Ontario Health

ONTARIO HEALTH TECHNOLOGY ASSESSMENT SERIES

Robotic-Assisted Hysterectomy for Endometrial Cancer in People With Obesity: A Health Technology Assessment

Key Messages

What Is This Health Technology Assessment About?

Hysterectomy (the surgical removal of the uterus) is the most common treatment for early-stage endometrial cancer (cancer in the lining of the uterus). Types of hysterectomy include open hysterectomy (OH; an invasive procedure that involves a large surgical incision), laparoscopic hysterectomy (LH; a minimally invasive procedure that involves several smaller incisions and the use of smaller surgical tools), and robotic-assisted hysterectomy (RH; a minimally invasive procedure that involves the use of a robotic system operated by the surgeon).

RH may offer a clinical benefit over LH for people with obesity because the robotic instruments may optimize operative technique and exposure, with the robotic arms supporting the weight of the abdominal wall and facilitating ventilation by allowing for reduced pressure in the abdomen.

This health technology assessment looked at how safe, effective, and cost-effective RH is for the treatment of endometrial cancer in people with obesity. It also looked at the budget impact of publicly funding RH and at the experiences, preferences, and values of people with endometrial cancer and obesity, as well as those of cancer surgeons.

What Did This Health Technology Assessment Find?

Compared with LH, RH is associated with fewer conversions (switches) to OH in people with endometrial cancer and obesity (i.e., those with a body mass index ≥ 40 kg/m^2). Rates of perioperative complications were similarly low for both LH and RH (≤ 3.5%).

We did not perform a primary economic evaluation. RH may be more costly than OH and LH; however, the evidence was not generalizable to the Ontario context. Publicly funding RH is estimated to increase costs to the province by about $1.14 million over 5 years.

People with lived experience of endometrial and cancer and obesity, as well as surgeons, spoke favourably of RH, particularly in terms of safety and quick recovery.

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The statements, conclusions, and views expressed in this report do not necessarily represent the views of those we consulted.

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A Note About Terminology

As a government agency, Ontario Health can play an active role in ensuring that people of all identities and expressions recognize themselves in what they read and hear from us. We recognize that gender identities are individual and that some people who undergo hysterectomy are not women, despite being assigned female sex at birth. Thus, in this health technology assessment, we use gender-inclusive pronouns and terms as much as possible. However, when citing published literature that uses the terms “woman” and “women,” we also use these terms for consistency with the cited studies.

Citation

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Abstract

Background

Robotic-assisted surgery has been used in Ontario hospitals for over a decade, but there is no public funding for the robotic systems or the disposables required to perform robotic-assisted surgeries ("robotics disposables"). We conducted a health technology assessment of robotic-assisted hysterectomy (RH) for the treatment of endometrial cancer in people with obesity. Our assessment included an evaluation of the effectiveness, safety, and cost-effectiveness of RH, as well as the 5-year budget impact for the Ontario Ministry of Health of publicly funding RH. It also looked at the experiences, preferences, and values of people with endometrial cancer and obesity, as well as those of health care professionals who provide surgical treatment for endometrial cancer.

Methods

We performed a systematic literature search of the clinical evidence to identify systematic reviews and randomized controlled trials relevant to our research question. We reported the risk of bias from the included systematic review. We assessed the quality of the body of evidence according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria. We performed a systematic economic literature search. We also analyzed the 5-year budget impact of publicly funding RH (including total, partial, and radical procedures) for people with endometrial cancer and obesity in Ontario. To contextualize the potential value of RH for people with endometrial cancer and obesity, we spoke with people with lived experience of endometrial cancer and obesity who had undergone minimally invasive surgery (either laparoscopic hysterectomy [LH] or RH), and we spoke with gynecological cancer surgeons who perform hysterectomy.

Results

We included one systematic review in the clinical evidence review. An indirect comparison showed that conversion rates to open hysterectomy (OH) were similar for LH and RH in patients with a body mass index (BMI) ≥ 30 kg/m^2 (6.5% vs. 5.5%, respectively) (GRADE: Very low). An indirect comparison within a subset of patients with a body mass index (BMI) ≥ 40 kg/m^2 showed that a higher proportion of patients who underwent LH required conversion to OH compared with patients who underwent RH (7.0% vs. 3.8%, respectively) (GRADE: Very low). Rates of perioperative complications were similarly low for both LH and RH (≤ 3.5%) (GRADE: Very low). We identified two studies that met the inclusion criteria of our economic literature review. The included economic studies found RH to be more costly than OH or LH for endometrial cancer; however, because these studies were conducted in other countries, the results were not applicable to the Ontario context. Assuming a moderate increase in the volume of robotic-assisted surgeries, our reference case analysis showed that the 5-year budget impact of publicly funding RH for people with endometrial cancer and obesity would be $1.14 million. The budget impact analysis results were sensitive to surgical volume and the cost of robotics disposables. The people we spoke with who had lived experience of endometrial cancer and obesity, as well as gynecological cancer surgeons, spoke favourably of RH and its perceived benefits over OH and LH for people with endometrial cancer and obesity.

Conclusions

Compared with LH, RH is associated with fewer conversions to OH in patients with endometrial cancer and obesity (i.e., those with a BMI ≥ 40 kg/m^2). Rates of perioperative complications were similarly low for both LH and RH. The cost-effectiveness of RH for people with endometrial cancer and obesity is

unknown. We estimate that the 5-year budget impact of publicly funding RH for people with endometrial cancer and obesity would be $1.14 million. People we spoke with who had lived experience of endometrial cancer and obesity reported favourably on their experiences with minimally invasive hysterectomy (either LH or RH) and emphasized the importance of the availability of safe surgical options for people with obesity. Gynecological surgeons perceived RH as a superior alternative to OH and LH for people with endometrial cancer and obesity.

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Objective

This health technology assessment evaluates the effectiveness, safety, and cost-effectiveness of robotic-assisted hysterectomy for endometrial cancer in people with obesity. It also evaluates the budget impact of publicly funding robotic-assisted hysterectomy and the experiences, preferences, and values of people with endometrial cancer and obesity, as well as those of surgeons who perform hysterectomy for people with endometrial cancer and obesity.

Background

Health Condition

Endometrial cancer is cancer of the endometrium (the lining of the uterus). It is the most common type of cancer that affects the female reproductive organs.[1]

Current Treatment Options

Hysterectomy (the surgical removal of the uterus) is the most common treatment strategy for early-stage endometrial cancer (cancer that develops in the lining of the uterus). Surgical modalities include open hysterectomy (invasive hysterectomy), laparoscopic hysterectomy (minimally invasive hysterectomy), and robotic-assisted hysterectomy (minimally invasive hysterectomy with the use of a robotic system). Open hysterectomy first requires panniculectomy (a procedure to remove excess skin and tissue from the lower abdomen), which is associated with a risk of complications such as infection.

Laparoscopic hysterectomy to treat endometrial cancer is a technically challenging surgical procedure in people with obesity. Accordingly, people with obesity are often required to undergo an open procedure, which is more invasive, poses greater surgical risks, and is associated with both more and more serious postoperative complications compared with minimally invasive procedures.

Health Technology Under Review

Robotic-assisted hysterectomy may offer a clinical benefit over laparoscopic hysterectomy in the context of obesity because the robotic instruments may optimize operative technique and exposure, with the robotic arms supporting the weight of the abdominal wall and facilitating ventilation by allowing for reduced intraperitoneal and intrathoracic pressures.[2]

A clinical expert with whom we consulted (Sarah Ferguson, MD, virtual conversation, May 13, 2022) stated that RH optimizes operative technique and exposure in patients with endometrial cancer and morbid obesity because of the length and flexibility of the wristed instrumentation used in RH compared with the limited reach and motion available during LH. Surgeons typically have difficulty reaching the uterus through the abdominal cavity in a patient with morbid obesity. RH facilitates visualization in the abdomen via magnification of the uterus and surrounding tissue. In addition, the robotic arms support the weight of the abdominal wall, facilitating ventilation by allowing for reduced intraperitoneal and airway pressures while the patient is in a steep Trendelenburg position, in which the patient is supine on the operating table with their head declined below their feet at an angle of roughly 25°.

According to the clinical expert, because of the surgical limitations of LH, people with endometrial cancer and morbid obesity have reduced options for hysterectomy. The expert also stated that OH is

associated with increased infections, cardiac complications, and a longer hospital stay compared with minimally invasive procedures (LH and RH).

The clinical expert stated that randomized controlled trials are unlikely to be conducted in this population since RH is considered an extension of an established procedure (i.e., LH).

Regulatory Information

Four robotic surgical systems are currently licensed by Health Canada (Table 1).

Table 1: Robotic Surgical Systems Licensed by Health Canada

System	Manufacturer (location)	Device class	Licence number	Date of first issue
Da Vinci Si Surgical System	Intuitive Surgical, Inc. (Sunnyvale, CA)	IV	81353	December 3, 2009
Da Vinci Xi Surgical System	Intuitive Surgical, Inc. (Sunnyvale, CA)	IV	97378	July 27, 2016
Da Vinci X Surgical System	Intuitive Surgical, Inc. (Sunnyvale, CA)	IV	103348	July 26, 2019
Hugo robotic-assisted surgery system	Medtronic (Minneapolis, MN)	III	107066	December 3, 2021

Ontario Context

From fiscal year (FY) 2019 to FY 2021, 11 hospitals in Ontario performed more than 100 robotic-assisted surgical procedures. Five of these hospitals accounted for 72% of all robotic-assisted surgical procedures in Ontario (4,249 out of 5,926) (Discharge Abstract Database, Canadian Institute for Health Information, IntelliHealth Ontario, November 2022).

The existing robotic systems in Ontario have largely been purchased through charitable donations to hospital foundations. The costs of the disposables required to perform robotic-assisted surgical procedures and the maintenance costs of robotic systems are typically covered by a hospital's global budget or foundation funds. This funding arrangement is in keeping with that of other technologies used in the operating room.

Equity Considerations

In Ontario, people with endometrial cancer and morbid obesity face stigma and experience treatment delays because of cancelled or abandoned surgeries at centres with inadequate resources to manage the complexities of their surgery.[3] Referrals are often redirected to larger urban centres with greater experience in performing minimally invasive procedures,[4] meaning that cost and travel requirements may pose substantial challenges for people not living near such a centre.

Expert Consultation

We engaged with an expert in the specialty areas of oncology and gynecology to help inform our understanding of aspects of the health technology and our methodologies and to contextualize the evidence.

Expedited Summary of the Clinical Evidence

Research Question

What are the clinical effectiveness and safety of robotic-assisted hysterectomy (RH) for endometrial cancer in people with obesity?

Appendix 1 provides the full methods for the clinical evidence summary.

Results

The clinical literature search retrieved 270 publications from the MEDLINE and Cochrane bibliographic databases published between January 1, 2017, and March 21, 2022 (Appendix 2). The grey literature search yielded an additional two items. We identified one systematic review[2] that met our inclusion criteria (Table 2; Appendix 3, Figure A1). We identified no randomized control trials that met our inclusion criteria.

Table 2: Characteristics of the Included Systematic Review

Objective	Literature search time frame	Inclusion criteria
Assess conversion to OH and perioperative complications after LH or RH in patients with endometrial cancer and obesity (BMI ≥ 30 kg/m^2)	January 1, 2000, to July 18, 2018	Population: at least 20 female patients with endometrial cancer and obesity (BMI ≥ 30 kg/m^2) Intervention: total LH or RH,[a] with or without lymphadenectomy Perioperative outcomes reported separately for each approach RCT or observational study (single-arm or multiple-arm)

Abbreviations: BMI, body mass index; LH, laparoscopic hysterectomy; OH, open hysterectomy; RCT, randomized controlled trial; RH, robotic-assisted hysterectomy.

[a]Total hysterectomy is the surgical removal of the uterus and cervix.

Source: Cusimano et al.[2]

Cusimano et al[2] identified no randomized controlled trials comparing RH with laparoscopic hysterectomy (LH) or open hysterectomy (OH). Overall, the authors included 22 single-arm observational studies (LH, n = 16; RH, n = 6) and 29 multiple-arm comparative studies (OH and LH, n = 18; OH and RH, n = 6; LH and RH, n = 1; OH, LH, and RH, n = 4). The authors extracted data from the minimally invasive (LH or RH) arms only to calculate the pooled proportion of patients with endometrial cancer who required conversion to OH (meaning their minimally invasive surgery had to be converted to an open surgery). Similarly, the pooled proportions of patients who experienced a perioperative blood transfusion, organ or vessel injury, or venous thromboembolism were reported as secondary outcomes. No comparative estimates (e.g., RH vs. LH or OH) were calculated for any outcomes.

Risk-of-Bias Assessment

SINGLE-ARM OBSERVATIONAL STUDIES

Cusimano et al[2] assessed the risk of bias of the included single-arm observational studies using the Institute of Health Economics Quality Appraisal Checklist. Of these studies (including those comparing LH vs. OH), the authors considered 41% (9/22 studies) to be at low risk of bias and 59% (13/22 studies) to be at moderate risk of bias. The authors stated, "Moderate risk single-arm studies generally were deemed as such because of retrospective designs and inadequate description of patient characteristics, again underscoring the likelihood of selection bias. Additional limitations included a lack of methodologic or statistical details and inadequate or unclear follow-up duration."

MULTIPLE-ARM COMPARATIVE STUDIES

Cusimano et al[2] assessed the risk of bias for multiple-arm comparative studies using the Newcastle–Ottawa Quality Assessment Scale. Of these studies (including those comparing LH vs. OH), the authors considered 79% (23/29 studies) to be at low risk of bias and 21% (6/29 studies) to be at moderate risk of bias. Reasons for studies being assessed at moderate risk of bias included failure to control or adjust for important covariates, drawing comparator groups from a different time or place than that of the intervention group, and inadequate or unclear follow-up duration.

Summary of Results

Table 3 provides a summary of the results from the systematic review by Cusimano et al.[2]

Table 3: Summary of Results From the Systematic Review

Outcome	Robotic-assisted hysterectomy (pooled proportion of patients)	Laparoscopic hysterectomy (pooled proportion of patients)
Conversion to OH: BMI ≥ 30 kg/m^2	5.5% (95% CI, 3.3 to 9.1) 91 events among 1,341 patients (14 studies)	6.5% (95% CI, 4.3 to 9.9) 173 events among 1,826 patients (29 studies)
Conversion to OH: BMI ≥ 40 kg/m^2	3.8% (95% CI, 1.4 to 9.9) 26 events among 470 patients (8 studies)	7.0% (95% CI, 3.2 to 14.5) 40 events among 422 patients (9 studies)
Blood transfusion	2.1% (95% CI, 1.2 to 3.8) 16 events among 743 patients (11 studies)	2.8% (95% CI, 1.5 to 5.1) 47 events among 1,133 patients (18 studies)
Organ or vessel injury	1.2% (95% CI, 0.4 to 3.4) 14 events among 709 patients (9 studies)	3.5% (95% CI, 2.2 to 5.5) 51 events among 1,164 patients (18 studies)
Postoperative venous thromboembolism	0.5% (95% CI, 0.1 to 2.0) 2 events among 388 patients (5 studies)	0.5% (95% CI, 0.2 to 1.2) 5 events among 1,015 patients (14 studies)

Abbreviations: BMI, body mass index; CI, confidence interval; OH, open hysterectomy.

Source: Cusimano et al.[2]

Based on an indirect comparison, there were no appreciable differences in conversion from LH (6.5%) or RH (5.5%) in patients with a body mass index (BMI) equal to or greater than 30 kg/m^2.[2] Based on an indirect comparison within a subset analysis, a higher proportion of conversions from LH (7.0%) relative to RH (3.8%) in patients with a BMI equal to or greater than 40 kg/m^2 was observed. Rates of perioperative complications were low for both LH and RH.

Inadequate exposure because of adhesions or visceral adiposity was the most common reason for conversion for both LH (32%) and RH (61%).[2] Intolerance of the Trendelenburg position caused 31% of conversions among patients who underwent LH and 6% of conversions for those who underwent RH.

Using the risk-of-bias assessment by Cusimano et al,[2] we determined the quality of the body of evidence for each outcome listed in Table 3 to be very low according to the *Grading of Recommendations Assessment, Development, and Evaluation* (GRADE) *Handbook*.[5] We based this determination on issues related to risk of bias (i.e., inclusion of single-arm observational studies, use of a retrospective study design, inadequate description of patient characteristics, inadequate or unclear follow-up duration, indirect comparisons between RH and LH) and precision (i.e., subset analysis indirectly comparing RH with LH for patients with a BMI ≥ 40 kg/m^2).

Ongoing Studies

We did not identify any upcoming studies in ClinicalTrials.gov that matched our inclusion criteria for this expedited summary of the clinical evidence.

Discussion

In their systematic review, Cusimano et al[2] found that more than 30% of LH conversions and 6% of RH conversions were caused by obesity-related anaesthetic indications. The authors suggested that RH may provide a benefit over LH in the setting of morbid obesity (i.e., BMI ≥ 35 kg/m^2 with comorbidities [e.g., diabetes, hypertension] or BMI ≥ 40 kg/m^2) because of the ability of the robotic arms to support the weight of the abdominal wall and thus enable a reduction in intraperitoneal and intrathoracic pressures. However, reasons for conversions were not documented for about 50% of events, so this suggestion should be interpreted with caution.

Limitations

Limitations to the studies included in the systematic review by Cusimano et al[2] include the following:

- All studies were observational in design; no randomized controlled trials were identified
- Twelve of the 14 RH studies included in the analysis for conversion to OH were retrospective in design
- While the studies specifically included patients with a BMI equal to or greater than 30 kg/m^2, not all studies reported the mean or median BMI for their intervention or comparator arm
- About half the included studies did not report reasons for conversion to OH
- Selection bias: Patients chosen for RH may be different from those chosen for LH. The skill level and preference of the surgeons who make these decisions may vary as well. Few studies adequately described or accounted for these details
- The criteria for concurrent lymphadenectomy were highly variable. Studies did not describe whether surgeons did not need to perform or chose to forgo lymphadenectomy in order to avoid conversion and maintain an LH or RH approach
- Length of hospital stay, operating time, and oncological outcomes (e.g., adjuvant therapy, survival, recurrence) were not reported

- It is difficult to compare the rate of conversion to OH of patients with obesity with rates reported in previous studies composed largely of patients with normal or slightly increased weight. Major differences other than patient BMI – such as study design (randomized or observational), requirements for pelvic or paraaortic lymphadenectomy, and experience or skill of surgeons – would have influenced the observed conversion rates and thus limited any direct comparisons

For this review, we searched for systematic reviews and randomized controlled trials. We are aware of some retrospective, observational studies (e.g., Corrado et al,[6] El-Achi et al,[7] Lindfors et al[8]) published after the completion of the systematic review by Cusimano et al,[2] which could provide additional evidence for any updates to the systematic review by Cusimano et al.[2]

Comparison With Studies of Robotic-Assisted Hysterectomy With No Body Mass Index Limitations

Lawrie et al[9] systematically reviewed randomized controlled trials to determine the effectiveness and safety of RH in the treatment of women with benign and malignant gynaecologic disease. The authors placed no limitations on BMI for inclusion in the systematic review.

The authors[9] concluded that the evidence on the effectiveness and safety of RH compared with those of LH for benign disease is of low certainty but suggests that surgical complication rates might be comparable. The evidence on the effectiveness and safety of RH compared with LH or OH for malignant disease is more uncertain, particularly because survival data are lacking. RH is an operator-dependent and expensive technology, meaning that a bias-free independent evaluation of the safety of this technology will be challenging.

Conclusions

We examined the peer-reviewed published and grey literature to determine what is known about the clinical effectiveness and safety of RH for the treatment of endometrial cancer in people with obesity and found the following:

- We identified one systematic review that focused on RH for endometrial cancer in people with obesity
- An indirect comparison showed that conversion rates to OH were similar for LH and RH in patients with a BMI equal to or greater than 30 kg/m^2 (6.5% vs. 5.5%, respectively) (GRADE: Very low)
- An indirect comparison within a subset of patients with a BMI equal to or greater than 40 kg/m^2 showed that a higher proportion of patients who underwent LH required conversion to OH compared with patients who underwent RH (7.0% vs. 3.8%, respectively) (GRADE: Very low)
- Rates of perioperative complications were low for both LH and RH (GRADE: Very low)
- Studies of RH had numerous methodological limitations; for example, most were retrospective in design and conducted at a single centre, the length of follow-up and mean or median BMI in study arms were rarely reported, and most studies failed to control or adjust for important covariates

Expedited Summary of the Economic Evidence

Research Question

What is the cost-effectiveness of robotic-assisted hysterectomy (RH) for endometrial cancer in people with obesity?

Appendix 1 provides the full methods for the economic evidence summary.

Results

The economic literature search retrieved 106 publications from the MEDLINE and Cochrane bibliographic databases published between January 1, 2017, and March 21, 2022 (Appendix 2). The grey literature search yielded one additional item. We identified two studies that met the inclusion criteria: one retrospective observational study[10] and one prospective randomized trial.[11]

Direct Comparison

Sofer et al[10] conducted a retrospective observational study in Israel comparing perioperative measures, costs, and quality-of-life and survival outcomes associated with RH and open hysterectomy (OH) among obese women diagnosed with low-grade endometrial cancer (Table 4). The study included 138 women with a body mass index (BMI) equal to or greater than 30 kg/m^2 who underwent OH (n = 61) or RH (n = 77) between 2013 and 2016. RH was found to be associated with a shorter length of hospital stay and fewer postoperative complications than OH but to require longer operative time. The cost of RH varied depending on surgical volume and was considered equivalent to that of OH if at least 350 robotic-assisted surgeries were performed per year and the initial system costs were excluded. Ratings on quality-of-life measures were found to be better after RH than after OH. There was no significant difference in 5-year survival between OH and RH.

Indirect Comparison

Silva et al[11] conducted a prospective randomized study in Brazil from 2015 to 2017. It included 89 patients with endometrial cancer clinically restricted to the uterus (Table 5). Forty-four patients were randomized to receive RH, and 45 were randomized to receive laparoscopic hysterectomy (LH). The study found that compared with LH, RH was associated with similar perioperative morbidity, but the duration and total cost of surgery were higher. While the median BMI of patients in this study was greater than 30 kg/m^2, patients with a BMI lower than 30 kg/m^2 (i.e., patients without obesity) were also included. For this reason, we considered this study as providing indirect evidence. Further, there is uncertainty regarding the prospective nature of this study and the randomization methods used.

We also identified several systematic reviews that included economic outcomes (Iavazzo et al,[12] Ind et al,[13] Kristensen et al[14]). However, we excluded these studies because all primary studies included in these systematic reviews were published before 2017; therefore, the costing information may now be outdated and less relevant for current decision-making.

The systematic review and meta-analysis by Ind et al,[13] which specifically assessed a population without obesity, concluded that compared with LH, RH was associated with more favourable clinical outcomes but a mean additional cost of $1,869 per surgery (95% CI, $268 to $3,471 USD, currency year unspecified).

Other systematic reviews also concluded that RH seemed to be associated with an increased cost compared with the equivalent laparoscopic procedures, although increased operative efficiency (i.e., a decrease in operative time) may reduce overall costs (Iavazzo et al,[12] Kristensen et al[14]).

Table 4: Direct Comparison: Robotic-Assisted vs. Open Hysterectomy

Author, year, country	Analytic technique, study design, perspective, time horizon	Population	Intervention and comparator	Results		
				Health outcomes[a]	Costs, $[b]	Cost-effectiveness
Sofer et al, 2020, Israel[10]	Cost-effectiveness analysis Economic analysis based on a retrospective observational study Hospital perspective Time horizon: 30 d post-surgery	Obese women (BMI ≥ 30 kg/m^2) diagnosed with low-grade endometrial cancer (N = 138; RH = 77, OH = 61) OH) Age: ≥ 18 y (34–89 y; mean : 65.4 y)	RH vs. OH	*Total operative time (mean), min* RH: 228 OH: 162 *P* < .001 *Perioperative measures* Length of hospital stay, d RH: 1.7 OH: 4.8 *P* = .001 Complication rate (Clavien–Dindo classification), % RH: 5.2 OH: 19.7 *P* = .008 *Quality of life, SF-36 score* Physical: RH, 56; OH, 38.7 Mental: RH, 72.9; OH, 56.0 *P* < .01 *5-year survival, %* RH: 94 (88.7–99.3) OH: 89.8 (82.2–97.4) *P* = .330	*Mean total cost per patient, excluding initial and maintenance costs of robotic system* RH: $8,850 OH: $8,270 *P* = .148 (Annual surgical volume not reported) Costs calculated using cost per day of hospitalization (including, e.g., laboratory, medication, and staff costs) and cost per hour of operating room time (including surgical instrument and disposable costs) *Estimated mean cost per patient, including maintenance cost of robotic system* RH: $10,850 (per 100 procedures per robotic system); $9,422 (per 350 procedures per robotic system) OH: $8,270 *P* = .001 (per 100 procedures) *P* = .11 (per 350 procedures)	In all scenarios, OH was less costly than RH; however, differences were statistically significant only when the initial and maintenance costs of the robotic system were included RH required longer total operative time than OH 5-year survival rates were not statistically significantly different between groups RH was associated with more favourable results in certain outcomes than OH, including increased quality of life, reduced surgery-related complications, and reduced total length of hospital stay Overall, the cost-effectiveness of RH depends on surgical center volumes and the cost components included in the analysis

Author, year, country	Analytic technique, study design, perspective, time horizon	Population	Intervention and comparator	Results		
				Health outcomes[a]	Costs, $[b]	Cost-effectiveness
					Estimated mean cost per patient, including initial and maintenance costs of robotic system RH: $14,422 (per 100 procedures per robotic system); $10,442 (per 350 procedures per robotic system) OH: $8,270 *P* = .001 (per 100 procedures) *P* = .003 (per 350 procedures)	

Note: Table is not comprehensive; some outcome measures have not been included.

Abbreviations: BMI, body mass index; OH, open hysterectomy; RH: robotic-assisted hysterectomy; SF-36, 36-Item Short-Form Survey.

[a]Sofer et al[10] reported health outcomes as means, whereas Silva et al[11] (see Table 5) reported health outcomes using median values.

[b]In 2016 US dollars.

Table 5: Indirect Comparison: Robotic-Assisted vs. Laparoscopic Hysterectomy

Author, year, country	Analytic technique, study design, perspective, time horizon	Population	Intervention and comparator	Results		
				Health outcomes[a]	Costs, $[b]	Cost-effectiveness
Silva et al, 2018, Brazil[11]	Cost-effectiveness analysis Economic analysis based on a prospective randomized trial[c] Hospital perspective Time horizon not specified	Patients (obese and nonobese) with endometrial carcinoma (N = 89; RH = 44, LH = 45) Age: ≥ 18 y (47–69 y; median: 60 y)	RH vs. LH	*Number of retrieved lymph nodes* RH: 19 (3–61) LH: 20 (4–34) *P* = .36 *Total operative time, min* RH: 319.5 (170–520) LH: 248 (85–465) *P* = .000042 *Blood loss, mL* RH: 162 (0–2,915) LH: 105.5 (0–1,465) *P* = .64 *Length of hospital stay, d* RH: 3 (2–5) LH: 3 (2–43) *P* = .078 *Complications* Total, major RH: 8 LH: 8 *P* = .96	*Median total cost per patient, excluding initial and maintenance costs of robotic system* RH: $9,655 (SD ± $850) LH: $6,812 (SD ± $1,849) *P* < .001 Total costs were calculated as the sum of the following costs: daily hospitalization; daily use of ICU; materials; medication; operating room time (per minute); medical gas (per minute); orthoses, prostheses, and special materials; therapeutic diagnostic support services; and personnel	RH was 41.7% more expensive than LH RH required longer total operative time than LH RH and LH had equivalent perioperative morbidity No statistically significant differences were identified between groups regarding the perioperative outcomes of blood loss, length of hospital stay, major and minor surgical complications, or conversation rate

Author, year, country	Analytic technique, study design, perspective, time horizon	Population	Intervention and comparator	Results		
				Health outcomes[a]	Costs, $[b]	Cost-effectiveness
				Total, minor RH: 6 LH: 2 *P* = .97 *Conversion rate* RH: 1 LH: 2 *P* = .31		

Note: Table is not comprehensive; some outcome measures have not been included.

Abbreviations: ICU, intensive care unit; LH, laparoscopic hysterectomy; RH, robotic-assisted hysterectomy; SD, standard deviation.

[a]Silva et al[11] reported health outcomes using median values, whereas Sofer et al[10] (see Table 4) reported health outcomes as means.

[b]In US dollars (costing year not specified).

[c]We identified uncertainty regarding the prospective nature of this study and the randomization methods used.

Discussion

- Neither included study was conducted in a Canadian jurisdiction, and the health care resource use and costs in the settings reviewed could be very different from those in Ontario. Therefore, the results are not generalizable to the Ontario context
- We did not identify any model-based cost-effectiveness analyses or any cost–utility studies that reported quality-adjusted life years as an outcome. Both included studies were short-term economic analyses based on clinical studies
- Neither included study explicitly assessed oncological outcomes or associated costs
- Costing calculation varied substantially between the included studies: Silva et al[11] did not consider the acquisition and maintenance costs of a robotic system, whereas Sofer et al[10] did. To adequately evaluate the cost of RH, the costing components must be clearly defined
- Sofer et al[10] assessed only low-grade endometrial cancers, which are associated with lower mortality rates than higher-grade endometrial cancers. Their cost-effectiveness results may have differed had they also included higher-grade endometrial cancers
- Many studies have described factors that may contribute to the cost-effectiveness of RH compared with standard care (i.e., OH or LH). These factors include but are not limited to surgical volume, inpatient-versus-outpatient status, and both the anticipated and actual learning curves of surgeons as they adapt to new surgical techniques

Conclusions

We examined the peer-reviewed published literature to determine what is known about the cost-effectiveness of RH for the treatment of endometrial cancer in people with obesity and found the following:

- In the past 5 years, very limited economic evidence has been published evaluating the cost-effectiveness of RH for the treatment of endometrial cancer in people with obesity. In one study that compared RH with OH in this population, RH was found to be associated with more favourable clinical outcomes but increased costs versus OH. This study found that the cost of RH would be lower than that of OH only if the initial and maintenance costs of the robotic system were excluded from the cost-effectiveness analysis and if the surgical volume was more than 350 cases per year per robotic system
- In one study that conducted an indirect comparison, RH was found to have similar clinical outcomes to those of LH but higher costs, with the total cost being 41% higher than that of LH

Expedited Budget Impact Analysis

Research Question

What is the potential 5-year budget impact for the Ontario Ministry of Health of publicly funding robotic-assisted hysterectomy (RH) for people with endometrial cancer and obesity?

Methods

Analytic Framework

We estimated the budget impact of publicly funding total, partial, and radical RH using the cost difference between two scenarios: (1) current clinical practice without public funding for RH (the current scenario), and (2) anticipated clinical practice with public funding for RH (the new scenario). (Total hysterectomy is the surgical removal of the uterus and cervix; partial hysterectomy is the surgical removal of only the uterus; radical hysterectomy is the surgical removal of the uterus, cervix, part of the vagina, and a wide area of ligaments and tissues around these organs.[15])

Figure 1 presents the budget impact model schematic.

RH for people with obesity is typically an inpatient procedure, and the costs are covered by the Ontario Health Insurance Plan. However, there is currently no public funding for robotic systems or the disposables required to perform robotic-assisted surgical procedures ("robotics disposables"). The existing robotic systems in Ontario have largely been purchased through charitable donations to hospital foundations. Hospitals with robotic systems manage the costs of robotics disposables from the hospital's existing global budget or hospital foundation funds. At the time of writing this report, there are no public funding allowances for the additional expenses associated with robotics disposables.

We explored the budget impact of publicly funding RH in the long term. Therefore, for simplicity, we assumed that there is no public funding for robotics disposables in the current scenario.

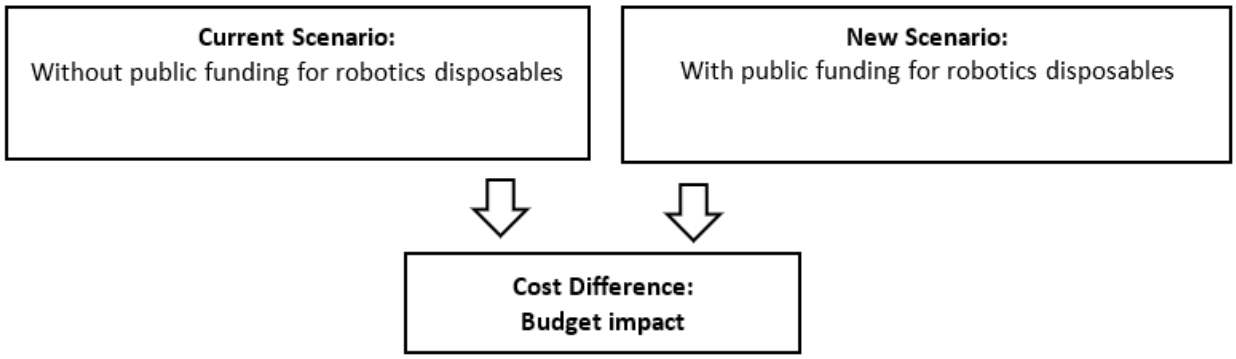

Figure 1: Schematic Model of Budget Impact

Flow chart describing the model for the budget impact analysis. The current scenario explores resource use and total costs without public funding for robotics disposables. The new scenario explores resource use and total costs with public funding for robotics disposables. The budget impact represents the difference in cost between the two scenarios.

Key Assumptions

- The total number of robotic systems in Ontario would stay relatively stable over the next 5 years. When a robotic system approaches the end of its service life, we assume it would be replaced; if a hospital currently does not have a robotic system, we assume the hospital would be unlikely to purchase one in the near future (because performing robotic-assisted surgical procedures requires both the equipment and the surgical expertise)
- Most RH procedures would be performed using the da Vinci Surgical System, and the market share of other robotic systems for RH would be limited over the next 5 years
- Public funding for robotics disposables would lead to a moderate increase in the total volume of robotic-assisted surgeries performed

Population

Our population of interest was people with endometrial cancer and obesity undergoing RH. We searched administrative databases to understand the historical data for robotic-assisted surgeries in Ontario and predicted the surgical volumes in the current and new scenarios based on historical volumes.

Overview of Robotic-Assisted Surgeries in Ontario, Fiscal Years 2012 to 2021

We estimated the numbers of different types of robotic-assisted surgeries performed in Ontario for recent years using administrative data. We primarily searched the Discharge Abstract Database (DAD; Canadian Institute for Health Information [CIHI], IntelliHealth Ontario, November 2022) to identify inpatient robotic-assisted surgeries between fiscal years (FYs) 2012 and 2021. (Note: In this budget impact analysis, a fiscal year is expressed as the year in which reporting begins; for example, "FY 2012" means the fiscal year beginning April 1, 2012, and ending March 31, 2013.) We also searched the National Ambulatory Care Reporting System (NACRS; CIHI, IntelliHealth Ontario) to supplement our data. To understand recent trends in robotic-assisted surgeries, we analyzed the main diagnosis, principal intervention, and hospital for all robotic-assisted surgical procedures conducted in the province over the most recent 3 years (FY 2019 to FY 2021). Most robotic-assisted surgeries are inpatient procedures, and the statistics we report are based on inpatient data from the DAD unless otherwise specified. Our main findings can be summarized as follows (see Appendix 4 for detailed findings):

- The overall volume of robotic-assisted surgeries (for all indications) increased over time, from 909 procedures in FY 2012 to 2,223 procedures in FY 2021 (Appendix 4, Table A1)
- The most common indications for robotic-assisted surgery were prostate cancer (45.7%), arthrosis of the knee (9.5%), endometrial cancer (7.9%), kidney cancer (5.8%), and lung cancer (5.4%) (Appendix 4, Table A2 [volumes by main diagnosis] and Table A3 [volumes by principal intervention]). Of note, robotic-assisted knee surgeries were not performed using the da Vinci Surgical System

Volumes of Robotic-Assisted Hysterectomy, Fiscal Years 2012 to 2021

We searched the DAD to obtain the volumes of RH procedures performed between FY 2012 and FY 2021 in Ontario. (The Canadian Classification of Health Interventions [CCI] codes used to identify these procedures can be found in Appendix 4, Table A4.) Table 6 presents the total volumes for this period,

along with main surgical approach and main diagnosis. Table 7 presents the yearly volumes of RH procedures for this period.

Although a small number of RH surgeries have been conducted in the day surgery setting (NACRS, CIHI, November 2022), people with obesity typically need inpatient postoperative care. Therefore, we searched only the DAD, which provides inpatient data, to obtain historical volumes.

Table 6: Total Volumes of Robotic-Assisted Hysterectomy, FY 2012–2021

Procedure	Volume, N	Main CCI code (surgical approach): N (%)	Main diagnosis (ICD-10-CA): N (%)
Robotic-assisted hysterectomy	2,264	–	–
Excision total, uterus	1,956	1.RM.89.AA (combined laparoscopic and vaginal) + 7.SF.14.ZX (robotic): 1,041 (53.2%) 1.RM.89.DA (laparoscopic) + 7.SF.14.ZX (robotic): 769 (39.3%)	Malignant neoplasm of corpus uteri (C54): 1357 (69.4%) Other noninflammatory disorders of uterus, except cervix (N85): 189 (9.7%)
Excision radical, uterus	160	1.RM.91.AA (combined laparoscopic and vaginal) + 7.SF.14.ZX (robotic): 105 (65.6%) 1.RM.91.DA (laparoscopic) + 7.SF.14.ZX (robotic): 42 (26.3%)	Malignant neoplasm of cervix uteri (C53): 80 (50%) Malignant neoplasm of corpus uteri (C54): 67 (41.9%)
Excision partial, uterus	148	1.RM.87.DA-GX (laparoscopic) + 7.SF.14.ZX (robotic): 139 (93.9%)	Leiomyoma of uterus (D25): 136 (91.9%)

Abbreviation: CCI, Canadian Classification of Health Interventions; ICD-10-CA, International Statistical Classification of Diseases and Related Health Problems, 10th revision, Canada.

Source: Discharge Abstract Database (Canadian Institute for Health Information, IntelliHealth Ontario), November 2022.

Most RH procedures conducted from FY 2012 to FY 2021 were total hysterectomy, followed by radical and then partial hysterectomy. The most common diagnosis was endometrial cancer. The volume of all RH procedures for any diagnosis fluctuated between 188 and 258 per year over the past 10 years, with no clear upward or downward trend. Over the last 5 years (FYs 2017–2021), the average volume of all types of RH procedure (i.e., total, partial, and radical) for people with endometrial cancer and obesity was 103 per year. Over the same 5-year period and for the same population, the average RH volume for total hysterectomy (i.e., excluding partial and radical) was 92 per year. In the same period, the volume of RH procedures for people with obesity and either endometrial cancer or endometrial benign neoplasm and obesity was 116 per year.

A large number of people could be eligible for RH when we consider it as an alternative to open and laparoscopic hysterectomy. According to administrative data, between 2012 and 2018 in Ontario, more than 10,000 total hysterectomy procedures (including open, laparoscopic, and robotic-assisted) were conducted each year, but the treatment share for RH was small.[16] About 12% of people who underwent

hysterectomy had a body mass index (BMI) equal to or greater than 40 kg/m^2;[16] however, it is unknown how many had a BMI equal to or greater than 30 kg/m^2 (often used as a cut-off for obesity). In addition to endometrial cancer, people with other diagnoses and obesity might be also suitable candidates for RH. The historical volumes of RH procedures did not reflect need for robotic-assisted surgery, likely because the volume of RH procedures was constrained by resource availability.

Table 7: Yearly Volumes of Robotic-Assisted Hysterectomy, FY 2012–2021

Fiscal year	Volume, any diagnosis, N[a]	Volume, endometrial cancer, N[a,b]	Volume, endometrial cancer and BMI ≥ 30 kg/m^2, N[a,b,c]
2012	188	151	113
2013	224	155	116
2014	251	153	115
2015	258	159	119
2016	251	159	119
2017	218	149	112
2018	195	106	80
2019	245	149	112
2020[d]	191	116	87
2021	243	166	125
Total	**2,264**	**1,463**	**1,098**

[a]This is the volume of all RH procedures (i.e., total, partial, and radical).

[b]This volume includes the number of surgeries for which the main ICD-10-CA (International Statistical Classification of Diseases and Related Health Problems, 10th revision, Canada) code was C54 (malignant neoplasm of corpus uteri) or C55 (malignant neoplasm of uterus, part unspecified).

[c]For this health technology assessment, we defined obesity as a BMI ≥ 30 kg/m^2. It has been reported that about 42.6% of patients (531 out of 1,247) who undergo total hysterectomy have a BMI ≥ 40 kg/m^2, but we were unable to find statistics for the proportion of people with a BMI ≥ 30 kg/m^2.[16] We assumed that 75% of people undergoing RH would have a BMI ≥ 30 kg/m^2 (i.e., would have obesity).

[d]The COVID-19 pandemic likely affected the volume of RH procedures conducted in FY 2020.

Source: Discharge Abstract Database (Canadian Institute for Health Information, IntelliHealth Ontario), November 2022.

Volumes of Robotic-Assisted Hysterectomy in the Current Scenario

The current scenario considered current clinical practice without public funding for RH. With no funding for robotics disposables, the volume of robotic-assisted procedures in the next 5 years will largely be affected by the availability of funding from hospitals' global budgets and foundations allocated to robotic-assisted surgeries, as well as by competing funding needs for inpatient health care services. However, given that we specifically evaluated the budget impact of providing public funding for RH, the total costs in the current scenario are zero over the next 5 years regardless of volume, because there is currently no public funding for robotics disposables. Therefore, for simplicity, based on historical volumes, we estimated the volumes of RH procedures in the current scenario without public funding for robotics disposables.

From FY 2017 to FY 2021, an average of 103 RH procedures were conducted per year for people with endometrial cancer and obesity. Given that we were unable to detect a historical trend in volume (either increasing or decreasing), we estimated that the annual volume would remain at 103 procedures per year over the next 5 years in the reference case, for a total of 515 procedures (including total, partial, and radical procedures; Table 8).

Table 8: Volumes of Robotic-Assisted Hysterectomy for People With Endometrial Cancer and Obesity in the Current and New Scenarios – Reference Case

Scenario	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Current scenario	103	103	103	103	103	515
New scenario	124	136	150	165	182	757

Volumes of Robotic-Assisted Hysterectomy in the New Scenario

We consulted stakeholders and reviewed historical volumes to estimate the volumes of RH procedures in the new scenario (with public funding for robotics disposables). We expected the volume would increase with public funding because patients generally prefer a minimally invasive surgical approach, and many surgeons prefer robotic-assisted procedures over conventional laparoscopic procedures. However, we also expected that hospitals would continue providing open and conventional laparoscopic surgeries in the future. Therefore, in the new scenario, we expected that the overall volume of robotic-assisted surgeries would increase moderately in the near future.

We estimated that the volume of RH procedures (including total, partial, and radical) for people with endometrial cancer and obesity in year 1 would be 20% higher than the average annual volume between FY 2017 and FY 2021 (103 × 120% = 124). In the subsequent 4 years, we estimated that the annual increase would be 10% higher than the previous year. In total, we estimated that 757 RH procedures would be conducted over the next 5 years in the new scenario (Table 8).

Resources and Costs

ROBOTIC SYSTEM COSTS AND CONTEXT

We obtained the costs of a robotic system from the manufacturer of the da Vinci Surgical System (email communication, Intuitive Surgical Canada Inc., September 2022). We also reviewed recent published literature and consulted clinical experts. The following summarizes our findings regarding the costs and context of the use of the da Vinci Surgical System in Canada:

- According to the Intuitive 2021 annual report,[17] the cost of the da Vinci Surgical System varied from $0.5 million USD and $2.5 million USD, depending on model, configuration, and geography. Annual service fees ranged from $80,000 USD to $190,000 USD
- An Australian hospital reported that the purchase cost of the da Vinci Xi Surgical System was $3.9 million AUD and that the cost for the sterilizing equipment was $150,000 AUD.[18] The cost of the da Vinci Xi Surgical System was close to the upper band of the cost reported in the Intuitive 2021 annual report[17]

- Presently, both the da Vinci Si (third generation) and Xi (fourth generation) Surgical Systems are used in Ontario. The da Vinci Si system was phased out of the Canadian market in 2019. The disposables, services, and support for this generation will not be available beyond 2024 (Intuitive Surgical Canada Inc., email communication, September 2022)
- Robotic systems other than the da Vinci Surgical System are used for robotic-assisted knee replacement surgeries in Canada.[19-21] Medtronic's Hugo robotic-assisted surgery system has received a Health Canada licence and is being used in Canada for hernia and colorectal surgeries.[22] The costs of these other robotic systems and their disposables are unknown

SCOPE OF BUDGET IMPACT ANALYSIS

In the budget impact analysis, we included the costs of robotics disposables. These costs are the direct costs related to the use of robotic systems. In the present analysis, for the new scenario, the Ontario Ministry of Health would be providing funding only for robotics disposables.

We did not include the following costs:

- Cost of the robotic system: We assumed that the robotic system would have been donated to or purchased by the hospital
- Operating room costs: Robotic-assisted surgeries have different operating room standards from those of conventional surgeries, such as the requirement for a larger operating room.[23] However, because we did not consider the cost of purchasing a robotic system for hospitals that do not currently have one, we did not consider the potential costs of upgrading the operating room
- Cost of annual maintenance/service: We did not include this cost because it is usually covered by the hospital's global budget

COST OF ROBOTICS DISPOSABLES

We obtained the cost of robotics disposables from the manufacturer of the da Vinci Surgical System (email communication, Intuitive Surgical Canada Inc., September 2022). The cost of robotics disposables can vary; for example, because surgeons may use different instruments for the same procedure and because a surgeon may use different instruments for total, partial, and radical RH procedures. The cost of robotics disposables may also vary because the disposables used may vary by diagnosis (e.g., malignant vs. benign neoplasm).

We arrived at an approximate cost for robotics disposables of $1,507.26 (2022 CAD) per procedure. This cost was based on the most common disposables used in robotic-assisted surgeries and included the costs of instruments (e.g., needle drivers, forceps, scissors) and accessories (e.g., drapes, seals, tip covers). However, we did not include the costs of stapling or a trocar (a device placed in the abdomen during laparoscopic surgery).

We conducted sensitivity analyses to capture the uncertainty of the cost of robotics disposables.

Internal Validation

The secondary health economist conducted formal internal validation. This process included checking for errors and ensuring the accuracy of parameter inputs and equations in the budget impact analysis.

Analysis

We conducted a reference case analysis and several sensitivity analyses. Our reference case analysis represents the analysis with the most likely set of input parameters and model assumptions. Our sensitivity analyses explored how the results are affected by varying input parameters and model assumptions. We conducted the following scenario analyses for RH procedures:

- **Scenario 1, all types of RH (i.e., total, partial, and radical) for people with any main diagnosis and any BMI:** In this scenario, we aimed to capture the use of RH in real clinical practice in Ontario, so we estimated the volumes of all types of RH (i.e., total, partial, and radical) for any main diagnosis and any BMI. In the current scenario, the volume of RH procedures is 218 per year (i.e., the same as the average annual volume from FY 2017 to FY 2021) over the next 5 years. In the new scenario, the volume in year 1 is 262 (20% higher than the average annual volume from FY 2017 to FY 2021), and the volumes in years 2 to 5 increase by 10% annually compared with the previous year (Table 9)
- **Scenario 2, slower increase in RH volumes for people with endometrial cancer and obesity:** The volumes of RH procedures for people with endometrial cancer and obesity in the current scenario are the same as those in the reference case. In the new scenario, the volume in year 1 is 113 (10% higher than the average annual volume from FY 2017 to FY 2021), and the volumes in years 2 to 5 increase by 5% annually compared with the previous year (Table 9)
- **Scenario 3, varying RH volumes:** RH volumes may vary from current estimates for many reasons, including funding being limited to total hysterectomy (i.e., excluding partial and radical), funding being provided for broader indications (i.e., additional main diagnoses), the use of different BMIs to define obesity, more people being referred for robotic-assisted surgeries, and more hospitals purchasing a robotic system. For simplicity, we considered potential lower and higher volumes for any reason. In scenario 3a, we assumed a volume 10% lower than in the reference case. In scenario 3b, we assumed a volume 15% higher than in the reference case. We assumed that the volumes in both the current and new scenarios would increase proportionally to the corresponding volumes in the reference case
- **Scenario 4, varying costs of robotics disposables:** The costs of robotics disposables may vary, as discussed earlier. In scenarios 4a and 4b, we assumed that these costs were 25% higher and 50% higher, respectively, than those in the reference case (scenario 4a: $1,884 per procedure; scenario 4b: $2,261 per procedure). In scenario 4c, we assumed that the costs were 25% lower than those in the reference case ($1,130 per procedure)

Table 9: Volumes of Robotic-Assisted Hysterectomy – Scenario Analyses for Scenarios 1 and 2

Scenario	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Scenario 1: All types of RH[a] for people with any main diagnosis and any BMI						
Current scenario	218	218	218	218	218	1,090
New scenario	262	288	317	349	384	1,600
Scenario 2: Slower increase in RH[a] volumes for people with endometrial cancer and obesity						
Current scenario	103	103	103	103	103	515
New scenario	113	119	125	131	138	626

[a]Includes the volume of all types of RH (i.e., total, partial, and radical).

Results

Reference Case

Table 10 provides the results of the budget impact analysis. Since robotics disposables are not currently publicly funded, costs in the current scenario are zero. Therefore, for the new scenario, the budget impact is equal to the cost of the robotics disposables. Over 5 years, the total cost for robotics disposables for RH is $1.14 million.

Table 10: Budget Impact Analysis Results – Reference Case

	Budget impact, $ million[a,b]					
Scenario	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total**
Current scenario[c]	0	0	0	0	0	0
New scenario	0.19	0.20	0.23	0.25	0.27	1.14
Budget impact	**0.19**	**0.20**	**0.23**	**0.25**	**0.27**	**1.14**

[a]In 2022 Canadian dollars.

[b]Some numbers may appear inexact due to rounding.

[c]Given that there is currently no public funding for robotics disposables, we assumed costs of zero for the current scenario. Therefore, in the new scenario, the budget impact is equal to the cost of the disposables.

Sensitivity Analysis

Table 11 summarizes the results of our scenario analyses. The budget impact analysis results were sensitive to changes in surgical volume and the cost of robotics disposables.

Table 11: Budget Impact Analysis Results – Scenario Analyses

Scenario	Budget impact, $ million[a,b,c]					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Reference case						
Budget impact	**0.19**	**0.20**	**0.23**	**0.25**	**0.27**	**1.14**
Scenario 1: All types of RH for people with any main diagnosis and any BMI						
Budget impact	0.39	0.43	0.48	0.53	0.58	2.41
Scenario 2: Slower increase in RH volumes for people with endometrial cancer and obesity						
Budget impact	0.17	0.18	0.19	0.20	0.21	0.94
Scenario 3a: Volumes 10% lower than in reference case						
Budget impact	0.17	0.18	0.20	0.22	0.25	1.03
Scenario 3b: Volumes 15% higher than in reference case						
Budget impact	0.21	0.24	0.26	0.29	0.32	1.31
Scenario 4a: Cost of disposables 25% higher than in reference case						
Budget impact	0.23	0.26	0.28	0.31	0.34	1.43
Scenario 4b: Cost of disposables 50% higher than in reference case						
Budget impact	0.28	0.31	0.34	0.37	0.41	1.71
Scenario 4c: Cost of disposables 25% lower than in reference case						
Budget impact	0.14	0.15	0.17	0.19	0.21	0.86

[a]In 2022 Canadian dollars.

[b]Some numbers may appear inexact due to rounding.

[c]Given that there is currently no public funding for robotics disposables, we assumed costs of zero for the current scenario. Therefore, in the new scenario, the budget impact is equal to the cost of the disposables.

Discussion

We reviewed the volumes of RH procedures (i.e., total, partial, and radical) conducted in Ontario between FY 2012 and FY 2021 and estimated the potential budget impact of publicly funding these procedures over the next 5 years. If robotics disposables do become publicly funded, it is likely that the volume of robotic-assisted surgeries will increase. Thus, it will be necessary to understand the following impacts of expanding the use of robotic-assisted surgeries:

- Although funding for robotic systems was not the focus of this budget impact analysis, it will be necessary to plan for funding these systems in the long term. The manufacturer of the da Vinci Surgical System will not provide service or support for its third-generation system (da Vinci Si) beyond 2024. However, some hospitals are currently using this system; therefore, funding to replace these systems must be determined
- In addition to the da Vinci Surgical System, other robotic systems have entered the market and may expand the indications for robotic-assisted surgery over time. Because of existing market

competition, it is expected that the prices of robotic systems and robotics disposables are unlikely to increase in the near future. However, given that the overall volume of robotic-assisted surgeries is likely to continue increasing, the total budget for robotic systems and robotics disposables may also increase

- Robotic systems have been used for an increasing number of indications in recent years. In Appendix 4, Table A5, we present the volumes of the less commonly performed robotic-assisted surgeries (i.e., all those except hysterectomy, nephrectomy, and radical prostatectomy) conducted between FY 2012 and FY 2021. Compared with hysterectomy, nephrectomy, and radical prostatectomy, there is greater uncertainty about the volumes of the less common surgeries, and these volumes are likely to be strongly affected by the funding status of robotics disposables. Therefore, guidance for the proper use of robotic systems for less common indications will be necessary
- From an economic perspective, the per-surgery attributable costs of capital investment for robotic systems and annual service fees for equipment maintenance would decrease with an increase in the volume of robotic-assisted surgeries performed. However, an increase in surgical volume would be associated with an increase in the cost of robotics disposables. Centralizing robotic-assisted surgeries within a few high-volume hospitals is one approach to increase the ratio of robotic-assisted surgical volume to number of robotic systems. But centralizing specialized surgical procedures is a complex process, affected by many factors beyond the scope of the present budget impact analysis. It would be difficult to determine the optimal number of robotic systems in Ontario, as well as the optimal volume of surgeries per system per year

Strengths and Limitations

Our study had the following strengths:

- We searched administrative databases to obtain the volumes of robotic-assisted surgeries conducted in Ontario between FY 2012 and FY 2021. These data reflect the real-world clinical use of robotic-assisted surgeries in Ontario
- We consulted several stakeholders to understand the current costs of robotics disposables and the current context of robotic-assisted surgery in Ontario

The following limitations should be noted when interpreting the findings of this analysis:

- There is a lack of high-quality clinical data to allow us to quantify the potential savings of RH compared with open or laparoscopic hysterectomy
- This analysis did not address the impact of RH on the volumes of open or laparoscopic hysterectomy or the volumes of alternative treatment options for endometrial cancer. Indeed, because of the availability of other treatment options, the overall volume of hysterectomy procedures has decreased over the last 10 years,[24] whereas the volumes of RH procedures have been relatively stable or have increased slightly. Estimating the potential volume of RH procedures after robotics disposables are funded is not straightforward

Conclusions

We expect that publicly funding the disposables required to perform robotic-assisted surgeries would lead to a moderate increase in the volume of these surgeries conducted in Ontario. We estimate that the 5-year budget impact of publicly funding RH for people with endometrial cancer and obesity would be $1.14 million.

Preferences and Values Evidence

Objective

The objective of this analysis was to explore the underlying values, needs, and priorities of those who have lived experience with endometrial cancer and obesity. In addition, this analysis aimed to examine patient, family, and caregiver preferences regarding and perceptions of robotic-assisted hysterectomy (RH). This analysis also explored the preferences and values of health care professionals who provide surgical treatment for endometrial cancer regarding the use of RH.

Background

Exploring patient preferences and values provides a unique source of information about people's experiences of a health condition and the health technologies or interventions used to manage or treat that health condition. It includes the impact of the condition and its treatment on the person with the health condition, their family and other caregivers, and the person's personal environment. Engagement also provides insight into how a health condition is managed by the province's health system.

Information shared from lived experience can also identify gaps or limitations in published research (e.g., outcomes important to those with lived experience that are not reflected in the literature).[25-27] Additionally, lived experience can provide information and perspectives on the ethical and social values implications of health technologies or interventions.

Because the needs, preferences, priorities, and values of those with lived experience in Ontario are important to consider to understand the impact of the technology on people's lives, we may speak directly with people who live with a given health condition, including those with experience of the technology or intervention we are exploring.

For this analysis, the preferences and values of people with lived experience of endometrial cancer and obesity and of health care professionals who provide surgical treatment for endometrial cancer were examined via direct engagement. The initiative was led by the Patient and Public Partnering team at Ontario Health, and direct engagement with eligible participants was completed through telephone interviews and emailed responses.

Direct Patient Engagement

Methods

PARTNERSHIP PLAN

The partnership plan for this health technology assessment focused on consultation to examine the experiences of people who have been directly affected by endometrial cancer and obesity and their family members and caregivers. We engaged with participants via telephone interviews.

We conducted qualitative interviews, as this method of engagement allowed us to explore the meaning of central themes in the experiences of people with endometrial cancer and obesity, as well as the experiences of their families and caregivers.[28] The sensitive nature of exploring people's experiences of a health condition and their quality of life further supported our choice of methodology.

PARTICIPANT OUTREACH

We used an approach called purposive sampling,[29-32] which involves actively reaching out to people with direct experience of the health condition and health technology or intervention being reviewed. We approached a variety of community organizations, clinical experts, and community-based health programs in Ontario that support people with endometrial cancer in an effort to increase the public's awareness of our engagement activity and to connect with people who would like to share their lived experiences.

Inclusion Criteria

We sought to speak with adults with lived experience of endometrial cancer and obesity who have undergone or are planning to undergo a hysterectomy. Participants did not have to have direct experience with RH.

Exclusion Criteria

We did not set exclusion criteria for participants who otherwise met the inclusion criteria.

Participants

We spoke with six individuals with lived experience of endometrial cancer and obesity. All participants had experience with a minimally invasive procedure, either RH or conventional laparoscopic hysterectomy (LH).

APPROACH

At the beginning of the interview, we explained the role of our organization, the purpose of this health technology assessment, the risks of participation, and how participants' personal health information would be protected. We gave this information to participants both verbally and in a letter of information (Appendix 5) if requested. We then obtained participants' verbal consent before starting the interview. With the participants' consent, we audio-recorded and then transcribed the interviews.

Interviews lasted approximately 20 to 60 minutes. The interview was semistructured and consisted of a series of open-ended questions. Questions were based on a list developed by the Health Technology Assessment International Interest Group on Patient and Citizen Involvement in Health Technology Assessment.[33] Questions focused on the impact of endometrial cancer and obesity on participants' quality of life, their experiences with hysterectomy, and their perceptions of the benefits or limitations of RH. Appendix 6 provides the patient interview guide.

DATA EXTRACTION AND ANALYSIS

We used a modified version of a grounded-theory methodology to analyze interview transcripts. This approach allowed us to organize and compare experiences across participants. This method consists of a repetitive process of obtaining, documenting, and analyzing responses while simultaneously collecting, analyzing, and comparing information.[34,35] We used the qualitative data analysis software program NVivo[36] to identify and interpret patterns in the data. The patterns we identified allowed us to describe the impact of endometrial cancer, obesity, and cancer treatment on those interviewed.

Results

STIGMA AND DISCRIMINATION

Participants reported being stigmatized and discriminated against by health care providers when trying to navigate the health care system. Examples included being spoken to in a condescending tone and not having their concerns be taken seriously, with some providers attributing all their health concerns to their weight. Before getting diagnosed, some reported having to advocate for themselves by pushing their primary care team to refer them to a specialist when they first experienced signs of endometrial cancer such as postmenopausal bleeding, bleeding between menstrual cycles, or an abnormal pap smear result.

> *I think you need to really push them for a specialist …* so I did. I called every day for two weeks and until they gave me a specialist.

> *Generally my sense was the doctor was quite condescending and a little bit infantilizing. I couldn't tell whether that is because I'm a fat woman or because I'm a gay woman, or just because I'm a woman. But I would tell you either way, there it is an equity concern in women's health care for sure when we come in with what is perceived to be menstrual complications or gynecological concerns. We are often not taken seriously, and I wasn't terribly surprised that I wasn't taken seriously.*

Once participants received their cancer diagnosis, they expressed feelings of shock, uncertainty, and fear. They had many questions about what their future might look like and decisions that needed to be made. Younger patients reported needing to make quick decisions regarding fertility and whether to freeze their eggs. Those who hadn't yet reached menopause questioned the impact menopause would have on their weight.

> *What does this mean for my future? How serious is this? What does this mean for my sex life? Am I going to die? How* sure am that I didn't want kids? I was overwhelmed, scared, and uncertain. Lots of questions for sure.

> *I was scared because I really wasn't expecting it. I really wasn't* because I've had heavy periods my whole life, so I just never thought it would happen.

> *I was worried about weight gain, additional* weight gain. I was very transparent and said, "A lot of women gain weight with menopause, and I'm very, very concerned."

AWARENESS OF ROBOTIC-ASSISTED HYSTERECTOMY

There was variation among participants regarding their awareness of RH. Some had a good understanding of the procedure from information provided through the internet, TV shows, and other media. Some were aware of the procedure but thought they would not be candidates owing to their weight. Some were unaware of the availability of the procedure in Canada. Others had no awareness of the procedure or how it was performed.

> *I'm a little bit of a medical drama* nerd, and so you see a little bit about it on TV, but that's pretty much the extent of my awareness of that.

> *I knew that there* [were] robot-assisted surgeries; I just didn't know that they were available in Canada.
>
> *I think of restaurants where the robot delivers food*. I think of a robot with slicer hands going in with lasers; that was my visual.
>
> *What came to my mind was a robot doing the surgery. I didn't really understand that it was the doctor in another room essentially performing the surgery through this device.*
>
> *I suppose my initial thought was* they modernized and improved the actual instruments. I didn't really visualize this big thing with the big metal arms. It wasn't what I had in my head.

For those who were unaware of RH, we provided information about the procedure verbally during the interview. Whether having been informed by their surgeon or by the interviewer, participants reported seeing RH as an innovative surgical tool that could greatly benefit patients. Participants who had developed foundational knowledge of the procedure through independent research spoke about its benefits for the surgeon, including improved precision and visualization. Overall, participants reported a strong preference for RH over open hysterectomy (OH) and LH. Key factors informing this preference included the technology's perceived clinical effectiveness and its minimal invasiveness.

> It's less invasive; they [surgeons] have more control. The wrist movements of the tools, they're more flexible. They have more of a 3D scope to see [which means] they can obviously zoom in and see things better. They can manipulate the things better. And it can be more than one person because you're going to have a few people working the different parts of the robot.

DECISION-MAKING

Participants emphasized the importance of having information about the type of surgical procedure they would be receiving, including its potential risks and benefits. Many reported being aware of the increased risk of surgery for people with obesity and reported relying on their care team's expertise to guide them toward the safest surgical option. All participants reported preferring a minimally invasive surgical option over an open procedure, citing recovery as one of the most significant factors of their decision-making.

> *It was obvious that the robotic surgery was the way to go*, and the quick recovery time as well. I knew I was going to be stuck in hospital overnight at least. But with the conventional surgery, I'm sure it would have been two or three days more than that. And then obviously my risk increased because I'm fat, [my risk] for healing and infection and all that stuff. So yeah, the decision was easy. The robotic surgery was definitely the best decision for me.
>
> *I went the minimally invasive route, then, [because] that was a much lesser risk … . I didn't want to be laid up and unable to move. …* I wanted to be able to recover as quickly as possible, obviously. Who doesn't?

When asked about the reduced scarring associated with RH, participants noted that it wasn't an important factor in their decision-making and that it wouldn't have influenced their treatment decision. However, a few mentioned that it would have been a factor if they were younger.

> *The [minimal] scarring, it's nice that I haven't got a huge line there. But really, if I were 25 it might be different, but at my age the only time I'm unclothed is when I'm swimming, and I wear a one-piece bathing suit, so nobody's going to see anything. But having said that, obviously with the minimal scarring, it's healed that much quicker. But really, the reduction in scarring for me personally at my age and my state of life wasn't the most important thing.*

> *No,* it's not important to me. I don't have a problem with having scars.

Several participants who were aware of the increased risk of surgery for people with obesity reported feeling relieved and surprised when they had been told that a minimally invasive procedure was an option for them. Some had been unaware that minimally invasive surgery was available to people with obesity.

> *I* was pleased that I wouldn't have the old-fashioned way of having a hysterectomy. So, I was pleasantly surprised with the laparoscopic approach.

> *I mean, any* time you're putting an overweight patient under anaesthetic or doing surgeries, there's additional risk.

> *I was always under the impression that laparoscopic surgery wasn't really an* option because when you're obese, nobody wants to do anything for a start.

SURGICAL EXPERIENCE

All participants underwent a minimally invasive procedure, either RH or LH. Participants reported that knowing they were having a minimally invasive procedure allowed them to feel more relaxed when going into surgery. Most reported feeling comfortable and being well informed about the procedure and stated that they had gone into surgery feeling optimistic about achieving a full recovery. They attributed this mindset to their trust and confidence in the expertise of their surgeon. Participants also reported valuing efforts made by their surgical team to provide streamlined care.

> *They told you where you were go*ing to go, and everybody was so coordinated and well organized. I really had no apprehension at all.

> *I wasn't really anxious about what they were go*ing to find, because all throughout they were telling me that everything looks really good, so this looks like it's going to be a very positive outcome. So, going into it, outside of just normal anxiety, I felt good.

A few participants reported feeling nervous and anxious before surgery, particularly regarding anaesthesia and same-day discharge.

> *My biggest concern was* with the day surgery. I just couldn't imagine having that surgery and just going home after.

> *I think it was probably one of the scariest times … I was quite nervous, very anxious …* I could hardly speak because I was just so nervous about the surgery.

RECOVERY

All participants spoke positively about their experience with recovery.

> *There* [are] no symptoms from the surgery at all. It's been quite incredible, almost to the point where you think, "Surely, I should have more issues than this," but I really don't. It's wonderful. You recover so quickly and feel so good.
>
> *I would absolutely* recommend it to anybody.
>
> *The robotic surgery was the best decision for me.*

The most notable benefit that participants spoke about was the quick recovery time. They were surprised by how well they felt physically after waking up from surgery. Further, they were able to go back to their day-to-day lives with minimal constraints, the primary one being to avoid lifting or pushing heavy objects.

> *I was walking by 10 o'clock the night of the surgery*. And at home there was very little pain, more discomfort and tenderness than any actual pain.
>
> *I'm sort of banned from lugging the shopping in and shoving the vacuum cleaner around daily. But realistically I don't feel any different.*
>
> *No pain, no discomfort, no bleeding, nothing. There [are] no symptoms from the surgery at all.*

Other factors participants reported as contributing to their positive surgical experience included the short hospital stay, having no postoperative complications, having minimal to no scarring or pain, and the decreased caregiver burden.

> *I was in hospital overnight. And* it's not long. It's not long at all.
>
> *To only have to stay overnight in the hospital was great. You want to be in your own bed*, and you want to be with your own people around you. I've got a very, very supportive family. I'm very lucky. So I really haven't lifted a finger for the last three weeks, which I'm kind of getting used to. But no, not having to stay in hospital was definitely an advantage.

Participants reflected on the importance of preventing surgical site infections, particularly because people with obesity are at greater risk of infection than those without obesity. Participants mentioned following infection control guidance diligently. They also attributed a shorter hospital stay to lowering their risk of infection.

> *Everybody wants to avoid infection, obviously. I've done everything they told me to do. I do the washing in the shower everyday and really haven't had any issues. It's go*t to be a good thing if you can reduce [the risk of] infection. I also think by you not having to stay in hospital so long your risk of infection must be reduced.
>
> *[Preventing surgical site infections is] d*efinitely important, especially through COVID, having to deal with infections and having to go back to doctors or clinics to deal with those things. It's best just to reduce the exposure to having to go places.

One participant compared their positive experience of RH with a family member's negative experience of open hysterectomy.

> *She was in the hospital for 3 weeks because she got a wound infection. Then she had a DVT [deep vein thrombosis]. Then she had a pulmonary embolism. She had all sorts of horrible issues and was very, very sick afterwards. … H*er experience was a total nightmare, but mine really was a bit of a breeze.

Most participants reported being discharged after an overnight hospital stay. All participants felt positive about the short hospital stay, citing their preference to recover in the comfort of their home.

> *I was in hospital over*night. And. It's not long. It's not long at all.

> *To only have to stay in* the hospital overnight was great, [because] you know you want to be in your own bed, and you want to be with your own people around you.

BARRIERS

A number of participants reflected on the potential barriers to accessing RH, including the stigma and discrimination they have experienced in the health care system, an example of which is having all their health concerns attributed to their weight.

> *If* you could lose 100 pounds, it would be much easier for you to have this surgery," [one participant was told]. Yeah, well, you can die from cancer in the length of time it takes you to lose 100 pounds.

Another barrier mentioned was a lack of awareness about RH and about people with obesity being eligible for minimally invasive surgery.

> *Now that I know more, I might ask more questions. At the time I just didn't have that information to be able to ask for the different types of surgery. Had I known my laparoscopic surgery would have been six hours … i*t would have been nice to at least know about the robotic surgery option.

Participants living outside large city centers mentioned geography as a barrier, particularly in terms of the out-of-pocket costs they incurred by having to travel to large city centres for treatment, such as hotel and parking costs. It was mentioned that such costs could be a barrier for people with lower socioeconomic status.

> *The hotel and travel, gas, food, I guess we're maybe $600 to $700 out of pocket …* I'm lucky, but I'm sure there must be people in the position where they just simply couldn't have gotten there. There are a lot of hotels in Toronto that don't have parking; that was also an expense that had to be covered. That was the biggest barrier, the distance.

> *Like me living in [a small town] reduced my chances of having robotic hysterectomy*, and I guess if somebody wasn't able to get to [a large city] easily, like people [who] don't have a car – how would they even get there for appointments and for surgery?

Participants also mentioned having to miss work and the associated financial constraints as a barrier. A few participants who were retired and those who were employed but had sick time and vacation time available to them reported being grateful to be in those situations.

> *I'm lucky in that my husband and I are both retired*, and I have two supportive daughters and sons-in-law who were quite prepared to drop everything.

> *I don't get paid if I'm not at work.*

> *I was* a workaholic, and I was in my head trying to figure out how, even though I [have] benefits – I was just thinking about going back to work.

One participant who identified as being gay raised an equity issue in terms of the educational materials provided to patients about their recovery. This participant reported that the materials they were given addressed only heteronormative sexual intercourse; thus, they had to seek out relevant information.

> *The conversation on recovery and returning to normal activity and trying sexual activity was very focused on heteronormative recovery. …* The office person gives you a lot of the information. And I had to say to her, "No, I'm gay. This doesn't apply to me. This information is not helpful. I need a different set of information." Not everybody's life looks the same, and giving out information that is so heteronormative could be really damaging. If I wasn't a person who spoke up and said, "Hey, I probably need a different answer on this, or I need different information . . ."

DESIRE FOR SAFE, EFFECTIVE SURGICAL OPTIONS FOR PEOPLE WITH OBESITY

Robotic-assisted hysterotomy was viewed favourably by all those we interviewed. Participants emphasized the need for safe surgical options for people with obesity and the importance of having robotic-assisted surgery widely available.

> *On a purely personal point of view, why shouldn't we fatties have something that's designed to help us? …* They [the health care system] should really consider this as an option. We need robotic-assisted surgery to be much more widely available.

> *My general belief is that anything that can make surgery safer for people who are overweight [should be done] because we are all very aware of the risks of surgery when we're overweight or obese. Anything that can make it safer, anything that can make it faster, so that we're under [anaesthesia] for less time. Anything that can make recovery better because the overweight body is …* we're healing deeper wounds. It's just that simple. And so, anything that can [be done] to reduce the risks is awesome. It is my understanding that robotic-assisted [surgery] in the right hands can really improve outcomes, and if that is the case, if that's what the data shows, then I think that that is amazing, and it should be made more widely available.

Discussion

We engaged with people with lived experience of endometrial cancer and obesity, all of whom had experience with RH or LH. Participants spoke to their values and preferences regarding surgical treatment for endometrial cancer, factors that affected their decision-making, and the impact of their treatment and their experience with the health care system on their recovery and quality of life. All

participants spoke of the positive impact of having a minimally invasive surgical option made available to them. They viewed robotic-assisted surgery favourably and emphasized the importance of having minimally invasive surgical options made widely available for people with obesity.

There were a few limitations of this work. We experienced a low recruitment rate, which could be attributed to the specificity of the recruitment criteria (i.e., people with experience of both endometrial cancer and obesity), as well as the stigmatizing nature of obesity, which could have made people less willing to speak about their experiences. Further, only a few participants had experience with RH. There was also a lack of geographic representation among participants, most of whom lived in southern Ontario. However, we did have representation from both urban and rural perspectives, which provided robust narrative data.

Conclusions

All participants spoke favourably about their experiences with minimally invasive surgery, particularly the quick recovery. They viewed RH positively owing to its minimally invasive nature and the potential benefits it may provide over LH. They also emphasized the need for safe surgical options for people with obesity owing to the higher risk of complications they face. Participants felt strongly that RH should be publicly funded.

However, participants also raised an important key system-level barrier: the stigma and discrimination faced by people with obesity in their interactions with the health care system. Several reported their health concerns not being taken seriously and all concerns being attributed to obesity.

Participants also emphasized the importance of awareness; that is, ensuring that people with obesity are made aware that minimally invasive surgery is an option for them and that RH is available in Ontario. They also highlighted the importance of access, with geography, cost, and time mentioned as potential barriers to treatment for people who do not live near large city centres where treatment is provided, those unable to afford the out-of-pocket costs associated with treatment (e.g., hotels, parking), and those unable to take time off work without experiencing financial constraints.

Direct Provider Engagement

We engaged directly with health care professionals to provide contextual information from a clinical perspective on the use of RH in Ontario for people with endometrial cancer and obesity.

Methods

PARTNERSHIP PLAN

The partnership plan for this health technology assessment focused on consultation to examine the experiences of gynecological cancer surgeons who perform hysterectomies for people with endometrial cancer and obesity. We engaged with participants via telephone interviews and emailed responses.

We conducted qualitative interviews, as this method of engagement allowed us to explore the meaning of central themes in the experiences of gynecological cancer surgeons performing hysterectomies.

PARTICIPANT OUTREACH

We used an approach called purposive sampling,[29-32] which involves actively reaching out to people with direct experience of providing treatment for the population and with the health technology being reviewed. We also used snowball sampling to identify additional contacts.

Inclusion Criteria

We sought to speak with gynecological cancer surgeons with experience conducting hysterectomies on people with endometrial cancer and obesity. Participants did not have to have direct experience with RH.

Exclusion Criteria

We did not set exclusion criteria for participants who otherwise met the inclusion criteria.

Participants

We spoke with five gynecological cancer surgeons with experience conducting hysterectomies on people with endometrial cancer and obesity.

APPROACH

At the beginning of the interview, we explained the role of our organization, the purpose of this health technology assessment, and the risks of participation. We then obtained participants' verbal consent before starting the interview. With the participants' consent, we audio-recorded and then transcribed the interviews.

Interviews lasted approximately 30 minutes. The interview was semistructured and consisted of a series of open-ended questions. Questions focused on the impact of the various surgical options for hysterectomy for people with endometrial cancer (i.e., OH, LH, and RH) and participants' perceptions of the benefits and limitations of RH. The provider interview guide can be found in Appendix 7.

DATA EXTRACTION AND ANALYSIS

We used a modified version of a grounded-theory methodology to analyze interview transcripts. This approach allowed us to organize and compare experiences across participants. This method consists of a repetitive process of obtaining, documenting, and analyzing responses while simultaneously collecting, analyzing, and comparing information.[34,35] We used the qualitative data analysis software program NVivo[36] to identify and interpret patterns in the data.

Results

We spoke with gynecological cancer surgeons to understand their experiences of performing OH, LH, and RH for people with endometrial cancer and obesity.

OPEN HYSTERECTOMY

Participants spoke of the difficulties of performing open surgery, which is an invasive procedure, on people with obesity. Open hysterectomy poses a variety of challenges related to the amount of subcutaneous fat in people with obesity, including visualization and difficulty accessing the pelvis. Patients also require larger and horizonal incisions, which are difficult to keep dry, thus increasing the risk of infection. Participants also emphasized their concerns for patient safety owing to the increased risks of postoperative complications, including bleeding, blood clots, infection, longer hospital stay, and

longer recovery time. Ergonomic challenges are also experienced by surgeons in open hysterectomy, which contribute to increased fatigue and muscle strain (e.g., caused by holding up the abdominal wall during surgery).

LAPAROSCOPIC HYSTERECTOMY

Participants spoke of the value of being able to offer a minimally invasive surgical option but noted the difficultly of performing LH on people with obesity. Participants stated that for people with a high body mass index, laparoscopic hysterectomy is very challenging, if not impossible. One noted the obstacle of the patient needing to be placed in the Trendelenburg position. This position makes it difficult to ventilate the patient because of the abdominal weight being pushed onto the chest. Patients with obesity also face the risk of converting from a laparoscopic to an open surgery if the surgery cannot be completed laparoscopically. Participants also spoke about the ergonomic challenges of performing laparoscopic surgery, which can lead to muscle strain.

ROBOTIC-ASSISTED HYSTERECTOMY: SURGEON BENEFITS

All participants reported that RH provides benefits to both patients and surgeons. Participants mentioned the benefits of being able to offer a safer minimally invasive option to their patients. Regarding benefits to the surgeon, participants described various advantages based on their experience, including improved ergonomics (because the surgeon is seated during the procedure), thus leading to less fatigue and muscle strain. The wristed instruments allow for improved dexterity, precision, and suturing. The robotic system can also support the abdominal wall, which reduces pressure on the patient's lungs, thus improving ventilation. Participants also mentioned the superiority of the three-dimensional imaging, which negates the need for tactile feedback. Improved mindset and confidence were highlighted as key benefits to surgeons when performing RH, owing to the benefits RH provides over OH and LH.

ROBOTIC-ASSISTED HYSTERECTOMY: PATIENT BENEFITS

The surgeons we spoke with emphasized the advantages of minimally invasive procedures for patients, especially those with obesity. Participants stated that the benefits of RH over OH and LH make it possible to offer patients with obesity a minimally invasive option. Compared with open surgery, a minimally invasive surgical procedure allows patients to recover more quickly and to experience must less pain, with patients typically needing minimal to no pain management. RH in particular usually allows for same-day or next-day discharge. This is an especially important consideration for those travelling long distances, as they can reduce their travel costs and time away from family and work. These advantages were reinforced by our participants in the Direct Patient Engagement section, all of whom had undergone a minimally invasive procedure.

BARRIERS AND IMPLEMENTATION

Participants mentioned several barriers to accessing RH. Lack of funding was reported as the most prominent, as lack of funding limits the number of patients who can be treated with RH. Health human resources was also reported as a key barrier, especially in terms of the current nursing shortage in Ontario and specifically in terms of surgical nurses trained on the use of robotic systems. Training for current and new gynecological cancer surgeons is also lacking because of the unavailability of the technology. Participants also spoke about scheduling challenges, given that robotic systems are used for a number of procedures in addition to RH.

Surgeons mentioned two important logistical implementation considerations. First was the need for hospitals to have dedicated robotics teams, as this would allow for greater standardization and contribute to improved efficiency and outcomes. Second was ensuring that RH is implemented only in high-volume centres to ensure that surgeons and surgical staff maintain their proficiency in conducting robotic-assisted procedures. Concentrating robotic-assisted surgeries in high-volume centres would also allow surgical teams' skills to improve over time and increase their ability to take on more complicated cases.

EQUITY CONSIDERATIONS

Surgeons spoke about RH not being available consistently across the province, creating an issue of geographic inequity that particularly affects people with lower socioeconomic status who cannot afford the out-of-pocket costs associated with travelling for treatment or the financial constraints imposed by taking time off work. It was stressed by all those interviewed that people with obesity are discriminated against and stigmatized by the health care system. This population is further disadvantaged by including those from lower socioeconomic status and visible minorities. Additionally, because of the increased risk of surgical and postoperative complications faced by people with obesity, it is important to ensure this population has equitable access to safe, effective surgical options.

Discussion

We engaged with six gynecological cancer surgeons with experience performing hysterectomy for people with endometrial cancer and obesity. A key strength of this engagement was the inclusion of the perspectives of health care professionals who provide surgical treatment for endometrial cancer in addition to those of people who have received this treatment. Assessing the perspectives of health care professionals allowed for rich narrative data on provider preference and values regarding RH.

Most participants had experience performing RH and spoke to the advantages of this technology over OH and LH but also to the clinical, administrative, and operational barriers to providing RH. Surgeons spoke of the challenges faced by people with obesity in accessing surgical treatment options for endometrial cancer and that RH was therefore an important option for them. Participants spoke about the positive clinical outcomes of their patients with obesity and endometrial cancer who had received RH. They were also able to compare the experiences of patients who had received RH with those who had received OH or LH. One participant who did not have direct experience with RH spoke about the perceived advantages that having access to RH would have for her practice and her patients.

Limitations to this work include our low participation rate and geography, with representation only from southern Ontario (five from Toronto and one from London). Further, we had no representation from other key members of the surgical team, such as surgical nurses or anaesthetists.

Conclusions

All participants were supportive of publicly funding RH and perceived RH as a superior alternative to OH and LH. They emphasized the importance of people with endometrial cancer and obesity having access to RH because of the advantages it offers in this population. Participants noted that the main barrier to providing wider access to RH was funding, which currently limits the number of people who can receive this treatment. Other important barriers include health human resources, a lack of training because of the unavailability of the technology, and scheduling challenges. In terms of implementation, surgeons spoke of the need for hospitals to have dedicated robotics team and for robotic-assisted surgeries to be

performed at high-volume centres to improve standardization, efficiency, surgical team skill, and the ability of surgical teams to take on more complicated cases.

Conclusions of the Health Technology Assessment

Compared with laparoscopic hysterectomy, robotic-assisted hysterectomy is associated with fewer conversions to open hysterectomy in people with endometrial cancer and obesity (i.e., those with a body mass index ≥ 40 kg/m^2). Rates of perioperative complications were similarly low for both laparoscopic and robotic-assisted hysterectomy.

The cost-effectiveness of robot-assisted hysterectomy for people with endometrial cancer and obesity is unknown. We estimate that the 5-year budget impact of publicly funding robotic-assisted hysterectomy for people with endometrial cancer and obesity would be $1.14 million.

People with lived experience of endometrial cancer and obesity, as well as gynecological cancer surgeons, spoke favourably of robotic-assisted hysterectomy and its perceived benefits over open and laparoscopic hysterectomy for people with endometrial cancer and obesity, particularly in terms of safety and quick recovery.

Abbreviations

BMI: body mass index

CCI: Canadian Classification of Health Interventions

CIHI: Canadian Institute for Health Information

DAD: Discharge Abstract Database

FY: fiscal year

GRADE: Grading of Recommendations Assessment, Development, and Evaluation

ICD-10-CA: International Statistical Classification of Diseases and Related Health Problems, 10th revision, Canada

LH: laparoscopic hysterectomy

NACRS: National Ambulatory Care Reporting System

OH: open hysterectomy

RH: robotic-assisted hysterectomy

Glossary

Adverse event: An adverse event is any noxious, pathological, or unintended change in a physical or metabolic function, revealed by signs or symptoms or a change in the results of laboratory tests, in any phase of a clinical study, whether or not the change is considered treatment related.[37] It may involve the exacerbation of a preexisting condition, intercurrent diseases, an accident, a drug interaction, or a significant worsening of the disease.

Budget impact analysis: A budget impact analysis is an evaluation of the financial impact of the introduction of a technology or service on the capital and operating budgets of a government or agency.[37]

Cost-effective: A health care intervention is considered cost-effective when it provides additional benefits, compared with relevant alternatives, at an additional cost that is acceptable to a decision-maker based on the maximum willingness-to-pay value.

Cost-effectiveness analysis: A cost-effectiveness analysis is an economic evaluation consisting of comparing various options, in which costs are measured in monetary units, then aggregated, and outcomes are expressed in natural (nonmonetary) units.[37]

Endometrial cancer: Endometrial cancer is a type of cancer that develops in the endometrium (the layer of tissue that lines the uterus).

Equity: Unlike the notion of equality, equity is not about treating everyone the same way.[38] It denotes fairness and justice in process and in results. Equitable outcomes often require differential treatment and resource redistribution to achieve a level playing field among all individuals and communities. This requires recognizing and addressing barriers to opportunities for all to thrive in our society.

Hysterectomy: A hysterectomy is the surgical removal of the uterus.

Laparoscopic hysterectomy: A laparoscopic hysterectomy is a minimally invasive surgical procedure to remove the uterus. It involves several smaller incisions and the use of smaller surgical tools than in an open hysterectomy.

Market distribution: When evaluating more than two technologies, the market distribution is the proportion of the population that uses each technology.

Minimally invasive surgery: A minimally invasive surgery is a surgical procedure that is performed laparoscopically, meaning with the use of a thin tube with a video camera, which allows the surgeon to see inside the body. Compared with open (invasive) surgery, it involves several smaller surgical incisions and the use of smaller surgical tools.

Ministry of Health perspective: The perspective adopted in economic evaluations determines the types of costs and health benefits to include. Ontario Health develops health technology assessment reports from the perspective of the Ontario Ministry of Health. This perspective includes all costs and health benefits attributable to the Ministry of Health, such as treatment costs (e.g., drugs, administration, monitoring, hospital stays) and costs associated with managing adverse events caused by treatments.

This perspective does not include out-of-pocket costs incurred by patients related to obtaining care (e.g., transportation) or loss of productivity (e.g., absenteeism).

Open hysterectomy: An open hysterectomy is an invasive surgical procedure to remove the uterus. It involves a large surgical incision, or cut into the skin.

Partial hysterectomy: Partial hysterectomy is the surgical removal of only the uterus.[15]

Radical hysterectomy: Radical hysterectomy is the surgical removal of the uterus, cervix, part of the vagina, and a wide area of ligaments and tissues around these organs.[15]

Reference case: The reference case is a preferred set of methods and principles that provide the guidelines for economic evaluations. Its purpose is to standardize the approach of conducting and reporting economic evaluations, so that results can be compared across studies.

Robotic-assisted hysterectomy: Robotic-assisted hysterectomy is a minimally invasive surgical procedure to remove the uterus that involves the use of a robotic system operated by the surgeon.

Robotic-assisted surgery: Robotic-assisted surgery is a minimally invasive surgical procedure that involves the use of a robotic system operated by the surgeon.

Scenario analysis: A scenario analysis is used to explore uncertainty in the results of an economic evaluation. It is done by observing the potential impact of different scenarios on the cost-effectiveness of a health care intervention. Scenario analyses include varying structural assumptions from the reference case.

Sensitivity analysis: A sensitivity analysis is a means for evaluating the robustness of a mathematical model by testing a plausible range of estimates of key independent variables to determine whether such variations result in meaningful changes in the model's results.[37]

Time horizon: In economic evaluations, the time horizon is the time frame over which costs and benefits are examined and calculated. The relevant time horizon is chosen based on the nature of the disease and health care intervention being assessed, as well as the purpose of the analysis. For instance, a lifetime horizon would be chosen to capture the long-term health and cost consequences over a patient's lifetime.

Total hysterectomy: Total hysterectomy is the surgical removal of the uterus and cervix.[15]

Willingness-to-pay value: A willingness-to-pay value is the monetary value a health care consumer is willing to pay for added health benefits. When conducting a cost–utility analysis, the willingness-to-pay value represents the cost a consumer is willing to pay for an additional quality-adjusted life-year. If the incremental cost-effectiveness ratio is less than the willingness-to-pay value, the health care intervention of interest is considered cost-effective. If the incremental cost-effectiveness ratio is more than the willingness-to-pay value, the intervention is considered not to be cost-effective.

Appendices

Appendix 1: Evidence Methods

Clinical Evidence Methods

LITERATURE SEARCH

We performed literature searches on March 21, 2022, to retrieve studies published from January 1, 2017, until the search date. We used the Ovid interface to search MEDLINE, the Cochrane Database of Systematic Reviews, and the Cochrane Central Register of Controlled Trials. A medical librarian developed the search strategies using controlled vocabulary (e.g., Medical Subject Headings) and relevant keywords. We used methodological filters to limit retrieval to systematic reviews, meta-analyses, health technology assessments, and randomized controlled trials. The final search strategies were peer-reviewed using the PRESS Checklist.[39]

We created database auto-alerts in MEDLINE and monitored them until May 1, 2022. We performed a focused grey literature search of the International HTA Database, the websites of Canadian, US, and UK health technology assessment agencies, and ClinicalTrials.gov. See Appendix 2 for our literature search strategies, including all search terms.

ELIGIBILITY CRITERIA

Studies

- English-language full-text publications
- Studies published between January 1, 2017, and March 21, 2022
- Health technology assessments, systematic reviews, or randomized controlled trials

Population

- Adults with endometrial cancer and obesity (body mass index [BMI] ≥ 30 kg/m^2)

Intervention

- Robotic-assisted hysterectomy (RH)

Comparators

- Laparoscopic hysterectomy (LH)
- Open hysterectomy (OH)

Outcome Measures

- Operating time
- Conversion rate
- Length of hospital stay
- Complications
- Oncological outcomes (e.g., adjuvant therapy, survival, recurrence)

LITERATURE SCREENING

A single reviewer conducted an initial screening of titles and abstracts using Covidence[40] and then obtained the full texts of studies that appeared eligible for review according to the inclusion criteria. A single reviewer then examined the full-text articles and included eligible studies.

DATA EXTRACTION

We extracted relevant data on study characteristics, methods, and outcomes.

CRITICAL APPRAISAL OF EVIDENCE

A single reviewer evaluated the quality of the body of evidence for each outcome according to the *Grading of Recommendations Assessment, Development, and Evaluation* (GRADE) *Handbook*.[5] The body of evidence was assessed based on the following considerations: risk of bias (as reported in the systematic review by Cusimano et al[2]), inconsistency, indirectness, imprecision, and publication bias. The overall rating reflects our certainty in the evidence.

Economic Evidence Methods

LITERATURE SEARCH

We performed a literature search on March 21, 2022, to retrieve studies published from January 1, 2017, until the search date. We used the Ovid interface to search MEDLINE, the Cochrane Database of Systematic Reviews, and the Cochrane Central Register of Controlled Trials. A medical librarian developed the search strategy using controlled vocabulary (e.g., Medical Subject Headings) and relevant keywords. To retrieve relevant studies, we developed a search using the clinical search strategy with an economic and costing filter applied. The final search strategies were peer-reviewed using the PRESS Checklist.[39]

We created database auto-alerts in MEDLINE and monitored them until May 1, 2022. We performed a focused grey literature search of the International HTA Database, the websites of Canadian, US, and UK health technology assessment agencies, and ClinicalTrials.gov. See Appendix 2 for our literature search strategies, including all search terms.

ELIGIBILITY CRITERIA

Studies

Inclusion Criteria

- English-language full-text publications
- Studies published between January 1, 2017, and March 21, 2022
- Cost–benefit analyses, cost-effectiveness analyses, cost-minimization analyses, cost–consequence analyses, cost–utility analyses, or cost analyses

Exclusion Criteria

- Narrative reviews, letters/editorials, case reports, commentaries, conference abstracts, posters, and unpublished studies

Population

- Adults with endometrial cancer and obesity (BMI ≥ 30 kg/m^2)

Intervention

- RH

Comparators

- LH
- OH

Outcome Measures

- Costs
- Health outcomes (e.g., quality-adjusted life-years, number of adverse events)
- Incremental costs and incremental effectiveness
- Incremental cost-effectiveness ratios

LITERATURE SCREENING

A single reviewer conducted an initial screening of titles and abstracts using Covidence[40] and then obtained the full texts of studies that appeared eligible for review according to the inclusion criteria. A single reviewer then examined the full-text articles and selected studies eligible for inclusion. The reviewer also examined reference lists for any additional relevant studies not identified through the search.

Appendix 2: Literature Search Strategies

Clinical Literature Search

Search date: March 21, 2022

Databases searched: Ovid MEDLINE, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials

Database segments: EBM Reviews - Cochrane Central Register of Controlled Trials <January 2022>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to March 16, 2022>, Ovid MEDLINE(R) ALL <1946 to March 18, 2022>

Search strategy:

---

1 Robotic Surgical Procedures/ (12959)
2 Surgery, Computer-Assisted/ (20287)
3 Video-Assisted Surgery/ (2450)
4 Robotics/ (24664)
5 (((procedur* or surg* or techni* or excis*) adj5 (robot* or comput* assist*)) or (robot* adj3 assist*) or remote* surg*).ti,ab,kf. (37245)
6 (da vinci* or davinci or hugo* or versius* or ottava*).ti,ab,kf. (5823)
7 or/1-6 (73456)
8 exp Hysterectomy/ (34582)
9 (hysterectom* or colpohysterectom* or cervicectom* or trachelectom* or TLH or LAVH or LAVHO).ti,ab,kf. (48954)
10 exp Ovariectomy/ (27185)
11 (ovariectom* or oophorectom*).ti,ab,kf. (41908)
12 exp Genital Neoplasms, Female/su [Surgery] (40283)
13 ((cervix or cervical or endometri* or fallopian or gyn?ecologic* or ovar* or uterine or uterus) adj3 (adenoma* or adenocarcinoma* or cancer* or carcinoma* or carcinogenes#s or malignan* or metastas#s or neoplas* or oncolog* or tumo?r*) adj3 (surg* or excision* or operat*)).ti,ab,kf. (10758)
14 or/8-13 (131616)
15 7 and 14 (2490)
16 (robot* adj3 hysterectom*).ti,ab,kf. (1016)
17 or/15-16 (2599)
18 (Systematic Reviews or Meta Analysis).pt. (155860)
19 Systematic Review/ or Systematic Reviews as Topic/ or Meta-Analysis/ or exp Meta-Analysis as Topic/ or exp Technology Assessment, Biomedical/ (298385)
20 ((systematic* or methodologic*) adj3 (review* or overview*)).ti,ab,kf. (275134)
21 (meta analy* or metaanaly* or met analy* or metanaly* or meta review* or metareview* or health technolog* assess* or HTA or HTAs or (technolog* adj (assessment* or overview* or appraisal*))).ti,ab,kf. (261840)
22 (evidence adj2 (review* or overview* or synthes#s)).ti,ab,kf. (46433)
23 (review of reviews or overview of reviews).ti,ab,kf. (1002)
24 umbrella review*.ti,ab,kf. (911)
25 GRADE Approach/ (79)

26 ((pool* adj3 analy*) or published studies or published literature or hand search* or handsearch* or manual search* or ((database* or systematic*) adj2 search*) or reference list* or bibliograph* or relevant journals or data synthes* or data extraction* or data abstraction*).ti,ab,kf. (267370)
27 (medline or pubmed or medlars or embase or cinahl or web of science or ovid or ebsco* or scopus).ab. (295009)
28 cochrane.ti,ab,kf. (132198)
29 (meta regress* or metaregress*).ti,ab,kf. (12798)
30 (((integrative or collaborative or quantitative) adj3 (review* or overview* or synthes*)) or (research adj3 overview*)).ti,ab,kf. (16536)
31 (cochrane or (health adj2 technology assessment) or evidence report or systematic review*).jw. (37776)
32 ((comparative adj3 (efficacy or effectiveness)) or relative effectiveness or ((indirect or indirect treatment or mixed-treatment) adj comparison*)).ti,ab,kf. (32174)
33 or/18-32 (719914)
34 Clinical Trials as Topic/ (232858)
35 controlled clinical trials as topic/ (5696)
36 exp Randomized Controlled Trials as Topic/ (165762)
37 controlled clinical trial.pt. (187701)
38 randomized controlled trial.pt. (1107783)
39 Pragmatic Clinical Trial.pt. (4058)
40 Random Allocation/ (127457)
41 Single-Blind Method/ (54508)
42 Double-Blind Method/ (316758)
43 Placebos/ (60388)
44 trial.ti. (631612)
45 (random* or sham or placebo* or RCT*1).ti,ab,kf. (2676163)
46 ((singl* or doubl*) adj (blind* or dumm* or mask*)).ti,ab,kf. (487375)
47 ((tripl* or trebl*) adj (blind* or dumm* or mask*)).ti,ab,kf. (3552)
48 or/34-47 (3386466)
49 33 or 48 (3850504)
50 17 and 49 (633)
51 exp Animals/ not Humans/ (4975313)
52 50 not 51 (631)
53 limit 52 to english language [Limit not valid in CDSR; records were retained] (521)
54 limit 53 to yr="2017 -Current" (270)
55 54 use medall (168)
56 54 use cctr (100)
57 54 use coch (2)
58 remove duplicates from 54 (234)

Economic Literature Search

Search date: March 21, 2022

Databases searched: Ovid MEDLINE, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews

Database segments: EBM Reviews - Cochrane Central Register of Controlled Trials <January 2022>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to March 16, 2022>, Ovid MEDLINE(R) ALL <1946 to March 18, 2022>

Search strategy:

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1 Robotic Surgical Procedures/ (12959)
2 Surgery, Computer-Assisted/ (20287)
3 Video-Assisted Surgery/ (2450)
4 Robotics/ (24664)
5 (((procedur* or surg* or techni* or excis*) adj5 (robot* or comput* assist*)) or (robot* adj3 assist*) or remote* surg*).ti,ab,kf. (37245)
6 (da vinci* or davinci or hugo* or versius* or ottava*).ti,ab,kf. (5823)
7 or/1-6 (73456)
8 exp Hysterectomy/ (34582)
9 (hysterectom* or colpohysterectom* or cervicectom* or trachelectom* or TLH or LAVH or LAVHO).ti,ab,kf. (48954)
10 exp Ovariectomy/ (27185)
11 (ovariectom* or oophorectom*).ti,ab,kf. (41908)
12 exp Genital Neoplasms, Female/su [Surgery] (40283)
13 ((cervix or cervical or endometri* or fallopian or gyn?ecologic* or ovar* or uterine or uterus) adj3 (adenoma* or adenocarcinoma* or cancer* or carcinoma* or carcinogenes#s or malignan* or metastas#s or neoplas* or oncolog* or tumo?r*) adj3 (surg* or excision* or operat*)).ti,ab,kf. (10758)
14 or/8-13 (131616)
15 7 and 14 (2490)
16 (robot* adj3 hysterectom*).ti,ab,kf. (1016)
17 or/15-16 (2599)
18 economics/ (27480)
19 economics, medical/ or economics, pharmaceutical/ or exp economics, hospital/ or economics, nursing/ or economics, dental/ (44066)
20 economics.fs. (441931)
21 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).ti,ab,kf. (534650)
22 exp "costs and cost analysis"/ (267475)
23 (cost or costs or costing or costly).ti. (137338)
24 cost effective*.ti,ab,kf. (186680)
25 (cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)).ab,kf. (119304)
26 models, economic/ (11243)
27 markov chains/ or monte carlo method/ (44263)
28 (decision adj1 (tree* or analy* or model*)).ti,ab,kf. (24657)

29 (markov or markow or monte carlo).ti,ab,kf. (78188)
30 quality-adjusted life years/ (15940)
31 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).ti,ab,kf. (43233)
32 ((adjusted adj1 (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).ti,ab,kf. (75289)
33 or/18-32 (1272901)
34 17 and 33 (279)
35 limit 34 to english language [Limit not valid in CDSR; records were retained] (257)
36 limit 35 to yr="2017 -Current" (106)
37 36 use medall (88)
38 36 use coch (0)
39 36 use cctr (18)
40 remove duplicates from 36 (95)

Grey Literature Search

Performed: March 22, 2022

Websites searched:
Alberta Health Evidence Reviews, Alberta Health Services, BC Health Technology Assessments, Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INESSS), Institute of Health Economics (IHE), Ontario Health Technology Assessment Committee (OHTAC), McGill University Health Centre Health Technology Assessment Unit, Centre Hospitalier de l'Universite de Quebec-Universite Laval, Contextualized Health Research Synthesis Program of Newfoundland (CHRSP), Health Canada Medical Device Database, International HTA Database, Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers, National Institute for Health and Care Excellence (NICE), and clinicaltrials.gov

Keywords used:
robot, robot assisted surgery, robotic assisted surgery, robotic surgery, robotic surgeries, robotic surgical procedures, robotics, robot assisted hysterectomy, hysterectomy, hysterectomies, gynaecologic, gynecologic, da vinci, davinci, hystérectomie, gynécologique

Clinical results (included in PRISMA): 2

Economic results (included in PRISMA): 1

Ongoing clinical trials: 24

Appendix 3: PRISMA Flow Diagrams

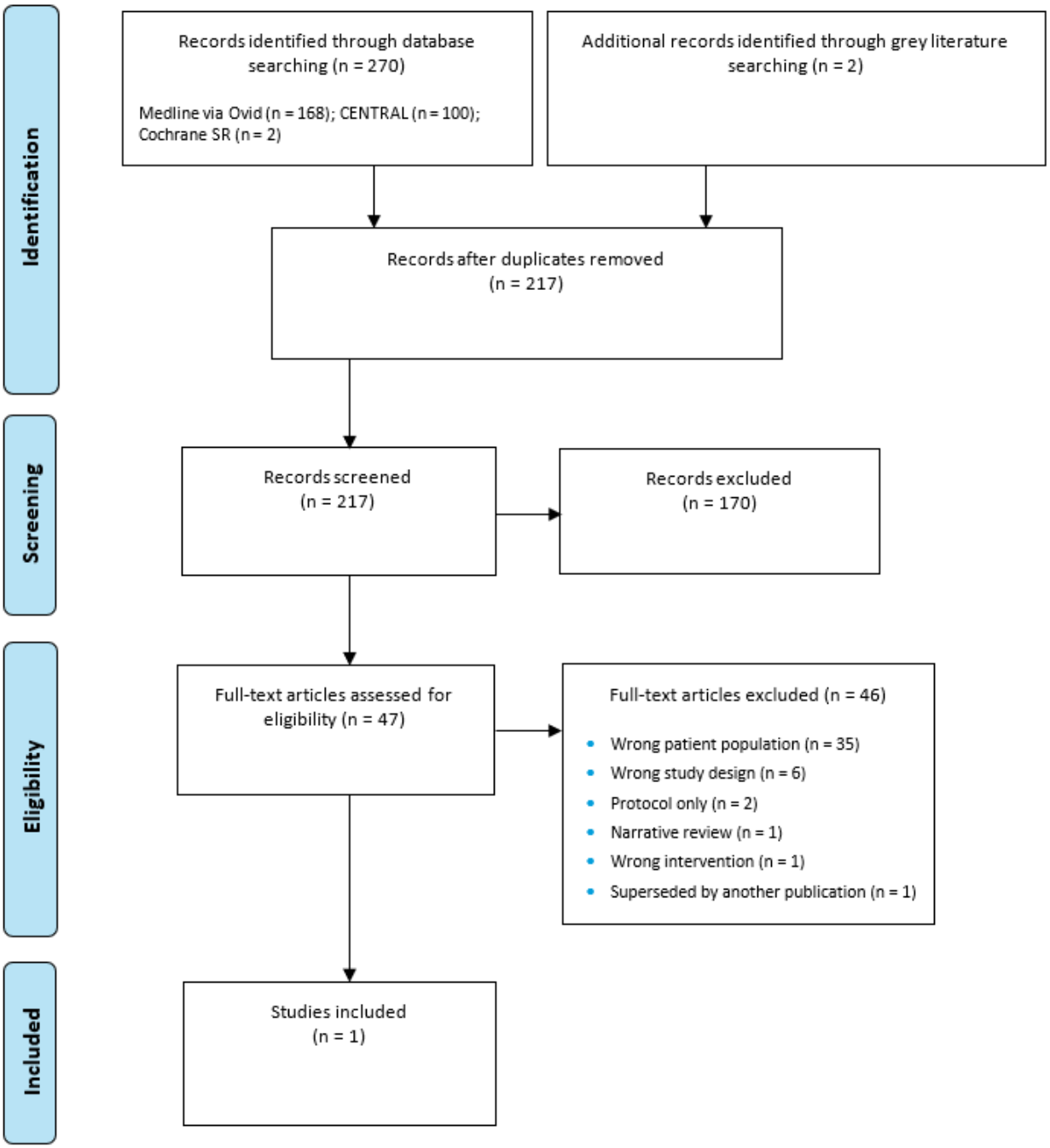

Figure A1: PRISMA Flow Diagram – Clinical Search Strategy

PRISMA flow diagram showing the clinical search strategy. The database search of the clinical literature yielded 270 citations published between January 1, 2017, and March 21, 2022. We identified 2 additional eligible studies from other sources. After removing duplicates, we screened the abstracts of 217 studies and excluded 170. We assessed the full text of 47 articles and excluded a further 46. In the end, we included 1 article.

Abbreviation: PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses.

Source: Adapted from Page et al, 2021.[41]

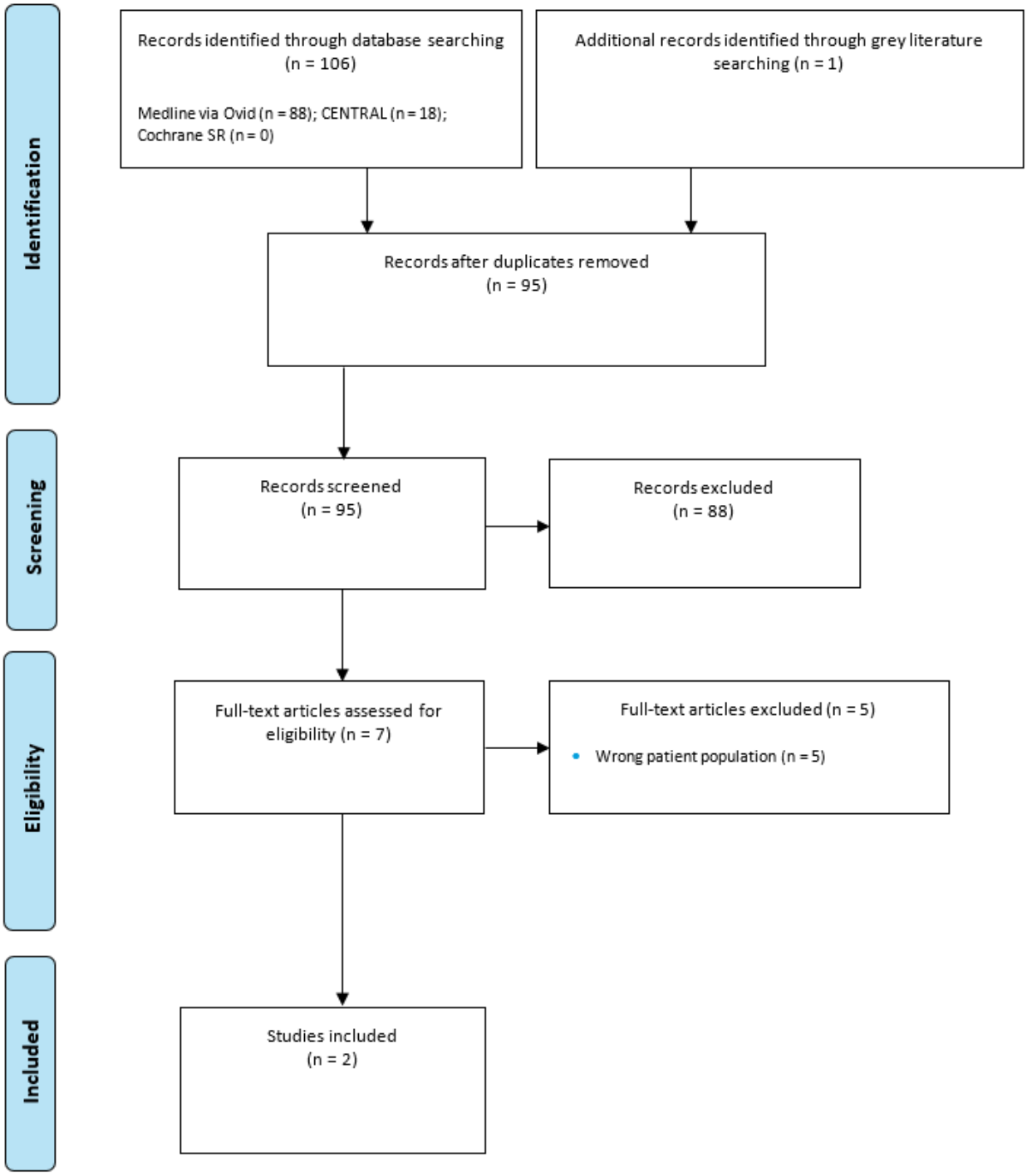

Figure A2: PRISMA Flow Diagram – Economic Search Strategy

PRISMA flow diagram showing the economic search strategy. The database search of the economic literature yielded 106 citations published between January 1, 2017, and March 21, 2022. We identified 1 additional eligible study from other sources. After removing duplicates, we screened the abstracts of 95 studies and excluded 88. We assessed the full text of 7 articles and excluded a further 5. In the end, we included 2 articles.

Abbreviation: PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses.

Source: Adapted from Page et al, 2021.[41]

Appendix 4: Robotic-Assisted Surgical Volumes in Ontario

We used the Discharge Abstract Database and the National Ambulatory Care Reporting System (Canadian Institute for Health Information, IntelliHealth Ontario, November 2022) to identify robotic-assisted surgeries performed between fiscal years (FYs) 2012 and 2021.

A recent study by Muaddi et al[16] evaluated adverse events following robotic-assisted prostatectomy, hysterectomy, pulmonary lobectomy, and partial nephrectomy between 2008 and 2018 in Ontario.[16] We used a search strategy similar to that used by Muaddi et al[16] (i.e., we used the Canadian Classification of Health Interventions [CCI] codes), but we included all robotic-assisted procedures for people with a valid Ontario health card number (i.e., eligible to receive health care services covered by the Ontario Health Insurance Plan) and extended the search period to FY 2021. (Of note, the data we obtained were encrypted, meaning that no personal identifying information was available to us.) We identified robotic-assisted procedures through a combination of two codes: the "principal procedure code," which indicates the specific treatment (e.g., hysterectomy) a person received and the "all procedure code" of 7.SF.14.ZX, which indicates a robotic-assisted surgical approach.[42] Although other robotic systems have begun to be used for various procedures in Ontario in recent years, we understand that robotic-assisted hysterectomy is generally performed using the da Vinci Surgical System.

The total annual volumes in our searches were consistent with Muaddi et al.[16] The objective of the study by Muaddi et al[16] was to evaluate the surgical complications of four robotic-assisted procedures, whereas we aimed to understand the volumes of and indications for robotic-assisted surgeries in Ontario. Our data extraction methods differed slightly from those of Muaddi et al.[16] For example, Muaddi et al excluded patients with missing rural or income quintile status and patients at hospitals that performed fewer than 10 robotic-assisted procedures during the study period, but we did not make such exclusions. Further, we reported volumes by fiscal year, whereas Muaddi et al reported volumes by calendar year. As a result of these methodological differences, our results differed slightly from those of Muaddi et al.[16] However, given that our aim was to understand the overall trend in the use of robotic-assisted surgery in Ontario, we expect that the precision of our data was sufficient to meet our objective.

Table A1: Volumes of All Robotic-Assisted Procedures, FY 2012–2021

Fiscal year	Volume
2012	909
2013	1,198
2014	1,376
2015	1,497
2016	1,570
2017	1,613
2018	1,791
2019	1,958
2020	1,745
2021	2,223
Total	**15,880**

Source: Discharge Abstract Database (Canadian Institute for Health Information, IntelliHealth Ontario), November 2022.

Table A2: Volumes of Robotic-Assisted Procedures by Main Diagnosis (N > 100), FY 2019–2021

ICD-10-CA code	Main diagnosis	Volume, N	Percent
C61	Malignant neoplasm of prostate	2,711	45.7
M17	Gonarthrosis (arthrosis of knee)	562	9.5
C54	Malignant neoplasm of corpus uteri (endometrial cancer)	471	7.9
C64	Malignant neoplasm of kidney, except renal pelvis	345	5.8
C34	Malignant neoplasm of bronchus and lung	321	5.4
N13	Obstructive and reflux uropathy	156	2.6
C20	Malignant neoplasm of rectum	125	2.1
N85	Other noninflammatory disorders of uterus, except cervix	104	1.8

Abbreviation: ICD-10-CA, International Statistical Classification of Diseases and Related Health Problems, 10th revision, Canada.[43]

Source: Discharge Abstract Database (Canadian Institute for Health Information, IntelliHealth Ontario), November 2022.

Table A3: Volumes of Robotic-Assisted Procedures by Principal Intervention (N > 100), FY 2019–2021

CCI code	Principal intervention	Volume, N	Percent
1.QT.91.DA	Excise radical prostate using laparoscopic approach	2,617	44.2
1.PC.87.DA	Excision partial, kidney using apposition technique (e.g., suturing, stapling) and endoscopic (laparoscopic, laparoscopic-assisted, hand-assisted) approach	361	6.1
1.RM.89.AA	Excision total, uterus and surrounding structures – using combined laparoscopic and vaginal approach	317	5.3
1.RM.89.DA	Excision total, uterus and surrounding structures – using endoscopic (laparoscopic) approach	253	4.3
1.VA.53.LA-PN-N	Implantation of internal device, hip joint – dual component prosthetic device (femoral with acetabular)	207	3.5
1.GR.89.DA	Excision total, lobe of lung, using endoscopic approach (VATS)	163	2.8
1.GR.87.DA	Excision partial, lobe of lung, using endoscopic approach (VATS)	154	2.6
1.VG.53.LA-PP-N	Implantation of internal device, knee joint – TRI component prosthetic device	127	2.1
1.NQ.87.DE	Excision partial, rectum – colorectal anastomosis	115	1.9
1.VG.53.LA-PP-Q	Implantation of internal device, knee joint – TRI component prosthetic device, with combined sources of tissue (e.g., bone graft, cement, paste)	104	1.8

Abbreviations: CCI, Canadian Classification of Health Interventions; TRI, three components (i.e., femoral, tibial, and patellofemoral or a patellar button); VATS, video-assisted thoracoscopic surgery.

Source: Discharge Abstract Database (Canadian Institute for Health Information, IntelliHealth Ontario), November 2022.

Table A4: Canadian Classification of Health Interventions Codes for Robotic-Assisted Hysterectomy

Procedure name	CCI code[a]
Robotic-assisted hysterectomy[b]	
Excision total, uterus	1.RM.89.^^ + 7.SF.14.ZX
Excision partial, uterus	1.RM.87.^^ + 7.SF.14.ZX
Excision radical, uterus	1.RM.91.^^ + 7.SF.14.ZX

Abbreviation: CCI, Canadian Classification of Health Interventions.

[a]The symbol "^^" refers to the use of any approach or technique (e.g., laparoscopic, open).

[b]We identified robotic-assisted procedures through a combination of two codes: the "principal procedure code," which indicates the specific treatment (e.g., hysterectomy) a person received and the "all procedure code" of 7.SF.14.ZX, which indicates a robotic-assisted surgical approach.[42]

Table A5: Volumes of Less Common Robotic-Assisted Procedures, FY 2012–2021

Fiscal year	Inpatient procedures except radical prostatectomy, hysterectomy, and nephrectomy	Outpatient procedures
2012	167	NA
2013	219	16
2014	301	41
2015	364	24
2016	355	27
2017	445	36
2018	503	45
2019	600	58
2020	631	70
2021	924	187
Total	**4,509**	**504**

Abbreviation: NA, not applicable.

Sources: Discharge Abstract Database (Canadian Institute for Health Information, IntelliHealth Ontario) (for inpatient procedures), November 2022; National Ambulatory Care Reporting System (Canadian Institute for Health Information) (for outpatient procedures), November 2022.

Appendix 5: Letter of Information

LETTER OF INFORMATION

Ontario Health

Ontario Health is conducting a review of **robot-assisted hysterectomy for endometrial cancer in obese patients**. The purpose is to understand whether this technology should be publicly funded in Ontario.

An important part of this review involves gathering perspectives of patients and caregivers of those who have been diagnosed with endometrial cancer and obesity and who may or may not have experience with robot-assisted hysterectomy.

WHAT DO YOU NEED FROM ME

- ✓ Willingness to share your story
- ✓ 20-40 minutes of your time for a phone
- ✓ Permission to audio- (not video-) record the interview

WHAT YOUR PARTICIPATION INVOLVES

If you agree to share your experiences, you will be asked to have an interview with Ontario Health staff. The interview will last about 20-40 minutes. It will be held over the telephone and with your permission, the interview will be audio-taped. The interviewer will ask you questions about your or your loved one's condition and your perspectives on screening options in Ontario.

Participation is voluntary. You may refuse to participate, refuse to answer any questions or withdraw before or at any point during your interview. Withdrawal will in no way affect the care you receive.

CONFIDENTIALITY

All information you share will be kept confidential and your privacy will be protected except as required by law. The results of this review will be published, however, no identifying information will be released or published. Any records containing information from your interview will be stored securely until project completion. After the project's completion, the records will be destroyed.

If you are sending us personal information by email, please be aware that electronic communication is not always secure and can be vulnerable to interception.

RISKS TO PARTICIPATION

There are no known physical risks to participating. Some participants may experience discomfort or anxiety after speaking about their experiences.

IF YOU ARE INTERESTED, PLEASE CONTACT US BEFORE FEBRUARY 20, 2023:

Appendix 6: Patient Interview Guide

Patient Interview Guide: Robotic-Assissted Hysterectomy

Care and Treatment Journey
History of cancer – type, diagnosis and background (general only)
How did you feel when diagnosed?
Post-diagnosis journey(Impact)
-wait times

Decision-Making
What treatment options were you offered?
Enough information going into surgery? Risks vs benefits?
How did you feel going into surgery? Concerns?
Menta health impacts
Why or why not are the below important to you:

1. Minimally invasive options (smaller cuts/incisions)
2. Reduction in hospital length of stay
3. Reduction of scarring
4. Reduction of infections
5. Reduction in post surgical complications

Robotic-Assissted Surgery Experience
Information given about robotic-assisted surgery
-how was robotic-assisted surgery presented to you
Decision-making surrounding surgery
Access/barriers?-wait times, travel, out of pocket costs

Robotic-Assisted Surgery
Awareness of robotic assisted surgery
Comfort level
Preference (robotic vs conventional)
Procedure itself- pre and post op experience
Recovery-length of stay, post discharge (discharge information), readmission
Impact on qualify of life

Any equity/ethical concerns? (theoretically)
Any thing else you want to add?

Appendix 7: Provider Interview Guide

Robotic-Assisted Surgical Systems: Provider Interview Guide

Background Information

1. How long have you been practicing as a surgical specialist?
2. Where do you currently practice?
3. How often do you perform hysterectomies in obese patients with endometrial cancer?
    a. Open hysterectomy
    b. Laparoscopic hysterectomy
    c. Robotic-assisted hysterectomy

Robot-Assisted Surgery

4. What is your experience with robotic surgical systems to date?
    - Exposure to training?
    - Access to information about robotic systems?
    - How does robotic surgery compare to laparoscopic surgery for hysterectomies in obese patients?
        - How often do you perform the procedure with robot assistance versus laparoscopically?
        - Challenges
        - Benefits
    - How does robotic surgery compare to open surgery for hysterectomies in obese patients?
        - How often do you perform the procedure with robot assistance versus open?
        - Challenges
        - Benefits

5. How would the public funding of robot-assisted hysterectomies impact your experience as a healthcare provider?
    - Enhanced continuity of care? Patient eligibility? Service provision?
    - Impact on workplace environment (e.g., efficiency, team dynamics, cognitive load, time spent engaging with patients)?
    - Barriers or concerns?
    - Equity or ethical considerations?

Conclusion

6. Is there anything else you would like to add or revisit?
7. Assisting with the recruitment of patients or other providers?
8. Do you have any questions for me?

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We are an agency created by the Government of Ontario to connect, coordinate and modernize our province's health care system. We work with partners, providers and patients to make the health system more efficient so everyone in Ontario has an opportunity for better health and wellbeing. We work to enhance patient experience, improve population health, enhance provider experiences, improve value and advance health equity.

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Equity, Inclusion, Diversity and Anti-Racism

Ontario Health is committed to advancing equity, inclusion and diversity and addressing racism in the health care system. As part of this work, Ontario Health has developed an Equity, Inclusion, Diversity and Anti-Racism Framework, which builds on existing legislated commitments and relationships and recognizes the need for an intersectional approach.

Unlike the notion of equality, equity is not about sameness of treatment. It denotes fairness and justice in process and in results. Equitable outcomes often require differential treatment and resource redistribution to achieve a level playing field among all individuals and communities. This requires recognizing and addressing barriers to opportunities for all to thrive in our society.

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