Washington State Health Care Authority
Health Technology Assessment

Robotic Assisted Surgery

Health Technology Assessment Program

FINAL EVIDENCE REPORT

Appendices

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Robotic Assisted Surgery - Appendices

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Appendix A. MEDLINE® Search Strategy

Database: Ovid MEDLINE®(R) and Ovid OLDMEDLINE®(R) <1946 to February Week 1 2012>
Search Strategy:
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1 exp Robotics/ (9390)
2 exp Surgical Procedures, Operative/ (2145324)
3 exp General Surgery/ (31224)
4 su.fs. (1427999)
5 2 or 3 or 4 (2708446)
6 1 and 5 (5468)
7 exp Surgery, Computer-Assisted/ (6902)
8 robot$.mp. (13004)
9 7 and 8 (1297)
10 6 or 9 (5547)
11 exp "Outcome and Process Assessment (Health Care)"/ (580943)
12 exp survival analysis/ (144692)
13 exp Mortality/ (242698)
14 mo.fs. (357802)
15 exp "Quality of Life"/ (95741)
16 exp "Activities of Daily Living"/ (44187)
17 exp "Costs and Cost Analysis"/ (160841)
18 exp Postoperative Complications/ (376177)
19 exp Intraoperative Complications/ (32412)
20 exp "Recovery of Function"/ (23041)
21 exp "Length of Stay"/ (49077)
22 exp Patient Readmission/ (6161)
23 exp Reoperation/ (59302)
24 10 and 11 (1231)
25 12 or 13 or 14 (562632)
26 10 and 25 (190)
27 15 or 16 (131810)
28 10 and 27 (105)
29 18 or 19 (397886)
30 10 and 29 (637)
31 20 or 21 (71487)
32 10 and 31 (340)
33 22 or 23 (65330)
34 10 and 33 (60)
35 10 and 17 (128)
36 24 or 26 or 28 or 30 or 34 or 35 (1772)
37 limit 36 to english language (1639)

38 limit 37 to humans (1606)
39 limit 38 to (controlled clinical trial or meta analysis or randomized controlled trial) (67)
40 random$.mp. (701391)
41 38 and 40 (141)
42 limit 38 to systematic reviews (69)
43 39 or 41 or 42 (200)
44 limit 43 to yr="2002 -Current" (198)
45 Comparative Study/ (1554044)
46 38 and 45 (359)
47 46 not 43 (290)
48 43 or 46 (490)
49 35 or 48 (568)
50 limit 49 to english language (558)
51 limit 50 to yr="2002 -Current" (537)

Appendix B. Excluded Studies

Study design not relevant

Abreu, A. L., Gill, I. S., & Desai, M. M. (2011). Zero-ischaemia robotic partial nephrectomy (RPN) for hilar tumours. *BJU International, 108*(6 Pt 2), 948-954. doi:http://dx.doi.org/10.1111/j.1464-410X.2011.10552.x

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Appendix C. MEDLINE® Search Dates by Procedure

Procedures and Key Questions with searches of the full date range (2002-2012) are highlighted in peach. Procedures and Key Questions highlighted in blue represent those with a SR or TA where subsequent search dates were limited.

Procedures	Review	MEDLINE® Beginning Search Dates		
		Key Questions 1 and 2	Key Question 3	Key Question 4
Adjustable gastric band	Maeso	Aug-09	2002	2002
Adnexectomy	Reza	Oct-09	2002	2002
Adrenalectomy	None	2002	2002	2002
Atrial septal repair	CADTH	Sep-11	2002	Sep-11
CABG	CADTH	Sep-11	2002	Sep-11
Cholecystectomy	Maeso	Aug-09	2002	2002
Colorectal resection	Maeso	Aug-09	2002	2002
Cystectomy	Thavaneswaran	Feb-09	2002	2011
Esophagectomy	Clark	Apr-10	2002	2002
Fallopian tube reanastomosis	Reza	Oct-09	2002	2002
Gastrectomy	Clark	Apr-10	2002	2002
Heller myotomy	Maeso	Aug-09	2002	2002
Hysterectomy	CADTH	Sep-11	2002	Sep-11
Ileovesicostomy	None	2002	2002	2002
Liver resection	None	2002	2002	2002
Lung surgery	None	2002	2002	2002
Mesorectal excision	None	2002	2002	2002
Mitral valve repair	CADTH	Sep-11	2002	Sep-11
Myomectomy	Reza	Oct-09	2002	2002
Nephrectomy	CADTH	Sep-11	2002	Sep-11

Procedures	Review	MEDLINE® Beginning Search Dates		
		Key Questions 1 and 2	Key Question 3	Key Question 4
Nissen fundoplication	Maeso	Aug-09	2002	2002
Oropharyngeal surgery	None	2002	2002	2002
Pancreatectomy	None	2002	2002	2002
Prostatectomy	CADTH	Sep-11	2002	Sep-11
Pyeloplasty	Thavaneswaran	Feb-09	2002	2002
Rectopexy	Maeso	Aug-09	2002	2002
Roux-en-Y gastric bypass	Maeso	Aug-09	2002	2002
Splenectomy	Maeso	Aug-09	2002	2002
Sacrocolpopexy	Reza	Oct-09	2002	2002
Thoracoscopic resection	None	2002	2002	2002
Thymectomy	None	2002	2002	2002
Thyroidectomy	None	2002	2002	2002
Trachelectomy	None	2002	2002	2002
Vesico-vaginal fistula repair	None	2002	2002	2002

Appendix D. Summary **of Findings Tables by Procedure**

Adjustable Gastric Band

Reviews

Reference	Study Design and Number of Studies & Subjects	Intervention Comparator Follow-up	<u>Outcomes Assessed</u> Main Findings	Quality Comments
Maeso 2010	SR + MA 1 retrospective cohort N = 20 Muhlmann 2003 N = 20 Robotic = 10 Laparoscopic = 10	Robotic Laparoscopic No follow-up	*Operative time (p=0.04):* Robotic: 137m (range 110-175) Laparoscopic: 97m (range 60-140) *Procedural costs (p < 0.001)* Robotic: $9,505 Laparoscopic: $6,260 *Mean HLOS (NS):* Both groups: 3 days (range 2-4)	Good quality SR Study rated as good quality by SR

Individual studies (published after review)

Reference	Study Design	Sample size	Patient Characteristics	Intervention Comparator Follow-up	<u>Outcomes Assessed</u> Main Findings	Quality Comments
Edelson 2011	Retrospective cohort	407 robotic, 287 laparoscopic, 120	*Robotic; Laparoscopic* Mean age: 45±11.3 yrs;	Robotic Laparoscopic 1 yr	*Outcome: Robotic; Laparoscopic* Operating time: 91.5±21.1 min; 92.1±30.9 min (NS)	Poor Retrospective study;

			47±11.2 yrs Men/women: 57/230; 31/89 Mean BMI: 45.4±5.5 kg/m^2; 45.1±6.7 kg/m^2 Comorbidities: Similar distribution in each group; NS differences No specific inclusion/exclusion criteria		Operating time in patients with BMI ≥50 kg/m^2: 91.3±19.7 min; 101.3±23.7 min (*P*=0.04) HLOS: 1.3±0.6 days; 1.3±0.6 days (NS) Weight loss at 1 yr: 34.2±0.2%; 34.3±0.2% (NS) Conversion to open procedure: 0%; 0.8% (NS) Postoperative hospitalization: 3.8%; 4.2% (NS) Reoperation: 3.1%; 2.5% (NS)	procedure choice was nonsystematic

Adnexectomy

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Reza 2010	SR/MA 1 prospective cohort n = 176 Robotic = 85 Conventional laparoscopic = 91 Magrina 2009 n = 176	Robotic Laparoscopic No follow-up	*Operative time* Robotic = 12 minutes longer (level of significance not specified) SR reports that all other outcomes reported by Magrina were not statistically different	Good quality SR/MA SR notes that study was not randomized or blinded, but the objective was clearly stated. Other quality indicators were assessed but not described for the individual study.

Adrenalectomy

Individual Studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Brunaud 2004	Chronologically determined controls (controls preceded introduction of robotic equipment)	33 Robotic, 19 Laparoscopic, 14	*Robotic; Laparoscopic* Mean age: 48±2.9 yrs; 44.8±3.3 yrs (NS) BMI: 27.3 kg/m^2; 28.1 kg/m^2 (NS) Tumor type, size, and nonfunctional/ functional ratio were similar Inclusion: Adrenalectomy Exclusion: Open adrenalectomy; Cushing's disease	Robotic Laparoscopic Follow-up: 6 wks	*Outcome: Robotic; Laparoscopic* Operating time: 107±6.6 mins; 86±7.8 mins (NS) Morbidity: 15.8%; 14.2% (NS) Pain, quality of sleep, and sleep duration were similar All SF36 scores were similar, with exception of 1 (role limitations; increased in robotic group, *P*=0.03) No mortalities	Poor Financial disclosure was not reported Historical controls; small sample size; choice of surgical method was made chronologically; surgical data not reported

Atrial Septal Defect Repair

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention** **Comparator** **Follow-up**	**Outcomes Assessed** **Main Findings**	**Quality Comments**
CADTH 2011	SR + MA 1 prospective cohort with retrospective controls and 1 retrospective cohort Total n = 92 Total robotic = 38 Total open = 54 Sternotomy = 16 Mini-thoracotomy = 38 Ak 2007 (n=64) Morgan 2004 (n=28)	Robotic Open procedures (sternotomy, mini-thoracotomy) *Follow-up* Ak 2007: 30 +/- 24.3 months (range 3-105) Morgan 2004: 30 days, robotic group only.	*Operative time (minutes)* Ak 2007 Robotic = 262.6 (60.6) Sternotomy = 147.3 (21.3) P < 0.0001 Morgan 2004 Robotic = 155 (61.5) Mini-thoracotomy = 66.7 (38.2) P < 0.001 *Length of stay (days)* Ak 2007 Robotic = 7.9 (1.9) Sternotomy = 8.2 (2.2) NS Morgan 2004 Robotic: 5.6 (2.6) Mini-thoracotomy = 6.6 (3.7) NS *Transfusion rate* Ak 2007 Robotic = 1/24	Good quality SR/MA Both studies rated fair-good by SR Meta-analysis not performed because comparators differed

			Sternotomy = 0/16 Morgan 2004 NR *Complication rate* Ak 2007 Robotic = 3/24 Sternotomy = 3/16 Morgan 2004 NR	

Coronary Artery Bypass Grafting

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
CADTH 2011	SR + MA 1 prospective cohort (Poston 2008) Total n = 200 Total robotic = 100 Total off-pump CABG = 100	Robotic CABG Off-pump CABG *Follow-up* 1 year	*Operative time (minutes)* Robotic = 348 Non-robotic = 246 P < 0.001 *Length of stay (days)* Robotic = 3.77 (1.51) Non-robotic = 6.38 (2.23) P < 0.001 *Complication rate* Robotic = 24/100 Non-robotic = 57/100 NS	Good quality SR Study rated as high quality by SR

Cholecystectomy

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Maeso 2010	SR + MA 1 RCT and 3 cohort studies Total n = 511 Robotic n = 124 Laparoscopic n = 387 Ruurda 2003 (n = 20) Breitenstein 2008 (n = 100) Heemskerk 2005 (n = 24) Giulianotti 2003 (n = 367)	Robotic Laparoscopic Individual study follow-up not described	*Meta-analysis:* *Surgery time* Robotic = 16.96 minutes longer (7.95, 25.96) *LOS* Robotic = 0.73 days shorter (-1.43, -0.03) *Costs* Robotic = $1,692 more ($1,139, $2,245) *Complications* (NS) Robotic = 2.15 greater odds of complications (0.64, 7.25) *Total conversions to open* (NS) Robotic pooled risk difference = -0.01 (-0.04, 0.02) *Incision-closure time* (NS) Robotic = 4.14 minutes	Good quality SR SR notes that quality items were assessed for studies but does not specify quality of individual studies; all had clearly described objectives and interventions. SR concludes that robotic cholecystectomy is associated with a shorter hospital stay than laparoscopic procedures, but has longer

					longer (-6.62, 14.89)	surgery times.
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Jayaraman 2009	Retrospective cohort	36 Robotic, 16 Laparoscopic, 20	*Robotic; Laparoscopic* Mean age: 48.9 yrs; 53.7 yrs Men/women: 7/9; 6/14 Comorbidity: 3; 15 Previous abdominal surgery: 1; 2 Inclusion: Elective cholecystectomy Exclusion: History of extensive upper abdominal surgery	Robotic Laparoscopic No follow-up	*Outcome: Robotic; Laparoscopic* Operating time: 91 mins; 48 mins (*P*<0.001) Time to clear operating room: 14 mins; 11 mins (P=0.015) Anesthesia time: 23 mins; 15 mins (NS) No conversions to open procedure Robotic: 1 incisional hernia at 8mm port site; 1 retained biliary stone Laparoscopic: 1 hospitalization for delayed recovery from anesthesia	Poor Retrospective study; control group had more comorbidities than test group; possible difference s in other surgical risks; data represents first use of robotic procedure in institution
Wren 2011	Historic control group	20 Robotic, 10 Laparoscopic, 10	*Robotic; Laparoscopic* Mean age: 58.8±15.9 yrs; 61.8±15.6 yrs (NS) Men/Women: 7/10; 7/10	Robotic Laparoscopic 2-3 wks	*Outcome: Robotic; Laparoscopic* Operating time: 105.3 mins, range 82-139; 106.1 mins, range 70-142 (NS) Conversion to open	Poor Author affiliations with manufacturer; small sample size; historical controls

			BMI: 28, 28 Inflammatory disease: 60%; 40% Inclusion: >18 yrs of age; appropriate candidate Exclusion: Significant comorbidities or abdominal history		procedure: 10%; 0% Urinary retention: 20%; 20% Major complications: 0%; 10%	

Colorectal Surgery (Colorectal Resection, Colectomy, Mesorectal Excision)

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Maeso 2010	SR + MA 7 non-randomized controlled studies Total n = 532 Robotic n = 205 Laparoscopic n = 327 Baik 2009 (n = 107) Spinoglio 2008 (n = 211) Rawlings 2007 (n = 57) Pigazzi 2006 (n = 12) Woeste 2005 (n = 27) D'Annibale 2004 (n = 106) Delaney 2003 (n = 12)	Robotic Laparoscopic Individual study follow-up not described	*Meta-analysis:* *Surgery time* Robotic = 39.42 minutes longer (14.99, 63.84) *LOS* Robotic = 0.26 days shorter (-1.55, -1.02) *Costs* Robotic = $792 more ($42, $1,543) *Estimated blood loss* Robotic = 7.04mL fewer (-22.73, 8.66) *Complications* (NS) Robotic = 0.99 odds of complications (0.59, 1.65) *Total conversions to open* (NS) Robotic pooled risk	Good quality SR Studies considered "good quality" by SR SR notes that baseline characteristics not provided in Woeste study; Delaney and Pigazzi had small sample sizes; sections of colon removed were not the same across studies; none of the studies were randomized or blinded.

			difference = -0.01 (-0.01, 0.05) *Lymph nodes* Robotic = 0.20 fewer (-2.40, 2.00) *Distal resection margin* Robotic = 0.38cm (-0.18, 0.95) *Bowel function recovery* Robotic = 0.11 days earlier (-0.46, 0.23) Time to oral diet Robotic = 0.26 days earlier (-0.74, 0.22) *Incision-closure time* (NS) Robotic = 4.14 minutes longer (-6.62, 14.89)	

Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Patriti 2009	Randomized controlled trial	66 Robotic, 29 Laparoscopic, 37	*Robotic; Laparoscopic* Mean age 68±10 yrs; 69±10 yrs Men:Women: 1:1.6; 1:2 BMI: 24, 25 (NS) ASA score and tumor stage: Similar Previous surgery: 18; 11 (*P*<0.01) Tumor distance from anal verge: 5.9±4.2 cm; 11±4.5 (*P*<0.01) Inclusion: Rectal adenocarcinoma Exclusion: None reported	Robotic, 19 mos Laparoscopic, 29 mos	*Outcome: Robotic; Laparoscopic* Operating time: 202±12 mins; 208±7 mins (NS) Blood loss: 137.4±156 mL; 127±169 mL (NS) Conversion to open procedure: 0; 7 (*P*<0.05) HLOS: 11.9±7.5 days; 9.6±6.9 days (NS) 30-day Morbidity: 30.6%; 18.95 (NS) Long-term morbidity: 26%; 32.8% (NS) Local tumor recurrence rate: 0%; 5.4%	Poor Randomized design abandoned after advantage of robotic surgery for low mesorectal dissection was noted, introducing selection bias; differences between groups for previous surgery and tumor distance from anal verge
de Souza 2010	Retrospective cohort	175 Robotic, 40 Laparoscopic, 135	*Robotic; Laparoscopic* Mean age: 71.4±14.1 yrs; 65.3±18.8 yrs	Robotic Laparoscopic No follow-up	*Outcome: Robotic; Laparoscopic* Operating time: 158.9±36.7 mins; 118.1±38.1 mins	Poor Retrospective study; procedure choice was nonsystematic;

			Men/Women: 22/18; 62/73 BMI: 27, 27 Cancer: 18; 66 Crohn's: 0; 14 Tumor characteristics: Similar Inclusion: Right hemicolectomy Exclusion: Emergency procedures; use of hand port; additional procedures		(*P*<0.001) Blood loss: 50 mL, range 10-240; 50 mL, range 10-600 (*P*=0.5) Conversion to open procedure: 1; 1 Complications: 8; 28 (NS) HLOS: 5 days, range 3-10; 5 days, range 2-16 (NS) Readmission: 4; 2 (*P*=0.3)	fewer patients in robotic group; possible selection bias regarding disease/condition and/or surgical risk
Park 2011a	Retrospective cohort	263 Robotic, 52 Laparoscopic, 123 Open, 88	*Robotic; Laparoscopic: Open* Mean age: 57.3±12.3 yrs; 65.1±10.3 yrs; 62.3±10.4 yrs Men/Women: 28/24; 70/53; 57/31 BMI: 24, 24, 24 ASA score and preop serum CEA:	Robotic Laparoscopic Open surgery no follow-up	*Outcome: Robotic; Laparoscopic; Open* Operating time: 232.6±52.4 mins; 158.1±49.2 mins; 233.8±59.2 mins (significantly shorter in laparoscopic group, *P*<0.001) Intraoperative transfusion: 1; 1; 0 Pain score: 5.2±1.2; 5.5±1.2; 6.4±1.3 (lower	Poor Retrospective; procedure choice made by patient and physician; small number of patients in robotic group; robotic group significantly younger than comparators

			Similar Prior abdominal surgery: 17.3%; 20.3%; 14.8% (NS) Distance from anal verge: Similar Robotic group more likely to have extraperitoneal location; intraperitoneal more likely in other groups (trend; global *P*=0.077) Tumor stage: Similar Inclusion: Tumor located ≤15 cm from anal verge Exclusion: Local tumors; intestinal obstruction or perforation; adjacent organ invasion; metastasis		for robotic and laparoscopic groups, *P*<0.001) HLOS: 10.4±4.7 days; 9.8±3.8 days; 12.8±7.1 days (shorter for robotic and laparoscopic groups, *P*<0.001) Perioperative mortality: 0; 0; 1 Complications: 19.2%; 12.2%; 20.5% (NS) No cases converted to open surgery	
Baek 2010	Retrospective	82	*Robotic;*	Robotic	*Outcome: Robotic;*	Poor

	cohort (case-matched)	Robotic, 41 Laparoscopic, 41	*Laparoscopic* Mean age: 63.6 yrs, range 48-87; 63.7 yrs, range 42-88 Men/Women: 25/16; 25/16 BMI: 25.7 kg/m^2; 26.7 kg/m^2 ASA: similar History of abdominal surgery: 24.4%; 43.9% (*P*=0.06) Chemoradiotherapy: 80.5%; 43.9% (*P*=0.001) Tumor location and stage were similar Inclusion: Rectal surgery; primary rectal cancer Exclusion: Anal cancer; recurrent tumor; benign tumor; concomitant surgery	Laparoscopic Follow-up: 30 days	*Laparoscopic* Operating time: 296 mins (range 150-520); 315 mins (range 174; 584)(NS) Conversion to open procedure: 7.3%; 22% (NS) Diverting stoma: 94.3%; 40% (P=0) Blood loss: 200 mL; 300 mL HLOS: 6.5 days; 6.6 days Total hospital costs: $83,915; $62,601 (NS) (no detail provided regarding cost calculations) Postoperative complication rates were similar No mortalities	Retrospective; small sample size; baseline differences in patient characteristics; possible selection bias

			Matching based on gender, age, BMI, and type of procedure			
Bianchi 2010	Retrospective cohort	50 Robotic, 25 Laparoscopic, 25	*Robotic; Laparoscopic* Mean age: 69 yrs, range 33-83; 62 yrs, range 42-77 (NS) Men/Women: 18/7; 17/8 BMI: 24.6 kg/m^2 ; 26.5 kg/m^2 (*P*=0.06) Chemoradiothera py: 52%; 40% (NS) Inclusion: Rectal cancer Exclusion: Emergency cases; stage T4; previous colonic resection	Robotic Laparoscopic Follow-up: mean 10 mos	*Outcome: Robotic; Laparoscopic* Operating time: 240 mins, range 170-420; 237 mins, range 170-545 (NS) Conversion to open procedure: 0; 1 Ileostomy: 40%; 20% (NS) HLOS: 6.5 days; 6 days (NS) Overall complications: 16%; 24% (NS) Reoperation: 1; 2 Pathological findings: similar Survival: 100%, 100% Disease-free survival: 100%, 100%	Poor Retrospective; small sample size; patients assigned to groups based upon availability of robot
Park 2010	Retrospective cohort (case-matched)	123 Robotic, 41 Laparoscopic, 82	Robotic; Laparoscopic Mean age: 61.2±9.4 yrs; 63±9 yrs (NS)	Robotic Laparoscopic No follow-up	*Outcome: Robotic; Laparoscopic* Operating time: 231.9±61.4 mins; 168.6±49.3 mins	Poor Retrospective; surgical procedure

			Men/Women: 24/17; 49/33 BMI: 23.4 kg/m^2; 23.4 kg/m^2 (NS) Chemoradiation: 34.1%; 20.7% (NS) Previous abdominal surgery: 22%; 17.1% (NS) ASA, CEA, and tumor stage were similar Inclusion: Rectal cancer within 8 cm of anal verge Exclusion: Intestinal obstruction or perforation; adjacent organ invasion; local tumor resectable with transanal access Matching based on age, gender, BMI, date of		(*P*<0.001) HLOS: 9.9 days; 9.4 days (NS) Transfusion: 1; 1 (NS) Specimen extraction via natural orifice: 48.8%; 13.4% (*P*<0.001) Postoperative morbidity: 29.3%; 23.2% (NS) No conversions to open procedure Pathological findings: similar No mortalities	decided by patient and physician

			surgery, ASA score, and tumor stage			
Patel 2011	Nested, matched case-control (robotic surgery patients matched with 2 control groups); matching based on 6 criteria	90 Robotic, 30 Laparoscopic, 30 Hand-assisted laparoscopic, 30	*Robotic; Laparoscopic; Hand-assisted laparoscopic* Mean age: 53.9±11 yrs; 56.3±12.2 yrs; 61.0±13.2 yrs (NS) Men/Women: 19/11; 19/11; 19/11 BMI: 28, 27, 27 Benign vs. malignant diagnosis: Similar ASA score: Similar Prior abdominal or pelvic surgery: 56.7%; 40%; 60% (NS) Distance to anal verge (cm): Similar Inclusion: Surgical procedure of rectum or rectosigmoid	Robotic Laparoscopic Hand-assisted laparoscopic no follow-up	*Outcome: Robotic; Laparoscopic; Hand-assisted laparoscopic* Operating time: 237±56.8 mins; 181.6±52.5 mins; 158.3±51 mins (Robotic significantly longer than comparators) Estimated blood loss: 100.8±48.5 mL; 129.4±108.3 mL; 149.1±122 mL (all analyses NS) Procedural complications: 2 (thermal injury, serosal traction injury of bowel); 0; 0 HLOS: 2.9±1.2 days; 3.9±2.5 days; 3.3±1.1 days (Robotic vs. laparoscopic *P*<0.01) Complications: 13.3%; 10%; 13.3% (all analyses NS) Readmission: 3.3%;	Poor Small sample size; selection process for 30 out of 70 robotic procedures not reported; data represents early use of robotic procedure in institution

					6.7%; 6.7% (all analyses NS)	

Cystectomy

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Thavaneswaran 2009	SR of 4 non-randomized comparative studies Total n = 173 Total robotic n = 82 Total laparoscopic n = 20 Total open n = 71 Sterrett 2007 (n = 52) Wang 2007 (n = 54) Abraham 2007 (n = 34) Guru 2007 (n = 33)	Robotic cystectomy Open cystectomy or laparoscopic cystectomy No follow-up reported	*Operative time (min)* Study: robotic (range); open (range) Wang 2007: 390 (210-570), 300 (165-540), NS Abraham 2007 NS Guru 2007 NR Sterrett 2007 606 [171], 396 [116], p<0.05 EBL (mL) Study: robotic; open Wang 2007: 400 (100-1200), 750 (250-2500), p=0.002 Abraham 2007: 212 (50-500), laparoscopic: 653 (300-1400) p<0.01 Guru 2007 NR Sterrett 2007: 500 (50-4000), 850 (100-10200), p<0.05	Good quality SR Sterrett 2007, Abraham 2007, Guru 2007: rated as III-3 by SR Wang 2007: rated as III-2 by SR

			HLOS Study: robotic, open Wang 2007: 5 (4-18), 8 (5-28), p=0.007 Abraham 2007: NS Guru 2007: NR Sterrett 2007: 8 (4-23), 10 (2-55), p<0.05 Conversions n/N (%) Study: robotic, open/laparoscopic Wang 2007: 1/33 (3%) Abraham 2007: 0/14 (0%) laparoscopic: 3/20 (15%) Guru 2007: 1/16 (6.3%) Sterrett 2007 NR Transfusions Study: robotic, laparoscopic/open Wang 2007: NR Abraham 2007: 6/14 (42.8%) laparoscopic 14/20 (70%) p<0.01 Guru 2007: NR Sterrett 2007: 10/19 (53%), 23/33 (70%), NS	

			Positive surgical margins: Study: robotic, laparoscopic/open Wang 2007: NS Abraham 2007: 1/14 (7.1%) laparoscopic: 0/20 (0%) Guru 2007: NR Sterrett 2007: NR Complications Study, robotic, open/laparoscopic Wang 2007: 7/33 (21.2%), 5/21 (23.8%), NS Abraham 2007 4/14 (28%), laparoscopic: 14/20 (70%), NS Guru 2007: NR Sterrett 2007 6/19 (32%), open: 10/33 (30%), NS	
Lee 2011a	Economic review 3 cost studies Robotic = 122 Open = 137	Robotic cystectomy Open cystectomy	Clinical outcomes LOS, days Study: robotic, open Smith: 4.7, 5.3, NS Martin: 5.0, 10.0, NS	Good quality economic review Authors conclude that robotic

	Smith (n=40) Martin (n=33) Lee (n=186)		(used for both modeled and actual costs) Lee: IC: 5.5, 9.0, p<0.05 CCD: 5.8, 8.0, p<0.05 ON: 5.0, 7.8, p<0.05 Operative duration, h Smith: 4.1, 3.8, NS Martin: 4.7, 5.3, NS (used for both modeled and actual costs) Lee: IC: 6.7, 6.0, p<0.05 CCD: 7.5, 8.5, NS ON: 9.0, 7.8, p<0.05 Complication rate, % Smith: 30, 33 Martin: 8, 57 (modeled costs only) Lee: IC: 49.4, 68.6, NS CCD: 50, 65.2, p<0.05 ON: 50, 44.8, NS Direct cost Smith, $16,248,	cystectomy is most cost efficient when costs of complications are considered. Route of urinary diversion may diminish cost performance Cost studies not assigned quality ratings, but limitations in sample size, generalizability (academic institution vs. community setting), selection bias (pts choosing ileal conduit may have fewer complications). 90-d follow-up may have been too short to capture cost of all complications.

			$14,608 (11% increase for robotic) Martin Model: robotic = -15% off of baseline costs for open Actual: open = -16% off of baseline costs for robotic Lee: IC: $19,034, $18,303 (4% increase for robotic) CCD: $20,190, $20,178 (0.06% increase for robotic) ON: $20,862, $19,057 (10% increase for robotic) Indirect costs: Smith: N/A Martin: N/A but considered in analysis Lee: IC: $1624, $7202 (77% decrease for robotic) CCD: $1911, $2520 (24% decrease for robotic)	All studies had two-way sensitivity analyses

					ON: $1823, $1633 (12% increase for robotic) Total cost Smith: $16,248, $14,608 (11% increase for robotic) Martin: Model: Robotic 15% lower than open baseline cost Actual: Robotic 60% lower than baseline cost Lee: IC: $20,659, $25,505 (19% decrease for robotic) CCD: $22,102, $22,697 (3% decrease for robotic) ON: $22,685, $20,719 (10% increase for robotic)	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Richards 2010	Retrospective	N = 70	No statistically	Robotic	Operative duration	Fair

	cohort	Robotic = 35 Open = 35	significant differences. Inclusion criteria = patients with clinically localized bladder cancer No exclusion criteria described Men/Women Robotic: 30/5 Open: 25/10 Age: Med (IQR) Robotic: 65 (59-73) Open: 66 (59-73) BMI: Med (IQR) Robotic: 27 (23-31) Open: 26 (24-29) Previous abdominal surgery: Robotic: 15 (43%) Open: 19 (54%) Abdominal	cystectomy Open cystectomy 1 month follow-up	(min): Robotic: 530 (458, 593) Open: 420 (368, 492) Diversion (NS): Ileal conduit: Robotic: 30 (86%) Open: 31 (89%) EBL (mL): Med (IQR) Robotic: 350 (250-600) Open: 1000 (500-2000) Transfusion ($p<0.01$) Robotic: 6 (17%) Open: 25 (71%) Total complications (NS) None: Robotic: 14 (40%) Open: 12 (34%) 1-2: Robotic 14 (40%) Open: 14 (40%) 3+: Robotic: 7 (20%) Open: 9 (25%)	Surgeons chose procedure based on preference Funding source not disclosed Patient characteristics very similar between treatment groups Two surgeons performed both open and robotic; one surgeon performed only robotic All surgeons fellowship-trained urological oncologists with prior open and robotic experience

			radiation: Robotic: 0 Open: 1 (3%) Systemic chemotherapy Robotic: 1 (3%) Open: 3 (9%)			
Nepple 2011	Retrospective cohort	N=65 Robotic=36 Open=29	Inclusion criteria: All patients treated with radical cystectomy by a single surgeon from June 2007 to June 2019 for urothelial Ca Exclusion criteria: Patients had relative contraindications to robotic surgery Robotic vs. Open cohorts: male/female%: 86/14 vs. 55/45 (p=0.05); Ave Age: 72/67 (p=0.04;	Median follow-up 12.2 months	3 patients converted from robotic to open surgery due to difficult dissection; Mean surgical time was longer in robotic cohort (410 mins vs. 345 mins, p<0.01; Cystectomy pathology was not different for robotic vs. open surgery for stage, margin status, or mean node count. On survival analysis robotic and open cystectomy outcomes were similar with respect to recurrence-free, disease-specific, and overall survival (all	Good

			Groups were not statistically different in median BMI, Comorbidity index, clicial stage, neoadjuvant chemotherapy exposure;		log-rank *P* values > 0.05). (K-M estimates for 2-year outcomes are reported however medican patient follow-up was 12.2 mos)	
Nix 2009	Prospective RCT	N = 41 Robotic = 21 Open = 20	Inclusion criteria: Patients with clinically localized urothelial carcinoma of the bladder Exclusion criteria: (1) Those not surgical candidates for either approach (2) those not allowing randomization (3) those with preconceived preference for a specific surgical modality	Robotic cystectomy Open cystectomy Follow-up = through hospital discharge	EBL (mL), Mean (Median) (p<0.01) Robotic: 258 (200) Open: 575 (600) OR time, Mean (Median) (h) (p<0.01) Robotic: 4.20 (4.2) Open: 3.52 (3.4) Time to flatus (d) Robotic: 2.3 (2) Open: (3.2) 3 Median time to BM (d) Robotic: 3.2 (3) Open: 4.3 (4) Median LOS (d) Robotic: 5.1 (4) Open: 6.0 (6)	Fair quality RCT Block randomization performed by desire to educate residents, may have introduced selection bias Varying skill levels of surgeons (residents), no description of learning curve

			14 exclusions resulted No statistically significant demographic differences between treatment groups Age (y) Robotic: 67.4 (33-81) Open: 69.2 (51-80) Male:Female Robotic: 14:7 Open: 17:3 BMI Robotic: 27.5 Open: 28.4 ASA classification Robotic: 2.71 Open: 2.70 Clinical stage: cT1 or lower: Robotic: 6		In-house analgesia (mg morphine equivalent) Robotic: 89.0 (87.5) Open: 147.4 (121.5) Median Clavien units Robotic: 2.3 (2) Open: 2.6 (2)	

			Open: 5 cT2: Robotic: 12 Open: 14 cT3: Robotic: 3 Open: 1 Diversion type: Neobladder: Robotic: 7 Open: 6 Ileal conduit: Robotic: 14 Open: 14			
Ng 2009	Prospective cohort	N = 187 Robotic = 83 Open = 104	Inclusion/exclusion criteria not described No statistically significant baseline demographic differences Male:Female Robotic: 65:18 Open: 73:31 Mean age, SD (y)	Robotic cystectomy Open cystectomy Follow-up = 90 days	Operative time, h (SD) Robotic: 6.25 (1.5) Open: 5.95 (2.2) p=02.9 EBL, mL (SD) Robotic: 460 (299) Open: 1172 (916) p<0.01 PRBC transfused, units (SD) Robotic: 1.42 (1.6) Open: 3.65 (3.9)	Good quality Small loss to follow-up (7%) at 90-d in robotic group, unlikely to bias results

			Robotic: 70.9, 10.8 Open: 67.2, 10.6 Mean BMI, SD Robotic: 26.3, 3.9 Open: 27.2, 6.0 ASA score 1-2 Robotic: 47 (56.6%) Open: 54 (51.9%) CACI ≤ 2 Robotic: 49 (59.0%) Open: 72 (69.2%) Previous abdominal surgery Robotic: 30 (36.1%) Open: 42 (40.4%) Diversion: Ileal conduit: Robotic: 47 (56.6%) Open: 51 (49.0%)		p<0.01 Median LOS, d (range) Robotic: 5.5 (3-28) Open: 8 (3-60) P<0.01 Pts w/major complications, no (%); 30d, 90d Robotic: 8 (9.6), 13 (16.9) Open: 31 (29.8), 32 (30.8) p<0.01, p=0.03 Pts w/complications, no (%); 30d, 90d Robotic: 34 (41.0), 37 (48.1) Open: 61 (58.7), 64 (61.5) p=0.04, p=0.07	

			Neobladder: Robotic: 26 (31.3%) Open: 29 (27.9%) Indiana pouch: Robotic: 10 (12.0%) Open: 23 (22.1%)			
Sung 2011	Retrospective cohort	N=136 Open n=35 Robotic n=104	Robotic; open; p-value Age, y 62.2 ± 10.5; 65.9 ± 9.4; p=0.05 NS differences between groups in gender, BMI, ASA classification, previous pelvic surgery, intravesical BCG or chemotherapy history, and clinical stage	Robotic Open 90 day follow-up for complications	Robotic; open; p-value *Perioperative outcomes* Mean overall operating time, min 578.2 ± 152.9; 500.6 ± 109.7; p=0.008 Mean overall operating time, ileal conduit, min 482.3 ± 101.2; 494.3 ± 104.3; NS Mean overall operating time, neobladder, min 634.9 ± 151.5; 510.3 ± 102.9; p=0.004 Mean EBL, mL	Fair quality Non-randomized, retrospective design; small sample size; differences between groups in diversion (neobladder vs. ileal conduit)

					448.0 ± 231.6; 1063.4 ± 892.7; p<0.001 Mean LN removed 19.1 ± 8.2; 12.9 ± 9.0; p<0.001 Mean LOS 28.9 ± 11.9; 27.1 ± 13.4; NS NS differences in pathologic stage, organ confined, and LN metastasis *Complications* % Pts w/grade II or greater complications (n) 37.1 (13); 68.2 (71); p=0.001 % Pts w/multiple complications (n) 14.3 (5); 37.5 (39); p=0.011 NS differences in % patients with	

					complications, % with grade I complications, % with major complications, % readmission 4 mortalities within 90 days post-op: 3 in open group, one in robotic group *Detailed complications* % wound problem (n) 2.8 (1); 16.3 (17); p=0.043 % urine leakage (n) 8.6 (3); 0.9 (1); p=0.049 % transfusion (n) 11.4 (4); 56.7 (59); p<0.001 NS differences in UTI, ileus, small bowel obstruction, cardiac problem, bleeding, CVA, lymphocele, fistula, death, scrotal edema, duodenal ulcer	

					perforation, vaginal vault prolapsed, peritonitis, C. difficile colitis, ureteral stent fracture, and rectal injury *Predictors of grade II or greater complications* Type of operation OR = 3.64 (1.64-8.11) for open Sex = 4.06 (1.12-14.11) for female EBL = 2.75 (1.24-6.10) for EBL > 500mL *Learning curve* Operative time decreased with increasing number of surgeries (Pearson correlation r = -0.599, p<0.001) Operative times for last five cases 415.0 ± 89.6 min; 439 ± 63.7 min; p=0.639	

Esophagectomy

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Clark 2009	SR Total n =130 Robotic n = 130 8 non-comparative case series and cohorts Giulianotti (n=5) Bodner (n=4) Ruurda (n=22) Van Hillegesberg (n=21) Kernstein (n=14) Anderson (n=25) Galvani (n=18) Kim (n=21)	Robotic esophagectomy No comparator Operative outcome follow-up = 30-day (n=130) Oncological outcome follow-up = 3-29 months (n=57 cases)	*Robotic only (no comparative studies identified in SR search), Non-weighted means* Operating time (min) = 377 EBL (mL) = 226 ITU stay (days) = 3.72 Hospital stay (days) =15.9 Lymph nodes (n) = 20.7 Pulmonary complications (%) = 25.4 Complications (%) = 31 Perioperative mortality (%) = 2.4	Good quality SR SR notes marked heterogeneity of studies in terms of operative approach and extent of robotic involvement; quality of identified studies described as level 4 evidence based on Oxford Evidence-based Medicine Levels of Evidence

			Disease-specific recurrence rate = 14% (n=8/57) 30-day mortality = 2.4% (3/126) Anastomotic leak rate = 18% (24/130) Conversion to conventional approach = 8 (7%)	

Fallopian tube reanastomosis

Review				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Reza 2010	SR + MA 1 prospective cohort and 1 prospective cohort with retrospective controls Total n = 95 Robotic n = 44 Open n = 51 Rodgers 2007 (n=67) Dharia Patel (n=28)	Robotic fallopian tube reanastomosis Open fallopian tube reanastomosis (laparotomy or mini-laparotomy) Follow-up described as adequate by SR	MA results Robotic surgery vs. open surgery Hospital stay (days) MD = -0.64 (-1.86, 0.58) NS Complications (%) OR = 0.41 (0.08, 2.06) NS Time to return to work (days) MD = -15.97 (-19.55, -12.38) favoring robotic method Pregnancies (%) OR = 0.86 (0.37, 1.99) NS Miscarriages (%) OR = 0.37 (0.11, 1.20)	Good quality SR/MA Summary quality ratings described, but not specified by individual study. SR notes that both studies had clear objectives, were controlled, neither were randomized, but had adequate follow-up (length of follow-up not reported)

			Ectopic pregnancies (%) OR = 1.13 (0.30, 4.33) NS Intrauterine pregnancies (%) OR = 1.99 (0.74, 5.36) NS Duration of surgery (min) MD = 46.85 (34.66, 59.04) favoring open procedures EBL (Rodgers only): Similar between procedures (numbers not reported) Cost: Rodgers: DVS.S associated with significant extra cost of $1446 Dharia Patel: $2000 increase in costs for robotic, + $300/newborn	

Fundoplication

Review				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Maeso 2010	SR + MA 4 RCTs and 5 non-randomized controlled studies Total n = 398 Robotic n = 179 Open n = 219 RCTS Muller-Stich (n=40) Draaisma (n=50) Morino (n=50) Nakadi (n=20) Non-randomized studies Hartmannet (n=80) Heemskerk (n=22) Ayav (n=20) Giulianotti (n=76) Melvin (n=40)	Robotic fundoplication Laparoscopic fundoplication Follow-up cited as adequate but not quantified	Meta-analysis results: Surgery time (min) MD = 20.67 (-9.69, 51.02) NS Incision-closure time (min) MD = -8.40 (-35.91, 19.10) NS LOS (d) MD = -0.08 (-0.41, 0.25) NS Complications RD = -0.02 (-0.12, 0.08) NS Open conversions RD = -0.01 (-0.05, 0.03) NS	Good quality SR SR notes that only 1 RCT described randomization and only 1 RCT involved blinding. Non-RCTs did not involve blinding. All but one study compared baseline characteristics. All but two provided statistical comparisons.

	Nissen fundoplication: Muller-Stich, Draaisma, Morino, Nakadi, Heemskerk, Giulianotti, Melvin Dor fundoplication: Hartmannet, Ayav		Total conversions RD = 0.00 (-0.04, 0.04) NS Costs MD = $1,594 (-$181, $3,374) NS Outcomes reported in SR but not included in meta-analysis: Robotic vs. laparoscopic: Postoperative reflux: NS in 4 studies Dysphagia: NS in 2 studies Quality of life: NS in 3 studies Intra-abdominal pressure, blood pH during follow-up: NSD (2 studies) % requiring daily antisecretory meds after surgery	SR authors conclude that no differences between procedures in terms of surgery time, length of hospital stay, complications, or conversion to another technique

			Robotic: 0% Laparoscopic: 30% ($p<0.05$) (Melvin) NSD (Muller-Stich, Hartmann) Learning curve: Robotic procedure time still longer (131m vs. 97m, p=0.006) after first 10 cases eliminated (Melvin) Surgery time for first 10 cases and last 10 cases NSD (Melvin, Morino); first 21 compared to last 20 significantly different (133m vs. 92m) (Giulianotti)	

Gastrectomy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Maeso 2010	SR + MA 2 non-randomized controlled studies	Robotic gastrectomy Laparoscopic	**MA results:** LOS (d) -1.38 (-1.84, -0.93)	Good quality SR/MA

	Total n = 87 Robotic n = 36 Laparoscopic n = 51 Song (n=60) Kim (n=27)	gastrectomy	favoring robotic Bowel function recovery (d) -0.21 (-0.42, -0.01) favoring robotic Surgery time (min) 37.60 (1.28, 73.92) favoring laparoscopic EBL (mL) 15.88 (-51.84, 83.59) NS Lymph nodes (number) 0.58 (-4.66, 5.81) NS Complications OR=0.44 (0.07, 2.94) NS	SR notes that neither study was randomized or blinded; baseline differences between treatment groups in both studies: BMI (Kim study), and age and year (Song study)
Clark 2010	SR Identified 1 additional prospective cohort study published after Maeso 2010 Guzman 2009 n = 64 Robotic = 16 Open = 48	Robotic gastrectomy Open gastrectomy 30-day follow up	No statistical tests Operation time (min) Robotic: 399 Open: 298 EBL (mL) Robotic: 200 Open: 353	Fair quality SR SR rates quality of identified studies as level 4 evidence based on Oxford Evidence-based

					Complications (%) Robotic: 30% Open: 46% Conversion (n=) Robotic: 0 Open: 0 Hospital stay (days) Robotic: 7 Open: 10 30-day mortality n (%) Robotic: 0 Open: 1 Lymph node (numbers) Robotic: 24 Open: 25	Medicine Levels of Evidence
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Woo 2011	Retrospective Cohort	827 Robotic, 236 Laparoscopic, 591	*Robotic; Laparoscopic* Mean age: 54±12.7 yrs; 58.3±11.6 yrs (*P*<0.001) Men/Women:	Robotic Laparoscopic No follow-up	*Outcome: Robotic; Laparoscopic* Operating time: 219.5±46.8 mins; 170.7±55.8 mins (*P*<0.001)	Poor Retrospective; procedure choice made by patient; patient assumes

			136/100; 364/227 BMI: 24, 24 Comorbidities: 42%; 49% (NS) Inclusion: Radical resection for gastric cancer Exclusion: Concomitant procedures		Blood loss: 91.6±152.6 mL; 147.9±269 mL (*P*=0.002) HLOS: 7.7±17.2 days; 7±5.7 days (*P*=0.004) Complications: 11%; 13.7% (NS) Mortality: 0.4%; 0.3% None were converted to open procedure	expense of robotic surgery, which would cause selection bias
Eom 2012	Prospective cohort	N = 92 Robotic n = 30 Laparoscopic n = 62	*Robotic; Laparoscopic* Age (range): 52.8 (28, 74), 57.9 (34, 78), p = 0.04 Male:Female: 21:9, 41:21, NS Mean BMI (range): 24.2 (17, 35), 24.1 (19, 30), NS Tumor size, cm (range): 2.7 (0.4, 9.5), 2.6 (0.5, 5.5) Location: Middle: 17, 30 Lower: 13, 32 NS Histology type: Differentiated: 14, 31	Robotic gastrectomy Laparoscopic gastrectomy No follow-up	*Robotic, Laparoscopic* Operative time, min (range): 229.1 (165, 307), 184.4 (125, 272), p<0.001 LN dissection time, min (range): 91.7 (42, 136), 70.2 (23, 118) # retrieved LN: 30.2 (13, 60), 22.4 (10, 67) Proximal resection margin: 3.4 (1, 6), 4.3 (1, 10) p = 0.035 DRM: 5.8 (1, 11), 4.7 (1, 13) EBL, mL: 152.8 (10, 500), 88.3 (10, 400), NS Time to diet: 3.4 (3, 6), 3.4 (2, 5) NS Other NS findings:	Fair quality cohort Insufficient follow-up, baseline differences between treatment groups not addressed, may have biased results either direction (robotic group was younger, but had more advanced stage cancer)

			Undifferentiated: 16, 31 NS Lauren classification NS pT (n1, n2, n3, n4): 26, 2, 1, 1; 56, 6, 0, 0, p < 0.001 pN (n0, n1, n2, n3): 24, 3, 1, 2; 52, 6, 3, 1, NS Stage (nI, nII, nIII): 25, 3, 2; 56, 6, 0, p<0.001 Inclusion: diagnosed distal gastric cancer Exclusion criteria not described		WBC count C-reactive protein No conversions in either group Complications: 4, 4, NS LOS, days: 7.9 (7, 20), 7.8 (5, 17) NS Hospital cost: $11,402 ($7604, $15,292), $6071 ($55, $8995), p<0.001	Patients chose procedure (potential for selection bias, direction unknown but likely favoring robotic procedure)

Heller myotomy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Maeso 2010	SR + MA	Robotic Heller myotomy	Meta-analysis results: Perforations:	Good quality SR

	3 non-randomized controlled trials Total n = 252 Huffman (n=61) Iqbal (n=70) Horgan (n=121)	Laparoscopic Heller myotomy	OR = 0.11 (0.02, 0.56) favoring robotic procedures Surgery time (min) MD = 38.01 (-8.79, 84.81) NS Outcomes not included in meta-analysis: Hospital length of stay Both procedures: 2-3 days LOS longer after robotic in 2 studies (0.2 and 0.7 days), NS EBL (no significant differences) Postoperative difference in pressure exerted by inferior esophageal sphincter = 3mm in favor of robotic procedure (significant, p-value not specified) (Horgan) Postoperative quality	SR notes that Iqbal and Huffman not randomized or blinded and did not compare baseline characteristics of groups. Horgan study did described baseline differences. Affect baseline differences may have had on findings not specified. SR concludes robotic Heller myotomy associated with lower risk of perforation and better quality of life.

			of life = better in robotic patients for 2 of 9 categories (Huffman) Learning curve steeper for robotic patients; similar surgery time reached in last 30 robotic patients (Horgan)	

Hysterectomy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
CADTH 2011	N=2,831 *Da Vinci* (n=1,165) Open hysterectomy (n=438) Laparoscopic hysterectomy (n=483) Open radical hysterectomy (n=94) Open type III radical hysterectomy (n=93) Open radical hysterectomy using a modified unilateral Wertheim procedure (n=20) Open total hysterectomy with pelvic lymphadenectomy (n=106) Open hysterectomy and lymphadenectomy (n=191) Laparoscopic total radical hysterectomy (n=8) Laparoscopic total hysterectomy (n=44) Laparoscopic hysterectomy and lymphadenectomy (n=76) Laparotomy (hysterectomy combined with pelvic lymph node dissection, or pelvic paraaortic lymph node dissection) (n=12) Laparoscopic hysterectomy, bilateral salpingo-ppohorectomy, pelvic and periaortic lymph node resection, and cystoscopy (n=20) Laparoscopic staging for endometrial cancer (n=25) Open surgery staging for endometrial cancer (n=56)	Robotic hysterectomy Laparoscopic hysterectomy Follow-up ranged from 14 to 1,382 days	MA Findings for RARH-RATH compared with ORH-OTH *Shorter operative duration* (WMD 63.57 minutes, 95% CI 40.91 to 86.22); *Shorter length of hospital stay* (WMD −2.60 days, 95% CI −2.99 to −2.21); *Reduction in the extent of blood loss* (−222.03 mL, 95% CI −270.84 to −173.22, NS); and *Reduced risk of transfusion* (RR 0.25, 95% CI 0.15 to 0.41, NS).	Good quality SR SR included 5 good quality, 16 fair to good quality, and 5 poor to fair quality studies

	13 Prospective observational studies 13 Retrospective comparison studies		MA Findings for RARH-RATH compared with LRH-LTH: *A meta-analysis was not performed for the "operative duration" outcome due to the high degree of heterogeneity among study findings, which were inconclusive*; *Shorter length of hospital stay* (WMD −0.22 days, 95% CI −0.38 to −0.06); *Reduction in the extent of blood loss* (−60.96 mL, 95% CI −78.37 to −43.54); and *The risk of transfusion exposure was found to be inconclusive* (RR 0.62; 95% CI 0.26 to 1.49) with mixed results reported	

				among the studies.		
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Lim 2011	Prospective cohort	244, RHBPPALND, 122 LHBPPALND, 122	Robotic, laparoscopic, p-value Age 62.1 ± 8.4, 61.6 ± 11.8, NS BMI 31.0 ± 8.8, 29.9, ± 7.0, NS	Robotic assisted hysterectomy with lymphadenectomy (RHBPPALND) vs. total laparoscopic hysterectomy with lymphadenectomy (LHBPPALND)	Robotic, laparoscopic, p-value Operating time 147.2 ± 48.2, 186.8 ± 59.8, p<0.001 EBL 81.1 ± 45.9, 207.4 ± 109.4, p<0.001 Lymph node yield 25.1 ± 12.7, 43.1 ± 17.8, p<0.001 Pelvic lymph node yield 19.2 ± 9.0, 24.7 ± 11.9, p<0.001 Para-aortic lymph node yield 5.8 ± 7.8, 18.4 ± 9.7, p<0.001	Fair quality favoring robot

					LOS 1.5 ± 0.9, 3.2 ± 2.3, p<0.001 Measuring operative time with respect to chronological order of each patient who had undergone their respective procedure Case proficiency numbers: RHBPPALND = 24th case LHBPPALND = 49th case The incidence of conversion to open (0.8% vs. 6.5%, respectively; P=0.033), & major complications (4% vs. 12.3%, respectively; P=0.033) was noted to be less for RHBPPALND when compared to	

					LHBPPALND RHBPPALND is associated with shorter hospitalization, less blood loss and less intraoperative and major complications, and lower rate of conversion to open procedure	
Escobar 2011	Matched retrospective cohort	N=90; 30 endometrial CA pts with SPL matched 1:1:1 to 2 cohorts tx'd by traditional or robotic laparoscopy	*Robotic, laparoscopic, P* Age: 59.7, 60.9, NS BMI: 31.4, 31.2, NS Stage IA: 22/30, 8/30 Stage IB: 8/30, 20/30 Stage IC: 0/30, 1/30 Stage 2A: 0/30, 1/30 Grade I: 6/30, 11/30 Grade II: 17/30, 12/30	SPL vs. traditional vs. robotic laparoscopy; f/u NA	*Outcome: Robotic, laparoscopic* OR time, min: 174.0, 219.5 EBL, cc: 75, 100, 0.06 Pelvic LN, % having done: 33.3, 55 Pelvic LN, Median #: 17.0, 13.0 P=0.04 Para-aortic LN, % having done: 33.3, 30 Para-aortic LN, Median #: 3.5, 6.0 Transfusion: 2/30, 0/30 Conversion: 0/30, 1/30	Fair quality Small N, surgeon-skill-dependent outcomes, retrospective design; matched well for most relevant factors

			Grade III: 5/30, 5/30 HTN: 14/30, 13/30 CAD: 2/30, 3/30 DM: 2/30, 3/30 Asthma: 2/30, 2/30		Complications; 1/30 (hypoxia), 2/30 (bowel injury, cystotomy) HLOS (range): 1.4 (1-4), 1.8 (0-7)	
Geppert 2011 (BMI subgroup study)	Retrospective cohort	N=114 Robotic, 50 (25 early; 25 late cases); Open, 64	*Robotic; Open* Mean age: 52.5 yrs (range 35-85); robot grp older (p<0.05); median BMI 32.5kg/m^2; robot grp had higher BMI (p=0.04) Comorbidities: ASA class, co-morbidities, previous laparotomies (all NS diff.) Inclusion: Indications for hysterectomy were low risk endometrial cancer,	Robotic Open follow-up 12 mos	*Outcome: Robotic; open* Operating time: late robot grp 136 (range 100-183) vs. 110 (49–269) (*P*<0.0004) Blood loss: late robot grp 100 (0–400); 300 (30–2300) (*P*<0.0001) HLOS: 1.6 (1–4)days; 3.8 (1–17)days (*P*<0.0001) Complications: 6/50; 23/64 (*p*=0.003)	Poor quality Open grp had retrospective chart review; robot group had prospective data collection

			bleeding disorders, adenomyosis and myomas Exclusion: 7 (11%) women had uterine size too large for robotic procedure; 10 women (23%) had adnexal mass unsuited for lap. Removal			
Martino 2011	Retrospective cohort	N=215 Robotic hysterectomy: 101 Laparoscopic hysterectomy: 114	Endometrial CA patients; no sig. diff in age, BMI, stage, nodes, comorbidities	Robotic hysterectomy Laparoscopic hysterectomy 24-hr follow-up	*Outcome: Robotic, Laparoscopy; p* **Patient pain score, initial:** 2.1/10, 3.0/10; p = 0.012 Later pain scores: no significant difference **Nursing non-drug pain intervention:** 69/101, 40/114; p<0.01 **Nursing narcotic intervention:** 116/101, 164/114; P=NR **Nursing non-narcotic pain drug:** 46/101, 55/114; p=0.473	Poor quality Risk of selection bias, relies on verbal pain scale, risk of confounding, questionable clinical significance

					Pain med costs, day 1: \$12.24, \$24.45; p<0.01 **Pain med costs, remainder of stay:** \$3.63, \$8.17; p<0.01	
Seamon 2009	Retrospective cohort	Robotic Staging: 109 Laparotomy: 191 Matched for surgeon and BMI	Robotic: Age 58y (±10.0) BMI 39.6kg/m^2 (±7.0) ≥3 comorbids: 42.9% Prior surg: 50.5% Laparotomy: Age 62y (±11.5), P=0.03 BMI 39.9kg/m^2 (±6.9) (matched) ≥3 comorbids: 26.3% (P=0.05) Prior Surg: 62.6% (P=0.04)	Robotic staging vs. open laparotomy; non-robotic laparoscopy not considered. Follow-up time not specified; "All postoperative complications were recorded."	*Outcome: Robotic, open* **Adequate staging:** 85%, 91.3%, P=0.16 **Lymphadenectomy:** 87%, 85.2%, P=0.65 **Pelvic LN dissection only:** 27.5%, 28.3%, P=0.98 **Pelvic & aortic LN dissection:** 72.5%, 71.7%, P=0.75 **≥6 Pelvic nodes:** 90.0%, 94.9%, P=0.16 **Pelvic node count:** 18.5±9.5, 18.7±8.7, P=0.91 **≥4 Aortic nodes:** 75.9%, 78.8%, P=0.70 **Aortic node count:** 8.5±5.5, 7.2±4.5, P=0.11 **Rt Aortic node count:**	Poor quality Open pts were older, more prior surgeries; robotic pts had more comorbidities. No intention-to-treat analysis, 17 robotic-to-open conversions and their 29 corresponding matches were dropped from the final analysis

					4.5±2.9, 4.2±2.6, P=0.53 **Lt Aortic node count:** 4.8±3.5, 3.5±3.0, P=0.02 **Total node count:** 24.7±13.2, 23.9±11.8, P=0.45 **Blood loss:** 109mL, 394mL, P<0.001 **Transfusion:** 2%, 9%, OR 0.22 (95%CI 0.05-0.97, P=0.046) **Op time:** 228±43 min, 143±47 min, P<0.001 **Room time:** 284±49 min, 186±51 min, P<0.001) **HLOS:** 1d, 3d, P<0.001 **Non-wound complications:** 11%, 27%, OR 0.29(95%CI 0.13-0.65), P=0.003 **Wound complications:** 2%, 17%, OR 0.10 (95%CI 0.02-0.43, P=0.002)	
Soliman 2011	Prospective cohort	N=95 radical hysterectomy	No diff in age, BMI, race, stage,	Robotic radical hysterectomy	*Outcome: RAH, LRH, RRH; P*	Good quality Strong design,

		Open = 30 Lap = 31 Robot = 34	histology	(RRH) Laparoscopic radical hysterectomy (LRH) Open radical hysterectomy (RAH) Follow-up NR	**Operative time (min, median):** 265, 338, 328; p=0.002 **EBL (mL, median):** 509.3, 100, 100; p <0.001 **Transfusion, %:** 24, 16, 3; p<0.001 **Conversion, %:** NA, 16, 3; p=0.1 LOS **Post-op infection:** 16/30, 8/31, 3/34; p<0.001 **Negative margins, %:** 96, 97, 97; p=0.99 **Median # pelvic LN:** 19, 14, 17; p=0.26 **Median # lt pelvic LN:** 8.5, 7.0, 7.0; pp=0.96 **Median # rt pelvic LN:** 10.5, 7.0, 9.0; p=0.01 **Median vaginal cuff length, cm:** 1.5, 1.5, 1.5; p=0.10	small N, does not allow comparison between surgeons
Subramaniam 2011	Retrospective cohort	N=177; 73 Robotic (11% converted); 104 laparotomy	<u>Obese</u> women w/endometrial CA; mean age 57.0 (SD=11.2) robotic;	Robotic hysterectomy Open laparotomy	*Outcome: Robotic, Laparotomy; p-value* **% LN removal:** 65.8, 56.7; p=0.227	Poor quality Retrospective; Selection bias; confounding

			61.3 (SD-10.8) laparotomy; p=0.01 Vag Del: 1.79, 2.63; p=0.007	hysterectomy 30-day follow-up	**# LN:** 8.01, 7.24; p=0.505 **Op time (min):** 246.2, 138.2; p<0.001 **EBL (cc):** 95.9, 408.9; p<0.001 **Hct Chg, %:** 4.67, 4.12; p=0.283 **LOS:** 2.73, 5.07; p<0.001 **Wound comp, %:** 4.1, 20.2; p=0.002 **30-day mort:** 0%, 1%; p=1.00	(age, parity); authors employed by DaVinci
Tinelli 2011	Prospective cohort	99, TLRH, 76 RRH with pelvic lymph node dissection, 23	Robotic, laparoscopic, p-value Age 43.1 ± 8.9, 41.9 ± 7.1, NS BMI 28 ± 4, 29 ± 3, NS	Laparoscopic radical hysterectomy (TLRH) with lymphadenectomy vs. total robotic radical hysterectomy (RRH) with lymphadenectomy	Blood loss; LOS; OR time; recurrence rate Mean blood loss: RRH = 157 ml (95% CI 50–400); TLRH = 95 ml (95% CI 30–500) (Not Significant) Median length of hospital stay: RRH = 3 days (95% CI 2–7); TLRH = 4 days (95% CI 3–7) (NS)	Good quality

					Mean operating time: RRH = 323 min (95% CI 161–433) (P\0.05); TLRH = 255 min (95% CI 182–415) No significant difference was found between the 2 groups when comparing the recurrence rate	

Ileovesicostomy

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Vanni 2011	Retrospective cohort	15 Robotic, 8 Open, 7	Robotic; Open Mean age: 53 yrs, range 41-68; 42 yrs, range 23-57 Men/Women: 4/4; 3/4 BMI: 29.2 kg/m^2; 28.4 kg/m^2 Indications for surgery, urodynamics, comorbidities, and medications were similar Inclusion: Incontinent ileovesicostomy; symptomatic neurogenic bladder; unresponsive to medical or conservative	Robotic Open Procedure Median follow-up: Robotic, 15 mos; Open, 13 mos	*Outcome: Robotic; Open* Operating time: 330 mins, range 240-420; 293 mins, range 240-360 (NS) Blood loss: 100 mL, range 10-250; 257 mL, range 100-800 (NS) Transfusion: 0; 1 HLOS: 8 days; 11 days (NS) Incontinence: 2; 4 (NS) Postoperative complications were similar Total hospital costs: $17,344; $12,356 (*P*=0.05) Operating room supplies cost: $3770; $609 (*P*<0.001) Costs for OR fees, room and board, anesthesia, and SICU were similar	Poor Financial disclosure was not reported Retrospective; small sample size; patient chose surgical method; standard deviations of baseline characteristics not reported

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			treatments; poor candidates for indwelling catheters Exclusion: Not reported		Costs included direct fixed and variable costs from hospital billing department; professional fees; and robotic maintenance fees ($200,000/year spread across 300 cases) but not purchase price included. Post discharge costs were excluded.	

Liver Resection

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Berber 2010	Retrospective cohort	32 Robotic, 9 Laparoscopic, 23	*Robotic; Laparoscopic* Mean age: 66.6±6.4 yrs; 66.7±9.6 yrs (NS) Men/Women: 7/2; 12/11 Tumor size and type were similar Inclusion: Peripherally-located liver lesions of <5 cm Exclusion: Not reported	Robotic Laparoscopic Mean follow-up: 14 mos	*Outcome: Robotic; Laparoscopic* Operating time: 258.5±27.9 mins; 233.6±16.4 mins (NS) Blood loss: 136±61 mL; 155±54 mL (NS) Conversion to open procedure: 1; 0 Complications: 11%; 17% Tumor recurrence: 2; 6 (NS) Overall survival and disease-free survival were similar	Poor Two authors are consultants for robot manufacturer Retrospective; small sample size; surgical method selected by robot availability and preference of surgeon; statistical significance of data not always reported

Lung Surgery, Thoracoscopic Resection

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Veronesi 2010	Retrospective cohort (with matched controls)	108 Robotic, 54 Open, 54	*Robotic; Open* Mean age: <55 yrs: 8; 11 55-59 yrs: 12; 13 60-64 yrs: 19; 14 >65 yrs: 15; 16 (all analyses NS) Men/Women: 38/16; 34/20 (NS) Tumor stage, lymph node status, ASA score, disease stage, and BMI were similar Inclusion: Suspected or proven stage I or II lung cancer; lesion <5 cm; <75 yrs of age; normal	Robotic Open 30 days	7 pts converted to open lobectomy Postoperative complications and transfusions were similar No mortalities at 30-days Outcomes analyzed according to 3 chronologically defined tertiles of robotic procedures (earliest 18, next 18, last 18) *Outcome: Robotic tertile 1; 2; 3; Open* Operating time: 260 mins; 213 mins; 235 mins; 154 mins (tertile 1 vs. tertile 2+3, *P*=0.02; tertile 2+3 vs. open, *P*<0.001) HLOS: 6 days; 5 days; 4 days; 6 days (tertile 1 vs. tertile 2+3, *P*=0.002;	Fair Financial disclosure not reported Retrospective; surgical method determined by surgeon's choice, robot availability, and location of lesion; robotic operative data presented as tertiles and overall data was not directly compared with control group

Reference	Study Design	Sample size	Patient Characteristics	Intervention Comparator Follow-up	Outcomes Assessed Main Findings	Quality Comments
Individual studies						
			respiratory function Exclusion: Prior thoracic surgery; neoadjuvant treatment Matching conducted using propensity score based upon 10 criteria		tertile 2+3 vs. open, *P*=0.002) Number of lymph nodes removed at first level were similar, however, number at second level was greater for open group (*P*=0.04) Robotic procedure cost 2000 Euros more than the open procedure (no details provided).	
Balduyck 2011	Retrospective cohort	36 Robotic, 14 Open, 22	*Robotic; Open* Mean age: 49 yrs, range 18-63; 56 yrs, range 23-84 (NS) Men/Women: 4/10; 12/10 Inclusion: Resectable anterior mediastinal	Robotic Open median sternotomy 12 mos	*Outcome: Robotic; Open* Operating time: 242.2±66.5 mins; 243.8±55.5 mins (NS) HLOS: 9.6 days; 11.8 days (NS) Mass diameter: 6.37±3.97 cm; 10.32±3.78 cm (*P*=0.005) Mean follow-up: Robotic, 34.2 mos; Open, 50.1 mos (*P*<0.003)	Poor Financial disclosure not reported Retrospective; small sample size; limited patient characteristics; patients in

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			mass Exclusion for robotic: Mass >4 cm; local invasion in surrounding great vessels; inability to sustain single-lung ventilation Patients with masses >4 cm were treated by open sternotomy		1 pt converted to open sternotomy Perioperative and postoperative complications and pathological diagnoses were similar QOL questionnaire revealed that open group had physical, role, and social functioning impairment, and fatigue at 1 mo, unlike robotic group. Open group still had thoracic pain at 3 mos, unlike robotic group. Robotic group had shoulder dysfunction at 3 mos, but not at 1 mo.	open sternotomy group had larger masses; entry criteria varied for different treatment groups; QOL scores not compared between groups
Park 2008	Cost analysis	N=281 Robotic n = 12 Open lobectomy n = 269	Not described.	Robotic lobectomy Open lobectomy No follow-up	Robotic, open Total relative cost: $4,380, $8,368 Robotic group had add’l $730 in direct costs from	Poor quality cost analysis No description of patient characteristics;

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
					disposable instrument costs	no sensitivity analysis; most patients undergoing robotic procedure also underwent concurrent procedure; no assumptions stated

Mitral Valve Surgery

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
CADTH 2011	N=761 Folliguet (2006) n=50 *Da Vinci* (n=25) Sternotomy mitral valve repair (n=25) Prospective observational (robotic) compared with historical cohort	Robotic mitral valve repair Sternotomy Follow-up 24 months	Findings for RA MVR compared with sternotomy • *Operative time (minutes)* = 241±53.3 vs. 188±24.3 (P=0.002) • *LOS (days)* = 7±3.22 vs. 9±4.5 (NS) • *Transfusion Rate* = 2/25 vs. 4/25 (NS) • *Complication Rate* = 8/25 vs. 5/25	Good quality SR SR included 4 fair to good quality, and 1 poor to fair quality studies
	Tabata (2006) n=128 *Da Vinci* (n=5) Minimally invasive mitral valve repair with direct vision for MR (n=123)	Sternotomy Follow-up 45 ± 10 months for *Da Vinci*; 54±32 months for comparator	Findings for RA MVR compared with sternotomy • *Operative time (minutes)* = 213±52 vs. 125±39 • *LOS (days)* = 6.6±5.3 vs. 7.9±6.3 (P not	

	Retrospective comparison		reported) • *Transfusion Rate* = NR • *Complication Rate* = NR	
	Woo (2006) n=64 *Da Vinci* (n=25) Sternotomy (n=39) Retrospective comparison	Sternotomy Length of follow-up not reported	Findings for RA MVR compared with sternotomy • *Operative time (minutes)* = 2391±12 vs. 162±10 (P=0.001) • *LOS (days)* = 7.10±0.9 vs. 10.6±2.1 (P=0.039) • *Transfusion Rate* = NR • *Complication Rate* = NR	
	Mihalijevic (2011) n=375 *Da Vinci* (n=261) Complete sternotomy (n=114) Retrospective Comparison	Sternotomy Follow-up ≥ 30 days	Findings for RA MVR compared with sternotomy • *Operative time (minutes)* = 387 vs. 278 (P=0.001) • *LOS (days)* = 4.2±1.93 vs. 5.2±2.6	

					(P<0.001) • *Transfusion Rate* = NR • *Complication Rate* = 54/106 vs. 71/106	
	Kam (2010) n=144 *Da Vinci* (n=104) Conventional mitral valve repair (n=40) Retrospective comparison			Sternotomy Length of follow-up not reported	Findings for RA MVR compared with sternotomy • *Operative time (minutes)* = 238.6 vs. 162 (mean relative difference 1.18; 95% CI 1.11, 1.27; P<0.001) • *LOS (days)* = 6.5±2.99 vs. 8.8±4.4 (mean relative difference 0.74; 95% CI 0.68, 0.80; P<0.001P=0.039) • *Transfusion Rate* = NR *Complication Rate* = NR	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient**	**Intervention**	**<u>Outcomes Assessed</u>**	**Quality**

			Characteristics	Comparator Follow-up	Main Findings	Comments
Suri 2011	Retrospective observational comparative study, propensity matched	190, Robot, 95, Open, 95	Robotic, open, p-value Age 54.88 ± 11.04, 55.69 ± 14.09, NS BMI 26.83 ± 3.57, 26.95 ± 4.41, NS Other NS differences: Creatinine, ejection fraction, cerebrovascular disease, chronic lung disease, congestive heart failure, coronary disease, diabetes, dyslipidemia, hypertension, gender, myocardial infarction, NYHA 1 and 2, preoperative atrial fibrillation,	Mitral valve repair robot vs. open	Median crossclamp & bypass times were longer in robotic group but decreased significantly over time (P<.001). There were no conversions to open sternotomy, repair rate & early survival were 100%, dismissal mitral regurgitation grade was similar (P=1.00), & all pts in the robotic group had mild or less mitral regurgitation at 1 month after repair. There were no differences in adverse events (5% open vs. 4% robotic, P=1.00). Pts in the robotic group had shorter postoperative ventilation time, intensive care unit stay, & hospital stay.	Good quality The incidence of early major AEs after open & robotic degenerative MV repair are similarly low and less than recently reported in the EVEREST II trial, thereby establishing an appropriate benchmark against which future nonsurgical therapies should be evaluated.

			Charlson score			

Myomectomy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Reza 2010	SR/MA Three prospective cohorts, one used historical controls N = 189 Robotic n = 84 Laparoscopic n = 76 Laparotomy n = 29 Advincula 2007 (n=58) Bedient 2009 (n=81) Nezhat 2009 (n=50)	Robotic myomectomy Laparoscopic myomectomy Open myomectomy	Meta-analysis results: Robotic vs. laparoscopic surgery: (95% CI) Blood loss (mL) MD = -72.36 (-133.22, -11.50) favoring robotic procedure Duration of surgery (min) MD = 0.18 (-54.42, 54.79) NS Outcomes not included in meta-analysis but reported in SR: Robotic vs. open: Cost: Robotic procedure associated with increased costs of $18,000 (p<0.001)	Good quality SR Summary quality ratings described, but not specified by individual study. SR notes that all studies had clear objectives, were controlled, were not randomized, but had adequate follow-up (length of follow-up not reported)

					Duration of surgery (min) Robotic = 80 minutes longer (p<0.001) Hospital stay = 2 days shorter in robotic group (p = 0.001) Blood loss was reduced by 170 ml (*P* = 0.011).	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Ascher 2010	Retrospective review and historical control group	125 Robotic: 75 Open: 50	Robotic; Open Mean age: 36.5±7.2; 37.2±5.4 (NS) BMI: 21.7 kg/m^2; 20.1 kg/m^2 (NS) Inclusion: Uterus ≤20 wks in size; ≤3 myomas Exclusion: Previous uterine surgery	Robotic Open No follow-up	*Outcome: Robotic; Open* *(95% CI)* Operating time: 192.3 mins (58.6, 326.0); 138.6 mins (30.3, 246.8)(*P*=0.01) Blood loss: 226.3 mL (-271.7, 724.4); 459 mL (-405.5, 1323.5)(*P*=0.009) HLOS: 0.51 days (-0.8, 1.8); 3.3 days (1.1, 5.4)(*P*=0)	Poor Selection bias, while suspected, could not be assessed. Retrospective; historical control group; patients in robotic grp were outpatients so

					# of Fibroids: 2.4 (-2.1, 6.8); 1.7 (0.1, 3.2)(NS) Febrile morbidity: 1.3%; 38% (*P*=0) Operative and postoperative complications were similar	they self monitored body temperature, therefore fever may not have been detected or reported Authors noted that uterine suture repair which is critical to avoid future pregnancy-related uterine rupture is difficult to perform laparoscopically; the robotic approach is more comparable to an open approach in addressing this concern; furthermore, the inability to palpate for

						small myomas is not possible with the robotic approach as it is with the open surgery which potential could lead to different long-term pathologic outcomes.
Advincula 2007	Nested case-control (derived from a retrospective chart review); Controls were open procedures performed during same time frame, matched to cases of robotic surgery according to weight of	58 Robotic, 29 Open, 29	*Robotic; Laparotomy* Mean age: 37 yrs; 35 yrs Men/women: 7/9; 6/14 BMI: 25, 28 Leiomyoma weight (g): 228, 224 *Inclusion criteria for robotic procedure:* Symptomatic leiomyomata thought to be approachable with conventional laparoscopic	Robotic Laparotomy (open) No follow-up No comparison with laparoscopy because prior to introduction of robotic system, primary author preferred to avoid laparoscopy due to dissatisfaction with instrumentation	*Outcomes: Robotic; Laparotomy* Operative time (min) (mean and 95% CI) : 231.38 (199.01-263.75); 154.41 (138.00-170.82) (*P*<0.0001) Blood loss (mL) (mean and 90% CR): 195.69 (50.00-700.00); 364.66 (75.00-1550.00) (*P*=0.0112) HLOS: (day and 90% CR): 1.48 (1.00-3.00); 3.62 (3.00-8.00) (*P*<0.0001) (CR=central range for	Good-quality cost analysis but poor-fair operative outcomes data Single surgeon performed robotic procedures but 6 surgeons performed control procedures; control procedures not necessarily eligible for laparoscopic

	leiomyomata (most important) and patients' BMI and age.		myomectomy because of size, #, location, or combination.		nonnormally distributed data) Primarily a U.S. hospital perspective; direct variable costs, including professional costs. Costs derived from internal hospital systems, collected May 2000 – June 2004 and inflation-adjusted to June 2004. Charges included operating department, anesthesia, nursing, laboratory, pharmacy, and recovery department. Remaining cost of hospital stay and cost of follow-up care excluded. Intent-to-treat analysis (conversions counted in originally planned surgical group). *Charges (professional plus hospital, equated with hospital costs):*	myomectomy at other institutions; robotic group had more numerous symptoms; results may not generalize to institutions using a donated robotic system; omission of postsurgical costs of the hospital stay limits usefulness even from a hospital perspective; costs were apparently adjusted according to general rather than medical inflation index

					Robotic; Open $36,031 (90% CR 28,528-50,618); $18,065 (90% CR 12,737-31,647) *Reimbursement (professional plus hospital): Robotic; Open* $15,444 (90% CR 1134-3,753); $8857 (90% CR 4766-12,258) Total hospital and professional components of charges and reimbursements were greater for robotic procedures, but robotic-open difference in professional reimbursement was NS. The biggest single difference was in a component of hospital charges, operating department charges ($16,916 robotic vs. $2165 open); most other hospital charges	

					were greater for open procedures). 5-year depreciation costs accounted for $10,569 of operating room costs for each robotic procedure.	
Barakat 2011	Retrospective cohort assembled from single clinic	N=575 Open n=393 Laparoscopic n=93 Robotic n=89	*Robotic; laparoscopic; open* Age (IQR) 37 (33-40); 38 (35-44); 37 (33-41), p=0.053 Weight (IQR) 68.04 (57.65, 82.56); 64.86 (59.1, 76.66); 75.57 (62.85, 90.72); p<0.001 BMI (IQR) 25.15 (22.14, 29.44); 24.10 (22.00, 28.01); 27.61 (23.43, 32.81) Previous myomectomy, operative laparoscopy, tubal ligation or	Open myomectomy; laparoscopic myomectomy; robotic-assisted myomectomy No follow-up	*Robotic; laparoscopic; open* Surgical time, min (IQR) 181 (151, 265); 155 (98, 200); 126 (95, 177), p=0.003 abdominal vs. robotic; p=0.083 laparoscopic vs. robotic Blood loss, mL (IQR) 100 (50, 212.50); 150 (100, 200); 200 (100, 437.50), p<0.001 abdominal vs. robotic; p=.818 robotic vs. laparoscopic Hemoglobin drop, g/dL (IQR) 1.30 (0.80, 2.28); 1.55 (1.20, 2.40); 2.00 (1.40, 2.90), p<0.001 abdominal vs. robotic; p=0.431 laparoscopic vs. robotic	Poor quality Not randomized; no follow-up; unclear whether "experienced surgeons" had experience specifically with robotic surgery; significant differences between groups at baseline (robotic and laparoscopic groups had lower BMI than open group; robotic group was less likely to have had prior

			cesarean section significantly different between groups (fewer in robotic group had previous surgery) Height, parity, other previous abdominal surgery not statistically significant different between groups Inclusion/exclusion criteria not described		Hospital stay, days (IQR) 1.0 (1.0, 1.0); 1.0 (0.0, 1.0); 3.0 (2.0, 3.0), p<0.001 abdominal vs. robotic; p=0.506 laparoscopic vs. robotic Blood transfusion, frequency 7.41%, 0.00%, 92.6%; p=0.008 Postoperative complications, frequency 0.00%, 66.67%, 33.33%, p=0.13	abdominal surgery)
Behera 2011	Cost-minimization analysis		*Parameter estimates, baseline, range: open; laparoscopic; robotic* Operative time, min: 154 (85-154); 264 (79-264); 234 (152-234)	Open myomectomy; laparoscopic myomectomy, robotic myomectomy	*Open, laparoscopic, robotic* *Existing robot model* $4937; $6199; $7280 Open procedure remained least expensive after sensitivity analysis, unless: Length of hospital stay for open surgery was greater than 4.3 days	Fair quality Underlying evidence limited on long term outcomes; outcomes related to quality of life were not incorporated or valued; only

			Conversion risk, % N/A; 8.8 (0-13.3); 6.9 (0-6.9) Transfusion risk, % 6.1 (6.1-6.9); 0 (0-0); 0 (0-0) Length of stay, days 2 (2-4.1); 1.6 (0.6-2.2); 1.5 (0.2-1.5) *Cost estimates* Preoperative costs 94; 94; 94 Intraoperative costs (range) 1068 (1068-4902); 1047 (1047-5207); 1047 (1047-5207) Anesthesia setup fee 339, 339, 339 Disposable instrument costs 200 (0-1000); 1151		(laparoscopic became least expensive); or Surgeon's fee for open surgery was greater than $3473 (laparoscopic became least expensive; robotic was less expensive than open, but more than laparoscopic) Cost of robotic procedure consistently higher than laparoscopic; robotic only less expensive if disposable instrument costs were less than $1400 and laparoscopic disposable costs remained $1151 *Robot purchase model* Robotic cost increased incrementally by $2814, $1939, and $1090 when purchase of robot is amortized over 12, 18 and 32 months, respectively	direct costs were assessed

			(500-2000); 2511 (1000-4000) Early conversion costs N/A; 712, 1154 Postoperative anesthesia care unit cost (range) 400 (101-808); 214 (76-374); 214 (76-374) Robot acquisition and maintenance costs, monthly costs, amortized 7 years for 5% at base case N/A; N/A; 34893 (33036-41172)			
Nash 2011	Retrospective cohort at single institution	N=133 Robotic n=27 Open n=106 Propensity matched comparison Open n=54	*Open; robotic; OR (95% CI)* *BMI (SD)* 26.5 (6.16); 24.97 (4.81); 0.93 (0.83-1.03) Age (SD) 35.78 (5.47); 38.26	Open myomectomy Robotic myomectomy	*Open, robotic, p-value* *Results stratified by specimen size: smallest, intermediate, largest* Mean total hospital charges: $26,865, $27,645, $34,892; $43,465,	Fair quality Small sample size, may be underpowered to detect smaller differences;

		Robotic n=27	(6.30); 1.10 (0.99-1.22) Uterine size (SD) 16.06 (4.80); 12.74 (4.55); 0.76 (0.65-0.90) Medicaid 7.7%; 3.7%; 0.17 (0.01-2.74) White/other 68.9%; 59.3%; reference African American 23.6%; 37.0%; 3.02 (0.97-9.38) Hispanic 7.5%; 3.7%; 0.31 (0.02-5.26) Indication pain 56.6%; 77.8%; 2.03 (0.65-6.37) Indication bleeding 73.6%; 51.9%; 0.26 (0.08-0.81) Indication gastrointestinal 10.4%; 29.6%; 2.01 (0.55-7.39) *Inclusion/exclusion*		$48,549, $52,478, p<0.0001 Mean operating room charges: $16,790, $17,313, $22,173; $34,796, $39,981, $41,517, p<0.0001 Mean total operating room minutes (SD): 106.15 (36.84), 117.82 (51.77), 157.86 (56.93); 183.90 (70.54), 239.33 (76.41), 280.40 (121.66), p<0.0001 Mean length of stay (SD) 2.31 (0.63), 2.38 (0.70), 2.65 (1.17); 0.50 (0.71), 0.67 (0.65), 1.20 (1.64), p=0.007 Median (IQR) grams of specimen removed per operating room hour 57.46 (140.46), 129.47 (79.49), 208.53	selection bias well accounted for using propensity score matching; cost outcomes include only direct costs

			criteria Propensity score modeling uses to exclude pts who underwent open procedure who would have been unlikely to undergo robotic		(273.31); 19.61 (24.08), 39.9 (57.05), 102.36 (90.58), p<0.0001 Percent IV hydromorphone 84.6%, 80.0%, 81.4%; 50.0%, 66.7%, 40.0%, p=0.01 NS differences in estimated blood loss, post op hemoglobin, maximum pain score, % any complications *Propensity score 2-1 matched comparison* Efficiency outcomes Mean (SD) total hospital charges $26,720 (7,830); $47,478 (10,883), p<0.0001 Mean (SD) operating room charges $17,037 ($4,516); $37,901 ($10,324), p<0.0001	

					Mean (SD) total operating room minutes 114.54 (39.06); 226.41 (88.33), p<0.0001 Median (IQR) grams of specimen removed per operating room hour 139.66 (115.98); 38.56 (75.90), p<0.0001 Mean (SD) length of stay 2.3 (0.662); 0.70 (0.91), p=0.001 Clinical outcomes NS (estimated blood loss, post op hemoglobin, max pain score, any complications)	

Nephrectomy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
CADTH 2011	SR + MA N=737 *Da Vinci* (N=343) Laparoscopic partial nephrectomy (N=130) Laparoscopic partial nephrectomy (N=172) Laparoscopic partial/wedge nephrectomy (N=11) Laparoscopic tranperitoneal partial nephrectomy (N=15) Laparoscopic radical nephrectomy (N=15) Laparoscopic nephrectomy with hand assistance (N=21) Laparoscopic nephrectomy (N=12) Open radical nephrectomy (N=18) 4 Prospective observational studies 6 Retrospective comparison studies	Laparoscopic or open surgery Follow-up ranged from 4 months to 4 years	MA Findings for RAPN compared with LRN: *For operative duration*, there is a high degree of heterogeneity and mixed results among studies, and a meta-analysis was not performed ; Shorter length of hospital stay (WMD −0.25 days, 95% CI −0.47 days to −0.03 days); *The extent of blood loss in this comparison was not statistically significant* (−17.44 mL, 95% CI −53.63 to 18.75 mL); *Risk of transfusion*	Good quality SR SR included 1 good quality, 8 fair to good quality, and 1 poor to fair quality studies

			was found to be inconclusive in this comparison (RR 0.85, 95% CI 0.24 to 3.09, NS); and *Reduced warm ischemic time* (WMD −4.18 minutes, 95% CI −8.17 to −0.18 minutes). MA Findings for Radial Nephrectomy compared with Laparoscopic Radical Nephrectomy and Open Radical Nephrectomy: *Longer operative times were statistically significant in both studies*; and *LOS, blood loss, and risk of transfusion were inconclusive* between the 2 studies.	

Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Hillyer 2011	Comparative retrospective review	26 Bilateral RPN, 9 Sequential bilateral LPN, 17	Men (%), black race (%), age, BMI, preoperative estimated glomerular filtration rate, average ASA score, tumor location all NS differences between groups Robotic, laparoscopic, p-value Tumor size 2.85, 2.7, p=0.03 Pattern (exophytic, mesophytic or endophytic) More endophytic in robotic group, p = 0.008 Position, fewer	Robot (RPN) vs. laparoscopic partial nephrectomy (LPN) bilaterally	A total of 18 procedures were performed in the RPN group and 32 in the LPN group. The median warm ischemia time was shorter in the RPN group than in the LPN group (19 vs. 37 minutes, respectively; *P*=0.059). The median tumor size was 2.85 and 2.7 cm in the RPN and LPN group, respectively (*P*=0.03). The final median postoperative glomerular filtration rate was 68.7mL/min/1.73 m2 (interquartile range 14-73) and 26.9 mL/min/1.73 m2 (interquartile range 20-70) in the RPN and	Good quality To our knowledge, this represents the first study to offer such a comparative analysis of a specific subset of patients with bilateral synchronous tumors.

			lateral in robotic group, p=0.02 Sinus fat invasion more common in robotic group, p=0.006		LPN groups, respectively (*P*=0.004). No difference was found in the complications in the RPN group (n=2) compared with the LPN group (n= 4).	
Pierorazio 2011	Retrospective cohort design	N=150 Robotic=48 Laparoscopic=102	Baseline characteristics robot vs. lap: Gender mostly male (NS); Age median 62 vs. 56 (p=.006); BMI 28.2 vs. 30.3 (p=.053); Tumor characteristics similar (NS); Inclusion criteria: single surgeon since 2006 cases of renal mass solid tumor undergoing either type surgery to present (2011) Exclusion criteria: unclear	Laparoscopic partial nephrectomies (LPN) and Robot-assisted partial nephrectomies (RAPN); cohorts were divided groups of 25 consecutive patients in each group to study the learning curve effect on surgical outcomes; Follow-up: to discharge in most but 57 patients are reported for GRF with a median 7 months,	Perioperative outcomes: LPN vs. RAPN Mean operative times (min): 193 (100-420); vs. 152 (108-265) p<.001; Warm ischemic time (min): 18 (8-65) vs. 14 (8-30) p<.001; Mean EBL (mL): 245 (50-1700) vs. 122 (0-500) p=.001; Transfusions (%): 4.9 vs. (NS); LOS (days): 2 vs. 2 (NS)	Good Very experienced laparoscopic surgeon was sole surgeon in both treatment arms of study. Results of learning curves may not be generalizable to other surgeons.

				range 1-43 months…(unclear which group or groups this represents)		

Oropharyngeal Surgery

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Dean 2010	Retrospective cohort	21 Robotic salvage, 7 Open salvage, 14 (an additional 15 patients were reported to have undergone robotic resection for primary neoplasms without a comparison group)	*Robotic; Open* Mean age: 67.7 yrs ±NR; 59.0 yrs ±NR (P=NR) Men/Women: 6/1; 12/2 (NR) Primary tumor subsite: Base of tongue (5), Soft palate/Pharyngeal wall (1); Base of tongue (5), Tonsil (5), Soft palate (4) T stage: T1 4/3; T2 3/11 (NR) Previous head/neck therapy: Surgery 0/1; Radiation 2/6; Chemoradiotherapy	Robotic or Open Salvage; Follow-up 6 months	*Outcome: Robotic; Open* HLOS: 5.0; 8.2 (NS) Gastrostomy tube dependent at 6 months 0%/43% (NR) Complications: 0/2 (NS)	Poor Retrospective; small sample size; baseline group differences only statistically analyzed between all 3 groups; most outcomes reported in narrative form; comparative groups drawn from 2 time epochs;

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			2/4; Surgery + radiation 1/3; Surgery + chemoradiotherapy 2/0 (NR) Inclusion: Recurrent T1 or T2 oropharyngeal neoplasms; Exclusion: T3 or T4 disease			patient's selected their treatment modality

Pancreatectomy

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Kang 2011a	Retrospective cohort	45 Robotic, 20 Laparoscopic, 25	*Robotic; Laparoscopic* Mean age: 44.5±15.9 yrs; 56.5±13.9 yrs (P=0.02) Men/Women: 8/12; 11/14 (NS) BMI: 24.2 kg/m^2; 23.4 kg/m^2 (NS) Inclusion: Distal pancreatectomy for benign and borderline malignant tumors; intent to preserve spleen Exclusion: Central pancreatectomy	Robotic Laparoscopic No follow-up	*Outcome: Robotic; Laparoscopic* Operating time: 348.7±121.8 mins; 258.2±118.6 mins (P=0.02) Blood loss: 372.0±341.5 mL; 420.2±445.5 mL (NS) Transfusion: 4; 4 (NS) HLOS: 7.1±2.2; 7.3±3 (NS) Complications: 2; 4 (NS) Failed spleen preservation: 1; 9 (*P*=0.03) Total cost (converted from Korean won, July 2010 rate): \$8304.8±870.0; \$3861.7±627.5 (*P*<0.001) Operation cost: \$5752.6±380.5; \$2222.1±627.5 (*P*<0.001) (no cost details were provided)	Poor Retrospective; small sample size; age difference favoring robotic group; patients chose surgical method
Zhou 2011	Retrospective cohort	16 Robotic, 8 Open, 8	*Robotic; Open* Mean age: 64.4±9.1 yrs;	Robotic Open No follow-up	*Outcome: Robotic; Open* Operating time: 718.8±186.7 mins;	Poor Financial

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			59.4±9.4 yrs (NS) Men/Women: 5/3; 4/4 (NS) Levels of bilirubin, CA19-9, and CEA were similar Inclusion: Pancreatoduoden-ectomy Exclusion: None reported		420.0±127.2 mins (*P*=0.011) Blood loss: 153.75±43.4 mL; 210±53.2 mL (*P*=0.045) HLOS: 16.4±7.1 days; 24.3±7.1 days (*P*=0.04) Reoperation: 0; 1 Complications: 25%; 75% (*P*=0.05) Mortality: 0; 1	disclosure was not reported Retrospective; small sample size; patients chose surgical method; BMI and surgical history not reported
Kang 2011b	Retrospective cohort	15 Robotic, 5 Open, 10	*Robotic; Open* Mean age: 50±12.3 yrs; 38.7±16.5 yrs (NS) Men/Women: 5/0; 4/6 Symptomatic: 0; 7 (*P*=0.026) Inclusion: Central pancreatectomy; Borderline malignant tumor in the neck or	Robotic Open Median follow-up 19 mos	*Outcome: Robotic; Open* Operating time: 432.0±65.7 mins; 286.5±90.2 mins (*P*=0.013) Blood loss: 275.0±221.7 mL; 858.3±490 mL (P=0.038) Transfusion: 0; 3 (NS) Reoperation: 0; 2 (NS) HLOS: 14.6±7.7 days; 22.1±13.3 days (NS) Complications: 1; 5 (NS) No mortalities	Poor Retrospective; small sample size; possible age-related selection bias favoring control group; BMI and surgical history not reported

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			proximal body of the pancreas Exclusion: None reported		Diabetes during follow-up: 0, 0	
Waters 2010	Retrospective cohort (chart review of prospectively collected data)	57 Robotic, 17 Laparoscopic, 18 Open, 22 Operative approach according to surgeon and patient preference.	*Robotic; Laparoscopic; Open* Mean age (yrs): 64; 59; 59 (NS) Men (%): 35%; 50%; 45% (NS) ASA score, specimen length: Similar Lesion sizes: Smaller in robotic group; global *P*=0.01 (radiographic measurement) and global *P*=0.06 (pathologic measurement) Indications: Overall differences in	Robotic Laparoscopic, Open Hospital discharge	*Intraoperative outcomes: Robotic; Laparoscopic; Open* Positive margins (n): 0, 0, 2 Lymph nodes obtained (n): 5, 11, 14 (global *P*=0.04) Spleen preservation (%): 65%, 28%, 14% (*P*=0.04 for robotic vs. laparoscopic) Splenic artery and vein preserved (%): 65%, 18%, 9% (*P*=0.006 for robotic vs. laparoscopic) Conversion rate (%): 12%, 11%, N/A (NS) Blood loss (mL): 279, 667, 681 (overall difference, NS) Operative time (min and	Fair-quality cost analysis but Poor-quality operative outcome data No disclosure of conflicts of interest or funding source Retrospective; small sample size; potential bias from unsystematic assignment to operative approach; results may not generalize

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			indication were NS, but 50% open and none of robotic procedures were for adenocarcinoma. *Inclusion criteria:* Pancreatectomy during 1-yr time frame *Exclusion criteria:* Emergent or urgent surgery, concurrent major surgery, surgery indicated for pancreatitis		95% CI): 298 (191-418), 224 (100-346), 234 (136-437) (global *P*=0.01) *Postoperative outcomes: Robotic; Laparoscopic; Open* HLOS (day and 95% CI): 4 (2-6); 6 (3-34); 8_3-25) (global *P*=0.04) Morbidity (%): 18%, 33%, 18% (overall, NS) U.S. hospital perspective; direct variable costs, excluding professional costs. Costs from hospital accounting records, collected August 2008 – August 2009; operative time and supplies, anesthesia, nursing, laboratory, overall hospital stay. Adjusted operative costs include amortized cost of robotic	to patients requiring surgery for pancreatitis or to surgeons without prior training and experience

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
					system. Post discharge and other follow-up care excluded. Intent-to-treat analysis. *Costs: Robotic; Laparoscopic; Open* Operative, unadjusted: \$4898; \$3072; \$3510 (global *P*=0.04) Operative, adjusted: \$6214; N/A; N/A Hospital stay: \$5690; \$9828; \$12;011 (global *P*=0.01) Total, unadjusted: \$10,588; \$12,900; \$15,521 (NS) Total, adjusted: N/A; N/A; \$11,904 (NS for comparison of adjusted robotic with other unadjusted costs)	

Prostatectomy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
CADTH 2011	SR + MA N = 21,470 *Da Vinci* (N=11,196) Open radical prostatectomy (N=3,212) Open radical retropubic prostatectomy (N=1,920) Open radical perineal prostatectomy (N=91) Laparoscopic radical prostatectomy (N=1,149) Radical retropubic prostatectomy (N=2,736) Radical perineal prostatectomy (N=16) Retropubic total prostatectomy (N=29) Transperitoneal laparoscopic prostatectomy (N=213) Conventional prostatectomy (N=152) 24 Prospective observational studies 27 Retrospective comparison studies	Robotic prostatectomy Open or laparoscopic surgery Follow-up 6 weeks to 58 months	MA findings for RARP compared with ORP *Longer operative duration* (WMD 37.74 minutes, 95% CI 17.13 to 58.34); *Shorter length of hospital stay* (WMD −1.54 days, 95% CI −2.13 to −0.94); *Reduction in positive margin rate in pT2 patients* (RR 0.6, 95% CI 0.44 to 0.83, NS). The results of this comparison in pT3 patients and in two trials that did not report pT2 and pT3 subclasses, was inconclusive; *Reduction in the*	Good quality SR SR included 1 high quality, 6 good quality, 35 fair to good quality, 6 poor to fair quality, and 1 poor quality studies.

			extent of blood loss (WMD −470.26 mL, 95% CI −587.98 to −352.53) *Reduced risk of red blood cell transfusion* (RR 0.20, 95% CI 0.14 to 0.30); *Urinary continence after 12 months* (RR 1.06, 95% CI 1.02 to 1.10, NS); and *Likelihood of sexual function after 12 months* (RR 1.55, 95% CI 1.20 to 1.99). MA Results for RARP compared with LPR: *Shorter operative duration* (WMD −22.79 minutes, 95% CI −44.36 to −1.22); *Shorter length of hospital stay* (WMD −0.80 days, 95% CI −1.33 to −0.27);	

					Positive margin rate comparisons were inconclusive for pT2 and pT3; *Reduction in the extent of blood loss* (WMD −89.52 mL, 95% CI −157.54 to −21.49); *Reduced risk of red blood cell transfusion* (RR 0.54, 95% CI 0.31 to 0.94, NS); *Urinary continence after 12 months*, pooled estimates trended in favor of RARP (RR 1.08, 95% CI 0.99 to 1.18, NS).	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Kasraeian 2011	Retropective cohort design	N=4000 Robotic n= 200 Laparoscopic n =	Robotic, laparoscopic, p-value	RALP vs. LRP Follow-up n/a	Comparison of RALP vs. LRP, p-value	Good quality

		200	Median (range) age 60.8 (44-73), 61.9 (45-75), 0.067 Median (range) BMI 24.9 (19.1-34), 25.7 (19.1-56.3), 0.003 Prostate size 50 (27-122), 55 (21-136), <0.001 PSA 6.4 (2.1-19.8), 6.8 (2.7-48.8), <0.001 Median stage T1c, T1c, 0.578 Median Gleason score 6, 6, 0.317		*Median (range) operating time, min* 120 (60-240), 150 (75-300), <0.001 *Median (range) est. blood loss, mL* 350 (50-1500), 400 (50-1300), 0.069 *Median (range) hospital stay, days* 4 (3-11), 4 (3-23), 0.056 *Nerve-sparing, n%* 197 (98.5), 177 (88.5), <0.001 *Non-nerve-sparing, n(%), mL* 3 (1.5), 23 (11.5), <0.001PSM rate similar between groups 13.5% vs. 12% (NS) however in different locations…LRP were mostly at apex (53.8%; p=0.038)	

					while posterolateral after RALP (48%; p=0.046); Median margin size: 2mm vs. 3.5mm; (p=0.041)	
Kim 2011a	Comparative Prospective	763 Robotic n = 528 Open n = 235	Robotic, open, p-value Age 64.2 ± 7.3, 66.5 ± 5.7, p<0.001 Mean PSA 10.4 ± 16.0, 14.6 ± 22.1, p=0.003 Mean BMI 24.5 ± 2.7, 25.1 ± 3.6, p=0.014 Mean membranous urethral length 1.15 ± 0.32, 1.11 ± 0.30, p = 0.042 Pts receiving neoadjuvant therapy (%)	RARP vs. Open (RRP) Pts serially followed post-operatively for comparative analysis	Continence and potency recovery were checked serially by interview and questionnaire at 1, 3, 6, 9, 12, 18, and 24 mo postoperatively After the initial 132 cases, pts who underwent RARP demonstrated faster recovery of urinary continence compared to RRP pts. Potency recovery was more rapid in the RARP group at all evaluation time points, beginning from the initial cases. In multivariate analysis, younger age & longer preoperative membranous urethral	Poor quality favoring robot Limitations: Non-randomized; used interview to evaluate potency recovery 2 groups were dissimilar in age, neoadjuvant hormone therapy use, nerve-sparing surgery frequency , pre-op PSA levels

			49 (9.3), 41 (17.4), p= 0.007 Clinical stage less advanced in robotic group, p = 0.004 Gleason score lower in robotic group, p=0.004 NS differences in mean testosterone, tumor volume		length seen by prostate MRI demonstrated statistical significance as independent prognostic factors for continence recovery; younger age, surgical method (RARP vs. RRP), and higher preoperative serum testosterone were independent prognostic factors for potency recovery. **Conclusions:** Patients after RARP demonstrated superior functional recovery. Moreover, membranous urethral length on preoperative MRI and patient age were factors independently predictive of continence recovery, while patient age and higher preoperative	

					serum testosterone were independent prognostic factors for potency recovery.	
Tollefson 2011	Retrospective cohort study	5908 Robotic n = 1084 Retropubic radical prostatectomy n = 4824	Robotic, open, p-value Median age (range) 60 (38-81), 61 (31-84), 0.012 Median (range) BMI 27.8 (18.9-60.3), 27.5 (16.2-56.8), 0.094 Biopsy Gleason score 12, 57, <0.001 Median Pre-op PSA (range), ng/mL 5.0 (0.1-42.3), 5.4 (0.1-194), <0.001	RARP vs. RRP Follow-up: at least 30 days	Comparison of RARP vs. RRP, p-value *Incidence of surgical site infection* 6 (0.6%), 216 (4.6 %), <0.001 *Incidence of urinary tract infection* 17 (1.6%), 58 (1.2%), NS *Sepsis/bacteremia* 1 (0.1%), 7 (0.1%), NS	Poor quality Baseline characteristics favored robotic group
Masterson 2011	Retrospective cohort	N=1041 Robotic n=669 Open n=357	Robotic; open; p-value Mean preoperative PSA, ng/mL	Open Robotic	Robotic; open; p-value NS differences between groups in +SM location for all	Fair quality Non-randomized retrospective

			7.1; 7.6; p=0.02 Mean prostate weight, g 48.2; 44.2; p<0.01 % lymph node involvement 8; 1; p=0.001 NS differences between groups in age, tumor volume, largest tumor dimension, Gleason sum, pathologic stage, +SM, benign capsular incision Exclusion criteria Pts receiving neoadjuvant or adjuvant therapy w/androgen deprivation, radiation or chemotherapy (n=6); pts undergoing radical		patients Mean +SM length in mm (range) for all patients 3.0 (0.05, 17.5); 5.6 (0.1, 38); p=0.04 NS differences in +SM location for pT2, pT3, bilateral NVB preservation patients Biochemical recurrence-free survival 24-months 87%; 87%; NS 60-months 73%; 71%; NS	design, though consecutive pts were enrolled; experience of surgeon may have biased towards open group; no comorbidities or other health indicators included in analysis which may have introduced bias (direction unknown) Single pathologist and single surgeon for all cases

			perineal (n=2), open salvage (n=2), and pure laparoscopic RP w/o robotic assistance (n=5)			

Pyeloplasty

Review				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Thavaneswaran 2009	SR Four non-randomized comparative studies N=224 Robotic n = 77 Laparoscopic n = 147 Link 2006 (n=20) Yanke 2008 (n=145) Weise 2006 (n=45) Bernie 2005 (n=14)	Robotic pyeloplasty Laparoscopic pyeloplasty Follow-up ranged 5.6 months to 24 months	Operative time (min) Study; Robotic [SD] or (range), Laparoscopic [SD] or (range) Link; 100.2 (9.1), 80.7 [21.9], p=0.018 Yanke; NR Weise; 271 (207-444), 299 (193-376), NS Bernie; 324 (252-420), 312 (240-390), NS EBL (mL) Study; Robotic (range), Laparoscopic (range) Link: P=NS (data not provided) Yanke: NR Weise; <100 (10-300), <100 (20-200), NS Bernie; 60(50-100), 40(5-200), NS	Good quality SR SR notes that all four studies describe objective clearly. None were randomized or blinded. One study rated as III-2 level of evidence; Three studies rated as III-3 level of evidence

			LOS (days) Study; Robotic (range), Laparoscopic (range) Link: P=NS (data not provided) Yanke NR Weise; 2 (1-3), 2 (2-5), NS Bernie; 2.5 (2-6), 3 (2-4), NS Conversions, n/N (%) Link NR Yanke NR Weise; 0/31 (0%), 0/14 (0%), NS Bernie NR Surgical success rate, n/N (%) Link; 10/10 (100%), 10/10 (100%), NS Yanke; 29/29 (100%), 103/116 (88.8%), p=NR Weise; 19/29 (66%), 7/11 (64%), p=NR Bernie; NR	

			Complications, n/N (%) Link; 1/10 (10%), 0/10 (0%), p=NR Yanke; NR Weise; 2/31 (6%), 2/14(14%), p=NR Bernie; 2/7 (28.6%), 2/7 (28.6%), NS Pain: Study: robotic; laparoscopic Weise: 83% no pain, 14% mild, 3% significant; 73% no pain, 27% mild pain, 0% significant pain Renal function: Bernie: improvement 30-44% both groups Weise: robotic 44% had significant improvement, 52% no change, 4% decrease; laparoscopic 25% improved, 75% no change, 0%	

					decreased.	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Bird 2011	Retrospective cohort	172 Robotic, 98 Laparoscopic, 74	*Robotic; Laparoscopic* Mean age: 39.6±15.2 yrs; 39.8±13.9 yrs (NS) Men/Women: 46/52; 35/39 BMI: 25.7 kg/m^2; 26.0 kg/m^2 (NS) Secondary uteropelvic junction obstruction: 17.3%; 6.8% (P=0.04) Inclusion: Uteropelvic junction obstruction; transperitoneal approach Exclusion:	Robotic Laparoscopic Long-term follow-up (not defined)	*Outcome: Robotic; Laparoscopic* Operating time: 189±62 mins; 187±69 mins (NS) Blood loss: <50 mL; < 50 mL HLOS: 2.5 days; 2.5 days (NS) Intraoperative and postoperative complications: similar Radiographic success rate at follow-up: 93.4%; 95% 136/172 pts (79%) at long-term follow-up	Poor Financial disclosure was not reported Retrospective; baseline clinical difference between groups; high dropout rate for long-term f/u

Link 2006	Prospective nonrandomized trial (10 consecutive pyeloplasties performed with robotic system; next 10 performed laparoscopically)	20 Robotic, 10 Laparoscopy, 10	*Robotic; Laparoscopic* Mean age: 47 yrs, 38 yrs (NS) BMI: 23, 24 (NS) Men (%): 30%, 40% Surgical side, presence of crossing vessels, and need for renal pelvic reduction were similar *Inclusion criteria:* Primary uretropelvic junction obstruction and scheduled for laparoscopic dismembered pyeloplasty *Exclusion criteria:* Previous ipsilateral renal surgery	Robotic Laparoscopic Mean 5.6 mos (too short to allow comparison of failures) Single surgeon performed all procedures; had previously performed >20 robotic procedures, including 3 for pyeloplasty.	*Operative outcomes contributing to cost differences:* Greater total room time for robotic procedures (173.8±15.4 min vs. 134.8±20.6 min, *P*<0.001) (total operative time [100.2±9.1 min vs. 80.7±21.9 min; P=0.018] and all other components were greater for robotic procedures; also, no robot docking or undocking time for laparoscopic procedures). No differences in complications or blood loss. No learning curve was detected. U.S. hospital (academic) perspective. All direct/indirect inpatient costs: (a)	Fair-quality cost analysis but poor-quality outcomes data No disclosure of conflicts of interest or funding source. Nonrandomized treatment assignment (although temporal bias unlikely given the short time frame);possible bias in favor of laparoscopic group if robotic procedures were the first for pyeloplasty; results would not generalize to smaller institutions unable to maintain the

					operating room (direct and indirect costs for second half 2004 from hospital accounting system); (b) anesthesia professional fees (2004 Medicare rates); (c) disposables (costs, not charges); (d) amortized cost of robotic system (5 years; assume 150 cases/year); and (e) amortized cost of laparoscopy video tower equipment (5 years; 400 cases/year). Factors that did not differ between robotic and laparoscopic in a previous cost comparison were excluded (e.g., surgeon professional fees, per diem hospital stay costs, analgesics, postoperative visits,	assumed volume of procedures

					and standard laparoscopic instruments used in both types of procedure). Operative data collected March-November, 2004. *Cost: Robotic; Laparoscopic* Total: $5324, $1990 (graphic display of SD values indicated no overlap in CIs) Mainly due to differences in total room time (134 min vs. 135 min, P<0.0001) and consumables: ($934 vs. $73; testing not reported) *One-way sensitivity analysis:* (a) Laparoscopic operative time (one component of total time) would have to	

					increase from 81 to 388 min for costs to be equivalent. (b) With elimination of robotic system depreciation costs, robotic surgery was still 1.7 greater than laparoscopic. (c) Increasing use of robotic system to 400 cases/year would decrease per-case depreciation costs from $2000 to $750.	

Rectopexy

Review				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Maeso 2010	SR 1 non-randomized controlled study N=33 Robotic n = 14 Laparoscopic n = 19 Heemskerk (n=33)	Robotic rectopexy Laparoscopic rectopexy	No meta-analysis performed (only 1 study identified) Length of surgery (min) Robotic = 39 minutes longer LOS = 4 days both groups Conversions: Robotic = 5% Laparoscopic = 0% Time to defecation, postoperative constipation or incontinence = NSD Cost = €600 more for robotic procedures	Good quality SR SR notes that study was not randomized or blinded, and that objective was clearly stated. Significant difference in age between treatment groups; effect on results not described. SR concludes that based on one study, robotic procedure is slower and more costly

Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Wong 2011	Retrospective cohort	63 Robotic, 23 Laparoscopic, 40	*Robotic; Laparoscopic* Mean age: 61±11 yrs; 59±13 yrs (NS) BMI: 27 kg/m2; 24 kg/m2 (*P*=0.03) Inclusion: Symptomatic complex rectocele; conservative treatments ineffective Exclusion: Complete rectal prolapsed; isolated internal rectal prolapse	Robotic Laparoscopic Follow-up: 6 mos	*Outcome: Robotic; Laparoscopic* Operating time: 221±39 mins/ 162±60 mins (*P*=0.0001) Blood loss: 6±23 mL; 45±91 mL (*P*=0.048) Conversion to open procedure: 1; 4 (NS) Postoperative complications: 0; 5 No mortalities or recurrences	Poor Retrospective; small sample size; patients assigned to robotic group based upon availability of robot; Robotics group had higher BMI
de Hoog 2009	Retrospective cohort	82 Robotic, 20 Laparoscopic, 15 Open, 47	Mean age: 56.4 yrs, range 21-88 Men/Women: 11/71	Robotic Laparoscopic Open Procedure Mean follow-up 1.95 yrs	*Outcome: Robotic; Laparoscopic; Open* Operating time: 154±47 mins; 119±31 mins; 77±33 mins (all analyses	Poor Retrospective; small sample size; varied

			Inclusion: Full-thickness rectal prolapse Exclusion: <18 yrs of age; patients with history of extensive abdominal surgery were ineligible for robotic or laparoscopic procedures		*P*≤0.02) HLOS: 2.6 days, range 1-6; 3.5 days, range 1-14; 5.7 days, range 2-30 (*P*<0.001) Recurrence: 20%; 27%; 2% (*P*=0.008) OR for recurrence: laparoscopic vs. open, 13.94 (95% CI 0.9, 215.6); robotic vs. open, 24.41 (95% CI 1.45, 410.7)	entry criteria for different surgical methods; operative data not presented per procedure type

Roux-en-Y Gastric Bypass

Review				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Maeso 2010	SR/MA 1 RCT 3 non-randomized comparative studies N=321 Robotic n = 121 Laparoscopic n = 200 Sanchez (n=50) Hubens (n=90) Artuso (n=161) Mohr (n=20)	Roux-en-Y robotic Roux-en-Y laparoscopic	**<u>Meta-analysis results:</u>** Total conversions: OR = 9.46 (1.72, 52.15) favoring laparoscopy Surgery time (min) MD = 10.12 (-69.86, 90.11) NS Complications OR = 0.58 (0.21, 1.64) NS Open conversions RD = 0.06 (-0.04, 0.16) Outcomes reported in SR but not included in MA: Cost: Robotic €1,000 more expensive	Good quality SR Sanchez RCT rated as good quality by SR; other three studies not randomized or blinded. Artuso and Hubens did not compare baseline characteristics. SR concludes robotic and laparoscopic procedures have similar surgery times, length of stay, number of complications, but robotic procedure has more surgical conversions

Reference	Study Design	Sample size	Patient Characteristics	Intervention Comparator Follow-up	Outcomes Assessed Main Findings	Quality Comments
					Learning curve: Mohr: Robotic learning curve less steep than laparoscopic Sanchez: Surgery time in continuous groups of 10 patients, Robotic/Laparoscopic (min): 154, 124, 99 / 163, 141, 139 Artuso: learning curve present (data not reported) Hubens: last 10 robotic patients similar to laparoscopic (136m vs. 127m)	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Ayloo 2011	Chronologically determined controls (45 laparoscopic procedures followed by 90	135 Robotic, 90 Laparoscopic, 45	*Robotic; Laparoscopic* Mean age: 39±9 yrs; 43±8 yrs (*P*=0.01) Men/Women:	Robotic Laparoscopic Follow-up: 1 yr	*Outcome: Robotic; Laparoscopic* Operating time: 207±31 mins; 227±31 mins (*P*=0.0006) HLOS: 2; 3	Poor Financial disclosure was not reported Retrospective review;

	robotic over 3-year time frame)		12/78; 3/42 (NS) BMI: 48 kg/m^2; 46 kg/m^2 (NS) Weight: 137±23 kg; 132±21 kg (NS) Inclusion: Morbid obesity; surgical indication criteria of NIH Exclusion: Not reported		(*P*=0.0002) Reoperation: 1; 1 (NS) Readmission: 5; 1 (NS) Early morbidity: 1.1%; 1.2% (NS) Late morbidity: 1.1%; 8.8% (*P*=0.04) There were no conversions to open surgery, transfusions, or fatalities. Difference between groups in weight loss at 3 mos, 6 mos, and 1 yr was not statistically significant	noncontemporaneous controls; patients in robotic group were slightly younger and slightly more obese than laparoscopic group; choice of surgical method was made chronologically; weight loss data not reported for laparoscopic group; no data on comorbidities
Park 2011	Retrospective cohort	300 Robotic: 105 Laparoscopic: 195	*Robotic; Laparoscopic* Mean age: 42.2±11 yrs; 43.9±10.9 yrs (NS) Men/Women: 22/83; 54/141 (NS) BMI: 46.8	Robotic Laparoscopic Follow-up: 1 yr	*Outcome: Robotic; Laparoscopic* Operating time: 169±38 mins; 152±50 mins (*P*=0.003) Blood loss: 59.0±43.8 mL; 57.2±45.9 mL (NS) HLOS: 3.4 days; 3.0 days (NS)	Poor One author receives honoraria from a manufacturer of surgical instruments Retrospective; procedure for assigning patients to

			kg/m²; 47.7 kg/m² (NS) Comorbidities and ASA were similar Inclusion: Morbid obesity Exclusion: Not reported		Conversion to open procedure: 0; 3 (1 robotic procedure was converted to a laparoscopic procedure) Complications: 9.5%; 9.7% (NS) Follow-up: 61.9%; 66.2% Weight loss at 1 yr: 61.9%; 61.3% (NS) Total hospital charges: similar (no detail provided)	surgical method was not reported; high dropout rate for 1-year results
Sanchez 2005 (analyzed by BMI)	Randomized, controlled trial	50 Robotic: 25 Laparoscopic: 25	Robotic; Laparoscopic Median age: 43.3 yrs, range 27-58; 44.4 yrs, range 20-59 (NS) Men/Women: 2/23; 3/22 BMI: 45.5 kg/m²; 43.4 kg/m² (NS) Comorbidities and history of prior	Robotic Laparoscopic No follow-up	*Outcome: Robotic; Laparoscopic* Operating time: 130.8 min; 149.4 min (*P*=0.02) Operating time/BMI: 2.94; 3.47 (*P*=0.02) Operating time in patients with BMI >43 kg/m²: 123.5 mins; 153.2 mins (*P*=0.009) Operating time/BMI in patients with BMI >43 kg/m²: 2.49; 3.24	Good Financial disclosure was not reported Small sample size; randomization and concealment method were not reported;

			abdominal surgery were similar Inclusion: Surgical indication criteria of NIH Exclusion: Not reported		(*P*=0.009) HLOS: 2.72; 2.72 (NS) 1 robotic procedure was converted to a laparoscopic procedure No postoperative complications	
Hagen 2011	Retrospective cohort with cost analysis	N=990 Open n=524 Laparoscopic n=323 Robotic n=143	NS differences in age, gender, BMI between all three groups Significant differences between open and robotic groups in ASA scores (robotic group having lower scores); NS difference between laparoscopic and robotic groups Cost inputs:	Laparotomy Laparoscopic Robotic	NS differences between all groups in overall complications, pulmonary complications, death, bleeding, wound infections, neurologic complications, other complications NS differences between open and robotic groups in anastomotic leaks, anastomotic strictures, or reoperations Laparoscopic vs.	Poor quality cohort Poor quality cost analysis Authors declare employment and consult work with Intuitive; differences in ASA scores at baseline (robotic patients were healthier), possibly introducing bias in favor of robotic group; retrospective study design. Temporal distribution between groups not discussed, but study

			OR material costs Laparotomy, laparoscopy, robotic Drapes 112.84; 147.36; 546.22 Staplers 1860.95; 3560.83; 1860.95 Other instruments 187.1; 1737.84; 1368.01 Robot-specific costs = 1582.91 Suturing material 90.45; 48.076; 69.37 Total costs 2251.34;		robotic, p-value Anastomotic leaks, n (%) 13 (4.0) vs. 0 (0), p=0.0349 Anastomotic strictures, n (%) 22 (6.8) vs. 0 (0), p=0.0002 Conversions, n (%) 16 (4.9) vs. 2 (1.4), p=0.0388 Reoperations, n (%) 13 (4.0) vs. 1 (0.7), p=0.0349 Hospitalization outcomes Laparotomy; laparoscopy; robotic ICU stay, mean 2.0; 0.6; 0.2, p<0.0001 (open vs. robotic), p=0.0517 (laparoscopic vs. robotic)	period included cases post-1997, possibly introducing bias towards robotic group, which was likely operated on more recently. No discussion of surgeon experience between groups, which may introduce bias of unknown direction. Cost analysis limitations include use of only direct costs, only selected variables included in sensitivity analysis, unknown source of cost inputs, potential differences in health system costs (data from Switzerland) when compared to US practice

			5494.11; 5427.46		Length of hospital stay: 10.9; 11.0; 7.4, p<0.0001 (open vs. robotic), p=-0.001 (laparoscopic vs. robotic) Cost analysis findings Laparotomy; laparoscopy; robotic Baseline costs $23,000; $21,697; $19,363 Robotic procedure cheaper when at least 7 procedures performed, assuming anastomotic leak rate of 4%; 10 robotic procedures must be performed if laparoscopic leak rate reduces to 2% With 4% leak rate, OR time could be up to 135 minutes longer without	

					exceeding costs of laparoscopy; 30 minutes longer with 2% leak rate	

Sacrocolpopexy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Reza 2010	SR/MA 1 prospective study using historical controls N = 178 Robotic n = 73 Open n = 105 Geller 2008 (n = 178)	Robotic sacrocolpopexy Open sacrocolpopexy	Meta-analysis not performed (only 1 study identified) Outcomes reported in SR: EBL (mL) [SD] Robotic = 109 [93] Open = 255 [155] P<0.001 HLOS (days) Robotic = 1.3 [0.8] Open = 2.7 [1.4] P<0.001 Duration of surgery (min) Robotic = 328 [55] Open = 225 [61] P<0.001 Postoperative fever Robotic = 4% Open = 0%	Good quality SR SR notes that study was not randomized or blinded, but had a clear objective. No other quality indicators discussed.

			P<0.04	

Individual studies (published after review)

Reference	Study Design	Sample size	Patient Characteristics	Intervention Comparator Follow-up	<u>Outcomes Assessed</u> Main Findings	Quality Comments
Paraiso 2011	Randomized, controlled trial	78 Robotic, 40 Laparoscopic, 38	*Robotic; Laparoscopic* Mean age: 61±9 yrs; 60±11 yrs BMI: 29 kg/m^2; 29 kg/m^2 History of pelvic surgery was similar Inclusion: Posthysterectomy vaginal apex prolapsed; ≥21 yrs of age; preferred laparoscopic method Exclusion: History of sacrocolpopexy; pelvic inflammatory disease; morbid obesity; rectal prolapsed	Robotic Laparoscopic Follow-up: 1 yr	*Outcome: Robotic; Laparoscopic* Operating time: 265±50 mins; 199±46 mins (95% CI 43, 90) Conversion to another procedure: 3; 2 (NS) HLOS: 43 hrs; 34 hrs (95% CI -4, 23) Total healthcare system cost : $16,278±3326; $14,342±2941 (*P*=0.008; 95% CI 417, 2941); driven by difference in operating room cost ($1667; 95% CI 448, 2885; P=0.008) Costs of hospitalization and 6-wk postoperative care were similar. Cost data in 2011 U.S. dollars collected	Fair Small sample size; high 1-year dropout rate

					health from system-wide (multispecialty clinic) accounting system; all direct and indirect costs, except initial purchase and maintenance of robotic system, for procedure related care through 6-week postoperative visit were included. Intraoperative and postoperative complications were similar Narcotic use, return to daily activities, anatomic outcome, and quality-of-life measures were similar Patients in robotic group reported significantly more pain and used more NSAIDS at 3-5 wks postoperatively than the laparoscopic group (all analyses *P*≤0.04)	
White 2009	Retrospective	30	*Robotic;*	Robotic	*Outcome: Robotic;*	Poor (especially for 6-

	cohort with matched controls (cases were single port procedures from a prospectively collected database; robotic and laparoscopic were retrospectively matched)	Robotic, 10 Laparoscopic, 10 Single port, 10	*Laparoscopic; Single port* Mean age: 61.3 yrs; 62.5 yrs; 59.5 yrs (NS) BMI: 26.0 kg/m^2; 27.6 kg/m^2; 25.8 kg/m^2 (NS) Prior prolapse surgery and prolapse stage were similar Inclusion: Symptomatic ≥stage II pelvic organ prolapse Exclusion: Not reported Patients in robotic and laparoscopic group chosen by age and BMI matching to single port group	Laparoscopic Single port laparoscopy Follow-up: 6 mos	*Laparoscopic; Single port* Operating time: 150±16 mins; 151±19 mins; 162±25 mins (NS) Blood loss: 87 mL; 65 mL; 47.5 mL (P=0.5) HLOS: 1.6 days; 1.6 days; 1.5 days (NS) Reoperation: 0; 0; 3 No complications 90% of patients completed follow-up (treatment group was not specified) At follow-up, all patients reported symptom relief and had excellent prolapsed reduction based upon pelvic organ prolapsed questionnaire.	mo outcomes) Financial disclosure was not reported Retrospective; noncontemporaneous controls (but short time frame); small sample size; follow-up data not shown; standard deviation was not always reported
Patel 2009	Retrospective cohort	15 Robotic, 5 Laparoscopic,	*Robotic; Laparoscopic; Open*	Robotic Laparoscopic Open	*Operative outcomes: Robotic; Laparoscopic; Open*	Fair-quality cost analysis Poor-quality

		5 Open, 5	Median age: 58, 58, 56 Median BMI: 28, 24, 28 # vaginal deliveries: 3, 2, 3 Prolapse stage and # prior prolapsed surgeries: Same across groups Inclusion criteria: None other than sacrocolpopexy Exclusion criteria: Concurrent hysterectomy, other, incontinence procedures, or other types of pelvic reconstruction (concurrent paravaginal defect repair or Burch, posterior colporrhaphy, or cystourethroscopy		Blood loss (cc): 210±74.2, 150±61.2, 235±134.2 (NS) Operative time (min): 358±86, 510±372, 418±249 (NS) # nights in hospital: 2±0, 3±1.3, 3±2.7 (NS) Cost-minimization analysis, assuming equivalent follow-up outcomes, was conducted. Costs included all direct and indirect costs associated with procedure and inpatient stay. Data from procedures performed 2002 through 2007 were inflation-adjusted using Consumer Price Index. *Costs: Robotic; Laparoscopic; Open* Operating room, direct:	outcomes data Retrospective and nonsystematic treatment assignment; very small sample size; patients undergoing laparoscopy were less obese; 56 of 71 sacrocolpopexies were excluded because of concurrent procedures, so results may not be generalizable to typical practice; costs adjusted by general rather than medical index

			was eligible)		\$4520.63±1874.59; \$3141.79±2130.00; 1594.22±353.14 (global *P*=0.48)* Instruments/materials, direct: \$2207.88±292.69; \$1940.55±514.79; \$465.01±553.36 (global *P*=0.0001)* Anesthesia, direct: \$426.93±121.09; \$503.82±73.56; \$36.00±126.49) (NS) Miscellaneous, direct: \$136.51±28.43; \$186.15±181.32; \$152.27±108.12 (NS) Hospital room, direct: \$853.39±18.26; \$1043.21±420.98; \$959.30±405.19 (NS) Indirect: Comparable between robotic and laparoscopic; slightly greater than open but difference NS. Total direct and indirect:	

					\$12,525.50±2519.38; \$11,093.90±6123.73; \$6816.90±1696.79 (global *P*=0.098) *Robotic and laparoscopic significantly greater than open Charges: \$24,162; 19,309; \$13,150 (global *P*=0.004) Reported profits followed the same pattern as total costs and charges, but the method of calculation was not clear.	
Judd 2010	Cost-minimization analysis; decision analytic model (equivalent clinical effectiveness assumed, based on a previously published retrospective	N/A	Hypothetical cohort of women with advanced pelvic organ prolapse electing sacrocolpopexy with synthetic polypropylene mesh. Model included 4 outcomes: (a) operative time; (b) possibility for	Robotic Laparoscopic Abdominal (open) No follow-up after discharge	U.S. healthcare system perspective, 2008 dollars. Professional fee costs derived from Medicare rates for professional anesthesia and surgeon services. All other inpatient costs incurred at Duke medical center: peri- and postoperative services; disposables;	Poor Outcome and cost data from different sources; no data on assumed surgical risk of patients (possibly unreliable operative outcome estimates); unclear whether fixed costs were included; absolute results would not generalize

	cohort study [Geller 2008] showing equivalent vaginal vault support at 6 weeks between robotic and abdominal approach and the similarity of the procedure performed through the 3 different routes)		both robotic and laparoscopic procedures of conversion to an abdominal (open) procedure; (c) blood transfusion (but not enterotomy or ureteral injury); (d) HLOS. Parameters (base case values and ranges for sensitivity analyses) for these outcomes were derived from 7 observational studies identified in a systematic literature review (PubMed; February 2009) and from expert opinion where necessary; key sources were Geller 2008 and		transfusion packs; extra time and fewer laparoscopic instruments for conversion (calculated differently for early* and late conversions); laboratory; pharmacy (varied according to surgical approach; Medicare Part B maximum allowable and online prices); room and board (billing department); robotic system purchase ($1.65M) plus maintenance years 2-5 ($149,000/year), amortized over 7 years with 5% interest rate and distributed to each procedure, assuming 24 robotic procedures/month (robotic system costs excluded from the Existing Robot Model). Cost-charge ratio of	to smaller institutions with lower volumes of robotic procedures

			Paraiso 2005.		0.6 applied where necessary. *Total cost: Robotic; Laparoscopic; Abdominal* Existing Robot Model (hospital already owns): $8508, $7353, $5792. Only extreme reduction in robotic operative time or extreme reduction in robotic disposables combined with extreme increase in laparoscopic disposables predicted equivalent cost between robotic and laparoscopic Robot Purchase Model: $9962, $7353, $5792 Sensitivity analyses showed no situations in which robotic became less expensive than laparoscopic.	
Tan-Kim 2011	Retrospective	104	*Robotic;*	Robotic	*Outcome: Robotic;*	Poor

	cohort	Robotic, 43 Laparoscopic, 61	*Laparoscopic* Mean age: 60 + 8 yrs; 65 + 8 yrs (p<0.01) History of pelvic surgery (not including hysterectomy) was similar Inclusion: women with post-hysterectomy sacroplexy using one of minim Exclusion: History of concurrent hysterectomy and/or anterior vaginal wall repair	Laparoscopic Follow-up data recorded at 3 wks and all follow-up visits (variable length 6-12 mos.)	*Laparoscopic* Operation time: 281 + 58 mins; 206 + 42 mins (p< 0.001) Costs: Robotic surgery costs significantly higher than laparoscopic (p<0.01;for 2724 vs. 2295 standard "cost units"). Cost for hospital stay were similar. Median hospital stay, mean follow-up and patients with mesh erosion were similar Complications (intraoperative and postoperative) were similar.	small sample size; limited long term follow-up outcomes; CIs not provided; no financial disclosure
Seror 2011	Prospective cohort	67 Robotic, 20 Laparoscopic, 27	*Robotic; Laparoscopic* Mean age: 60 yrs;	Robotic Laparoscopic Follow-up at 1,	*Outcome: Robotic; Laparoscopic* Blood loss: 55 vs. 280	Poor Different baseline population

			66.7 (p=0.05) BMI and history of gynecological surgery were similar	3, 6 mos and annually. Also as needed for urinary symptoms	ml (median) (p= 0.03) Operation time (125 vs. 220 min. p = 0.03) but overall operation room time similar No significant difference between hospital stay, amount of pain medicines, hospital stay or median length of follow-up	characteristics Small sample size Different baseline populations Short term outcomes

Splenectomy

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Bodner 2005	Retrospective cohort	12 Robotic, 6 Laparoscopic, 6	*Robotic; Laparoscopic* Median age: 42 yrs; 62 yrs (NS) Women/Men: 2/4; 0/6 BMI: 27 kg/m^2; 26.3 kg/m^2 ASA score, platelet counts, and previous abdominal surgery were similar Inclusion: First 6 robotic or first 6 laparoscopic splenectomies by surgeon Exclusion: Not reported	Robotic Laparoscopic Mean follow-up: Robotic, 11 mos; Laparoscopic, 21 mos	*Outcome: Robotic; Laparoscopic* Operating time: 154 mins, range 115-292; 127 mins, 95-174 (P<0.05) HLOS: 7; 6 (NS) Blood loss was similar There were no conversions to open surgery or major complications 1 pt in laparoscopic group died 14 mos postoperatively (unrelated to splenectomy) All other patients were asymptomatic relative to surgery Overall procedural cost: $6927; $4084 ($P$<0.05) Cost difference attributed to longer operation time, use of special instruments, and	Poor Financial disclosure not reported Retrospective; very small sample size

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
					disposable supplies (total $2843) in robotic group. Initial cost of robotic system was not added into cost determinations but maintenance costs were included.	

Thymectomy

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Ruckert 2011	Retrospective cohort w/ historic controls (79 thoracoscopic procedures followed by 74 robotic over 12-year time frame)	153 Robotic, 74 Thoracoscopic, 79	*Robotic; Thoracoscopic* Median age: 39 yrs, range 7-75; 37 yrs, range 11-74 Men:Women ratio: 1:1.3; 1:2.4 Myasthenia gravis severities were similar Inclusion: Myasthenia gravis Exclusion: Not reported	Robotic Thoracoscopic 42 mos	*Outcome: Robotic; Thoracoscopic* Operating time: 187±48 mins; 198±48 mins Conversion to sternotomy: 1; 1 Postoperative morbidity: 2.7%; 2.5% No mortality at 30-days Bleeding incidence and phrenic nerve resections were similar Histologic findings were similar with exception of follicular hyperplasia, which was more prevalent in thoracoscopic group (45% vs. 68%) Complete remission	Fair Retrospective; noncontemporaneous controls; limited patient characteristics; statistical analyses not reported

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
					at follow-up: 39.3%; 20.3% (*P*=0.01)	
Cakar 2007	Retrospective cohort with historic controls (10 sternotomy procedures followed by 9 robotic over 10-year time frame)	19 Robotic, 9 Open, 10	Age, sex distribution, BMI, ASA score, myasthenia gravis classification were similar (data not shown) Inclusion: Thymectomy for myasthenia gravis Exclusion: Not reported	Robotic Open 12 mos	*Outcome: Robotic; Open* Operating time: 154 min, range 94-312; 110 mins, range 42-152 (*P*<0.05) HLOS: 5 days; 10 days (*P*<0.05) Postoperative complications: 1; 3 Reoperation: 0; 2 Follow-up: 13±10 mos; 74±23 mos Thymoma: 44%; 30% Disease improvement at follow-up: 9/9; 8/10 There were no major complications and blood loss was <50 mL in all cases There were no conversions to open surgery	Poor Financial disclosure not reported Retrospective; small sample size; noncontemporaneous controls; patient characteristic data were not shown; statistical significance of data not always reported

Thyroidectomy

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Lang 2011	Retrospective cohort	46 Robotic, 7 Endoscopic, 39	*Robotic; Endoscopic* Mean age: 43.4 yrs, range 20.2-54.7; 44.4 yrs, range 20.3-58.3 (NS) Men/Women: 0/7; 1/38 (NS) Size of largest nodule: 1.6 cm, range 0.5-3; 2.5 cm, range 0.8-3.5 (NS) Inclusion: <60 yrs of age; benign nodule <4 cm or malignant nodule <2 cm Exclusion: Not reported	Robotic Endoscopic 6 mos	*Outcome: Robotic, Endoscopic* Operating time: 149 mins, range 92-190; 100 mins, range 50-220 (*P*=0.018) Time for first 7 cases: 149 mins, range 92-190; 120 mins, range 95-220 (*P*=0.004) Conversions to open procedure: 0; 1 (NS) Blood loss: 30 mL, range 20-60; 20 mL, range 10-60 (NS) Weight of excised thyroid: 11.3 g, range 6-67.1; 19 g, range 10.7-37 (*P*=0.021) HLOS: 2 days; 2 days (NS) Pain score day 0: 4; 2 (*P*=0.025) Pain score day 1: 2; 2	Poor Retrospective, small sample size; patients chose surgical method; robotic group had significantly fewer patients; robotic group composed of first patients to be treated with robotic surgery at institution

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
					(NS) Extent of resection, final pathology, and surgical complications were similar Robotic surgery cost approximately $1300 more than endoscopic surgery (details not provided)	
Lee 2011c	Retrospective cohort	411 Robotic, 174 Open, 237	*Robotic; Open* Mean age: 39.9±8.8 yrs; 51.1±11.1 yrs (*P*<0.001) Women: 88.5%; 78.9% (*P*=0.012) BMI: 22.9 kg/m2; 23.9 kg/m2 (*P*<0.001) Inclusion: Total thyroidectomy with central node dissection; papillary thyroid	Robotic Open No follow-up	*Outcome: Robotic; Open* *Radioablation sessions: 1.95±0.49; 2.05±0.51 (*P*=0.05) * Mean total RAI ablation dose (mCi): 62.2±19.1; 66.8±27.3 (NS) * Measures of surgical completeness Matched pairs had similar clinical parameters of surgical completeness (thyroid	Fair Financial disclosure not reported Retrospective; robotic group was younger, had more women, had lower BMI, and had less advanced disease; perioperative

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			carcinoma; radioactive iodine ablation Exclusion: Not reported Operative findings: Tumor size, prevalence of multifocality, lymph node metastasis, and T-stage were similar. Robotic group more likely to be stage I disease and open group more likely to have stage III disease (*P*<0.001). Authors also generated subgroup of		bed-to-background ratio of radioactive iodine uptake, thyroglobulin levels on first radioactive iodine scan, and total number of ablation sessions or dose needed to ablate remnant thyroid)	data not reported

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			matched cases (108 pairs) based upon propensity scores derived from 8 criteria (3 demographic and 5 pathologic)			
Kim 2011b	Retrospective cohort	302 Robotic, 69 Endoscopic, 95 Open, 138	*Robotic; Endoscopic; Open* Mean age: 41.3±7.8 yrs; 39.9±9.1 yrs; 51.8±8.9 yrs (Open group older, *P*<0.001) Men/Women: 6/63; 2/93; 34/104 (Robotic vs. Open, *P*=0.005) BMI: 22.7 kg/m2; 22.7 kg/m2; 24.4	Robotic Endoscopic Open No follow-up	*Outcome: Robotic; Endoscopic; Open* Operating time: 3:16±0:45 hrs; 2:16±0:31 hrs; 1:21±0:16 hrs (all analyses *P*<0.001) Tumor size: 0.6±0.2 cm; 0.6±0.2 cm; 0.7±0.2 cm (Open group vs. other groups, *P*=0.038) HLOS: 3.1±0.7 days; 3.1±0.9 days; 2.8±0.9 days (NS) Number of retrieved nodes and metastatic nodes was similar There were no	Poor Financial disclosure not reported Retrospective; criteria for determining surgical method were not reported; Significant differences in patient age, sex ratio, and BMI between

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			kg/m2 (Robotic vs. Open, *P*<0.001) Inclusion: Total thyroidectomy and ipsilateral central lymph node dissection; <1 cm papillary thyroid carcinoma Exclusion: Lobectomies; poorly differentiated cancer; bilateral lymph node dissection; distant metastasis; invasion to adjacent organs Patients with severe		conversions to open surgery Complications were similar	robotic and open groups; thyroiditis more likely in open group; data on complications was obtained via telephone interview of patients; no follow-up

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			thyroiditis was relative contraindication for robotic or endoscopic surgery.			
Lee 2011b	Retrospective cohort	259 Robotic, 163 Endoscopic, 96	Robotic; Endoscopic Mean age: 38.7±8.2 yrs; 39.9±6.5 yrs (NS) Men/Women: 6/157; 2/94 BMI: 22.9 kg/m^2; 23 kg/m^2 (NS) Bilateral total thyroidectomy: 29.4%; 2.1% (global *P*<0.001 No lymph node dissection: 6.8%, 45.8% (global *P*<0.001*)* Operative findings: Benign lesions:	Robotic Endoscopic Min 3 mos	*Outcome: Robotic; Endoscopic* Operating time: 110.1±50.7 mins; 142.7±52.1 mins (*P*=0.041) Blood loss: 4.5±3.8 mL; 5.1±3 mL (NS) HLOS: 2.8 days; 3.2 days (NS) Postoperative complications: 11%; 10.4% (NS) HLOS: 3.2±1.9 days; 2.8±1.1 days (NS) Learning curve was less steep for robotic procedure. Dissected lymph nodes: 4.5±1.5; 2.4±1.9	Poor Financial disclosure not reported Retrospective; robotic group had more severe disease than endoscopic group; authors did not discuss whether 6-12 months was sufficient follow-up to determine recurrence

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			6.7%; 42.7% (*P*<0.001) Pathology measures were similar except for significantly greater presence of adenomatous hyperplasia in endoscopy group Inclusion: Follicular neoplasm tumor ≤5 cm; differentiated thyroid carcinoma tumor ≤2 cm Exclusion: Previous neck surgery; severe Graves' disease; malignancy with		(*P*=0.004) There were no conversions to open procedure At 3-6 mos follow-up, serum thyroglobulin and antithyroglobulin antibody levels were similar; At 6-12 mos, there was no tumor recurrence. Operating time steady state achieved after 35-40 cases of robotic and 55-60 cases of endoscopic thyroidectomy.	rates or how many patients were followed this long.

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			extrathyroid invasion or distant metastasis; lesion in dorsal thyroid			
Lee 2010	Prospective cohort	84 Robotic, 41 Open, 43	Robotic; Open Mean age: 39±7 yrs; 37.7±6.5 yrs (NS) Men/Women: 3/38; 3/40 (NS) Inclusion: Follicular thyroid carcinoma ≤4 cm; papillary thyroid carcinoma ≤2 cm Exclusion: Previous neck surgery; 21-65 yrs of age; vocal fold paralysis; voice or	Robotic Open 3 mos	*Outcome: Robotic; Open* Operating time: 128.6±36.3 mins; 98±22.2 mins (*P*=0.001) Blood loss: 3.5±3 mL; 4.9±3.6 mL (P=0.54) HLOS: 2.5 days; 3.2 days (NS) Hyperesthesia or paresthesia of neck at 1 wk: 36.6%; 95.3% (*P*=0.01) and at 3 mos: 9.8%; 65.1% (*P*=0.002) Complications were similar Analgesic use and pain scores were similar Patients in robotic group Swallowing impairment	Poor Small sample size; patients chose surgical method

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			laryngeal disease requiring therapy; malignancy with extrathyroid invasion; distant metastasis; lesion in dorsal thyroid Tumor characteristics: Multiplicity, bilaterality, tumor size and stage, and number of metastatic lymph nodes were similar		index at 1 wk: 7.2±2.9; 14.1±5.4 (*P*=0.001) and at 3 mos: 4.7±2.2; 9.3±4.6 (*P*=0.007) Voice handicap index was similar at all times	

Trachelectomy

Individual studies

Reference	Study Design	Sample size	Patient Characteristics	Intervention Comparator Follow-up	Outcomes Assessed Main Findings	Quality Comments
Nick 2012	Retrospective cohort	37 Robotic, 12 Open, 25	Robotic; Open Mean age: 29.8 yrs, range 25.3-33.3; 28.7 yrs, range 21.4-37.2 (NS) Parity, Tumor stage, Tumor histology were similar (NS) Inclusion: Early stage cervical Ca with desire for fertility Exclusion: NR	Robotic Open Median follow-up 17.0 months (range 0.30-64.9 months)	Outcome: Robotic; Open Operating time: 294 mins, range 207-379; 328 mins, range 203-392 (NS); Blood loss: 62.5 mL, range 25-450; 300 mL, range 50-1100 (*P*=0.0001) HLOS: 1 day range 1-2; 4 range 3-9 (*P*<0.001); Transfusion rate similar (NS); Rate of conversion to hysterectomy: 4 (33%); 1 (4%) (p=0.03) Morbidity <30 days similar for fever, UTI, and retention (NS); Morbidity >30 days overall: 1 (13%); 14 (58%) (p=0.07)	Good Retrospective; small sample size; Authors conclusion: Reduced blood loss, and LOS but concerned with high conversion rate to hysterectomy in fertility seeking women

Vesico-vaginal Fistula

Individual studies

Reference	Study Design	Sample size	Patient Characteristics	Intervention Comparator Follow-up	Outcomes Assessed Main Findings	Quality Comments
Gupta 2010	Retrospective cohort with matched controls	32 Robotic, 12 Open, 20	Robotic; Open Mean age: 27.1 yrs, range 16-46; 27.5 yrs, range 18-44 (NS) Parity, previous delivery location, cause of fistula, history of surgical repair, and fistula size were similar Inclusion: Recurrent vesico-vaginal fistula Exclusion: Not reported	Robotic Open No follow-up	Outcome: Robotic; Open Operating time: 140 mins, range 110-180; 148.5 mins, range 100-210 (NS) Blood loss: 88 mL, range 50-200; 170 mL, range 110-400 ($P<0.05$) HLOS: 3.1 days; 5.6 days ($P<0.05$) Complications: 0; 2 (NS) Success: 100%; 90% (NS)	Poor Retrospective; small sample size; matching process and criteria unclear

Appendix E. Guideline Summary Table

Recommending Body, Year Published	Recommendation(s)[1]	Evidence Base Quality
American Urological Association (2010) *Guideline on the Management of Benign Prostatic Hyperplasia (BPH)*	*Surgical Procedures* *Laparoscopic and Robotic Prostatectomy p.22* Option: Men with moderate to severe LUTS and/or who are significantly bothered by these symptoms can consider a **laparoscopic or robotic prostatectomy**. There are insufficient published data on which to base a treatment recommendation. [Based on review of the data and Panel consensus.]	*Systematic review* **Poor**
European Association of Urology (2011) *Guidelines on Bladder Cancer Muscle-invasive and Metastatic*	*7.5 Conclusions on urinary diversion after radical cystectomy p.31* **Laparoscopic and robotic-assisted laparoscopic cystectomy** is feasible but still investigational. Level of Evidence: 3 [Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports] *7.6.1 Recommendations for radical cystectomy* **Laparoscopic and robotic-assisted laparoscopic cystectomy** may be options. However, current data have not sufficiently proven the advantages or disadvantages of laparoscopic cystectomy. Grade: C [Made despite the absence of directly applicable clinical studies of good quality]	*Systematic review* **Fair**
NCCN (2011) *Esophageal and esophagogastric junction cancers*	*Principles of Surgery p.26* Acceptable operative approaches for resectable esophageal and esophagogastric junction cancer: • **Robotic minimally invasive esophagogastectomy**	*Systematic review* **Fair**
NCCN (2012) *Kidney cancer*	*Principles of Surgery p.9* **Open, laparoscopic, or robotic surgical techniques** may be used to perform radical and partial nephrectomies. Grade: Category 2A [Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.]	*Systematic review* **Fair**
NCCN (2012) *Prostate Cancer*	*Principles of Surgery p.17* Pelvic Lymph Node Dissection (PLND): can be performed using an open, **laparoscopic or robotic technique**. Grade: Category 2A [Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.]	*Systematic review* **Fair**

[1] The information provided is not meant to describe indications for surgery. It simply notes references to robotic surgery in coordination with guideline recommendations.

Recommending Body, Year Published	Recommendation(s)[1]	Evidence Base Quality
	Radical Prostatectomy: **Laparoscopic & robotic-assisted radical prostatectomy** are used commonly. In experienced hands, the results of these approaches appear comparable to open surgical approaches.	
NICE (2008) *Totally endoscopic robotically assisted coronary artery bypass grafting*	*1 Guidance p.1* 1.1 Current evidence on the safety and efficacy of **totally endoscopic robotically assisted coronary artery bypass grafting** does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake **totally endoscopic robotically assisted coronary artery bypass grafting** should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the public* is recommended. • Enter all patients having totally endoscopic robotically assisted coronary artery bypass grafting onto the UK Central Cardiac Audit Database.	*Systematic review* **Fair**
NICE (2008) *Laparoscopic prostatectomy for benign prostatic obstruction*	*1 Guidance p.1* 1.1 Current evidence on the safety and efficacy of laparoscopic prostatectomy for benign prostatic obstruction (BPO) is inadequate in both quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake laparoscopic prostatectomy for BPO should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy, make them aware of alternative treatment options and provide them with clear written information. 1.3 This procedure should only be carried out by surgeons with special training and experience in laparoscopic radical prostatectomy. 1.4 Patients should only be offered this procedure if they would otherwise be considered for open prostatectomy, rather than transurethral resection, for BPO. *2.2 Outline of the procedure* 2.2.1 **Laparoscopic prostatectomy is performed with the patient under general anaesthesia, using either a transperitoneal or an extraperitoneal approach, with or without computer (robotic) assistance**.	*Systematic review* **Fair**
NICE (2008) *Prostate cancer: diagnosis and treatment*	*4.4 Initial Treatment Options p.24* The treatment options for men with localised prostate cancer are:	*Systematic review* **Good**

Recommending Body, Year Published	Recommendation(s)[1]	Evidence Base Quality
	• **Radical prostatectomy (open, laparoscopic or robotically assisted laparoscopic)** *Recommendations p.27* • Healthcare professionals should offer radical prostatectomy or radical radiotherapy (conformal) to men with intermediate-risk localised prostate cancer. • Healthcare professionals should offer radical prostatectomy or radical radiotherapy (conformal) to men with high-risk localised prostate cancer where there is a realistic prospect of long-term disease control. Qualifying statement: There is no strong evidence for the benefit of one treatment over another. Relatively little health gain is required for these interventions to become demonstrably cost-effective.	
NICE (2009) *Endopyelotomy for pelviureteric junction obstruction*	*1 Guidance p.1* 1.1 Current evidence shows that endopyelotomy for pelviureteric junction (PUJ) obstruction is efficacious in the short and medium term although there is a risk of obstruction recurrence in the long term. The evidence on safety raises no major concerns. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 This procedure should be carried out only in units with specific expertise in endopyelotomy for PUJ obstruction, by specialist teams who can offer a range of procedures including laparoscopic pyeloplasty. *2 The procedure* 2.1 Indications and current treatments 2.1.2 Conservative treatment may include long-term use of low-dose antibiotics. Current surgical options to reconstruct and normalise the anatomy of the PUJ include **open or laparoscopic pyeloplasty (with or without robotic assistance)** and electrocautery cutting balloon treatment.	*Systematic review* **Fair**
NICE (2009) *Laparoscopic cystectomy*	*1 Guidance p.1* 1.1 Current evidence on the safety and efficacy of laparoscopic cystectomy appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 Patient selection for laparoscopic cystectomy should involve a multidisciplinary team experienced in the management of bladder cancer. 1.3 Clinicians undertaking laparoscopic cystectomy should have special training. The British Association of Urological Surgeons (BAUS) has produced training standards. 1.4 Clinicians should submit data on all patients undergoing this procedure to the BAUS Cancer Registry & Sections Audit with a view to further publication on long-term survival outcomes. *2.2 Outline of the procedure* 2.2.4 There are various ways of carrying out **laparoscopic cystectomy and the procedure may be performed**	*Systematic review* **Fair**

Recommending Body, Year Published	Recommendation(s)[1]	Evidence Base Quality
	with computer (robotic) assistance.	
NICE (2006) *Laparoscopic radical prostatectomy*	*2.2 Outline of the procedure p.1* 2.2.1 A laparoscope and trocars are inserted through small incisions in the abdominal wall. The approach can be either transperitoneal or extraperitoneal. The prostate, adjacent tissue and lymph nodes are dissected and removed, and the urethra, which is cut during the procedure, is reconnected. Lymph nodes can be removed during the procedure for histological examination before removing the prostate. **Robotically assisted laparoscopic prostatectomy** is a development of this procedure but it is not yet clear whether there is any advantage over conventional laparoscopy.	*Systematic review* **Fair**
Society of American Gastrointestinal and Endoscopic Surgeons (2011) *Surgical Treatment of Esophageal Achalasia*	*Types of surgical approach: Recommendations p.9* Compared with laparoscopy, **robotic assistance** has been demonstrated to decrease the rate of intraoperative esophageal mucosal perforations (++, weak), but no clear differences in postoperative morbidity, symptom relief, or long-term outcomes have been described. Further study is necessary to better establish the role of **robotic myotomy**. ++ = low quality of evidence	*Systematic review* **Fair**
Society of American Gastrointestinal and Endoscopic Surgeons (2010) *Surgical Treatment of Gastroesophageal Reflux Disease*	*Use of robotic surgery p.11* While **robotic assistance** can be safely and effectively used for fundoplication, its higher cost compared with conventional laparoscopy and similar short-term patient outcomes make it a less than ideal initial choice (Grade B). Nevertheless, further study regarding learning curves and surgeon workload with the **robotic technique** are needed before stronger recommendations can be made. Grade: B [Based on high level, well-performed studies with varying interpretations and conclusions by the expert panels]	*Systematic review* **Fair**
Spanish NHS (2008) *Clinical Practice Guideline for Prostate Cancer Treatment*	*5.3 Surgery – Questions to answer p.40* • In patients with clinically localised prostate cancer for which surgery is indicated, what is the safety and efficacy of different types of **laparoscopic radical surgery (transperitoneal or extraperitoneal, robotic-assisted or not)** in comparison with open radical prostatectomy? *Recommendation p.45* In clinically localised prostate cancer with radical prostatectomy indicated, either laparoscopic or open surgery can be employed. Grade B [A body of evidence consisting mainly of studies rated as 2++, directly applicable to the target population of the guideline, which demonstrate overall consistency of results; or evidence extrapolated from studies rated as 1++ or 1+.]	*Systematic review* **Good**

***Individual Guideline Rating Keys**

Appendix F. Quality Assessment of Selected Guidelines

Criteria	Guideline Developer, Year													
	NCCN, 2011	NCCN, 2012a	NCCN, 2012b	NICE, 2008a	NICE, 2008b	NICE, 2006	NICE, 2009a	NICE, 2009b	NICE, 2008c (full guideline)	SAGES, 2011	SAGES, 2010	AUA, 2010	EAU, 2011	Spanish NHS, 2008
Section 1: Primary Criteria														
Rigor of Development: Evidence	Fair	Fair	Fair	Fair	Fair	Fair	Fair	Fair	Good	Good	Good	Poor[2]	Fair	Good
Rigor of Development: Recommendations	Fair	Fair	Fair	Fair	Fair	Fair	Fair	Fair	Good	Fair	Fair	Good	Fair	Fair[3]
Editorial Independence	Fair	Fair	Fair	Good	Good	Good	Good	Good	Good	Good	N/A	Good	Good	Good
Section 2: Secondary Criteria														
Scope and Purpose	Good	Good	Good	Good	Good	Good	Good	Good	Good	Fair	Fair	Good	Fair	Good
Stakeholder Involvement	Poor	Poor	Poor	Good	Good	Good	Good	Good	Good	Poor	Fair	Fair	Fair	Fair
Clarity and Presentation	Good	Good	Good	Good	Good	Good	Good	Good	Good	Fair	Fair	Fair	Good	Good
Applicability	Good	Good	Good	Fair	Fair	Fair	Fair	Fair	Fair	Poor	Poor	Poor	Poor	Fair
Section 3: Overall Assessment of the Guideline														
How well done is this guideline?	**Fair**	**Fair**	**Fair**	**Fair**	**Fair**	**Fair**	**Fair**	**Fair**	**Good**	**Fair**	**Fair**	**Poor**	**Fair**	**Good**

[2] Rated poor because quality of individual studies and overall strength of the evidence were not assessed. Other elements of the guideline were mostly good to fair.

[3] Rigor of development: Recommendations received a Fair rating because risk of bias was assessed and included using a rating system but not described or discussed in the text.

Appendix G. Quality Assessment Tools

MED PROJECT	**Methodology Checklist: Systematic Reviews and Meta-analyses**				
Study citation (*Include last name of first author, title, year of publication, journal title, pages*)					
MED Topic:		Key Question No.(s):			
Checklist completed by:				Date:	
SECTION 1: INTERNAL VALIDITY					
In a well conducted systematic review		***In this study the criterion is met:***			
1.1	The study addresses an appropriate and clearly focused question.	YES	NO	UNCLEAR	N/A
1.2	An adequate description of the methodology used is included, and the methods used are appropriate to the question.	YES	NO	UNCLEAR	N/A
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	YES	NO	UNCLEAR	N/A
1.4	The criteria used to select articles for inclusion is appropriate.	YES	NO	UNCLEAR	N/A
1.5	Study quality is assessed and taken into account.	YES	NO	UNCLEAR	N/A
1.6	There are enough similarities between the studies selected to make combining them reasonable.	YES	NO	UNCLEAR	N/A
1.7	Competing interests of members have been recorded and addressed.	YES	NO	UNCLEAR	N/A
1.8	Views of funding body have not influenced the content of the study.	YES	NO	UNCLEAR	N/A
SECTION 2: OVERALL ASSESSMENT OF THE STUDY					
2.1	How well was the study done to minimize bias? *Code: Good, Fair or Poor*	GOOD	FAIR	POOR	

2.2	If coded as fair or poor, what is the likely direction in which bias might affect the study results?	
2.3	Are the results of this study directly applicable to the patient group targeted by this Key Question?	YES NO UNCLEAR N/A
2.4	Other reviewer comments:	

MED Project 2009. Adapted from NICE and SIGN materials.

MED PROJECT	Methodology Checklist: Randomized Controlled Trials					
Study identification (*Include author, title, year of publication, journal title, pages*)						
MED topic:		Key Question No(s):				
Checklist completed by:		Date:				
SECTION 1: INTERNAL VALIDITY						
In a well conducted RCT study…		***In this study this criterion is met:***				
RANDOM ALLOCATION OF SUBJECTS						
1.1	An appropriate method of randomization was used to allocate participants to intervention groups.	YES	NO	UNCLEAR	N/A	
1.2	An adequate concealment method was used such that investigators, clinicians, and participants could not influence enrolment or intervention allocation.	YES	NO	UNCLEAR	N/A	
1.3	The intervention and control groups are similar at the start of the trial. (The only difference between groups is the treatment under investigation.)	YES	NO	UNCLEAR	N/A	
ASSESSMENT AND FOLLOW-UP						
1.4	Investigators, participants, and clinicians were kept 'blind' about treatment allocation and other important confounding/prognostic factors. If the answer is no, describe any bias that might have occurred.	YES	NO	UNCLEAR	N/A	
1.5	The intervention and control groups received the same care apart from the intervention(s) studied.	YES	NO	UNCLEAR	N/A	
1.6	The study had an appropriate length of follow-up.	YES	NO	UNCLEAR	N/A	
1.7	All groups were followed up for an equal length of time (or the analysis was adjusted to allow for differences in length of follow-up).	YES	NO	UNCLEAR	N/A	

1.8	What percentage of the individuals or clusters recruited into each group of the study dropped out before the study was completed? What percentage did not complete the intervention(s)?	
1.9	All the subjects were analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	YES NO UNCLEAR N/A
ASSESSMENT AND FOLLOW-UP, Cont.		
1.10	All relevant outcomes are measured in a standard, valid and reliable way.	YES NO UNCLEAR N/A
1.11	The study reported only on surrogate outcomes. (If so, please comment on the strength of the evidence associating the surrogate with the important clinical outcome for this topic.)	YES NO UNCLEAR N/A
1.12	The study uses a composite (vs. single) outcome as the primary outcome. If so, please comment on the appropriateness of the composite and whether any single outcome strongly influenced the composite.	YES NO UNCLEAR N/A
CONFLICT OF INTEREST		
1.13	Competing interests of members have been recorded and addressed.	YES NO UNCLEAR N/A
1.14	Views of funding body have not influenced the content of the study.	YES NO UNCLEAR N/A
Section 2: Overall Study Assessment		
2.1	How well was the study done to minimize bias? *Code Good, Fair, or Poor*	GOOD FAIR POOR
2.2	If coded as Fair or Poor what is the likely direction in which bias might affect the study results?	
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES NO UNCLEAR N/A
2.4	Other reviewer comments:	

MED Project 2009. Adapted from NICE and SIGN materials.

MED PROJECT	**Methodology Checklist: Cohort Studies**	
Study identification (*Include author, title, year of publication, journal title, pages*)		
Review topic:		Key Question No.(s), if applicable:
Checklist completed by:		Date:
SECTION 1: INTERNAL VALIDITY		
In a well conducted cohort study:		***In this study the criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	YES NO N/A
SELECTION OF SUBJECTS		
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	YES NO N/A
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	YES NO N/A
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	YES NO N/A
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed?	
1.6	Comparison is made between full participants and those who dropped out or were lost to follow up, by exposure status.	YES NO N/A
ASSESSMENT AND FOLLOW-UP		
1.7	The study employed a precise definition of outcome(s) appropriate to the Key Question(s).	YES NO N/A
1.8	The assessment of outcome(s) is made blind to exposure status.	YES NO N/A
1.9	Where outcome assessment blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	YES NO N/A
1.10	The measure of assessment of exposure is reliable.	YES NO N/A

1.11	Exposure level or prognostic factor is assessed more than once.	YES NO N/A
1.12	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	YES NO N/A
1.13	The study had an appropriate length of follow-up.	YES NO N/A
1.14	All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up)	YES NO N/A
CONFOUNDING		
1.15	The main potential confounders are identified and taken into account in the design and analysis.	YES NO N/A
STATISTICAL ANALYSIS		
1.16	Have confidence intervals been provided?	YES NO N/A
CONFLICT OF INTEREST		
1.17	Competing interests of members have been recorded and addressed.	YES NO N/A
1.18	Views of funding body have not influenced the content of the study.	YES NO N/A
SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimize the risk of bias or confounding, and to establish a causal relationship between exposure and effect? *Code Good, Fair, or Poor*	GOOD FAIR POOR
2.2	If coded as Fair, or Poor what is the likely direction in which bias might affect the study results?	
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES NO N/A
2.4	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated?	YES NO N/A
2.5	Other reviewer comments:	

MED Project 2009. Adapted from NICE and SIGN materials.

MED PROJECT	Methodology Checklist: Economic Evaluation	
Study citation (*Include last name of first author, title, year of publication, journal title, pages*)		
MED Topic:	Key Question No.(s):	
Checklist completed by:		Date:

Cost
Cost analysis (no measure of benefits)

Economic Evaluations (please circle):

Study Type	*Measurement of Benefits*
Cost minimization	Benefits found to be equivalent
Cost effectiveness analysis	Natural units (e.g., life years gained)
Cost utility analysis	Healthy years (e.g. quality adjusted life years, health years equivalent)
Cost-benefit analysis	Monetary terms

Section 1: applicability

	In a well conducted economic study…	*In this study the criterion is met:*
1.1	The results of this study are directly applicable to the patient group targeted by this Key Question.	YES NO UNCLEAR N/A
If criterion 1.1 is rated no, the study should be excluded.		
1.2	The healthcare system in which the study was conducted is sufficiently similar to the system of interest in the topic Key Question(s).	YES NO UNCLEAR N/A

SECTION 2: Study Design, Data Collection, and Analysis

	In a well conducted economic study…	*In this study the criterion is met:*
2.1	The research question is well described.	YES NO UNCLEAR N/A
2.2	The economic importance of the research question is stated.	YES NO UNCLEAR N/A
2.3	The perspective(s) of the analysis are clearly stated and justified (e.g. healthcare system, society, provider institution, professional organization, patient group).	YES NO UNCLEAR N/A

2.4	The form of economic evaluation is stated and justified in relation to the questions addressed.	YES	NO	UNCLEAR	N/A
Methods to estimate the effectiveness of the intervention					
2.5	*Circle one* a. Details of the methods of synthesis or meta-analysis of estimates are given (if based on a synthesis of a number of effectiveness studies). b. Details of the design and results of effectiveness study are given (if based on a single study).	YES	NO	UNCLEAR	N/A
2.6	Estimates of effectiveness are used appropriately.	YES	NO	UNCLEAR	N/A
2.7	Methods to value health states and other benefits are stated.	YES	NO	UNCLEAR	N/A
2.8	Outcomes are used appropriately.	YES	NO	UNCLEAR	N/A
2.9	The primary outcome measure for the economic evaluation is clearly stated.	YES	NO	UNCLEAR	N/A
2.10	Details of the subjects from whom valuations were obtained are given.	YES	NO	UNCLEAR	N/A
2.11	Competing alternatives are clearly described.	YES	NO	UNCLEAR	N/A
Methods to estimate the costs of the intervention					
2.12	All important and relevant costs for each alternative are identified.	YES	NO	UNCLEAR	N/A
2.13	Methods for the estimation of quantities and unit costs are described.	YES	NO	UNCLEAR	N/A
2.14	Quantities of resource use are reported separately from their unit costs.	YES	NO	UNCLEAR	N/A
2.15	Productivity changes (if included) are reported separately.	YES	NO	UNCLEAR	N/A
2.16	The choice of model used and the key parameters on which it is based are justified.	YES	NO	UNCLEAR	N/A
2.17	All costs are measured appropriately in physical units.	YES	NO	UNCLEAR	N/A

2.18	Costs are valued appropriately.	YES NO UNCLEAR N/A
2.19	Outcomes are valued appropriately.	YES NO UNCLEAR N/A
2.20	The time horizon is sufficiently long enough to reflect all important differences in costs and outcomes.	YES NO UNCLEAR N/A
2.21	The discount rate(s) is stated.	YES NO UNCLEAR N/A
2.22	An explanation is given if costs and benefits are not discounted.	YES NO UNCLEAR N/A
2.23	The choice of discount rate(s) is justified.	YES NO UNCLEAR N/A
2.24	All future costs and outcomes are discounted appropriately.	YES NO UNCLEAR N/A
2.25	Details of currency of price adjustments for inflation or currency conversion are given.	YES NO UNCLEAR N/A
2.26	Incremental analysis is reported or it can be calculated from the data.	YES NO UNCLEAR N/A
2.27	Details of the statistical tests and confidence intervals are given for stochastic data.	YES NO UNCLEAR N/A
2.28	Major outcomes are presented in a disaggregated as well as aggregated form.	YES NO UNCLEAR N/A
2.29	Conclusions follow from the data reported.	YES NO UNCLEAR N/A
2.30	Conclusions are accompanied by the appropriate caveats.	YES NO UNCLEAR N/A
SECTION 3: sensitivity Analysis		
In a well conducted economic study…		*In this study the criterion is met:*
3.1	The approach to sensitivity analysis is given.	YES NO UNCLEAR N/A
3.2	All important and relevant costs for each alternative are identified.	YES NO UNCLEAR N/A

3.3	An incremental analysis of costs and outcomes of alternatives is performed.	YES	NO	UNCLEAR	N/A
3.4	The choice of variables for sensitivity analysis is justified.	YES	NO	UNCLEAR	N/A
3.5	All important variables, whose values are uncertain, are appropriately subjected to sensitivity analysis.	YES	NO	UNCLEAR	N/A
3.6	The ranges over which the variables are varied are justified.	YES	NO	UNCLEAR	N/A
SECTION 4: CONFLICT OF INTEREST					
In a well conducted economic study…		*In this study the criterion is met:*			
4.1	Competing interests of members have been recorded and addressed.	YES	NO	UNCLEAR	N/A
4.2	Views of funding body have not influenced the content of the study.	YES	NO	UNCLEAR	N/A
SECTION 5: OVERALL ASSESSMENT					
5.1	**How well was the study done to minimize bias?** ***Code: Good, Fair or Poor***	GOOD	FAIR	POOR	
5.2	If coded as fair or poor, what is the likely direction in which bias might affect the study results?				
5.3	Other reviewer comments:				

MED Project 2011. Adapted from BMJ, NICE, and the Consensus on Health Economic Criteria (CHEC).

MED PROJECT	**Methodology Checklist: Guidelines**
Guideline citation *(Include name of organization, title, year of publication, journal title, pages)*	
MED Topic:	Key Question No.(s), if applicable:
Checklist completed by:	Date:

SECTION 1: PRIMARY CRITERIA		
To what extent is there		***Assessment/Comments:***
1.1	**RIGOR OF DEVELOPMENT: Evidence** • Systematic literature search • Study selection criteria clearly described • Quality of individual studies and overall strength of the evidence assessed • Explicit link between evidence & recommendations *(If any of the above are missing, rate as poor)*	GOOD FAIR POOR
1.2	**RIGOR OF DEVELOPMENT: Recommendations** • Methods for developing recommendations clearly described • Strengths and limitations of evidence clearly described • Benefits/side effects/risks considered • External review	GOOD FAIR POOR
1.3	**EDITORIAL INDEPENDENCE**[4] • Views of funding body have not influenced the content of the guideline • Competing interests of members have been recorded and addressed	GOOD FAIR POOR
If any of three primary criteria are rated poor, the entire guideline should be rated poor.		
SECTION 2: SECONDARY CRITERIA		
2.1	**SCOPE AND PURPOSE** • Objectives described • Health question(s) specifically described • Population (patients, public, etc.) specified	GOOD FAIR POOR
SECTION 2: SECONDARY CRITERIA, CONT.		
2.2	**STAKEHOLDER INVOLVEMENT** • Relevant professional groups represented • Views and preferences of target population sought • Target users defined	GOOD FAIR POOR
2.3	**CLARITY AND PRESENTATION** • Recommendations specific, unambiguous • Management options clearly presented • Key recommendations identifiable • Application tools available	GOOD FAIR POOR

[4] Editorial Independence is a critical domain. However, it is often very poorly reported in guidelines. The assessor should not rate the domain, but write "unable to assess" in the comment section. If the editorial independence is rated as "poor", indicating a high likelihood of bias, the entire guideline should be assessed as poor.

	Updating procedure specified	
2.4	**APPLICABILITY** • Provides advice and/or tools on how the recommendation(s) can be put into practice • Description of facilitators and barriers to its application • Potential resource implications considered Monitoring/audit/review criteria presented	GOOD FAIR POOR
SECTION 3: OVERALL ASSESSMENT OF THE GUIDELINE		
3.1	How well done is this guideline?	GOOD FAIR POOR
3.2	Other reviewer comments:	

[This tool is adapted from the Appraisal of Guidelines Research & Evaluation (AGREE) II tool. The full AGREE II tool is available from http://www.agreetrust.org/resource-centre/agree-ii/]

Description of Ratings: Methodology Checklist for Guidelines

The checklist for rating guidelines is organized to emphasize the use of evidence in developing guidelines and the philosophy that "evidence is global, guidelines are local." This philosophy recognizes the unique situations (e.g., differences in resources, populations) that different organizations may face in developing guidelines for their constituents. The second area of emphasis is transparency. Guideline developers should be clear about how they arrived at a recommendation and to what extent there was potential for bias in their recommendations. For these reasons, rating descriptions are only provided for the primary criteria in section one. There may be variation in how individuals might apply the good, fair, and poor ratings in section two based on their needs, resources, organizations, etc.

Section 1. Primary Criteria (rigor of development and editorial independence) ratings:

Good: All items listed are present, well described, and well executed (e.g., key research references are included for each recommendation).
Fair: All items are present, but may not be well described or well executed.
Poor: One or more items are absent or are poorly conducted

Appendix H. Summary of Federal and Private Payer Policies

Payer	Coverage summary
Medicare Effective: May 2005	CMS Manual System, Medicare Claims Processing, Updated to the Medicare Outpatient Code Editor (May 20, 2005). S2900 added to list of valid codes; S2900 added to list of non-reportable codes.
Medicare LCDs	No local coverage determinations have been issued.
Aetna	No policies identified addressing coverage of robotic assisted surgery.
Regence BCBS Washington	Regence Washington, Reimbursement Policy, Invalid Services "Providers will not be reimbursed nor allowed to retain reimbursement for Invalid services. Invalid services are denied provider write-off. The following are examples of services that Regence considers to be Invalid. This is not an all inclusive list. … • Surgical techniques requiring use of robotic surgical system (S2900 - list separately in addition to code for primary procedure)"
Group Health	No policies identified addressing coverage of robotic assisted surgery.

Appendix I. Public Comments and Disposition

Table of Contents

OVERVIEW OF PUBLIC COMMENTS AND DISPOSITION

The Center for Evidence-based Policy is an independent vendor contracted to produce evidence assessment reports for the WA HTA program. For transparency, all comments received during the comments process are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

This document responds to comments from the following parties:

Key Questions

- Phil Colmenares, MD, MPH
- James R. Porter, MD (Swedish Medical Center)
- Andrew Yoo, MD; and Matt Moore, MHA (Ethicon Endo-Surgery, Inc)

Draft Report

- Scott Adams (Pullman Regional Hospital)
- Kristen Austin, MD (Swedish Medical Center)
- Ralph Aye, MD, FACS (Swedish Cancer Institute)
- Michael Blee (Kootenai Health)
- Steven R. Brisbois (Sacred Heart Medical Center)
- D. Mark Brown, MD (Southwestern Washington Urology Clinic)
- Michael F. Burke, MD, FACS (Valley Medical Center)
- Eve Cunningham

- Paul H. Eun, MD (Dedicated to Women's Health Specialists, Inc)
- Michael Florence, MD, FACS (Swedish Medical Center)
- Joel B. Flugstad, MHPA (Swedish Medical Center)
- Brian Fong, MD, FRCS(C) (Western Washington Medical Group)
- Theresa Froelich, DO (University Place Medical Clinic)
- Heidi J. Gray, MD (University of Washington)
- Peter Grimm, DO (Prostate Cancer Center of Seattle)
- Patti Holten
- Catherine Hunter, DO
- Peggy Hutchison, MD (Seattle OB/GYN Group)
- Intuitive Surgical
- John Paul Isbell, MD
- Frank Kim, MD
- Richard Koehler, MD
- Baiya Krishnadasan, MD, FACS (Franciscan Health System)
- David Kummerlowe (CADRE, Inc.)
- Roque Lanza, MD, FACOG
- Thomas Lendvay, MD, FACS
- John Lenihan Jr., MD (University of Washington School of Medicine)
- Brian E. Louie, MD, FRCSC, FACS (Swedish Cancer Institute and Medical Center)
- John Luber, MD, FACS
- Gordon L. Mathes, Jr., MD (Rocky Mount Urology Associates)
- Patris Marandi, MD (Providence Everett Medical Center)
- Heather Miller, MD (Swedish Medical Center)

- Karen Nelson, MD
- Kerilyn Nobuhara, MD, MHA (Senior Medical Consultant, Washington Health Care Authority)
- Steve Poore, MS, MD, FACOG (Women's Clinic-MultiCare Northshore Clinic)
- James Porter, MD; Todd Strumwasser, MD; and Mary G. Gregg, MD, MHA (Swedish Medical Center)
- Charles Richards, MD (Pullman Regional Hospital)
- Clifford W. Rogers, MD (Minimally-Invasive Gynecologic Surgery)
- Dennis W. Shook
- Leland Siwek, MD (Providence Sacred Heart Medical Center)
- Doug Sutherland, MD (MultiCare Urology)
- Kim Tillemans, DO
- Renata R. Urban, MD (University of Washington Medical Center)

Specific responses pertaining to each comment are included in Table 1 and 2. The full version of each public comment received along with additional resources provided by parties is available in the Public Comments and Responses supplemental document.

Table 1. Response to Public Comments on Key Questions

<table>
<tr><th>Reviewer</th><th>Comment</th><th>Disposition</th></tr>
<tr><td colspan="3">Phil Colmenares, MD</td></tr>
<tr><td></td><td>"Robotic Assisted Surgery" is too general. It seems to me that you need to go procedure by procedure.

Next comment about KQ1:

The function of an HTA program is to deal directly with clinical effectiveness. In looking at the final determinations for Lumbar Fusion and Total Knee Replacement, the WA-HTA addressed clinical effectiveness. You did not "water down" the question by conflating it with clinical efficacy. Clinical efficacy studies will certainly be reviewed, but a formal HTA program should review all data with one focus: To what extent does each study (including clinical efficacy studies) address clinical effectiveness? Clinical efficacy studies need to be reviewed, but the question is about clinical effectiveness.

The last part of the question addresses outcomes. I don't know whether the WA-HTA has a hierarchy of outcomes, but I'm not sure that I would lump outcomes such as "complete cancer eradication" with outcomes such as "reduced anesthesia use." I think that patients might differ on the valuation of those two outcomes as well. In addition, you should distinguish between hard clinical outcomes, and other outcomes. As I discuss below with regard to the example of robotic assisted laparoscopic prostatectomy (RALP), the value of the "trifecta" outcome of reduced impotence/incontinence/positive surgical margins is probably exponentially more important to patients than "reduced anesthesia use" or even "reduced hospital stay." All of these are worthy outcomes to consider, but the integrity of a health technology assessment process depends on how well you are able to place each outcome in proper perspective.

For the few robotic procedures that do demonstrate evidence of clinical or comparative effectiveness, the next crucial question (which you have unfortunately not even acknowledged) should be the volume of procedures necessary to achieve consistently</td><td>Thank you for your comments.

Results will be presented by procedure in the report.

The report will include assessment of efficacy and effectiveness as available in the evidence.

Assessment of clinically meaningful outcomes added to Key Question #1.

Experience by provider and facility volume were added to Key Question# 3.</td></tr>
</table>

Reviewer	Comment	Disposition
	low levels of complications. This is much different, and a higher (but more patient-oriented outcome) than mere competency in performing the procedure. **Proposed KQ5:** What is the minimum number of robotic surgeries required to attain consistently low levels of the most concerning complications? For example, for robotic prostatectomy, Dr. Patel has called for using a "trifecta" outcome: (1) impotence; (2) incontinence; (3) positive surgical margins. How many robotic prostate surgeries should be expected to consistently achieve the level of expertise necessary to consistently demonstrate low levels of this trifecta oucome? Robotic prostatectomy may be a bad example because it is not clear that patient-oriented outcomes are better with RALP. Therefore, asking the question KQ5 is not even indicated. KQ5 would only be indicated for robotic procedures that demonstrate comparative effectiveness. Nevertheless, this is a crucial question to include. In few other areas of clinical medicine than this new, radical departure from past surgical techniques should **questions of surgical expertise** be an explicit part of the technology assessment. And, specifically, not just competency with the procedure, but, of far more importance to patients, expertise that **consistently** yields the lowest complications and the highest successes. (The numbers for RALP have been as low as 100, but as high as 1,600 to achieve the necessary expertise.) Again, questions of surgical expertise are often mentioned in technology assessments, but in this particular arena I strongly suggest that it needs its own separate question.	
James R Porter, MD (Swedish Medical Center)		
	Key Question 1: there are several studies showing comparative superiority of robotic-assisted surgery over laparoscopic or traditional open surgery. There are few, if any randomized controlled trials comparing robotic-assisted surgery to laparoscopic or open surgery. So most of the information is gained from case series with historical	*Thank you for your comments.* *All references were forwarded to the TAC.*

Reviewer	Comment	Disposition
	comparisons to open or laparoscopic surgery. ○ It is important to recognize that the experience of robotic assisted prostatectomy is very early and the comparison studies are looking at a very mature open prostatectomy experience in the literature with a very early robotic assisted prostatectomy experience. ○ If the early literature of open prostatectomy (1982 – 1995) is carefully evaluated the complication rates, cancer control rates and morbidity are much greater than what is seen with current assisted prostatectomy series. (1) – publication indicated patients undergoing robotic assisted prostatectomy showed surgical site infection rate as compared to patients undergoing open prostatectomy. ▪ ▪ (2) – study indicated no significant difference and complications between the open prostatectomy patient's compared to the robotic assisted prostatectomy patients. This paper shows equal outcomes with decreased hospital stay and decreased bladder neck contracture rate for the robotic assisted procedures versus open. ▪ (3) – found that robotic-assisted partial nephrectomy was superior to laparoscopic partial nephrectomy with regard to blood loss and length of hospital stay. The major advantage of robotic-assisted partial nephrectomy was a decrease in the warm ischemia time that the kidney was clamped during partial nephrectomy. This significant difference speaks to the improved reconstructive abilities of the robotic platform. This improved warm ischemia time has significant implications for renal function recovery. ▪ (4) – demonstrated superior adjusted perioperative outcomes after robotic assisted prostatectomy as compared to open prostatectomy in virtually all examined outcomes. ▪ Key Question 4: studies look at operating room costs and do not take into account the cost savings created by shorter length of hospital stay which has been clearly demonstrated in multiple studies of robotic prostatectomy. Another savings which is difficult to measure is the money saved by employers when a patient is able to return to work sooner after robotic surgery as compared to open surgery. The charge to insurance payers for robotic procedures is the same charge as the laparoscopic procedure given the equivalent CPT codes for robotic and laparoscopic surgery. In the state of Washington, there is no additional charge to insurance company's or the state for robotic-assisted procedures. The increased capital costs associated with the robotic surgical systems has been incurred by hospital systems in an effort to provide patients with state of the art surgical care. Cited the following: ○ (1). Publication from the Mayo Clinic in Urology (Urology Oct. 2011; 78(4), pages 827-31. Epub 2011 July 29) ○ (2). Study from the Mayo Clinic published in the British Journal of Urology (BJU Int 2009 Feb; 103(4), pages 448-53. Epub 2008 Sept 3). ○ (3). Article published in the Journal of Urology in 2009 (J Urol 2009 Sept; 182(3), pages 866-72. Epub 2009 July 17). (4). National Inpatient Sample was published in European Urology (Eur Urology: 2011 Dec. 22)	*Studies provide evidence. No changes to the Key Questions.* *The report will describe all cost perspectives and model assumptions as described by the identified evidence.*
Andrew Yoo and Matt Moore (Ethicon Endo-Surgery, Inc)		
	Policy Context – Population: the specific pathology and patient populations is important to note when comparing surgical approaches. This not only can profoundly generally effect outcomes but also directly effects the procedure itself.	*Thank you for your comments.* *No changes to context, PICO*

Reviewer	Comment	Disposition
	Policy Context – Intervention: Robotic assisted surgery is perhaps more precisely defined as Robotic assisted endoscopic surgery. In the specific anatomic location – robotic assisted laparoscopic surgery and robotic assisted video assisted thoracic surgery (VATS). Policy Context – Comparator: Precisely defining the comparative approach and current gold standard is of the utmost importance when evaluating the effectiveness of Robotic assisted endoscopic surgery. Policy Context – Outcomes: Note the difference between statistical significance and clinical relevance. Requested three distinct modifications to the draft key questions: ○ The data should compare robot to open *and* traditional minimally invasive procedures versus one *or* the other; ○ That the evidence asked for is segmented by procedure, as the outcomes can greatly vary based on the type of surgery performed; and ○ A broad term such as "traditionally minimally invasive" would be a more inclusive and appropriate terminology. **KQ1:** What is the procedure and indication (e.g. benign vs. malignant disease) specific evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open ~~or~~ AND traditionally minimally invasive, i.e., laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes compared to open AND laparoscopic procedures? Include consideration of short and long-term outcomes including complete cancer eradication, reduced hospital stay, and reduced anesthesia use. **KQ2:** For robotic assisted surgery, what is the procedure and indication specific evidence of the severity and incidence of safety or adverse event concerns compared with open ~~or~~ AND laparoscopic approaches? Include consideration of morbidity, mortality, reoperation, excess bleeding, and extended hospital stay. **KQ3:** What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations compared to open AND laparoscopic procedures? Including consideration of: Gender	*sections, or KQs.* *The report will be organized by procedure.* *No changes to Key Questionss to affect "or"/"and". We do not think this will impact the meaning.* *Terminology change (e.g., traditionally minimally invasive) will not affect the report evidence base.*

Reviewer	Comment	Disposition
	Age Psychological or psychosocial co-morbidities Other patient characteristics or evidence based patient selection criteria, especially comorbidities of diabetes and high BMI, prior operations, Provider type, setting or other provider characteristics, stage (for malignancy), Payer / beneficiary type including worker's compensation, Medicaid, state employees **KQ4:** What is the evidence of cost and cost-effectiveness of robotic surgery compared with open ~~or~~ AND laparoscopic approaches (or perhaps other well accepted approaches including – vaginal hysterectomy, open appendectomy, open inguinal hernia repair)? This should include consideration of operative consumables, patient care, and capital costs.	

Table 2. Response to Public Comments on Draft Report

Reviewer	Comment	Disposition
Scott Adams (Pullman Regional Hospital)		
	"We have been providing robotic assisted laparoscopic surgery since December of 2011. We have performed about 35 cases to date. We have one trained urologist, 2 trained gynecologists, and one trained general surgeon. Since we began providing robotic assisted surgery we have seen an overall decline in the length of stay for all robotic assisted surgery patients to about 2 days. Hysterectomy patients have an average length of stay of 1 day. Blood loss for all procedures has declined and for hysterectomies the average blood loss is less than 50 cc. Patients comment on better pain control, quicker recovery time, and returning to their normal daily activities sooner. We have found this to be a truly break-through improvement in surgical outcomes for the specified procedures and feel that it warrants continued recognition for payment by the Health Care Authority. A dramatic improvement that is often overlooked is the tremendous influence that this new technology has on the surgeon. I have heard trained robotic surgeons tell me that this technology has changed their practice and they know they are able to treat patients in a minimally invasive manner that previous to this technology would have had to have open surgery. Additionally, the positive impact on the surgeon cannot be overlooked. Less fatigue, higher degree of visibility, improved ergonomics all argue for a better outcome for the patient. We urge your continued support for the availability of surgical technologies that provide better outcomes and lower costs for patients."	*Thank you for your comment.* *No changes to draft report.*
Kristen Austin, MD (Swedish Medical Center)		
	"I use robotic surgery for hysterectomies, myomectomies, and pelvic floor suspension. The daVinci technique allows for patients to return to work more quickly than standard laparoscopy or open cases due to decreased pain. They also use less post operative pain medication, have fewer infections, less blood loss, and fewer postoperative complications. As a surgeon, my back pain is drastically improved after switching to the daVinci robotic technique. I	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	have done standard laparoscopy for many years and was beginning to have back pain that was threatening my ability to continue practicing medicine. This benefits patients, because they will have more experienced surgeons able to operate longer. Thank you for your concern."	
Ralph Aye, MD, FACS (Swedish Cancer Institute)		
	"I'm a surgeon and former chief of surgery at Swedish Medical Center. Our group made a conscious decision to enter robotic surgery and now use it for selected thoracic and esophageal procedures. I have a few thoughts. 1. The robot allows surgeons with average or limited minimally invasive laparoscopic skills to do more complex cases that they would otherwise perform open. It most cases that would result in a longer hospital stay and a longer recovery. Most of the studies showing lack of benefit to the robot compare results with surgeons highly skilled in both laparoscopic and robotic surgery and would therefore not show this dynamic. 2. The robot is being over-utilized by surgeons wanting to improve their skills or to market their practice. This is natural with any newer technology. 3. Robotics will continue to improve and increasingly provide benefit. It is important to support its advance. 4. If restrictions are necessary for financial reasons, it would be much preferable to create boundaries either by institution or practice rather than prohibiting it altogether."	*Thank you for your comment.* *No changes to draft report.*
Michael Blee (Kootenai Health)		
	"As a Healthcare administrator and a recent robotic heart surgery patient (Mitral valve repair) I think that it is important that I share with you how very different can be the course a "Robotic assisted	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition

surgery" patient from that of a patient undergoing a traditional open procedure:

Parameter	Averages (per Society of Thoracic Surgery) for open procedures	My experience with a Robotically Assisted Procedure
Hours spent in intensive Care post procedure	68.7	Less than 12
Post procedure Ventilator hours	22	Less than 4
Total days in spent in the hospital post procedure	9.1	Less Than 3

In addition to the above, I think that it is important to note that I was able to return to normal activities on my 5th post operative day & in fact was mowing my lawn on my 7th post operative day.

Lost time from work was far less in my robotic experience (7 days total) than the typical 6-10 weeks that we see in traditional open procedures.

In short, if my experience is any indicator of the reduced hospital resources consumed and the vastly shortened recovery times that can be realized through the use of Robotic assisted surgery, then this is a technology that should encouraged for all appropriate procedures."

Steven R. Brisbois (Sacred Heart Medicad Center)

	"I have dedicated my career to MIS. I began doing complex Laporoscopic surgery in the 80's, and performed the first laporoscopic hyst in the state of Wash in 1990. When I was appproached in 2005 re doing robotic surgery, I asked the question "will the robot allow me to perform procedures using MIS that I am currently unable to do, or allow me to do them safer and better?" At that time, no one could answer that question. I began performing robotic Gyn in 2006. After a few cases, the answer to	*Thank you for your comment.* *No changes to draft report.*

<table>
<tr><th>Reviewer</th><th>Comment</th><th>Disposition</th></tr>
<tr><td></td><td>my question became obvious----it was a resonding yes! I weekly perform cases that I never could perform with staight laporoscopy. These include: 1 Large patients. I not only operate on pts with BMI's in the 50's, but also, 60's, 70's, and recently 80's. Thfe allternative for these patients would be an open laporotomy with very high morbidity, and prolonged stays. My robot pts go home the same day, or the next AM. 2. Sacrocolpopexy. Previously, these pts required a complex laporotomy with high morbidity.

Using the robot, these pts now either go home the same day, or the following AM. 3. Myomectomies. I have done fibroids to 27 weeks size with the robot, and taken out as many as 36 fibroids at one time. Again, they either go home the same day, or the next AM. What I am able to do with the Robot was unheard of in the past. Patients come here from west Washinton, oregon, Idaho, Mt, and as far away as North Dakota to seek MIS, as m;ost o;f them have been told that they will require an open procedure. I could not practice what I do without the robot. I do not believe that it should dreplace all other MIS procedures. I still do TVH's, and straight lporoscopic hysts in appropriate pts. However, for the above pts, the robot has revolutionized safer care.”</td><td></td></tr>
<tr><td colspan="3">D. Mark Brown, MD (Southwestern Washington Urology Clinic)</td></tr>
<tr><td></td><td>Radical Retropubic prostatectomy is the GOLD standard in therapy for localized prostate cancer. All other therapies are compared to this GOLD standard in terms of efficacy, safety, morbidity, cost, and mortality rates. I have been performing this operation for 22 years and am an expert at Open Radical Retropubic Prostatectomy with Bilateral pelvic Lymph Node Dissection.

Comparing Open Radical as above to Robotic Assisted Radical Prostatectomy reveals the following: IN EXPERIENCED HANDS:

<table>
<tr><th></th><th>Open Procedure</th><th>Robotic Procedure</th></tr>
<tr><td>Operating room time:</td><td>70 to 120 minutes</td><td>180 to 360 minutes</td></tr>
<tr><td></td><td>1.17 to 2.0 hours</td><td>3.0 to 6.0 hours</td></tr>
</table>
</td><td>Thank you for your comment.

No changes to draft report.</td></tr>
</table>

Reviewer	Comment	Disposition
	Blood Loss: 20 to 300cc's 150 to 500cc's Operative Mortality: 0.2% 0.6% Impotence Rates: 25 to 75% 10 to 60% Incontinence Rates: 0.2% to 5% 20% to 45% Cost: $8,130 $15,550 Average Length of Stay: 23 to 96 hours 23 to 48 hours Wound Infection Rate: 0.1 to 1.5% 0.1 to 0.8% Postoperative Pain: 48mg morphine 10mg morphine As you can clearly see the only benefits to the robotic procedure are decreased pain, marginally decreased length of stay and perhaps slightly less wound infection rates. The open procedure is better in terms of cost, operative time, blood loss, and incontinence rates. The most important thing is the open procedure has a lower operative mortality rate because surgeons are doing these procedures untrained, thinking that the robot gives them an advantage when it really doesn't and they are doing an extremely dangerous operation with relatively little training. Hope this helps. I would love to testify in a public hearing about this issue!!"	
Michael Burke, MD, FACS (Valley Medical Center)		
	"With the advent of Robotic technology we are entering a new phase in virtual surgery with more precision and less trauma to patients. The dichotomy between new technology and evidence based medicine is that the early lack of data to demonstrate value inhibits the training, use and deployment of technologies that will likely benefit a significant number of patients. Robotic surgery allows surgeons to perform minimally invasive surgery with better visualization and precision than in laparoscopic procedures. Unfortunately the cost and training in robotic surgery is expensive but the benefits to the patients will be realized as it has been in laparoscopic surgery. The cost will come	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	down with more competition as it has in laparoscopic surgery. The learning curve for specific robotic procedures varies. Prior experience in laparoscopic surgery is extremely valuable in reducing the robotic learning curve. Colon, pancreas and GI surgery can be done with less morbidity and hopefully better outcomes. Robotic programs should critically analyze their data to bolster the evidence to support this valuable technology."	
Eve Cunningham		
	"For the past year and a half and I have embraced the newest technological advancements in gynecologic surgery with fervor. My leap to training and using the robot for gyn surgery has helped so many of my patients. Prior to using the robot for gyn surgery, I was attempting a laparoscopic approach in complex surgical situations. While laparoscopy is still a valuable tool, I found that my dependence on my assistant surgeon during the case and my limited ability to articulate the laparoscopic instruments would sometimes lead to requiring an open laparotomy incision (large incision) in order to finish the case. This was most unfortunate for my patients, especially the morbidly obese patients with complex medical problems. Ever since I started using the robot, I have only used a laparotomy incision (large incision) on one patient in gyn surgery. The robot has given me the tools I need to perform minimally invasive surgery on some of the most complicated and challenging patients. Patients with medicaid are often some of the most challenging to operate on. By using the robot, i have been able to minimize their stays in the hospital and shorten recovery times. My understanding is that medicaid does not pay any extra fees for robotic surgery on patients. The robot is considered a laparoscopic tool and therefore all cases are reimbursed as though they were straight laparoscopic. If this is the case, then I confused as to why the state would be concerned as to whether Robotic surgery is covered in their plans or not. Technological advancements in medicine are not going away. Twenty-five years ago, the utility of laparoscopy was questioned. Now, laparoscopy is considered standard of care. Robotic surgery is not going away any time soon. And, patients benefit from robotics by avoiding large incisions that often	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	lead to secondary complications such as infections, seromas, separations and longer healing times."	
Paul H. Eun, MD (Dedicated Women's Health Specialists, Inc)		
	"Although not necessary for everyone, robotic surgery has clear benefits for some patients. It allows patients the opportunity to undergo minimally invasive surgery when there are no other reasonable alternatives except traditional open surgery at significantly greater cost due to longer hospital stay and recovery time."	*Thank you for your comment.* *No changes to draft report.*
Michael Florence, MD, FACS (Swedish Medical Center)		
	"Opinion: Although Robotic assisted surgery has clear advantages over traditional laparoscopic surgery for certain specific procedures, it adds to the cost of the procedure and thereby reduces hospital profits on a case by case basis unless the use of the Robot significantly decreases LOS and complication rates. For prostatectomy, this may well be the case, but for some other procedures it is less clear. Robotic assisted surgery is clearly part of the "medical arms race" in that purchasing the equipment is driven by the desire on the part of hospital administrators to maintain their market share in a given community. Some surgeons have commented that the best business decision is to buy and market a robot, but to never use it. Procedures that would be controversial include cholecystectomy and oophorectomy. Clearly the push by the device manufacture to use a single port robotic approach to cholecystectomy is purely driven by profit. The likelihood that we could ever prove a single port robotic approach is safer and more cost effective than current laparoscopic approaches is extremely hard to imagine. Multiple other procedures fall in the middle including robotic gastrectomy, pancreatectomy, and colectomy to name a few. The safety, efficacy and cost benefits might favor the robotic approach, but would require considerable study."	*Thank you for your comment.* *No changes to draft report.*
Joel B. Flugstad, MHPA (Swedish Medical Center)		
	"This letter contains comments and recommendations on behalf of The Robotics Committee at	*Thank you for your comment.*

<table>
<tr><th>Reviewer</th><th>Comment</th><th>Disposition</th></tr>
<tr><td></td><td>Swedish Health Services (SHS) in response to the Health Technology Assessment draft evidence report (HTA) for Robotic Assisted Surgery (RAS). We commend the efforts that have been undertaken by this HTA. In support of continually working to improve patient care, our comments are as follows:

JUSTIFICATION OF INTERESTS
SHS currently has the largest robotics program by volume and specialty within Washington State. Established in 2005, the program has grown each consecutive year, and performed over 1,3000 RAS cases in 2011. The program currently operates at 4 SHS campuses, First Hill, Cherry Hill, Edmonds, and Issaquah, with physicians practicing in the following disciplines:
• Urology
• Colorectal
• General
• Gynecology
• Gynecologic Oncology
• Otolaryngology
• Thoracic
• Cardiac Surgery

SHS has developed and implemented an extensive administrative framework to support a sustainable robotics program that strives to deliver high quality, appropriate care, in an efficient environment. As the program has evolved, SHS and affiliated providers have raised many of the same concerns contained within this HTA. SHS has effectively mediated many of these concerns through collaborative efforts between surgeons, staff, management, and vendors. These efforts include standardized credentially of physicians and allied health providers seeking privileges for robotic surgery, ongoing quality assessment of robotic surgical procedures, and data collection of robotic surgeries for research and publication.</td><td>No changes to draft report.</td></tr>
<tr><td></td><td>COMMENT 1
In response to the HTA’s recognition regarding the low volume of literature related to RAS, RAS is a relatively new surgical procedure. Published literature often is many years behand new technology. A key example of this was with the adoption of laparoscopic surgical techniques. While the use of laparoscopy and other minimally invasive methods are now commonly accepted as the standard of</td><td>Thank you for your comment.

No changes to draft report.</td></tr>
</table>

Reviewer	Comment	Disposition
	care, at their inception, literature supporting their use was lacking. RAS, especially as a subset of minimally invasive technique, has unfolded in the same manner. The current literature cited by the HTA compares an immature experience with RAS with a mature experience in open and laparoscopic techniques. This makes meaningful comparison between techniques challenging especially at this early stage in adoption. **RECOMMENDATION 1** In light of the HTA's recognition of the limited volume of literature related to RAS, further study and data related to RAS must be generated before meaningful comparisons can be made to current treatment standards. Furthermore, at this time there is no data to suggest that RAS is unsafe or compromises patient care. SHS requests that the analysis continue until sufficient literature exists. At such time, the HTA can effectively generate recommendations related to the efficacy of the modality as a whole.	
	COMMENT 2 Improved outcomes associated with RAS has been recognized in centers where a high volume of surgery is routinely performed. Several studies have shown that the greater the experience of the surgeon performing robotic procedures, the better the overall outcomes. Experience of not only the surgeon is important, but also of the nursing staff, anesthesia staff, and ancillary care team. This would suggest that centers that perform a high volume of RAS would be the most efficient and provide the best quality of care. This model has proven successful in other care disciplines such as stroke and trauma where regional centers of excellence are created to facilitate best practices and provide the highest level of care. SHS has grown to become the regional leader in RAS and has more experience providing RAS procedures than any other center. The organizational structure of our RAS program has allowed ongoing assessment of RAS quality measures such as length of stay, blood loss, operative time, and complication rate. These outcomes are reviewed by our Robotics Steering Committee and recommendations are made to improve outcomes for each specialty performing RAS. Each specialty performing RAS has maintained on ongoing collection of data for review and publication. This allows improvement in RAS by assessing outcomes. Finally, SHS has also taken an active role in training	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	other surgeons from across the country in RAS. **RECOMMENDATION 2** Regional data regarding RAS and its comparative efficacy to open surgery can be obtained from regional centers of excellence. This data it would would be more meaningful in making recommendations for RAS in the state of Washington. Our recommendation is that HTA work with high volume RAS centers to obtain quality data for assessment and determination of future scope of robotic surgery practice in our state.	
	COMMENT 3 Currently there are additional costs associated with performing RAS procedures. However, the cost to the state of Washington for RAS is the same charges as the laparoscopic procedure given the equivalent CPT codes for robotic and laparoscopic surgery. There is no additional charge to insurance company's or the state for robotic-assisted procedures. The increased capital costs associated with robotic surgical systems have been incurred by hospital systems in an effort to provide patients with state of the art surgical care. In addition, studies that look at operating room costs do not take into account the cost savings created by shorter length of hospital stay which has been clearly demonstrated in multiple studies of RAS. The economic advantage to employers when a patient is able to return to work sooner after RAS as compared to open surgery is difficult to measure, but represents a downstream advantage of RAS over conventional surgery. **RECOMMENDATION 3** Cost analysis of RAS versus open or laproscopic surgery should include the savings associated with shorter length of stay and earlier return to work.	*Thank you for your comment.* *No changes to draft report.*
	COMMENT 4 Operative times associated with RAS are by in large longer than the open surgical counterpart in the initial experience of robotic surgeons. This is related to increased time associated with gaining minimally invasive access to the body. However, with experience the RAS procedure approaches the operative times associated with the open surgical procedure. In our experience with RAS at SHS, the	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	operative times associated with high voume procedures such as prostatectomy and hysterectomy are now equivalent to the open surgical times and in some cases faster. There is one RAS procedure that has demonstrated faster operative times than the open counterpart from the beginning and this is trans-oral surgery for base of the tongue cancer. This use of RAS is not only more efficient than the open procedure but is less morbid for the patient andleads to better functional outcomes. **RECOMMENDATION 4** With increasing experience, the costs associated with longer operative times in RAS procedures will decrease. Therefore, further study should be undertaken in high volume RAS centers to determine the true cost of the procedure as it related to operative time.	
Brian Fong, MD, FRCS(C) (Western Washington Medical Group)		
	"Within urologic surgery, robotic surgery has transformed the quality and effectiveness of care I provide to patient with urologic disease such as prostate cancer, kidney cancer, and congenital urinary obstructive diseases. While the upfront costs may be higher, the actual overall costs are less, as patients consistently have a decrease hospital stay, decreased rate of blood transfusion and decreased complication rate. An unmeasured advantage is the quicker return to work for patients which increases their productivity within their employment environment. I raise my concerns about the potential for a decision of refusal of reimbursement for minimally invasive robotic-assisted surgery when my own experience suggests excellent outcomes, overall cost effectiveness, and improve patient satisfaction. With robotics, surgery can be offered to a wider range of patients (obesity, prior abdominal surgery) with excellent outcomes. In kidney cancer, there is the benefit of preservation of kidney function with robotic partial nephrectomy and decreased long term possibility of renal failure and the potential health care cost related to this (esp. dialysis). My belief is that within urologic surgery there is no going back to open surgery or traditional laparoscopy as the robotic approach is superior to those old techniques. It would be a great tragedy	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	for Washington State Health Care Authority to declare urologic robotic surgery to be a non-covered procedure given the multiple medical studies suggesting equivalence and possible superiority to traditional open/laparoscopic techniques with the bonus of less morbidity and consistent excellent outcomes. Washington state has a impressive track record of building high technologies industries (e.g. computers, aviation) and high-tech surgery should be supported with the same pride and ambition."	
Theresa Froelich, DO (University Place Medical Clinic)		
	"To Washington State Health Care Authority, I have been doing robotic laparoscopic surgery for the last 2 years and it certainly has a place in women's health care. This procedure improves outcomes in obese women, women with prior abdominal surgery and it shortens recover (decreases length of stay). Women are back to work sooner with less post operative complications. I believe it would be a disservice to your patients to not offer this innovative procedure."	*Thank you for your comment.* *No changes to draft report.*
Heidi J. Gray, MD (University of Washington)		
	"I am a Gynecologic Oncologist in Washington State who has specialty training in robotic surgery for gynecologic cancer. I am writing you to strongly consider the benefits of robotic surgery for women patients with gynecologic malignancies. I used to perform over 80% of my endometrial cancer hysterectomies as an open procedure with 3-7 day hospital stay and 20-50% wound infection rate. Most patients with endometrial cancer are overweight, obese or morbidly obese (BMI >30). The improved technological advances of robotic surgery has enabled me to now perform 70-80% of my patients with endometrial cancer with minimally invasive surgery as robotic assisted laparoscopy. They stay overnight in the hospital, have less infections, quicker recovery, less blood loss, less pain. I have less postoperative office visits for wound care and complications compared to open surgery. There are many studies now showing the benefit of robotic assisted surgery over open procedures. Please contact me if you have any further questions. I have no financial ties or disclosures to Intuitive."	*Thank you for your comment.* *No changes to draft report.*
Peter Grimm, DO (Prostate Cancer Center of Seattle)		

Reviewer	Comment	Disposition
	"The effectiveness of Robotic surgery for Prostate cancer compared to open prostatectomy or other treatments should deal specifically with effectiveness of the treatment to eradicate cancer as a sole modality. In prostate cancer the most specific measurement is PSA based evaluation, as the result is entirely dependent on the effectiveness of the treatment. Other measures such as overall survival, metastasis free survival and other endpoints not PSA based are dependent on the nature of the disease and the overall health of the patient (as well as the effectiveness of the treatment) and therefore are less reliable tools for comparing results of the treatment itself."	*Thank you for your comment.* *No changes to draft report.*
Patti Holten		
	"As a patient of a Robotic assisted heart valve surgery, I wanted to give my input on the difference between a Robotic surgery and a open sternotomy. There is more then a couple positives to be said about the Robot, recovery time is much faster then an actual open sternotomy, with only a 3 day stay in the hospital and discharged home without restrictions so your back to work and your daily living that much faster, compared to the 5 to 7 day stay in the hospital with an open sternotomy along with weeks of care giving at home. I have the pleasure of working in a cardiothoracic surgeons office and I see the amazing difference between a patient having a Robotic surgery done and the one who has an Open Sternotomy.We see the occasional patients with infection and those with lingering depression. From my own personal experience of having a Robotic assisted heart surgery, my recovery was so much faster and all in all was so much better, I feel great and didn't have all the down time that comes with open heart surgery's."	*Thank you for your comment.* *No changes to draft report.*
Catherine Hunter, DO		
	"As a practicing OBGYN for nearly twenty-seven years, I have seen many changes and innovations in my field; first, laparoscopy, fiber optics, anesthesic improvements, better electrocautery instruments, etc. There is no innovation in surgery that has impacted my ability to care for my patients as much as the robot. The haptics of robotic surgery allow the surgeon to move on all planes of articulation, not just pronation, supination, pushing and pulling. Acute angles around difficult or	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	large pathology become manageable. Three-D vision allows for unparalleled visibility. I can get my scope within inches of structures to assess an adhesed area or difficult anatomy. Now 500-lb endometrial cancer patients can have minimally invasive surgery and be home the next day ,resuming nearly all activities and start adjunctive therapy sooner. In short, almost all patients now have access to minimally invasive surgery. But, just as the experienced pilot must spend many hours in the cockpit on normal, routine flights to be able to make the decision and land the plane in trouble safely in the river, so must the robotic surgeon spend time in the 'cockpit' honing his/her skills for the challenging cases. To limit or restrict this is a disservice to all patients, I might even say discriminatory to 'normal' patients, and to the surgeons who spend the time and energy to maintain excellence in their field. Of course, you can find any number of studies showing better overall outcomes, length of stays (my patients go home the same day),complications, blood loss, and patient satisfaction. Of my last 210 robotic cases I have opened three. Please allow the surgeons to make the medical decisions we were trained to make in the best interest of our patients. For your information, Please reference the two editorial letters regarding this subject in the March, 2012 issue of OB.GYN News on page 16. Thank you very much for your consideration in this matter. "	
Peggy Hutchison, MD (Seattle OB/GYN Group)		
	"I am a Gynecological surgeon. I work at Swedish Medical Center. I do all types of hysterectomies including vaginal hysterectomies, abdominal hysterectomies, and Robotic laparoscopic hysterectomies. I have done over 100 Robotic laparoscopic hysterectomies. Prior to this I had done about 250 Laparoscopic hysterectomies. I have a very clear perspective on the difference between the 2 approaches. The Robotic assisted laparoscopic total hysterectomies is a great improvement over the laparoscopic hysterectomy. The visualization is in 3-D and allows the surgeon to see the uterine vessels, the bladder and the ureters better. The visualization is such an improvement that I have been able to remove larger uterus, dissect the bladder off the uterus with more precision and see the ureters to avoid injury. I can also see the uterine vessels and transect them saver and far away from the	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	bladder and ureters. This provides added safety to the patient. I have also been able to do hysterectomies on women who have endometriosis and adhesions or scar tissue from prior surgery. These cases would never have been done with laparoscopy only. Again, the visualization as well as the fine instrumentation has greatly enhanced the ability to do this. This allows a woman to avoid a large open incision with greater risk of infection, bladder, bowel and ureteral injuries, bowel obstructions, and deep venous thrombosis. The patient with a Robotic hysterectomy will not only have fewer complication, their recovery is better. They can be back to work in 2 weeks, they use far less narcotics, they are less constipated and they are very happy with the outcome. In addition, my patients leave the hospital in less than 24 hours. They are up walking, eating and functioning at a very high level. Some of them use no narcotics. The articulation of instrumentation is superior with the Robot as compared with traditional laparoscopy. They allow you the ability to rotate the instruments in such a way that there is less risk of injury to other organs. You are also able to grasp the major vessel of the uterus with more accuracy. You are able to move into anatomical spaces you could not do with traditional laparoscopy. When you operate on a person you can encounter unexpected problems which complicate you surgery. Your patient can have adhesions, scarring from endometriosis, obstructed view of the uterine vessels, a bladder that is adherent to the surface of the cervix or uterus, or vessels that are difficult to get to with traditional no articulated instruments. There is no doubt the robot is far superior in these situations than traditional strait stick laparoscopy. All of these increase the chance the patient will need an open laparotomy for their hysterectomy if it is approached by traditional laparoscopy. After many years of operating I have told many people the da Vinci Robot is the greatest invention in medicine in 25 years. Every MD that starts to use the Robot in gynecology will never return to straight stick laparoscopy or large open incisions.	

Reviewer	Comment	Disposition
	The da vinci Robot is better for the patient and the MD. It is safer and much easier to use than traditional laparoscopy. It allows for complicated surgeries to be performed through small incisions with fewer complications, less pain, better visualization, and faster recovery to the work force. In addition, when doing a total hysterectomy the vagina has to be closed with sutures. It is very difficult to suture with tradition laparoscopy. When using the da Vinci Robot the ability to suture is simple and very easy. Your ability to tie knots is better. Your ability to hold the tissue is better and more delicate and the risk of injuring the bladder or ureters is decreased. Supporting modern technology which is changing the face of women's health care is very important. This is a medical technology that is well studied, used throughout the United States and a major improvement over all types of approaches to hysterectomies. Please don't revert back to old technology. Please allow medicine to continue to progress and deliver the best health care to women. If you would like to hear from me in person I would be happy to testify on behalf of my patients. I would be happy to have my patients also come to tell you how well they did with this surgery and how happy they are with the outcome. The return to society is good, but it will be greater and greater as every hysterectomy is done either with the da Vinci Robot or by a vaginal approach. There will be less time off work, fewer readmissions to the hospital, lowered hospitals stays, less narcotic use, and healthy women. "	
Intuitive Surgical		
	"Robotic surgery's primary contribution has centered around its ability to enable complex surgeries to be performed in a minimally invasive fashion. Prior to the introduction of robotic surgery, the percentage of prostate, cervical, endometrial, and other types of cancers and complex pathologies treated with minimally invasive surgery (MIS) was a small minority. Save for a handful of highly trained surgeons, the precision, articulation, and vision necessary to safely and efficaciously complete these procedures did not allow meaningful adoption of MIS. However, with the introduction of robotic surgery, the majority of these procedures are not done minimally invasively.	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	This has had a profound effect on the economics and outcomes of these procedures: Patients go on to adjuvant therapies sooner and healthier; they leave the hospital sooner, thus consuming fewer resources and costing less; while returning to their normal lives more quickly. This enabling of MIS for complex and oncologic surgeries has provided substantial value to everyone in the treatment equation, from patients to surgeons to hospitals to payers. In general, Intuitive Surgical finds this draft report to be a thorough review covering many of the prospective and retrospective comparison studies of outcomes following prostatectomy, hysterectomy, nephrectomy, colorectal, general, thoracic and cardiac surgery performed with robotic assistance, laparoscopy, or an open approach. We note, however, that there are gaps in the representation of available comparative studies of robotic-assisted surgery and insufficient detail on the methods of statistical analysis. We appreciate the significant amount of work and effort that was required to complete this draft report and the pressing need for these types of analyses. The peer-reviewed clinical literature base pertaining to the da Vinci Surgical System and its uses is growing at a rate of approximately 4-5 articles per day. At present therea re over 4,800 peer-reviewed articles related to the *da Vinci* Surgical System of which more than 570 are comparative cohort studies. Intuitive Surgical belives it is important to insure the includsion of all relevant previous health technology assessments and publiced peer reviewed articles in order to complete a comprehensive analysis of the clinical benefits of the da Vinci technology. As a document that will be used by policy makers, it is important to provide the complete landscape for accurate and concise decision making."	
	The main parts of the Washington State HTA (WASHTA) appear to be based on the findings of the CADTH (Canadian Agency for Drugs and Technologies in Health) Technology Report, Issue 137, September 2011. We are aware of a more recent HTA report conducted by the Health Information and Quality Authority, Ireland (HIQA) published on Jan 11, 2012. We believe that this report would supersede the CADTH findings. The HIQA HTA dealth with the same research questions as the CADTH and included data through Jan 2011. Thus the HIQA report is more recent, of equal quality and at least as comprehensive as the CADTH report (HIQA included Urology, Gynecology, Cariothoracic and ENT/Head & Neck indication).	*Thank you for your comments.* *A 'best evidence' systematic review methodology was used to complete the report. We strictly adhere to "the methodology description which appears on page 4 <Executive summary> <in detail in Methods section page 26-30> of*

Reviewer	Comment	Disposition
	We are enclosing a copy of the HIQA HTA for your review. On page 27 of the hIQA report it is explicityly stated that "the systematic review performed by the Canadian Agency (CADTH) was updated with appropriate analysis of the data and expert support by the CADTH team." We believe it is advisable for the Washington State Health Care Authority to include the highly relevant, recent HIQA HTA (which followed the CADTH methodology) and exclude the more outdated CADTH HTA in accordance with the methodology description which appears on page 4 of the WASHTA draft report.	*the WASHTA draft report"…as excerpted below:* *The Canadian Agency for Drugs and Technologies in Health (CADTH) technology assessment (TA) titled <u>Robotic-assisted Surgery Compared with Open Surgery and Laparoscopic Surgery: Clinical Effectiveness and Economic Analyses (2011)</u> was used, in consultation with the Washington HTA, as the primary evidence base for Key Questions #1 through #4. Where there were high quality comprehensive reviews, they were summarized. A MEDLINE® literature search (September 2011 through January 2012) was completed to identify subsequently published studies. If there were no high quality reviews identified for a procedure, a search, appraisal, and summary of primary individual studies were completed for the past 10 years (January 2002-January 2012).* *The CADTH TA was updated to*

Reviewer	Comment	Disposition
		publication in September 2011. The cited Health Technology Assessment of Robotic-assisted Surgery in Selected Surgical Procedures, published by the Health Information and Quality Authority (HIQA), Ireland September 21, 2011 as noted on page 28 of this document, "A systematic literature search using the CADTH HTA approach was carried out to update the review to January 2011." This TA, therefore, was superseded by the CADTH TA and was excluded. Furthermore, the meta-analyses performed in the HIQA TA, as compared to the CADATH TA, included the identical studies, though fewer, with smaller pooled sample sizes. This further supports the more current status of the CADATH TA and underscores the CEbP's use of a "best eveidence" systematic review methodology.
	"The replacement of the CADTH HTA by the HIQA HTA would have the following key implications: **Prostatectomies** • Addition of data to support higher percentage of patients who regain urinary continence. (Robotic versus Open surgery).	*Please see comment above addressing the HIQA HTA.*

<table>
<tr><th>Reviewer</th><th>Comment</th><th>Disposition</th></tr>
<tr><td></td><td>Statistically significant reduction in complication rates in robotic surgery versus open surgery
Demonstration of a larger reduction in length of stay after robotic surgery versus open surgery than was demonstrated in clinical articles included in the CADTH review.
Cost-effectiveness analysis rather than cost minimization analysis
A cost-minimization analysis as performed by CADTH assumes no differences in outcomes between treatment groups. However, HIQA acknowledged the superiority of RALP (Robotic Assisted Laparoscopic Prostatectomy) versus open and thus performed a cost-effectiveness analysis. The CADTH approach raises concerns as today's evidence does suggest superiority and not equivalent outcomes.
The economic analysis performed by the CADTH does not seem appropriate due to the dramtic differences in the healthcare economic factors between the Canadian and U.S. health care systems.</td><td></td></tr>
<tr><td></td><td><u>Hysterectomies</u>
Robotic assisted versus open radical hysterectomy: Statistically significant reduction in extent of blood loss, transfusions and complication rates in favor of robotic surgery versus open hysterectomy.
Robotic assisted versus laparoscopic radical hysterectomy: Statistically significant reduction in extent of blood loss, transfusions and complication rates in favor of robotic assisted versus laparoscopic radica hysterectomy. Operating time demonstrate no statistically significant difference between robotic and laparoscopic approaches.
Robotic assisted versus laparoscopic hysterectomy for benign disease: Statistically significant reduction in complication rates, conversion to open surgery and transfusion rates. Operating time demonstrate no statisitically sifnificant difference between robotic and laparoscopic approaches.</td><td>Please see comment above addressing the HIQA HTA.</td></tr>
<tr><td></td><td>Additional Literature Search
Although the Washington State HTA performed an extensive literature search spanning the past ten years including all English language articles, there are potentially relevant articles that this search failed to identify. For example, the Journal of Robotic Surgery, a PubMed reference journal that is available onlike at: http://www.springerling.com/content/120470/, is not represented. In all, we found twenty four relevant comparative articles on robotic surgery in JRS covering robotic prostatectomy (10), parial nephrectomy (1), hysterectomy for cancer (9) and benign hysterectomy (4) that were not included in the present report.

There were other publication with potentially relevant data that are also missing from the data</td><td>Thank you for your comment.

We strictly adhere to the methodology description which appears on page 4 <Executive summary> <in detail in Methods section page 26-30> of the WASHTA draft report. The search strategy used MEDLINE® to identify relevant articles. Journals that are not indexed in MEDLINE®</td></tr>
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Reviewer	Comment	Disposition
	analysis. Across all of the covered surgical specialties, we found 38 comparative articles that we belive are *highly informative* to the scientific discussion of robotic surgery. Of these, 30 were published prior to January 31st, 2012, the reported inclusion date for the WASHTA. The remaining 7 have been published since the end of the search period, but contain highly relevant, large sample size, comparative studies that we believe should be considered in the final report. For your convenience, we have also included in Appendix B (Urology Articles) and Appendix C (Gynecology Articles) 167 additional comparative articles which seem to be relevant to the discussion, but were not cited in your report.	*were therefore not included in this report.* *The submitted articles have been reviewed and citations that met the report's inclusion criteria (n=20 studies) have been incorporated into the report. Excluded studies, along with rationale for exclusion, are listed in the Notes section.*
	Data Extraction, Analysis, and Reporting Although this report includes 51 prostatectomy robotic comparison papers, we feel that the weight of evidence found in the missing papers could affect the conclusions reported in the WASHTA report. The combined study size of the missing papers is significant. For example, by including just three articles on Prostate Cancer (Trinh (Appendix A #2); Tewari (Appendix A #3)), the analysis would benefit from data on an additional 167,184 ORP (Open Radical Prostatectomy) patients, 57,303 Laparoscopic Radical Prostatectomy patients and 62,389 RARP (Robotic Assisted Radical Prostatectomy) patients. It is unclear how the results of multiple meta-analyses as well as individual studies were combined from a statistical standpoint as well as how the issues of study heterogeneity and publication bias were quantified.	*Thank you for your comment.* *The additional studies (Trinh 2012, Tewari 2012) were both published after this report's end search date (January 2012), and are therefore not included in this report.*
	Additional Considerations After review of the WASTHA report, we would also like to point out the following: On page 7 of the WASHTA report it states that "There is low strength of evidence that robotic surgery was a safe and effective technique for performing hysterectomy on morbidly obese women." The WASHTA, however, overlooked multiple publications within the specified timeframe which draw a different conclusion: • Seamon, L.G., S.A. Bryant, et al. (2009). "Comprehensive Surgical staging for Endometrial Cancer in Obese Patients: Comparing	*Thank you for your comment.* *Gehrig's inclusion in the CADTH TA precluded its inclusion as an additional study. The Seamon article met inclusion criteria and has been incorporated into the report.*

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	Robotics and Laparotomy." Obstet Gynecol 114(1): 16-21. ○ This case-matched comparison of robotic hysterectomy to abdominal hysterectomy in an obese patient population demonstrated a lower estimated blood loss (109mL vs. 394mL; p<0.001), a shorter length of stay (1 day vs. 3 day; p<0.001), fewer wound problems (2% vs. 17%; p=0.002), and fewer complications (11% vs. 27%; p=0.003) in the robotic cohort. • Gehrig, P.A., L.A., Cantrell, et al. (2008). "What is the optimal minimally invasive surgical procedure for endometrial cancer staging in the obese and morbidly obese women?" Gynecologic Oncology. 111(2008) 41-45 ○ This comparative study of robotic hysterectomy to laproscopic hysterectomy in an obese and morbidly obese patient population deomonstrated that the robotic group experience a lower blood loss (50ml vs. 150ml; p<0.001), a shorter operative time (189mins vs. 215mins; p=0.004), increased lymph node retrieval (31.4 vs. 24 nodes; p=0.004) and a shorter hospital stay (1.02 days vs. 1.27 days; p=0.0119).	
	On page 18 of the WASHTA report, the Overall Summary section, provides a broad statement that, "the complication rates of robotic procedures are comparable to those of open and laparoscopic procedures." • This statement is contradicted on page 35 of the WASHTA report, which describes lower complication rates for robotic prostatectomy versus open surgery • Additionally, the paper by Carlsson et al (Carlsson 2010) reporting on 1,253 RARP versus 485 ORP, provides further evidence to show a conclusive advantage of robotics over open surgery and laparoscopic surgery. • Trihn 2012 and Tewari 2012 provide substantial evidence to show a conclusive advantage of robotics over open surgery and laparoscopic surgery.	*Thank you for your comment.* *The broad comment on page 18 in the Executive Summary addresses the general complication rates for all procedures. Complication rates for specific procedures (e.g., prostatectomy) are discussed individually under KQ2 for each procedure.* *Results of the Carlsson study, along with other studies, are included in the CADTH report and CADTH's meta-analyses.* *Trinh (2012) and Tewari (2012) were excluded from this report because both were published after*

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		the end search date.
	On page 20 of the WASHTA report it states "Each year, approximately 158,000 prosteatectomy procedures are performed in the US (NCI 2011)" • The volume from third party data vendors such as AHRQ and Solucient which are based on payor claims estimate between 85,000-100,000 surgical prostatectomy procedures annually. • NCI, National Cancer Bulletin August 9, 2011, Volume 8 / Number 16 estimate 88,000 prostatectomies were performed in 2008.	*Thank you for your comments.* *Data from the National Center for Health Statistics, based on the National Hospital Discharge Survey, 2009 indicate that 158,000 prostatectomy procedures were performed in 2009 in the United States. Please see: http://www.cdc.gov/nchs/data/nhds/4procedures/2009pro4_numberprocedureage.pdf* *No changes to the report.*
	On page 21 of the WASHTA report it states that "nephrectomy is the most common treatment modality for kidney cancer, with an estimated 150,000 radical nephrectomies and 39,000 partial nephrectomies performed across the US between 2003 and 2008 (Kim 2011) • Please consider that the American Urological Association, in 2009 issued a clinical guideline declaring"…Partial Nephrectomy isnow considered the treatment of choice for most clinical T1 renal masses, even in those with a normal contralateral kidney." ○ The literature demonstrates improved peri-operative outcome for Robotic Partial Nephrectomy, including lower warm ischemia time, and less blood loss.	*Thank you for your comments.* *No change to the report. The quoted passage provides background on the frequency of nephrectomy procedures, and is not intended to review guidance on the type of procedure that professional organizations recommend.*
	On page 32 of the WASHTA report it states that inconsistent results were reported for incidence of complications. The report states that through meta-analysis, retrospective studies, and high or good quality studies it did not show a significant difference. • Carlsson and Trinh 2012 both showed significant reductions in complications for Robotyic Assisted procedures versus open procedures.	*Thank you for your comments.* *Results of the Carlsson study, along with other studies, are included in the CADTH report and*

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		CADTH's meta-analyses. *Trinh (2012) was not included in this report because it was published after the end search date.*
	On page 39 of the WASHTA report it states the following: "The cost of the robot included in this economic analysis is for the new model (*da Vinci* Si; US$2.6 million). However, the model reported in most of the literature is the older model (*da Vinci*; US$1.2 million). If this analysis had been carried out using the costs of the earlier model, the increased incremental costs of both comparisons (RARP vs. ORP and RARP vs. LRP), would have been roughly half what is reported above." • The pricing quoted in the WASHTA draft report is incorrect, the list price of the da Vinci Si System is $1.75 million U.S. dollars.	*Thank you for your comments.* *The pricing information has been corrected.*
	On page 41 of the WASHTA report it indicates that inconclusive evidence was found when comparing robotic hysterectomy to laparoscoptic hysterectomy with respect to complications and length of stay. • Scandola, M., L. Grespan, et al. (2011). "Robotic-assisted Laparoscopic Hysterectomy vs. Traditional Laparoscopic Hysterectomy: Five Meta-analysis."Journal of Minimally Invasive Gynecology 18(6): 705-715. ○ Meta-analysis of 1,280 robotic hysterectomy patients vs. 1,386 laparoscopic patients found no difference in operative time but a shorter length of stay (Odds ratio =-0.43; CI=-0.68, -0.17), fewer conversions to laparotomy (Odds ratio = 0.49; CI=0.31, 0.77), and fewer complications (Odds radio = 0.68; CI=0.49, 0.94), all in favor of robotic hysterectomy	*Thank you for your comments.* *Scandola (2011) was not indexed in MEDLINE® at the time of our search (MEDLINE® index date Feb 24, 2012). However, given its publication during the search window, the article was reviewed. It did not meet inclusion criteria because it was superseded by the more comprehensive CADTH report.*
	On page 47 fo the WASHTA report it incorrectly states that "Another cost-consequence study reported total mean per-patient costs in the robotic, laparoscopic, and open surgery groups as $50,758, $41,436, and $48,720, respectively." • These dollar values are actually patient charges, not costs to conduct the procedures. Charges are typically not reflective of the true costs of a procedure.	*Thank you for your comment.* *The text has been revised for clarity.*
	On page 52 of the WASHTA report, the following statement is made: "Most of the sub-populations listed in the Key Questions of the WASHTA report were not reported in [CADTH] (2011). Information	*Thank you for your comment.*

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	about surgeons' experience was insufficient to perform a sensitivity analysis regarding the impact of the learning curve on clinical outcomes for any of the nephrecotmy study results" • Consider Bjayani 2009, Journal of urology: In this retrospective series, Robotic Partial Nephrectomy had some significant benefits compared with Laparoscopic Partial Nephrectomy, including shorter ischemic times and a shorter hospitalization. ○ Reported results were obtained by a surgeon with expert laparoscopic skills versus the same surgeon during their learning curve of Robotic renal procedures.	*"Bjayani 2009" appears to refer to Wang & Bhayani (2009), which was included in the CADTH report.*
John Paul Isbell, MD		
	"I am a practicing OB-GYN physician board certified since 1983. I have used robotic surgery for over 2 years at Evergreen Hospital Kirkland, WA. Though skeptical initially, I cannot imagine not having this surgical tool available after 2 plus years of use. The improved recovery patients experience is phenomenal. I am able to perform this minimally invasive surgical technique on obese patients, nulliparous patients, and patients with large uteri. Prior to this technology, a major abdominal incision would have been required in most cases. Besides the amazingly rapid recovery, patients experience marked reduction in pain, reduction in excessive operative blood loss, and reduction in time spent hospitalized (an over night stay is all that is required in 99% plus). I would place robotic surgery's impact on gynecologic surgical patients in a comparable position as was the development of ultrasound technology to the management of obstetrical patients."	*Thank you for your comment.* *No changes to draft report.*
Frank Kim, MD		
	"I am a urologist who have been performing robotic surgery especially for prostatectomies and partial nephrectomies. Clearly robotic approach is the standard of care for these surgeries as oppose to open or pure laparoscopic approaches, in reducing morbidities."	*Thank you for your comment.* *No changes to draft report.*
Richard Koehler, MD		
	"Although I have performed robotic cases, I don't feel its benefits outweigh the importance of adhering evidence based medicine and responsible stewardship of health care resources. Thus far the demand for robotic surgery has been largely driven by Intuitive Surgical the makers of daVinci and the uninformed public. Allowing industry and the public to set health care policy is a recipe for disaster, and an unaffordable disaster at that. The clinical data thus far has not been able to clearly	*Thank you for your comment.* *No changes to draft report.*

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<tr><td></td><td>or reliably demonstrate improved outcomes yet its expensive is much higher. Personally I think that these robotic cases should only be covered by insurance if they are part of a research protocol evaluating the effectiveness and clinical outcomes. That way cases are concentrated at high volume centers, minimizing risks to patients, and the robotic wave will not propagate in the absence of data at the expense of precious health care resources based upon corporate greed and public misinformation.”</td><td></td></tr>
<tr><td colspan="3">Baiya Krishnadasan, MD, FACS (Franciscan Health System)</td></tr>
<tr><td></td><td>“I am a general thoracic surgeon at St. Joseph Medical Center in Tacoma, Washington. I am writing to you regarding your recent call for comments regarding the State of Washington Robotic Surgery HTA. The primary focus of my practice is in the chest, however the issues relating to abdominal surgery can be applied to thoracic surgery as well.

I am a strong proponent for robotic surgery. I have incorporated robotics into my practice since 2008 and it has made a large impact in the care of my patients. Specifically the three dimensional visualization and the robotic wristed instruments have made work in the chest dramatically easier and more effective. I have utilized robotics for chest masses, lung and esophageal cancer as well as for benign problems. I have found that

patients leave the hospital earlier and recover to their work quicker with the smaller incisions and more precise dissection. I would be happy to share my data with you if you are interested.

Patients with larger BMI’s are particularly easier to manage with robotics, primarily because of the ability of the robotic instruments to overcome the issues related to chest wall depth and recovery from larger incisions.

I strongly discourage your from curtailing the access of patients to robotic surgery. This would be very short sighted and possibly disastrous for some patients.”</td><td>Thank you for your comment.

No changes to draft report.</td></tr>
<tr><td colspan="3">David Kummerlow (CADRE, Inc.)</td></tr>
<tr><td></td><td>“On Feb. 1, 2012 I underwent mitral valve repair under the expert care of Dr. Siwek using the robotic (DaVinci) method. I did not approach the surgery lightly and only scheduled it after multiple</td><td>Thank you for your comment.</td></tr>
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<tr><td></td><td>consultations with other physicians and hours of research. The results of my research and discussion with another patient who had undergone the same procedure gave me confidence I was making the correct choice. Dr. Siwek and my local cardiologist Dr. Rodrigues screened and tested me carefully to insure I was a good candidate for this procedure.

The surgery was flawless and my recovery timeline fast:
1 day, discharged from ICU, short walks
2 days, discharged from hospital to a nearby hotel
4 days, 1 hour walk inside the Spokane Mall
7 days, driving and in my home office doing light work and emails
12 days, working 1/2 days, attending meetings with clients, regularly walking 1 to 2 miles
3 weeks, flew to California on college visits with our son
4 weeks, back at work full time including an out of town driving trip

My wife is a Physical Therapist with over 30 years of ongoing experience including treating patients who have undergone the more traditional sternotomy. During my recovery she would frequently compare how much faster I was returning to a normal life compared to her patients who had "the big zipper".

I would recommend that anyone who requires this type of surgery strongly consider having it done through the robotic method under the care of an experienced surgeon like Dr. Siwek. Compared to the traditional sternotomy method my hospital stay was shorter, recovery time considerably faster and I had no complications to speak of. As a self employed individual, it was very beneficial for me to get back to work quickly. As a devoted husband and father of 3 I am just glad to be healthy and able to write this quick note to you.”</td><td>No changes to draft report.</td></tr>
<tr><td colspan="3">Roque Lanza, MD, FACOG</td></tr>
<tr><td></td><td>“As an Obstetrician Gynecologist for the last 32 years I have seen the evolution of laparoscopic surgery from a diagnostic procedure to what it is now. Robotic assistance needs to be viewed as an evolutionary development of laparoscopic surgery . It is a fine instrument that allows better dissection techniques , visualization and more precise surgery. It will allow more procedures to be</td><td>Thank you for your comment.

No changes to draft report.</td></tr>
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Reviewer	Comment	Disposition
	done laparoscopic ally that would otherwise been done with laparotomy. The benefits of minimally invasive surgery over laparotomy are not disputed by any study or survey. I remember when laparoscopic cholecystectomies were considered too costly and time consuming …They are now the standard of care. In my practice, I have all but eliminated open laparotomy by developing my laparoscopic skills over the years including robotic assisted surgery. I truly believe the "long" learning curves discussed in comparing traditional laparoscopy with robotic assisted laparoscopy, reflects an individual's surgical skills with the procedure ,not necessarily learning to do traditional laparoscopy or robotic assisted surgery. By restricting the use of robotic assistance in selective patients you would be preventing the surgeon from using the best instrument available to perform a specific surgery safely . It doesn't make sense . Cost effectiveness is hard to measure, at times it may take common sense. Think of the evolution of transportation; Horse and buggy…Bicycle… automobile..airplane …space craft. Would these have evolved if cost effectiveness were the only measure?. "	
Thomas Lendvay, MD FACS		
	"I am a pediatric urologist at Seattle Children's Hospital and provide laparoscopic and robotic surgery options to my pediatric patients. Many of these children are covered by Medicaid. I have been committed to offering the less invasive robotic approach for historically open surgeries because I have witnessed dramatic reductions in hospital stays times, post-operative narcotic use, and more rapid return to school/daycare in the robotic patients compared to the open cohorts for ureteral reimplantation and pyeloplasties (birth defect surgery to correct urinary reflux and blocked kidneys, respectively). I feel that being able to provide children with the open and robotic options of surgical approach ensures that certain patient populations will not unnecessarily experience higher morbidity and convalescence just because their healthcare is funded by the state. Such a scenario would be in my	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	view socially discriminatory. I understand the need for the state to reign in healthcare costs, however, I oppose eliminating the option for certain patient populations to undergo less invasive surgery.”	
John Lenihan Jr., MD (University of Washington School of Medicine)		
	“I would like to provide feedback and comment on the issue you are studying regarding robotic surgery. I have been performing robotic surgery since 2005 and have become a staunch supporter of this advanced technique of performing minimally invasive surgery. The utilization of computers and surgical robots is a game changer for surgeons. This is clearly the way we will be f=performing almost all surgeries in the future. The utilization of computers will not only enable us to perform more precise and less invasive surgeries with better outcomes for patients, but will also enable us to utilize computer simulation for future training and for the validation of surgical competence. The thought of going backwards and subjecting patients to traditional large incisions with prolonged recoveries and the potential for chronic disabilities afterwards seems similar to the argument that we should go back to horses and carriages and forgo modern modes of transportation.”	*Thank you for your comment.* *No changes to draft report.*
	“There have been clear recommendations to utilize minimally invasive surgery approaches to hysterectomy.[1,2,3] Despite over 100 years of vaginal hysterectomies and 23 years of Laparoscopic hysterectomies,12 over 66% of all hysterectomies are still done using a traditional open approach.[4,5] Reasons for this are predominantly lack of training and perceived difficulty of performing both vaginal and laparoscopic approaches.[6,13] Robotic surgery is simply computer assisted laparoscopic surgery. The computer allows significant improvements in surgeon vision (3-D HD instead of 2-D), increased dexterity (full articulation equivalent to the human hand compared to no articulation of instruments using “straight sticks,” and smaller less painful incisions (due to the remote centers of the laparoscopic trocars that done pull or stretch like traditional laparoscopic trocars do.[7] Second, Physicians are not paid any more for using this advanced system of laparoscopy. Hospitals have been able to add a “surcharge” for this technology, but not all payors will reimburse this. Third, the outcomes are clearly improved in a variety of ways. Patients recover faster and with less pain.[8] This is hard to prove in randomized trials because they haven’t been done yet (Robotic technology was only approved for GYN use in 2005.) There is also substantial benefit to the surgeon with improved ergonomics when compared to laparoscopic and vaginal surgery resulting in far less orthopedic and	*Thank you for your comment.* *References provided do not meet inclusion criteria based on study design, outcomes, and availability of references. See Notes section for exclusion criteria. No changes to draft report.*

Reviewer	Comment	Disposition
	musculoskeletal complaints.[9,10] The main impact of this technology has been to reduce the open incision rate for traditional procedures to very low rates. Prior to the introduction of robotics, almost all prostatectomies were done through open incisions despite over 15 years of experience with laparoscopic approaches. In 2011, over 85% of all of the prostatectomies done in the USA were done with a robotic approach. This allows a much faster recovery with much less morbidity for the patient than the traditional approach. Hysterectomies are the second most common operation done in this country. As noted above, the rate of Open hysterectomies (Total Abdominal Hysterectomies) in the USA is still 66% despite over a hundred years experience with vaginal hysterectomy and twenty years experience with Laparoscopic hysterectomy.[4,5] In our hospital system, we have lowered the open hysterectomy rate to less than 10% utilizing robotic approaches. This approach enables surgeons who don't feel well enough trained to perform laparoscopic hysterectomies or who can only offer vaginal hysterectomies to a few of their patients to now offer a minimally invasive approach to almost all of their patients. The cost saving of robotic hysterectomies compared to abdominal hysterectomies are substantial. And when you include the societal benefits of patients returning to normal and to work months sooner, there is even greater cost benefit noted. In 2011, there were more robotic surgeries performed in the USA than vaginal and laparoscopic put together. And as computer assisted surgeries continue to evolve and improve with newer innovations, this will only increase."	
	"The risk of complications with robotic surgery has been shown to be significantly lower than the risk with abdominal surgery in multiple studies. The risk is comparable to laparoscopic surgery (1.3-3%). The risk of complications has been shown to be higher during the surgeon's learning curve for robotic surgery, but approaches acceptable levels with experience. The main morbidities of abdominal surgeries include excessive blood loss, wound infections, and prolonged hospital stays. The main risks of laparoscopic and robotic surgeries include vaginal cuff issues such as separation and dehiscense (up to 1.5%) and ureteral injury (1%). Blood loss, vaginal cuff infections and prolonged length of stay are all significantly reduced with robotic surgery compared to open surgery.[14] "	*Thank you for your comment.* *References provided do not meet inclusion criteria based on the study being superseded by a systematic review.See Notes section for exclusion criteria. No changes to draft report.*
	"Robotic surgery has substantial benefits in Obese patients when compared to open, laparoscopic or vaginal surgery.[17] Multiple studies have shown less complications, less blood loss, and lower overall	*Thank you for your comment.*

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	hospital stays with faster return to normal when compared to open surgeries. We presented a paper at the Pacific Coast OB-GYN Society in 2010 showing our results with morbidly obese patients to be equivalent to outcomes with normal weight women with the only parameter that was significantly different was increased blood loss in the morbidly obese group.[18] This difference however was less than 50 cc's and not clinically significant. There have only been published studies comparing robotic to laparoscopic and vaginal surgeries; and these have usually included cases performed during the learning curves of the surgeons. Robotic learning curves have been reported to be 50-100 cases for OB-GYNs and 150-200 cases for urologists. Outcomes for cancer patients are similar to open procedures when considering ability to resect all of the visible disease and obtain adequate lymph node sampling. Future developments utilizing fluorescent imaging technology (only available on robotic platforms) will provide even more precise surgeries that cannot be accomplished using traditional techniques such as open or laparoscopic approaches that aren't capable of this advanced ability to see diseased tissue. There is no particular age or gender benefit for robotic surgery since computer assisted surgery is more precise and less invasive for all ages and genders. Regarding benefits to payors, workers who are able to return to the work force weeks and months sooner due to the significantly lower recovery times required for robotics are clearly beneficial to the payors bottom line and to the economy as a whole. [8] "	*References provided do not meet inclusion criteria based on study design, and availability of references.See Notes section for exclusion criteria. No changes to draft report.*
	"There are mixed studies on cost-effectiveness of robotics compared to other modalities based on the methodology of the studies. Most studies published look at direct OR Costs. The primary cost of of surgery is OR's time; and there is a long leaning curve for robotics, so operative times are usually much longer. If indirect costs are also calculated (cost of the entire hospitalization), the robot does better since robotic patients require less post op care, less medications, have less complications, and are discharged sooner. If societal costs are included, the robot is the clear winner due to the significantly shortened recovery period and faster return to normal. [15,16] "	*Thank you for your comment.* *References provided do not meet inclusion criteria based on comparator/intervention,and availability of references.See Notes section for exclusion criteria. No changes to draft report.*
Brian E. Louie, MD, FRCSC, FACS (Swedish Cancer Institute and Medical Center)		

Reviewer	Comment	Disposition
	"I read with interest the health technology assessment on robotic assisted surgery since we are one of the only groups in Washington State to use the robotic for thoracic surgery. Overall, I thought this was an excellent review of the current status of robotic surgery across all surgical specialties and procedures. It confirms my impression as well as my group's impressions that there is preciously few comparative studies particularly in the newer specialties now accessing the robot. From a thoracic surgery standpoint, I think the evaluations of robotic lung resection, robotic thymectomy, fundoplication and myotomy for achalasia were all appropriate. For lung and thymus, there is little evidence for robotic surgery as of the data of this review. However, for lung resection there are several comparative reports forthcoming this year including our own comparison with VATS lobectomy that will be published in the Annals of Thoracic Surgery later this year that are starting to highlight the benefits. Clearly, more information is required to confirm oncologic benefit and cost comparisons. For thymectomy, our initial evaluation, which was cited in the references and clearly is an early analysis continues to show benefit, has continued to be correct with the average length of stay now about 1.25 days and a return to work by the patients within 10 days. In my opinion, for the areas like ours where there is little comparative data, robotic surgery should be covered with conditions. I think ongoing assessment of the data will be key in determining payment. I don't think that there should be any additional payment for robotic surgery since it remains a platform to conduct an operation. Providers like us who are at the forefront of technology and care and who are reviewing our data and outcomes should have the opportunity to show how we have used the robotic to improve the outcomes of patients, shortening LOS and get the patients back to work sooner. Congratulations on an excellent review."	*Thank you for your comment.* *No changes to draft report.*
Jonh Luber, MD, FACS		

Reviewer	Comment	Disposition
	"I have been a cardiac surgeon in practice for 31 years. Over half of my career has been spent in academics, from Asst Professor to Chairman of the largest academic program in New York, Albany Medical College, from 1994 to 1998. I have reviewed both the outcomes in robotics in CT surgery as well as the opinions from the current RUC Chair. There appears to be only marketing and no demonstrable improved outcomes for a substantial increase in cost and an unacceptable learning curve. I believe that robotics deserves close study in the academic environment but is currently a technique in search of an indication. It should be supported for study but not for routine patient care in any specialty. No acceptable outcomes studies demonstrating superiority exist."	*Thank you for your comment.* *No changes to draft report.*
Gordon L. Mathes, JR., MD (Rocky Mount Urology Associates)		
	"I am a urologist in North Carolina. I perform robotic prostatectomy and robotic partial nephrectomy, among other robot-assisted procedures. There is NO question at all that the surgical robot enhances outcomes for my patients. Surgical blood loss, which is decreased by 90% with the use of robotics, is enough of a reason BY ITSELF to prove the superiority of the robotic technique."	*Thank you for your comment.* *No changes to draft report.*
Patris Marandi, MD (Providence Everett Medical Center)		
	"I have recently started to perform Robotic assisted colon surgery and cholecystectomy. In have 10 years plus experience in laparoscopic colon resection and much longer experience with other laparoscopic abdominal surgeries. In Robotic assisted colon surgery, I have seen decrease in length of stay by one to two days in comparison to laparoscopic colon resection and less narcotic pain mediaction use. In regards to Robotic cholecystectomy, my patients have required less narcotic pain medication in comparison to laparoscopic cholecystectomy. I see great advantage in use of Robotic surgery in all colonic surgeries specially in rectal tumors and upper abdominal surgeries(such as Nissen funduplication) so far. I encourage you to allow this technology to be offered to all patients equally."	*Thank you for your comment.* *No changes to draft report.*
Heather Miller, MD (Swedish Medical Center)		

Reviewer	Comment	Disposition
	"I understand that there is a comment period regarding coverage of robotic surgery? the vast majority of the hysterectomies and myomectomies at our institution are done robotically. This has been a revolution in gyn surgical care. Prior to the robot (2005/2006) most of these procedures were being done through large laparotomy incisions. There is no question that the morbidity from a laparotomy incision is much greater than that from a laparoscopic/robotic procedure. The hospitalization is less than 24 hours in many cases and recovery is in the 2 - 4 week range as opposed to 6 - 8 weeks. Many surgeons are not trainned to perform hysterectomy or myomectomy with simple laparoscopy ie without the robot. Laparoscopy without the robot assist would not be a reasonable alternative/option in most cases because the surgeon would not be able to do the case without the robot. Covering laparoscopy but not robotics would basically limit the patient to laparotomy in most cases. Robotically assisted laparoscopy should be covered."	*Thank you for your comment.* *No changes to draft report*
Karen Nelson, MD		
	"I want to voice my strong concern that reimbursement for robotically assisted minimally invasive surgery may be eliminated for certain patients, including state employees and Medicaid patients. I have been performing robotically assisted gynecologic surgery since 2005. Prior to that, I performed minimally invasive surgery vaginally and laparoscopically. Studies are clear that many advantages accrue to patients who undergo minimally invasive surgery including shorter hospital stays, shorter recoveries and quicker return to work. Minimally invasive surgery also reduces the risk of adhesion formation. Adhesions may result in pain and/or bowel obstructions necessitating additional surgeries. In some cases, minimally invasive surgery can be performed vaginally or laparoscopically. However, robotically assisted surgery is especially well suited for patients with higher body mass indices (obese patients), patients with prior surgeries and patients with enlarged uteri. Many of these patients would require a large abdominal incision if robotics were unavailable. Higher hospital costs are associated with open procedures, as are greater risks of wound infection and adhesion formation. This is an injustice to the patient."	*Thank you for your comment.* *No changes to draft report*
Kerilyn Nobuhara, MD, MHA (Senior Medical Consultant, Washington Health Care Authority)		

Reviewer	Comment	Disposition
	"Here is my initial draft for the agency comments on this OHSU report. I was disappointed with the overall quality of the report, but this is probably more reflective of the lack of medical evidence in general for robotic assisted surgery. I will probably add some additional commentary about the meta-analyses performed for this review."	*Thank you for your comment.* *No changes to draft report*
	"This report highlights the absence of high quality medical evidence addressing the impact of robotic assisted technology on clinically meaningful surgical outcomes. The best available evidence confirms that robotic assisted technology is associated with higher costs per procedure per patient. The report does not emphasize that robotic assisted surgery must only be considered in the context of the standard (open or laparoscopic) approach itself being supported by medical evidence. Robotic assisted surgery is a method of performing a surgical procedure and is a matter of choice of the surgeon. At present, robotic assisted surgery is not treated as a separate service by the American Medical Association, but is considered incidental to the primary surgical procedure, and therefore not separately billable. While this report attempts to consider robotic assisted technology as a separate service, by structuring the key questions around different surgical procedures, the actual determination of the medical necessity and impact of this specific technology on meaningful clinical outcomes is problematic at best. Another key point which is undermined in this report is that the robotic assisted technology cannot equilibrate technical or decision making skills among different surgeons, and therefore, as is the case for all procedure based clinical studies, the widespread applicability of outcome measurements cannot be assessed. With individual surgeon expertise as the primary confounding variable, many of the evidence ratings require further scrutiny."	*Thank you for your comment.* *No changes to draft report*
	"p. 2 "Many procedures are associated with increased complexity, operative times, and technical difficulty when attempted laparoscopically, and open laparotomy approaches are the current standard of care." This statement is incorrect, and for several surgical procedures a laparoscopic approach rather than an open laparotomy is the established standard of care. This baseline assumption lead to several incorrect comparator selections for this report, which are highlighted below."	*Thank you for your comment.* *The Washington HTA identified the comparators used in this report. All comparative studies using either open or lapararoscopic procedures were therefore included. This does recognize that, for some procedures, laparoscopy is either*

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		not available as a surgical option (i.e. various cardiac and gynecologic surgeries), or extremely difficult to perform (i.e. partial nephrectomy). In these cases, open procedures are the standard of care and, therefore, are the comparator studied.
	"pp. 5-6 For both the radical prostatectomy and hysterectomy KQ 1 comparators, robot assisted surgery was associated with reduced blood loss and risk of transfusion as compared with the open procedure. Selection bias was not taken into account and these statements are misleading, as these patients were only stratified by tumor grade (p. 31). "	*Thank you for your comments.* *Your concerns are addressed in the overall summary section in the ES and in more detail in the Findings/ Limitations section of individual topics In addition, the overall report summary re-emphasizes the presence of dissimilar comparison groups in many studies.*
	"pp. 7-15 Highlight a general lack of evidence regarding the use of robotic assistance in various surgical procedures. However, the amount of discussion in the report is not proportional to the quality or volume of evidence. We recommend that the findings be summarized in a table, listed by procedure and prioritized by the associated strength of evidence: prostatectomy, hysterectomy, nephrectomy, cardiac surgery, gastric band, adnexectomy, adrenalectomy, cholecystectomy, colorectal surgery, cystectomy, esophagectomy, fallopian tube reanastomosis, fundoplication, gastrectomy, ileovesicostomy, liver resection, lung surgery, myomectomy pancreatectomy, pyeloplasty, rectopexy, roux-en-Y Gastric bypass, sacrocolpopexy, splenectomy, thymectomy, thyroidectomy, vesico-vaginal fistula."	*Thank you for your comments.* *This report was organized in concert with the work plan developed for the Washington HTA. Reports on over 25 procedures were reported individually addressing all of the Key Questions. We will consider this recommendation for the clinical committee presentation.*

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	"p. 32 The report states a "significant heterogeneity" was present between meta-analysis studies, yet a pooled meta-analysis was performed. Given the heterogeneity between studies we question the rating of a "moderate strength" of evidence. This comment is highlighted again on p. 35, "The quality ratings of the studies, which were observational in design, varied. The choice of patient participation in the treatment arms was subject to selection bias. Those in the robotic intervention arm frequently were younger, had less advanced tumors, and lower PSA baseline scores." "	*Thank you for your comments.* *"Moderate strength of evidence" is defined in detail on page 29 of the report. It is based on the GRADE system. Systematic heterogeneity was investigated and reported by CADTH and CEbP..*
	"p. 43 "Robotic prostatectomy is compared with a laparoscopic approach", this is a typographical error, it should be hysterectomy rather than prostatectomy."	*Thank you, typographical error corrected.*
	"p. 43 The report states that robotic-assisted radical hysterectomy compared with laparoscopic radical hysterectomy is associated with a lower complication rate. However, on p.41 the report states that "inconsistent results were reported for incidence of complications across all meta-analyses." These two statements appear to be conflicting, and clarification is requested."	*Thank you, typographical error corrected.*
	"p. 49 The meta-analysis of pooled data with significant heterogeneity between studies was again utilized to generate the conclusion that weighted mean difference was significant in favor of robot assisted partial nephrectomy in terms of shorter length of hospital stay, at -.25 days, compared with laparoscopic partial nephrectomy."	*Thank you for your comments.* *As noted above, systematic heterogeneity was investigated by CADTH and the CEbP. In addition, Table 5 is preceded by the qualifier "In general, there was consistency across most meta-analyses for the following outcomes: hospital stay, incidence of complications, blood loss, and incidence of transfusion."*
	"p. 112 "Guideline Recommendations Summary" table should be titled "Guideline Summary." The "Quality" of the guideline is unclear. Is this the quality of the evidence on which the guideline is	*Thank you for your comments.* *This table has been renamed as*

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	based? On what basis was this determination made?"	*suggested. The guidelines were quality assessed (pg. 30) using an adapted instrument from the Appraisal of Guidelines Research and Evaluation (AGREE) collaboration. The instrument is provided in Appendix G. The quality of the guidelines is stated in the text. The AGREE instrument takes into account the rigor of development of the guideline which includes systematic methods were used to search for and include evidence.*
	"The report mentions repeatedly the "lack of definition" of an experienced robotic surgeon. Without evidenced-based determinations to establish a minimum case volume requirement in order to achieve competency, we would reiterate that the pooled meta-analysis technique used by this report is fundamentally flawed. If outcome measurements are so clearly associated with the level of experience of the robotic surgeon and center, then insufficient evidence is available to answer Key Question #2, regardless of the associated surgical procedure."	*Thank you for your comments.* *None of the meta-analyses in this report were stratified by surgeons' experience. This was amplified (addressing overall conclusions specifically regarding key question #3) in paragraph 1, pg. 115.*
Steve Poore, MS, MD, FACOG (Women's Clinic-MultiCare Northshore Clinic)		
	"I have been in woman's healthcare for approximately 25 years. As an obstetrician gynecologist I have seen the transition from traditional open laparotomy, to the laparoscopic, and now Robotic minimally invasive approach. Having reviewed the draft evidence report submitted together with the cost analysis versus benefits realized, it becomes clear the focuses on upfront costs is playing a major role in the direction of this	*Thank you for your comment.* *No changes to draft report.*

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	discussion. One area of conversation that has been grossly overlooked is the reduction of pain experienced by the patient. As a direct result of the lower pain and shortened recovery, the patient's return to normal activities is markedly reduced. This important point has resulted in a reduction of recovery interval from what was originally 4-6 weeks for major abdominal surgery(i.e. hysterectomy), 2-4 weeks for minimally invasive straight laparoscopic/vaginal hysterectomy, to what is now seen routinely for robotic surgery: 2 weeks for return to normal activities. Clinical examples are numerous; one that comes to my mind involved a hard working woman whose job was driving an 18 wheel truck cross-country. Surgery was clearly in her best interest and on reviewing the options, return to normal activities(to include work) was paramount in her choice. I'm happy to report her surgery proceeded uneventfully. She returned to full activities in less than 2 weeks; earlier than any other operative approach would've allowed. Examples of clinical outcomes as we are reviewing here are important, and I encourage it's continued review and process. Unfortunately to overlook the implications of reduced pain and return to normal activities grossly under estimates value of this surgical approach: Robotic surgery. As everyone is already aware, use of the da Vinci robotic approach results and no additional compensation to the surgeon or the institution. In my practice, transition from abdominal approach to laparoscopic and now Robotic approach is for more reasons than just cost. Better clinical outcomes which already have been indicated in your monologue. In addition a reduction in pain experienced with a much quicker return to normal activities for patient's. I would hope that in the final analysis, implementation of new technology in an effort to provide superior outcomes and quicker return to normal activities for our patient's is not ruled out for certain covered individuals based on a cost analysis by given insurance plan. Reimbursement policy regarding da Vinci robotic surgery as we all know, results in no additional reimbursement to the physician or cost to the insurance plan over that of straight laparoscopic approach. It is for OUR patients benefit we accept the undervalued reimbursement, for the improved wellbeing of the patient and their earlier return to normal life activities."	
James Porter, MD; Todd Strumwasser, MD; and Mary G. Gregg, MD, MHA (Swedish Medical Center)		

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	"This letter contains comments and recommendations on behalf of The Robotics Committee at Swedish Health Services (SHS) in response to the Health Technology Assessment draft evidence report (HTA) for Robotic Assisted Surgery (RAS). We commend the efforts that have been undertaken by this HTA. In support of continually working to improve patient care, our comments are as follows: **JUSTIFICATION OF INTERESTS** SHS currently has the largest robotics program by volume and specialty within Washington State. Established in 2005, the program has grown each consecutive year, and performed over 1,3000 RAS cases in 2011. The program currently operates at 4 SHS campuses, First Hill, Cherry Hill, Edmonds, and Issaquah, with physicians practicing in the following disciplines: • Urology • Colorectal • General • Gynecology • Gynecologic Oncology • Otolaryngology • Thoracic • Cardiac Surgery SHS has developed and implemented an extensive administrative framework to support a sustainable robotics program that strives to deliver high quality, appropriate care, in an efficient environment. As the program has evolved, SHS and affiliated providers have raised many of the same concerns contained within this HTA. SHS has effectively mediated many of these concerns through collaborative efforts between surgeons, staff, management, and vendors. These efforts include standardized credentially of physicians and allied health providers seeking privileges for robotic surgery, ongoing quality assessment of robotic surgical procedures, and data collection of robotic surgeries for research and publication.	*Thank you for your comment.* *No changes to draft report.*
	COMMENT 1 In response to the HTA's recognition regarding the low volume of literature related to RAS, RAS is a	*Thank you for your comment.* *No changes to draft report.*

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	relatively new surgical procedure. Published literature often is many years behand new technology. A key example of this was with the adoption of laparoscopic surgical techniques. While the use of laparoscopy and other minimally invasive methods are now commonly accepted as the standard of care, at their inception, literature supporting their use was lacking. RAS, especially as a subset of minimally invasive technique, has unfolded in the same manner. The current literature cited by the HTA compares an immature experience with RAS with a mature experience in open and laparoscopic techniques. This makes meaningful comparison between techniques challenging especially at this early stage in adoption. **RECOMMENDATION 1** In light of the HTA's recognition of the limited volume of literature related to RAS, further study and data related to RAS must be generated before meaningful comparisons can be made to current treatment standards. Furthermore, at this time there is no data to suggest that RAS is unsafe or compromises patient care. SHS requests that the analysis continue until sufficient literature exists. At such time, the HTA can effectively generate recommendations related to the efficacy of the modality as a whole.	
	COMMENT 2 Improved outcomes associated with RAS has been recognized in centers where a high volume of surgery is routinely performed. Several studies have shown that the greater the experience of the surgeon performing robotic procedures, the better the overall outcomes. Experience of not only the surgeon is important, but also of the nursing staff, anesthesia staff, and ancillary care team. This would suggest that centers that perform a high volume of RAS would be the most efficient and provide the best quality of care. This model has proven successful in other care disciplines such as stroke and trauma where regional centers of excellence are created to facilitate best practices and provide the highest level of care. SHS has grown to become the regional leader in RAS and has more experience providing RAS procedures than any other center. The organizational structure of our RAS program has allowed ongoing assessment of RAS quality measures such as length of stay, blood loss, operative time, and complication rate. These outcomes are reviewed by our Robotics Steering Committee and	*Thank you for your comment.* *No changes to draft report.*

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	recommendations are made to improve outcomes for each specialty performing RAS. Each specialty performing RAS has maintained on ongoing collection of data for review and publication. This allows improvement in RAS by assessing outcomes. Finally, SHS has also taken an active role in training other surgeons from across the country in RAS. **RECOMMENDATION 2** Regional data regarding RAS and its comparative efficacy to open surgery can be obtained from regional centers of excellence. This data it would would be more meaningful in making recommendations for RAS in the state of Washington. Our recommendation is that HTA work with high volume RAS centers to obtain quality data for assessment and determination of future scope of robotic surgery practice in our state.	
	COMMENT 3 Currently there are additional costs associated with performing RAS procedures. However, the cost to the state of Washington for RAS is the same charges as the laparoscopic procedure given the equivalent CPT codes for robotic and laparoscopic surgery. There is no additional charge to insurance company's or the state for robotic-assisted procedures. The increased capital costs associated with robotic surgical systems have been incurred by hospital systems in an effort to provide patients with state of the art surgical care. In addition, studies that look at operating room costs do not take into account the cost savings created by shorter length of hospital stay which has been clearly demonstrated in multiple studies of RAS. The economic advantage to employers when a patient is able to return to work sooner after RAS as compared to open surgery is difficult to measure, but represents a downstream advantage of RAS over conventional surgery. **RECOMMENDATION 3** Cost analysis of RAS versus open or laproscopic surgery should include the savings associated with shorter length of stay and earlier return to work.	*Thank you for your comment.* *No changes to draft report.*
	COMMENT 4 Operative times associated with RAS are by in large longer than the open surgical counterpart in the	*Thank you for your comment.*

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	initial experience of robotic surgeons. This is related to increased time associated with gaining minimally invasive access to the body. However, with experience the RAS procedure approaches the operative times associated with the open surgical procedure. In our experience with RAS at SHS, the operative times associated with high voume procedures such as prostatectomy and hysterectomy are now equivalent to the open surgical times and in some cases faster. There is one RAS procedure that has demonstrated faster operative times than the open counterpart from the beginning and this is trans-oral surgery for base of the tongue cancer. This use of RAS is not only more efficient than the open procedure but is less morbid for the patient andleads to better functional outcomes. **RECOMMENDATION 4** With increasing experience, the costs associated with longer operative times in RAS procedures will decrease. Therefore, further study should be undertaken in high volume RAS centers to determine the true cost of the procedure as it related to operative time."	*No changes to draft report.*
Charles Richards, MD (Pullman Regional Hospital)		
	"I am an OB/GYN who has been recently been trained in robotic surgery. I have been very impressed by the advantages that robotic surgery offers both for me and my patients. The advanced optics allow me to see anatomical structures that I would not otherwise see at surgery,and allows me to operate more precisely. I must say that I have been impressed by the lessened pain and quicker discharge of patients from the hospital as a result of this. Blood loss is extremely minimal and healing is quicker. In a progressive country where patients demand the best, I feel it would be unwise to eliminate robotic surgery as an option for any group of patients. I feel that robotic surgery is here to stay and is a great option for patients considering hysterectomy or other gynecological procedures."	*Thank you for your comment.* *No changes to draft report*
Clifford W. Rogers, MD (Minimally-Invasive Gynecologic Surgery)		
	"I have practiced Obstetrics and Gynecology in Everett, Washington since 1988. Since 2006, I have limited my practice to Gynecology.	*Thank you for your comment.* *No changes to draft report*

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	Robotic assisted surgery has become a major part of my Gynecology practice the past 3 years. I have performed over 200 robotic hysterectomies since early 2009. Like most ob/gyn physicians, for most of my career 60% or more of the hysterectomies I performed were done through large abdominal incisions. The majority of these patients had 3-4 day hospital stays and were on disability for an average of 6 weeks while recuperating. Starting in 2004, I committed myself to advancing my laparoscopic surgical skills, and began performing more laparoscopic hysterectomies. These patients were often able to go home in 1-2 days, and some were able to go back to work in 2 to 3 weeks. However, my open hysterectomy rate remained about 40%, as I found that the limitations of standard laparoscopic instruments caused me to have to abandon the laparoscopic approach and convert to an open hysterectomy in a significant number of patients. There were additional patients I would not consider for laparoscopic hysterectomy because of anticipated surgical complexity due to obesity, multiple prior laparotomies, larger fibroids, or severe endometriosis. That has all changed dramatically since 2009 with the introduction of robotic-assisted laparoscopic surgery into my practice. My abdominal hysterectomy rate has declined to 5-10% per year the past 3 years. This has made an enormous difference for my patients. Many are discharged from the hospital on the day of surgery, the remainder are routinely discharged after a one night stay. Most of my patients return to work, school, or their other normal activities within 3 weeks. My complication rates have been very low. For example, none of my 200+ robotic hysterectomy patients have required a blood transfusion. Only 1 patient has required re-admission to treat a post op infection. Many of these robotic-assisted surgeries have been complex surgeries due to multiple prior abdominal surgeries, obesity, diabetes, and other risk factors. With the exception of massively enlarged fibroid uteruses or large pelvic masses, I find that the capabilities of the robotic instrumentation allows me to operate with more safety and precision than open abdominal surgery. In summary, the advantage of robotic-assisted laparoscopic surgery (in my experience) is that the	

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	improved instrumentation and capabilities of the robotic platform allows me to avoid an open laparotomy incision in a much higher percentage of my operative patients, perform more complex surgeries more safely, dramatically decrease hospital stays, and allow the majority of my patients to return to work and other normal activities much earlier."	
Dennis W. Shook		
	"The entire surgical process is viewed, by many, as cold and impersonal. Adding a "Robot" to the scenario will only enhance this opinion to many. Further more there is no overall conclusive evidence or opinion that robotic assisted surgeries improve the surgical outcome for the patient. It should be an elective, but , not covered option for the patient"	*Thank you for your comment.* *No changes to draft report*
Leland Siwek, MD (Providence Sacred Heart Medical Center)		
	"I would like to take this opportunity to provide some input regarding the effectiveness and benefits of robotic assisted open heart surgery. I am a practicing cardiac surgeon with extensive personal experience with robotic open heart surgery, having one of the largest experiences with robotic mitral valve surgery in the country. Having trained in the 1980s and being a practicing heart surgeon for 25 years I of course am well aware that conventional open heart surgery via a sternotomy has been the "gold standard". That said I also see that this major life-saving surgery is hard on patients and we have to strive to make that better. Our own interest in robotic assisted heart surgery began as an attempt to make mitral valve surgery better tolerated and more acceptable to patients, hopefully without compromising the excellent results which could be achieved with conventional techniques. We began conservatively with selective cases but soon realized that the robotic approach has definite advantages and the outcomes are even better than with standard approaches. Our initial efforts to do minimally invasive mitral valve surgery were via a mini-thoracotomy endoscopic approach. While this had some advantages it was technically difficult and more importantly not as reliably predictable as we would want. Some cases were simply too difficult to complete that way. We hoped, and subsequently found, that the assistance of the robot with its enhanced instrument dexterity and magnified 3-D vision would make the procedure much more	*Thank you for your comment.* *No changes to draft report*

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	predictable and reliable. We began doing robotic mitral valve surgery at Sacred Heart Medical Center in 2003. We began with more simple, predictable valve repairs but gradually realized that we were able to repair much more complex valves *even better* than we were doing via conventional open surgery! Now when we see complex mitral valve pathology we feel significantly more confident approaching that repair robotically than via other techniques. I think our results over these years indicate the excellent outcomes which can be achieved via a robotically assisted approach. The following results include our very earliest “learning curve” cases and cases done with the first generation of robot. The current robotic system, along with our experience, has made the recent results even better. From June 2003 through March 2012 we have performed 461 robotic assisted mitral valve repair operations and 55 robotic assisted mitral valve replacements. All but one of the valve replacements were planned pre-operatively to be replaced (usually due to rheumatic pathology) with only *one* patient converted from planned repair to replacement. While the cardiopulmonary bypass times are somewhat longer the overall operative times are similar to conventional open procedures and the outcomes are outstanding. I recently summarized our results with mitral valve repair for a book chapter I’ve been asked to write, I will copy that summary here: Between June 2003 and June 2011 we performed 410 robotic mitral valve repairs. (During that same time we performed 53 mitral valve replacements usually for rheumatic valve disease). 61.5% of patients were males and mean age was 59 +/- 13 years (20-86). The repair techniques included leaflet resection (63%), sliding leaflet reconstruction (20%), Gore-Tex suture (W.L.Gore & Assoc. Inc, Flagstaff, AZ) neo-chordae (18%) and isolated ring placement (17%). Concomitant procedures included closure of left atrial appendage in 63% of patients, closure of PFO or ASD in 26% of patients, and Cryo-Maze procedure in 17% of patients. Concomitant robotic CABG was performed in three patients. In this series of 410 consecutive robotic mitral valve repairs there were only two conversions from robotic to open procedure: an 80 y.o. woman who developed an aortic dissection immediately upon institution of cardiopulmonary bypass and a 77 y.o. woman converted to sternotomy at the end of the procedure to control bleeding from the aorta. There was one operative mortality (the patient	

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	with the aortic dissection). There was one conversion from planned repair to replacement (a remodeling annuloplasty ring placement for "functional" mitral regurgitation that still had 2+ MR). Total cardiopulmonary bypass time was 143 +/- 29 min and cross clamp time was 99 +/- 21 min. Both of these times have trended down over the course of our experience despite increasing complexity and frequency of concomitant procedures. During the last two years the cardiopulmonary bypass and cross clamp times were 121 +/- 19 min and 84 +/- 16 min for mitral valve repair without Maze procedure and 164 +/- 44 min and 101 +/- 21 min with concomitant Maze procedure. Post operative TEE showed 0 or trace MR in 98% of patients and no more than 1+ MR in any patient. There were four (1%) perioperative strokes, and 2% reoperation for bleeding (0.5% the last two years). Hospital length of stay was 4.0 +/- 2.5 days. Two patients required early reoperation, one for endocarditis and one for delayed aortic dissection. Five patients have required late reoperation, two for endocarditis, one for dehiscence of a rigid ring, one for mitral stenosis 6 years after quadrangular resection, and one for ruptured Gore-Tex chordae. As you can see these are truly outstanding results with >99% successful valve repair. At least in our experience this is significantly better than we were achieving previously with open conventional techniques. While shorter recovery times are important considerations for minimally invasive surgery we believe the most important priority in mitral valve surgery is optimizing the likelihood of valve repair and we feel we have definitely achieved that with robotic assisted mitral valve repair. Comparison to open sternotomy is difficult, particularly since the patient benefits (successful repair and improved recovery) seemed so obvious to our regional referring cardiologists that they send all mitral valve patients to us for a robotic approach and virtually all the mitral valve procedures at Sacred Heart are performed robotically. Since Sacred Heart's mitral valve data reflects primarily robotic procedures and most of the data from the rest of the state is from conventional procedures, comparison of Sacred Heart to the rest of the state in the COPE database gives at least some indication of the relative effectiveness of the robotic approach: [*see page for graphs*] I'm afraid we don't have extensive cost data, but our hospital did audit the results of patients from 2008 and found that open mitral valve procedure patients had an average length of stay of 12 days vs. 4.8 days for those done robotically. The hospital's costs were an average of $51,669 for open	

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	procedures vs. $36,483 for the robotic procedures. Based partly on this data as well as patient satisfaction etc our hospital confirmed their commitment to our robotic surgery program. While difficult to quantify, our patients have a definite improvement in recovery time. Hospital length of stay is shorter (most of our patients are discharged 3 days after surgery) but more importantly they are able to return to physical activities much quicker. Not only are they not restricted because of sternotomy healing issues, but they generally feel capable of physical activities quicker. We have had active patients return to sports in weeks, or patients with physically demanding jobs return to work in weeks rather than the 2-3 months they would have to wait for a sternotomy to heal. While difficult to capture this obviously saves employers significantly when their employees can return to full capacity sooner. In addition the robotic approach avoids some of the complications associated with conventional surgery, in particular we obviously do not have any sternal wound infections or healing problems and almost never have even minor port incision healing issues. As you know even an occasional sternal healing problem is a huge issue for the patient and adds significantly to the cost of care. Lastly I'd like to make a couple of comments about other robotic open heart surgery. While our interest and experience has emphasized mitral valve surgery we do have a fairly sizeable experience with other robotic cardiac surgery. We have done 72 ASD closures with excellent outcomes and the patient benefits of avoiding a sternotomy. This has become our preferred approach to remove atrial tumors – we have done 22 of these procedures in the past few years. We don't have as much experience with totally robotic coronary bypass (TECAB) as a few other centers in the country but have performed 52 TECABs with average length of stay of 3 days and angiographically confirmed LIMA graft patency in all patients! In summary, I believe that robotic technology is a useful tool which allows an experienced surgeon to offer patients a less invasive approach for certain open heart surgical procedures. In experienced hands the results can be excellent and the patients have the additional benefit of fewer complications and faster recovery and return to normal activities. A hospital such as Sacred Heart which places patient outcomes as the primary priority sees the value of these procedures even though there is significant cost involved. Particularly in a system where the payer is paying based on	

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	the procedure performed (eg Mitral Valve Repair) and not based on the surgical approach used, I would hate to see patients told they had to have an open sternotomy and would not be allowed a less invasive approach just because they are dependent on State coverage. I hope you will take these comments into consideration as you reach your coverage decisions."	
Doug Sutherland, MD (MultiCare Urology)		
	"I am writing in response to the upcoming debate on robotic surgery within the WA Health Technology Assessment program. I applaud the effort. Ideally we can move to prospective analysis of medical technology before implementation, but until that day, this process adds value. That said, I am curious why robotic surgery is being reviewed individually given that the payment for state employees and Medicaid made to hospitals and surgeons is for a laparoscopic surgery with no additional sum for the use of the robot. It would be more accurate to assess "laparoscopy" as a whole I believe. Isolating robotic surgery would make more sense if we were paid additionally for it, which I believe is not the case. Much has been said about robotics. There is essentially no level 1 data to support it, which is not surprising. Robotics represents the frontier of surgical innovation, along with single site surgery and natural orifice surgery (NOTES). And since American citizens get to determine 'their' best option, it is unlikely that such RCTs will be done. So, your committee will also be making a judgement on how surgical innovation is delivered - whether or not it can continue in the market place or will be confined to IRB controlled, state/industry funded trials. More to the point, I believe you are making a judgement about laparoscopy vs. open surgery by tackling the issue of robotics. It can no longer be assumed that a patient with a surgical disease can opt between 3 equally good choices: open, laparoscopic, and robotic approaches. The surgeries we perform now with the robot in many cases cannot be performed nearly as well as with a purely laparoscopic approach, it at all. In the field of urology, that is most evident with partial nephrectomy for renal cell carcinoma. As recently as 2006 there is clear evidence from the Medicare data that partial nephrectomy was severely underutilized for tumors that could have been treated in a	*Thank you for your comment.* *No changes to draft report*

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	nephron-sparring manner, thus sparring the patients the risk of longer term renal insufficiency and related sequelae. That has largely been overcome in large part due to the robotic platform. Why? Because when offered the choice between a *laparoscopic radical* nephrectomy or an *open partial* nephrectomy, patients will favor the less invasive, less painful route. The robot levels the field surgically-speaking: those surgeons who can perform a good open partial nephrectomy can do the same with the robot, but cannot with pure laparoscopy. The primary reason that laparoscopic partial nephrectomy is so incredibly difficult to perform is the need for complex laparoscopic suturing skills (the same is true for laparoscopic radical prostatectomy, pyeloplasty, and cystectomy). The learning curve associated with this procedure is incredibly steep and that is why the procedure is isolated to major academic centers in general. Thus, in the case of the small renal mass the alternatives are open partial nephrectomy, which requires a large midline or flank incision; laparoscopic or percutaneous tumor ablation, which requires a longer radiographic follow-up and a higher risk of recurrence and potential need for additional procedures, or laparoscopic radical nephrectomy. We have looked at our institution's length of stay for open, laparoscopic and robotic partial nephrectomy. On average, the robotic patients stay 2.3 days, the open patients stay 6.3 days (see below). No doubt there are practice patterns and pre-operative selection bias that are influencing those numbers, but a flank incision unquestionably more difficult to recovery from, which is why laparoscopic *radical* nephrectomy and cholecystectomy have become the standard of care over the open approach. *MultiCare Urology Partial Nephrectomy stats:* *Open partial (n=3): Blood loss (ave) 533cc, Ischemia time 55.5 minutes, Hospital stay 6.3 days* *Laparoscopic partial (n=5): Blood loss (ave) 200cc, Ischemia time 23.8 minus, Hospital stay 2.2 days* *Robotic partial (n=26): blood loss (ave) 103cc, Ischemia time 22 minutes, Hospital state 2.3 days.* One might look at those numbers and argue that 4 days of hospital stay is not that much savings for	

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	the cost of the laparoscopic and robotic equipment for an entire population. That is a rational argument indeed. That however is not an argument against robotics, it is an argument about the cost effectiveness of robotics, which is quite different. Considering that we are not paid additionally for robotics, as I said above, the argument is really examining open surgery vs. laparoscopy, not robotic surgery."	
Kim Tillemans, DO		
	"I practice in Minneapolis, MN. I have come to realize having the ability of robotic surgery helps me operate more accurately. Specifically for endomtriosis resection or TLH and myomectomy laparoscopically. It helps me operate with precision with minimal blood loss. I recommend it being available for all patients."	*Thank you for your comment.* *No changes to draft report*
Renata R. Urban, MD (University of Washington Medical Center)		
	"My name is Renata Urban, and I am a gynecologic oncologist at the Seattle Cancer Care Alliance/University of Washington Medical Center. I am writing regarding the upcoming Health Technology Assessment of Robotic Surgery, currently being reviewed by the Washington State Health Care Authority. I am currently trained to offer patients surgery via an open or minimally invasive approach. My minimally invasive skills are in both laparoscopic as well as robotic surgery. My experience with minimally invasive surgery parallels that of the literature (Seamon LG et al Gynecol Oncol 2009, Bell MC et al Gynecol Oncol 2008, Boggess et al, Am J Obstet Gynecol 2008), in that robotic surgery allows me and my colleagues within the field of Gynecologic Oncology to perform minimally invasive surgery with increased safety. In addition robotic surgery allows me to offer minimally invasive surgery to medically morbid patients, such as the morbidly obese. There are certainly patients for whom I choose to perform laparoscopic surgery, instead of roboticassisted laparoscopic surgery. However, certain patients are much better candidates for robotic surgery. I would like to continue to be able to offer my patients the best treatment possible for them, and to be able to offer robotic-assisted laparoscopic surgery as an option."	*Thank you for your comment.* *No changes to draft report*

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