2). For example, Canadian women reporting the effect of stroke had a mean HUI3 of 0.57, whereas for those with chronic obstructive pulmonary disease it was 0.74. The mean HUI differences for conditions were smaller after age standardization, indicating that some conditions that have a large impact on HRQOL were more common in older people.

Table 3 shows that the life expectancy for men and women in Canada was 76.0 and 81.5 years respectively, and HALE was estimated to be 67.9 years for men and 71.1 years for women. All cancers represented the greatest burden of disease in the population, and eliminating them would have increased men's life expectancy to 79.6 from 76.0 years and women's to 85.1 from 81.5 years. HALE would rise to 70.7 years for men and 73.6 years for women. Eliminating ischemic heart disease had

**TABLE 2**
**Mean HUI3 by condition and sex, adjusted and unadjusted**

| Condition | Sex | Number (unweighted) | Mean HUI3 (unadjusted) | Mean HUI3 (age-adjusted*) (95% CI†) |
|---|---|---|---|---|
| All causes | F | 5,612 | 0.85 | 0.89 (0.80, 0.98) |
| | M | 4,549 | 0.87 | 0.89 (0.82, 0.96) |
| All others | F | 3,041 | 0.91 | 0.90 (0.83, 0.97) |
| | M | 2,438 | 0.92 | 0.89 (0.82, 0.96) |
| Ischemic heart disease | F | 397 | 0.71 | 0.83 (0.76, 0.90) |
| | M | 365 | 0.75 | 0.89 (0.82, 0.97) |
| Stroke | F | 101 | 0.57 | 0.80 (0.74, 0.87) |
| | M | 83 | 0.47 | 0.69 (0.63, 0.76) |
| All cancers | F | 151 | 0.76 | 0.89 (0.82, 0.96) |
| | M | 102 | 0.70 | 0.75 (0.68, 0.81) |
| Diabetes | F | 308 | 0.73 | 0.87 (0.80, 0.94) |
| | M | 284 | 0.76 | 0.89 (0.81, 0.95) |
| COPD (chronic obstructive pulmonary disease) | F | 285 | 0.74 | 0.82 (0.75, 0.89) |
| | M | 176 | 0.75 | 0.79 (0.73, 0.86) |
| Osteoarthritis | F | 1,855 | 0.75 | 0.84 (0.78, 0.91) |
| | M | 900 | 0.75 | 0.81 (0.74, 0.88) |
| Mental disorders | F | 457 | 0.70 | 0.80 (0.73, 0.87) |
| | M | 201 | 0.76 | 0.85 (0.78, 0.92) |

* Standardized to the 1996 Canadian population using the direct method.
† 95% CI = 95% confidence interval

a similar effect on life expectancy but resulted in smaller gains in HALE compared with cancer.

In Figure 2, the gain in life expectancy and HALE from the elimination of the various conditions is compared. This figure also provides a useful illustration of the compression or expansion of morbidity. Expansion of morbidity is evident when the years of HALE gained were less than the years of life expectancy gained, as in the case of cancer and heart disease. Compression of morbidity refers to a situation in which the proportion of life in less than perfect health decreases, or when the HALE gained is greater than the life expectancy gained. This was the case with osteoarthritis and mental conditions, for which the gain in life expectancy if these conditions were eliminated would be very small, but there would be an overall gain in HALE.

## Discussion

This study used cause-deleted HALE to estimate the burden of disease from a number of chronic conditions through the use of a general population health survey, which contained questions on both a utility-based health status index and the presence of chronic conditions.

As with previous studies, heart disease and cancer have the greatest impact on HALE because of the high death rates associated with them.[4,6,25,27,28] However, eliminating cancer would result in an expansion of morbidity. The cause-deleted approach assumes that the people surviving after a disease is eliminated will have the same health as the rest of the population. This may not be the case, depending on the approach taken to reduce the burden of disease. Reducing disease burden through prevention is thought to have a larger impact on HRQOL than on life expectancy because it will delay the onset of disabling disease.[8] Since the outcome of current medical therapy is often improved HRQOL, secondary and tertiary care may also improve HRQOL more than life expectancy, resulting in a compression of morbidity for conditions such as ischemic heart disease and cancer. Evidence in Canada suggests that there has been a compression of morbidity in recent years.[6,29]

There are different methods of estimating the burden of health of chronic conditions using summary measures of population health (SMPH), most broadly defined as either DALYs or cause-deleted health expectancy. Deciding which method to use depends on the conceptual purpose of measuring disease burden and the sources of data that are available for their calculation.[30,31] Since Canada has the data sources necessary for estimating both types of measure, it is worth highlighting important method differences and relatively unique Canadian opportunities. Most importantly, DALYs are generally described as incidence-based measures of HRQOL impact, as compared with a prevalence-based method that is most commonly used in health expectancy measures.

Incidence- and prevalence-based indicators measure different things, and which is more appropriate to use depends on the application. Incidence measures are generally regarded as useful for monitoring the trends of disease occurrence and, therefore, measure the progress towards disease prevention. Health expectancy measures the current impact of disease, which in turn is the combined influence of mortality and either past incidence and duration or current prevalence of disease conditions. Therefore, HALE, using Canadian population health surveys and mortality data, estimates the current overall impact of conditions on health, and cause-deleted HALE estimates the long-term consequence of eliminating or reducing specific conditions.

DALYs typically use information for estimating condition incidence and HRQOL impact from different sources. If a broad definition of a condition is used to estimate incidence but a narrower (typically more

**TABLE 3**
**Cause-deleted life and health expectancy by disease group and sex**

| | Cause-deleted life expectancy (LE) (years) | | | | Cause-deleted health-adjusted life expectancy (HALE) (years) | | | |
|---|---|---|---|---|---|---|---|---|
| | Male | | Female | | Male | | Female | |
| | | 95% CI* | | 95% CI* | | 95% CI* | | 95% CI* |
| Overall (no cause eliminated) | 76.0 | | 81.5 | | 67.9 | | 71.1 | |
| All cancers | 79.6 | 79.6, 79.7 | 85.1 | 85.0, 85.1 | 70.7 | 70.3, 71.1 | 73.6 | 73.3, 74.0 |
| Ischemic heart disease | 78.4 | 78.3, 78.4 | 83.3 | 83.3, 83.4 | 70.1 | 69.7, 70.5 | 72.6 | 72.3, 73.0 |
| Lung cancer | 77.0 | 77.0, 77.1 | 82.2 | 82.2, 82.3 | 68.8 | 68.5, 69.1 | 71.7 | 71.4, 72.0 |
| Female breast cancer | | | 82.1 | 82.0, 82.1 | | | 71.6 | 71.2, 71.9 |
| Stroke | 76.5 | 76.5, 76.6 | 82.3 | 82.2, 82.3 | 68.6 | 68.3, 69.0 | 71.8 | 71.0, 72.2 |
| Chronic obstructive pulmonary disease | 76.4 | 76.4, 76.5 | 81.8 | 81.8, 81.9 | 68.4 | 68.1, 68.8 | 71.6 | 71.3, 71.9 |
| Colorectal cancer | 76.4 | 76.3, 76.4 | 81.9 | 81.8, 81.9 | 68.3 | 68.0, 68.6 | 71.4 | 71.1, 71.7 |
| Diabetes | 76.3 | 76.2, 76.3 | 81.8 | 81.7, 81.8 | 68.4 | 68.0, 68.7 | 71.5 | 71.2, 71.9 |
| Melanoma | 76.1 | 76.0, 76.1 | 81.5 | 81.5, 81.6 | 68.1 | 67.7, 68.4 | 71.2 | 70.8, 71.5 |
| Osteoarthritis | 76.0 | 76.0, 76.1 | 81.5 | 81.4, 81.5 | 68.9 | 68.5, 69.2 | 73.5 | 73.2, 73.8 |
| Mental disorders | 76.7 | 76.6, 76.8 | 81.9 | 81.9, 81.9 | 68.8 | 68.5, 69.1 | 72.2 | 71.9, 72.5 |

* 95% CI = 95% confidence interval

severe) definition is used to estimate HRQOL impact, combining the two estimates would result in an overestimate of disease impact. In addition, HRQOL impact is usually approximated through a process of expert and lay panels that review different sources of epidemiologic evidence.

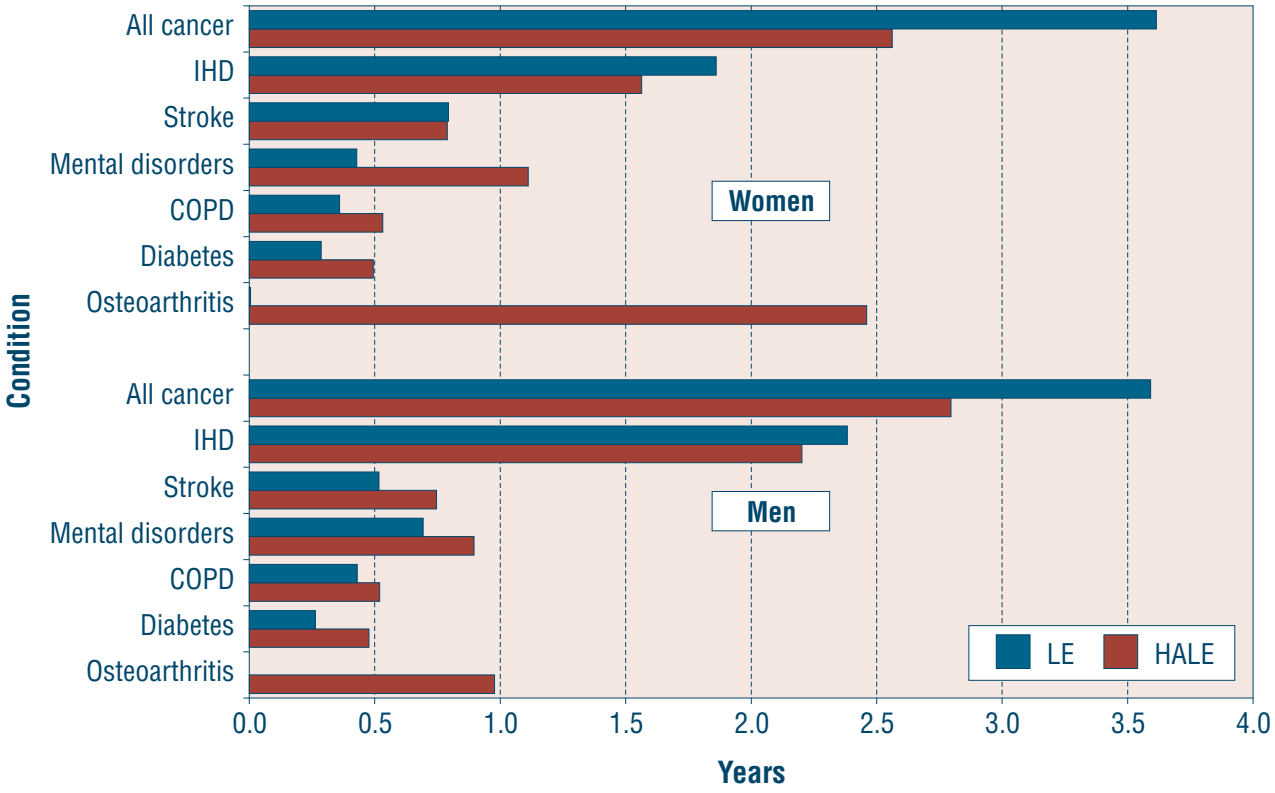
Population health surveys can be used to estimate the current Canadian HRQOL impact and the prevalence of different chronic conditions, reflecting the same definition of the condition for prevalence and HRQOL assessment without the need for other epidemiologic evidence or a panel ranking process. As an example of the benefit of using Canadian data, consider what would happen to HRQOL burden if a new medication that dramatically improved pain and mobility were to be widely introduced into Canada for the treatment of older patients with osteoarthritis. The ongoing Canadian Community Health Surveys and the National Population Health Surveys would capture the current improvement. The DALY method, as commonly derived, would require further epidemiologic methods and expert opinion to readjust disability weights and the incidence in different populations of disease severity to reassess disease burden. Without adjusting disability weights or severity levels for different ages, the DALY method may not appropriately adjust for the HRQOL effect of the medication introduction in older people. As there are many factors that affect disease burden (such as socioeconomic conditions, physical and social environment, medical therapies, health risk behaviour) in different populations it would seem improbable that the current DALY approach could reflect the actual disease burden in any one population.

Canada's population health surveys have several additional benefits. Measures of HRQOL can be combined with other survey components, such as sociodemographic and behavioural characteristics, to estimate HALE based on different factors. The NPHS has used this approach to estimate health expectancy based on socioeconomic and smoking status together with other factors.[32] The population health surveys allow for adjustment of comorbidity (defined as the effect of a person's HRQOL as influenced by other chronic conditions).

The methodology of many studies, particularly those using dichotomous measures of disability and the WHO DALY method, assumes that eliminating a condition results in a non-disabled state (perfect health) regardless of age.[25,27,28,33,34] We controlled for comorbidity by assuming that elimination of a condition would result in HRQOL equal to that of people of the same age without the condition. However, it is important to note that in our study we assumed that the HRQOL level of people reporting a condition was attributable only to that condition, even if a person had more than one chronic condition. This means that our estimates were not mutually exclusive between conditions, although it was possible to adjust for comorbidity aris-

**FIGURE 2**

**Gains in life expectancy (LE) and health-adjusted life expectancy (HALE) after eliminating conditions, Canada, 1998–1999**




ing from multiple conditions, as other studies have, since the NPHS captured information on the presence of multiple chronic conditions.[6,32] In the same manner, the recent addition of routinely recording multiple causes of death in vital statistics will allow different approaches to adjust for comorbidity or defining the cause of death in the mortality component of SMPH.[35]

Schultz and Kopec have shown that comorbid conditions are common at older ages and, therefore, influence HUI3 estimates, although the rank order of HUI3 level does not change between conditions if comorbidity is considered.[36] This means that gains in cause-deleted HALE (and, potentially, cause-deleted life expectancy) would be smaller if comorbidity were considered, but the rank order of disease burden would likely not change.

Increasingly, Canada's health surveys should not be considered as isolated sources of health data but, rather, as a family of cross-sectional and longitudinal surveys that can be linked by individual respondent to other sources of data. Repeated cross-sectional samples allow for the surveillance of health expectancy measures over time. Longitudinal surveys facilitate the assessment of disease incidence and/or the development of hybrid summary measures of population that consider both disease incidence and prevalence.[37] Similarly, the large selection of HRQOL measures in the health surveys can be used in the development of weights for Canadian DALY disability estimates.

There are several important limitations to our study. Reliance on respondents' self report in health interviews that contain either an open-ended question or a checklist of chronic conditions may bias results. Compared with medical examinations and disease registries, self reports often underreport chronic conditions.[38–41] However, since the survey can be directly linked to disease registries and health care data, reporting bias can be overcame by ascertaining condition status (incidence or prevalence) using these alternative sources of information. This approach was used to estimate HALE and cause-deleted HALE for people with diabetes in Ontario.[42]

An additional important limitation of the study was the exclusion of people in institutions. Berthelot et al. have shown that this population would reduce population HRQOL utility estimates by up to 30% for women in the oldest age groups.[43] On the basis of their findings, the overall HALE estimates would be about 0.6 to 0.8 years lower if institutionalized people were included (calculations not shown). The bias resulting from excluding this population may be appreciably higher for conditions such as stroke, which are overrepresented in institutions.

## Conclusions

Population health surveys with a utility-based health status measure should be regarded as a valuable component of population health surveillance, as they can describe the incremental differences in

HRQOL between conditions using fewer assumptions about the relation with age, sex or level of severity. As such, these surveys are well suited to describe the health status of a population for selected conditions – a product of all the health influences of that disease, from health promotion to palliation. The greatest limitation of health surveys for this purpose is the inherent difficulty in estimating disease prevalence based on self report. Opportunities exist to overcome this limitation by linking population health surveys with other health data better suited to estimate the prevalence/incidence of several conditions. These data sources introduce a number of other applications for improved and expanded surveillance of the burden of conditions in different populations.

## Acknowledgements

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# Geographic variation in health services use in Nova Scotia

*Paul J Veugelers, Alexandra M Yip and David C Elliott*

## Abstract

*To further our understanding of factors underlying geographic variation in health and the potential role of availability of and access to health services, we sought to quantify the geographic variation in health services use in the province of Nova Scotia. For the period 1996 to 1999 we examined the variation in the use of health services across 64 geographic areas in conjunction with health and socio-economic factors, using multilevel methods and empirical Bayesian estimates based on provincial physician billings and hospital separation records. We revealed moderate geographic variation in the use of family physician services and large variation in specialist and hospital services. In the two urban centres, Metropolitan Halifax and the Cape Breton Regional Municipality, use of specialist services was respectively 26.24% and 15.59% higher than the provincial average, and use of hospital services was respectively 21.55% and 37.67% higher. Geographic areas in which residents had better health were characterized by more use of family physician services and reduced use of specialist and hospital services. These associations seem to support policy strategies that aim to improve health and to reduce health care costs by investing in prevention and primary health care, and they highlight the potential implications of the shortage of family physicians across Canada.*

***Key words:*** *compression of morbidity; health policy; health services accessibility; life expectancy; medically underserved area; multilevel analysis; socioeconomic factors*

## Introduction

Nova Scotia shows geographic variation in the health status of its residents, as evidenced by differences in local life expectancy and primary underlying causes of death in communities across the province.[1] This variation in health may result from differences in age, socio-economic status, lifestyle behaviours such as smoking and diet, and the delivery of appropriate preventive and curative health services.[2–8]

Universal health care coverage has been implemented to ensure delivery of services on the basis of need rather than ability to pay and, in so doing, implicitly recognizes individuals' differential need for health care based on differences in their health status. While differential need for care would be expected to drive differential use of such care, remaining inequities in availability and access to appropriate health services may also contribute to disparities in health and even further augment existing inequities.[8]

A socio-economic gradient in health, whereby wealthier, more highly educated individuals and groups experience better health has been widely demonstrated. It has also been shown that, even where health care coverage exists, there are socio-economic disparities in the amount and type of health care used.[6,8,9–11] For example, socio-economically disadvantaged individuals are more likely to use emergency room services for conditions that could be addressed by a primary care physician during regular office hours.[10,12] People of higher socio-economic status use specialist physician services disproportionately to their need, demonstrating a possible referral bias by primary care physicians or such patients' ability to better negotiate the health care system.[6,11] Clearly, differential access to and differential availability of health services may affect the health of individuals and contribute to geographic variation in health.

In order to further our understanding of factors underlying geographic variation in health and the potential role of availability of and access to health services, we sought to quantify the geographic variation in health services use in Nova Scotia.

## Methods

### Geographic definitions and measures

Nova Scotia comprises approximately 940,000 residents, 9 district health authorities, 18 counties, 52 census consolidated subdivisions, 110 census subdivisions, 1,511 federal enumeration areas and 18,864 postal codes. Census subdivisions comprise cities, towns, villages, municipal districts and subdivisions of counties.[13] A census consolidated subdivision is a grouping of census subdivisions in which the smaller, more urban census subdivisions (towns, villages, etc.) are combined with the surrounding, larger, more rural census subdivision (municipal districts and subdivisions of counties).[13] Aggregation of information at the level of census consolidated subdivision is functional, as

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rural residents often use services and mailboxes with postal codes in nearby communities and thus researchers will introduce misclassification when using geographic units smaller than census consolidated subdivisions.[14] A census consolidated subdivision is also a functional grouping to local policy makers and community health boards, which often operate on a similar geographic scale. For these reasons, we use the census consolidated subdivision as our unit of comparison in non-urban areas.

The two urban areas, Metropolitan Halifax and Cape Breton Regional Municipality, are subdivided into areas not exceeding 50,000 residents. Metropolitan Halifax was subdivided by grouping enumeration areas into 11 neighbourhoods, and the Cape Breton Regional Municipality was subdivided by grouping enumeration areas into four areas largely divided by natural borders (lakes and rivers). This brings the number of customized areas to a total of 64 with populations ranging from approximately 2,500 to 41,000 (see Appendix).

Information on health care use from 1996 to 1999 was obtained through residential postal codes of provincial administrative physician claims and hospital discharge records and was linked, on the basis of residents' postal codes, to the 64 areas. We considered all recorded physician billings, with a maximum of one per day, to estimate the number of visits to family physicians and specialists. For hospital use, we considered only inpatient hospitalizations, excluding day surgeries. We used life expectancy as a measure of local health status. Life expectancy for residents in each of the 64 geographic areas was averaged over the years 1995 to 1999 and calculated from mortality data in the provincial Vital Statistics registry and population estimates based on the Census, Statistics Canada's online statistical database (CANSIM), and Nova Scotia's Medical Services Insurance registration file (see Appendix). Average household income for each of the 64 geographic areas was calculated according to enumeration area estimates from the 1996 Canada Census.[1,8,15] For each of the 64 areas, using multilevel methods, we generated empirical Bayesian estimates for life expectancy and health care use to overcome over-dispersion, the phenomenon of unstable small area estimates resulting from varying population sizes. This methodology is described in detail elsewhere.[1]

### Statistical approaches

We depict geographic variation of health services use by means of geographic maps of the age- and sex-standardized mean number of family physician visits, specialist visits, and days in hospital, all expressed as percentage deviation from the provincial average. We further examined possible regional and urban-rural differences by using multilevel regression methods and by considering the 64 areas as co-variates (level 1) nested within regions (level 2). These regions were as follows: non-metropolitan mainland (rural), metropolitan Halifax (urban), non-metropolitan Cape Breton Island (rural) and Cape Breton Regional Municipality (urban). Next we considered the potential modulating effect of area level (level 1) confounders in the multilevel analysis of regional and urban-rural difference in health services use. In this regard, we considered both area level life expectancy and household income, as both have been demonstrated to determine health services use.[7,8] Also, both have been demonstrated to vary substantially across the 64 geographic areas,[1] area level estimates of life expectancy ranging from 76.34 years to 81.21 years (see Appendix) and average annual household income ranging from $29,112 to $60,496. In the present analyses, life expectancy was expressed as years of deviation from the provincial average and household income as increments of $10,000. All analyses were weighted by geographic population size and conducted using SAS Release 8.02 and HLM5 statistical software packages.

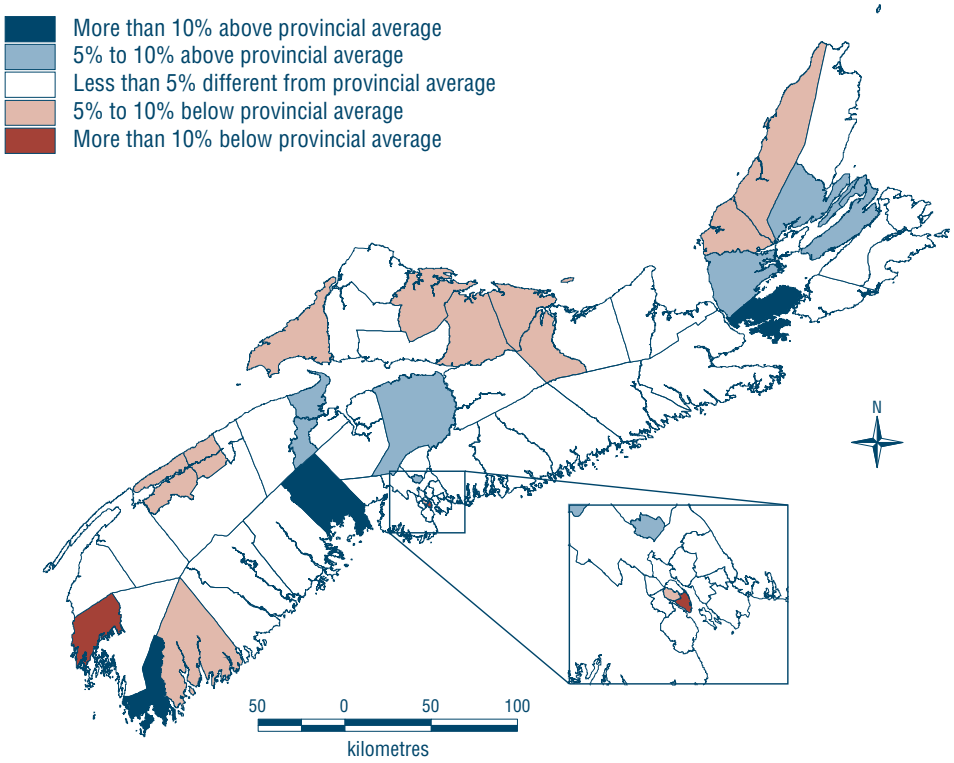
## Results

The average number of visits to family physicians between 1996 and 1999 equaled 3.83 visits and ranged from 3.12 to 4.48 visits (see Appendix). Figure 1 depicts the geographic distribution of the age- and sex-standardized number of family physician visits; areas with the lowest levels of family physician use are depicted in dark red, and those with the highest levels of use are depicted in dark blue. The age- and sex-standardized variation ranged from 18.71% below to 16.91% above the provincial average. While Figure 1 illustrates the moderate variation in the volume of family physician visits, there are no clear regional or urban-rural differences (Table 1). When region, geographic life expectancy and household income were considered simultaneously, there was a 1.08% increase (statistically significant, $p$ value of 0.04) in family physician use with each year of increase in local life expectancy, and a 0.52% decrease (not statistically significant) with each $10,000 increase in household income (Table 1).

Figure 2 is a map depicting the distribution of specialist visits. There is a clear pattern of higher use in and near the urban centres of Halifax and Cape Breton Regional Municipality (blue) and reduced use in rural areas (red). The provincial average number of specialist visits was 1.16 per person annually, and the variation was larger than that of family physician visits, ranging from averages of 0.83 to 1.52 for each of the areas (see Appendix). After standardization for age and sex, the range was from 28.20% below to 31.27% above the provincial average. The large geographic variation was also reflected in large urban-rural differences (Table 2). There was a substantial and statistically significant ($p$ value of 0.04) decrease in local use of specialist services with higher life expectancy (a 2.30% drop for each year of increase) and a positive, but weak, relation between local use and income.

The map in Figure 3 presents the distribution of hospital services use. Similar to the pattern of specialist services use, more days were spent in hospital by residents of Halifax and Cape Breton Regional Municipality as well as much of Cape Breton Island (blue), and fewer hospital days by residents in rural areas (red). Hospital use averaged 0.22 days per person annually, ranging from 0.16 to 0.35 (see Appendix). After standardization for age and sex, this large variation ranged from 27.58% below to 57.94% above the provincial average. The large variation was also reflected in large urban-rural differences (Table 3).

**FIGURE 1**
**Age- and sex-standardized number of family physician visits in Nova Scotia, 1996–1999**




There was a significant negative association between local life expectancy and hospital use (a 5.14% drop for each year of increase) and a non-significant negative relation between income and hospital use. This association between life expectancy and hospital use was not substantially different from the one presented in Table 3 if the confounding effect of household income was not controlled for. Similarly, the associations of life expectancy with family physician and with specialist services use were not substantially different when household income was not considered as a confounder.

**TABLE 1**
**Geographic variation in family physician use in Nova Scotia**

| | Unadjusted estimates | | Adjusted estimates | |
|---|---|---|---|---|
| | | *p*-value[a] | | *p*-value[a] |
| Regional differences | | >0.50 | | >0.50 |
| Non-metropolitan mainland | reference | | reference | |
| Metropolitan Halifax | 0.00% | | 0.00% | |
| Non-metropolitan Cape Breton Island | 0.00% | | +0.01% | |
| Cape Breton Regional Municipality | 0.00% | | +0.02% | |
| Life expectancy[b] | 0.88% | 0.30 | 1.08% | 0.04 |
| Household income[c] | 0.11% | 0.92 | -0.52% | 0.47 |

[a] *p*: probability that the estimated regional differences and associations with life expectancy and household income equal zero

[b] percentage increase in family physician visits with each year increase in local life expectancy

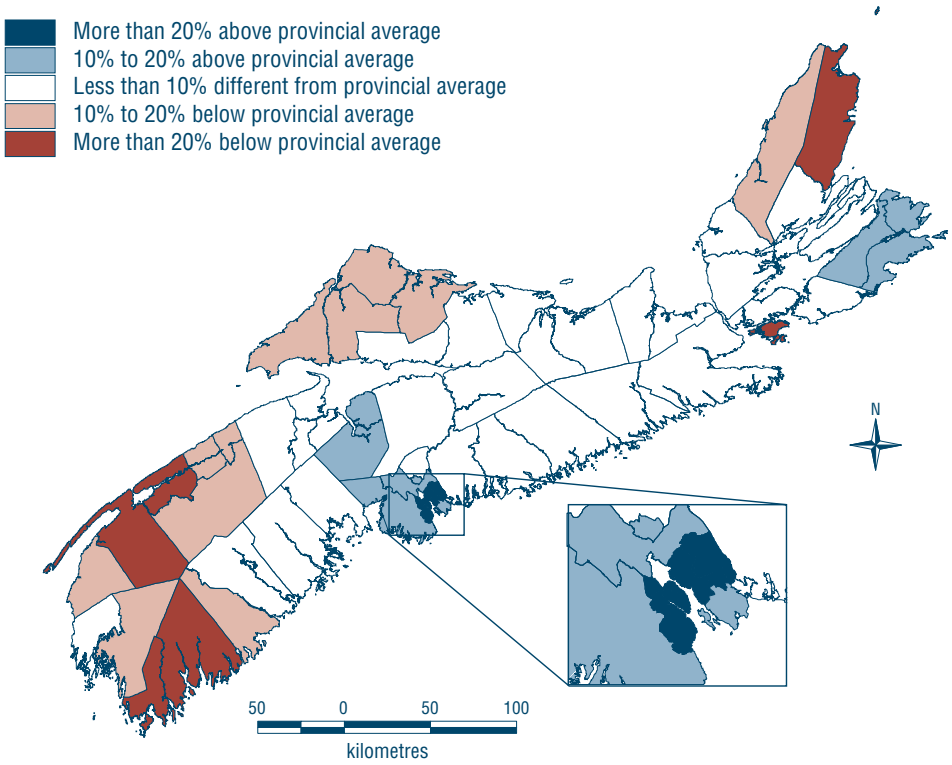
[c] percentage increase in family physician visits with each $10,000 increase in average local household income

## Discussion

This study of the geographic distribution in health services use across Nova Scotia revealed moderate, non-systematic variation in family physician services use and large geographic variation and urban-rural differences in specialist and hospital services use.

The use of specialist and hospital services was higher among residents of Metropolitan Halifax and the Cape Breton Regional Municipality, the two sites of the province's tertiary care facilities, which offer the full gamut of specialized health services. This volume of use was progressively reduced among residents of rural areas at an increasing distance from the tertiary care facilities. While the existence of this gradient is consistent with that observed in various other studies, we are

**FIGURE 2**
**Age- and sex-standardized number of specialist visits in Nova Scotia, 1996–1999**




not aware of other studies that have depicted this gradient by means of small area comparisons and on a population-based scale, making it difficult to conclude how the variation within Nova Scotia relates to that of other jurisdictions.

Nevertheless, because the observed inequities are of such high magnitude, i.e. 26% more use of specialist services in Metropolitan Halifax and 38% more use of hospital days in the Cape Breton Regional Municipality, they should receive appropriate priority among health policy makers and be the subject of further investigation. Family physician services, in contrast, are provided throughout the province, and the variation in their use appeared to be of a lesser magnitude and was without a clear geographic gradient.

**TABLE 2**
**Geographic variation in specialist services use in Nova Scotia**

| | Unadjusted estimates | | Adjusted estimates | |
|---|---|---|---|---|
| | | *p*-value[a] | | *p*-value[a] |
| Regional differences | | <0.001 | | <0.001 |
| Non-metropolitan mainland | reference | | reference | |
| Metropolitan Halifax | +27.50% | | +26.24% | |
| Non-metropolitan Cape Breton Island | -2.16% | | -3.24% | |
| Cape Breton Regional Municipality | +18.81% | | +15.59% | |
| Life expectancy[b] | -1.79% | 0.41 | -2.30% | 0.04 |
| Household income[c] | 9.81% | <0.01 | 1.45% | 0.67 |

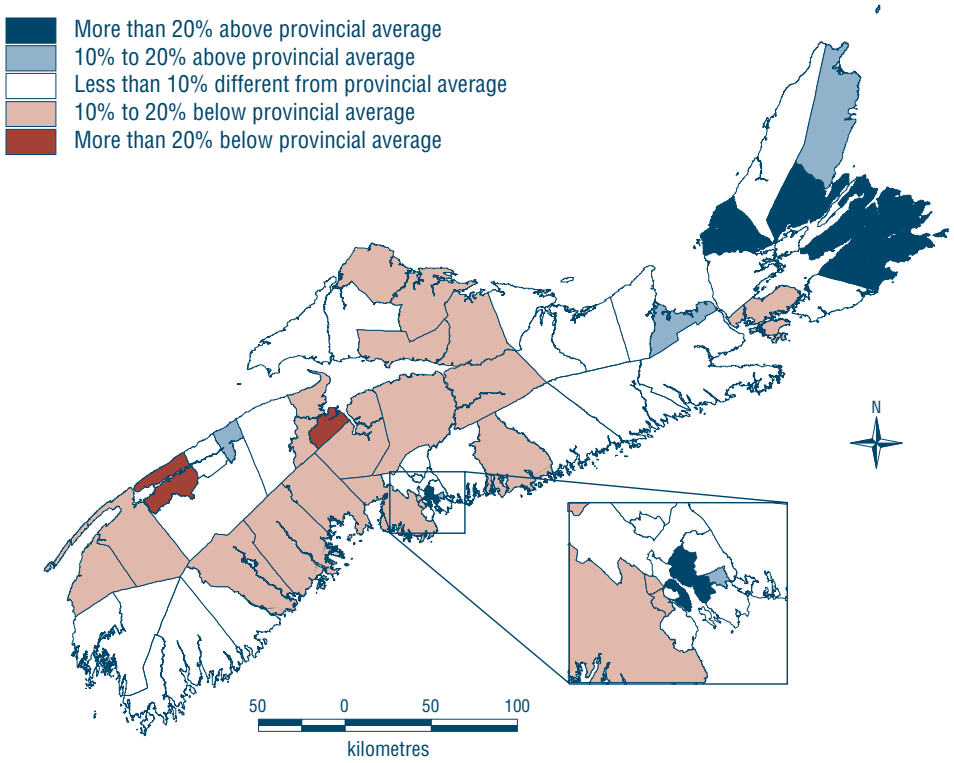
[a] *p*: probability that the estimated regional differences and associations with life expectancy and household income equal zero

[b] percentage increase in specialist visits with each year increase in local life expectancy

[c] percentage increase in specialist visits with each $10,000 increase in average local household income

Geographic areas with better health (higher life expectancy) among residents were characterized by more use of primary care physician services and reduced use of specialist and hospital services. Compression of morbidity, the phenomenon whereby prevention and risk reduction reduce individuals' disease burden,[16,17] may be acting at the community level as well: residents of areas with higher expenses for preventive and primary care services seem to experience better health, and they incur fewer expenses for specialist and hospital services. These observations also support policy strategies that aim to improve health and reduce health care costs by investing in prevention and primary health care, as was recently proposed in the report of the Romanow Com-

**FIGURE 3**
**Age- and sex-standardized number of hospital days in Nova Scotia, 1996–1999**




mission on the *Future of Health Care in Canada*.[18] The observations further underline the importance of the shortage of primary care practitioners across Canada,[19–20] potentially resulting in fewer visits relative to need and consequently increasing future expenses in terms of specialist and hospital services. In fact, this may be of particular importance to other provinces, since Nova Scotia has a more equitable distribution of primary care practitioners, in that 94% of adults report access to a regular family physician, in contrast, for example, to 76% in Quebec.[21]

**TABLE 3**
**Geographic variation in hospital services use in Nova Scotia**

| | Unadjusted estimates | | Adjusted estimates | |
|---|---|---|---|---|
| | | *p*-value[a] | | *p*-value[a] |
| Regional differences | | <0.001 | | <0.001 |
| Non-metropolitan mainland | reference | | reference | |
| Metropolitan Halifax | +16.60% | | +21.55% | |
| Non-metropolitan Cape Breton Island | +14.66% | | +12.76% | |
| Cape Breton Regional Municipality | +47.09% | | +37.67% | |
| Life expectancy[b] | -12.45% | <0.01 | -5.14% | <0.01 |
| Household income[c] | -3.25% | 0.38 | -4.39% | 0.19 |

[a] *p*: probability that the estimated regional differences and associations with life expectancy and household income equal zero

[b] percentage increase in hospital services with each year increase in local life expectancy

[c] percentage increase in hospital services with each $10,000 increase in average local household income

The present study demonstrates large urban-rural differences in the use of specialist and hospital services and no systematic urban-rural gradient in the use of family physician services. These findings, to some extent, may be the result of geographic differences in physician practice patterns. For example, the vast majority of inpatients at the tertiary care facilities in Halifax are admitted under the care of specialists, and admitting privileges for family physicians are limited to one family medicine teaching unit and primary care obstetric cases. In contrast, in many of Nova Scotia's rural community hospitals, patients are admitted under the care of their family physicians, and specialist care is provided on a consultation basis. The extent to which differences in practice patterns and access to health services affect the health of individuals should receive research priority.

We previously reported that socioeconomically advantaged individuals use relatively more specialist services.[8] We confirmed this finding in the present comparison of geographic areas (Table 2). This association, however, strongly diminished when local life expectancy was simultaneously considered, indicating that need for health services is better characterized by local health than by local socioeconomic conditions. While none of the adjusted associations between socioeconomic conditions and health services use was statistically significant, they are in keeping with findings by others: that individuals and groups of higher socioeconomic status use relatively fewer family physicians and hospital services.[6,8,11,12,22–26] Conversely, wealthier and better-educated individuals and groups tend to make more frequent use of specialist care relative to their need. This may be because of a higher referral rate by primary care physicians in combination with the patients' better ability to recognize their need and then ask for such services.[6,8,11]

This study is a continuation of work previously reported in *Chronic Diseases in Canada*,[1] in which we developed appropriate methods, such as the definition of areas that are relevant to local health policy makers and the handling of over-dispersion in small area comparisons. The previous and current studies included ecological comparisons and have consequent limitations. Previously, we reported how selective migration to nursing homes may affect geographic comparisons of health. They may similarly affect geographic comparisons of health services use, although they are unlikely to account for the large differences in specialist and hospital services. In addition, in ecological comparisons, we should also be cautious about causal directions. For example, the positive association between family physician visits and the health of communities is interpreted as a result of participation in more preventive and primary care. However, one should also consider that residents of healthier communities are relatively released from the stress of engaging in curative care and may therefore more actively seek preventive care. Such quandaries cannot be addressed in ecological studies and require further research to reveal the exact nature of the relationships. Likewise, more knowledge can be gained from small area comparisons focusing on specific services and health outcomes. In this respect, small area comparisons provide new opportunities and, if considered as an integrated part of health policy, should receive increased investment to improve the quantity and quality of geographic information.

In summary, we described the geographic distribution in health services use across Nova Scotia and revealed moderate, nonsystematic variation in family physician services use and large geographic variation and urban-rural differences in specialist and hospital services use. Healthy areas were characterized by higher use of family physician services and reduced use of specialist and hospital services.

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## APPENDIX

| No | Region | Geography | Population | Life expectancy | Average income | Family physician visits | Specialist visits | Hospital days |
|---|---|---|---|---|---|---|---|---|
| 1 | NMM | Barrington | 9,061 | 78.79 | 41,145 | 4.39 | 0.86 | 0.23 |
| 2 | NMM | Shelburne | 8,268 | 78.04 | 36,378 | 3.64 | 0.89 | 0.22 |
| 3 | NMM | Argyle | 9,155 | 79.14 | 43,497 | 3.79 | 0.98 | 0.20 |
| 4 | NMM | Yarmouth | 19,082 | 77.61 | 35,485 | 3.34 | 1.07 | 0.21 |
| 5 | NMM | Clare | 9,513 | 78.44 | 38,287 | 3.82 | 0.94 | 0.18 |
| 6 | NMM | Digby | 11,708 | 78.30 | 31,375 | 3.81 | 0.83 | 0.19 |
| 7 | NMM | Queens Subdivision A | 6,534 | 78.40 | 47,488 | 3.75 | 0.93 | 0.21 |
| 8 | NMM | Queens Subdivision B | 6,136 | 78.11 | 37,743 | 3.99 | 1.02 | 0.20 |
| 9 | NMM | Annapolis Subdivision D | 2,895 | 78.77 | 33,679 | 3.84 | 1.02 | 0.20 |
| 10 | NMM | Annapolis Subdivision A | 7,755 | 78.66 | 33,226 | 3.50 | 0.84 | 0.17 |
| 11 | NMM | Annapolis Subdivision B | 5,042 | 78.44 | 33,166 | 3.63 | 0.93 | 0.20 |
| 12 | NMM | Annapolis Subdivision C | 6,833 | 78.49 | 36,078 | 3.67 | 1.01 | 0.25 |
| 13 | NMM | Lunenburg | 37,847 | 78.70 | 37,993 | 4.12 | 1.12 | 0.19 |
| 14 | NMM | Chester | 11,117 | 78.53 | 38,002 | 4.26 | 1.26 | 0.20 |
| 15 | NMM | Kings Subdivision A | 25,094 | 78.93 | 39,064 | 3.83 | 1.10 | 0.21 |
| 16 | NMM | Kings Subdivision C | 13,705 | 78.25 | 40,420 | 4.18 | 1.23 | 0.18 |
| 17 | NMM | Kings Subdivision B | 12,003 | 81.21 | 38,293 | 4.15 | 1.17 | 0.18 |
| 18 | NMM | Kings Subdivision D | 9,416 | 79.81 | 38,306 | 4.02 | 1.18 | 0.16 |
| 19 | NMM | West Hants | 19,282 | 78.52 | 38,382 | 3.97 | 1.31 | 0.19 |
| 20 | NMM | East Hants | 21,400 | 78.58 | 42,971 | 4.12 | 1.23 | 0.20 |
| 21 | NMM | Halifax Subdivision E | 20,926 | 78.39 | 47,909 | 3.89 | 1.26 | 0.21 |
| 22 | NMM | Halifax Subdivision F | 6,505 | 79.03 | 38,850 | 3.94 | 1.16 | 0.19 |
| 23 | NMM | Halifax Subdivision G | 4,316 | 77.74 | 33,509 | 4.16 | 1.09 | 0.23 |
| 24 | MH | Sambro | 29,830 | 79.78 | 51,847 | 3.90 | 1.38 | 0.19 |
| 25 | MH | Upper Sackville | 21,568 | 79.35 | 55,604 | 3.98 | 1.27 | 0.21 |
| 26 | MH | Herring Cove | 12,341 | 77.34 | 44,092 | 4.00 | 1.45 | 0.21 |
| 27 | MH | Sackville | 25,472 | 78.94 | 49,816 | 4.08 | 1.33 | 0.23 |
| 28 | MH | Clayton Park | 24,261 | 78.63 | 49,216 | 3.67 | 1.46 | 0.20 |
| 29 | MH | Spryfield / Armdale | 19,850 | 78.13 | 43,346 | 3.82 | 1.47 | 0.20 |
| 30 | MH | Peninsula South End | 20,097 | 78.74 | 49,377 | 3.12 | 1.47 | 0.30 |

## APPENDIX *(cont'd)*

| No | Region | Geography | Population | Life expectancy | Average income | Family physician visits | Specialist visits | Hospital days |
|---|---|---|---|---|---|---|---|---|
| 31 | MH | Peninsula West End | 23,912 | 78.64 | 46,122 | 3.60 | 1.52 | 0.22 |
| 32 | MH | Peninsula North End | 17,011 | 76.77 | 33,572 | 3.81 | 1.43 | 0.30 |
| 33 | MH | Bedford | 25,719 | 80.56 | 60,946 | 3.70 | 1.35 | 0.20 |
| 34 | MH | Crichton Park Albro Lake | 23,882 | 78.24 | 34,651 | 3.97 | 1.45 | 0.27 |
| 35 | MH | Southdale Regional Woodside | 22,982 | 78.75 | 46,034 | 3.89 | 1.46 | 0.35 |
| 36 | MH | Eastern Passage Cow Bay | 18,015 | 77.38 | 58,250 | 3.88 | 1.36 | 0.24 |
| 37 | MH | Portland Estates | 24,200 | 78.38 | 53,964 | 3.87 | 1.43 | 0.26 |
| 38 | MH | Woodlawn Montebello Forest Hills | 15,292 | 79.00 | 52,783 | 3.84 | 1.40 | 0.24 |
| 39 | NMM | Colchester Subdivision C | 28,242 | 77.92 | 37,428 | 3.72 | 1.13 | 0.19 |
| 40 | NMM | Colchester Subdivision B | 18,864 | 79.09 | 40,131 | 3.56 | 1.04 | 0.19 |
| 41 | NMM | Colchester Subdivision A | 3,886 | 78.88 | 33,347 | 3.72 | 1.09 | 0.19 |
| 42 | NMM | Cumberland Subdivision A | 4,449 | 78.59 | 29,120 | 3.49 | 0.98 | 0.21 |
| 43 | NMM | Cumberland Subdivision B | 8,582 | 78.77 | 31,621 | 3.69 | 1.00 | 0.20 |
| 44 | NMM | Cumberland Subdivision C | 17,041 | 78.28 | 35,737 | 3.65 | 0.95 | 0.19 |
| 45 | NMM | Cumberland Subdivision D | 4,930 | 77.93 | 35,326 | 3.63 | 0.98 | 0.19 |
| 46 | NMM | Pictou Subdivision A | 10,997 | 78.37 | 37,875 | 3.61 | 1.04 | 0.21 |
| 47 | NMM | Pictou Subdivision B | 16,349 | 78.62 | 37,311 | 3.63 | 1.09 | 0.21 |
| 48 | NMM | Pictou Subdivision C | 23,039 | 78.28 | 39,428 | 3.64 | 1.10 | 0.23 |
| 49 | NMM | St. Mary's | 2,805 | 77.98 | 32,295 | 3.66 | 1.09 | 0.22 |
| 50 | NMM | Guysborough | 8,391 | 78.41 | 31,887 | 3.66 | 1.19 | 0.23 |
| 51 | NMM | Antigonish Subdivision A | 12,905 | 78.86 | 46,273 | 3.67 | 1.09 | 0.24 |
| 52 | NMM | Antigonish Subdivision B | 7,383 | 78.95 | 40,018 | 3.92 | 1.08 | 0.25 |
| 53 | NMCBI | Inverness Subdivision C | 7,855 | 78.10 | 45,076 | 4.03 | 1.12 | 0.22 |
| 54 | NMCBI | Inverness Subdivision B | 7,065 | 77.60 | 38,338 | 3.52 | 1.14 | 0.27 |
| 55 | NMCBI | Inverness Subdivision A | 6,828 | 78.46 | 37,718 | 3.59 | 0.94 | 0.23 |
| 56 | NMCBI | Richmond Subdivision B | 4,292 | 78.38 | 36,954 | 4.48 | 0.92 | 0.19 |
| 57 | NMCBI | Richmond Subdivision A | 4,467 | 78.13 | 36,593 | 4.24 | 1.05 | 0.19 |
| 58 | NMCBI | Richmond Subdivision C | 2,504 | 78.30 | 35,712 | 3.94 | 1.24 | 0.24 |
| 59 | CBRM | CBRM:Louisbourg Area | 3,937 | 78.33 | 36,248 | 3.79 | 1.31 | 0.28 |
| 60 | CBRM | CBRM:Sydney | 40,602 | 76.34 | 37,658 | 3.79 | 1.35 | 0.29 |
| 61 | CBRM | CBRM:North Sydney | 35,559 | 78.02 | 36,579 | 4.19 | 1.20 | 0.30 |
| 62 | CBRM | CBRM:Glace Bay | 41,401 | 76.62 | 33,248 | 3.66 | 1.38 | 0.35 |
| 63 | NMCBI | Victoria Subdivision B | 5,243 | 78.20 | 38,409 | 4.08 | 1.08 | 0.28 |
| 64 | NMCBI | Victoria Subdivision A | 3,673 | 77.78 | 38,615 | 3.81 | 0.89 | 0.25 |

Regional abbreviations: NMM, non-metropolitan mainland; MH, metropolitan Halifax; NMCBI, non-metropolitan Cape Breton Island; CBRM, Cape Breton Regional Municipality.

Population: average population size calculated as previously described. (1)

Life expectancy: empirical Bayesian estimates calculated as previously described. (1)

# Using a linked data set to determine the factors associated with utilization and costs of family physician services in Ontario: effects of self-reported chronic conditions

*Karey S Iron, Douglas G Manuel and Jack Williams*

## Abstract

*Evidence-based health care planning for persons with chronic conditions is difficult. Routinely collected data are not specific enough to obtain prevalence estimates for chronic conditions and accompanying health determinants, whereas available survey data do not provide accurate utilization and/or cost information. The purpose of this study was to determine the association of self-reported demographic factors (age, sex), access (having a regular doctor), socio-economic factors (education/income) and need (comorbidity) with actual family physician costs for persons with arthritis/rheumatism, asthma, back pain, high blood pressure and migraines. Data from consenting Ontario respondents to the 1994 Canadian National Population Health Survey were linked with provincial physician billing claims. More than half of Ontario adults aged 25 and over reported a chronic condition; 24% reported two or more. Age, sex, access, socio-economic status and need were independently associated with family practice utilization and costs, and the magnitude of the effects varied by condition. Linked survey/administrative data can provide valuable information to assist in evidence-based health care planning.*

***Key words:*** *administrative data; chronic diseases; cost; health determinants; linked data; physician use; survey data*

## Introduction

The societal health burden of chronic conditions and associated disability is a concern to health planners and caregivers. People with chronic conditions incur direct costs three times greater than persons without chronic conditions.[1] In Canada, approximately 33% of the total health costs (direct and indirect) for men and 36% for women are due to short- and long-term disability.[2] In Nova Scotia, almost 60% of medical costs are attributed to chronic conditions.[3] Previous studies that examined the utilization and costs of health services for chronic conditions[1,4–7] did not have the opportunity to use population-based information to determine prevalence and total costs.[8]

Traditionally, health services research focuses on "who does and does not receive medical care and why; and for those who do, how much and what types of care do they consume".[9] Administrative data provide accurate information about the utilization of health services but have limited information about individual-level health determinants and prevalence estimates. Such detail is frequently found in population health surveys; however, surveys seldom contain measures of health care use and, if present, the measures are self-reported and lack detail on health care services received and actual costs.

The purpose of this study was to use a unique, linked population-based data set consisting of survey and physician claims data to examine factors associated with the utilization and costs of family physician services for persons reporting chronic conditions in Ontario. The relations between self-reported demographic factors, need, access and socio-economic factors and the actual costs of consultation visits with family physicians were examined for persons reporting the five most prevalent chronic conditions. These conditions were arthritis/rheumatism, asthma, back pain, high blood pressure and migraines.

## Methods

### Data sources and variable selection

**National Population Health Survey.** The 1994/95 National Population Health Survey (NPHS) was the first of a series of longitudinal, population-based household surveys organized by Statistics Canada to help initiate and monitor provincial population health goals. The survey used a stratified, multi-stage, cluster sampling frame across pre-existing provincial/territorial geographic regions. Excluded were people living in remote areas, persons living on native reserves and Canadian Forces Bases and persons living in institutions. The national

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household response rate was 88.7% and in Ontario was 85.2%.[10]

The survey was conducted in two parts. The first was a comprehensive face-to-face interview. One member in each sample household acted as a proxy for all other household members. This portion included 17,221 Ontario respondents. The second part was self-administered and completed by one household member 12 years of age or over, amounting to 5,187 respondents in Ontario.

In Canada, a unique health card number is issued to each citizen as part of the universal, publicly funded health insurance program. The self-administered portion of the survey asked respondents to provide their health card number and to give consent to share their responses with the provincial/territorial ministries of health for research purposes. Of the 5,187 Ontario respondents who completed the self-administered survey, 93% agreed to share their information and, of these, 89% provided a valid card number. The results were generalizable to the Ontario population on the basis of statistical weights calculated by Statistics Canada.

The prevalence of chronic conditions for this study was estimated using the NPHS survey question "Do(es)….have any of the following long-term conditions that have been diagnosed by a health professional?" (Appendix). The five leading self-reported conditions were arthritis/rheumatism, asthma, back pain, migraines and high blood pressure. These conditions are the focus of this paper. Age was aggregated into three groups (25–44 years, 45–64 years and 65 and over) to reflect the varying degrees of disease prevalence and health care use.

There is a body of literature focusing on the concepts of health care need and access to health services, and their relation to health services utilization.[9,11] Most often, proxy measures of need and access are used because the two concepts are very difficult to define and quantify using available data. Need reflects a threat to health that can be addressed with health care. People may have health needs for primary or secondary prevention before the clinical presentation of disease. Physician care is provided for the spectrum of disease but more so for tertiary prevention. For this reason we used the presence of two or more self-reported concomitant conditions as a proxy for increased health care need, as compared with persons who had either one chronic condition or none.

Health care use varies depending on the ability of people to access health care services. People may have health needs but not use health care services because of access barriers. Others may have a high use of health care if they seek care for health concerns that may not be related to actual health needs. These examples demonstrate the potential for many different factors that contribute to health care access, from the level of service availability to knowledge of services. An indicator of access that encompasses many of these aspects is having a regular physician. Thus, self-report from the NPHS of having regular access to physician services ("Do you have a regular doctor?") was used as a measure of access in this analysis.

The highest level of education completed and household income variables were used as measures of socio-economic status (SES). Educational level completed was categorized to reflect employment opportunities (less than high school, high school, diploma and university degree). Five levels of income adequacy were derived by Statistics Canada that accounted for the number of persons in each household and the household income. Levels 1 and 2 reflected Statistics Canada's definition of low income[12] (Appendix).

**Ontario Health Insurance Plan data.** In Ontario, physicians are paid by the universal Ontario Health Insurance Plan (OHIP), whereby a claim for each service rendered is submitted through a centrally administered provincial system. Physicians are subsequently remunerated for their service. These data are often used to assess the overall cost of physician services for a procedure or disease. Many diseases, including chronic conditions, are difficult to capture based on these data because a diagnosis is not a requirement for claim submission.[13–15] OHIP has almost complete coverage, although, according to a recent report published by the Canadian Institute for Health Information, about 5% of Ontario physicians are paid mainly through alternative payment and not fee-for-service modes;[16] the services of these physicians are therefore not captured in the OHIP database.

OHIP consultative claims were recoded to reflect fee-for-service family physician visits. All laboratory-related, emergency, surgical and procedural codes were excluded for this analysis. Even after maternity care has been controlled for, women are traditionally cited as having higher health care utilization than men.[17–20] To control for the effects of maternity care in this study, all associated claims were re-coded as non-events in this analysis.

## Linkage

The working NPHS file was obtained through a special research agreement from the Ontario Ministry of Health and Long-term Care to ensure respondent privacy. Individual health card numbers provided by survey respondents were scrambled according to a unique algorithm. Scrambled health card numbers were used to prospectively link survey responses with over two years of physician billing data.

## Analysis

The characteristics of the Ontario sample were derived for each chronic condition. Point estimates were derived, weighted to the Ontario population. The median number of family physician visits and the median cost ($ CDN) of physician services per person were derived and stratified by physician specialty. Variations in utilization and costs were described through calculation of the 5$^{th}$, 25$^{th}$, median, 75$^{th}$ and 95$^{th}$ percentiles.

Multivariate linear regression analysis examined the independent factors associated with the annual median costs of family physician services per person for each chronic condition. Confidence intervals (95%) and Wald tests for significance of the model terms were calculated using a modified bootstrap variance utilities program provided by Statistics Canada.[21] The choice of reference groups for the

multivariate analysis was predominantly based on the covariate level for which the worst outcomes were assumed. For the SES variables, however, the sample size was not adequate for this level, and therefore another level was used as the reference. The models were adjusted for all covariates. The resulting beta coefficients refer to the incremental physician costs per person per year compared with the covariate baseline (either higher or lower than baseline). The model intercept refers to the adjusted cost for a person with all the baseline characteristics (for example, a female 65 years or older with two or more chronic conditions, a university degree and in the highest income adequacy level).

## Results

### *Population characteristics and prevalence*

There were 3,830 NPHS survey respondents, weighted to an Ontario population of 7.2 million aged 25 and over, who consented to share their health card number and survey responses with the Ontario Ministry of Health and Long-term Care. Eighty-five percent of the chronic conditions reported included arthritis/rheumatism, back pain, asthma, high blood pressure or migraine. These conditions also incurred about 80% of the total physician costs for all conditions in the NPHS.

Table 1 illustrates the characteristics of the Ontario population who reported no chronic conditions (47.5%), arthritis/rheumatism (17.7%), back pain (17.6%), asthma (6.0%), high blood pressure (10.9%), migraine (8.5%) or others (10.6%) (multiple responses were allowed). The majority of persons who reported no conditions were young, had

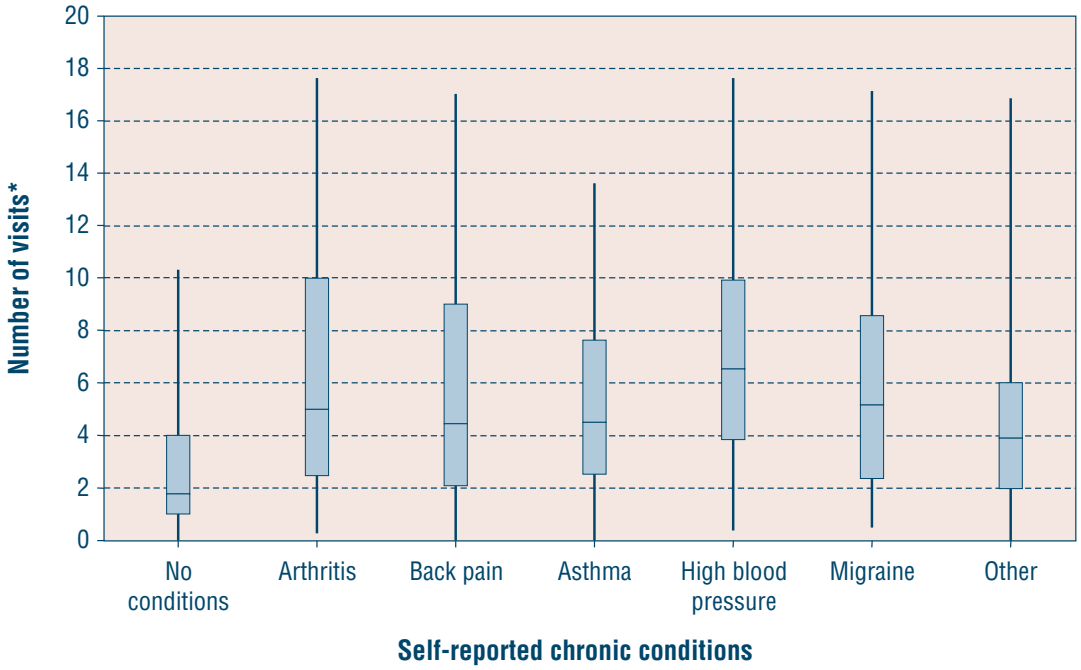
**TABLE 1**
**Characteristics of persons aged ≥ 25 by leading self-reported chronic conditions in Ontario, 1994–1995**

| Factor | Ontario (%) | None (%) | Arthritis[a] (%) | Back pain[a] (%) | Asthma[a] (%) | High blood pressure[a] (%) | Migraine[a] (%) | Other[a] (%) |
|---|---|---|---|---|---|---|---|---|
| Estimated population | 7,150,386 | 3,396,433 (47.5) | 1,267,860 (17.7) | 1,256,946 (17.6) | 425,487 (6.0) | 780,013 (10.9) | 608,269 (8.5) | 758,106 (10.6) |
| Age: | | | | | | | | |
| 25–44 | 51.2 | 64.5 | 15.9 | 38.0 | 61.2 | 13.0 | 60.7 | 44.9 |
| 45–64 | 31.5 | 28.9 | 38.2 | 41.1 | 25.1 | 41.6 | 29.9 | 31.3 |
| 65+ | 17.3 | 6.6 | 45.8 | 20.9 | 13.7 | 45.4 | 9.4 | 23.8 |
| Sex: | | | | | | | | |
| Women | 51.4 | 51.4 | 61.8 | 52.9 | 48.2 | 56.8 | 71.2 | 51.3 |
| Men | 48.6 | 48.6 | 38.2 | 47.1 | 51.8 | 43.3 | 28.8 | 48.7 |
| Comorbidity: | | | | | | | | |
| One condition only | 28.4 | – | 26.8 | 34.9 | 39.1 | 27.6 | 33.2 | 87.0 |
| Two or more conditions | 24.1 | – | 73.2 | 65.8 | 60.9 | 72.4 | 66.8 | 13.0 |
| Regular MD: | | | | | | | | |
| Yes | 93.4 | 89.8 | 98.4 | 97.0 | 93.6 | 98.9 | 93.8 | 97.3 |
| No | 6.6 | 10.2 | 1.7 | 3.0 | 6.4 | 1.1 | 6.3 | 2.7 |
| Education: | | | | | | | | |
| Less than high school completed | 23.7 | 17.8 | 37.7 | 30.5 | 28.1 | 37.8 | 21.3 | 26.3 |
| High school completed | 39.7 | 42.2 | 33.4 | 37.4 | 37.6 | 37.6 | 45.5 | 39.0 |
| Diploma | 19.0 | 20.6 | 18.8 | 19.0 | 17.2 | 14.3 | 19.6 | 16.3 |
| University degree | 17.6 | 19.4 | 10.2 | 13.1 | 17.1 | 9.4 | 13.6 | 18.4 |
| Household income adequacy level: | | | | | | | | |
| First – lowest | 4.6 | 4.0 | 5.9 | 5.1 | 6.7 | 5.2 | 4.3 | 6.2 |
| Second | 9.9 | 7.2 | 15.6 | 10.6 | 11.9 | 13.4 | 15.6 | 10.7 |
| Third – median | 26.5 | 24.6 | 31.2 | 27.2 | 26.4 | 31.5 | 21.8 | 26.5 |
| Fourth | 38.7 | 39.3 | 30.7 | 35.5 | 35.4 | 36.6 | 36.3 | 36.4 |
| Fifth – highest | 20.3 | 20.9 | 14.2 | 17.2 | 17.6 | 10.4 | 19.6 | 15.4 |

[a] Chronic conditions were not mutually exclusive in the survey; therefore, the sum of chronic condition populations is higher than the Ontario population

Source: National Population Health Survey, 1994/95

**FIGURE 1**
**Annual family consult visits per person aged ≥ 25 by self-reported chronic condition in Ontario, 1994–1995**




*(5th, 25th, median, 75th, 95th percentile)

Source: National Population Health Survey, 1994/95; Ontario Health Insurance Program, 1994 and 1995

completed high school and were in the higher income levels. Persons reporting arthritis/rheumatism and high blood pressure tended to be older women in the lower educational and income adequacy levels. Over 60% of persons reporting asthma and migraine were in the youngest age group. Over 70% of persons reporting migraine were women, and almost 20% were in the highest income adequacy level. Having two or more conditions was prevalent across all five conditions (over 60%). Over 90% of persons across all conditions reported having a regular doctor.

For persons with one, two or no chronic conditions, wide variations in the number of family physician visits were observed across each of the conditions (Figure 1), with less variation for persons who reported no chronic conditions. There was also variation in the physician costs (Figure 2). The variation was less for persons reporting none of the chronic conditions.

## *Factors associated with family physician costs ($ CDN)*

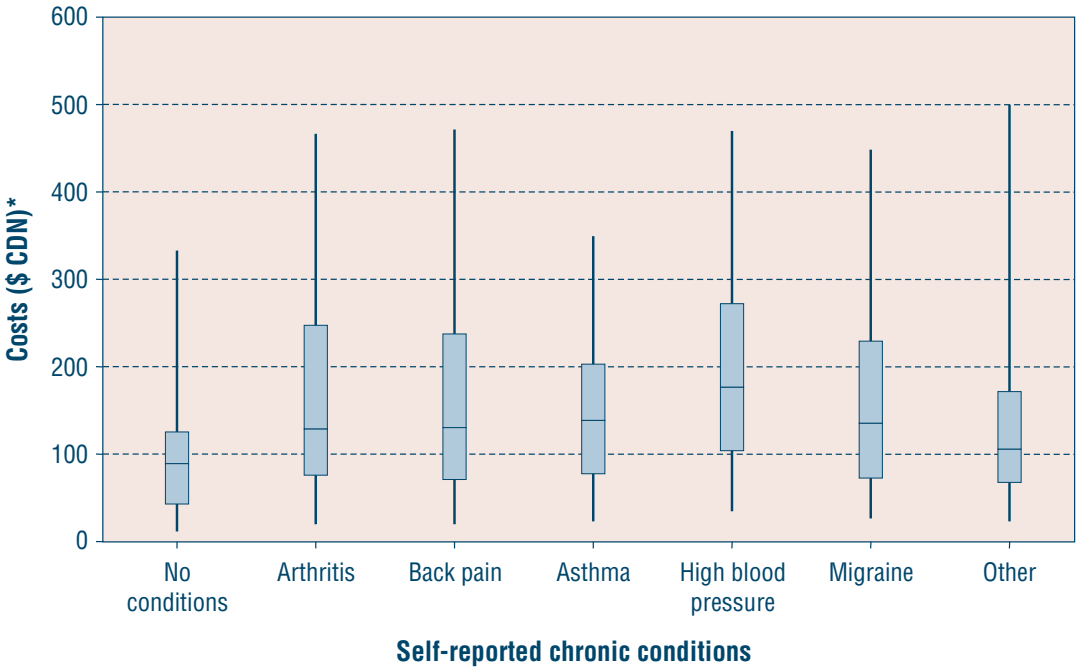
Table 2 shows the results of multivariate linear regression models for median cost of 1 year of family physician service (per person) for each of the study conditions. All of the covariates are presented, but only those that are statistically significant are discussed. The last line of the table is the unadjusted median cost of family physician care for one person in a year. The model presented adjusts the crude median cost by taking into account the effects of all the other covariates. By adding the model intercept and the beta coefficients, an adjusted cost can be calculated. For example, Table 2 shows that the crude median family physician cost per year for a person with back pain is $126.37. The adjusted cost for a person with all the baseline characteristics (a female 65 and over with two or more chronic conditions, who has a university education and is in the highest income adequacy level) would be $96.95. However, the physician cost for a 45–64 year old man with back pain as his only reported condition, who has a regular doctor, a high school diploma and who is in the highest income adequacy level would be as follows:

$96.95 (model intercept) – $42.35 (44–64 years) – $67.86 (male) – $29.73 (back condition only) + $87.71 (regular doctor) + $37.56 (high school diploma) + $0.00 (highest income adequacy) = $82.28.

The value of the betas is comparative – positive betas describe costs higher and negative betas describe costs lower than baseline values. The following presents the adjusted costs for each condition in Table 2. The costs reflect 1 year of family physician services per person for each condition.

**Arthritis/rheumatism.** The yearly median physician cost was $132.33. After adjustment for all the baseline covariates, the cost was $97.61. The adjusted incremental physician cost for persons aged 25 to 44 years was lower than for persons 65 and over (beta = –$54.01), as were the costs of

**FIGURE 2**
**Annual cost ($ CDN) of family physician consult visits per person aged ≥ 25 by self-reported chronic condition in Ontario, 1994–1995**




*(5th, 25th, median, 75th, 95th percentile)

Source: National Population Health Survey, 1994/95; Ontario Health Insurance Program, 1994 and 1995

persons reporting only arthritis/rheumatism (beta = –$76.58). The adjusted cost for persons with a regular doctor was higher than for those without a regular doctor (beta = $90.64). Further, persons in the second lowest (beta = $90.61) and the middle (beta = $78.66) income adequacy levels had higher costs per year than persons in the highest income adequacy level.

**Back Pain.** The median physician cost was $126.37. With adjustment for all model covariates, the incremental increase in physician costs was $96.95 (intercept beta). The costs were lower for persons aged 45 to 64 compared with individuals who were 65 and over (beta = –$42.35), were lower for men than women (beta = –$67.86) and higher for persons who reported having a regular doctor (beta = 87.71) than for persons who did not. Persons who did not complete high school or those who did not attain a post-secondary degree incurred higher physician costs than persons who attained a university degree (betas = 52.74 and 37.56 respectively). Finally, physician costs were higher for the second lowest income adequacy level than for the highest (beta = 68.24).

**Asthma.** The median physician cost was $127.56. The adjusted incremental increase in physician costs was $191.24 (intercept beta). The annual median cost was significantly lower for persons aged 25 to 44 than those aged 65 and over (beta = –$80.49) and lower for men than women (beta = –$45.23). The cost was lower for a person who reported just asthma, as compared with someone who reported asthma and additional conditions (beta = –34.55). Costs were higher for persons in the middle income level (beta = $65.44) than in the highest.

**High blood pressure.** The crude median physician cost was $169.41. A person aged 45 to 64 incurred lower costs (beta = –45.20) than an older person aged 65 and over, adjusted for model covariates. Persons with a regular doctor had higher costs than those without a regular doctor (beta = $172.79).

**Migraine.** The physician cost per person per year was $128.00. Persons who reported migraines only (no other conditions) incurred lower physician costs than those who reported having other conditions (beta = –45.80), adjusted for all other model covariates. Income was associated with costs for migraines. Persons in the lowest, second lowest and middle income levels (betas = $110.02, $84.10 and $94.70 respectively) had significantly higher costs than those in the highest income adequacy level.

**Other.** The cost was $102.69. Persons in the second lowest income level incurred higher physician costs than persons who had completed university (beta = $73.38).

## Discussion

Using linked population-based survey/administrative data, this study examined the

**TABLE 2**
**Factors associated with annual median general practitioner consult costs per person aged ≥ 25 by self-reported chronic conditions in Ontario, 1994–1995**

| Covariate | Arthritis/rheumatism | | | Back pain | | | Asthma | | |
|---|---|---|---|---|---|---|---|---|---|
| | Adjusted beta | Adjusted LCI[a] (95%) | Adjusted UCI[b] (95%) | Adjusted beta | Adjusted LCI[a] (95%) | Adjusted UCI[b] (95%) | Adjusted beta | Adjusted LCI[a] (95%) | Adjusted UCI[b] (95%) |
| Model intercept | 97.61 | NS[c] | | 96.95 | 25.31 | 168.59 | 191.24 | 79.2 | 303.46 |
| Age: | | | | | | | | | |
| 25–44 | -54.01 | -100.63 | -7.39 | -25.54 | NS | | -80.49 | -146.46 | -14.52 |
| 45–64 | -34.01 | NS | | -42.35 | -83.30 | -1.39 | -52.66 | NS | |
| 65 and over | 0.00 | – | – | 0.00 | – | – | 0.00 | – | – |
| Sex: | | | | | | | | | |
| Male | -10.20 | NS | | -67.86 | -102.77 | -32.96 | -45.23 | -79.11 | -11.36 |
| Female | 0.00 | – | – | 0.00 | – | – | 0.00 | – | – |
| Comorbidity: | | | | | | | | | |
| One chronic condition only | -76.58 | -109.45 | -43.71 | -29.73 | NS | | -34.55 | -67.36 | -1.75 |
| Two or more conditions | 0.00 | – | – | 0.00 | – | – | 0.00 | – | – |
| Regular MD: | | | | | | | | | |
| Yes | 90.64 | 26.45 | 154.83 | 87.71 | 39.76 | 135.66 | 31.45 | NS | |
| No | 0.00 | – | – | 0.00 | – | – | 0.00 | – | – |
| Education: | | | | | | | | | |
| Less than high school completed | -19.37 | NS | | 52.74 | 2.26 | 103.22 | -25.76 | NS | |
| High school completed | -1.03 | NS | | 37.56 | 1.01 | 74.12 | -16.43 | NS | |
| Diploma | -2.65 | NS | | 50.80 | NS | | 33.78 | NS | |
| University degree | 0.00 | – | – | 0.00 | – | – | 0.00 | – | – |
| Household income adequacy level: | | | | | | | | | |
| First – lowest | 51.47 | | | 38.66 | | | 66.01 | NS | |
| Second | 90.61 | 32.41 | 148.82 | 68.24 | 9.32 | 127.15 | 64.55 | NS | |
| Third – median | 78.66 | 11.26 | 146.07 | 40.70 | NS | | 65.44 | 6.21 | 124.80 |
| Fourth | 37.82 | NS | | 10.55 | NS | | 19.59 | NS | |
| Fifth – highest | 0.00 | – | – | 0.00 | – | – | 0.00 | – | – |
| Median visits per person per annum: | $132.33 | | | $126.37 | | | $127.56 | | |

[a] Lower confidence interval
[b] Upper confidence interval
[c] Not significant

*Table 2 continued on next page*

effects of socio-demographic factors, socio-economic status, need and access on the costs of family physician consultations for persons reporting chronic conditions in Ontario, Canada. Diagnosed chronic conditions are estimated to be prevalent in more than half of Ontario adults aged 25 and over; almost half of these persons have two or more conditions. These results are slightly higher than U.S. estimates (46% of Americans are deemed to have a chronic illness).[1]

The findings from this study are consistent with the health services utilization framework set out by Aday,[9] which suggests that health care use is contingent on a multitude of factors, such as individual-level SES, health care need and access to services. Aday's framework is often cited but used rarely in health services research because of a paucity of accurate individual-level data and difficulty in the measurement of need and access. The unique linked survey and administrative data used for this study allowed for the analysis of individual-level factors that are often examined only on an ecological basis. Further, this study used proxy measures of need (two or more chronic conditions) and

**TABLE 2 (*continued*)**
**Factors associated with annual median general practitioner consult costs per person aged ≥ 25 by self-reported chronic conditions in Ontario, 1994–1995**

| Covariate | High blood pressure | | | Migraine | | | Other | | |
|---|---|---|---|---|---|---|---|---|---|
| | Adjusted beta | Adjusted LCI[a] (95%) | Adjusted UCI[b] (95%) | Adjusted beta | Adjusted LCI[a] (95%) | Adjusted UCI[b] (95%) | Adjusted beta | Adjusted LCI[a] (95%) | Adjusted UCI[b] (95%) |
| Model intercept | 71.84 | NS[c] | | 125.49 | NS | | 58.81 | NS | |
| Age: | | | | | | | | | |
| 25–44 | 53.15 | NS | | -34.53 | NS | | 7.61 | NS | |
| 45–64 | -45.20 | -87.99 | -2.40 | -25.39 | NS | | 18.67 | NS | |
| 65 and over | 0.00 | – | – | 0.00 | – | – | 0.00 | – | – |
| Sex: | | | | | | | | | |
| Male | -20.91 | NS | | -32.33 | NS | | -31.59 | NS | |
| Female | 0.00 | – | – | 0.00 | – | – | 0.00 | – | – |
| Comorbidity: | | | | | | | | | |
| 1 chronic condition | -0.78 | NS | | -45.80 | -83.36 | -8.24 | -22.00 | NS | |
| 2 or more conditions | 0.00 | – | | 0.00 | – | – | 0.00 | – | – |
| Regular MD: | | | | | | | | | |
| Yes | 172.79 | 12.75 | 332.84 | 54.50 | NS | | 61.34 | NS | |
| No | 0.00 | – | – | 0.00 | | | 0.00 | – | – |
| Education: | | | | | | | | | |
| Less than high school complete | -77.14 | NS | | -10.67 | NS | | 9.53 | NS | |
| High school complete | -69.70 | NS | | 1.16 | NS | | 33.20 | NS | |
| Diploma | -79.54 | NS | | 13.38 | NS | | -10.55 | NS | |
| University degree | 0.00 | – | – | 0.00 | – | – | 0.00 | – | – |
| Household income adequacy level: | | | | | | | | | |
| First – lowest | 41.86 | NS | | 110.02 | 25.09 | 194.96 | 99.08 | NS | |
| Second | 75.63 | NS | | 84.10 | 19.02 | 149.19 | 73.38 | 11.02 | 135.74 |
| Third – median | 96.44 | NS | | 94.70 | 13.08 | 176.31 | 51.11 | NS | |
| Fourth | 32.02 | NS | | 29.34 | NS | | 32.57 | NS | |
| Fifth – highest | 0.00 | – | – | 0.00 | – | – | | | |
| Median visits per person per annum: | $169.41 | | | $128.00 | | | $102.69 | | |

[a] Lower confidence interval
[b] Upper confidence interval
[c] Not siginificant
Source: National Population Health Survey, 1994/95; Ontario Health Insurance Program, 1994 and 1995

access (having a regular doctor); the extent that these proxies captured the complexities of need and access and their effect on health care costs is not known. Nevertheless, the effect of these proxy measures across the studied conditions underscores the importance of examining such factors when planning health care services.

The findings of this study raise some important issues. Limitations encountered by using either administrative or survey data for health care planning can be offset by using a linked data set. Accurate prevalence estimates for chronic conditions in concert with actual utilization and physician cost data provide powerful information not available through other means. Health planners could use such linked data to develop case-costing and other measures necessary for disease-specific program planning. Adjusting for determinants such as age, sex, SES or the presence of concomitant chronic conditions can profoundly change the crude estimated cost of physician care. This underscores the need for condition-specific health care costing

that, wherever possible, takes into account the complexities of the population that will use the health services.

As a practical illustration of the use of this analysis, consider the task of planning for asthma services if the prevalence of asthma is expected to increase. First, this study suggests that people with asthma have more intense health care use than persons without asthma. Our analysis shows that several factors have an important influence on physician costs, such as being a young male with average income. Health planners could more accurately anticipate the use and costs of physician services by taking these factors into account.

The limitations of this study are few. Estimates of chronic conditions and covariates in this study are based on self-reported survey data. The validity of self-reported chronic conditions is known to vary by condition,[22–26] but there is little evidence that self-reported chronic disease status affects the factors examined in this study.[27] Although relations between survey covariates and costs are evident, no causal effects can be inferred because of the cross-sectional design of the NPHS. Further, the costs derived from the OHIP data are underestimated because some physicians are not included in the provincial fee-for-service payment plan. This study included all actual physician visits and costs incurred by persons who reported chronic conditions and not just consultations particular to the condition itself. This is important, because care for chronic conditions is not episodic – there may be various physician visits related to, but not specifically focused on the reported chronic condition.

This study used a unique linked survey/administrative database to determine that demographic factors, need, access and SES were independently associated with physician costs. These results suggest the need for condition-specific analyses and detailed, individual-level data. The assessment and consideration of disease-specific health determinants in planning for future health care planning and delivery are critical. Finally, sponsors of large population health surveys should continue to ensure the capability of linkage to provincial utilization/cost information, and provinces should continue to allow such linkage to occur.

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## APPENDIX
## Survey questions from the National Population Health Survey, 1994/95

**1. Questions on chronic conditions:**

"Do(es)….have any of the following long-term conditions that have been diagnosed by a health professional?"

The conditions listed were food allergies, other allergies, asthma, arthritis/rheumatism, back problems, high blood pressure, migraine, chronic bronchitis/emphysema, sinusitis, epilepsy, diabetes, heart disease, cancer, stomach/intestinal ulcers, stroke, urinary incontinence, acne requiring medication, Alzheimer's disease, cataracts, glaucoma or another condition not listed.

Acne, food and other allergies that were included in the NPHS were excluded in this analysis because they had almost no impact on reported health status.[25]

**2. Education:**

"What was the highest level of education that you have attained?"

1. Less than high school
2. High school graduate (includes some college/university)
3. Diploma/certificate
4. University degree

**3. Income derived from an income adequacy index based on household income and the number of persons in the household, as follows:**

1. lowest income
2. lower middle income
3. middle income
4. upper middle income
5. highest income

This was not adjusted for regional differences in the cost of living. Income adequacy levels 1 and 2 represent the low income cut-off defined by Statistics Canada.[12]

## Book Review

# Child Health and the Environment

*Donald T. Wigle*

New York, Oxford University Press, 2003
XVII + 396 pp; ISBN 01951 3559 8; $96.50 (CDN)

In *Child Health and the Environment*, Donald Wigle, MD, PhD, has written what is believed to be the first textbook that deals specifically with the links between a range of environmental pollutants and their potential health effects on children who are exposed to them, either while still in the womb or during their formative years. From this viewpoint, the book plays a valuable role in filling a gap in the literature.

Dr. Wigle, a former official with Health Canada who served as Senior Medical Advisor to the Safe Environments program, has conducted a thorough literature review of the many studies that have looked at the possible effects of numerous environmental influences, ranging from lead exposure to environmental tobacco smoke. His summaries of those studies provide a good synopsis of the potential biological and chemical effects of various elements and compounds on the human body.

Unfortunately, much of what Dr. Wigle discovered during his research was that scientifically valid knowledge about the actual effects of many of these environmental contaminants is sadly lacking, particularly as it pertains to children but in too many cases even as it pertains to adults. He points out that, in many cases, it is unclear whether adult studies can be reliably extrapolated to children, either because children are likely to receive larger "doses" of exposure relative to their body size, or because their bodies may be more vulnerable to exposures during the time when they are growing and developing. Without clear evidence based on childhood exposure, he concludes from his review of a large majority of the environmental issues covered in the book that there is "limited evidence," "inadequate evidence," or "suggestive evidence" of a possible link between the environmental exposure and detrimental health consequences. In only a few cases – virtually all of them already well known to medical practitioners – can he point to clear and compelling evidence of a link, for example, high-level radiation exposures and cancer, severe lead poisoning and cognitive deficits.

Dr. Wigle is meticulous in pointing out the gaps in evidence in each and every individual case. Yet the cumulative effect of the lengthy lists of potential links that he provides is to leave the reader with quite a different overall impression by the time the book is finished. The overall impression, in fact, is that nearly all the children in the world are at grave risk of one or several disastrous health problems as a result of the food they eat, the water they drink, the surfaces they sleep or play on, and/or the air they breathe. Even averagely protective parents reading the book would be tempted to move their infant into a hermetically sealed dome supplied with distilled water for the next 15 years, doing the best they could to avoid food contaminated with pesticides, dioxins, or heavy metals.

In fact, the lack of compelling evidence for many of the links leads to the book's greatest weaknesses when Dr. Wigle moves into the areas of risk management and prevention. Although parents, caregivers, and schools can undertake some worthwhile preventive programs, for example, limiting sun exposure and eliminating exposure to environmental tobacco smoke, the number of possible hazards from which they can protect their children is minimal. Given the ubiquitous nature of the environmental exposures that Dr. Wigle covers, many of the preventive changes discussed would actually amount to major new government regulation programs governing everything from pesticide applications on food crops to new vehicle emission standards. Were any government to attempt to bring in all the proposed new regulations within a short period of time – admittedly a highly unlikely possibility – the social, political, and economic implications would probably be substantial enough to cause significant upheaval in the day-to-day lives of many citizens. Those changes themselves could lead to detrimental health outcomes. New regulations for those who grow food, for instance, would undoubtedly lead to cost increases that would be passed on to consumers – cost increases that might well result in low-income parents skimping on the fresh vegetables and fruit that they provide for their children.

Dr. Wigle suggests that the "precautionary principle" should be invoked in dealing with many of the environmental exposures that could pose a health danger to children. He notes that "policy makers generally encounter a high level of uncertainty about children's environmental health risks because of knowledge gaps concerning relevant exposures and dose-response relationships for individual toxicants and mixtures. In the face of such uncertainty, a requirement for scientific consensus on causality is not necessarily appropriate for management of children's environmental health risks."

It is unfortunate that he does not look at what the unintended consequences might be for many of the regulatory steps he recommends in following that principle. Given the low level of evidence establishing the links in many cases, it could truly be a case in which the cure is worse than the disease. ■

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# Calendar of Events

| | | |
|---|---|---|
| **January 30–31, 2004**<br>**Toronto, Ontario** | "Better Breathing 2004"<br>Ontario Thoracic Society's annual scientific conference on respiratory health | |
| **January 31, 2004**<br>**Toronto, Ontario** | "Better Breathing 2004, Family Practice Program"<br>Ontario Lung Association's annual scientific conference on respiratory health | International Plaza Hotel, Toronto, Ontario<br>The Ontario Thoracic Society<br>573 King Street East, Suite 201<br>Toronto, Ontario M5A 4L3<br>Information: Bernie Voulgaris, OTS Administrator<br>Tel.: (416) 864-9911 x 254<br>Fax: (416) 864-9916<br>E-mail: ots@on.lung.ca<br>< www.on.lung.ca > |
| **June 13–16, 2004**<br>**Milan, Italy** | "Positioning Technology to Serve Global Heart Health"<br>5th International Heart Health Conference<br>*Deadline for abstracts: February 5, 2004* | Università "Vita-Salute" San Raffaele<br>The International Advisory Board of the International Heart Health Conference<br>E-mail: 5ihh@g8cardio.org<br>< www.g8cardio.org/5ihh > |

## Departure of Associate Scientific Editor

We regretfully announce the retirement of Dr. Gerry Hill, long-time Associate Scientific Editor of *Chronic Diseases in Canada*, due to ill health.

We thank Dr. Hill for his many years of devoted service and knowledgeable contributions to the development of CDIC and we wish him all the best in the future.

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