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The impact of Quality-Based Procedures on radical prostatectomy outcomes in Ontario

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Abstract

Ontario's new health funding model, Quality-Based Procedures (QBP), designated certain performance outcomes that would determine future cancer care funding. We examined pre-specified outcomes for radical prostatectomy, one of the procedures integrated into QBP funding in 2015.

We conducted two retrospective studies using provincial administratively-linked databases, including patients who underwent radical prostatectomy between April 2010 and March 2019. Our first study evaluated the 30-day complication rate and the trend in surgical approach. Our second study compared QBP outcomes before and after implementation of the funding model.

The first study demonstrated that complication rate improved over the study period, possibly due to a transition to robotic approach for radical prostatectomy. The second study showed that complication rate and length of stay did improve after implementation of QBP, but not clearly because of the model. Unplanned visit rate and Wait 2 time worsened significantly, and there was no change in re-operation rate.

Keywords

Quality-Based Procedures, QBP, Quality-indicators, QI, activity-based funding, Cancer Care Ontario, prostate cancer, radical prostatectomy, robotic-assisted radical prostatectomy, retropubic radical prostatectomy, laparoscopic radical prostatectomy, perineal prostatectomy, minimally-invasive, complication, readmission, re-operation, mortality, length of stay, Wait 2, emergency department visit.

Summary for Lay Audience

In 2015, the Ministry of Health and Long-Term Care of Ontario and Cancer Care Ontario transitioned away from the old lump sum funding model to an outcomes-based funding model for the delivery of certain surgical oncology procedures. This was done to incentivize improvement in quality of care and outcomes delivered by cancer care groups. This new health funding model, called Quality-Based Procedures (QBP), designated certain Quality-Indicators (QIs) as performance outcomes that would be tracked by the province in order to determine future funding that cancer care groups would receive. As there is a need to evaluate whether the new model is improving outcomes, our project examined the QIs for radical prostatectomy, one of the procedures now integrated into QBP funding. We performed a brief review of the evidence behind funding model efficacy at improving outcomes. We reviewed the literature behind each QI outcome and expected rates. Prostate cancer as a disease, along with radical prostatectomy as a surgery were reviewed.

We conducted two retrospective studies using provincial administratively-linked databases, including patients who underwent a radical prostatectomy between April 2010 and March 2019. Our first study evaluated the 30-day complication rate in depth, as well as the trend in surgical approach to radical prostatectomy. Our second study compared QI outcomes, which include 30-day mortality, 30-day complication rate, 30-day re-operation rate, 30-day unplanned visit rate, proportion meeting the Wait 2 target, and proportion meeting the length of stay (LOS) target before and after implementation of the QBP funding model.

There was improvement in both 30-day complication rate and proportion meeting LOS target. However, more detailed analysis demonstrated both outcomes had already been improving, and did not get altered significantly upon implementation of the QBP model. However, this does align with greater utilization of robotic surgical approach, casting uncertainty as to whether conclusions can be drawn about the effect of the funding model in isolation. Other outcomes including 30-day unplanned visit rate and Wait 2 target time worsened significantly, while the 30-day re-operation rate remained unchanged. Overall, this study did not demonstrate that the QBP model improved outcomes, but further study is needed.

Co-Authorship Statement

This thesis was primarily written by the author, Dr Nickan Motamedi.

Synthesis of the initial study idea was developed by Dr Jacob McGee. Numerous modifications to this initial idea were made into what it became, and Dr Nickan Motamedi and Andrew McClure contributed to this process.

The study plan and design was created primarily by Andrew McClure and Nickan Motamedi, with additional contributions by Dr Jacob McGee, Dr Stephen Pautler, Dr Nicholas Power, Dr Blayne Welk, and Dr Lillian Gien.

The data analysis was done by Lucie Richard.

The integrated articles were primarily written by Dr Nickan Motamedi, with contributions from Dr Jacob McGee, Andrew McClure, Dr Stephen Pautler, Dr Nicholas Power, Dr Blayne Welk, and Lucie Richard. The tables were designed by Dr Nickan Motamedi. The interrupted time series figure in Chapter 3 was created by Lucie Richard.

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Chapter 1

1 Introduction: Cancer Surgery in Ontario and healthcare funding models

1.1 Cancer Care Ontario and cancer figures

Cancer care delivery, coordination, and funding in Ontario is largely driven by Cancer Care Ontario (CCO).[1] Per the CCO publicly available mandate, CCO outlines four key factors to ensure that they can measurably improve the cancer delivery system, quoted below:[1]

1. **Accountability:** We established a chain of accountability from the provincial level to the local level.
2. **Data:** We collect solid data, which allows us to measure and identify problems across the province, determine process and treatment effectiveness, and create benchmarks.
3. **Planning:** We develop multi-year cancer plans to give focus and direction to our priorities, and outline how healthcare providers, organizations, cancer experts and the government will work together.
4. **Performance:** We apply CCO's performance improvement model to generate evidence-based guidelines, conduct research, inform policy analysis and planning.

Per CCO's research and data division latest analysis done in 2018, the 10-year prevalence of all cancer diagnoses in Ontario is 393,785 persons (for January 1, 2006 – December 31, 2016), and 72,289 for prostate cancer.[2] The age-standardized incidence rate (ASIR) of cancer in Ontario is 551.8 per 100,000 persons, and 103.8 per 100,000 men for prostate cancer.[3]

Just as with incidence and prevalence, cancer mortality and survival are complex metrics influenced by multiple factors, chief of which is screening which may create a lead-time bias. This is well described in epidemiology literature.[4–6] Nevertheless, overall cancer mortality has decreased in Ontario based on CCO's latest public data, from 177.2 deaths per 100 000 age-standardized person-years in 2000, to 139.2 per 100 000 in 2016. For prostate cancer specifically, the rate has decreased from 25.4 in 2000 to 16.4 in 2016.[7]

The ultimate goal for CCO is to optimize the balance of the costs of cancer care with outcomes. The focus of this thesis will be to determine how outcomes have been affected by the latest funding model.

1.2 Funding models

There are many different funding models that have been implemented and trialed throughout the world, each with its own benefits and limitations. The two models of interest for the purposes of this thesis are known as the lump sum funding model, and the Activity-Based Funding (ABF) model (colloquially known as the outcomes-based model).

Historically, Ontario has functioned via a lump sum funding model. The province distributes a lump sum of funding at the beginning of each fiscal year to each hospital. The size of the funding is generally associated with the size of the hospital, as measured by any one of or a combination of several metrics such as inpatient bed capacity, service catchment, number of encounters, or variety of services provided. The hospital then allocates funding to various departments as is needed.

Since 2012, the province of Ontario has tried to move to fund various health services via an ABF model, rather than within the traditional lump sum that hospitals and health teams received annually.[8] The rationale for the change is that by tying health outcomes to funding allocation, health care teams may be incentivized to provide better care. While this model in theory would lead to better outcomes, the evidence is not as clear. Issues with the implementation of these models has been shown to be difficult, as choosing metrics that accurately reflect quality is contentious – leading some to suggest that mixed models incorporating both outcomes and base funding as more ideal.[9] A Norwegian study, where there was a national change in funding model to an ABF model, found that there was marked heterogeneity amongst the hospital systems in how the new ABF model affected their health care outcome metrics, with some improving and some worsening.[10] A systematic review and meta-analysis of studies evaluating the following outcomes after implementation of ABF models: mortality (acute and post-acute care); readmission rates; discharge rate to post-acute care following hospitalization; severity of illness; and volume of care.[11] They found a significant increase in discharge to post-acute care facilities (rehab centres, intermediate care, nursing homes, long-term care centres), and an increase in readmission rate to hospital. There was no improvement in mortality or volume of care. Severity of illness also increased in ABF models, which the authors offered may be due to differences in diagnostic coding. Overall, there was no evidence to support ABF models.

There is one model worthy of specific attention, as it pertains to the QBP model – the Danish Quality Model, from Denmark. The publicly-funded healthcare model in Denmark allowed for a good framework for tracking health outcome and demographic data, so the Quality Model was established in the 1990s for quality improvement.[12] This program expanded through the early to mid-2000s to create the Danish National Indicator Project.[13] The latter was an initiative that create panels of disease-specific experts to determine quality-indicators that could be tracked for various diseases, with the purpose

of creating clinical practice guidelines and standards for clinicians and improving care. This model is very similar to the design of the QBP funding model which will be outlined further in **Section 1.3**. The Danish National Indicator Project initially targeted quality-improvement of medical management of diseases that were most frequent and expensive, but has since branched to surgical quality improvement. In the mid-2000s, they began tracking cholecystectomy outcomes, and demonstrated that the new clinical practice guideline that was developed for it may have led to a reduction in laparoscopic cholecystectomy conversion to open rates declining from 8.8% in 2006 to 7.1% in 2008.[14] A nearly 20% improvement in only 3 years is quite dramatic. For healthcare models such as this, the Hawthorne effect must be considered as a possible mechanism at play, beyond simply guiding clinicians. The Hawthorne effect posits that subjects may behave differently when they know they are being observed. In this case, if general surgeons know that their laparoscopic to open conversion rate is being monitored and compared, they may be less inclined to do so – even if they have followed all of the clinical practice recommendations offered by the program.

Despite some promising findings, published research examining the effect of the Danish Quality Model in Denmark on surgical outcomes has been limited. Comparatively, there is a plethora of research that has been done using the data registries that were created by the Quality Model and the National Indicator Project, for various areas of surgical oncology.[15–17] This highlights one of the important differences between the Danish Quality Model and their tracking compared with that of CCO in Ontario is the data sourcing: In Denmark, they created data registries with tracking data for the express purpose of quality improvement and clinical practice change. In Ontario, much of the data we have on cancer surgery and other disease outcomes is based on administratively-linked databases, which will inevitably miss important variables or be inadequate for clinical use in some ways.

1.3 Ontario's cancer care QBP funding model

CCO moved towards the Quality-Based Procedures (QBP) funding model (an ABF model) in the 2015-2016 fiscal year (FY 2015-2016) for prostate cancer surgery, colorectal cancer surgery, breast cancer surgery, and thyroid cancer surgery.[18,19] Ontario's Ministry of Health and Long-Term Care had already begun rolling out this QBP model of funding in years prior for selected procedures and services within the broader funding allocation, in a mixed fashion.[8] For example, unilateral hip replacement, knee replacement, and chronic kidney disease management had already had a portion of funding allocation to their health teams tied to quality metrics that was followed by the province for each respective service beginning in 2012-2013. Though it started as a portion, the province made clear in their implementation guide that the intention was for the full funding allocation to eventually be tied to performance or outcome measures. The express purpose of the QBP funding model is to standardize care, improve patient outcomes, and optimize costs associated with common services.[8,18]

CCO's move towards the QBP outcomes-based model marked the first instance of cancer care being linked with funding allocation. As part of the QBP model, a QBP handbook was created for each service being evaluated. In it, CCO outlined standards of care and practice they expected cancer care teams to meet in order to achieve best practice and best outcomes. The process of developing these standards was rigorous, and outlined in the handbooks. Briefly, the first step was identifying diseases and clinical groups that were costly, and could be conceivably made more efficient. Next, there had to be adequate data and reporting available, as well as leaders in those fields who could help drive the change in standards. Next, there had to be identifiable variations in practice that could be standardized, and good scientific evidence of what a standard of care would entail.

For prostate cancer/radical prostatectomy, the QBP handbook included recommendations at several stages: pre-surgical assessment, day before surgery, intra-operative, and postoperative standards.[18,19] A few examples of these standards include obtaining a complete blood count pre-operatively, ensuring that an equipment checklist is completed on the day of surgery, and post-operative strategies such as breathing exercises and early ambulation to facilitate discharge. However, these recommendations are actually not evaluated by CCO. Instead, quality-indicators (QIs) are outlined – these are metrics that CCO has designated for use to determine outcomes and funding allocation. The QIs are listed and outlined in detail with a review of the evidence behind each of them in Chapter 3 *Ontario's QBP Quality-Indicators for radical prostatectomy*.

Chapter 2

2 Prostate cancer and radical prostatectomy

2.1 Introduction

Prostate cancer is the third most common cancer worldwide, and second most common among men, according to the WHO.[20] Prostate cancer is generally a very slow progressing cancer and often is not the cause of death for those who have it; studies have shown that in men dying of other causes, as many as 50% aged 70 or older had prostate cancer on autopsy.[21] Canadian research has demonstrated that while 1 in 7 Canadian men will be diagnosed with prostate cancer in their lifetime, only 1 in 29 will die from it.[22] Over time, prostate cancer incidence has evolved dramatically in North America, mainly due to detection bias, given the advent of routine asymptomatic prostate-specific antigen (PSA) screening with subsequent prostate biopsy.[23,24] These factors have made the management of prostate cancer nuanced, and screening has been a subject of debate. Given the low rate of morbidity from prostate cancer as compared to its high prevalence, routine PSA screening is now not advised according the Canadian Task Force on Preventive Health Care (CTFPH).[25] The latest figures from CTFPH suggest a relatively stable age-standardized incidence rate of approximately 120 per 100 000, acknowledging that if routine PSA screening was implemented, the discovered incidence would be much higher and population prevalence would increase as well.[24]

There are four main established risk factors for prostate cancer: age, ethnicity, genetic history, and diet.

Prostate cancer has a strong and well-defined association with age, with age being the most important of the four risk factors. This has been demonstrated globally and in

Canada, with age-standardized incidence rates of 10.9, 310.1, and 510.1 per 100 000 men aged less than 54, 55-69, and 70 or older respectively, according to latest national data.[26,27] However, this risk factor is not modifiable.

Ethnicity appears to be associated with prostate cancer incidence as well, though this epidemiologic finding is not without controversy.[28–30] As previously mentioned, the advent of PSA screening has increased the incidence, and because PSA screening varies by nation and region, it is hypothesized that this has played a role in the dramatic differences identified from different regions.[31] Other postulated hypotheses attempting to explain the variance include underdiagnosis and underreporting in certain regions, differences in access to care, and lower life expectancies in developing countries accounting for lower rates, in a disease that is largely age-associated.[31,32] Nevertheless, there seems to be a growing consensus that while all of these factors play a role, there may also be an inherent predisposition for various ethnicities to develop prostate cancer.

Prostate cancer has an association with genetic history. Inherited mutations can implicate each level of the disease, from screening, staging, treatment, and testing of family members.[33–36] One study found that as many as 18.5% of metastatic prostate cancers involved germline mutations.[37] Patients with strong family histories of prostate cancer may be referred for genetic counseling and testing, as various gene mutations have been associated; these include BRCA1/2, CHEK2, ATM, MUTYH, HOXB13, APC, MSH2, TP53, and PMS2.[38] This is a growing area of research, and with the advent of new therapies such as Poly-ADP-ribose Polymerase enzyme inhibitors (PARP inhibitors), some of these genetic mutations can be targeted if identified.[39]

There are some dietary associations as risk factors for prostate cancer, but an exhaustive list is beyond the scope of this section. The major risk factors that have been demonstrated consistently in the literature are diets high in animal fat, or low in

vegetables; this has been demonstrated in case control studies, screening trials, and prospective studies, though most of the literature is outdated.[40–43] Hazard ratios in these studies tended to vary only between 1.1 and 3.0, so this appears be a minor risk factor.

2.2 Prostate cancer pathology

The dominant malignancy of the prostate is the prostatic adenocarcinoma, accounting for greater than 95% of all prostatic cancers.[44,45] Other epithelial and non-epithelial malignancies of the prostate such as neuroendocrine tumors, stromal tumours, and other carcinomas are quite rare, and will not be covered in this review as they are typically not staged or managed in the same manner.

Adenocarcinoma of the prostate is similar to other tissue-types of adenocarcinoma; it is characterized by erratically infiltrating glands, composed of dense and prominent nucleoli. Prostatic adenocarcinoma is predominantly acinar-type, with only approximately 5% being ductal-type. The acinar and ductal types are distinguished mainly from their architectural differences. Acinar-type is composed of smaller and more benign-appearing glands, while ductal-type has larger glands that may be papillary in nature. Lastly, it is notable that over 70% of prostatic adenocarcinoma arises from the peripheral zone of the prostate.[45]

2.3 Risk stratification and staging

Risk stratification and staging of prostate cancer is essential in selecting a treatment modality. There are effectively four characteristics that aid in determining which patient and their disease should get a therapy: extent of disease or disease burden (defined by

Tumour, Node, Metastasis (TNM) staging), serum PSA, histologic grade defined by the Gleason score, and patient factors such as their comorbidities and goals of care.

With respect to TNM staging of prostate cancer, it begings with Tumour staging, which can be clinical or pathological. The full TNM guide for prostate cancer is developed by the American Joint Committee on Cancer (AJCC)/Union for International Cancer Control (UICC) in their latest Cancer Staging Manual, and where summary tables can be found in the *Appendices* (Appendix A) as drawn from Buyyounouski et al. (2017).[46]

From the clinical staging of the Tumour category, T1 is a clinically inapparent tumour to palpation, and is only evident on biopsy. T1a and T1b distinguish whether or not the tumour makes up more or less than 5% of the transurethral prostate biopsy sample, and T1c denotes a non-palpable tumour on transrectal ultrasound guided biopsy. If a tumour is palpable, it is upgraded to T2. In T2, if the tumour is confined to less or more than half of one side of the prostate, it is denoted as T2a or T2b respectively, and if it is present on both sides, it is T2c. T3 is reserved for the tumour that is extraprostatic, with T3a being extracapsular extension and T3b being tumour that specifically invades seminal vesicles. Lastly, T4 is extraprostatic with extension to the external urethral sphincter, rectum, bladder, levator ani muscles, or pelvic wall.

Pathologic staging of the Tumour category begins at T2, which is defined by disease confined to the prostate. T3 denotes extraprostatic extension including microscopic invasion into the bladder neck, and T3b remaining as seminal vesicle involvement. T4 is unchanged as well.

Node category is defined by N0 which is no positive regional lymph nodes, and N1 which denotes regional lymph node involvement. The Metastasis category is defined by

M0 which is no distant metastasis, M1a being metastasis to non-regional lymph nodes, M1b being any bone metastasis, and M1c being any other side with or without bone disease.

The next component to risk stratification and staging according to AJCC is identifying the serum PSA. This is divided into <10 ng/mL, ≥10 ng/mL to <20 ng/mL, and ≥20 ng/mL. These correspond to stages as shown in the *Appendices,* Appendix A.

The Gleason score was used internationally as the standard histological system for grading prostate cancer on biopsy, until it was replaced by the International Society of Urologic Pathology (ISUP) Grading System in 2014.[47] The Gleason scoring procedure is still used, but the classification and grouping now follows the ISUP Grading System. Histologic sampling of the tumour is done using a core needle biopsy, most commonly transrectally and via ultrasound guidance. The gold standard initial technique is transrectal ultrasound-guided extended prostate biopsy, which obtains 10-14 core samples.[48] Historically, fine-needle aspiration was used but this method fell out of favour due to inferior performance as compared to the core-needle biopsy.

The procedure of transrectal ultrasound-guided prostate biopsy (TRUS-Bx) is approximately 10 minutes in duration. As a standard of practice, the “Standard 12-core” involves the physician sampling the tumour and then taking random biopsies of the rest of the prostate for a total of 12 cores, with each sampling less than 1% of the actual prostate organ. This technique can be repeated if the initial biopsy yield is negative, but index of suspicion for prostate cancer is still present. Other methods, such as “Saturation biopsy” have been described where at least 24 cores are taken by random sampling, with the benefit being increased detection of tumour – the standard procedure misses tumour in at least 20% of cases and underestimates Gleason score in an additional 20-30% of cases.[48] While the saturation biopsy method can be used in repeat biopsies, the

morbidity associated with more sampling has also been described which dissuades from using it as a first-line technique.[49]

The Gleason score is given by the pathologist as a composite of two values. The pathologist will examine the histologic pattern of the prostatic samples, and look for patterns of atypia or cellular differentiation. These are scored 1 through 5, with 1 being well-differentiated and 5 being poorly differentiated. If two differentiation patterns are seen, then they are each scored and added together to create the cumulative Gleason score. If more than two differentiation patterns are seen, then the pathologist will use the most prevalent pattern in the sample, along with the most poorly differentiated pattern to create the composite Gleason score. Once the Gleason score is ascertained, it is then further given a Grade Grouping, which is a grouping system designed with prognostication in mind. The groups are numbered 1 through 5, with 1 bearing the best prognosis, and 5 prognosticating the worst. The introduction of the ISUP 2014 is what brought about this grouping system. An example of the scoring system is shown below:

In a TRUS-Bx sample, the pathologist notes that there is prostatic adenocarcinoma present. In the majority of the sample, it is scored as a Gleason score 3 (most prevalent). In one sample, it is more poorly differentiated and scored 4 (worst differentiation). In total, 3+4=7, making the Gleason score 7. 3+4=7 corresponds to a Grade Group 2.

A special note should be made about the difference between 4+3=7 and 3+4=7, where the former is known to have a significantly worse prognosis than the latter. This is outlined in the aforementioned AJCC guideline, and illustrates why convention mandates that the scoring communicated by its components, not just the overall score.

2.4 Non-surgical treatment options and adjuvant therapies

Non-surgical treatment options of prostate cancer broadly includes androgen deprivation therapy (ADT), and radiotherapy – which includes external beam radiation therapy (RT), and brachytherapy (either radiotherapy option may be used alone or together).

ADT is employed frequently in conjunction with RT, though generally this combination is reserved for metastatic or recurrent disease.[50] The principle behind ADT is that androgens are essential for the growth of prostatic tissue, so anti-androgens (such as bicalutamide) can help blunt the progression of prostate cancer cells in castration-sensitive prostate cancer. ADT as an approach typically involves either surgical castration (bilateral orchiectomy) or medical castration with gonadotropin-releasing hormone agonists or antagonists (GnRH agonists or antagonists) to suppress the testes. Androgen-axis targeted therapies (ARATs) may act on the androgen-receptor signaling pathway, and are another available option for use in some cases. Examples include abiraterone, apalutamide, and enzalutamide.

In certain cases of localized disease, such as those in which patients have undergone radical prostatectomy but experience biochemical recurrence in the form of an up-trending PSA, RT with or without ADT may be indicated, according to the latest American Society of Clinical Oncology (ASCO) guideline update on the Initial Management of Noncastrate Advanced, Metastatic, or Recurrent Prostate Cancer.[50]

In general, RP and RT are used for localized disease, and other treatments such as ADT are typically for metastatic disease. A review of the evidence and best practice is beyond the scope of this review but can be found in the ASCO guideline.

2.5 The radical prostatectomy

The radical prostatectomy is a more aggressive resection than the simple prostatectomy. It is an en bloc resection of the prostate with the prostatic urethra, and generally includes other adjacent structures such as the seminal vesicles and regional lymph nodes. The bladder is then re-anastomosed to the urethra. The objective is to achieve resection with good oncologic margins. As mentioned in the **Section 2.3: Risk stratification and staging**, radical prostatectomy is generally selected for patients with localized disease, as the procedure can be morbid.

The nerves running adjacent to the prostate facilitate erectile function and the procedure itself involves resection of the internal urethral sphincter. As such, patients will have voiding dysfunction and erectile dysfunction in the immediate post-operative period, and are discharged home with a urinary catheter. Loss of the internal urethral sphincter leads to stress urinary incontinence, which is overcome with pelvic floor physiotherapy alone in most patients, though some will require adjunctive procedures (artificial sphincter implantation or slings) in order to achieve continence.

The most common modern approaches for radical prostatectomy include the open retropubic, and increasingly popular robotic-assisted approach. The general steps of the procedure are the same, and outlined by Huynh & Ahlering (2018), but will not be reviewed in this thesis.[51]

2.6 Expected complications

Complications from RP should be divided into expected and unexpected. In this section, I have labelled “expected” complications as those inherent to the procedure – that is,

complications associated with local trauma to the nerves of the urogenital tract. Inevitably, there will be some degree of iatrogenic injury of the regional nerve bundles, whether or not the nerves were spared. The expected complications associated with RP include voiding or urinary dysfunction and erectile dysfunction. Some degree of urinary dysfunction, mostly in the form of stress urinary incontinence is consistently seen post-operatively.[52][53] The most common manifestation of this is with stress urinary incontinence, and it does improve with time. This is in contrast to radiotherapy, which may also lead to irritative urinary dysfunction (frequency, urgency, dysuria), but it tends to develop over a longer period of time. Overall, the consensus is that the rate of urinary dysfunction is comparable in the long-term, but that surgical approach will lead to higher early rates of urinary dysfunction.[52,53]

Erectile dysfunction is also an expected morbidity after radical prostatectomy. As with urinary dysfunction, erectile dysfunction does seem to improve up until 2-5 years later.[52,53] Radiotherapy may also lead to erectile dysfunction, though the effect is seen more long-term rather than immediately.

“Unexpected” complications as I have labelled them, are effectively short-term surgical complications inherent to most surgeries, and surgeries in the pelvis. These include bleeding requiring blood transfusion, post-operative surgical site infection, urogenital complications such as urinary tract infections, and general systemic adverse events associated with any surgery or general anesthetic (pneumonia, myocardial infarction, cerebrovascular accident, etc).

In Chapter 3 *Ontario’s QBP Quality-Indicators for radical prostatectomy*, quality indicators for RP will be reviewed. 30-day complication rates are discussed, and because of the unique presence of the expected complications (urinary dysfunction and erectile

dysfunction) for nearly every patient in some capacity, it would seem appropriate to leave those out of the calculation of 30-day complication rate.

2.7 Prognosis

The survival after radical prostatectomy is generally excellent. 30-day mortality as a metric is described in greater detail in the *30-day mortality rate* section. With respect to oncologic prognosis, studies have examined the benefit of RP on cancer-related outcomes. Randomized control trials have shown that RP improves prostate cancer-related mortality modestly compared to watchful waiting at 10 years and at 15 years.[54,55] Population-based data has also shown that after controlling for patient-specific factors, RP seems to provide better survival benefit over radiotherapy for localized disease.[56] Other metrics such as complications and need for re-operation rates are discussed in the *Ontario's QBP Quality-Indicators for radical prostatectomy* chapter.

Chapter 3

3 Ontario's QBP Quality-Indicators for radical prostatectomy

3.1 Preamble

Two QBP handbooks were published by the Ontario MOHLTC: the first, for the 2015-2016 fiscal year, which was the year of establishment, and the second, in 2019 – an update and an expansion. The QBP handbooks outlined the QIs that the province were to focus on to assess for outcome improvement. These QIs were developed after the consultation of leading Urologists across the province. Below is a literature review of each QI with emphasis on the current literature and on how they apply to radical prostatectomies. It is worth noting that while many of the QIs were emphasized in both the 2016 and 2019 QBP handbook publications, some of them were only present in 2016, and removed for the 2019 iteration. Conversely, there are also cases of QIs not mentioned in the 2016 handbook, but added for the 2019 iteration. For the purposes of this study, these QIs have been examined, and discussion with regard to why they were added or removed follows in the respective section. The majority of the QIs apply to all cancer surgeries (re-operation rate, mortality rate, etc.).

The literature review below touches on only the most major and relevant studies that shed light onto each of the quality indicators (for example, many single institution studies were largely left out), followed by considerations that must be made when attempting to capture the variables in this study, in the context of how they were captured in the previous literature. Doing so will provide rationale for our methodology, and give validity to the findings when compared with historic evidence.

3.2 30-day reoperation rate

The QBP handbook outlines that "Re-operation rate within 30 days after resection" is an all-cancer surgery QI.[18] However, it does not define what diagnoses or procedures would be included or excluded as part of this variable. Indeed, the literature on this variable is quite heterogenous, with different studies measuring it quite differently, and few studies aiming to capture it as a primary outcome. Given the heterogeneity and lack of landmark definition, below are outlined numerous studies offering different approaches to capturing this variable.

Jaffe et al (2001) performed a retrospective cohort study, comparing laparoscopic radical prostatectomy outcomes in those with and without a history of transurethral prostate resection, using a matched-pairs design from cases performed from their single centre.[57] One of their outcomes was re-operation rate, where they saw a 4.2% and 1.7% rate respectively, from their 238 study participants (119 subjects in each group). Unfortunately, they did not define the post-operative follow-up period, so it remains unclear when these cases were re-operated on. Additionally, they did not define what surgeries or diagnoses would be included. In the discussion, they did explain that of the seven "re-operations", three were due to bleeding, and two were due to bowel injuries that were initially unidentified. This study is difficult to draw interpretation from, as our study must pre-define the variables that require assessment, and the duration of follow-up (30 days) to assess for re-operation.

Hu et al. (2008) examined the "need for re-operation" within 90 days after radical prostatectomy, using a national Medicare database of radical prostatectomies between 2003-2005 to assess several other outcome measures.[58] Their study included "need for re-operation", naming it "Miscellaneous surgical", as part of a composite within their "perioperative complication rate" outcome. The CPT codes they used to capture this

variable was predominantly diagnosis codes involving genitourinary fistulas. Thus, they did not actually capture a group that was re-operated on within 30 days, as is defined by the QBP QI. However, this study sets a benchmark that re-operation after radical prostatectomy might occur secondary to fistulisation of the urogenital tract.

Toujier et al (2008) performed a prospective cohort study comparing outcomes between laparoscopic and retropubic RP at a single centre from 2003 to 2005.[59] Re-operation within 30 days of RP was examined, with a statistically significant difference between groups for RRP and LRP respectively (0.4% vs 1.9% p=0.03). There were 12 re-operations in total (3 and 9 respectively). This study is more useful as it informs us of the expected re-operation rate within 30 days. However, the investigators did not pre-define indications for re-operation that would be included, or define all of the indications for re-operation. They did explain that 6 of the 9 cases in the LRP group were re-operated for the indication of bleeding, which is consistent with the study by Jaffe et al. (2001), but not Hu et al. (2008). Nevertheless, the applicability to our study remains limited, as this was a single institution study, and biased to not reflect true population trends as a result.

Pereira et al. (2018) sought to further characterize the association between age and perioperative morbidity and mortality among men undergoing radical prostatectomy using NSQIP database data between 2010 and 2015.[60] As part of their analysis, they examined 30-day re-operation rate. They found a re-operation rate of 1.2% overall, with no significant difference across age groups. This is likely the most relevant study, as it is most recent and adapted to modern minimally-invasive techniques, and the study designs is similar to ours in that it uses population data. While the study does not discuss indications for re-operation, our study will not either, given the design. It is also consistent with a previous NSQIP study conducted by Pilecki et al. (2014), which used a NSQIP cohort from the year 2011, though they used complication rate as their primary outcome of interest, with reoperation rate as a secondary outcome.[61] They found a

reoperation rate of 0.99%, relatively consistent with the Pereira et al. (2018) finding of 1.2%.

With the outcome of reoperation rate, the NSQIP studies are likely the strongest and most representative of what our study will find, given the methodological similarity, recency, and size. Given that previous literature also found rates close to 1%, it is reasonable to expect this estimate for Ontario.

3.3 30-day mortality rate

In contrast to 30-day re-operation rate, the literature is more consistent in measuring 30-day mortality after radical prostatectomy, and there are some population-scale database studies that will allow us to get an accurate estimate of the targets we should expect to see from our study, or to target as a province. When reviewing the literature on this topic, single institution studies were excluded as there was concern for bias, and their methodological difference with ours, a population-scale database studies, affects the validity of a comparison.

The earliest of the most recent studies comes from Alibhai et al. (2005) who performed an ICES database study of 30-day morbidity and mortality after radical prostatectomy, from 1990 to 1999 in Ontario.[62] In this era, it was mainly open radical prostatectomy performed, as minimally-invasive techniques had not yet been widely adopted. The mortality rate was 0.48% for all patients, and patients were stratified by age group, which

was a focus of their study. Now an accepted concept, they found mortality independently increased for every 5-year increase in age. In addition to older age category, univariate analysis found comorbidity score (Charlson index or Diagnosis Count), or the presence of cardiac disease, hypertension, or stroke were statistically significantly associated with higher 30-day mortality after surgery. It was also noted that there was lower mortality from 1995-1999 than from the years prior. While this study used the same geographic population that our study will draw from, there have been dramatic advances in surgical technique, notably minimally-invasive surgery, which affects how valid the comparison with our study's finding would be.

Konety et al (2006) performed a cross-sectional analysis of a national database in the United States from 1998 to 2002 to assess whether or not mortality after major urologic surgery was improved if performed at high-volume hospitals by high-volume surgeons.[63] For their analysis of radical prostatectomy, they found a 30-day mortality rate of 0.11%, lower than the rate of 0.48% in the study by Alibhai et al (2005), but consistent with a similarly designed Swedish study from the same period.[62,64] Konety et al (2006) happened to find that hospital and surgeon volume of RP did predict post-operative mortality, with high and moderate volume centres having lower mortality. This finding has been reproduced since the publication of this study in 2006.[65] Though there is discrepancy in the mortality figure between Konety et al (2006) and Alibhai et al. (2005), the findings suggests that any study assessing for 30-day mortality should also measure whether cases are coming from high or low volume centres.

Walz et al (2008) also performed a Quebec provincial database analysis of the effect of surgical volume, age, and comorbidities on 30-day mortality from 1989-2000.[65] They cite discrepancy in the mortality figure from the Konety et al (2006) and Alibhai et al. (2005), looking to identify the more accurate figure. They ultimately found a 30-day mortality rate of 0.52%, more in keeping with the figure produced by Konety et al (2006). Once again however, it is difficult to say based on this study what the mortality rate will be for our study population, which will reflect 10-30 years of surgical advancement, and minimally-invasive techniques. Furthermore, with the consistent finding that mortality rate improved with more recent years, confirmed again by the findings of Walz et al (2008), we expect an improved mortality rate from our study.

The most recent study, and perhaps thus the most relevant, is by Pereira et al (2018) who sought to further characterize the association between age and perioperative morbidity and mortality among men undergoing RP using NSQIP database data between 2010 and 2015.[60] They rationalized that the only modern studies examining RP perioperative mortality did not include minimally-invasive techniques (as we have seen in the above sections) or were single institution studies. This study found a 0.2% 30-day mortality for the cohort, and they did find statistically significant differences between age groups (<60 years 0.1% vs 70-89 years 0.3%, p=0.0004). This gives us a benchmark to compare with, as many Ontario institutions are included in the NSQIP dataset, so the trend should be

similar given that much of our study population would have been included in this study's cohort as well.

3.4 30-day unplanned visit rate

30-day readmission rate is a metric that involves significant morbidity and cost. For this reason, along with 30-day emergency department visit rate, they were included in the initial QBP handbook.[19] In the 2019 iteration of the handbook, the two metrics were combined, and renamed "unplanned visit rate" likely owing to the similar indication – that there has been some sort of unexpected issue mandating a re-visit to care.[18] The challenge becomes that while readmission rate and emergency department visit rate are captured in many studies, they are not commonly combined or even captured in the same study. Below we investigate only the recent evidence available in order to make the best estimation possible of benchmarks rates, and factors affecting it. Due to the adoption of Early Recovery After Surgery (ERAS), much of the literature prior to the 2010s is likely out of date or not as relevant as more recent literature.

The earliest relevant study is out of Japan, where investigators were examining a new perioperative pathway as a way to improve post-operative outcomes.[66] This study was conducted in 2007 and 2009, where the 2007 group was pre-intervention and the 2009 cohort was post-intervention. The strengths of this study are that it included 2610 patients and over 50 centres, and included a modern post-operative pathway that involves similar principles as with ERAS, such as early activity. They found a 1.9% and 2.5% re-admission rate pre and post-intervention, respectively, which was not a statistically significant difference. This study did also include both open and minimally-invasive radical prostatectomies, further improving the generalizability to today's practice. However, the key disqualifying feature revealed in this study is that mean length of stay

was 18 days in the pre-intervention group, and 15.8 days in the post-intervention group. This is in stark contrast to the 2-3 day length of stay for radical prostatectomy in Ontario, which will be explored in further detail in the section 1.4.8. Given these differences, it is impossible to compare 30-day re-admission rates in Ontario with a study that had over half that duration as mean length of stay.

A retrospective study was conducted in 2014 by authors based out of a single centre in Montreal, assessing for the impact of the adoption of ERAS on radical prostatectomy outcomes.[67] They included open and minimally-invasive radical prostatectomy outcomes at a single centre from 2009 through 2012 in the usual care cohort (100 patient-data gathered via chart review), followed by prospective inclusion of 99 patients undergoing both open and minimally-invasive approach with ERAS post-operative care. As part of their outcomes, they did include re-admissions and re-visits to the emergency department, but their definition for those outcomes was at 90 days. Comparing the usual care to the ERAS care groups, they found a 3% vs 7% rate of re-admission, though this difference was not statistically significant (p=0.18). Additionally, there appeared to be no significant difference between minimally-invasive and open approaches with respect to re-admission, though no analysis was given by the authors (5.5% vs 4.8% open vs minimally-invasive). When examining emergency department visit rates, both usual care and ERAS groups demonstrated a 12% visit rate (p=0.95). When comparing open vs minimally-invasive approaches, there was no analysis done, but rates were similar (12.3% vs 11.9%). Overall, this study gives us a ballpark rate to examine, but being a single centre study and having a relatively small sample size for outcomes that may average less than a 10% rate suggests these figures may not be entirely accurate.

The next studies are the NSQIP studies, and once again are most likely the best studies to draw estimates from.[60,61] As mentioned previously, the study by Pereira et al. (2018) examined age-related associations with morbidity and mortality using the population-based NSQIP database, while Pilecki et al. (2014) looked at similar outcomes but

comparing retropubic radical prostatectomy and robotic approach. The studies found 4.0% and 3.87% 30-day unplanned re-admission rates, respectively. However, these studies did not take into account 30-day re-visit to the emergency department. It is worth noting that in the study by Pilecki et al (2014), they used data from 2011 and they described that beginning in 2013, American hospitals would begin facing "readmission penalties" deducted from Medicare reimbursement. However, the rate of re-admission did not improve in the subsequent study by Pereira et al. (2018), where they used data from 2010-2015. Overall, these two studies are useful in estimating readmission rate, given the methodological similarities, recency, consistency of findings, and parallel with respect to financial motivation for hospitals to improve.

A meta-analysis in 2017 by Tang et al compared retropubic and robotic-assisted radical prostatectomy outcomes.[68] They included both retrospective and prospective studies, largely recruiting from the 2000s and 2010s. Overall, they included 78 studies, but only included 7 for the analysis of re-admission rate. They found an odds ratio of 0.83 when robotic-assisted approach was compared to retropubic approach (p=0.03). Due to the methodology, this study also does not give us a concrete re-admission rate, only an odds ratio by approach. This makes this study less useful for our purposes. Unfortunately, this study was riddled with issues related to significant heterogeneity; the I^2 for re-admission rate was 84%. A sensitivity analysis was performed in order to attempt to reduce this heterogeneity and provide more validity to the results, where only the four highest quality studies were included. For this analysis, n=4191, but their statistical significance was in fact lost, again with even more pronounced issues related to heterogeneity (OR = 0.53, 95% CI 0.23-1.21, p=0.13, I^2 = 88%). While the study was published in a known, reputed peer-reviewed journal, there is a reporting error in the abstract, citing a readmission rate OR of 0.70 which is not what the study found. Put together, unfortunately, this study cannot really be used to draw any conclusions on factors related to readmission.

Overall, the literature on what we can expect in Ontario with respect to 30-day re-admission and emergency department visit rates is quite poor, except for the NSQIP studies. Of the other studies discussed, the Canadian study in 2014 is likely the best one, but by nature of the study design, it would not be unusual if our study which is much larger to find different results. The safest suggestion is that the readmission rate will be approximately 4%, as evidenced by the NSQIP studies.

3.5 30-day composite complication rate

Complication rate is an important metric with which to evaluate, as it portends morbidity to patients, leads to visits, admissions, costs, and is central in the discussion of risks and benefits of the surgery. Unfortunately, there is no consensus on which diagnoses should be included in a composite metric of "complication rate". The QBP handbook defines the window for complication rate at 30 days, which will also vary by study. Unlike the re-admission and re-visit, complication rate is in fact well-studied, so distinguishing the various complications included in each study's composite is the main objective of critical analysis of the literature. Additionally, only large-scale population-based studies were selected for discussion in this section, as they are most pertinent to our own methodology and estimation of our own projected outcomes.

The earliest, most relevant large-scale study on this topic is a NSQIP study conducted by Pilecki et al. (2014).[61] They conducted a review of NSQIP data from participant-use files from 2011, looking to compare complication rates between retropubic radical prostatectomy and robotic-assisted approach. The authors note that by 2011, nearly 80% of radical prostatectomies were being done robotically in the United States. This study included 5471 patients in the NSQIP database who had a radical prostatectomy done by retropubic approach or robotically, and found a complication rate of 23.25% and 5.62% respectively ($p<0.001$), or a pooled complication rate of 9.16%.

Included in the complication list was the following: surgical infection (including deep and superficial spaces), hematologic (transfusion, and VTE), respiratory (pneumonia, re-intubation, and prolonged ventilation), cardiovascular (myocardial infarction, and cardiac arrest), genitourinary (renal insufficiency, acute renal failure, and urinary tract infection), neurologic (cerebrovascular accident, peripheral nerve deficit, and coma), and multisystem (sepsis) complications. When analyzing by complication type comparing retropubic approach to robotic, surgical infections (3.37% vs 0.97%; $p<0.001$), myocardial infarction (0.64% vs 0.11%; $p=0.004$), pneumonia (0.64% vs 0.21%; $p=0.027$), urinary tract infection (3.19% vs 1.71%; $p=0.002$), transfusion (17.68% vs 1.87%; $p<0.001$), and sepsis (1.73% vs 0.64%; $p<0.001$) accounted for significant differences. To summarize, robotic patients had far fewer blood transfusion, accounting for the majority of the difference in complication rate, and infectious complications accounting for a smaller but also significant difference. On the whole, because the study design involves retrospective cohort design using population-scale data, it is likely that our data will be very similar to that found in this study. As such, this study should be used as a benchmark, and attempts should be made to capture as many of the variables as in this study as possible, especially given that it was inclusive of so many.

As discussed previously, another NSQIP study was published several years later looking at the age-associated morbidity of radical prostatectomy from 2010-2015.[60] Since they used the same database as Pilecki et al. (2014), they had the same variable selection, albeit grouped into slightly different categories: cardiac, DVT/PE, infectious, respiratory, renal, neurologic, and surgical infection. Notably, they separated blood transfusion into a unique variable, apart from their composite complication outcome. They found a 5.0% pooled complication rate, which was consistent with the 9.16% complication rate from the 2014 study after accounting for blood transfusion rate (4.1% transfusion rate, for a combined 9.1% complication rate). As with the 2014 study, this study should be used as a benchmark.

Nam et al. (2014) attempted to ascertain non-erectile dysfunction and non-incontinence-related complication rates of radical prostatectomy as it compares to radiation therapy.[69] The authors are Ontario-based, and performed a population-based retrospective cohort study using data from the Institute of Clinical and Evaluative Sciences (ICES) which is the same dataset we will draw from. This study is worth brief discussion because the methodology is relevant to our present study objective, however, the follow-up period for complications in this study was on the scale of years. As such, this study is not really of interest.

Olvera-Posada et al. (2017) published an evaluation of the impact of repeated prostate biopsies on the major complication risk for patients who ultimately underwent radical prostatectomy.[70] They also used ICES data out of Ontario to conduct their study. The data is this study is from 2002 to 2013, where 99.3% of the volume of radical prostatectomy was done via open approach, per study results. Their primary outcome was a composite complication rate that represented "significant complications likely related to the radical prostatectomy, and generally requiring additional surgical procedures". This included postoperative treatment of urinary and rectourethral fistula, creation of intestinal diversion, upper urinary tract obstruction, or repair of ureteral injury within a year of the radical prostatectomy. Secondary outcomes were also more unique; incontinence, need for urodynamic testing, procedures associated with bladder neck contracture, readmission to hospital, blood transfusion, mortality, length of stay, and need for radiation or androgen deprivation therapy were examined. The primary outcome was observed in 1.07% of the cohort in this study, though this is somewhat misleading if taken as a complication rate. Another 13.24% had a blood transfusion, and 23.98% had a procedure associated with bladder neck contracture. Incontinence, urodynamic testing, and erectile dysfunction were seen at rates of 1.14%, 1.71%, and 0.12% respectively. This study differs significantly from the NSQIP studies because it deviates in their assessment of surgical complications, as seen in the primary composite outcome. Additionally, there is a stronger focus on urological surgical-related complications. This study also invaluably informs our analysis, because the authors included the codes they used in their analysis;

we can then use these codes to create an accurate comparison in outcomes. However, this study likely does not encompass the true nature of post-operative complication rate, as it did not report many of the general complications of surgery, such as myocardial infarction or venous thromboembolism, which the province will likely be evaluating, given that they have associated morbidity and costs as well.

Overall, our present study will need to draw concepts from both the NSQIP studies and Olvera-Posada et al. (2017). The purpose of the QBP outcomes-based model is to improve quality outcomes after radical prostatectomy, and it would be unusual if this definition included only urologic outcomes. As such, for a study aiming to evaluate the effectiveness of the outcomes-based model, the composite complication rate should include more generalized outcomes as in the NSQIP studies. However, the study by Olvera-Posada et al (2017) allows us to also assess for specific surgically-related outcomes, and confirm that important codes needed for complication analysis are included.

3.6 Proportion with positive resection margins that received post-op radiation oncology consultation or discussed at Multidisciplinary Care Conference

Radical prostatectomy is strictly indicated in localized disease, according to the joint consensus guideline from the American Urologic Association (AUA), American Society for Radiation Oncology (ASTRO), Society of Urologic Oncology (SUO), and American Society of Clinical Oncology (ASCO) published in 2017.[53] Thus, all patients with positive resection margins should receive a referral to a radiation oncologist. This study will look to trend referral rates in Ontario, though a high rate is expected given that this is standard of care for all practicing urological oncologists. Cancer Care Ontario does not publish this rate to compare with. Additionally, while there are means to elucidate which

study subjects would have been seen by a radiation oncologist, this QBP QI also includes those who have been discussed at Multidisciplinary Care Conference (MCC) according to the latest QBP handbook, and we do not have access to that via ICES databases.[18] As such, this will not be reviewed or assessed in our study.

3.7 Proportion meeting Wait 2 target time

Wait 2 priority target is the time from decision to proceed with radical prostatectomy, to actual surgery date. Cancer Care Ontario (CCO) has assigned priority levels to each cancer surgery, and prostate cancer falls into Priority 4 – the lowest priority. This Priority 4 target is 84 days, and the benchmark that health systems will be evaluated on by the QBP model. Presently in Ontario, Priority 4 patients are waiting an average of 68 days, but only 66% are being treated within the target time.[71] Evidently, patients and surgeons both seek to reach a surgical date sooner, and the basis for the Wait 2 time is to ensure that delays do not lead to cancer progression and worse oncologic outcomes. Conveniently, by far the highest quality study evaluating the impact of wait times for prostate cancer surgery oncologic outcomes was just recently published only months ago.

A population-based study done in the United States, utilizing the US National Cancer Database set out to analyze whether or not surgical delay for localized, high-risk prostate cancer is associated with biochemical recurrence.[72] They included 32 184 patients who underwent radical prostatectomy within 180 days from diagnosis, stratifying them in 30 day intervals from 31-60 days after diagnosis, up to 151-180 days after diagnosis. The study only included high risk diagnoses because it carried the assumption that higher risk pathology on biopsy portended higher risk of biochemical recurrence, which is a prudent assumption. High-risk patients were defined by the following: pre-operative PSA ≥20 ng/mL, or biopsy grade 4 to 5 (Gleason score 8-10). They found no statistically significant differences in this primary outcome across the different surgical delay time

groups, including the longest delay group. This study is very recent, being published in late 2020, and provides new evidence that localized prostate cancer surgery is a low priority, and may be safely delayed up to 6 months.

The significance of the study by Xia et al (2020) cannot be understated: the QBP quality indicator of Wait 2 time thus is likely not a patient outcome indicator, but should be thought of as a systems efficiency indicator. As such, this quality indicator is likely of lesser importance than the others, as it does not seem to adversely affect oncologic outcomes.

3.8 Length of stay

The advent of minimally-invasive radical prostatectomy has had benefits, none of which are more clear than minimizing length of stay in hospital, as demonstrated in the literature dating back to the early 2000s.[73] A landmark randomized-control trial in 2016 comparing robotic-assisted radical prostatectomy with retropubic approach found a significant difference in length of stay (1.55 vs 3.27 days; $p<0.001$).[74] Thus, this is effectively one of the least controversial outcomes reviewed.

CCO has set targets on mean post-operative length of stay for hospital systems, and this varies by approach. For open techniques, the target is 3 days, and for minimally-invasive approaches it is 2 days; these are the mean length of stay targets that will be evaluated by the QBP length of stay quality indicator.[18]

Chapter 4

4 Rationale and study design

4.1 Rationale for study, purpose, and hypothesis

The push to evolve the healthcare model to an outcomes-based funding model is controversial, as described in the Funding models section. While CCO intends to monitor metrics internally and devise payment schedules and hospital funding based on the QBP QIs, there is a need for transparency to evaluate whether or not the new model is working. CCO has not laid out any plan to publish how outcomes have changed with time, though they do make the proportion meeting the Wait 2 target publicly available.[75] The publicly available data goes back to 2018, showing a relatively stable quarterly rate of 81% of cases meeting the Wait 2 target time, until COVID-19 in Q1 2020 dropped the rate down to 66%. It has since rebounded in Q3 and Q4 2020 to 93%.

Nevertheless, there should be an investigation to audit before and after implementation of the QBP model in order to ascertain whether an overhaul has led to an improvement in the stated outcomes or savings within the system.

As such, the purpose or objective of this thesis is to determine the impact of the QBP model on the QI outcomes.

However, over the period where the QBP has been implemented (mid-2010s), there has been a shift towards robotic-approach for radical prostatectomy. This shift may conceivably affect outcomes, most clearly the complication rate – this has already been described in the literature in many retrospective studies. As such, this thesis will also seek to identify trends in complication rate and approach of radical prostatectomy in Ontario

from 2010-2019. This provides essential context to the interpretation of identified changes in QI outcomes over the study period.

Based on our literature review, the hypothesis would be no change in radical prostatectomy outcomes attributable to the QBP model. Additionally, with the gradual shift towards robotic-approach in recent years, we would expect that trend to continue.

4.2 Optimal study design

As the QBP model is being rolled out on a provincial level, we will need population-level databases for the province of Ontario. The data should be coded reliably to a reasonable degree, and should date back before implementation of the QBP model. As such, it would be a population-based retrospective cohort design.

Administratively-linked databases are the most readily available tool for this purpose. The Institute for Clinical and Evaluative Sciences (ICES) is an organization dedicated to doing retrospective data health research using their access to a multitude of health data sets in Ontario. They are being continuously updated and most, though not all, date back over a decade. They are coded by trained specialists around the province, and these databases are used both for clinical research as well as data gathering by the province. In fact, CCO uses these same databases to monitor provincial outcomes, though they do not publish which specific codes or analysis plans they run.

The period of interest would be several fiscal years (FYs) prior and several fiscal years after the implementation of the QBP for RP in FY 2015-2016. Data prior to 2009 would

require searching previous iterations of some of the databases and finding ICD-9 codes. Additionally, it is known that RARP was still not widely adopted prior to 2009, which would make the results less relevant, so the earliest FY selected was 2010-2011. The latest data reliably available data in all the databases required was 2019, so FY 2018-2019 is as recent as our study window could be.

4.3 Analysis considerations

OUTCOMES

The metrics that should be evaluated are the QBP QIs as outlined in the QBP handbooks, published in 2016 and 2019.[18,19] Interestingly, there are differences in the QIs outlined in each. In 2016, QIs included: 30-day re-operation rate, 30-day mortality rate, 30-day complication rate, 30-day re-admission rate, mean length of stay, and proportion of patients meeting Wait 2 target. There are also several others that are not amenable to study as they are not readily available using administrative databases; these include discipline participation in Multi-disciplinary Cancer Conferences (MCC), proportion who saw a radiation oncologist or were discussed at an MCC, proportion with positive pT2 resection margins, and proportion with positive resection margins who were seen by radiation oncology in consultation post-operatively. In 2019, the new iteration of the QIs added 90-day mortality rate, removed 30-day complication rate, modified 30-day re-admission rate to include Emergency Department visits (thus termed 30-day unplanned visit rate), and added proportion meeting Wait 1 target time. Of these changes, 90-day mortality should be easily added to our analysis. It is not clear why 30-day complication rate was removed, but it is certainly an outcome of tremendous interest in the surgical literature, and merits investigation as it accounts for patient morbidity and healthcare utilization. Wait 1 time, the time from referral to first visit with a surgeon, is

unfortunately not a metric that can be measured to our knowledge. There are other considerations that must be made when measuring some of these outcomes.

Firstly, Wait 2 time cannot be exactly specified using administrative data, as it is technically time from decision to proceed with RP to the surgery date. While we cannot know when the decision to proceed with surgery is made using administrative data, we can approximate it using time from first visit with the surgeon. This accepts that we will underestimate the Wait 2 time, as some cases will decide to proceed with surgery subsequent to the first visit, but this will just be a limitation. Additionally, with 30-day re-operation rate, we can capture any subsequent surgery that happens within 30 days of the RP date, but since a re-operation can be for any variety of reasons, we cannot easily exclude unrelated surgeries. Moreover, the province does not provide any guidance as to what a re-operation specifically entails (i.e. there is no clarity offered as to whether an occult bowel injury requiring revision is considered a re-operation, or if it's limited to urologic causes only). As such, our re-operation rate will overestimate the true rate.

When considering study design, two separate studies can be made with these outcomes. As 30-day complication rate was removed as a QBP QI but remains of great interest, we can design a study focusing on complication rates and how they have evolved over our study period. RP in Ontario will have evolved greatly in surgical approach and because of the QBP funding model affecting delivery, so these two metrics should be accounted for in a study evaluating complication trends. A comparison of the complication rates between RARP and RRP would be of interest as they are the two most common surgical approaches, and a similar comparison can be done before and after implementation of the QBP funding model.

A second study evaluating the rest of the measurable QBP outcomes can be designed similarly. This would include 30- and 90-day mortality, 30-day re-operation rate, 30-day

unplanned visit rate, mean wait time or proportion meeting length of stay target, and proportion meeting Wait 2 target. As this includes numerous outcomes defined by CCO, we would prioritize the comparison before and after the implementation of the QBP model for each outcome, with a secondary goal of comparing the outcomes by surgical approach if we have the resources to complete that level of analysis.

ANALYSIS

For outcome measures, a simple before and after comparison around the implementation of the QBP model for radical prostatectomy may or may not illustrate a difference, but would not be fair given real-world implementation logistics. For example, in the months after the implementation of the model on April 1st, 2015, it is unlikely that any drastic changes in care will have taken effect. To account for this, an interrupted-time series model allows us to compare before and after implementation with a grace period that can be excluded. This methodology would be more likely to reveal true differences in outcomes if they exist, as it allows more time for the QBP model to take its hold on care team practice. The actual comparison can be done with a simple independent sample t-test, as the data burden is large and expected to be approximately normal in distribution.

The other benefit of the interrupted time series model is that it allows us to compare the trend of each outcome before and after the QBP implementation. As an example, if hypothetically there was a significant difference in 30-day unplanned visit rate before and after implementation of the QBP model, but the trend or slope was the same before and after, it would suggest that the QBP model did not actually alter the outcome. Instead, it would suggest that the outcome was already changing before implementation and that the significant difference is a reflection of a sustained pattern of change across multiple years. This analysis is crucial to the understanding and context of the findings.

Logistic regression modeling should be done for the major factors known to affect radical prostatectomy outcomes: age, obesity, surgeon volume, and minimally-invasive technique. We can also include logistic regression modeling of the QBP period (using the pre-implementation period as a reference). The results from these logistic regressions will allow us to contextualize the findings if there are differences seen in baseline and outcomes between pre- and post-QBP implementation.

Chapter 5

5 Evaluating trends in radical prostatectomy approach and complication rate in Ontario from 2010-2019

5.1 Introduction

Radical prostatectomy (RP) is the surgical intervention for prostate cancer, with approximately 8000 men undergoing the procedure in Canada each year, according to the Canadian Institute of Health Information statistics.[76] Traditionally, this procedure has been done via open techniques, with open RP (ORP) including retropubic (RRP) or perineal (PRP) approaches. The advent of laparoscopic surgery allowed for the pioneering of the laparoscopic approach (LRP), and later with the commercial availability of the Da Vinci robot in 2000, the robotic-assisted RP (RARP). These two approaches collectively offered minimally-invasive RP (MIRP), with many studies investigating the benefits of MIRP over ORP. The most clear and consistent evidence summarized in a 2017 Cochrane review suggests that MIRP offers a lower complication rate (predominantly from reduced bleeding and blood transfusion requirement) and shorter length of stay in hospital, as compared to ORP.[77] Of particular interest is how the complication rate is affected, as patients who suffer perioperative complications contribute to increasing healthcare utilization and cost in the form of re-admission or hospitalization and re-operation. On the other hand, up front procedure cost and surgical procedure time are limitations of the MIRP, and specifically the popular RARP, compared to the ORP. Other factors affecting the complication rate that have been described include age, obesity, and surgeon volume.[62,78,79]

Nevertheless, in the United States, RARP in particular has quickly become popular for its benefits. According to national insurance data sources, RARP was the choice approach for just 1.9% of RPs in 2002, increasing to 29.5% in 2008, and accounting for over 65% of all RPs in 2017.[80,81] Accordingly, studies utilizing NSQIP data sources have

acknowledged a lowered complication rate in RP, though again primarily driven by a reduction in need for blood transfusion.[61] Ontario data would suggest that the adoption of the MIRP has not been as rapid as in the United States. The Canadian Institute for Health Information published a report demonstrating tremendous heterogeneity in RARP delivery among the provinces, with only Ontario, Alberta, Quebec, and British Columbia using RARP as an approach.[76] Nationally, only 19% of RPs were done robotically by 2013, ranging from less than 10% in BC to nearly 60% in Alberta, and Ontario and Quebec both at approximately 20%.[76]

Since then, there has been no population scale study in Canada or Ontario to evaluate the trend in radical prostatectomy approach, and the associated complication rate – the main purported benefit to MIRP. The objective of this study is to quantitatively describe the trend in the radical prostatectomy approach in the last decade in Ontario, and assess the trend in complication rate of the procedure within that context.

5.2 Methods

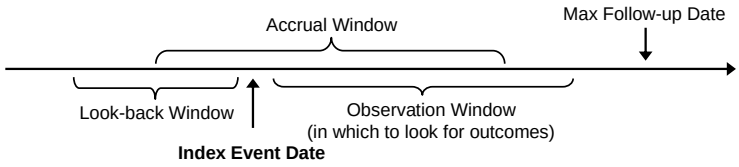
STUDY DESIGN AND DATA SOURCES

We conducted a population-based retrospective cohort study including all men who underwent radical prostatectomy for prostate cancer in the province of Ontario, Canada (population approximately 14.4 million in 2018) from April 1, 2010 to March 31, 2019.[82] We excluded non-Ontario residents, men who were less than 18 or greater than 105 years old, did not have a health insurance card, did not have a confirmed diagnosis of prostate cancer within 5 years of surgery date, had a non-urologist listed as surgeon, or who had a history of total or radical cystectomy, renal transplant, abdominal perineal

resection or other bowel resection, and any patient who had received pelvic radiation within the last 10 years (See **Figure 1 Time frame definitions**).

Figure 1 Time frame definitions

Project Time Frame Definitions



Accrual Start/End Dates	April 1, 2010 – March 31, 2019
Max Follow-up Date	April 30, 2019
When does observation window terminate?	• End of follow-up (max: 30-days after index event) • Death
Lookback Window(s)	• Exclusions: 10-years for pelvic radiation therapy andcystectomy • Baselines: 1-year for Charlson Index, 3-years for obesity

All Ontario residents have access to universal health care through the Ontario Health Insurance Plan (OHIP), with all insured services captured in administratively-linked databases. Patient demographic data was obtained using the Registered Persons Database (RPDB); comorbidity, patient characteristic, and complication data was obtained using the Discharge Abstract Database (DAD) and Same Day Surgery (SDS) databases; prostate cancer diagnosis was confirmed using Ontario Cancer Registry (OCR); and surgeon data was obtained using the Ontario Health Insurance Plan database.

OUTCOME DEFINITIONS

Our primary outcome was the annualized composite complication rate of RP. To build the composite complication list, we categorized complications into cardiac, pulmonary,

venous thromboembolism (VTE), wound, transfusion, rectal injury or colostomy, fistula, urinary tract, or ureteric injury complications. The complete list of CCI and ICD-10 codes used to identify the complications can be found in the additional files. We intentionally used a broad spectrum of complications, in an attempt to capture as many complications related to RP as possible. Several previous studies examining complications were considered in an attempt to increase the generalizability of the data, and those with complications that could be captured within the population-based data were included.[61,62,69,70,78] Notable exclusions were incontinence and erectile dysfunction, as these are assuredly present post-operatively in nearly all cases.

BASELINE VARIABLES

Patient age, comorbidity information (including obesity with BMI ≥40, diabetes, hypertension, chronic obstructive pulmonary disease, and composite Charlson Index score), centre of surgery, rurality and income quintile, surgical approach (highlighted separately), surgeon volume, and centre volume were obtained. The comorbidities were obtained using a 1 year look back window, and 3-year look back window for obesity. As BMI is not captured by administratively-linked datasets, we identified obesity using the obesity premium rider for billing surgical procedures, where patients with BMI ≥40 qualify. For surgeon volume and centre volume, we identified thresholds for high and low volume surgeons and centres independently, as there is no standard threshold in the literature. To define high volume surgeons, we tallied each surgeon's case volume in each year, identified the number of cases required to define a 90th percentile case-volume surgeon in each year (range: 36-22 cases/year), and then chose the lower end of that range and applied it to all years to standardize the case threshold. This procedure preserved the original case volume data and ensured that some high-volume surgeons are not mischaracterized in the low volume group in some years. The same procedure was applied to define high volume centre (65 cases/year).

ANALYSIS

We aimed to compare baseline characteristics for men who did and did not experience a complication from RP were compared using standardized differences (SD). For large cohorts, SDs have been shown to better reflect clinically important differences than p-values obtained by independent samples t-test.[83] With this method, we used SD ≥20% as a clinically meaningful indicator of between group difference, as differences up to this threshold are still considered to be small.[83] We used logistic regression modeling defining the effects of age, obesity, surgeon volume, and minimally-invasive approach on complication rate, as these have been identified as important factors in the literature.

5.3 Results

Our initial cohort consisted of 24 099 subjects. After applying exclusions criteria, 2771 were excluded leaving us with a final cohort of 22 118 who remained included for analysis Table 1.

Table 1 Cohort build

Exclusion criteria	Number excluded	Number included
Initial Cohort	N/A	24,099
Data cleaning	15	24,084
Non-Ontario resident	6	24,078
Age <18 or >75 years	311	23,767
No cancer within 5 years of index	790	22,977
No matching OHIP record	1,366	22,401
Total/radical cystectomy	113	22,288
Pelvic radiation therapy	133	22,155
Renal transplant	7	22,148
Concurrent procedure/Not by a urologist	30	22,118
TOTAL	**2,771**	**22,118**

Baseline characteristics are shown in Table 2. In the comparison between those with no complications and complications, variables that had an SD ≥0.2 included median age (63 years vs 64 years, SD=0.2), Charlson comorbidity score median (0 vs 1, SD=0.21), and high volume surgeon (53.5% vs 40.7%, SD=0.26). The number of cases stratified by surgical approach is shown separately to highlight the annual trend.

Table 2 Baseline characteristics

Variable	Value	Overall cohort	No complication	Complication	SD
		N=22,118	**N=19,647 (88.9%)**	**N=2471 (11.1%)**	
Age	Mean (SD)	62.49 ± 6.44	62.35 ± 6.43	63.58 ± 6.44	0.19
	Median	63 (58-67)	63 (58-67)	64 (60-68)	0.2
Morbid obesity (BMI ≥40)	Yes	2.0%	2.0%	2.3%	0.02
Diabetes	Yes	16.6%	16.2%	20.2%	0.1
Hypertension	Yes	52.1%	51.4%	57.2%	0.12
COPD	Yes	12.7%	12.3%	15.1%	0.08
Charlson comorbidity Score	Median	0	0	1	0.21
	0	94.8%	96.6%	80.9%	0.51
	≥1	5.2%	3.4%	19.1%	
Centre of surgery	Academic	44.1%	45.0%	37.3%	0.16
	Community	55.9%	55.0%	62.7%	0.16
Stage	1	8.8%	8.9%	8.3%	0.02
	2	50.4%	50.6%	49.0%	0.03
	3	31.5%	31.4%	32.7%	0.03
	4	3.7%	3.5%	5.2%	0.09
	Missing	5.6%	5.7%	4.7%	0.04
Income	Quintile 1	13.3%	13.1%	14.7%	0.05
	Quintile 2	18.2%	18.1%	18.8%	0.02
	Quintile 3	19.9%	19.8%	20.3%	0.01
	Quintile 4	22.3%	22.4%	21.3%	0.03
	Quintile 5	26.1%	26.3%	24.6%	0.04
	Missing	0.2%	0.2%	0.2%	0
Surgeon volume	Mean (SD)	39.99 ± 40.63			
	Median (IQR)	22 (13-52)			
	High volume	52.0%	53.5%	40.7%	0.26
Institution volume	Mean (SD)	106.42 ± 86.52			
	Median (IQR)	65 (38-183)			
	High volume	49.8%	50.5%	44.3%	0.12

The Table 3 shows the proportion of RP by surgical approach by each fiscal year. Over the 9-year study period, the majority of RPs were done via retropubic approach (66.3%), with the next most common being robotic-assisted (23.7%), and laparoscopic (6.7%) and perineal approach (3.3%) being less common. This 9-year period happens to define the increase in popularity of RARP, as in FY 2010-2011 only 6.8% of RPs were done via this approach, while in FY 2018-2019 it had reached 36.7%. This compares to the decreasing trend by retropubic approach, with 80.3% in FY 2010-2011 down to 55.6% in FY 2018-2019. Laparoscopic approach (10.3% to 4.6%) and perineal approach (2.6% to 3.1%) had smaller absolute changes.

Table 3 Annualized proportion of radical prostatectomies done by each surgical approach

Approach	Fiscal Year									Overall N=22,118
	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	
Perineal	2.6%	2.7%	3.5%	3.7%	4.1%	3.1%	4.9%	2.5%	3.1%	N=733 3.3%
Retropubic	80.3%	79.0%	70.7%	62.3%	61.2%	61.2%	58.1%	60.1%	55.6%	N=14,669 66.3%
Laparoscopic	10.3%	10.4%	7.8%	6.3%	4.3%	4.7%	4.7%	4.4%	4.6%	N=1,472 6.7%
Robotic	6.8%	7.8%	18.1%	27.7%	30.5%	31.0%	32.3%	33.0%	36.7%	N=5,244 23.7%

The overall composite complication rate of the cohort was 2471/22 118 (11.17%), and is shown in Table 4. The most common complication category was need for blood transfusion (6.26%), followed by wound-related (5.38%), urinary tract infection (2.13%), cardiac (1.59%), and rectal (0.66%), with the others being rare, or accounting for less than 0.5% respectively. There was a downtrend that was most notable in transfusion rate (7.96% FY 2010-2011; 3.47% FY 2018-2019), while the wound complication rate along with the others remaining stable.

Table 4 Annualized composite complication rate

Outcome	By Fiscal Year									Overall Rate
	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	
	N=2,939	N=3,007	N=2,529	N=2,291	N=2,156	N=2,260	N=2,321	N=2,248	N=2,367	N=22,118
Composite complication rate	13.24%	12.30%	11.19%	11.00%	11.22%	10.80%	10.17%	10.72%	9.04%	11.17%
Cardiac	1.74%	1.83%	1.27%	1.13%	1.72%	2.08%	1.38%	2.05%	1.10%	1.59%
Pulmonary	0.24%	0.27%	<=5*	0.39%	<=5*	<=5*	<=5*	0.36%	<=5*	0.24%
Neurologic	<=5*	<=5*	<=5*	<=5*	<=5*	<=5*	<=5*	<=5*	<=5*	0.10%
Venous Thromboembolism	0.41%	0.30%	NR**	0.48%	<=5*	0.49%	0.56%	0.67%	0.38%	0.42%
Wound	5.44%	4.56%	5.02%	5.54%	5.52%	5.75%	6.16%	5.56%	5.15%	5.38%
Transfusion	7.96%	6.75%	6.21%	5.11%	4.55%	3.85%	3.15%	3.47%	3.42%	6.26%
Rectal	0.68%	0.47%	0.95%	0.70%	0.42%	0.71%	0.78%	0.67%	0.63%	0.66%
Fistula	<=5*	0.20%	<=5*	<=5*	<=5*	<=5*	<=5*	<=5*	<=5*	0.12%
Urinary Tract Infection	2.18%	2.03%	1.46%	2.27%	2.27%	2.21%	2.37%	2.31%	2.15%	2.13%
Ureteric injury	<=5*	<=5*	<=5*	<=5*	<=5*	<=5*	<=5*	<=5*	<=5*	0.09%

*<=5 indicates that there was 5 or fewer occurrences, and the value or percentage cannot be published to preserve anonymity

**NR = None recorded

Table 5 demonstrates the composite complication rate by surgical approach annually. Complication rates for retropubic approach (12.70 % overall; range 10.57% to 14.49%) and robotic (7.47% overall; range 6.35% to 8.89%) remained relatively stable year over year, while perineal (12.29% overall; range <=5 annual complications to 17.98%) and laparoscopic (8.56% overall; range 0% to 14.95%) had greater fluctuations year over year. Overall, minimally-invasive approaches had fewer complications.

Table 5 Annualized 30-day composite complication rate for each surgical approach

Approach	Fiscal Year									Overall
	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	
Perineal	10.53%	13.41%	17.98%	11.76%	14.77%	11.43%	14.04%	<=5*	<=5*	12.29%
Retropubic	14.49%	13.26%	12.42%	13.24%	12.81%	12.00%	11.93%	11.83%	10.57%	12.70%
Laparoscopic	8.58%	7.99%	8.16%	NR**	<=5*	14.95%	8.26%	10.20%	7.27%	8.56%
Robotic	6.50%	8.05%	6.35%	6.47%	8.52%	7.71%	6.68%	8.89%	7.36%	7.47%

*<=5 indicates that there was 5 or fewer occurrences, and the value or percentage cannot be published to preserve anonymity

**NR = None recorded

The logistic regression analysis is shown in Table 6. Predictors selected based on our literature review were statistically significant, including age (OR 1.03 [1.022-1.037 95% CI], p<0.001), surgeon volume (OR 0.994 [0.993-0.996 95% CI], p<0.001), and minimally-invasive approach (OR 0.714 [0.634-0.804 95% CI], p<0.001). Obesity was not statistically significantly associated with composite complication rate (OR 1.31 [0.965-1.780 95% CI], p=0.0838).

Table 6 The effects of age, obesity, surgeon volume, and minimally-invasive approach on composite complication rate

Variable	OR	95% CI	P-value
Age	1.03	1.022-1.037	<0.001
Obesity	1.31	0.965-1.780	0.0838
Surgeon Volume	0.994	0.993-0.996	< 0.001
Minimally-invasive approach	0.714	0.634-0.804	< 0.001

5.4 Discussion

The strength of this study is the clear illustration of a trend away from open RP and shift to RARP that had not previously been quantified in this level of detail. Despite the trend, this study demonstrates that Ontario's most recent figure of 36.7% robotic-assisted approach in FY 2018-2019 remains fewer than the United States and United Kingdom who each have greater than 60% rates of RARP as choice approach.[80,81] Our study demonstrated a reduction in complication rate over the study period, as illustrated in Table 4, from 13.24% in FY 2010-2011 to 9.04% in FY 2018-2019. The main drivers of complication rate were transfusion rate and wound complications.

The complication rate decline mirrors the rise in robotic approach, which portends a lower complication rate than open approaches. The only complication that appreciably declined year over year was the transfusion rate. Thus, we suspect that it is the lower

transfusion rate of minimally-invasive techniques that has been demonstrated in the literature that accounts for this, though our study did not evaluate the individual complications by surgical approach to confirm this definitively.

Our study also confirmed that minimally-invasive approach (OR 0.714) is one of, if not the strongest protective factor against complication. Surgeon volume (OR 0.994) and age (OR 1.04) were analyzed as continuous variables, hence have smaller odds ratios, but are also important. Previous literature has categorized surgeon volume as “high” or “low” based on various thresholds or quartiles, where there is no agreed definition.[78,79] In treating surgeon case volume as a continuous variable, this study is strengthened as it assigns a quantifiable importance to additional case volume. Using our odds ratio, the complication rate odds ratio for a surgeon who does one case per month ($0.994^{12} = 0.930$) and the surgeon who does one per week ($0.994^{52} = 0.731$) can be defined, which numerically defines the importance of doing more cases. Obesity was not a statistically significant predictor of subsequent complication.

One of this study’s present limitations relates to resources. As the data was gathered as part of a larger study evaluating the effect of the Quality-Based Procedures funding model on pre-determined quality outcomes, much of the data was gathered within the context of the new funding model. This may have affected outcomes, and this study did not make a comparison as this is being studied separately. Additionally, a breakdown of each subcategory of complication by surgical approach would confirm the expectation that RARP has a lower complication rate related to blood transfusion specifically, but resources constrained adding on this analysis. This study also has limitations with regards to data sourcing. Many complications are not easily captured in administrative data, as the purpose of the data collection is not for clinical research purposes. For example, urinary tract infections are likely underestimated, as our databases would only capture those that are diagnosed in hospital or health facilities; outpatient urine studies, diagnoses, and treatments would not be captured. As such, our complication rate is likely

underestimated. From the baseline data, obesity is likely underestimated as not every surgeon will reliably bill the obesity rider, and the rider itself is only applied to BMI 40 and above which excludes many obese individuals. This would explain why this demographically is commonly associated with increased complications, but was not statistically significant in our study.

5.5 Conclusion

In Ontario, there has been a steady shift away from RRP and towards RARP in the last decade. RRP remains the most popular approach in Ontario, and RARP now accounts for over one third of cases. Minimally-invasive approaches including RARP in Ontario portend a significantly lower complication rate, and this is likely driven by a lower blood transfusion rate. Future studies should examine the cost-effectiveness of the current shift to RARP.

5.6 References

To avoid duplication of references in this integrated article thesis format, all references are included in the thesis References section.

Chapter 6

6 The impact of the Ontario Quality-Based Procedures funding model on radical prostatectomy outcomes

6.1 Introduction

Optimizing cost effectiveness and health outcomes is a priority in cancer care in Ontario's single payer healthcare system.[1] Since 2012, Ontario has tried to move to fund various health services via an Activity-Based Funding (ABF) model, rather than within the traditional lump sum that hospitals and health teams received annually.[8] The rationale for the change is that by tying health outcomes to funding allocation, health care teams may be incentivized to provide better care. The new funding model in Ontario is named Quality-Based Procedures (QBP), and with it are outcomes named Quality-Indicators (QIs) for various surgical procedures that will be tracked by the province to measure performance and in turn, allocate funding.[19] This is a similar design to the Danish Quality Model that was established in Denmark's publicly-funded health system over the past 20-30 years.[12]

While this model in theory would lead to better outcomes, the evidence is not as clear. Issues with the implementation of these models has been shown to be difficult, as choosing metrics that accurately reflect quality is contentious – leading some to suggest that mixed models of funding may be more ideal.[9]

To date, there has only been one study evaluating the efficacy of the QBP funding model. Li et al. (2020) published an interrupted time series study evaluating the impact of the new funding model on early rollouts of the new model which include congestive heart failure, pneumonia, hip fracture surgery, and prostate cancer surgery (radical prostatectomy).[84] As their study evaluated a range of conditions, their outcomes were

limited to mortality, re-admission rate, and length of stay. For radical prostatectomy, they found no change in mortality, re-admission, and a worsening in length of stay.

The QBP for RP, which was implemented in the fiscal year (FY) 2015-2016, outlines several additional QIs not covered by Li et al. (2020). In addition, there are several surgical factors known to affect outcomes that must be accounted for before drawing conclusions on the effects of the model; these include age, obesity, surgeon volume, and surgical approach.[62,68,79] RP can be done via perineal approach (PRP), retropubic approach (RRP), laparoscopic approach (LRP), and robotic-assisted approach (RARP), which have varied in popularity over the years, and have various expected lengths of stay and other outcome rates. As such, they should be accounted for in any comprehensive analysis of RP outcomes. Some surgical centres will inevitably lose some funding as a result of this funding model change, so it is imperative that there be a comprehensive analysis examining the impact of the QBP funding model on QI outcomes.

The purpose of this study was to assess the QBP QI outcomes before and after implementation of the QBP funding model in fiscal year (FY) 2015-2016 for RP, and to determine whether changes in these outcomes appear to be attributable to the new funding model.

6.2 Methods

STUDY DESIGN AND DATA SOURCES

We conducted a population-based retrospective cohort study including all men who underwent radical prostatectomy for prostate cancer in the province of Ontario, Canada (population approximately 14.4 million in 2018) from April 1, 2010 to March 31, 2019.[82] We excluded non-Ontario residents, men who were less than 18 or greater than 105 years old, did not have a health insurance card, did not have a confirmed diagnosis of prostate cancer within 5 years of surgery date, had a non-urologist listed as surgeon, or who had a history of total or radical cystectomy, renal transplant, abdominal perineal resection or other bowel resection, and any patient who had received pelvic radiation within the last 10 years. See **Figure 1 Time frame definitions**.

All Ontario residents have access to universal health care through the Ontario Health Insurance Plan (OHIP), with all insured services captured in administratively-linked databases. Patient demographic data was obtained using the Registered Persons Database (RPDB); comorbidity, patient characteristic, and complication data was obtained using the Discharge Abstract Database (DAD) and Same Day Surgery (SDS) databases; prostate cancer diagnosis was confirmed using Ontario Cancer Registry (OCR); and surgeon data was obtained using the Ontario Health Insurance Plan database.

OUTCOME DEFINITIONS

As the QBP funding model has numerous QIs, those that were measurable with our administrative databases were our outcomes of interest. This includes 30-day composite complication rate, 30- and 90-day mortality, 30-day re-operation rate, 30-day unplanned visit rate, proportion meeting Wait 2 target time, and proportion meeting length of stay target. Components or codes of the composite complication rate are included in the appendices, and were chosen based on what comparable studies had included, and what was available to us. Wait 2 target time was approximated by the time between consultation with the surgeon and the surgery index date. The length of stay target time in

Ontario is outlined in the QBP handbook; for perineal and retropubic approaches the target is 3 days, and for laparoscopic and robotic approaches the target is 2 days.

Other QI outcomes that we could not capture with our available data include (1) discipline participation in Multi-disciplinary Cancer Conferences (MCC), (2) proportion who saw a radiation oncologist or were discussed at an MCC, (3) proportion with positive pT2 resection margins, and (4) proportion with positive resection margins who were seen by radiation oncology in consultation post-operatively. MCC details are not captured in ICES administrative databases to our knowledge, so (1) and (2) could not be captured. We were able to retrieve pathology staging through OCR, but we did not have the detail of whether or not resection margins were positive, so we could not retrieve (3) and (4). We did contact administrators for OCR at ICES to find this data, but were unsuccessful.

BASELINE VARIABLES

Patient age, comorbidity information (including obesity with BMI ≥40, diabetes, hypertension, chronic obstructive pulmonary disease, and composite Charlson Index score), centre of surgery, rurality and income quintile, surgical approach (highlighted separately), surgeon volume, and centre volume were obtained. The comorbidities were obtained using a 1 year look back window, and 3-year look back window for obesity. As BMI is not captured by administratively-linked datasets, we identified obesity using the obesity premium rider for billing surgical procedures, where patients with BMI ≥40 qualify. For surgeon volume and centre volume, we identified thresholds for high and low volume surgeons and centres independently, as there is no standard threshold in the literature. To define high volume surgeons, we tallied each surgeon's case volume in each year, identified the number of cases required to define a 90th percentile case-volume surgeon in each year (range: 36-22 cases/year), and then chose the lower end of that

range and applied it to all years to standardize the case threshold. This procedure preserved the original case volume data and ensured that some high-volume surgeons are not mischaracterized in the low volume group in some years. The same procedure was applied to define high volume centre (65 cases/year).

ANALYSIS

We aimed to compare baseline characteristics for men who did and did not experience a complication from RP were compared using standardized differences (SD). For large cohorts, SDs have been shown to better reflect clinically important differences than p-values obtained by independent samples t-test.[83] With this method, we used SD ≥20% as a clinically meaningful indicator of between group difference. To compare before and after implementation of the QBP funding model, we used a FY 2015-2016 as a one-year implementation period, and compared baselines in the pre- and post-implementation periods. The purpose of defining an implementation period and excluding from analysis is to account for the realities associated with overhauling a funding model, and the expectation that surgical centres will not adopt changes immediately. Our outcomes were also gathered before and after implementation, and we performed the same comparison with an independent samples t-test. In order to preserve the original data as much as possible, we opted to run the logistic regression model for age and surgeon volume as continuous variables (years and number of cases), rather than categorizing them (i.e. high vs low volume).

We expected that some of these outcomes may be trending towards improvement or worsening independently of the implementation of the QBP funding model. To detect this, we designed an interrupted time series model for each outcome, comparing the trend in the pre- and post-implementation periods. We used monthly windows as our time measure, and monthly events for each outcome. As we expected no loss of generality (no

anticipated causes for major fluctuation in the monthly outcomes), we selected a Poisson regression to compare the trend lines pre- and post-implementation.

6.3 Results

Our initial cohort consisted of 24 099 subjects. After applying exclusions criteria, 2771 were excluded leaving us with a final cohort of 22 118 who remained included for analysis Table 1 (the same cohort was used as with "*Evaluating trends in radical prostatectomy approach and complication rate in Ontario from 2010-2019*"). Of these, 12 922 were classified within the pre-intervention period, 2260 were in the implementation period and excluded from comparison analyses, and 6936 were in the post-intervention period.

Baseline characteristics are shown in Table 7. Clinically significant differences between pre- and post-intervention based on SD ≥0.2 include mean age (62.49 years vs 63.29 years; SD = 0.2), retropubic approach (66.3% vs 57.9%; SD = 0.29), and robotic approach (23.7% vs 34.0%; SD = 0.4).

Table 7 Baseline variables

Variable	Value	Overall cohort	Pre-intervention period	Post-intervention period	Pre vs post-intervention periods
		FY 2010-2019 N=22,118	FYs 2010-2015 N=12,922	FYs 2016-2018 N=6,936	SD
Age	Mean (SD)	62.49 ± 6.44	62.04 ± 6.45	63.29 ± 6.29	0.2
	Median	63 (58-67)	63 (58-67)	64 (59-68)	0.19
Morbid obesity	Yes	2.0%	1.7%	2.2%	0.03
Diabetes	Yes	16.6%	16.0%	17.4%	0.04
Hypertension	Yes	52.1%	52.0%	52.0%	0
COPD	Yes	12.7%	12.1%	13.6%	0.04
Charlson Comorbidity Score	Mean (SD)	0.11 ± 0.48	1.09 ± 1.50	1.27 ± 1.63	0.12
	Median	0 (0-0)	0 (0-2)	1 (0-2)	0.11
	0	94.8%	94.8%	95.0%	0.01
	1	1.2%	1.3%	0.9%	0.04
	2	2.6%	2.5%	2.7%	0.01
	≥3	1.4%	1.4%	1.4%	0
Centre of surgery	Academic	44.1%	43.8%	44.6%	0.02
	Community	55.9%	56.2%	55.4%	0.02
Stage	1	8.8%	7.6%	10.7%	0.11
	2	50.4%	54.9%	43.2%	0.24
	3	31.5%	30.2%	34.2%	0.08
	4	3.7%	3.0%	4.6%	0.08
	Missing/Unk	5.6%	4.2%	7.4%	0.13
Income quintiles	Quintile 1	13.3%	13.3%	13.5%	0.01
	Quintile 2	18.2%	17.9%	18.7%	0.02
	Quintile 3	19.9%	19.6%	19.7%	0
	Quintile 4	22.3%	22.7%	21.8%	0.02
	Quintile 5	26.1%	26.4%	26.0%	0.01
	Missing	0.2%	0.3%	0.2%	0.02
Surgical approach	Open perineal	3.3%	3.3%	3.5%	0.01
	Retropubic	66.3%	71.7%	57.9%	0.29
	Laparoscopic	6.7%	8.1%	4.6%	0.15
	Robotic	23.7%	16.9%	34.0%	0.4
Surgeon volume	Mean (SD)	39.99 ± 40.63	38.80 ± 35.77	41.52 ± 46.41	0.07
	Median (IQR)	22 (13-52)	23 (14-54)	21 (12-52)	0.07
	High volume	52.0%	54.1%	49.1%	0.1
Institution volume	Mean (SD)	106.42 ± 86.52	104.60 ± 84.25	108.99 ± 88.70	0.05
	Median (IQR)	65 (38-183)	70 (40-173)	62 (36-199)	0.03
	High volume	49.8%	51.8%	48.8%	0.06

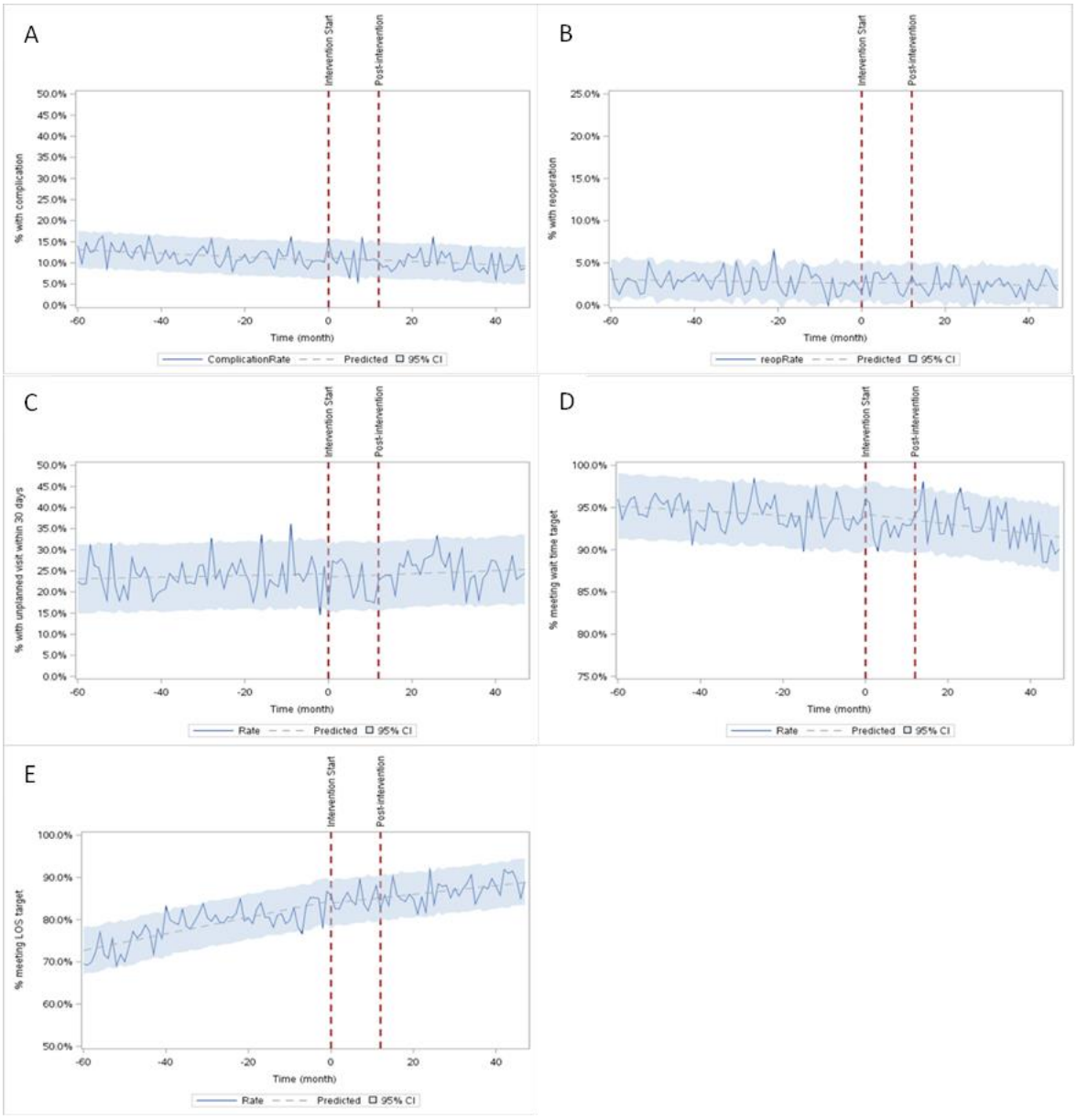
The QBP QI outcomes are shown in Table 8 with a comparison pre- and post-intervention. 30- and 90-day mortality were not included in the table, as there was no recorded deaths in the post-intervention period and we could not run the comparison. There was an overall 0.14% 30-day mortality in the study period. There was a significant improvement in 30-day composite complication rate (11.89% vs 9.96%; OR 0.82, CI 0.746-0.902; p<0.001) and proportion meeting length of stay target (78.11% vs 86.84%; OR 1.849 CI 1.705-2.005; p< 0.001), both in the case of open approach (77.67% vs 84.5%; OR 1.567, CI 1.424-1.725; p< 0.001) and minimally-invasive approach (79.42% vs 90.55%; OR 2.482, CI 2.126-2.898; p<0.001). The outcomes meeting statistical significance that worsened were 30-day unplanned visit rate (23.45% vs 25.00%; OR 1.088, CI 1.017-1.165; p=0.0147), and proportion meeting Wait 2 target (94.39% vs 92.88%; OR 0.775, CI 0.689-0.872; p< 0.001). There was no significant difference in 30-day re-operation rate (2.84% vs 2.45%; OR 0.860 CI 0.715-1.033; p=0.1074).

Table 8 QBP QI outcomes comparison pre- and post-intervention

Outcome	Overall	Pre-intervention	Post-intervention	Pre- vs post-intervention	
		FYs 2010-2015	FYs 2016-2018	Odds Ratio (95% CI)	p-value
		N=12,922	N=6,936		
Composite complication rate	11.17%	11.89%	9.96%	0.82 (0.746-0.902)	<0.001
30-day re-operation rate	2.69%	2.84%	2.45%	0.860 (0.715-1.033)	0.107
30-day unplanned visit rate	23.80%	23.45%	25.00%	1.088 (1.017-1.165)	0.015
Proportion meeting Wait 2 target	93.76%	94.39%	92.88%	0.775 (0.689-0.872)	<0.001
Length of stay mean days (mean SD)	2.61 (1.99)	2.82 (2.03)	2.28 (1.94)	N/A	N/A
Length of stay median days (median IQR)	2 (2-3)	3 (2-3)	2 (1-3)	N/A	N/A
Proportion meeting length of stay target	81.53%	78.11%	86.84%	1.849 (1.705-2.005)	<0.001
Open approach	80.16%	77.67%	84.5%	1.567 (1.424-1.725)	<0.001
Minimally invasive approach	84.68%	79.42%	90.55%	2.482 (2.126-2.898)	<0.001

The interrupted time series analysis was completed for each of the QBP QIs and is shown in **Figure 2**. The estimate slope change after intervention for the outcomes were as follows: 30-day complication rate 0.0041 (p=0.492), 30-day re-operation rate 0.0004 (p=0.887), 30-day unplanned visit rate 0.0127 (p=0.241), proportion meeting Wait 2 target 0.0163 (p=0.003), proportion meeting LOS target -0.0072 (p=0.429).

Figure 2 Interrupted time series comparison of pre- and post-intervention (a) 30-day composite complication rate (b) 30-day re-operation rate (c) 30-day unplanned visit rate (d) proportion meeting Wait 2 target (e) proportion meeting LOS target



6.4 Discussion

This study demonstrated mixed effects on QBP QIs after implementation of the QBP funding model. Improvements were seen in composite complication rate and proportion meeting LOS target. We demonstrated that LOS was improved even after accounting for surgical approach. However, the interrupted time series analysis did not reveal any difference in trend when comparing the pre- and post-intervention periods, which would suggest that the changes are not specifically attributable to the QBP funding model, but rather are a continuation of a pre-existing trend. The new funding model appears to have a deleterious effect on 30-day unplanned visit rate, and proportion meeting Wait 2 time. Among these, only proportion meeting Wait 2 time saw a significant worsening in the pre- vs post-intervention trend line, suggesting that it was related to the QBP model. The findings contrast with those of Li et al. (2020), who found that mean length of stay actually increased by 0.33 days in the post-intervention period, and that there was no difference in 30-day unplanned visit rate.[84] There are some key methodological considerations that may explain this difference. Firstly, Li et al (2020) evaluated the mean length of stay rather than the proportion meeting length of stay target. While this follows the definition of the QI in the QBP handbook, the handbook also describes that it is in fact the proportion meeting target that will be used to determine performance – this way, centre performance can be measured without the influence of surgical approach, as the surgical approach is dependent on which surgeons and equipment are available at a given centre. Still, our study found that with increasing popularity of RARP, mean length of stay decreased – this remains at odds with their findings. They also used a smaller window of evaluation (FY 2010-2017, while we included FY 2018), which shortened their post-intervention window; as RARP is being increasingly adopted year over year, removing FY 2018 will blunt any changes towards shortening the length of stay, which is what we found.

Our results demonstrated non-significant changes to the 30-day re-operation rate. As with all the QI outcomes that had no significant change in trend in the interrupted time series analysis, it is possible that with a larger post-intervention window, we would have been able to detect a significant difference. Indeed, one of the limitations of our study is that we could only gather a 3-year post-intervention observation window.

It is important to contextualize this study in the body of literature on ABF models, and specifically the Danish Quality Model which is similar to Ontario's QBP in that quality standards are outlined by governing bodies and then outcomes are tracked. While the Danish model has not specifically been evaluated for direct impact on cancer surgery outcomes as we have done in this study, The Danish Quality Model has been studied for it's impact on laparoscopic cholecystectomy outcomes where it was shown to be beneficial in the first 3 years of implementation. This can be attributed in part to the Hawthorne effect, which is the alteration of behavior by the subjects of a study due to their awareness of being observed, and is one of the mechanisms in which outcomes-based funding models are meant to achieve their objective. Surgical groups should be more likely to more strictly adhere to practice standard with the acknowledgement that the funding bodies are tracking their outcomes. However, our interrupted times series findings would argue against this, as we would expect the Hawthorne effect to be reflected in a change in trend in outcome. This was only seen for proportion meeting Wait 2 target, and was a trend to worsening, not improving. The contrast in findings between models is notable.

The study from Chapter 5: *Evaluating trends in radical prostatectomy approach and complication rate in Ontario from 2010-2019* demonstrated that the complication rate of RP has been decreasing, almost exclusively because of the shift to RARP and away from RRP, which has led to a decrease in blood transfusion rate. Given that the QBP funding model incentivizes surgical groups to minimize complication rates, we would expect that perhaps the QBP model is driving some of that shift to RARP. However, the interrupted

time series showed no significant change in the trend in complication rate, suggesting that the shift pre-dates the implementation of the new funding model. This is important context, as it clarifies why the complication rate has been decreasing and offers an explanation as to why this study's analysis did not find the QBP model to be effectual on complication rate. The other QBP QIs examined in this study have not been shown in the literature to be associated with any particular surgical approach, so this study by itself provides a thorough analysis of how they have been affected by the QBP model.

The strength of our stays lies in the methodology, in that we performed our comparisons with an implementation window in mind to allow us to more clearly detect true differences that exist. We also performed an interrupted time series regression model, which suggested that while differences were seen when comparing some outcomes before and after implementation of the QBP model, only Wait 2 time was likely to be affected by the model. One of the majors difference between the cohorts pre- and post-intervention is the popularity of RARP, and this may account for the discrepancy in findings between the pre- and post-intervention outcome comparison and the interrupted time series modeling.

One of this study's limitations relates to data sourcing and resources. Many complications are not easily captured in administrative data, as the purpose of the data collection is not for clinical research purposes. For example, urinary tract infections are likely underestimated, as our databases would only capture those that are diagnosed in hospital or health facilities; outpatient urine studies, diagnoses, and treatments would not be captured. As such, our complication rate is likely underestimated. Additionally, some of the outcomes are inexactly measured. This includes Wait 2 period, which is defined as time from decision to proceed with RP to surgery date. As we cannot know when the decision was made using administrative data, we have approximated this using first visit with the urologist. As such, our Wait 2 times were likely underestimated, and the true proportion meeting the target is likely even better than we found. Re-operation rate is

also approximated by capturing any surgery occurring within 30 days of the procedure – this will inevitably include some unrelated surgeries. As such, the true re-operation rate is likely lower than the values that we report. Lastly, there were QBP QI outcomes that we could not assess, that may be important. For example, the proportion of patients with positive resection margins may be an important metric for measuring quality of care and prognosticating, but we could not gather this data from the OCR database. If metrics such as these are improving, it would be more strongly suggestive of a positive impact of the QBP funding model in optimizing and standardizing cancer care outcomes.

Future studies should utilize more recent data as it becomes available in order to create a larger post-intervention window, and link CCO data that can evaluate the QBP QIs that we could not measure. These were non-modifiable factors for our study, but would strengthen the findings if our methodology is repeated. Ultimately, given how both the demographics of patients, as well as our approach to RP seem to be evolving more distinctly away from how these were pre-QBP, it may be the case that we never have a high-quality comparison. If the groups are continue to be more distinct with time, then we will not be able to isolate the effect of the QBP funding model with confidence.

6.5 Conclusions

The QBP funding model in Ontario appeared to improve post-operative length of stay for patients who have had a radical prostatectomy. However, there is a small but significant worsening in the proportion of patients meeting Wait 2 target and volume who require re-admission or presentation to the emergency department within 30 days. Future study should provide a longer post-intervention window of data to adequately assess the effects of the funding model on 30-day complication rate and re-operation rate, with strict adjustment for confounding factors.

6.6 References

To avoid duplication of references in this integrated article thesis format, all references are included in the thesis References section.

Chapter 7

7 Thesis study summaries and conclusions

In this integrated article format, the objective of this thesis was to identify if the QBP funding model has improved radical prostatectomy QI outcomes.

The QBP funding model for RP was implemented in FY 2015-16. This was in the middle of the 2010s decade, which corresponds to an important shift in RP approach to RARP, from RRP. As reviewed in Section 3.5 *30-day composite complication rate*, RARP has been associated with a lower complication rate in large retrospective studies, and more specifically with a lower blood transfusion rate. RARP is also associated with shorter length of stay. Given that these are both QIs that are tracked by QBP, it was essential to first quantify this shift in RP approach in order to contextualize any study of the effect of the QBP funding model.

In the first study, Section 5 *Evaluating trends in radical prostatectomy approach and complication rate in Ontario from 2010-2019*, we found a steady increase in the adoption of RARP from 6.8% of RPs in FY 2010, to 36.7% of RPs in FY 2018. This mirrored the decline in RRP from 80.3% to 55.6% in that same period. When examining the complication rate trend, there was a decline from 13.24% to 9.04% over the study period, which was driven by the decline in transfusion rate from 7.96% to 3.42%. RARP had a lower overall complication rate (7.47%) than RRP (12.70%), though we did not get a breakdown to determine which elements of the composite complication rate accounted for this difference. We also did a logistic regression and found that while age, surgeon volume, and surgical approach were significant predictors of complication, minimally-invasive approach was the most important predictor (OR 0.714). Put together, this study provided important context to demonstrate that over the decade, the complication rate

was steadily decreasing in the context of increasing utilization of the robotic-assisted approach. The crucial limitation lies in that this was a retrospective population-based study, and serves only to reinforce existing literature that RARP is associated with lower complication rates possibly due to lower transfusion rates. In other words, it cannot demonstrate a causal relationship. Nevertheless, for our broader objective of evaluating the effectiveness of the QBP funding model, it provides interesting and valuable context.

In the second study, Section 6 *The impact of the Ontario Quality-Based Procedures funding model on radical prostatectomy outcomes*, we evaluated the QBP QIs that we could track using administratively-linked data. We followed 30-day complication rate, 30-day unplanned visit rate, 30-day re-operation rate, proportion meeting Wait 2 target, and proportion meeting LOS target. Our comparison of before and after implementation, accounting for a first-year grace period excluded from analyses, revealed that the complication rate and proportion meeting LOS target improved over the study period. From our first study, *Evaluating trends in radical prostatectomy approach and complication rate in Ontario from 2010-2019*, we already expected to see this improvement in complication rate. In order to elucidate whether or not it was attributable to the funding model itself, we performed an interrupted time series analysis that compared the trend in complication rate before and after implementation of the model. This analysis showed that there was no change in the complication rate trend, suggesting the QBP model did not have an effect on complication rate. For the other QIs, proportion meeting LOS target also improved, but there was no difference in trend in the interrupted time series analysis. Once again, this would suggest that the model did not have a direct effect. Two QIs were worse in the post-implementation period, and this includes the 30-day unplanned visit rate and the proportion meeting Wait 2 target. Of these, the interrupted time series analysis showed a significant change in trend only for proportion meeting Wait 2 target, suggesting that the worsened Wait 2 target times may be attributable to the QBP funding model. Lastly, the 30-day re-operation rate was unchanged.

Put together, these studies illustrated that Ontario is shifting towards more robotic-approach to radical prostatectomy, and patients are experiencing lower complication rates. They are also spending less time in hospital, but may be waiting longer to have their surgery (Wait 2 time), and may be returning to hospital in greater frequency. Our study showed only one clear association between the implementation of the new model and QI outcomes, and that was with the worsened Wait 2 time. This lone outcome is of questionable significance, since we were not able to get a mean number of days for the Wait 2 time before and after implementation of the model. It is possible that the absolute extent of the difference is not all that meaningful (for example, a delay of 5 days may be statistically significant, but not clinically significant).

It is difficult to make definitive conclusions on the central objective of determining the effects of Ontario's QBP funding model on RP outcomes, based on the study findings. The only true way to determine if an intervention has made a difference is by conducting a randomized control trial, which is of course not feasible for this topic. Instead, the best realistic manner to conduct an evaluation on this topic is to look at population-based data as we have done, and accept the limitations. In this case, we found that the model generally did not impact RP outcomes. However, it is recognized that we used a small post-implementation window (only 3 years), and were unable to capture all of the relevant QIs due to data availability limitations. For example, proportion of cases with positive resection margins is an important QI to most surgeons, but we were not able to capture this. Additionally, there are no clear reasons to explain some of the findings, like longer Wait 2 times. As such, we would caution any definite conclusions about the effectiveness of the QBP model based on this thesis alone.

Future studies should employ similar methodology as ours, but with a lengthier post-implementation window, and better data sourcing from Cancer Care Ontario or pathology records.

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Appendices

Appendix A AJCC TNM staging for prostate cancer

TABLE 4. American Joint Committee on Cancer Prognostic Stage Grouping[a]

WHEN T IS...	AND N IS...	AND M IS...	AND PSA IS...	AND GRADE GROUP IS...	THEN THE STAGE GROUP IS...
cT1a-c, cT2a	N0	M0	<10 ng/mL	1	I
pT2	N0	M0	<10 ng/mL	1	I
cT1a-c, cT2a	N0	M0	≥10, <20 ng/mL	1	IIA
pT2	N0	M0	≥10, <20 ng/mL	1	IIA
cT2b-c	N0	M0	<20 ng/mL	1	IIA
T1-2	N0	M0	<20 ng/mL	2	IIB
T1-2	N0	M0	<20 ng/mL	3	IIC
T1-2	N0	M0	<20 ng/mL	4	IIC
T1-2	N0	M0	≥20 ng/mL	1-4	IIIA
T3-4	N0	M0	Any	1-4	IIIB
Any T	N0	M0	Any	5	IIIC
Any T	N1	M0	Any	Any	IVA
Any T	Any	M1	Any	Any	IVB

Abbreviation: PSA indicates prostate-specific antigen. [a]Note that, when either PSA or grade group is not available, grouping should be determined by T category and/or either PSA or grade group, as available.

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