A Population Based Analysis of the Impact of a Provincial Quality Improvement Program on Primary Health Care in Ontario.

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Abstract

Background

In Ontario, Canada, a province wide CQI initiative modeled on the IHI's breakthrough series methodology was implemented to support improved outcomes in Family Health Teams, a care model that includes many features of the Patient Centred Medical Home. We report on a population based evaluation of the impact of this program on diabetes care, cancer screening and health care utilization.

Methods

We used comprehensive linked administrative datasets to conduct a population based controlled before and after study. Outcome measures included diabetes process of care measures (test ordering, screening for retinopathy, medication prescribing and diabetes specific chronic disease management billings), colorectal and cervical cancer screening and health care utilization (emergency room visits, ambulatory care sensitive hospitalizations, specialist visits and continuity of care).

Results

We identified 78,192 patients from 53 intervention physicians and 1.66 million patients from 1178 control physicians. Diabetes process of care measures improved more in the intervention group than in the controls: HbAIC up to date 4.3% more (p=0.006), retinal screening 2.5% more (p=0.005), and diabetes preventive care visits 8.9% more (p=0.004). Medication prescribing also improved for use of statins (3.4% more, p=0.01), and use of ACE/ARB (4.1% more, p<0.001). Colorectal cancer screening improved

5.4% more ($p<0.001$), and cervical cancer screening improved 2.7% more ($p=0.004$). There were no significant differences in any of the healthcare utilization outcomes.

Discussion

This large controlled evaluation of a broadly implemented CQI initiative showed improvement for diabetes process of care and cancer screening outcomes, but not for proxy measures of access related to healthcare utilization.

Background:

Primary healthcare plays a key role in healthcare systems in Canada and around the world [1, 2]. Studies consistently show that the vast majority of care is delivered in primary care settings [3-7] and that strong primary care systems are associated with improved outcomes and decreased healthcare costs [5, 8, 9]. In Ontario, primary care is the backbone of the publically funded healthcare system, delivering about 80% of all visits annually [7, 10]. Improving and strengthening primary healthcare has been a key priority of successive governments in Ontario over the past decade which have implemented a series of reforms and initiatives in this key sector [10]. These include changes to payment models for physicians, support for multidisciplinary teams, support for the adoption of electronic health records and province wide quality improvement initiatives [8, 11, 12]. Family Health Teams (FHTs) represent the most highly reformed models of primary healthcare in Ontario and include all of the elements described above [13].

There is also consistent evidence that there is room for improvement in the quality of primary health care delivery in Canada and in Ontario. The much cited Commonwealth Fund survey on primary health care quality shows that Canada's performance, last or next to last on many measures, leaves much to be desired [14]. Recent studies comparing aspects of the new payment and organizational models in Ontario have either shown modest improvements or no differences between models, but have shown improvement in quality of care over time [15-20].

In order to help maximize the impact of the new models, a provincial quality improvement initiative, the Quality Improvement and Innovation Partnership (QIIP) (subsequently incorporated into Health Quality Ontario) was created to assist FHTs in three targeted areas: diabetes management, access to care and colorectal cancer screening, through a learning collaboratives (LC) program based on the Institute for Healthcare Improvement model [21-23]. Quality improvement (QI) teams in primary care practices were provided with training on QI and the Chronic Care Model as described by Wagner and others [10, 24].and professional practice facilitation and participated in learning sessions with other teams.

Tricco et al [25] conducted a systematic review and meta-analysis of any approach to quality improvement for diabetes management. Within their selected studies only 4 cluster randomized trials were classified as "continuous quality improvement" which was the closest match for the learning collaborative model in their taxonomy of interventions. They did not find any significant improvement in any process of care measures for this approach. Schouten et al [26] conducted a systematic review of quality improvement collaboratives and concluded that while there is some evidence that this approach can be effective, further evaluation, particularly with controlled study designs is warranted, as outcome improvements in prior studies have been modest and not always consistent or predictable. Of the controlled studies included in the Schouten et al. review, only Benedetti's single clinic study on diabetes reported on any of the outcomes targeted by the QIIP program [27]. The QIIP program and the overall results of a comprehensive mixed-methods evaluation are described in detail elsewhere [23, 28]. The mixed methods evaluation did not find statistically significant differences in the primary outcomes. This

paper reports on a supplementary analysis of administrative data that was conducted to explore the population level impact of the QIIP LC program on outcomes that could be assessed with administrative data.

Methods:

Participants and Setting

All patients of physicians included in the study during the study period were included in the study population. Patients were assigned to physicians if they had formally enrolled as a patient with the physician or using an established method of assigning patients to the physician who delivered the majority of a basket of primary care services [19,20,29]. All FHT physicians in Ontario with at least 100 patients during the study follow up period (Nov 2009-Feb 2013) were included in the study. Physicians who had participated in the QIIP LC program were requested to provide their registration number and consent to use this to identify their data within the health administrative data. Those physicians who agreed comprise the intervention group. Privacy limitations meant that we were unable to determine which QIIP LC participants had not consented, so all non-consenting eligible physicians made up the control group. Therefore the comparator group includes physicians who participated in the QIIP program but did not consent for this component of the evaluation.

Design and Data Sources

Administrative datasets were linked using unique, encoded identifiers and analyzed at the Institute for Clinical Evaluative Sciences (ICES) to measure the impact of the quality improvement program on the management of diabetes, cancer screening, and utilization of healthcare services. The datasets included payments to physicians from the Ontario Health Insurance Plan, the hospital Discharge Abstracts Database, the National Ambulatory Care Reporting System (for emergency room visits), laboratory and diagnostic imaging ordering data,the Ontario Cancer Registry, the Ontario Drug Benefit database, physician workforce data, data on primary care enrollment model attachments, the registered persons data base, the census and vital statistics. A controlled pre-post study design was used. All datasets are linked at the individual level using an anonymized key number. The control and intervention groups are described above under participants. As the QIIP LC occurred in 3 waves between 2008-2010 control physicians were randomly assigned index dates corresponding to these waves. Cross-sectional and longitudinal data were generated that included physician and practice demographics including case mix, health status of the practice population, patterns of health service utilization, and chronic disease prevention and management measures. Longitudinal data were used to evaluate outcomes and cross sectional data used to present comparisons between the QIIP and comparator patients and physicians. Data definitions and sources for each of the measures used in this paper are in alignment with the ICES' Primary Care in Ontario: ICES Atlas (2006).[29]

Statistical Analysis

Analyses compared baseline (12/24 months prior to the LC) with the post LC (12/24 months post LC) using generalized linear regression with adjustment made for the

baseline value, patient demographics (age, sex, rurality), and case mix. All analysis was conducted using SAS 13.1 [30]. We conducted the analysis at the level of the physician practice as that is where the intervention was targeted.

Ethics

This study was approved by the research ethics boards at Sunnybrook Hospital (ICES Central), Western University and Queen's University in Canada.

Results:

A total of 118 LC physicians practicing in FHTs were approached. The recruitment rate was 53.4% (63/118). Ten physicians were subsequently found to be ineligible and removed from the study. Figure 1 summarizes the steps in establishing the intervention group.

There were 1178 control physicians with at least 100 patients who were identified and randomly assigned to one of the 3 index dates. Table 1 presents the demographic data for the QIIP and control physicians. QIIP physicians were slightly more likely to be male, Canadian trained, and from rural areas.

A detailed comparison between the patients of the two groups on a range of demographic and clinical characteristics shows no clinically relevant differences other than a higher portion in the QIIP group residing in a rural location (18.1% vs 5.1% - Table 2).

Table 3 present the results for diabetes process of care measures including test ordering, completion of diabetes specific billing items and medications dispensed for

eligible patients. Process of care measures improved more in the intervention group than the control group: HbAIC (2 tests in 12 months) 4.3% more (p=0.006), retinal exams 2.5% more (p=0.005). The differential increase in the completion of lipid testing was not significant at 1.3% (p=0.466). Diabetes management specific billing items also improved more in the intervention group: 8.8% more (p<0.001) for flowsheet completions and 8.9% more (p=0.004) for diabetes preventive care visits. Differential increases in medication prescribing were noted for statins (3.4% more, p=0.011) and use of Angiotensin Converting Enzyme inhibitors and Angiotensin Receptor Blockers (4.1% more , p<0.001). There were no significant differences in the use of oral hypoglycemic agents or insulin.

Table 4 presents the findings for colorectal and cervical cancer screening. Screening for colorectal cancer increased more in the intervention group than in controls: fecal occult blood testing (FOBT) 11.1% vs 3.3% (P<0.001), any screening 9.9% vs 4.8% (p<0.001). There was a very small but statistically significant increase in cervical cancer screening being up to date over both 2 (1.8% increase vs 0.9% decrease, p=0.015) and 3 year periods (2.9% increase vs 0.2% decrease, p=0.004). Both screening intervals were considered due to changes in practice guidelines over the study period.

Table 5 presents data on health services utilization including emergency room visits, ambulatory care sensitive condition (ACSC) hospital admissions, admission rates for selected chronic diseases, and readmission rates to hospital. There were no significant changes in emergency room use, hospital admissions for ACSCs or hospital readmissions, with the exception of admissions for chronic obstructive pulmonary disease (COPD) which had a very small but statistically significant increase in the intervention

group (2.2/10,000 vs a decrease of 0.2/10,000 p=0.021). We also assessed continuity of care with the primary care physicians. Usual provider continuity (UPC) was similar at baseline (72.2% for the QIIP group vs 72.0% for the control group) and there were no significant changes over the study period (increase of 0.7% vs decrease of 0.3%, p=0.511).

Interpretation:

Main Findings and Comparison to Other Studies

For most of the measures that were targeted by the QIIP LC process, outcomes were improved compared to controls, with rates of change about double those in the control group. These differences were statistically significant due to the relatively large sample sizes that are made possible by population based analyses, but were in general modest in magnitude (absolute differences between 2% and 11%). It should be noted, however, that even small changes can be important if they are broadly applied to the population so those that are in the former group have the potential to provide system or population level benefits despite their modest impact.

The changes in diabetes process of care measures are consistent with those noted in other studies. Benedetti et al [27] found improvements in both process measures (test ordering, self management plans documented) in diabetes focused learning collaboratives in Washington State. Valk et al [31] compared QI programs on diabetes in the Netherland and the US and also found both process and outcome (HbAIC) improvements in both group. In our study the magnitude of changes (crude rate) noted in the intervention group before and after participation in QIIP are similar to those noted in the uncontrolled before

and after evaluation of another quality improvement initiative modeled on the IHI LC model in Ontario (Partnerships for Health) which found a 9% increase in annual HbAIC testing and a 9% increase in LDL testing [32]. Our adjusted analysis taking into account temporal changes in controls shows more modest increases, highlighting the importance of including a control group.

In contrast to the SCOPE trial [33], which found no significant improvement in colorectal cancer (CRC) screening for an intervention that combined learning collaboratives and on-site facilitation, this population based study shows an improvement in CRC screening comparable to other interventions such as audit and feedback noted in the Colorectal Cancer Screening in Primary Care Practice [34] and BETTER studies [35]. These results also contrast with those found in our chart audit, which failed to show a significant difference in screening rates in a small subsample of patients [28]. This highlights one of the advantages of using population level data to obtain more complete data than is feasible with resource intensive audits of patient records. We included cervical cancer screening to see if participation in the program might result in process changes that impacted cancer screening in general, and not just the targeted condition (spread). There was a statistically significant increase noted in the intervention group, but the magnitude of the difference between the interventions and controls was smaller (2.7% for cervical cancer screening vs 5.4% for CRC screening).

We found no clinically relevant changes in health services utilization measures such as low acuity emergency room visits and ACSC hospitalizations that are commonly used as outcome measures or proxy measures for access to primary health care. This is consistent with the limited number of other studies that have explored the relationship

between advanced access scheduling (the focus of the QIIP LC) and health system utilization. Rose et al conducted a systematic review of advanced access scheduling in 2011 and found that while most studies demonstrated improvements in time to third next available appointment and reduced no-show rates, the effects on patient satisfaction were mixed and the data on utilization was limited to very few studies [36]. Only two studies were identified in this review that reported on health care utilization and only one of these was controlled. Solberg et al [37] reported on an uncontrolled before and after study of advanced access for patients with chronic conditions and showed that despite significant improvements in access and improved continuity of care, there was very limited change in healthcare utilization, including ER visits and hospitalizations, or overall costs. Subramanian et al. conducted a controlled study of primary care clinics in Indiana that either transition to advanced access or did not [38]. This study showed no significant differences in ER and urgent care visits, hospitalizations or total outpatient visits.

Limitations

First, by using administrative data we were limited to collected process measures and measures of health care utilization. Secondly, as we were not permitted access to the list of all participating LC physicians due to privacy restrictions, physicians who participated in the LCs but who did not complete consent forms for this part of the evaluation were included in the control group. While this could introduce a bias towards a null result, they represent only 5% of the control group making this unlikely. This was a program implementation rather than a trial of an intervention, so the degree to which recommended processes were implemented and the way in which they were implemented

likely varied significantly across the participating teams. Finally, the implementation took place during a time of reform, with other changes and initiatives being implemented concurrently. To mitigate against this risk we applied the controlled before and after design and also limited controls to being other family health team patients, as the concurrent changes would be likely to be similar in both control and intervention practices. One other caveat is that this evaluation was based on a relatively limited follow up period. Repeating this analysis later in time to assess for the sustainability of the changes would provide important additional information about the role of the LC approach in improving quality in primary care.

Conclusions and Implications for Policy and Practice

This is one of the largest reported evaluations of the learning collaborative approach in primary care. The overall results are positive for diabetes care and cancer screening, with both clinically and statistically significant improvements in multiple outcomes noted, which supports the uses of IHI LC strategy in this setting. There were no improvements in healthcare utilization measures that were used as a proxy for improved primary care access. This is likely because there are only weak links between real improved access and these outcomes. Direct assessment of access to primary health care as well as patient experience with access would be better measures of success in this domain. Despite the relatively modest absolute levels of improvement noted, the success in achieving improvements of this scale for large populations is important. In our setting the learning collaborative approach seemed to be beneficial for outcomes that were more directly in control of health care providers when applied at large scale to a broad range of primary care practices. It seemed less effective in changing outcomes such as medication

use or healthcare utilization that are dependent on patient or system factors outside the control of the practice.

Conflicts of Interest:

None to declare.

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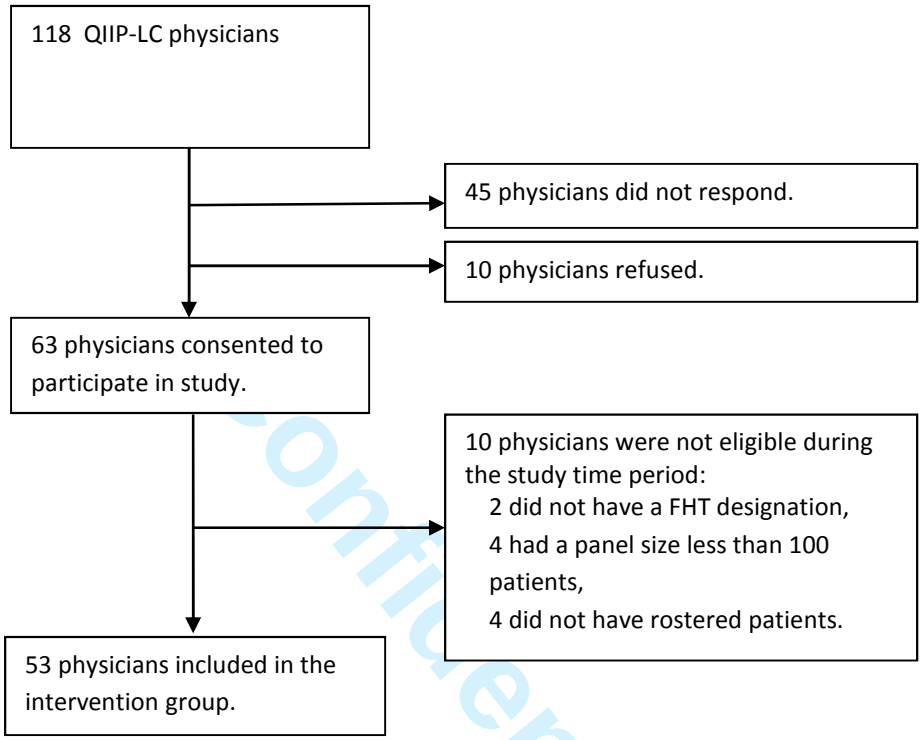
Figure 1. Recruitment flow chart



Appendix 2 Tables

Table 1 Demographics of Physicians by QIIP and Comparator Group

	QIIP Group		Comparator Group	
	%	**N**	**%**	**N**
Physicians	-	53	-	1178
Sex (male)	64.2	34	59.3	699
Country of Graduation (Canada)	92.5	49	87.9	1,035
Physician LHIN				
Erie St. Clair	0.0	0	2.0	23
South West	5.7	<=5	11.1	131
Waterloo Wellington	9.4	<=5	9.0%	106
Hamilton Niagara Haldimand Brant	11.3	6	14.1	166
Central West	0.0	0	1.9	22
Mississauga Halton	11.3	6	5.2	61
Toronto Central	3.8	<=5	7.0	82
Central	7.5	<=5	5.4	64
Central East	0.0	0	7.2	85
South East	13.2	7	7.7	91
Champlain	7.5	<=5	7.1	84
North Simcoe Muskoka	9.4	<=5	12.0	141
North East	11.3	6	6.4	75
North West	9.4	<=5	4.0	47
Physician Rurality Index of Ontario (RIO)				
Major Urban - 1 to 9	49.1	26	54.7	644
Suburban 10 to 39	22.6	12	28.0	330
Rural - 40+	28.3	15	16.1	190
Missing	0.0	0	1.2	14
	mean	**SD**	**mean**	**SD**
RIO	27.00	30.86	17.95	23.12
Age	49.85	8.40	48.27	9.47
Years in practice (yrs since graduation)	22.25	9.87	24.09	9.12
Mean number of patients	1475	-	1410	-

Table 2 *Demographics of Patients by QIIP & Comparator Group*

	QIIP Group		Comparator Group	
	%	N	%	N
All Patients	-	78,192	-	1,661,152
Patient Sex (Male)	47.4	37,061	46.6	773,869
Health Card Registration within 10 years of baseline	3.5	2,431	4.8	70,507
Age				
0-4 years	4.9	3,797	5.2	87,171
5-9 years	5.4	4,242	5.4	90,263
10-18 years	12.0	9,386	11.7	194,222
19-34 years	17.5	13,713	18.9	314,618
35-49 years	22.3	17,421	22.6	374,856
50-64 years	21.8	17,062	20.3	336,481
65-74 years	8.5	6,653	8.2	136,228
75-84 years	5.7	4,421	5.7	93,97
85 years +	1.9	1,497	2.0	33,336
Patient Rurality Index of Ontario (RIO)				
Major Urban (RIO 1 to 9)	49.5	38,688	53.2	883,085
10 to 39	29.0	22,644	30.3	502,829
Rural (RIO 40+)	18.1	14,148	5.1	250,538
Missing	3.5	2,712	1.5	24,700
Patient Income quintile				
Missing	0.7	520	0.7	520
Low Income (Quintile 1)	16.8	13,171	17.3	288,115
Quintile 2	18.2	14,218	19.2	318,724
Quintile 3	19.1	14,925	19.9	330,089
Quintile 4	22.1	17,296	21.6	358,818
High Income (Quintile 5)	23.1	18,062	21.2	351,419
Diagnostic Conditions				
Patients with diabetes	8.0	6,225	7.8	129,523
Patients with previous AMI*	1.4	1,090	1.4	23,082
Patients with asthma	13.5	10,539	13.4	223,053
Patients with chronic heart failure	2.0	1,602	2.0	32,455
Patients with COPD*	7.0	5,462	6.3	105,023
Patients with hypertension	21.6	16,859	21.2	352,751
Patients with mental health diagnoses	19.6	15,295	19.0	316,221
Adjusted Diagnosis Groups (ADG)				
0	5.8	4,538	5.7	94,961
1 to 5	53.5	41,814	52.4	871,048
6 to 9	34.5	26,956	35.4	587,558
≥10	6.2	4,884	6.5	107,585
	mean	SD	mean	SD
Resource Utilization Band (RUB)	2.62	1.10	2.63	1.10

*AMI = acute myocardial infarction; COPD = chronic obstructive pulmonary disorder

Table *3 Diabetes management*

		Baseline 12 months prior to LC		Post 12 months after LC		Adjusted Change (QIIP vs Controls)	*p value*
		%	*95% CI*	*%*	*95%CI*	*%*	
HbA1C test: ≥ 2 past 12 months	QIIP	41.1	36.0-46.3	51.4	46.6-56.3	4.3	0.006
	Comparator	42.7	41.5-43.9	48.0	46.9-49.0		
Retinal examination: ≥ 1 past 24 months	QIIP	72.5	70.4-74.6	76.6	74.8-78.3	2.5	0.005
	Comparator	71.6	71.1-72.1	73.3	72.8-73.7		
LDL Cholesterol test: ≥ 1 past 12 months	QIIP	56.9	50.1-63.6	64.0	57.8-70.3	1.3	0.466
	Comparator	59.5	58.3-60.8	64.7	63.7-65.8		
Billing for Diabetes Flowsheet (K030) ≥ 1 past year	QIIP	27.6	21.0-34.2	42.8	36.0-49.6	8.8	<0.001
	Comparator	34.4	32.9-35.9	39.0	37.6-40.4		
Billing for Preventative Care of Diabetes (Q040)	QIIP	21.7	15.5-27.9	39.1	32.0-46.3	8.9	0.004
	Comparator	28.8	27.7-30.3	35.0	33.4-36.6		
Diabetes Medication Management (Patients with type 2 diabetes over 65 years)							
Prescribed Statin	QIIP	66.5	62.8-70.2	74.5	71.2-77.7	3.4	0.011
	Comparator	67.6	66.8-68.5	71.9	71.2-72.6		
Prescribed ACE* or ARB**	QIIP	74.1	71.5-76.7	78.4	76.1-80.7	4.1	<0.001
	Comparator	76.0	75.3-76.7	75.0	74.4-75.6		
Oral hypoglycemic agents prescribed	QIIP	59.6	56.3-62.8	59.2	56.2-62.3	0.8	0.552
	Comparator	58.7	57.9-59.4	57.6	57.0-58.3		
Insulin Prescribed	QIIP	17.1	14.7-19.6	18.5	16.5-20.5	-0.3	0.764
	Comparator	15.9	15.4-16.4	17.9	17.4-18.4		

*Angiotensin Converting Enzyme Inhibitor
** Angiotensin Receptor Blockers
Change estimate and p-value: Generalized linear regression adjusted for baseline value, gender, rurality, age, and co-morbidity

Table 4 *Cancer screening*

		Baseline 12 months prior to LC		**Post** 12 months after LC		**Adjusted Change** (QIIP vs Controls)	***p value***
		%	***95%CI***	***%***	***95%CI***	%	
FOBT within past 2 years	QIIP	41.1	35.8-46.5	52.2	48.6-55.7	8.5	<0.001
	Comparator	39.5	38.4-40.6	42.8	41.8-43.8		
Colonoscopy within past 5 years	QIIP	24.5	22.0-27.0	29.7	27.1-32.3	0.02	0.979
	Comparator	26.6	25.9-27.3	31.7	31.0-32.3		
Flex sig/barium enema	QIIP	5.8	4.7-6.9	3.8	3.2-4.4	-0.03	0.359
	Comparator	6.3	6.1-6.6	4.4	4.2-4.6		
Any screening	QIIP	57.2	53.0-61.3	67.1	64.6-69.6	5.4	<0.001
	Comparator	57.6	56.8-58.5	62.4	61.7-63.0		
Other cancer screening (Women's Health)							
Cervical cancer screening* within past 2 years (%)	QIIP	61.7	57.9-65.5	63.5	60.6-66.3	2.3	0.015
	Comparator	62.3	61.5-63.1	61.4	60.6-62.2		
Cervical cancer screening* within past 3 years (%)	QIIP	72.2	68.5-75.8	75.1	72.2-78.1	2.7	0.004
	Comparator	72.9	72.1-73.6	72.7	71.9-73.4		

*Papanicolaou test

Change estimate post vs pre for QIIP vs controls using General Linear Regression for baseline value, gender, rurality, age and co-morbidity

Table 5 *Hospital admissions and emergency room visits*

		Baseline 12 months prior to LC		Post 12 months after LC		Adjusted Change (QIIP vs Controls)	*p value*
		Rate	***95%CI***	***Rate***	***95%CI***	**Rate Difference**	
Emergency Department Visits (per 100 patients per year)							
CTAS 1-3	QIIP	20.8	18.7-22.9	24.7	22.4-27.0	0.1	0.903
	Comparator	22.0	21.6-22.5	24.9	24.4-25.3		
CTAS 4-5 (low acuity)	QIIP	36.7	27.1-46.3	29.3	21.4-37.2	-1.0	0.358
	Comparator	28.8	27.3-30.2	24.6	23.5-25.8		
ACSC Hospital Admissions (per 10,000 patients per year)							
Overall	QIIP	52.8	40.6-65.1	51.5	41.3-61.7	3.0	0.497
	Comparator	42.7	40.6-44.8	42.1	40.2-44.1		
Diabetes	QIIP	8.0	5.2-10.8	8.4	6.1-10.8	0	0.985
	Comparator	7.5	5.2-8.2	7.2	6.5-7.9		
Asthma	QIIP	5.0	2.7-7.3	2.9	1.3-4.5	-1.0	0.418
	Comparator	4.1	3.6-4.6	3.3	3.0-3.7		
COPD*	QIIP	25.9	17.8-34.1	28.1	20.7-35.4	6.0	0.021
	Comparator	18.5	17.3-19.7	18.3	17.2-19.6		
CHF**	QIIP	13.9	9.1-18.7	12.1	8.8-15.5	-3.0	0.182
	Comparator	12.7	11.8-13.5	13.2	12.3-14.1		
Hospital Readmissions (% of those hospitalized)							
		%	**95%CI**	**%**	**95%CI**	%	
Within 30 days	QIIP	5.5	4.7-6.3	5.5	4.7-6.2	-0.03	0.947
	Comparator	5.1	5.0-5.3	5.3	5.1-5.4		
Within one year	QIIP	17.0	15.4-18.7	17.4	15.8-19.0	0.2	0.724
	Comparator	15.8	15.4-16.1	15.9	15.6-16.3		
	*COPD=chronic obstructive pulmonary disorder; ** CHF=cardiac heart failure Change estimate and p-value: Generalized linear regression adjusted for baseline value, gender, rurality, age, and co-morbidity						

STROBE Statement—checklist of items that should be included in reports of observational studies
Reviewed and incorporated these recommendations into the paper.

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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