Public Comments and Responses

Robotic Assisted Surgery

April 12, 2012

Center for Evidence-based Policy
Oregon Health & Science University
3455 SW US Veterans Hospital Road
Mailstop SN-4N, Portland, OR 97239-2941
Phone: 503.494.2182
Fax: 503.494.3807
http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/index.cfm

Table of Contents

RESPONSE TO PUBLIC COMMENTS

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)
- Kathryn Barry, MPH, MSN (Health Policy Consultant for Intuitive Surgical)
- 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 is available in Appendices B and C beginning on page 83.

Additional resources provided by parties can be found in Appendix A starting on page 61.

Table 1. Response to Public Comments on Key Questions

Reviewer	Comment	Disposition
Phil Colmenares, MD		
	"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 low levels of complications. This is much different, and a higher (but more patient-oriented outcome) than mere competency in performing the procedure.	*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.*

Reviewer	Comment	Disposition
	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 comparisons to open or laparoscopic surgery. o 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.	*Thank you for your comments.* *All references were forwarded to the TAC.* *Studies provide evidence. No changes to the Key Questions.* *The report will describe all cost*

Reviewer	Comment	Disposition
	○ 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:	*perspectives and model assumptions as described by the identified evidence.*

Reviewer	Comment	Disposition
	○ (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)	
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. 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	*Thank you for your comments.* *No changes to context, PICO 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
	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 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 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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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.*
Kathryn Barry (Health Policy Consultant to Intuitive Surgical)		
	• In 2007, the AMA determined that there was no need for a new code or unique modifier to report laparoscopic procedures completed with robotic-assistance. • In 2008, CMS determined that hospitals should code the primary surgical procedure in a routine and customary manner, and that the primary surgical procedure would be assigned to the clinically-relevant MS-DRG or APC.	*Thank you for your comment.* *The CMS policy and other select private payer policies are summarized in the report as directed by the WA HTA .* *No changes to draft report.*

Reviewer	Comment	Disposition
	• Since 2005, leading payers, such as BlueCross BlueShield, Aetna, CIGNA, HealthNET, United Healthcare, TRICARE, and themajority of managed care plans, have considered robotic-assistence incidental to the primary surgical procedure and not separately billable. Essentially, robotic-assistance is a technology enabler that is interal to the completion of an advanced laparoscopic procedure and should be consistent with any payer's existing laparoscopic medical policies. As the Washington State Healthcare Authority completes its technology assessment of robotic-assisted surgery, I am immediately available to answer your questions and provide additional coverage and reimbursement decisions. In acknowledgement of this established health policy foundation, I am hopeful that Washington State Healthcare Authority will reach the same conclusion for your beneficiaries, which is you will decide to cover laparoscopic surgery completed with robotic-assistance for any patient who presents to an advanced laparoscopist in need of surgery, consistent with your existing laparoscopic medical policies.	
	Health Policy History Related to Robotic-Assisted Surgery • In June 2007, the AMA CPT Editorial Panel, based upon input from several professional societies, lead by the American Urologic Association (AUA) and American College of Obstetricians and Gynecologists (ACOG), concluded that robotic assistance did not require a unique code or modifier, and that current Level I laparoscopic CPT codes were the appropriate consideration. After two years of discussion and review of experience reported by pararoscopic surgeons who routinely incorporated robotic-assistance into their primary plaparoscopic procedure, the AMA determined that there was no need for a new code or unique modifier. A copy of the AMA's 2007 letter to me documenting this decision is available upon request. In 2012, this decision continues to be supported by the professional societies, such as AUA, ACOG/AAGL and STS. In addition, I direct your attention to a recent editorial revision by the AUA that bundles robotic-assistance into the laparoscopic prostatectomy CPT code, 55866. This editorial revision became effective Janaury 1, 2011. I believe this serves as a precedent for future editorial revisions by other professional societies. • In January 2008, an application was submitted to the ICD-9-Cm Coding Coordination and Maintenance Committee at CMS requesting an ICD-9-CM procedure code for "laparoscopic robotic surgery". On March 19, 2008 a clinical presentation was made to this committee in Baltimore, Maryland. A copy of this application is available upon request. Effective October 1,	*Thank you for your comment.* *The AMA decision is discussed in the Background section of the report.* *Select private payer policies are summarized in the report as directed by the WA HTA .* *No changes to draft report.*

Reviewer	Comment	Disposition
	2008, CMS directed hospitals performing laparoscopic procedures with robotic-assistance to report the primary surgical procedure in a routine and customary manner, plus the ICD-9-CM procedure code 17.42, "laparoscopic robotic-assisted procedure". A complete listing of the ICD-9-CM robotic subcategory is available upon request. • United Healthcare and CIGNA Healthcare were the first private payers to issue cover decisions for robotic-assisance in 2005. Their medical policies were the first to state robotic-assistance was incidental to the primary surgery procedure and not separately billable. Many other payers have followed this precedent, as summarized in the table below.[*Note: see full comments for table*]	
	Technology Enabler I defer to others from Intuitive Surgical to provide you with additional peer-reviewed literature and introductions to key opinion leaders from a wide range of surgical specialties. In addition, I encourage your Technology Panel to reach out to practicing surgeons in the State of Washington who have incorporated robotic-assistance into their practices. Peer-to-peer reviews with the well-known limitations associated with standard (rigid) laparoscopic instrumentation. Technical advantages include three-dimensional vision, magnification, intuitive controls, elimination of hand-tremor, erogonomics, and sristed instruments that approximate the motion of the human hand; however, as conluded by the AMA, CMS, and leading payers, the primary surgical procedure remains a laparoscopic procedure. Patients still require abdominal insufflations, placement of trocars and the use of laparoscopic instruments. When the patient leaves the Operating Room, the primary intent of the surgical outcome remains a laparoscopic outcome. Robotic-assitance offers the surgeon technical advantages related to magnification, range of motion, dexterity and reproducibility that are not available with open and/or conventional laparoscopic surgery. As a result, robotic surgeons are able to offer their patients a minimally invasive option when they otherwise might only be eligible for an open surgical procedure. As you complete your deliberations, I hope you will find this information helpful and that it will lead your Committee to conclude that robotic-assisted surgery is consistent with your existing laparoscopic medical policies.	*Thank you for your comment.* *No changes to draft report.*

<table>
<tr><th>Reviewer</th><th>Comment</th><th>Disposition</th></tr>
<tr><td colspan="3">Michael Blee (Kootenai Health)</td></tr>
<tr><td></td><td>“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 surgery” patient from that of a patient undergoing a traditional open procedure:
<table>
<tr><th>Parameter</th><th>Averages (per Society of Thoracic Surgery) for open procedures</th><th>My experience with a Robotically Assisted Procedure</th></tr>
<tr><td>Hours spent in intensive Care post procedure</td><td>68.7</td><td>Less than 12</td></tr>
<tr><td>Post procedure Ventilator hours</td><td>22</td><td>Less than 4</td></tr>
<tr><td>Total days in spent in the hospital post procedure</td><td>9.1</td><td>Less Than 3</td></tr>
</table>
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.”</td><td>Thank you for your comment.
No changes to draft report.</td></tr>
<tr><td colspan="3">Steven R. Brisbois (Sacred Heart Medicad Center)</td></tr>
<tr><td></td><td>“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</td><td>Thank you for your comment.
No changes to draft report.</td></tr>
</table>

Reviewer	Comment	Disposition
	could answer that question. I began performing robotic Gyn in 2006. After a few cases, the answer to 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."	
D. Mark Brown, MD (Southwestern Washington Urology Clinic)		
	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: Open Procedure — Robotic Procedure Operating room time: 70 to 120 minutes — 180 to 360 minutes 1.17 to 2.0 hours — 3.0 to 6.0 hours Blood Loss: 20 to 300cc's — 150 to 500cc's	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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 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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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 lead to secondary complications such as infections, seromas, separations and longer healing times."	*Thank you for your comment.* *No changes to draft report.*
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.*

Reviewer	Comment	Disposition
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 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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	• 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.	
	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 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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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 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.	*Thank you for your comment.* *No changes to draft report.*
	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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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.	
	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 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.	*Thank you for your comment.* *No changes to draft report.*
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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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 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	*Thank you for your comment.*

Reviewer	Comment	Disposition
	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."	*No changes to draft report.*
Peter Grimm, DO (Prostate Cancer Center of Seattle)		
	"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.	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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.“	
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 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. “	*Thank you for your comment.* *No changes to draft report.*
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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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 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	

Reviewer	Comment	Disposition
	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. 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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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. 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 robot-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	*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*

Reviewer	Comment	Disposition
	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). 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.	*4 <Executive summary> <in detail in Methods section page 26-30> of the WASHTA draft report"…as excerpted below:* *The Canadian Agency for Drugs and Technologies in Health (CADTH) technology assessment (TA) titled Robot-Assisted Surgery Compared with Open Surgery and Laparoscopic Surgery: Clinical Effectiveness and Economic Analyses (2011) 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 Robot-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). • Statistically significant reduction in complication rates in robotic surgery versus open surgery	*Please see comment above addressing the HIQA HTA.*

Reviewer	Comment	Disposition
	• 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 o 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. o 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.	
	Hysterectomies • *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.	*Please see comment above addressing the HIQA HTA.*
	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	*Thank you for your comment.* *We strictly adhere to the methodology description which appears on page 4 <Executive*

Reviewer	Comment	Disposition
	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 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.	*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 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-analysies 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	*Thank you for your comment.* *Gehrig's inclusion in the CADTH TA precluded its inclusion as an additional study. The Seamon*

Reviewer	Comment	Disposition
	a different conclusion: • Seamon, L.G., S.A. Bryant, et al. (2009). "Comprehensive Surgical staging for Endometrial Cancer in Obese Patients: Comparing Robotics and Laparotomy." Obstet Gynecol 114(1): 16-21. o 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 o 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).	*article met inclusion criteria and has been incorporated into the report.*
	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,*

Reviewer	Comment	Disposition
		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 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.*

Reviewer	Comment	Disposition
	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 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). "Robot-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, it has been incorporated into the 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.	*Thank you for your comment.* *The text has been revised for clarity.*

Reviewer	Comment	Disposition
	Charges are typically not reflective of the true costs of a procedure.	
	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 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. o Reported results were obtained by a surgeon with expert laparoscopic skills versus the same surgeon during their learning curve of Robotic renal procedures.	*Thank you for your comment.* *"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	*Thank you for your comment.*

Reviewer	Comment	Disposition
	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 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."	*No changes to draft report.*
Baiya Krishnadasan, MD, FACS (Franciscan Health System)		
	"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."	*Thank you for your comment.* *No changes to draft report.*
David Kummerlow (CADRE, Inc.)		
	"On Feb. 1, 2012 I underwent mitral valve repair under the expert care of Dr. Siwek using the robotic	*Thank you for your comment.*

Reviewer	Comment	Disposition
	(DaVinci) method. I did not approach the surgery lightly and only scheduled it after multiple 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."	*No changes to draft report.*
Roque Lanza, MD, FACOG		
	"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 done laparoscopic ally that would otherwise been done with laparotomy. The benefits of minimally	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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 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."	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
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 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.	*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
	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 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	*Thank you for your comment.* *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.*

Reviewer	Comment	Disposition
	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] "	
	"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)		
	"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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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."	
Jonh Luber, MD, FACS		
	"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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	use of robotics, is enough of a reason BY ITSELF to prove the superiority of the robotic technique."	
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)		
	"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.	*Thank you for your comment.* *No changes to draft report*

Reviewer	Comment	Disposition
	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."	
Kerilyn Nobuhara, MD, MHA (Senior Medical Consultant, Washington Health Care Authority)		
	"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	*Thank you for your comment.* *No changes to draft report*

Reviewer	Comment	Disposition
	applicability of outcome measurements cannot be assessed. With individual surgeon expertise as the primary confounding variable, many of the evidence ratings require further scrutiny."	
	"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 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	*Thank you for your comments.* *This report was organized in*

Reviewer	Comment	Disposition
	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."	*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.*
	"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 robot-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,*

Reviewer	Comment	Disposition
		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 based? On what basis was this determination made?"	*Thank you for your comments.* *This table has been renamed as 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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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 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."	

Reviewer	Comment	Disposition
James Porter, MD; Todd Strumwasser, MD; and Mary G. Gregg, MD, MHA (Swedish Medical Center)		
	"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	*Thank you for your comment.*

Reviewer	Comment	Disposition
	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 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.	*No changes to draft report.*
	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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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 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	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	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."	
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. 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	*Thank you for your comment.* *No changes to draft report*

Reviewer	Comment	Disposition
	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 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	*Thank you for your comment.* *No changes to draft report*

Reviewer	Comment	Disposition
	an elective, but , not covered option for the patient"	
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 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	*Thank you for your comment.* *No changes to draft report*

Reviewer	Comment	Disposition
	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 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	

Reviewer	Comment	Disposition
	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 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	

Reviewer	Comment	Disposition
	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 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.	*Thank you for your comment.* *No changes to draft report*

Reviewer	Comment	Disposition
	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 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	

Reviewer	Comment	Disposition
	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 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	*Thank you for your comment.* *No changes to draft report*

Reviewer	Comment	Disposition
	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.”	

APPENDIX A. REFERENCE SUBMITTED BY INTUITIVE SURGICAL WITH DISPOSITION

Notes:
List of studies submitted by Intuitive Surgical with disposition in Italics following each reference.

Prostatectomy:

1. Carlsson, S., A. E. Nilsson, et al. (2010). "Surgery-related complications in 1253 robot-assisted and 485 open retropubic radical prostatectomies at the Karolinska University Hospital, Sweden." Urology 75(5): 1092-1097. I*ncluded in systematic review (CADTH)*

2. Trinh, Q. D., J. Sammon, et al. (2012). "Perioperative Outcomes of Robot-Assisted Prostatectomy Compared With Open Radical Prostatectomy: Results From the Nationwide Inpatient Sample European Urology. *Excluded, published after end search date*

3. Tewari, A., P. Sooriakumaran, et al. (2012). "Positive Surgical Margin and Perioperative Complication Rates of Primary Surgical Treatments for Prostate Cancer: A Systematic Review and Meta-Analysis Comparing Retropubic, Laparoscopic, and Robotic Prostatectomy." European Urology. *Excluded; published after end search date*

Nephrectomy/Partial:

4. Pierorazio, P. M., H. D. Patel, et al. (2011). "Robotic-assisted Versus Traditional Laparoscopic Partial Nephrectomy: Comparison of Outcomes and Evaluation of Learning Curve." Urology. *Thank you. This study has been incorporated into the report.*

5. Anderson, J. E., J. Kellogg Parsons, et al. (2011). "Hospital costs and length of stay related to robot-assisted versus open radical and partial nephrectomy for kidney cancer in the USA." Journal of Robotic Surgery: 1-4. *Excluded, published after end search date*

6. Masson-Lecomte, A., D. R. Yates, et al. (2011). "A prospective comparison of the pathologic and surgical outcomes obtained after elective treatment of renal cell carcinoma by open or robot-assisted partial nephrectomy." Urol Oncol. *Excluded, secondary to SR (CADTH)*

Pyeloplasty:

7. Lee, R. S., A. B. Retik, et al. (2006). "Pediatric robot assisted laparoscopic dismembered pyeloplasty: comparison with a cohort of open surgery." J Urol 175(2): 683-687; discussion 687. *Excluded, population not relevant*

8. Hemal, A. K., S. Mukherjee, et al. (2010). "Laparoscopic pyeloplasty versus robotic pyeloplasty for ureteropelvic junction obstruction: a series of 60 cases performed by a single surgeon." Can J Urol 17(1): 5012-5016. *Excluded, population not relevant*

Radical Cystectomy:

9. Lee, R., B. Chughtai, et al. (2011). "Cost-analysis comparison of robot-assisted laparoscopic radical cystectomy (RC) vs open RC." BJU International 108(6 B): 976-983 *Included in report*

10. Abaza, R., P. P. Dangle, et al. (2012). "Quality of Lymphadenectomy is Equivalent With Robotic and Open Cystectomy Using an Extended Template." Journal of Urology. *Excluded, after end search date*

Hysterectomy - Cancer

11. Paley, P. J., D. S. Veljovich, et al. (2011). "Surgical outcomes in gynecologic oncology in the era of robotics: Analysis of first 1000 cases." American Journal of Obstetrics and Gynecology **204**(6): 551.e551-551.e559. *Excluded, secondary to CADTH*

12. Seamon, L. G., S. A. Bryant, et al. (2009). "Comprehensive Surgical Staging for Endometrial Cancer in Obese Patients: Comparing Robotics and Laparotomy." Obstet Gynecol **114**(1): 16-21. *Thank you. This study has been incorporated into the report.*

13. Gortchev, G., S. Tomov, et al. (2011). "Robot-assisted radical hysterectomy-perioperative and survival outcomes in patients with cervical cancer compared to laparoscopic and open radical surgery." Gynecological Surgery: 1-8. *Excluded, not indexed in MEDLINE®*

14. Estape, R., N. Lambrou, et al. (2009). "A case matched analysis of robotic radical hysterectomy with lymphadenectomy compared with laparoscopy and laparotomy." Gynecologic Oncology. 113 (2009) 357–361. *Included in systematic review (CADTH)*

15. Lau, Susie; Vaknin, Zvi; Ramana-Kumar, Agnihotram V.; Halliday, Darron; Franco, Eduardo L.; Gotlieb, Walter H. "Outcomes and Cost Comparisons After Introducing a Robotics Program for Endometrial Cancer Surgery". Obstetrics & Gynecology. 2012, vol. 119(4):717-724. *Excluded, published after end search date*

Hysterectomy - Benign

16. Payne, T. N. and F. R. Dauterive (2008). "A comparison of total laparoscopic hysterectomy to robotically assisted hysterectomy: surgical outcomes in a community practice." J Minim Invasive Gynecol **15**(3): 286-291. *Included in systematic review (CADTH)*

18. Giep, B. N., H. N. Giep, et al. (2010). "Comparison of minimally invasive surgical approaches for hysterectomy at a community hospital: robotic-assisted laparoscopic hysterectomy, laparoscopic-assisted vaginal hysterectomy and laparoscopic supracervical hysterectomy." Journal of Robotic Surgery: 1-9. *Excluded, secondary to systematic review*

19. Scandola, M., L. Grespan, et al. (2011). "Robot-Assisted Laparoscopic Hysterectomy vs Traditional Laparoscopic Hysterectomy: Five Metaanalyses." Journal of Minimally Invasive Gynecology **18**(6): 705-715. *Thank you. This study has been incorporated into the report.*

20. Jonsdottir, G. M., S. Jorgensen, et al. (2011). "Increasing minimally invasive hysterectomy: effect on cost and complications." Obstetrics and Gynecology **117**(5): 1142-1149. *Excluded, intervention/comparator not relevant*

Myomectomy

21. Barakat, E. E., M. A. Bedaiwy, et al. (2011). "Robotic-assisted, laparoscopic, and abdominal myomectomy: a comparison of surgical outcomes." Obstetrics and Gynecology **117**(2 Pt 1): 256-266. *Thank you. This study has been incorporated into the report.*

22. Sangha, R., D. I. Eisenstein, et al. (2010). "Surgical outcomes for robotic-assisted laparoscopic myomectomy compared to abdominal myomectomy." Journal of Robotic Surgery: volume 4, Issue 4, December 2010, Pages 229-233. *Excluded, not indexed in MEDLINE®*

Sacrocolpopexy

23. Serror, J., D. R. Yates, et al. (2011). "Prospective comparison of short-term functional outcomes obtained after pure laparoscopic and robot-assisted laparoscopic sacrocolpopexy." World Journal of Urology. DOI 10.1007/s00345-011-0748-2*Thank you. This study has been incorporated into the report.*

24. Siddiqui, NY, Geller EJ, Visco AG. "Symptomatic and anatomic 1-year outcomes after robotic and abdominal sacrocolpopexy." Am J Obstet Gynecol. 2012; 206 *Excluded, published after end search date*

25. Elliott, C. S., M. H. Hsieh, et al. (2011). "Robot-Assisted Versus Open Sacrocolpopexy: A Cost-Minimization Analysis." Journal of Urology. Vol. 187, 638-643. *Excluded, published after end search date*

Colorectal

26. Kim, J. Y., N. K. Kim, et al. (2012). "A Comparative Study of Voiding and Sexual Function after Total Mesorectal Excision with Autonomic Nerve Preservation for Rectal Cancer: Laparoscopic Versus Robotic Surgery." Annals of Surgical Oncology: 1-9. *Excluded, published after end search date*

27. Patel, C. B., M. Ragupathi, et al. (2011). "A three-arm (laparoscopic, hand-assisted, and robotic) matched-case analysis of intraoperative and postoperative outcomes in minimally invasive colorectal surgery." Diseases of the Colon and Rectum **54**(2): 144-150. *Previously excluded, comparator not relevant*

28. Desouza, A. L., L. M. Prasad, et al. (2011). "A comparison of open and robotic total mesorectal excision for rectal adenocarcinoma." Diseases of the Colon and Rectum **54**(3): 275-282. *Previously excluded, comparator not relevant*

Adrenalectomy

29. Agcaoglu, O., S. Aliyev, et al. (2012). "Robotic Versus Laparoscopic Resection of Large Adrenal Tumors." Annals of Surgical Oncology: 1-7. *Excluded, published after end search date*

30. Agcaoglu, O., S. Aliyev, et al. (2012). "Robotic vs Laparoscopic Posterior Retroperitoneal Adrenalectomy." Archives of Surgery **147**(3): 272-275. *Excluded, published after end search date*

Gastrectomy

31. Huang, K. H., Y. T. Lan, et al. (2012). "Initial Experience of Robotic Gastrectomy and Comparison with Open and Laparoscopic Gastrectomy for Gastric Cancer." Journal of Gastrointestinal Surgery. *Excluded, published after end search date*

Pancreatectomy

32. Buchs, N. C., P. Addeo, et al. (2011). "Robotic Versus Open Pancreaticoduodenectomy: A Comparative Study at a Single Institution." World Journal of Surgery. *Previously excluded, comparator not relevant (hybrid procedure)*

33. Chalikonda, S., J. R. Aguilar-Saavedra, et al. (2012). "Laparoscopic robotic-assisted pancreaticoduodenectomy: a case-matched comparison with open resection." Surgical Endoscopy. *Excluded, published after end search date*

Roux-en-Y Gastric Bypass

34. Snyder, B. E., T. Wilson, et al. (2008). "Lowering gastrointestinal leak rates: A comparative analysis of robotic and laparoscopic gastric bypass." Journal of Robotic Surgery **2**(3): 159-163. *Excluded, journal not indexed in MEDLINE®*

35. Hagen, M. E., F. Pugin, et al. (2011). "Reducing Cost of Surgery by Avoiding Complications: the Model of Robotic Roux-en-Y Gastric Bypass." Obesity Surgery: 1-10. *Thank you. This study has been incorporated into the report.*

Thoracic Lobectomy:

36. Cerfolio, R. J., A. S. Bryant, et al. (2011). "Initial consecutive experience of completely portal robotic pulmonary resection with 4 arms." Journal of Thoracic and Cardiovascular Surgery. *Excluded, comparator not relevant*

37. Jang, H. J., H. S. Lee, et al. (2011). "Comparison of the early robot-assisted lobectomy experience to video-assisted thoracic surgery lobectomy for lung cancer: A single-institution case series matching study." Innovations: Technology and Techniques in Cardiothoracic and Vascular Surgery 6(5): 305-310. *Excluded, comparator not relevant*

ENT/Head & Neck

38. Dean N.R., Rosenthal E.L. et. al. (2010). "Robotic-Assisted Surgery for Primary or Recurrent Oropharyngeal Carcinoma. Arch Otolaryngology Head Neck Surg 136(4): 380-3. *Thank you. This study has been incorporated into the report.*

Appendix B: Additional Urology Publications for Consideration

Prostatectomy Additional Comparative Papers.

1. Coronato, E. E., J. D. Harmon, et al. (2009). "A multi-institutional comparison of radical retropubic prostatectomy, radical perineal prostatectomy, and robot-assisted laparoscopic prostatectomy for treatment of localized prostate cancer." Journal of Robotic Surgery 3(3): 175-178. *Excluded, secondary to systematic review (CADTH)*

2. Caceres, F., C. Sanchez, et al. (2007). "Laparoscopic radical prostatectomy versus robotic." Arch Esp Urol 60(4): 430-438. *Excluded, secondary to systematic review (CADTH)*

3. Ham, W. S., S. Y. Park, et al. (2008). "Open versus robotic radical prostatectomy: A prospective analysis based on a single surgeon's experience." Journal of Robotic Surgery 2(4): 235-241. *Excluded, secondary to systematic review (CADTH)*

4. White, M. A., A. P. De Haan, et al. (2009). "Comparative Analysis of Surgical Margins Between Radical Retropubic Prostatectomy and RALP: Are Patients Sacrificed During Initiation of Robotics Program?" Urology 73(3): 567-571. *Excluded, secondary to systematic review (CADTH)*

5. Breyer, B. N., C. B. Davis, et al. (2010). "Incidence of bladder neck contracture after robot-assisted laparoscopic and open radical prostatectomy." BJU International **106**(11): 1734-1738. *Included in systematic review (CADTH)*

6. Carlsson, S., A. E. Nilsson, et al. (2010). "Surgery-related complications in 1253 robot-assisted and 485 open retropubic radical prostatectomies at the Karolinska University Hospital, Sweden." Urology 75(5): 1092-1097. *Included in systematic review (CADTH)*

7. Chatterjee, A., L. Chen, et al. (2010). "Robotic Assisted Laparoscopic Prostatectomy versus Laparoscopic Assisted Prostatectomy: A Financial Analysis." J Surg Res **158**(2): 380. *Excluded, secondary to systematic review (CADTH)*

8. Cheetham, P. J., D. J. Lee, et al. (2010). "Does the presence of robotic surgery affect demographics in patients choosing to undergo radical prostatectomy? A multi-center contemporary analysis." Journal of Robotic Surgery: 1-6. *Excluded, secondary to systematic review (CADTH)*

9. CChoi, W. W., X. Gu, et al. (2010). "The effect of minimally invasive and open radical prostatectomy surgeon volume." Urologic Oncology: Seminars and Original Investigations. *Excluded, secondary to systematic review (CADTH)*

10. Cooperberg, M. R., C. J. Kane, et al. (2010). "Adequacy of lymphadenectomy among men undergoing robot-assisted laparoscopic radical prostatectomy." BJU International **105**(1): 88-92. *Excluded, secondary to systematic review (CADTH)*

11. Djavan, B., E. Eckersberger, et al. (2010). "Oncologic, Functional, and Cost Analysis of Open, Laparoscopic, and Robotic Radical Prostatectomy." European Urology, Supplements. *Excluded, secondary to systematic review (CADTH)*

12. Kang, D. C., M. J. Hardee, et al. (2010). "Low Quality of Evidence for Robot-Assisted Laparoscopic Prostatectomy: Results of a Systematic Review of the Published Literature." European Urology **57**(6): 930-937. *Excluded, secondary to systematic review (CADTH)*

13. Kermarrec, I., P. Mangin, et al. (2010). "Is robotic improve laparoscopic radical prostatectomy in complex surgical cases?" Le robot améliore-t-il la prostatectomie totale laparoscopique dans les cas complexes? *Excluded, secondary to systematic review (CADTH)*

14. Lo, K. L., C. F. Ng, et al. (2010). "Short-term outcome of patients with robot-assisted versus open radical prostatectomy: For localised carcinoma of prostate." Hong Kong Medical Journal **16**(1): 31-35. *Excluded, secondary to systematic review (CADTH)*

15. Trabulsi, E. J., J. C. Zola, et al. (2010). "Transition from pure laparoscopic to robotic-assisted radical prostatectomy: A single surgeon institutional evolution." Urologic Oncology: Seminars and Original Investigations **28**(1): 81-85. *Excluded, secondary to systematic review (CADTH)*

16. Truesdale, M. D., D. J. Lee, et al. (2010). "Assessment of lymph node yield after pelvic lymph node dissection in men with prostate cancer: A comparison between robot-assisted radical prostatectomy and open radical prostatectomy in the modern era." Journal of Endourology **24**(7): 1055-1060. *Excluded, secondary to systematic review (CADTH)*

17. Uvin, P., J. M. De Meyer, et al. (2010). "A comparison of the peri-operative data after open radical retropubic prostatectomy or robotic-assisted laparoscopic prostatectomy." Acta Chirurgica Belgica **110**(3): 313-316. *Excluded, secondary to systematic review (CADTH)*

18. Abdollah, F., L. Budus, et al. (2011). "Impact of caseload on total hospital charges: A direct comparison between minimally invasive and open radical prostatectomy a population based study." Journal of Urology **185**(3): 855-861. *Excluded, secondary to systematic review (CADTH)*

19. Albadine, R., M. E. Hyndman, et al. (2011). "Characteristics of positive surgical margins in robotic-assisted radical prostatectomy, open retropubic radical prostatectomy, and laparoscopic radical prostatectomy: a comparative histopathologic study from a single academic center." Human Pathology. *Exclude, published after end search date*

20. Ferronha, F., F. Barros, et al. (2011). "Is there any evidence of superiority between retropubic, laparoscopic or robot-assisted radical prostatectomy?" International Braz J Urol **37**(2): 146-158. *Excluded, secondary to systematic review (CADTH)*

21. Hatiboglu, G., D. Teber, et al. (2011). "Robot-assisted prostatectomy: the new standard of care." Langenbeck's Archives of Surgery: 1-10.Heer R A Rev Recent Clin Trials 2011 Critical Systematic Review of. *Excluded, published after end search date*

22. Heer, R., I. Raymond, et al. (2011). "A Critical Systematic Review of Recent Clinical Trials Comparing Open Retropubic, Laparoscopic and Robot-Assisted Laparoscopic Radical Prostatectomy." Rev Recent Clin Trials. *Excluded, secondary to systematic review (CADTH)*

23. Kasraeian, A., E. Barret, et al. (2011). "Comparison of the rate, location and size of positive surgical margins after laparoscopic and robot-assisted laparoscopic radical prostatectomy." BJU International. *Thank you. This study has been incorporated into the report.*

24. Kommu, S. S., C. G. Eden, et al. (2011). "Initial treatment costs of organ-confined prostate cancer: A general perspective." BJU International **107**(1): 1-3. *Excluded, secondary to systematic review (CADTH)*

25. Kowalczyk, K. J., A. C. Weinburg, et al. (2011). "Comparison of outpatient narcotic prescribing patterns after minimally invasive versus retropubic and perineal radical prostatectomy." Journal of Urology **186**(5): 1843-1848. *Excluded, intervention not specific*

26. Kowalczyk, K. J., H. y. Yu, et al. (2011). "Outcomes assessment in men undergoing open retropubic radical prostatectomy, laparoscopic radical prostatectomy, and robotic-assisted radical prostatectomy." World Journal of Urology: 1-5. *Excluded, published after end search date*

27. Ku, J. H., C. W. Jeong, et al. (2011). "Nerve-sparing procedure in radical prostatectomy: A risk factor for hernia repair following open retropubic, pure laparoscopic and robot-assisted laparoscopic procedures." Scandinavian Journal of Urology and Nephrology **45**(3): 164-170. *Excluded, secondary to systematic review (CADTH)*

28. Lallas, C. D., M. L. Pe, et al. (2011). "Comparison of lymph node yield in robot-assisted laparoscopic prostatectomy with that in open radical retropubic prostatectomy." BJU International **107**(7): 1136-1140. *Excluded, secondary to systematic review (CADTH)*

29. Lowrance, W. T., J. A. Eastham, et al. (2011). "Costs of medical care after open or minimally invasive prostate cancer surgery: A population-based analysis." Cancer. *Excluded, intervention not specific*

30. Plainard, X., E. Valgueblasse, et al. (2011). "[Urinary continence following radical prostatectomy: Comparison of open, laparocopic, and robotic approaches.]." Presse Medicale. *Excluded, secondary to systematic review (CADTH)*

31. Rochat, C. H., J. Sauvain, et al. (2011). "Mid-term biochemical recurrence-free outcomes following robotic versus laparoscopic radical prostatectomy." Journal of Robotic Surgery: 1-7. *Excluded, not indexed in MEDLINE®*

32. Tollefson, M. K., I. Frank, et al. (2011). "Robotic-Assisted Radical Prostatectomy Decreases the Incidence and Morbidity of Surgical Site Infections." Urology. *Thank you. This study has been incorporated into the report.*

33. Weerakoon, M., S. Sengupta, et al. (2011). "Predictors of positive surgical margins at open and robot-assisted laparoscopic radical prostatectomy: a single surgeon series." Journal of Robotic Surgery: 1-6. *Excluded, journal not indexed in MEDLINE®*

34. Barry, M. J., P. M. Gallagher, et al. (2012). "Adverse Effects of Robotic-Assisted Laparoscopic Versus Open Retropubic Radical Prostatectomy Among a Nationwide Random Sample of Medicare-Age Men." Journal of Clinical Oncology. *Excluded, published after end search date*

35. Gianino, M. M., M. Galzerano, et al. (2012). "Costs in surgical techniques for radical prostatectomy: A review of the current state." Urologia Internationalis **88**(1): 1-5. *Excluded, published after end search date*

36. Kowalczyk, K. J., H. Yu, et al. (2012). "Outcomes assessment in men undergoing open retropubic radical prostatectomy, laparoscopic radical prostatectomy, and robotic-assisted radical prostatectomy." World Journal of Urology **30**(1): 85-89. *Excluded, published after end search date*

37. Masterson, T. A., L. Cheng, et al. (2012). "Open vs. robotic-assisted radical prostatectomy: A single surgeon and pathologist comparison of pathologic and oncologic outcomes." Urol Oncol. *Thank you. This study has been incorporated into the report.*

38. Schroeck, F. R., T. L. Krupski, et al. (2012). "Pretreatment Expectations of Patients Undergoing Robotic Assisted Laparoscopic or Open Retropubic Radical Prostatectomy." Journal of Urology. *Excluded, published after end search date*

39. Trinh, Q. D., J. Sammon, et al. (2012). "Perioperative Outcomes of Robot-Assisted Prostatectomy Compared With Open Radical Prostatectomy: Results From the Nationwide Inpatient Sample." European Urology. *Excluded, published after end search date*

40. Villamil, W., N. Billordo Peres, et al. (2012). "Incidence and location of positive surgical margins following open, pure laparoscopic, and robotic-assisted radical prostatectomy and its relation with neurovascular preservation: a single-institution experience." Journal of Robotic Surgery: 1-7. *Excluded, journal not indexed in MEDLINE®*

41. Wang, R., D. P. Wood Jr, et al. (2012). "Risk factors and quality of life for post-prostatectomy vesicourethral anastomotic stenoses." Urology **79**(2): 449-457. *Excluded, published after end search date*

42. Tewari, A., P. Sooriakumaran, et al. (2012). "Positive Surgical Margin and Perioperative Complication Rates of Primary Surgical Treatments for Prostate Cancer: A Systematic Review and Meta-Analysis Comparing Retropubic, Laparoscopic, and Robotic Prostatectomy." European Urology. *Excluded, published after end search date*

43. Ball, A. J., B. Gambill, et al. (2006). "Prospective longitudinal comparative study of early health-related quality-of-life outcomes in patients undergoing surgical treatment for localized prostate cancer: a short-term evaluation of five approaches from a single institution." J Endourol **20**(10): 723-731. *Included in systematic review (CADTH)*

44. Chan, R. C., D. A. Barocas, et al. (2008). "Effect of a large prostate gland on open and robotically assisted laparoscopic radical prostatectomy." BJU International **101**(9): 1140-1144. *Excluded, secondary to systematic review (CADTH)*

45. Drouin, S. J., C. Vaessen, et al. (2009). "Comparison of mid-term carcinologic control obtained after open, laparoscopic, and robot-assisted radical prostatectomy for localized

prostate cancer." World J Urol **27**(5): 599-605.*Excluded, secondary to systematic review (CADTH)*

46. Durand, X., C. Vaessen, et al. (2008). "Retropubic, laparoscopic and robot-assisted total prostatectomies: comparison of postoperative course and histological and functional results based on a series of 86 prostatectomies." Prostatectomies totales re?tropubiennes, laparoscopiques et robot-assiste?es: comparaison des suites postope?ratoires, des re?sultats anatomopathologiques et fonctionnels: a? propos de 86 prostatectomies. **18**(1): 60-67. *Excluded, secondary to systematic review (CADTH)*

47. Gosseine, P. N., P. Mangin, et al. (2009). "Pure laparoscopic versus robotic-assisted laparoscopic radical prostatectomy: Comparative study to assess functional urinary outcomes." Prostatectomie totale laparoscopique standard versus laparoscopique robot-assistée : étude comparative sur les résultats fonctionnels urinaires **19**(9): 611-617. *Excluded, secondary to systematic review (CADTH)*

48. Herrmann, T. R., R. Rabenalt, et al. (2007). "Oncological and functional results of open, robot-assisted and laparoscopic radical prostatectomy: does surgical approach and surgical experience matter?" World J Urol. *Excluded, secondary to systematic review (CADTH)*

49. Hu, J. C., X. Gu, et al. (2009). "Comparative effectiveness of minimally invasive vs open radical prostatectomy." JAMA - Journal of the American Medical Association **302**(14): 1557-1564. *Excluded, secondary to systematic review (CADTH)*

50. Hye, W. L., M. L. Hyun, et al. (2009). "Comparison of initial surgical outcomes between laparoscopic radical prostatectomy and robot-assisted laparoscopic radical prostatectomy performed by a single surgeon." Korean Journal of Urology **50**(5): 468-474. *Excluded, secondary to systematic review (CADTH)*

51. Joseph, J. V., A. Leonhardt, et al. (2008). "The cost of radical prostatectomy: Retrospective comparison of open, laparoscopic, and robot-assisted approaches." Journal of Robotic Surgery **2**(1): 21-24. *Excluded, secondary to systematic review (CADTH)*

52. Kaufman, M. R., J. A. Smith, Jr., et al. (2006). "Positive influence of robotically assisted laparoscopic prostatectomy on the collaborative-care pathway for open radical prostatectomy." BJU Int **97**(3): 473-475. *Excluded, secondary to systematic review (CADTH)*

53. Krambeck, A. E., D. S. DiMarco, et al. (2009). "Radical prostatectomy for prostatic adenocarcinoma: A matched comparison of open retropubic and robot-assisted techniques." BJU International **103**(4): 448-453. *Excluded, secondary to systematic review*

54. Laurila, T. A. J., W. Huang, et al. (2009). "Robotic-assisted laparoscopic and radical retropubic prostatectomy generate similar positive margin rates in low and intermediate risk patients." Urologic Oncology: Seminars and Original Investigations **27**(5): 529-533. *Excluded, secondary to systematic review (CADTH)*

55. Madeb, R., D. Golijanin, et al. (2007). "Transition from open to robotic-assisted radical prostatectomy is associated with a reduction of positive surgical margins amongst private-practice-based urologists." Journal of Robotic Surgery **1**(2): 145-149. *Excluded, secondary to systematic review (CADTH)*

56. Martinez-Salamanca, J. I. and A. Allona Almagro (2007). "[Radical prostatectomy: open, laparoscopic and robotic. Looking for a new gold standard?]." Actas Urol Esp **31**(4): 316-327. *Excluded, secondary to systematic review (CADTH)*

57. Menon, M., A. Shrivastava, et al. (2002). "Laparoscopic and robot assisted radical prostatectomy: establishment of a structured program and preliminary analysis of outcomes." J Urol **168**(3): 945-949. *Excluded, secondary to systematic review (CADTH)*

58. Menon, M., A. Tewari, et al. (2002). "Prospective comparison of radical retropubic prostatectomy and robot-assisted anatomic prostatectomy: the Vattikuti Urology Institute experience." Urology **60**(5): 864-868. *Excluded, secondary to systematic review (CADTH)*

59. Mouraviev, V., I. Nosnik, et al. (2007). "Financial comparative analysis of minimally invasive surgery to open surgery for localized prostate cancer: a single-institution experience." Urology **69**(2): 311-314. *Excluded, secondary to systematic review (CADTH)*

60. Munver, R., I. A. Volfson, et al. (2007). "Transition from open to robotic-assisted radical prostatectomy: 7 years experience at Hackensack University Medical Center." Journal of Robotic Surgery **1**(2): 155-159. *Excluded, secondary to systematic review (CADTH)*

61. Nadler, R. B., J. T. Casey, et al. (2009). "Is the transition from open to robotic prostatectomy fair to your patients? A single-surgeon comparison with 2-year follow-up." Journal of Robotic Surgery: 1-7. *Excluded, secondary to systematic review (CADTH)*

62. Orvieto, M. A. and V. R. Patel (2009). "Evolution of robot-assisted radical prostatectomy." Scandinavian Journal of Surgery **98**(2): 76-88. *Excluded, secondary to systematic review (CADTH)*

63. Ou, Y. C., C. R. Yang, et al. (2009). "Comparison of Robotic-assisted versus Retropubic Radical Prostatectomy Performed by a Single Surgeon." Anticancer research **29**(5): 1637-1642. *Excluded, secondary to systematic review (CADTH)*

64. Pow-Sang, J. M., J. Velasquez, et al. (2007). "Pure laparoscopic and robotic-assisted laparoscopic radical prostatectomy in the management of prostate cancer." Cancer Control **14**(3): 250-257. *Excluded, secondary to systematic review (CADTH)*

65. Tewari, A., A. Srivasatava, et al. (2003). "A prospective comparison of radical retropubic and robot-assisted prostatectomy: experience in one institution." BJU Int **92**(3): 205-210. *Excluded, secondary to systematic review (CADTH)*

66. Webb, D. R., K. Sethi, et al. (2009). "An analysis of the causes of bladder neck contracture after open and robot-assisted laparoscopic radical prostatectomy." BJU International **103**(7): 957-963. *Excluded, secondary to systematic review (CADTH)*

67. Hu, J. C., R. A. Nelson, et al. (2006). "Perioperative complications of laparoscopic and robotic assisted laparoscopic radical prostatectomy." J Urol **175**(2): 541-546; discussion 546. *Excluded, secondary to systematic review (CADTH)*

68. Hu, J. C., Q. Wang, et al. (2008). "Utilization and outcomes of minimally invasive radical prostatectomy." J Clin Oncol **26**(14): 2278-2284. *Excluded, secondary to systematic review (CADTH)*

69. Jae, W. C., H. K. Tae, et al. (2009). "Laparoscopic radical prostatectomy versus robot-assisted laparoscopic radical prostatectomy: A single surgeon's experience." Korean Journal of Urology **50**(12): 1198-1202. *Excluded, secondary to systematic review (CADTH)*

Nephrectomy/Partial – Additional Comparative Papers:

70. Kandaswamy, R. (2006). "Laparoscopic donor nephrectomy (ldn): robotic-assisted (raldn) vs pure (pldn) vs hand-assisted (haldn)." Transplantation **82**(1 Suppl 2): 796-797. *Excluded, secondary to systematic review (CADTH)*

71. Heuer, R., I. S. Gill, et al. (2009). "A Critical Analysis of the Actual Role of Minimally Invasive Surgery and Active Surveillance for Kidney Cancer." Eur Urol. *Excluded, secondary to systematic review (CADTH)*

72. Jeong, W., S. Y. Park, et al. (2009). "Laparoscopic partial nephrectomy versus robot-assisted laparoscopic partial nephrectomy." Journal of Endourology **23**(9): 1457-1460. *Excluded, secondary to systematic review (CADTH)*

73. Wang (2009). "Robotic Partial Nephrectomy Versus Laparoscopic Partial Nephrectomy for Renal Cell Carcinoma: Single-Surgeon Analysis of >100 Consecutive Procedures." Urology **73**(2): 306-310. *Excluded, secondary to systematic review (CADTH)*

74. DeLong, J. M., O. Shapiro, et al. (2010). "Comparison of laparoscopic versus robotic assisted partial nephrectomy: one surgeon's initial experience." Can J Urol **17**(3): 5207-5212. *Excluded, secondary to systematic review (CADTH)*

75. Walz, J., S. Rybikowski, et al. (2010). "Role of robotic surgery in treatment of renal cancer." Intérêt de la robotique dans le traitement du cancer du rein: 1-6. *Excluded, secondary to systematic review (CADTH)*

76. Anderson, J. E., J. Kellogg Parsons, et al. (2011). "Hospital costs and length of stay related to robot-assisted versus open radical and partial nephrectomy for kidney cancer in the USA." Journal of Robotic Surgery: 1-4. *Excluded, published after end search date*

77. Hyams, E., P. Pierorazio, et al. (2011). "A Comparative Cost Analysis of Robotic-Assisted vs. Traditional Laparoscopic Partial Nephrectomy." Journal of Endourology. *Excluded, published after end search date*

78. Lavery, H. J., A. C. Small, et al. (2011). "Transition from laparoscopic to robotic partial nephrectomy: The learning curve for an experienced laparoscopic surgeon." Journal of the Society of Laparoendoscopic Surgeons **15**(3): 291-297. *Excluded, secondary to systematic review (CADTH)*

79. Lendvay, T. S. (2011). "EARLY COMPARISON OF NEPHRECTOMY OPTIONS IN CHILDREN (OPEN, TRANSPERITONEAL LAPAROSCOPIC, LAPARO-ENDOSCOPIC SINGLE SITE (LESS), AND ROBOTIC SURGERY)." BJU International. *Excluded, published after end search date*

80. Masson-Lecomte, A., D. R. Yates, et al. (2011). "A prospective comparison of the pathologic and surgical outcomes obtained after elective treatment of renal cell carcinoma by open or robot-assisted partial nephrectomy." Urol Oncol. *Excluded, secondary to systematic review (CADTH)*

81. Pierorazio, P. M., H. D. Patel, et al. (2011). "Robotic-assisted Versus Traditional Laparoscopic Partial Nephrectomy: Comparison of Outcomes and Evaluation of Learning Curve." Urology. *Thank you. This study has been incorporated into the report.*

82. Seo, I. Y., H. Choi, et al. (2011). "Operative outcomes of robotic partial nephrectomy: A comparison with conventional laparoscopic partial nephrectomy." Korean Journal of Urology **52**(4): 279-283. *Excluded, secondary to systematic review (CADTH)*

83. Sprenkle, P. C., N. Power, et al. (2011). "Comparison of Open and Minimally Invasive Partial Nephrectomy for Renal Tumors 4-7 Centimeters." European Urology. *Excluded, published after end search date*

84. White, M. A., R. Autorino, et al. (2011). "Robotic Laparoendoscopic Single-Site Radical Nephrectomy: Surgical Technique and Comparative Outcomes." European Urology. *Excluded, secondary to systematic review (CADTH)*

85. Williams, S. B., R. Kacker, et al. (2011). "Robotic partial nephrectomy versus laparoscopic partial nephrectomy: a single laparoscopic trained surgeon's experience in the development of a robotic partial nephrectomy program." World Journal of Urology. *Excluded, secondary to systematic review (CADTH)*

86. Guillotreau, J., G. P. Haber, et al. (2012). "Robotic Partial Nephrectomy Versus Laparoscopic Cryoablation for the Small Renal Mass." European Urology. *Excluded, published after end search date*

Pyleoplasty Additional Comparative Papers:

87. Lee, R. S., A. B. Retik, et al. (2006). "Pediatric robot assisted laparoscopic dismembered pyeloplasty: comparison with a cohort of open surgery." J Urol **175**(2): 683-687; discussion 687. *Excluded, population non relevant*

88. Yee, D. S., A. M. Shanberg, et al. (2006). "Initial comparison of robotic-assisted laparoscopic versus open pyeloplasty in children." Urology **67**(3): 599-602. *Excluded, population non relevant*

89. Hemal, A. K., S. Mukherjee, et al. (2010). "Laparoscopic pyeloplasty versus robotic pyeloplasty for ureteropelvic junction obstruction: a series of 60 cases performed by a single surgeon." Can J Urol **17**(1): 5012-5016. *Excluded, population non relevant*

90. Garcia-Galisteo, E., E. Emmanuel-Tejero, et al. (2011). "Comparison of the Operation Time and Complications between Conventional and Robotic-Assisted Laparoscopic Pyeloplasty." Actas Urologicas Espanolas. *Excluded, not in English*

91. Lucas, S. M., C. P. Sundaram, et al. (2012). "Factors That Impact the Outcome of Minimally Invasive Pyeloplasty: Results of the Multi-Institutional Laparoscopic and Robotic Pyeloplasty Collaborative Group." Journal of Urology. *Excluded, published after end search date*

Cystectomy: Additional Comparative Papers:

92. Atallah, M. M., & Othman, M. M. (2009). Robotic laparoscopic radical cystectomy inhalational versus total intravenous anesthesia: A pilot study. [2a]. *Middle East Journal of Anesthesiology, 20*(2), 257-264. *Excluded, intervention/comparator non relevant (compares anesthesia not surgical method)*

93. Chade, D. C., Laudone, V. P., Bochner, B. H., & Parra, R. O. (2010). Oncological Outcomes After Radical Cystectomy for Bladder Cancer: Open Versus Minimally Invasive Approaches. [Si]. [2b]. *Journal of Urology*. doi: S0022-5347(09)02908-5 [pii10.1016/j.juro.2009.11.019 [doi] *Previously excluded, superseded by higher quality review (Thavaneswaran)*

94. Challacombe, B. J., Bochner, B. H., Dasgupta, P., Gill, I., Guru, K., Herr, H., . . . Wiklund, P. (2011). The Role of Laparoscopic and Robotic Cystectomy in the Management of Muscle-Invasive Bladder Cancer With Special Emphasis on Cancer Control and Complications. [2b]. European Urology. doi: 10.1016/j.eururo.2011.05.012 *Previously excluded, study design*

95. Davis, J. W., Gaston, K., Anderson, R., Dinney, C. P. N., Grossman, H. B., Munsell, M. F., & Kamat, A. M. (2010). Robot Assisted Extended Pelvic Lymphadenectomy at Radical Cystectomy: Lymph Node Yield Compared With Second Look Open Dissection. [2b]. Journal of Urology. *Excluded, study design not relevant*

96. Guru, K. A., Wilding, G. E., Piacente, P., Thompson, J., Deng, W., Kim, H. L., . . . O'Leary, K. (2007). Robot-assisted radical cystectomy versus open radical cystectomy: assessment of postoperative pain. [2b]. Can J Urol, 14(6), 3753-3756. *Excluded, included in systematic review*

97. Kane, C. J. (2008). Robotic assisted laparoscopic radical cystoprostatectomy: Operative and pathologic outcomes Pruthi RS, Wallen EM, Division of Urologic Surgery, University of North

Carolina at Chapel Hill, Chapel Hill, NC. [2b]. Urol Oncol, 26(2), 221-222. doi: S1078-1439(08)00009-4 [pii] *Exclude, study design*

98. Lee, R., Chughtai, B., Herman, M., Shariat, S. F., & Scherr, D. S. (2011). Cost-analysis comparison of robot-assisted laparoscopic radical cystectomy (RC) vs open RC. [2b]. BJU International, 108(6 B), 976-983. doi: 10.1111/j.1464-410X.2011.10468.x *Previously included in report*

99. Lee, R., Ng, C. K., Shariat, S. F., Borkina, A., Guimento, R., Brumit, K. F., & Scherr, D. S. (2011). The economics of robotic cystectomy: cost comparison of open versus robotic cystectomy. [2a]. BJU International. doi: 10.1111/j.1464-410X.2011.10114.x *Previously include in report (Lee cost review)*

100. Martin, A. D., Nunez, R. N., & Castle, E. P. (2011). Robot-assisted radical cystectomy versus open radical cystectomy: A complete cost analysis. [2a]. Urology, 77(3), 621-625. *Previously included in report*

101. Nepple, K. G., Strope, S. A., Grubb Iii, R. L., & Kibel, A. S. (2011). Early oncologic outcomes of robotic vs. open radical cystectomy for urothelial cancer. [2b]. Urologic Oncology: Seminars and Original Investigations. doi: 10.1016/j.urolonc.2011.06.009 *Thank you. This study was incorporated into the report.*

102. Niegisch, G., Rabenalt, R., & Albers, P. (2011). [Robot-assisted radical cystectomy : Pilot study for the prospective evaluation of perioperative parameters compared to open radical cystectomy.]. [Si]. [2b]. *Urologe. Ausgabe A*. doi: 10.1007/s00120-011-2580-0 *Excluded, not in English*

103. Palou Redorta, J., Gaya, J. M., Breda, A., Gausa, L., Rodríguez, O., & Villavicencio, H. (2010). Robotic Cystectomy Versus Open Cystectomy: Are We There Yet? [2b]. *European Urology, Supplements, 9*(3), 433-437. *Excluded, study design*

104. Pruthi, R. S., & Wallen, E. M. (2007). Robotic Assisted Laparoscopic Radical Cystoprostatectomy: Operative and Pathological Outcomes. [2b]. *J Urol*. *Included in systematic review (Thavaneswaran)*

105. Smith, A., Kurpad, R., Lal, A., Nielsen, M., Wallen, E. M., & Pruthi, R. S. (2010). Cost Analysis of Robotic Versus Open Radical Cystectomy for Bladder Cancer. [2b]. *Journal of Urology, 183*(2), 505-509.

106. Sung, H. H., Ahn, J. S., Seo, S. I., Jeon, S. S., Choi, H. Y., Lee, H. M., & Jeong, B. C. (2011). A Comparison of Early Complications Between Open and Robot-Assisted Radical Cystectomy. [2b]. *Journal of Endourology*. doi: 10.1089/end.2011.0372 *Thank you. This study was incorporated into the report.*

Appendix C: Additional Gynecological Publications for Consideration

Hysterectomy for Cancer Additional Comparative Papers – Not Cited in Washington HTA review

2008

107. DeNardis, S. A., R. W. Holloway, et al. (2008). "Robotically assisted laparoscopic hysterectomy versus total abdominal hysterectomy and lymphadenectomy for endometrial cancer." Gynecol Oncol **111**(3): 412-417. *Included in systematic review (CADTH)*

108. 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 woman?" Gynecologic Oncology. *Included in systematic review (CADTH)*

109. Ko, E. M., M. G. Muto, et al. (2008). "Robotic versus open radical hysterectomy: A comparative study at a single institution." Gynecologic Oncology **111**(3): 425-430. *Included in systematic review (CADTH)*

110. Magrina, J. F., R. M. Kho, et al. (2008). "Robotic radical hysterectomy: comparison with laparoscopy and laparotomy." Gynecologic Oncology **109**(1): 86-91. *Excluded, secondary to systematic review (CADTH)*

111. Magrina, J. F. and V. L. Zanagnolo (2008). "Robotic surgery for cervical cancer." Yonsei Med J **49**(6): 879-885. *Excluded, secondary to systematic review (CADTH)*

2009

113. Cohn, D. E., L. G. Seamon, et al. (2009). "Comprehensive surgical staging for endometrial cancer in obese patients." Obstetrics and Gynecology **114**(1): 16-21. *Thank you. This study has been incorporated into the report.*

114. Feuer, G., B. Benigno, et al. (2009). "Comparison of a novel surgical approach for radical hysterectomy: Robotic assistance versus open surgery." Journal of Robotic Surgery **3**(3): 179-186. *Included in systematic review (CADTH)*

115. Lowe, M. P., A. V. Hoekstra, et al. (2009). "A comparison of robot-assisted and traditional radical hysterectomy for early-stage cervical cancer." Journal of Robotic Surgery: 1-5. *Included in systematic review (CADTH)*

116. Maggioni, A., L. Minig, et al. (2009). "Robotic approach for cervical cancer: Comparison with laparotomy. A case control study." Gynecologic Oncology **115**(1): 60-64. *Included in systematic review (CADTH)*

2010

117. Barnett, J. C., J. P. Judd, et al. (2010). "Cost comparison among robotic, laparoscopic, and open hysterectomy for endometrial cancer." Obstetrics and Gynecology **116**(3): 685-693. *Included in systematic review (CADTH)*

118. Cardenas-Goicoechea, J., S. Adams, et al. (2010). "Surgical outcomes of robotic-assisted surgical staging for endometrial cancer are equivalent to traditional laparoscopic staging at a minimally invasive surgical center." Gynecol Oncol **117**(2): 224-228. *Included in systematic review (CADTH)*

119. Göçmen, A., F. Şanlikan, et al. (2010). "Comparison of outcomes between laparotomy and robotic technique for cervical cancer." Journal of Robotic Surgery: 1-6. *Included in systematic review (CADTH)*

120. Halliday, D., S. Lau, et al. (2010). "Robotic radical hysterectomy: comparison of outcomes and cost." Journal of Robotic Surgery: 1-6. *Included in systematic review (CADTH)*

121. Jung, Y. W., D. W. Lee, et al. (2010). "Robot-assisted staging using three robotic arms for endometrial cancer: comparison to laparoscopy and laparotomy at a single institution." J Surg Oncol **101**(2): 116-121. *Included in systematic review (CADTH)*

122. Nevadunsky, N., R. Clark, et al. (2010). "Comparison of robot-assisted total laparoscopic hysterectomy and total abdominal hysterectomy for treatment of endometrial cancer in obese and morbidly obese patients." Journal of Robotic Surgery: 1-6. *Included in systematic review (CADTH)*

123. Schreuder, H. W. R., R. P. Zweemer, et al. (2010). From open radical hysterectomy to robot-assisted laparoscopic radical hysterectomy for early stage cervical cancer: aspects of a single institution learning curve. Gynecological Surgery**:** 1-6. *Excluded, secondary to SR (CADTH)*

124. Zapardiel, I., V. Zanagnolo, et al. (2010). "Avoiding vaginal cuff dehiscence after robotic oncological surgery: reliable suturing technique." International Journal of Gynecological Cancer **20**(7): 1264-1267. *Excluded, intervention not relevant (suture technique)*

2011

125. Boruta, D. M., 2nd, W. B. Growdon, et al. (2011). "Evolution of surgical management of early-stage endometrial cancer." American Journal of Obstetrics and Gynecology. *Excluded, intervention not relevant*

126. ElSahwi, K. S., C. Hooper, et al. (2011). "Comparison between 155 cases of robotic vs. 150 cases of open surgical staging for endometrial cancer." Gynecologic Oncology. *Excluded, published after end search date*

127. Escobar, P. F., M. Frumovitz, et al. (2011). "Comparison of Single-Port Laparoscopy, Standard Laparoscopy, and Robotic Surgery in Patients with Endometrial Cancer." Annals of Surgical Oncology. *Thank you. This study has been incorporated into the report.*

128. Espada, M., R. Muñoz, et al. (2011). "Minimally invasive approach to endometrial cancer: Robotics and laparoscopy." Current Women's Health Reviews **7**(4): 332-337. *Excluded, study design*

129. Estape, R., N. Lambrou, et al. (2011). "Robotic-assisted total laparoscopic hysterectomy and staging for the treatment of endometrial cancer: a comparison with conventional laparoscopy and abdominal approaches." Journal of Robotic Surgery: 1-7. *Excluded, secondary to systematic review (CADTH)*

130. Fleming, N. D., A. E. Axtell, et al. (2011). "Operative and anesthetic outcomes in endometrial cancer staging via three minimally invasive methods." Journal of Robotic Surgery: 1-8. *Excluded, not indexed in MEDLINE®*

131. Frey, M. K., S. B. Ihnow, et al. (2011). "Minimally Invasive Staging of Endometrial Cancer Is Feasible and Safe in Elderly Women." Journal of Minimally Invasive Gynecology **18**(2): 200-204. *Excluded, secondary to systematic review*

132. Goel, M., T. W. Zollinger, et al. (2011). "Surgical staging of endometrial can *Exclude, secondary to systematic review* cer: robotic versus open technique outcomes in a contemporary single surgeon series." Journal of Robotic Surgery: 1-6. *Excluded, secondary to systematic review*

133. Hong, D. G., Y. S. Lee, et al. (2011). "Robotic uterine artery preservation and nerve-Sparing radical trachelectomy with bilateral pelvic lymphadenectomy in early-Stage cervical cancer." International Journal of Gynecological Cancer **21**(2): 391-396. *Excluded, secondary to systematic review*

134. Krizova, A., B. A. Clarke, et al. (2011). "Histologic artifacts in abdominal, vaginal, laparoscopic, and robotic hysterectomy specimens: a blinded, retrospective review." American Journal of Surgical Pathology **35**(1): 115-126. *Excluded, intervention not specific*

135. Lèguevaque, P., S. Motton, et al. (2011). "Robotic surgery in gynecologic oncology." Gynecological Surgery: 1-9. *Excluded, secondary to systematic review (CADTH)*

136. Magrina, J. F., V. Zanagnolo, et al. (2011). "Robotic approach for ovarian cancer: Perioperative and survival results and comparison with laparoscopy and laparotomy." Gynecologic Oncology **121**(1): 100-105. *Excluded, secondary to systematic review (CADTH)*

137. Martino, M. A., J. Shubella, et al. (2011). "A cost analysis of postoperative management in endometrial cancer patients treated by robotics versus laparoscopic approach." Gynecologic Oncology. *Thank you. This study has been incorporated into the report.*

138. Mendivil, A. A., M. A. Rettenmaier, et al. (2011). "Acute and delayed complications from surgery and adjuvant radiotherapy in the treatment of high-risk endometrial cancer." Oncology **81**(2): 79-83. *Excluded, intervention not relevant*

139. Nick, A. M., M. M. Frumovitz, et al. (2011). "Fertility sparing surgery for treatment of early-stage cervical cancer: Open vs. robotic radical trachelectomy." Gynecologic Oncology. *Thank you. This study has been incorporated into the report.*

140. Nick, A. M., J. Lange, et al. (2011). "Rate of vaginal cuff separation following laparoscopic or robotic hysterectomy." Gynecologic Oncology **120**(1): 47-51. *Excluded, secondary to systematic review (CADTH)*

141. Pilka, R., R. Marek, et al. (2011). "[Robot assisted laparoscopic staging of endometrial cancer--comparison with standard laparotomy]." Ceska Gynekologie **76**(6): 462-468. *Excluded, not in English*

142. Soliman, P. T., M. Frumovitz, et al. (2011). "Radical hysterectomy: A comparison of surgical approaches after adoption of robotic surgery in gynecologic oncology." Gynecologic Oncology. *Thank you. This study has been incorporated into the report.*

143. Subramaniam, A., K. H. Kim, et al. (2011). "A cohort study evaluating robotic versus laparotomy surgical outcomes of obese women with endometrial carcinoma." Gynecologic Oncology. *Thank you. This study has been incorporated into the report.*

144. Venkat, P., L. M. Chen, et al. (2011). "An economic analysis of robotic versus laparoscopic surgery for endometrial cancer: costs, charges and reimbursements to hospitals and professionals." Gynecologic Oncology. *Excluded, published after end search date*

2012

145. Dennis, T., C. De Mendona, et al. (2012). "Study of surplus cost of robotic assistance for radical hysterectomy, versus laparotomy and standard laparoscopy." Étude du surcoût de la cœlioscopie assistée par robot dans l'hystérectomie élargie **40**(2): 77-83. *Excluded, published after end search date*

146. Dennis, T., C. de Mendonca, et al. (2012). "[Study of surplus cost of robotic assistance for radical hysterectomy, versus laparotomy and standard laparoscopy.]." Gynecologie, Obstetrique et Fertilite. *Excluded, published after end search date (duplicate of above)*

147. Leitao, M. M., Jr., G. Briscoe, et al. (2012). "Introduction of a computer-based surgical platform in the surgical care of patients with newly diagnosed uterine cancer: Outcomes and impact on approach." Gynecologic Oncology. *Excluded, published after end search date*

148. Lu, D., Z. Liu, et al. (2012). "Robotic assisted surgery for gynaecological cancer." Cochrane Database of Systematic Reviews **1**: CD008640. *Excluded, published after end search date*

149. Wright, J. D., W. M. Burke, et al. (2012). "Comparative Effectiveness of Robotic Versus Laparoscopic Hysterectomy for Endometrial Cancer." Journal of Clinical Oncology. *Excluded, published after end search date*

Benign Hysterectomy Additional Comparative Papers – Not Cited in Washington HTA review

2009

150. Nezhat, C., O. Lavie, et al. (2009). "Laparoscopic hysterectomy with and without a robot: Stanford experience." JSLS : Journal of the Society of Laparoendoscopic Surgeons / Society of Laparoendoscopic Surgeons **13**(2): 125-128. *Excluded, secondary to systematic review (CADTH)*

151. Rebeles, S. A., H. G. Muntz, et al. (2009). "Robot-assisted total laparoscopic hysterectomy in obese and morbidly obese women." Journal of Robotic Surgery **3**(3): 141-147. *Excluded, comparator not relevant*

2010

152. Brölmann, H. A. M., A. J. BijdeVaate, et al. (2010). "Hysterectomy or a minimal invasive alternative? A systematic review on quality of life and satisfaction." Gynecological Surgery: 1-6. *Excluded, superseded by systematic review (CADTH)*

153. Matthews, C. A., N. Reid, et al. (2010). "Evaluation of the introduction of robotic technology on route of hysterectomy and complications in the first year of use." American Journal of Obstetrics and Gynecology **203**(5). *Excluded, secondary to systematic review (CADTH)*

2011

154. Ceccaroni, M., R. Berretta, et al. (2011). "Vaginal cuff dehiscence after hysterectomy: A multicenter retrospective study." European Journal of Obstetrics Gynecology and Reproductive Biology **158**(2): 308-313. *Excluded, intervention not relevant*

155. Dauterive, E. and G. Morris Iv (2011). "Incidence and characteristics of vaginal cuff dehiscence in robotic-assisted and traditional total laparoscopic hysterectomy." Journal of Robotic Surgery: 1-6. *Excluded, secondary to systematic review (CADTH)*

156. Kilic, G. S., G. Moore, et al. (2011). "Comparison of Perioperative Outcomes of Total Laparoscopic and Robotically Assisted Hysterectomy for Benign Pathology during Introduction of a Robotic Program." Obstet Gynecol Int **2011**: 683703. *Excluded, secondary to systematic review (CADTH)*

157. Krizova, A., B. A. Clarke, et al. (2011). "Histologic artifacts in abdominal, vaginal, laparoscopic, and robotic hysterectomy specimens: a blinded, retrospective review." American Journal of Surgical Pathology **35**(1): 115-126. *Excluded, intervention not specific*

158. Landeen, L. B., M. C. Bell, et al. (2011). "Clinical and cost comparisons for hysterectomy via abdominal, standard laparoscopic, vaginal and robot-assisted approaches." South Dakota Medicine **64**(6): 197-199, 201, 203 passim. *Excluded, secondary to systematic review (CADTH)*

159. Nick, A. M., J. Lange, et al. (2011). "Rate of vaginal cuff separation following laparoscopic or robotic hysterectomy." Gynecologic Oncology **120**(1): 47-51. *Excluded, secondary to systematic review (CADTH)*

160. Sarlos, D. and L. A. Kots (2011). "Robotic versus laparoscopic hysterectomy: A review of recent comparative studies." Current Opinion in Obstetrics and Gynecology. *Excluded, secondary to systematic review (CADTH)*

161. Scandola, M., L. Grespan, et al. (2011). "Robot-Assisted Laparoscopic Hysterectomy vs Traditional Laparoscopic Hysterectomy: Five Metaanalyses." Journal of Minimally Invasive Gynecology **18**(6): 705-715. *Thank you. This study has been incorporated into the report.*

162. Shultz, T. M. (2011). "Preemptive multimodal analgesia facilitates same-day discharge following robot-assisted hysterectomy." Journal of Robotic Surgery: 1-9. *Excluded, intervention not relevant*

2012

163. Davenport, W. B., M. P. Lowe, et al. (2012). "Outcomes of obese versus non-obese subjects undergoing robotic-assisted hysterectomy: a multi-institutional study." Journal of Robotic Surgery: 1-6. *Excluded, comparator not relevant*

Myomectomy Additional Comparative Papers – Not Cited in Washington HTA review

2009

164. Nezhat, C., O. Lavie, et al. (2009). "Robotic-assisted laparoscopic myomectomy compared with standard laparoscopic myomectomy--a retrospective matched control study." Fertil Steril **91**(2): 556-559. *Included in systematic review (Reza)*

2011

165. Behera, M. A., C. E. Likes, 3rd, et al. (2011). "Cost Analysis of Abdominal, Laparoscopic, and Robotic-Assisted Myomectomies." Journal of Minimally Invasive Gynecology. *Thank you. This study has been incorporated into the report.*

166. Nash, K., J. Feinglass, et al. (2011). "Robotic-assisted laparoscopic myomectomy versus abdominal myomectomy: a comparative analysis of surgical outcomes and costs." Archives of Gynecology and Obstetrics. *Thank you. This study has been incorporated into the report.*

Sacrocolpopexy Additional Comparative Papers – Not Cited in Washington HTA review

2011

167. Tan-Kim, J., S. A. Menefee, et al. (2011). "Robotic-assisted and laparoscopic sacrocolpopexy: Comparing operative times, costs and outcomes." Female Pelvic Medicine and Reconstructive Surgery **17**(1): 44-49. *Thank you. This study has been incorporated into the report.*

Studies submitted by John Lenihan, Jr., MD - Disposition

1. Choosing the Route of Hysterectomy for Benign Disease. ACOG Committee Opinion No. 444. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009;114:1156–8. *Exlcuded, study design*

2. AAGL Position Statement: Route of Hysterectomy to Treat Benign Uterine Disease. J Minim Invasive Gynecol. 2011 Jan-Feb;18(1):1-3. Epub 2010 Nov 6. PMID: 21059487 *Exclude, study design*

3. Kelly K. Survey of Hysterectomy Patients, 2008; www.hystersisters.com *Excluded, study design*

4. Jacoby VL, Autry A, Jacobson G, Domush R, Nakagawa S, Jacoby A. Nationwide use of laparoscopic hysterectomy compared with abdominal and vaginal approaches. Obstet Gynecol 2009;114(5):1041-8. *Excluded, secondary to systematic review*

5. CDC-MMWR: Hysterectomy Surveillance-1994-99. July, 2002/51 (SS05); 1-8 *Excluded, study design*

6. Sung H, et al. Limits to Laparoscopy in Canada: presented AAGL ACM, Las Vegas NV Nov 2008 *Exclude, not published*

7. Nezhat C, Lavie O, Lemyre M, Unal E, Nezhat CH, Neshat F. Robotic-assisted laparoscopic surgery in gynecology: scientific dream or reality? Fertil Steril. 2009.91(6):2620-2622. DOI: 10.1016/j.fertnstert.2008.03.070. *Excluded, secondary to systematic review (CADTH)*

8. Lenihan JP, Kovanda CL. Cost Effectiveness of LAVH to Employers. Am J Obstet Gynecol, 2004:288;336-355. *Excluded, secondary to systematic review (CADTH)*

9. Godfrit,J et al. Surgeon's Perceptions and Injuries During and After Urologic Laparoscopic Surgery. Urology, 2008, 71, 404-407. *Excluded, study design*

10. Van der Schatt,K. Ergonomics, User comfort, and Performance in Standard and Robot-Assisted Laparoscopic Surgery. Surg Endosc. 2009, 23, 1365-1371. *Excluded, outcomes not relevant*

11. Payne, TN, Dauterive FR. Robotic Assisted Hysterectomy: 100 cases after the Learning Curve. J Robotic Surg. 2010; 4:1, 11-17 *Excluded, not comparative*

12. Reich, H, DeCaprio J, McGlynn F. Laparosopic Hysterectomy. J Gynaecol Surg. 1989;5:213-215. *Excluded, published prior to beginning search date*

13. Einarsson JI, Matteson KA, Schulkin J, Chavin NR, Sangi-Haghpeykar H. Minimally invasive Hysterectomies – A survey on Attitudes and Barriers among Practicing Gynecologists. J Minim Invasiv Gynecol. 2010;17:167-75. *Excluded, study design*

14. Visco AG, Advincula AP. Robotic Gynecologic Surgery. Obstet Gynecol 2008;112:1369-84. *Exclude, superceded by review*

15. Bell, M, et al. Traditional Laparotomy, Standard Laparoscopy and Robotic Techniques. J SD Med Soc, 2010, 35,1. *Excluded, could not identify journal/locate article*

16. Jonsdottir GM, Jorgensen S, Cohen SL, Wright KN, Shah NT, Chavan N, Einarsson JI. Increasing Minimally Invasive Hysterectomy: Effect on Cost and Complications. *Obstet Gynecol*. 2011 May;117(5):1142-9. *Excluded, intervention/comparator not relevant*

17. Stone, P, Burnett A, Burton B, Roman J. Overcoming Extreme Obesity With Robotic Surgrery. 2010, Int J Med Rob Com Assist Surg. 6,4, 382-385 *Excluded, study design*

18. Lenihan, J, Kovanda C. Outcomes of Robotic Surgery in the Morbidly Obese compared to Normal Weight Women. Presented Pacific Coast OB-GYN Society, October 2010, Kona Hawaii *Excluded, not published*

My first comment is that "Robotic Assisted Surgery" is too general. It seems to me that you need to go procedure by procedure. I really hope that you will reconsider taking on such a huge topic, and break it down to give each procedure the attention that it deserves. It think that in the long-run you will find this a much better approach.

Next comment about KQ1:

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes? Include consideration of short and long-term outcomes including complete cancer eradication, reduced hospital stay, and reduced anesthesia use.

There are a number of criticisms that come to mind with the current wording of this question. First, is including clinical "efficacy" and "effectiveness" in the same question. 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 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.

Sincerely,

Phil Colmenares MD MPH
(Emergency Physician)
5758 Forsythia Place
Madison, WI 53705
(608) 469-9559

Dear HCA:

In reference to the public comments on the key graft questions on the topic robotic-assisted surgery I would submit the following:

Key Question #1: There are several studies showing comparative superiority of robotic-assisted surgery over laparoscopic or traditional open surgery. Of note 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 comparisons to open or laparoscopic surgery. 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 robotic assisted prostatectomy series.

A recent publication from the Mayo Clinic in Urology (Urology 2011 Oct;78(4):827-31. Epub 2011 Jul 29) compared 4824 patients undergoing open prostatectomy with 1084 patients undergoing robotic prostatectomy in the same historical time period. Patients undergoing robotic assisted prostatectomy showed a lower surgical site infection rate as compared to patients undergoing open prostatectomy. The difference was statistically significant (0.6% robotic vs. 4.5% open, $p<0.001$).

Another study from the Mayo Clinic published in the British Journal of Urology (BJU Int 2009 Feb;103(4):448-53. Epub 2008 Sep 3) looked in a match comparison of open and robotic-assisted prostatectomy and compared outcomes. The patient's were matched to 2:1 open to robotic and involved 588 open prostatectomy patient's compared to 294 robotic assisted prostatectomy patients. The procedures were performed in the same time frame. The investigators found no significant difference and complications between the 2 groups with a higher rate of bladder neck contracture in the open prostatectomy group ($p<0.018$) and a higher rate of wound herniation in the robotic prostatectomy group($p<0.038$). The hospital stay were shorter in the robotic assisted prostatectomy group with 29% of patients leaving one day after surgery in the robotic-assisted group and 19% of patients leaving one day in the open prostatectomy group($p<0.004$). At one year a follow-up, there was no significant difference between the 2 groups with regard to urinary continence, erectile function, and cancer control as determined by PSA recurrence at 3 years postoperatively. This paper shows equal outcomes with decreased hospital stay and decreased bladder neck contracture rate for the robotic assisted procedure versus open. The stated rate of 29% staying one day in the hospital is very low compared to other series and and represents an underestimate of the improved length of stay of robotic assisted prostatectomy.

The use of the robot for partial nephrectomy has also been compared to laparoscopic partial nephrectomy. In an article published in the Journal of Urology in 2009(J Urol 2009 Sep;182(3):866-72. Epub 2009 Jul 17) 118 patients underwent laparoscopic partial nephrectomy while 129 underwent robotic-assisted partial nephrectomy. The partial nephrectomies were comparable with regard to tumor size and patient characteristics. What was found was that robotic-assisted partial nephrectomy was superior to laparoscopic partial nephrectomy with regard to blood loss(155 vs. 196 $p<0.03$) and length of hospital stay (2.4 vs 2.7, $p<0.0001$). The major advantage of robotic-assisted partial nephrectomy was a decrease in the warm ischemia time that the kidney was clamped during partial nephrectomy. Warm ischemia time for robotic-assisted partial nephrectomy was 19.7 minutes versus 28.4 minutes for laparoscopic partial nephrectomy. This was a significant difference($p<0.0001$) and speaks to the improved reconstructive abilities of the robotic platform. This improved warm ischemia time has significant implications for renal functional recovery.

Key Question #2:

A recent comparison of robotic prostatectomy to open prostatectomy was performed using the National Inpatient Sample was published in European Urology (Eur Urology: 2011 Dec 22. [Epub ahead of print). Using the registry, 11,889 patient's undergoing robotic prostatectomy were compared to 7389 undergoing open prostatectomy. Using multivariate analysis, patient's undergoing robotic prostatectomy were less likely to undergo blood transfusion (odds ratio [OR]: 0.34; 95% confidence interval [CI], 0.28-0.40), to experience an intraoperative complication (OR: 0.47; 95% CI, 0.31-0.71) or a postoperative complication (OR: 0.86; 95% CI, 0.77-0.96). Patient's undergoing robotic prostatectomy had a shorter length of stay as compared to open prostatectomy(OR: 0.28; 95% CI, 0.26-0.30). The officers concluded RARP has supplanted ORP as the most common surgical approach for RP. Moreover, they demonstrated superior adjusted perioperative outcomes after robotic assisted prostatectomy as compared to open prostatectomy in virtually all examined outcomes.

Key Question #4:

There is data looking at the cost of robotic surgery versus open and laparoscopic surgery. However, the 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 employer's when a patient is able to return to work sooner after robotic surgery as compared to open surgery. Global costs are difficult to measure and have not been assessed to make a fair comparison between robotic and open prostatectomy. That being said, 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 stay the art surgical care. There is no increased cost to society for a robotic procedure over the comparable laparoscopic procedure given that the CPT code charges are the same.

Respectfully,
James R. Porter, M.D.
Director, Robotic Surgery
Swedish Medical Center
Seattle, Washington

Ethicon
Endo-Surgery
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

3 January 2012

Washington State Health Care Authority
Health Technology Assessment

Re: Public Comments - DRAFT Key Questions and Background Robotic Assisted Surgery

Dear SHTAP,

Thank you for the opportunity to comment on the draft key questions for the HTA assessment of robotic surgery. At Ethicon Endo-Surgery we have been closely monitoring and studying both the clinical and economic value proposition of robotic surgery compared to traditional modalities and feel we have a great deal of insight to offer regarding the nuances' involved in understanding the use of the robot.

Included are comments specific to both the Policy Context and Draft Key Questions. Again, we would like to thank you for considering these comments as you move forward with this very important assessment of robotic surgical systems as compared to traditional laparospcopic/minimally invasive and open surgery.

Sincerely,

Andrew Yoo MD, Director, Medical Affairs
Matt Moore MHA, Director, Heath Care Policy and Economics

4 pages total

Policy Context

There is an increasing usage of robotic surgical systems. The impact of this technology on overall health outcomes is unclear compared with traditional open or laparoscopic surgical techniques. State agencies concerns: safety- Medium, efficacy- Medium, cost- Medium.

Population: Adults with planned surgeries that could be performed with the help of a robot-assisted surgery device (e.g., prostatectomy, hysterectomy, nephrectomy, coronary bypass, coronary valve replacement) under any diagnosis, including cancer.
Intervention: Surgery with the assistance of robotic control, any diagnosis
Comparator: Surgeries of the same type, performed open or laparoscopic, without robotic assistance
Outcomes: Length of stay, health care resource utilization, morbidity, mortality, increased bleeding, decreased healing time

It is important to clarify several issues that affect the policy context.

Population:

The specific pathology and patient populations (comorbidities, stage, age, BMI, performance status, etc.) is important to note when comparing surgical approaches. This not only can profoundly generally effect outcomes but also directly effects the procedure itself. For instance, procedures performed for malignancy may need to incorporate a more specific and precise dissection for a cancer free margin and adequate lymph node dissection when compared to a procedure performed for benign disease. In these instances differences that are associated with malignant indications and procedures may not be transferrable to a benign indication and vice versa. An example of this is hysterectomy whose predominant indication is for benign disease and not cancer.

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).

Comparator:

Precisely defining the comparative approach and current gold standard is of the utmost importance when evaluating the effectiveness of Robotic assisted endoscopic surgery. For instance in many cases the gold standard is actually conventional laparoscopy (with a overwhelming percentage of these procedures being carried out with this technique) and not the classically described open surgical technique. Examples of this would include conventionally performed laparoscopic: cholecystectomy and bariatric surgery. An example of a minimally invasive non endoscopic technique includes vaginal hysterectomy which in many cases is the preferred method for benign disease due to its excellent clinical outcomes and relatively lower expense. Other minimally invasive procedures may not have as high adoption rates, but for the most part have established at least equivalency in overall outcome and in many cases superiority in perioperative clinical parameters when compared to open surgery. Examples of this include colectomies, hysterectomy, and ventral hernia repairs. It is important to establish the most appropriate surgical approach comparator so that the value of the robotic assisted intervention can be most accurately determined.

Outcomes:

It is important to note the difference between statistical significance and clinical relevance. For instance surgeon estimated blood loss (EBL) is often found to be statistically different, despite the fact that intra-operative surgeon estimated blood loss is notoriously inaccurate. In some instances EBL was found to have been significantly different but serum hemoglobin (a much more accurate measure of blood volume) or even more importantly clinically blood transfusions showed no difference. In some cases this significantly difference in EBL was observed to be only several ounces, which is almost certainly clinically irrelevant. Another parameter that is often observed to be statistically different, but most likely clinically irrelevant is length of hospital stay (LOS). In some cases this difference may only be hours different. The key point of this is that the measurement should not only be statistically significant, but also taken in context of clinically relevance.

The comments specific to the **key draft questions** are included into the original questions in red font. There were three key distinctions that these modifications are attempting to address beyond the original format of the questions.

1) The data should compare robot to open ***and*** traditional minimally invasive procedures versus one ***or*** the other. The majority of the current data compares robotic assisted to open procedures not laparoscopic procedures. Laparoscopic versus open procedures can have very different outcomes around LOS, anesthesia, adverse events, etc. Therefore it is important to make sure this is an "and" not an "or" question.
2) "Procedure specific" has been inserted into the questions because we feel it is important to make sure that the evidence asked for is segmented by procedure, as the outcomes can greatly vary based on the type of surgery performed, i.e., hysterectomy versus a coronary bypass.
3) The comparison of robot-assisted to "laparoscopic" approaches is also limiting. Laparoscopic refers to surgeries in the abdomen and pelvis, but does not include thoracoscopic procedures i.e., cardiac/lung and natural orifice procedures i.e., vaginal hysterectomy. Therefore a broad term such "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
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.

APPENDIX C. SUBMITTED PUBLIC COMMENTS – DRAFT REPORT

From: Scott Adams [scott.adams@pullmanregional.org]
Sent: Monday, April 02, 2012 3:34 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

I am the CEO at Pullman Regional Hospital in Pullman, Washington. 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.

Scott Adams

"Between stimulus and response there is a space.
In that space is our power to choose our response.
In our response lies our growth and our freedom."
Viktor Frankl, MD Man's Search for Meaning

From: Austin, Kristen
To: HCA ST Health Tech Assessment Prog;
Subject: DaVinci
Date: Tuesday, April 03, 2012 7:54:48 PM

To Whom It May Concern:

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 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.

Kristen Austin, MD Medical Director

OB/GYN | 751 NE Blakely Drive, Suite 2030 | Issaquah, WA 98029 (o) 425.313.4190 | (f) 425.313.7174 | (c) 206.861.6825 kristen.austin@swedish.org | www.swedish.org

From: Aye, Ralph
To: HCA ST Health Tech Assessment Prog;
Subject: Public Comment for: Robotic Assisted Surgery
Date: Sunday, March 25, 2012 10:49:14 PM

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.

3. 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.

4. 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.

Ralph W. Aye MD FACS
Clinical Program Leader, Thoracic Oncology
Thoracic and Foregut Surgery
Program Director, Thoracic and Foregut Fellowship

Swedish Cancer Institute
Division of Thoracic and Foregut Surgery
1101 Madison, #850
Seattle, WA 98104
206-215-6800

From: kathryn.barry@kbreimbursement.com [mailto:kathryn.barry@kbreimbursement.com]
Sent: Thursday, April 05, 2012 9:54 AM
To: HCA ST Health Tech Assessment Prog
Cc: Morse, Josiah (HCA)
Subject: Robotic Assisted Surgery: Please include the attached comment in your deliberations

Hello:

In follow-up to a conference call with Mr. Josiah Morse last week, it is my pleasure to submit the attached comment for your deliberations about robotic-assisted surgery. As the Health Policy Consultant for Intuitive Surgical from many years, I have had the opportunity to work directly with AMA, CMS, leading professional societies and payers as it relates to robotic-assistance. The attached document summarizes important health policy decisions that should be considered by the WA Health Technology Assessment Program. Upon your review, please do not hesitate to call or email me for more information. In advance, thank-you.

Regards,

Kathryn Barry, MPH,MSN,RN

Health Policy Consultant

Phone: (203) 271-3366

Kathryn Barry
& Associates LLC

Medical Device Reimbursement Consultants

19 Wallingford Rd., Cheshire, CT 064 0
Tel: 203.271.3366 • Fax: 203.271.3844
kathryn.barry@kbreimbursement.com

March 31, 2012

Kerilyn Nobuhara, M.D.
Senior Medical Consultant
Health Care Authority

Josh Morse, MPH
Program Director
WA Health Technology Assessment Program
626 8th Avenue SE
Olympia, WA 98501

RE: Health Technology Assessment Topic - Robotic assisted surgery

Dear Dr. Nobuhara and Josh:

Thank-you very much for your recent phone calls regarding Washington State Health Care Authority's interest in robotic-assisted surgery. Josh, it was a pleasure speaking with you on Friday, March 30th and I thank-you for your follow-up email. As we discussed on March 30th, I have been the Health Policy Advisor to Intuitive Surgical, the manufacturer of the daVinci Surgical System, for the past eight years. During that time, important health policy decisions have been made by the American Medical Association (AMA); Centers for Medicare and Medicaid Services (CMS); majority of leading private payers, as well as the leading professional societies, such as the American Urologic Association (AUA), American College of Obstetricians and Gynecologists (ACOG) and Society of Thoracic Surgeons (STS).

The purpose of this correspondence is to share information and education that is consistent with these health policy decisions, as well as to make myself available to you and your Committee in order that you fully understand why:

- In 2007, the AMA determined that there was no need for a new code or unique modifier to report laparoscopic procedures completed with robotic-assistance.
- In 2008, CMS determined that hospitals should code the primary surgical procedure in a routine and customary manner, and that the primary surgical procedure would be assigned to the clinically-relevant MS-DRG or APC.
- Since 2005, leading payers, such as BlueCross BlueShield, Aetna, CIGNA, HealthNET, United Healthcare, TRICARE, and the majority of managed care plans, have considered robotic-assistance incidental to the primary surgical procedure and not separately billable. Essentially, robotic-assistance is a technology enabler that is integral to the completion of an advanced laparoscopic procedure and should be consistent with any payer's existing laparoscopic medical policies.

As the Washington State Healthcare Authority completes its technology assessment of robotic-assisted surgery, I am immediately available to answer your questions and provide additional background information as to why AMA, CMS and leading payers made these important coding, coverage and reimbursement decisions. In acknowledgement of this established health policy foundation, I am hopeful that Washington State Healthcare Authority will reach the same conclusion for your beneficiaries, which is you will decide to cover laparoscopic surgery completed with robotic-assistance for any patient who presents to an advanced laparoscopist in need of surgery, consistent with your existing laparoscopic medical policies.

Health Policy History Related to Robotic-Assisted Surgery

In brief,

- In June 2007, the **AMA CPT Editorial Panel**, based upon input from several professional societies, lead by the American Urologic Association (AUA) and American College of Obstetricians and Gynecologists (ACOG), concluded that robotic assistance did not require a unique code or modifier, and that current Level I laparoscopic CPT codes were the appropriate consideration. After two years of discussion and review of experiences reported by laparoscopic surgeons who routinely incorporated robotic-assistance into their primary laparoscopic procedure, the AMA determined that there was no need for a new code or unique modifier. A copy of the AMA's 2007 letter to me documenting this decision is available upon request. In 2012, this decision continues to be supported by the professional societies, such as AUA, ACOG/AAGL and STS. In addition, I direct your attention to a recent editorial revision by the AUA that bundles robotic-assistance into the laparoscopic prostatectomy CPT code, 55866. This editorial revision became effective January 1, 2011. I believe this serves as a precedent for future editorial revisions by other professional societies.

- In January 2008, an application was submitted to the ICD-9-CM Coding Coordination and Maintenance Committee at **CMS** requesting an ICD-9-CM procedure code for "laparoscopic robotic surgery". On March 19, 2008 a clinical presentation was made to this committee in Baltimore, Maryland. A copy of this application is available upon request. Effective October 1, 2008, CMS directed hospitals performing laparoscopic procedures with robotic-assistance to report the primary surgical procedure in a routine and customary manner, plus the ICD-9-CM procedure code 17.42, "laparoscopic robotic-assisted procedure". A complete listing of the ICD-9-CM robotic subcategory is available upon request.

- United Healthcare and CIGNA Healthcare were the first **private payers** to issue cover decisions for robotic-assistance in 2005. Their medical policies were the first to state robotic-assistance was incidental to the primary surgical procedure and not separately billable. Many other payers have followed this precedent, as summarized in the table below.

Table #1: Summary of U.S. Robotic Medical Policies

Payer	Title of Policy	Excerpt from policy
BC – Idaho 4/8/2009	Robotic Assisted Surgery	Additional professional or technical reimbursement will not be made for the robotic assisted technique. Payment will be based on the reimbursement for the standard surgical procedure(s). Any additional charges for the robotic assisted surgery will be bundled into the standard surgical procedure.
BCBS – Delaware 8/1/2011	Surgical Techniques (e.g., Robotic Surgery	No additional allowance is made for the robotic surgical technique. When a doctor reports code S2900, it should be denied as non-covered since this code is not representative of the surgical procedure being performed.
BCBS – Florida 5/14/2010	Robotic Assisted Surgery	Robotic assisted surgery technique (S2900) is considered included in the primary surgical procedure and not separately reimbursable.
BCBS – Kansas City 1/1/2010	Robotics in Surgery	Medical necessity and reimbursement will be based on the standard code for the procedure. If robotic assist is used for the procedure, no additional reimbursement will be made.
CareFirst BCBS 10/1/2010	Robotic Assisted Surgery	HCPCS Code S2900 may be reported separately in addition to the code for the primary procedure even though there is no separate reimbursement for this technique.
CIGNA 5/30/2011	Robotic Assisted Surgery	Does not provide additional reimbursement for the use of robotic surgical devices.
Health Net 3/1/2011	Robotic Surgery	Does not provide additional reimbursement for the use of robotic surgical devices.
Independence BC 8/7/2008	Use of a robotic surgical system	Considers the use of a robotic surgical system to be an integral part of the primary surgical procedure and is, therefore, not eligible for separate reimbursement.
MEDICA 3/14/2010	Robotic Assisted Surgery	Considers robotic assisted surgery an integral part of the procedure and not separately reimbursable service
Medicare Advant. – Highmark 8/1/2005	Surgery	No additional allowance is made for the robotic surgical technique, When a doctor reports code S2900, it should be denied as non-covered since this code is not representative of the surgical procedure being performed.
Medicare Advant. - United HealthCare 8/29/2011	Robotic Assisted Surgery	Robotic assisted surgery may be covered when criteria are met.
Oxford 3/1/2011	Robotic Assisted Surgery	A technique integral to the primary surgical procedure and not a separately reimbursed service.

3

Payer	Title of Policy	Excerpt from policy
Regence 1/1/2007	Robotic Assisted Surgery	Additional professional reimbursement will not be made for the robotic assisted technique. Reimbursement will be based on the reimbursement for the standard surgical procedure(s).
United Healthcare	Robotic-Assisted Surgery	Robotic- assisted surgery is proven as equivalent to, but not superior to, a standard minimally invasive surgical approach, where the standard minimally invasive surgical approach is itself supported by clinical evidence. It is a method of performing the procedure and not a separate service

Copies of medical policies are available, upon request.

Technology Enabler

I defer to others from Intuitive Surgical to provide you with additional peer-reviewed literature and introductions to key opinion leaders from a wide range of surgical specialties. In addition, I encourage your Technology Panel to reach out to practicing surgeons in the State of Washington who have incorporated robotic-assistance into their practices. Peer-to-peer reviews with practicing surgeons would quickly illustrate the technical advantages of robotic-assistance over the well-known limitations associated with standard (rigid) laparoscopic instrumentation. Technical advantages include three-dimensional vision. magnification, intuitive controls, elimination of hand-tremor, ergonomics, and wristed instruments that approximate the motion of the human hand; however, as concluded by AMA, CMS, and leading payers, the primary surgical procedure remains a laparoscopic procedure. Patients still require abdominal insufflation, placement of trocars and the use of laparoscopic instruments. When the patient leaves the Operating Room, the primary intent of the surgical outcome remains a laparoscopic outcome. Robotic-assistance offers the surgeon technical advantages related to magnification, range of motion, dexterity and reproducibility that are not available with open and/or conventional laparoscopic surgery. As a result, robotic surgeons are able to offer their patients a minimally invasive option when they otherwise might only be eligible for an open surgical procedure.

As you complete your deliberations, I hope you will find this information helpful and that it will lead your Committee to conclude that robotic-assisted surgery is consistent with your existing laparoscopic medical policies. Thank-you for your time and consideration. Please do not hesitate to call or email me if you would like additional information.

Sincerely,

Kathryn Barry, MPH, MSN
Health Policy Consultant
Phone: (203) 271-3366
Fax: (203) 271-3844
Email: kathryn.barry@kbreimbursement.com

From: Blee, Mike
To: HCA ST Health Tech Assessment Prog
Cc: "Siwek, Leland G"; lsiwek@nwheartlung.com
Subject: Public Comment for: Robotic Assisted Surgery
Date: Thursday, April 05, 2012 4:47:11 PM

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 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.

Thank you very much

Michael Blee
Director Cardiopulmonary and Imaging Services

Kootenai Health
2003 Kootenai Health Way
Coeur d'Alene, Idaho 83814

208.666.2890 phone
208.666.2394 fax
208.661.4578 cell
mblee@kmc.org
www.kootenaihealth.org

From: Brisbois, R. Steven [R.Steven.Brisbois@providence.org]
Sent: Monday, April 02, 2012 8:20 AM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

I am medical director of womans services at Sacred Heart Med Center here in Spokane, Wash. In addition I am director of the Providence Center for Gyn, Minamally Invasive and Robotic Surgery here.

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 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.

R. Steve Brisbois
New E-Mail: R.Steven.Brisbois@Providence.org

From: D. Mark Brown M.D. [dmb75@reachone.com]
Sent: Sunday, March 25, 2012 10:03 AM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

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:

	Open Procedure	Robotic Procedure
Operating room time:	70 to 120 minutes	180 to 360 minutes
	1.17 to 2.0 hours	3.0 to 6.0 hours
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: 4	8mg 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!!

Dr. Brown

D. Mark Brown M.D.
Southwestern Washington Urology Clinic, PLLC
402-A Black Hills Lane SW
Olympia, WA 98502

From: Michael Burke [Michael_Burke@Valleymed.org]
Sent: Saturday, March 31, 2012 12:31 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

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 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.

Michael F. Burke MD FACS

From: Cunningham, Eve (Tacoma)
To: HCA ST Health Tech Assessment Prog;
Subject: Public Comment for: Robotic Assisted Surgery
Date: Wednesday, April 04, 2012 11:44:28 AM

To whom it may concern:

My name is Eve Cunningham and I am an OB/GYN physician practicing in the Tacoma area. 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 lead to secondary complications such as infections, seromas, separations and longer healing times.

Thank you,

Eve Cunningham

From: PAUL EUN [PAULHEUN@msn.com]
Sent: Monday, April 02, 2012 9:45 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

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.

Paul H. Eun, M.D.
Dedicated Women's Health Specialists, Inc.
253-840-4444 Ext 110

www.dedicatedtowomen.com

From: Florence, Michael [Michael.Florence@swedish.org]
Sent: Saturday, March 24, 2012 4:17 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

Washington State Health Care Authority

Topic: Robotic assisted surgery

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.

I am not clear if this the type of input you are looking for and would be happy to try to submit more detailed information if that is what you need.

Dr. Michael G. Florence, MD FACS
Chief of Surgery, Swedish Medical Center

From: Flugstad, Joel
To: HCA ST Health Tech Assessment Prog
Subject: Swedish Robotics Program Response to HTA Draft Report
Date: Thursday, April 05, 2012 4:44:39 PM
Attachments: SHS Robotics HTA Response 4512.pdf

Dear HTA Program Administrators,

Please accept the attached document as comments related to the HTA draft report on robotic surgery. Please also confirm your receipt of this submission. Should you have any questions or concerns, please do not hesitate to contact me.

Kind Regards,

Joel B. Flugstad, MHPA
Administrative Fellow, Perioperative Services
Swedish Medical Center
747 Broadway
Seattle, WA 98122
206.215.2291 office
206.658.5683 cell
joel.flugstad@swedish.org

FIRST HILL
747 Broadway, Seattle, WA 98122-4307
T 206.386.6000
www.swedish.org

SWEDISH

Josh Morse, MPH
Program Director
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

Re: Robotic Assisted Surgery

April 5, 2012

Dear Sir,

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 1,300 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 credentialing 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.

COMMENT 1

In response to the HTA's recognition regarding the low volume of literature related to RAS, RAS is a relatively new surgical approach. Published literature often is many years behind 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 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 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 charge 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 laparoscopic surgery should include the savings associated with shorter length of stay and earlier return to work.

COMMENT 4

Operative times associated with RAS are by in large longer that 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 operative times associated with high volume 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 and leads 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 relates to operative time.

In closing, SHS appreciates your attention and review of this material, and supporting material submitted by members of SHS' medical staff. Please do not hesitate to contact us for any inquiries related to the information stated herein.

Sincerely,

James Porter, MD
Medical Director
Swedish Robotics Institute

Todd Strumwasser, MD
Senior Vice President & COO
Swedish Seattle

Mary G. Gregg, MD, MHA
Vice President of Medical Affairs
Medical Director, Quality &
Patient Safety
Swedish Seattle

From: Fong, Brian [brian.fong@wwmedgroup.com]
Sent: Friday, March 30, 2012 7:22 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

Dear Washington State Health Care Authority,

As a urologic surgeon and provider of high quality, cost-effective urologic care I would like to add my comments about your Health Technology Assessment of Robotic Surgery.

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 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.

Sincerely,
Brian C. Fong, MD, FRCS(C)
Western Washington Medical Group
Department of Urology
Tel: 425-252-8102
Fax: 425-339-0835
E-mail: brian.fong@wwmedgroup.com
Web: www.northwestdavinci.com

From: Froelich, Theresa (University Place) [TheresaFroelich@fhshealth.org]
Sent: Monday, April 02, 2012 1:00 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

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.

Sincerely,

Dr.Theresa Froelich
Gynecology, Gynecologic surgery and Women's Health
University Place Medical Clinic
7210 40th St. W.
University Place, Wa. 98466
253 534-4916
fax 253 534-4989

From: Heidi J. Gray
To: HCA ST Health Tech Assessment Prog
Subject: Comments on Robotic
Date: Thursday, April 05, 2012 12:50:24 PM

To whom it may concern,

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.

Heidi

Heidi J. Gray, MD

Associate Professor
Associate Fellowship Director
Division of Gynecologic Oncology
Department of OB/GYN
University of Washington
206-543-3669

From: Peter Grimm [peter@grimm.com]
Sent: Wednesday, March 28, 2012 12:37 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

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.

Peter Grimm, D.O.

Prostate Cancer Center of Seattle
Prostate Cancer Treatment Center
9730 3rd Ave NE Suite 208
Seattle Wa, 98115
Bus 206-453-2992
Cell 206-276-1940
www.prostatecancertc.com

From: Holten, Patti

To: HCA ST Health Tech Assessment Prog

Subject: Public

Date: Thursday, April 05, 2012 1:18:00 PM

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.

Patti Holten

From: Dr. Hunter
To: HCA ST Health Tech Assessment Prog
Cc: Somaly.Neal@Intusurg.com
Subject: HTA of robotic surgery
Date: Thursday, April 05, 2012 3:17:43 PM

Dear Panel members,

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 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.

Catherine Hunter DO

From: Peggy Hutchison
To: HCA ST Health Tech Assessment Prog;
cc: Megan Smith;
Subject: Public Comment for: Robotic Assisted Surgery
Date: Wednesday, April 04, 2012 11:44:26 AM

To whom it may concern, 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 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.

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.

Thank you for your consideration.

Margaret (Peggy) Hutchison, MD
Seattle OB/GYN Group
1101 Madison, Ste. 920
Seattle, Wa 98122
206-682-5800

From: Myriam Curet
To: HCA ST Health Tech Assessment Prog
Subject: Washington state HTA on robotics surgery
Date: Thursday, April 05, 2012 4:07:07 PM
Attachments: Combined Bibliography & Key Publications.doc
Washington State HTA-Intuitive Surgical Comments.pdf
Irish HTA-robot-assisted-surgery.pdf

Dear Dr. Nubuhara: Thank you very much for taking the time to speak with me today. I appreciated having the opportunity to ask you questions and learning more about the process of how the assessment was done. As I mentioned, we have comments on the draft that we wanted to share with you. I have attached the comments. In addition, I have attached a bibliography of key publications and a copy of the Irish HTA which we think would be of value. Please feel free to contact me if you have any questions or comments. Myriam Curet

Myriam J. Curet, MD, FACS
Chief Medical Advisor
Intuitive Surgical, Inc
1266 Kifer Road, Sunnyvale, CA 94086
408-523-2490

Sent: Thursday, April 05, 2012 3:38 PM
To: Myriam Curet
Cc: Frank Grillo
Subject: Washington HTA Intuitive Surgical Comments:

Myriam,

Here is the PDF with the Intuitive Surgical comments .

I'm also attaching two additional files – one is the appendix file with the bibliographies. The second is the Irish HTA for their reference.

Thank you for your help on this.

Greg

Greg Blair
Group Marketing Manager
Urology Clinical Marketing
Intuitive Surgical Inc.
Ofc: (408) 523-7506
Mobile: (408) 497-2764
Email: Greg.Blair@intusurg.com

INTUITIVE
SURGICAL

April 5, 2012

Dr. Kerilyn Nubuhara, M.D.
Senior Medical Consultant
Washington State Health Care Authority
628 8th Avenue SE
Olympia, WA 98501

Attention: Health Technology Assessment Clinical Committee

Re: Comments on 2012-3-22 draft of "Robotic Assisted Surgery, Health Technology Assessment Program, Draft Evidence Report"

Dear Dr. Nubuhara,

Intuitive Surgical appreciates the opportunity to offer the following comments on the draft report entitled "Robotic Assisted Surgery, Health Technology Assessment Program Draft Evidence Report." prepared for The Washington State Health Technology Assessment Clinical Committee.

Intuitive Surgical is the manufacturer of the *da Vinci* Surgical System which is the subject of this report. The system has been used in over 1500 hospitals in the United States to perform more than 290,000 procedures in 2011. As the leading organization in robotic surgery, Intuitive Surgical is dedicated to excellence in patient care through the development of leading edge technological advancements, the promotion of research and the dissemination of these results.

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 now done minimally invasively. This has had profound effects 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 robot-assisted surgery and insufficient detail on the methods of statistical analysis.

Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, California 94086

Ph: 408.523.2100
Fax: 408.523.1390
www.intuitivesurgical.com

INTUITIVE
SURGICAL®

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 there are over 4,800 peer–reviewed articles related to the *da Vinci* Surgical System of which more than 570 are comparative cohort studies. Intuitive Surgical believes it is important to insure the inclusion of all relevant previous health technology assessments and published peer reviewed articles in order to complete a comprehensive analysis of the clinical benefits of the daVinci 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.

Basis of the Analysis:

The main parts of the Washington State HTA (WASHTA) appear to be based on 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 dealt 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, Cardiothoracic and ENT / Head & Neck indications). We are enclosing a copy of the HIQA HTA for your review. On page 27 of the HIQA report it is explicitly 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 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 surgery versus Open surgery).
- 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.

Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, California 94086

Ph: 408.523.2100
Fax: 408.523.1390
www.intuitivesurgical.com

- The economic analysis performed by the CADTH does not seem appropriate due to the dramatic differences in the healthcare economic factors between the Canadian and the U.S. health care systems.

Hysterectomies

- *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 radical 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 statistically significant difference between robotic and laparoscopic approaches.

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 referenced journal that is available online at: http://www.springerlink.com/content/120470/, is not represented. In all, we found twenty four relevant comparative articles on robotic surgery in JRS covering robotic prostatectomy (10), partial nephrectomy (1), hysterectomy for cancer (9) and benign hysterectomy (4) that were not included in the present report.

There were other publications with potentially relevant data that are also missing from the data analysis. Across all of the covered surgical specialties, we found 38 comparative articles that we believe 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.

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

Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, California 94086

Ph: 408.523.2100
Fax: 408.523.1390
www.intuitivesurgical.com

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.

Intuitive Surgical's Search Methodology and Robotic Publication Clinical Library

Intuitive Surgical conducts extensive research on ongoing peer reviewed clinical publications related to Robotic Surgery. A monthly literature search is performed by using two search engines (Scopus and PubMed/Medline) with the following key words/search string ((da Vinci/davinci/da-vinci/robotic surgery/intuitive surgical/robotic assist*/robotic-assist*/robotic/robotically assisted) AND Surgery). All publication references returned by the search terms are reviewed by qualified clinical researchers for applicability to da Vinci robotic surgery. Only publications deemed applicable are included in the monthly reference library update. Following the filtering process, all references are labeled with their scientific level of evidence and are stored in a robotic clinical database.

Currently the database contains over 4,800 PubMed-indexed peer reviewed publications involving da Vinci robotic surgery. Over 570 of these publications are comparative cohort studies. An approximate breakdown of these comparative studies by surgical specialty is provided below.

Cardiac	22
General Robotic	21
General Surgery	102
Gynecology	117
Head & Neck	19
Thoracic	11
Training	10
Urology	277

Additional Considerations

After review of the WASHTA 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 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;

Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, California 94086

Ph: 408.523.2100
Fax: 408.523.1390
www.intuitivesurgical.com

p<0.001), a shorter length of stay (1 day vs. 3 days; 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 woman?" Gynecologic Oncology. 111 (2008) 41–45
  - This comparative study of robotic hysterectomy to laparoscopic hysterectomy in an obese and morbidly obese patient population demonstrated that the robotic group experienced a lower blood loss (50ml vs. 150ml; p<0.0001), a shorter operative time (189mins vs. 215mins; p=0.0004), increased lymph node retrieval (31.4 nodes 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 35of 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.
- Trinh 2012, and Tewari 2012 provide substantial evidence to show a conclusive advantage of robotics over open surgery and laparoscopic surgery.

On page 20 of the WASHTA report it states "Each year, approximately 158,000 prostatectomy 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 data estimate between 85,000 – 100,000 surgical prostatectomy procedures annually.
- NCI, National Cancer Bulletin August 9, 2011 • Volume 8 / Number 16 estimates 88,000 prostatectomies were performed in 2008.

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 is now considered the treatment of choice for most clinical T1 renal masses, even in those with a normal contralateral kidney." (http://www.auanet.org/content/media/renalmass09.pdf)
  - The literature demonstrates improved peri-operative outcomes for Robotic Partial Nephrectomy, including lower warm ischemia time, and less blood loss.

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 the high or good quality studies it did not show a significant difference.

- Carlsson and Trinh 2012 both showed significant reductions in complications for Robotic Assisted procedures versus open procedures.

Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, California 94086

Ph: 408.523.2100
Fax: 408.523.1390
www.intuitivesurgical.com

On page 39 of the WASHTA report it states the following: "The cost of the robot included in this economic analysis is for the newer 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 daVinci Si System is $1.75 million U.S. dollars.

On page 41 of the WASHTA report it indicates that inconclusive evidence was found when comparing robotic hysterectomy to laparoscopic hysterectomy with respect to complications and length of stay.

- Scandola, M., L. Grespan, et al. (2011). "Robot-Assisted Laparoscopic Hysterectomy vs Traditional Laparoscopic Hysterectomy: Five Meta-analyses." 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 ratio = 0.68; CI=0.49,0.94), all in favor or robotic hysterectomy

On page 47 of 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.

On page52 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 about surgeons' experience was insufficient to perform a sensitivity analysis regarding the impact of the learning curve on clinical outcomes for any of the nephrectomy study results."

- Consider Bhayani 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.

Conclusion

Intuitive Surgical appreciates the opportunity to provide comments on this draft report. We value the effort and expertise of the Washington State Health Care Authority staff and the authors from the Oregon Health and Science University. We are eager to work closely with the Washington State HCA to provide an accurate assessment of comparative clinical and cost effectiveness of robotic, open and laparoscopic surgical approaches.

We look forward to any further discussion and analysis we can provide. Please contact me at the information below with any questions or comments.

Taking surgery beyond the limits of the human hand.™

Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, California 94086

Ph: 408.523.2100
Fax: 408.523.1390
www.intuitivesurgical.com

INTUITIVE
SURGICAL

Sincerely,

Myriam Curet, M.D., FACS
Chief Medical Advisor
Intuitive Surgical Inc.
Email: Myriam.curet@intusurg.com
Phone: 408-523-2490

Enclosures:

- Appendix A: Key Papers Missing From Analysis
- Appendix B: Additional Urology Publications for Consideration
- Appendix C: Additional Gynecological Publications for Consideration
- Health Information and Quality Authority, Ireland HTA (published on Jan 11, 2012) (saved on included USB drive)

Intuitive Surgical also submitted the following documents for review:

- Health Information and Quality Authority. (2011). *Health technology assessment of robot-assisted surgery in selected surgical procedures*. Dublin: Health Information and Quality Authority. Available at: http://www.hiqa.ie/system/files/HTA-robot-assisted-surgery.pdf

- List of references to be included in the analysis (see Appendix A)

From: jpisbellmd@aol.com
Sent: Saturday, March 31, 2012 2:48 PM
To: HCA ST Health Tech Assessment Prog
Subject: robotic surgery

To whom it may concern:

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.

Sincerely,

John Paul Isbell MD

www.jpisbellmd.com

From: fykim234@yahoo.com
To: HCA ST Health Tech Assessment Prog;
Subject: Public Comment for: Robotic Assisted Surgery
Date: Wednesday, April 04, 2012 9:39:11 AM

Dear Sir or Madam:

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.

Sincerely,

Frank Kim, MD
(o) 253 383 4404

From: Koehler, Richard [Richard.Koehler@vmmc.org]
Sent: Friday, March 23, 2012 5:28 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

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 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.

Concerned Citizen,

Rich Koehler, MD

From: Krishnadasan, Baiya (Tacoma) [BaiyaKrishnadasan@fhshealth.org]
Sent: Monday, April 02, 2012 2:20 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

To whom it may concern:

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.

Thank you for your consideration

Baiya Krishnadasan MD, FACS
Medical Director General Thoracic Surgery
Franciscan Health System
Mailstop 04-06
1802 South Yakima
Suite 102
Tacoma, WA. 98405
Phone:(253) 272-7777
Fax:(253) 426-4142

disclosing this email is prohibited. If you received this email in error, immediately reply to the sender and delete the message completely from your computer system.

From: David Kummerlowe
To: HCA ST Health Tech Assessment Prog
Cc: Leland Siwek, MD
Subject: Kummerlowe, DaVinci Mitral Valve Repair - comments
Date: Thursday, April 05, 2012 3:52:18 PM

To: Health Care Authority, WA State

From: David Kummerlowe, 54 yr. old self employed patient

Procedure: Robotic (DaVinci) Mitral Valve repair

Surgeon: Dr. Leland Siwek, Sacred Heart Spokane

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 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.

Please feel free to contact me should you require any further information,

Dave Kummerlowe, President
CADRE, Inc.
hazcadre@mac.com
19103 194th Ave NE

Woodinville, WA 98077
24/7 voicemail: 425-883-8007
fax: 425-883-7950

From: Roque Lanza
To: HCA ST Health Tech Assessment Prog;
Subject: Public Comment for: Robotic Assisted Surgery
Date: Wednesday, April 04, 2012 10:44:15 AM

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 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?.

Roque A Lanza M.D. F.A.C.O.G.

Member AAGL

MULTICARE'S SHARED VALUES | Respect | Integrity | Stewardship | Excellence | Collaboration | Kindness

Mailgate1.multicare.org made the following annotations

==========

From: Lendvay, Thomas
To: HCA ST Health Tech Assessment Prog;
Subject: Public Comment for: Robotic Assisted Surgery
Date: Wednesday, April 04, 2012 11:16:23 AM

To Whom It May Concern,

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 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.

Sincerely,

Thomas Lendvay, MD, FACS

From: John Lenihan Jr. M.D. [jplenihan@tacomaobgyn.com]
Sent: Monday, April 02, 2012 9:01 AM
To: HCA ST Health Tech Assessment Prog
Subject: Christi.mccarren@multicare.org;Mark.shellmeyer@multicare.org;sharon.jenkins@multicare.org;melissa.brower@multicare.org
Attachments: Key Questions robotics.docx

Dear Sir:

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.

I will attach my specific comments to your queries to this email.

Please let me know if you require these in another format.

Sincere regards,

John L.

John Lenihan Jr., MD
Clinical Associate Profesor of Obstetrics nd Gynecology
University of Washington School of Medicine
Medical Director, Robotics and Minimaly Invasive Surgery
MultiCare Health Systems
314 ML King Jr. Suite # 104
Tacoma, WA 98405
253-403-5432 Fax: 253-403-5478
cell 253-279-0267

Key Questions

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes? Include consideration of short and long-term outcomes, and assessment of clinically meaningful outcomes.

First, 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 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.

HTAKQ 2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches? Include consideration of morbidity, mortality, reoperation, excess bleeding, and extended hospital stay.

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]

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations? Including consideration of: a. Gender b. Age c. Psychological or psychosocial co-morbidities d. Otherpatientcharacteristics or evidence based patients election criteria, especially comorbidities of diabetes and high BMI e. Provider type, experience, or other characteristics and setting (including facility / team experience) f. Payer / beneficiary type including worker's compensation, Medicaid, state employees

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 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]

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

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]

References:

1. Choosing the Route of Hysterectomy for Benign Disease. ACOG Committee Opinion No. 444. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009;114:1156–8.

2. AAGL Position Statement: Route of Hysterectomy to Treat Benign Uterine Disease. J Minim Invasive Gynecol. 2011 Jan-Feb;18(1):1-3. Epub 2010 Nov 6. PMID: 21059487

3. Kelly K. Survey of Hysterectomy Patients, 2008; www.hystersisters.com

4. Jacoby VL, Autry A, Jacobson G, Domush R, Nakagawa S, Jacoby A. Nationwide use of laparoscopic hysterectomy compared with abdominal and vaginal approaches. Obstet Gynecol 2009;114(5):1041-8.

5. CDC-MMWR: Hysterectomy Surveillance-1994-99. July, 2002/51 (SS05); 1-8

6. Sung H, et al. Limits to Laparoscopy in Canada: presented AAGL ACM, Las Vegas NV Nov 2008

7. Nezhat C, Lavie O, Lemyre M, Unal E, Nezhat CH, Neshat F. Robotic-assisted laparoscopic surgery in gynecology: scientific dream or reality? Fertil Steril. 2009.91(6):2620-2622. DOI: 10.1016/j.fertnstert.2008.03.070.

8. Lenihan JP, Kovanda CL. Cost Effectiveness of LAVH to Employers. Am J Obstet Gynecol, 2004:288;336-355.

9. Godfrit,J et al. Surgeon's Perceptions and Injuries During and After Urologic Laparoscopic Surgery. Urology, 2008, 71, 404-407.

10. Van der Schatt,K. Ergonomics, User comfort, and Performance in Standard and Robot-Assisted Laparoscopic Surgery. Surg Endosc. 2009, 23, 1365-1371.

11. Payne, TN, Dauterive FR. Robotic Assisted Hysterectomy: 100 cases after the Learning Curve. J Robotic Surg. 2010; 4:1, 11-17

12. Reich, H, DeCaprio J, McGlynn F. Laparosopic Hysterectomy. J Gynaecol Surg. 1989;5:213-215.

13. Einarsson JI, Matteson KA, Schulkin J, Chavin NR, Sangi-Haghpeykar H. Minimally invasive Hysterectomies – A survey on Attitudes and Barriers among Practicing Gynecologists. J Minim Invasiv Gynecol. 2010;17:167-75.

14. Visco AG, Advincula AP. Robotic Gynecologic Surgery. Obstet Gynecol 2008;112:1369-84.

15. Bell, M, et al. Traditional Laparotomy, Standard Laparoscopy and Robotic Techniques. J SD Med Soc, 2010, 35,1.

16. Jonsdottir GM, Jorgensen S, Cohen SL, Wright KN, Shah NT, Chavan N, Einarsson JI. Increasing Minimally Invasive Hysterectomy: Effect on Cost and Complications. *Obstet Gynecol*. 2011 May;117(5):1142-9.

17. Stone, P, Burnett A, Burton B, Roman J. Overcoming Extreme Obesity With Robotic Surgrery. 2010, Int J Med Rob Com Assist Surg. 6,4, 382-385

18. Lenihan, J, Kovanda C. Outcomes of Robotic Surgery in the Morbidly Obese compared to Normal Weight Women. Presented Pacific Coast OB-GYN Society, October 2010, Kona Hawaii

From: Louie, Brian [Brian.Louie@swedish.org]
Sent: Thursday, March 29, 2012 1:21 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

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.

Regards

Brian E. Louie MD, FRCSC, FACS
Director Research and Education
Co-director, MIS Thoracic Surgery Program
Section of Thoracic and Foregut Surgery
Swedish Cancer Institute and Medical Center

(206) 215-6800 (O)
(206) 215-6801 (F)
brian.louie@swedish.org
www.swedishthoracicsurgery.com

From: John M Luber Jr [johnlubermd@gmail.com]
Sent: Saturday, March 24, 2012 9:12 PM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

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 attention to this important issue,

John Luber MD, FACS

Sent from my iPhone

From: patris marandi
To: HCA ST Health Tech Assessment Prog;
Subject: Public Comment for: Robotic Assisted Surgery
Date: Wednesday, April 04, 2012 10:19:25 AM

Dear Committee;

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.

Sincerely Yours

Patris Marandi, MD
Providence Everett Medical Center
Department of General Surgery

From: Gordon Mathes [GLMathes@embarqmail.com]
Sent: Monday, April 02, 2012 2:31 AM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

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.

Truly,

Gordon L. Mathes, Jr., MD
Rocky Mount Urology Associates
Rocky Mount, NC

From: heath miller [heathmiller@msn.com]
Sent: Wednesday, March 28, 2012 8:51 AM
To: HCA ST Health Tech Assessment Prog
Subject: robotics

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.

heath miller md
chief OB/GYN
swedish medical center
seattle

From: kamane@comcast.net
To: HCA ST Health Tech Assessment Prog;
Subject: Public Comment for: Robotic Assisted Surgery
Date: Tuesday, April 03, 2012 6:04:54 PM

To Whom It May Concern;

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 considering these matters.

Karen Nelson, MD
OB/Gyn

From: Nobuhara, Kerilyn (HCA)
Sent: Monday, April 02, 2012 5:17 PM
To: Hammond, G. Steven (DOC); Hole-Curry, Leah B (LNI); Franklin, Gary M. (LNI); Dennis, Margaret (HCA); Morse, Josiah (HCA); Mootz, Robert D (LNI); Thompson, Jeffery (HCA); Kreiger, Gail (HCA); Glass, Lee (LNI); Manteuffel, Marie E (LNI); Masters, Christine V. (HCA); Silverman, Ellen (HCA); Houghton, Eric (HCA); Coyne, Carolyn (HCA); Salama, Sam (HCA)
Subject: Comments on Robotic Assisted Surgery Draft Report

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.

Kerilyn Nobuhara, MD MHA
Senior Medical Consultant
Health Care Authority
Office of Healthcare Benefits and Utilization Management
PO Box 45506
Olympia, WA 98504-5506
Phone: (360) 725-2032

Comments on Robotic Assisted Surgery 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.

A list of comments is below:

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.

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).

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.

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."

p. 43 "Robotic prostatectomy is compared with a laparoscopic approach", this is a typographical error, it should be hysterectomy rather than prostatectomy.

p. 43 The report states that robot-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.

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.

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 based? On what basis was this determination made?

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.

From: Steve Poore [Stephen.Poore@multicare.org]
Sent: Tuesday, April 03, 2012 2:30 PM
To: HCA ST Health Tech Assessment Prog
Cc: Brent Montgomery; John Lenihan
Subject: Public Comment for: Robotic Assisted Surgery

Washington State Healthcare Authority.
Health Technology Assessment of Robotic Surgery

Dear Sirs:

Thank you for the opportunity to comment on the upcoming technology utilization involving the DaVinci robotic surgery.

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 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.

Thank you for your time.

Stephen E Poore MD, FACOG
Stephen E Poore, MS, MD, FACOG
Women's Clinic-MultiCare Northshore Clinic
MS:4215-2-OB
4215 49th Ave. NE, Tacoma, WA 98422-2421
253-459-7699
253-459-7675 fax
Stephen.Poore@multicare.org

MULTICARE'S SHARED VALUES | Respect | Integrity | Stewardship | Excellence | Collaboration

Kindness Mailgate1.multicare.org made the following annotations

---

==========

FIRST HILL
747 Broadway, Seattle, WA 98122-4307
T 206.386.6000
www.swedish.org

SWEDISH

Josh Morse, MPH
Program Director
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

Re: Robotic Assisted Surgery

April 5, 2012

Dear Sir,

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 1,300 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 credentialing 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.

COMMENT 1

In response to the HTA's recognition regarding the low volume of literature related to RAS, RAS is a relatively new surgical approach. Published literature often is many years behind 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 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 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 charge 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 laparoscopic surgery should include the savings associated with shorter length of stay and earlier return to work.

COMMENT 4

Operative times associated with RAS are by in large longer that 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 operative times associated with high volume 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 and leads 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 relates to operative time.

In closing, SHS appreciates your attention and review of this material, and supporting material submitted by members of SHS' medical staff. Please do not hesitate to contact us for any inquiries related to the information stated herein.

Sincerely,

James Porter, MD
Medical Director
Swedish Robotics Institute

Todd Strumwasser, MD
Senior Vice President & COO
Swedish Seattle

Mary G. Gregg, MD, MHA
Vice President of Medical Affairs
Medical Director, Quality &
Patient Safety
Swedish Seattle

From: Charles Richards [charlesrichards7@me.com]
Sent: Tuesday, April 03, 2012 10:58 AM
To: HCA ST Health Tech Assessment Prog
Subject: Robotic surgery

To whom it may concern;

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.

Charles Richards MD
Pullman Regional Hospital

Sent from my iPad

From: Rogers, Cliff MD
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery
Date: Thursday, April 05, 2012 5:40:04 PM

To whom it may concern:

I have practiced Obstetrics and Gynecology in Everett, Washington since 1988. Since 2006, I have limited my practice to Gynecology.

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 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.

Sincerely,

Clifford W. Rogers, M.D.
Gynecology, Gynecologic Surgery
Minimally-Invasive Gynecologic Surgery
The Everett Clinic
425-339-5424

From: Shook, Dennis W. [Dennis.Shook@CWHS.com]
Sent: Tuesday, March 27, 2012 9:24 AM
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery

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

From: Siwek, Leland G
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for: Robotic Assisted Surgery
Date: Thursday, April 05, 2012 4:25:40 PM

Dear HTCC members,

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 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 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.

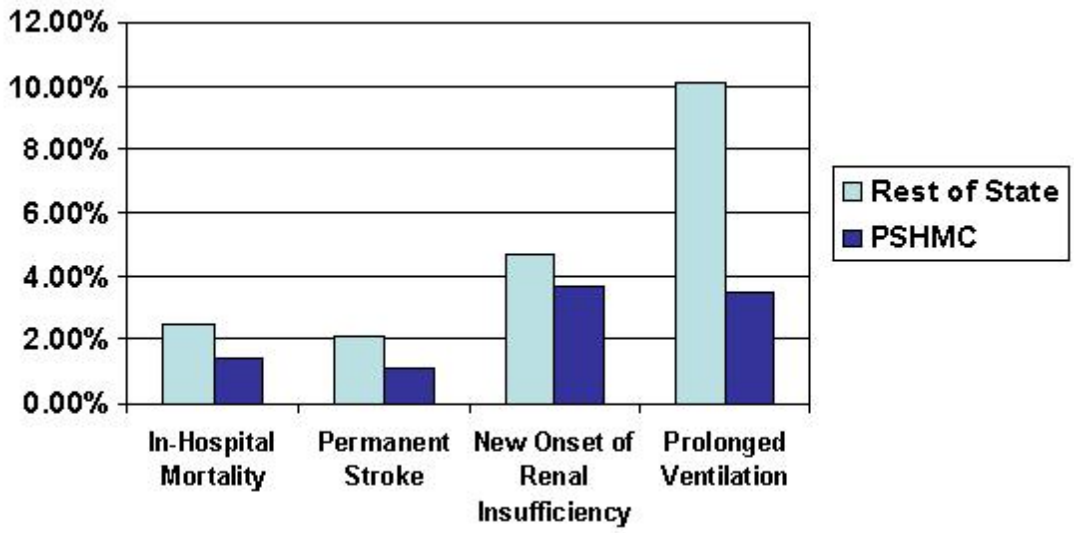
As you can see these are truly outstanding results with >99% successful valve repair. At least in our experience this is significantly better than we were achieving previously with open conventional techniques. While shorter recovery times are important considerations for minimally invasive surgery we 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.

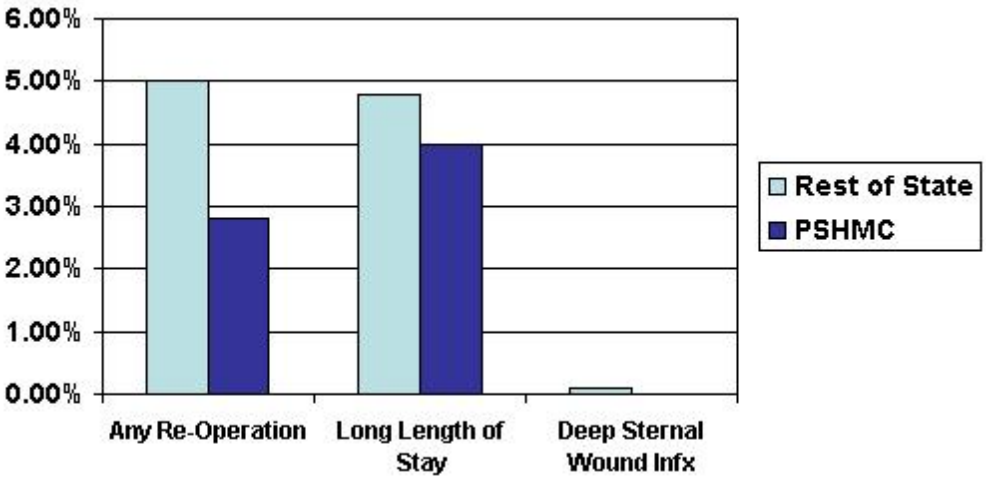
Comparison to open sternotomy is difficult, particularly since the patient benefits (successful repair and improved recovery) seemed so obvious to our regional referring cardiologists that they send all mitral valve patients to us for a robotic approach and virtually all the mitral valve procedures at 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:

Risk-adjusted quality indicators for Isolated MVRR, 2008-2010

(PSHMC 235; Rest of State 759)





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 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 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.

Sincerely,

Leland Siwek, M.D.
Providence Sacred Heart Medical Center

From: Doug Sutherland
To: HCA ST Health Tech Assessment Prog;
Subject: Public Comment for: Robotic Assisted Surgery
Date: Tuesday, April 03, 2012 10:27:27 PM

Good evening,

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 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 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.

Thank you for your time. Please do not hesitate to call on me if I can be of service to your committee. Cell 253 302 2931.

--
DS
--
Douglas E. Sutherland, M.D.
Chief of Urology, MultiCare Urology
Clinical Faculty, Madigan Department of Urology
Tacoma, Washington

From: Kim Tillemans [kmarie.tillemans@gmail.com]
Sent: Tuesday, April 03, 2012 2:02 PM
To: HCA ST Health Tech Assessment Prog
Subject: robotic surgery

Robotic surgery:

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.

Dr. Kim Tillemans

From: Renata Urban
To: HCA ST Health Tech Assessment Prog
Subject: Health Technology Assessment of Robotic Surgery
Date: Thursday, April 05, 2012 1:51:05 PM

To whom it may concern:

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.

Please feel free to contact me with any questions. I would appreciate notification that this email has been received.

Sincerely,

Renata R Urban MD
Assistant Professor, Gynecologic Oncology
Department of Obstetrics & Gynecology
University of Washington Medical Center
1959 NE Pacific St.
Seattle, WA 98195

APPENDIX A. REFERENCES SUBMITTED BY INTUITIVE SURGICAL

Appendix A: Key Papers Missing from Analysis:

Prostatectomy:

4. Carlsson, S., A. E. Nilsson, et al. (2010). "Surgery-related complications in 1253 robot-assisted and 485 open retropubic radical prostatectomies at the Karolinska University Hospital, Sweden." Urology 75(5): 1092-1097.
   - This study showed a significant reduction in the rate of complications including Clavien IIIb-V (major) complications in the RARP group versus the RRP group including:

5. Trinh, Q. D., J. Sammon, et al. (2012). "Perioperative Outcomes of Robot-Assisted Prostatectomy
Compared With Open Radical Prostatectomy: Results From the Nationwide Inpatient Sample European Urology.
   - Multivariate analysis of 19,462 men undergoing radical prostatectomy showed statistically significant improvement with robotic vs. open prostatectomy: Blood transfusion ($P < 0.001$); Intraoperative complications ($P < 0.001$); and Postoperative complications overall ($p = 0.007$); cardiac ($p = 0.047$); respiratory ($P < 0.001$); vascular ($p = 0.029$),

6. Tewari, A., P. Sooriakumaran, et al. (2012). "Positive Surgical Margin and Perioperative Complication Rates of Primary Surgical Treatments for Prostate Cancer: A Systematic Review and Meta-Analysis Comparing Retropubic, Laparoscopic, and Robotic Prostatectomy." European Urology.
   - Meta-analysis significantly lower intraoperative and perioperative complications, LOS, deep vein thrombosis and rates of robotic-assisted (RALP) versus lap and open prostatectomy. RALP also was also associated with significantly lower PT2 PSM rates versus lap.

Nephrectomy/Partial:

12. Pierorazio, P. M., H. D. Patel, et al. (2011). "Robotic-assisted Versus Traditional Laparoscopic Partial Nephrectomy: Comparison of Outcomes and Evaluation of Learning Curve." Urology.
    - CONCLUSIONS: RALPN appears to have shorter operative and ischemia times and less blood loss compared with LPN. After a LC of approximately 25 cases, the transition from LPN to RALPN can be undertaken without an additional LC and can be associated with immediate benefits.
13. Anderson, J. E., J. Kellogg Parsons, et al. (2011). "Hospital costs and length of stay related to robot-assisted versus open radical and partial nephrectomy for kidney cancer in the USA." Journal of Robotic Surgery: 1-4.

- In this large, population-based analysis, robot-assisted radical and partial nephrectomy were associated with shorter LOS and equivalent hospital charges compared with their open surgery counterparts. These data suggest that, for renal surgery, diminished LOS offsets other hospital costs associated with robot-assisted procedures

14. Masson-Lecomte, A., D. R. Yates, et al. (2011). "A prospective comparison of the pathologic and surgical outcomes obtained after elective treatment of renal cell carcinoma by open or robot-assisted partial nephrectomy." Urol Oncol.
    - CONCLUSION: We found that RAPN is superior to the reference standard (OPN) surgical treatment of small RCCs in terms of blood loss and length of hospital stay with equivalent complications, warm ischemia time, and effect on renal function. Larger randomized trials with longer follow-up will give us further information and insight into the oncologic equivalence

Pyeloplasty:

- Lee, R. S., A. B. Retik, et al. (2006). "Pediatric robot assisted laparoscopic dismembered pyeloplasty: comparison with a cohort of open surgery." J Urol 175(2): 683-687; discussion 687.
    - RALP showed advantages of decreased hospital stay, decreased narcotic use and operative times approaching those of open surgery. RALP is an option for pyeloplasty, and as robotic technology improves, this method of repair may become the minimally invasive treatment of choice.
- Hemal, A. K., S. Mukherjee, et al. (2010). "Laparoscopic pyeloplasty versus robotic pyeloplasty for ureteropelvic junction obstruction: a series of 60 cases performed by a single surgeon." Can J Urol 17(1): 5012-5016.
    - CONCLUSION: In this patient series, UPJ obstruction was managed effectively with either RP or LP, and outcomes were durable. Compared to pure LP, pure RP enabled the surgeon to achieve quicker dissection, reconstruction, and intracorporeal suturing with fine sutures and with antegrade double-J stenting. With RP, the operating time was decreased, and the procedure offered greater ergonomic convenience to the surgeon. Long term postoperative success, however, was equivalent on follow up in both patient groups.

Radical Cystectomy:

19. Lee, R., B. Chughtai, et al. (2011). "Cost-analysis comparison of robot-assisted laparoscopic radical cystectomy (RC) vs open RC." BJU International 108(6 B): 976-983
    - RESULTS Despite an increased materials cost, RALRC was less expensive than ORC when the cost of complications was considered. RALRC was less expensive than ORC for IC and CCD, but the cost advantage deteriorated for ON.
20. Abaza, R., P. P. Dangle, et al. (2012). "Quality of Lymphadenectomy is Equivalent With Robotic and Open Cystectomy Using an Extended Template." Journal of Urology.

- CONCLUSIONS: No difference was identified in the lymph node yield or the positive node rate when comparing open and robotic extended lymph node dissection. Local recurrence and survival data are needed to confirm whether the 2 techniques are oncologically equivalent

Hysterectomy - Cancer

26. Paley, P. J., D. S. Veljovich, et al. (2011). "Surgical outcomes in gynecologic oncology in the era of robotics: Analysis of first 1000 cases." American Journal of Obstetrics and Gynecology **204**(6): 551.e551-551.e559.
    - Comparison of robotic hysterectomy to abdominal hysterectomy for the treatment of endometrial cancer over a large (n=1000) patient population demonstrated significantly less blood loss (46.9mL vs. 197.6mL; p<0.0001), a shorter length of stay (1.4 vs. 5.3 days; p<0.0001) and a lower complication rate (6.4% vs. 20.6%; p<0.0001) in the robotic group.
27. Seamon, L. G., S. A. Bryant, et al. (2009). "Comprehensive Surgical Staging for Endometrial Cancer in Obese Patients: Comparing Robotics and Laparotomy." Obstet Gynecol **114**(1): 16-21.
    - This case-matched comparison of robotic hysterectomy to abdominal laparotomy 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 days; 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.
28. Gortchev, G., S. Tomov, et al. (2011). "Robot-assisted radical hysterectomy-perioperative and survival outcomes in patients with cervical cancer compared to laparoscopic and open radical surgery." Gynecological Surgery: 1-8.
    - A 3-arm cervical cancer study comparing robotic hysterectomy to laparoscopic and abdominal hysterectomy demonstrated a shorter operative time (152 mins vs. 232 mins and 168 mins; p=0.001) and shorter length of stay (4.1 days vs. 4.8 days and 9.6 days; p=0.001).
    - Additionally, the robotic cohort had a lower frequency of recurrences (1.4% vs. 6.5% and 14.3%; p=0.001) and a superior overall survival (100% vs. 94.9% and 84.9%; p=0.037)

29. Estape, R., N. Lambrou, et al. (2009). "A case matched analysis of robotic radical hysterectomy with lymphadenectomy compared with laparoscopy and laparotomy." Gynecologic Oncology. 113 (2009) 357–361.
    - This 3-arm cervical cancer study comparing robotic hysterectomy to laparoscopic and abdominal hysterectomy demonstrated a lower estimated blood loss for robotics than laparotomy (130mL vs. 621mL; p<0.0001), and patients in the robotic group also averaged less days on pain medication (10.3 vs. 29.0; p=0.002) and returned to work sooner (23.5 days vs. 46.4 days; p=0.003) than the abdominal group.

30. Lau, Susie; Vaknin, Zvi; Ramana-Kumar, Agnihotram V.; Halliday, Darron; Franco, Eduardo L.; Gotlieb, Walter H. "Outcomes and Cost Comparisons After Introducing a Robotics Program for
    Endometrial Cancer Surgery". Obstetrics & Gynecology. 2012, vol. 119(4):717-724.
    - Canadian study on endometrial cancer examining robotic hysterectomy vs. laparoscopic and abdominal hysterectomy. Patients undergoing robotic procedures had fewer adverse events (13% compared with 42%; p<.001), lower estimated median blood loss (50mL compared with 200mL; p<.001), and shorter median hospital stay (1 compared with 5 days; p.001)
    - At a 2-year follow-up, results indicate a lower [cancer] recurrence rate in the robotic cohort compared with the historical (laparoscopic and abdominal) cohort (Wilcoxon p<.001; log-rank P<.001)
    - The overall hospital costs were significantly lower for robotics compared with the historical group ($7,644 compared with $10,368 [Canadian dollars]; p<.001) even when acquisition and maintenance cost were included ($8,370 compared with $10,368; p=.001)

Hysterectomy - Benign

32. Payne, T. N. and F. R. Dauterive (2008). "A comparison of total laparoscopic hysterectomy to robotically assisted hysterectomy: surgical outcomes in a community practice." J Minim Invasive Gynecol **15**(3): 286-291.
    - Comparison of robotic hysterectomy to laparoscopic hysterectomy found lower blood loss (61ml vs. 113ml; p<0.0001), shorter length of stay (1.1 days vs. 1.6 days; p<0.007), fewer conversions (20% vs. 4%; p=0.0008) and faster operative times once through the learning curve (78.7mins vs. 92.4mins; p<0.0001)
19. Giep, B. N., H. N. Giep, et al. (2010). "Comparison of minimally invasive surgical approaches for hysterectomy at a community hospital: robotic-assisted laparoscopic hysterectomy, laparoscopic-assisted vaginal hysterectomy and laparoscopic supracervical hysterectomy." Journal of Robotic Surgery: 1-9.
    - 3-arm study comparing robotic hysterectomy to LAVH and LSH. Robotic cohort experienced shorter operative times relative to LAVH (89.9mins vs. 124.8mins; p<0.001) and less blood loss (59ml vs. 167.9ml; p<0.001) despite higher uterine weights (207.4g vs. 149.6g; p=0.005)

20. Scandola, M., L. Grespan, et al. (2011). "Robot-Assisted Laparoscopic Hysterectomy vs Traditional Laparoscopic Hysterectomy: Five Metaanalyses." 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 ratio = 0.68; CI=0.49,0.94)

21. Jonsdottir, G. M., S. Jorgensen, et al. (2011). "Increasing minimally invasive hysterectomy: effect on cost and complications." Obstetrics and Gynecology **117**(5): 1142-1149.
    - 4-arm study comparing robotic hysterectomy to abdominal, laparoscopic, and vaginal hysterectomy demonstrated fewer conversions to laparotomy (0% robotic vs. 1.5% vaginal and 4.4% laparoscopic) and fewer major post-operative complications (1.6% robotic vs. 3.4% laparoscopic, 4.5% vaginal and 9.1% abdominal)
    - In 2009, robotic hysterectomy was the least expensive means to complete a hysterectomy ($11,004 vs. $11,820 vaginal, $12,329 laparoscopic, and $12,678 abdominal)

Myomectomy

22. Barakat, E. E., M. A. Bedaiwy, et al. (2011). "Robotic-assisted, laparoscopic, and abdominal myomectomy: a comparison of surgical outcomes." Obstetrics and Gynecology **117**(2 Pt 1): 256-266.
    - 3-arm study comparing robotic myomectomy to laparoscopic and abdominal myomectomy. The robotic cohort demonstrated a lower estimated blood loss (100ml vs. 150ml vs. 200ml; $p<0.001$), a lower hemoglobin drop (1.3g/dL vs. 1.55 vs. 2.00; $p<0.001$) and a shorter length of stay (1 day vs. 3 days in the abdominal group; $p<0.001$).

25. Sangha, R., D. I. Eisenstein, et al. (2010). "Surgical outcomes for robotic-assisted laparoscopic myomectomy compared to abdominal myomectomy." Journal of Robotic Surgery: volume 4, Issue 4, December 2010, Pages 229-233.
    - Study comparing robotic myomectomy to laparoscopic myomectomy showed lower estimated blood loss (200ml vs. 100ml; $p<0.001$) and a shorter length of stay (3 days vs. 1 day; $p<0.001$) in the robotic group.

Sacrocolpopexy

26. J., D. R. Yates, et al. (2011). "Prospective comparison of short-term functional outcomes obtained after pure laparoscopic and robot-assisted laparoscopic sacrocolpopexy." World Journal of Urology. DOI 10.1007/s00345-011-0748-2
    - Comparison of robotic sacrocolpopexy to laparoscopic sacrocolpopexy demonstrated shorter operative times (128 mins vs. 231 mins; $p<0.0001$), lower estimated blood loss (55ml vs. 280 ml; $p=0.03$), and shorter duration of catheter (2.5 days vs. 3.1 days; $p=0.03$) in the robotic group.

27. Siddiqui, NY, Geller EJ, Visco AG. "Symptomatic and anatomic 1-year outcomes after robotic and abdominal sacrocolpopexy." Am J Obstet Gynecol. 2012; 206
    - Study comparing robotic sacrocolpopexy (n=125) to abdominal sacrocolpopexy (n=322) showed lower estimated blood loss in the robotic group (90ml vs. 228ml;

p<0.01) while anatomic cure rates (C point = -8.5 vs. -8.0; p=0.78) at a longer follow-up time (18.3 months vs. 11.7 months; p<0.01) remained equivalent.

31. Elliott, C. S., M. H. Hsieh, et al. (2011). "Robot-Assisted Versus Open Sacrocolpopexy: A Cost-Minimization Analysis." Journal of Urology. Vol. 187, 638-643.
    - 2-arm study comparing robotic sacrocolpopexy to abdominal sacrocolpopexy showed a shorter length of stay (1.0 days vs. 3.3 days; p<0.05) as well as a 10% overall cost savings for the robotic group ($10,178 vs $11,307; p<0.05)

Colorectal

32. Kim, J. Y., N. K. Kim, et al. (2012). "A Comparative Study of Voiding and Sexual Function after Total Mesorectal Excision with Autonomic Nerve Preservation for Rectal Cancer: Laparoscopic Versus Robotic Surgery." Annals of Surgical Oncology: 1-9.
    - This prospective study (n= 30 vs 39), concludes robotic TME (total mesorectal excision) compared to laparoscopic TME results in faster recovery of urinary function (3 months vs 6 months, p=0.036) and sexual function (6 months vs 12 months)

33. Patel, C. B., M. Ragupathi, et al. (2011). "A three-arm (laparoscopic, hand-assisted, and robotic) matched-case analysis of intraoperative and postoperative outcomes in minimally invasive colorectal surgery." Diseases of the Colon and Rectum **54**(2): 144-150.
    - Operating times associated with robotic group was found to be higher (181 mins, 158 mins, 237 mins, p <0.01)
    - LOS in Robotic group was shorter than conventional laparoscopic group (2.9 days vs 3.9 days, p<0.01)

34. Desouza, A. L., L. M. Prasad, et al. (2011). "A comparison of open and robotic total mesorectal excision for rectal adenocarcinoma." Diseases of the Colon and Rectum **54**(3): 275-282.
    - Compares robotic vs open (via hand port) TME in rectal adenocarcinoma patients (n= 36 vs 46).
    - There were more APRs (p=0.019) and more low and mid rectal tumors (p= 0.007) in the robotic group.
    - Total procedure time in robotic group was longer (337 mins vs 273 mins, p=0.003) but blood loss was less (187 ml vs 273 ml, p = 0.036).

Adrenalectomy

35. Agcaoglu, O., S. Aliyev, et al. (2012). "Robotic Versus Laparoscopic Resection of Large Adrenal Tumors." Annals of Surgical Oncology: 1-7.

- Operative time was shorter for the robotic versus laparoscopic group (159.4 ± 13.4 vs 187.2 ± 8.3 min, respectively, P = .043)
- The conversion to open rate was less in the robotic (4%) versus the laparoscopic (11%) group; P = .043
- Hospital stay was shorter for the robotic group (1.4 ± 0.2 vs 1.9 ± 0.1 days, respectively, P = .009)

36. Agcaoglu, O., S. Aliyev, et al. (2012). "Robotic vs Laparoscopic Posterior Retroperitoneal Adrenalectomy." Archives of Surgery **147**(3): 272-275.

Gastrectomy

35. Huang, K. H., Y. T. Lan, et al. (2012). "Initial Experience of Robotic Gastrectomy and Comparison with Open and Laparoscopic Gastrectomy for Gastric Cancer." Journal of Gastrointestinal Surgery.

Pancreatectomy

36. Buchs, N. C., P. Addeo, et al. (2011). "Robotic Versus Open Pancreaticoduodenectomy: A Comparative Study at a Single Institution." World Journal of Surgery.
- Compares robotic vs open pancreaticoduodenectomy (whipple) patients (n= 44 vs 39).
- Robotic group includes significantly higher age (63 vs 56, p =0.04), higher BMI (27.7 vs 24.8 kg/m2, p = 0.01) and higher ASA class (2.5 vs 2.15, p = 0.01) patients.
- Robotic surgery is favored in the following aspects:
  Operative times (444 mins vs 559 mins, p= 0.0001)
  Mean Blood loss (387 ml vs 827 ml, p = 0.0001)
  Mean Lymph Nodes (16.8 vs 11, p= 0.02)

37. Chalikonda, S., J. R. Aguilar-Saavedra, et al. (2012). "Laparoscopic robotic-assisted pancreaticoduodenectomy: a case-matched comparison with open resection." Surgical Endoscopy.
- Conclusion: Robotic surgery compared to Open surgery is associated with

Increased operative time (476.2 vs 366.4 min, p = 0.0005)
Reduced length of stay (9.79 days vs 13.26 days, p = 0.043)

Roux-en-Y Gastric Bypass

38. Snyder, B. E., T. Wilson, et al. (2008). "Lowering gastrointestinal leak rates: A comparative analysis of robotic and laparoscopic gastric bypass." Journal of Robotic Surgery **2**(3): 159-163.
- Perhaps the most comprehensive analysis (356 laparoscopic vs 249 robotic roux-en-y patients).
- All patients had a minimum of 90 days follow-up.
- Less anastomotic leakages in the robotic group (0% vs 1.7%, p=0.04)

38. Hagen, M. E., F. Pugin, et al. (2011). "Reducing Cost of Surgery by Avoiding Complications: the Model of Robotic Roux-en-Y Gastric Bypass." Obesity Surgery: 1-10.
    - Compares 524 open vs 323 laparoscopic vs 143 robotic cases.
    - There were no differences among the groups based on age, gender, BMI but there were more ASA 1-2 class and less ASA 3-4 class patients in the robotic group compared to open.
    - The following results of this study favored robotic surgery vs open vs lap:
      Lower anastomotic leakages in robotic vs lap (0% vs 4%, p = 0.0349)
      Lower anastomotic strictures in robotic vs lap (0% vs 6.8%, p = 0.0002)
      Less conversion in robotic vs lap to open surgery (1.4% vs 4.9%, p = 0.0388)
      Less reoperations needed in robotic vs lap (0.7% vs 4%, p = 0.0349)
      Shorter mean ICU days in robotic vs open (0.2 vs 2.0 days, p <0.0001)
      Shorter LOS in robotic vs lap vs open (7.4 vs 11.0 vs 10.9 days, p = 0.001)

Thoracic Lobectomy:

39. Cerfolio, R. J., A. S. Bryant, et al. (2011). "Initial consecutive experience of completely portal robotic pulmonary resection with 4 arms." Journal of Thoracic and Cardiovascular Surgery.
    - Cerfolio 2011 retrospectively compares 106 patients who underwent robotic lobectomy to 318 propensity-matched patients who received open lobectomy, demonstrating a comparable lymphadenectomy with reductions in LOS, EBL, chest tube duration, and verbal pain score in the robotic group
40. Jang, H. J., H. S. Lee, et al. (2011). "Comparison of the early robot-assisted lobectomy experience to video-assisted thoracic surgery lobectomy for lung cancer: A single-institution case series matching study." Innovations: Technology and Techniques in Cardiothoracic and Vascular Surgery 6(5): 305-310.
    - Jang 2011 retrospectively compares 40 patients who underwent robotic lobectomy to the authors first 40 initial VATS patients and most recent 40 VATS patients, demonstrating statistically significant reductions in postoperative complications, intraoperative bleeding, and LOS in the robotic group compared to the early VATS group

ENT/Head & Neck

39. Dean N.R., Rosenthal E.L. et. al. (2010). "Robotic-Assisted Surgery for Primary or Recurrent Oropharyngeal Carcinoma. Arch Otolaryngology Head Neck Surg 136(4): 380-3
    - This single-center, retrospective, case-controlled study was conducted to compare outcomes between patients who had undergone surgical resections for T1 and T2 oropharyngeal cancers. Patients were classified into three cohorts: Robotic-assisted for primary neoplasm (N=15), robotic-assisted salvage surgery for recurrent disease (N=7) and open salvage surgery for recurrent disease (N=14)
    - 0% of robotic-assisted salvage patients were gastrostomy tube dependent at 6 months, compared to 43% of open salvage patients. 0% of robotic-assisted salvage patients required a tracheostomy at the time of surgery, compared to 100% of open salvage

patients. Robotic-assisted salvage patients had an average length of stay of 5 days, compared to 8.2 days for open salvage patients.

Appendix B:
Additional Urology Publications for Consideration

Prostatectomy Additional Comparative Papers.

70. Coronato, E. E., J. D. Harmon, et al. (2009). "A multi-institutional comparison of radical retropubic prostatectomy, radical perineal prostatectomy, and robot-assisted laparoscopic prostatectomy for treatment of localized prostate cancer." Journal of Robotic Surgery 3(3): 175-178.

71. Caceres, F., C. Sanchez, et al. (2007). "Laparoscopic radical prostatectomy versus robotic." Arch Esp Urol 60(4): 430-438

72. Ham, W. S., S. Y. Park, et al. (2008). "Open versus robotic radical prostatectomy: A prospective analysis based on a single surgeon's experience." Journal of Robotic Surgery 2(4): 235-241.

.

73. White, M. A., A. P. De Haan, et al. (2009). "Comparative Analysis of Surgical Margins Between Radical Retropubic Prostatectomy and RALP: Are Patients Sacrificed During Initiation of Robotics Program?" Urology 73(3): 567-571.
74. Breyer, B. N., C. B. Davis, et al. (2010). "Incidence of bladder neck contracture after robot-assisted laparoscopic and open radical prostatectomy." BJU International **106**(11): 1734-1738.
75. Carlsson, S., A. E. Nilsson, et al. (2010). "Surgery-related complications in 1253 robot-assisted and 485 open retropubic radical prostatectomies at the Karolinska University Hospital, Sweden." Urology 75(5): 1092-1097.
76. Chatterjee, A., L. Chen, et al. (2010). "Robotic Assisted Laparoscopic Prostatectomy versus Laparoscopic Assisted Prostatectomy: A Financial Analysis." J Surg Res **158**(2): 380.
77. Cheetham, P. J., D. J. Lee, et al. (2010). "Does the presence of robotic surgery affect demographics in patients choosing to undergo radical prostatectomy? A multi-center contemporary analysis." Journal of Robotic Surgery: 1-6.
78. CChoi, W. W., X. Gu, et al. (2010). "The effect of minimally invasive and open radical prostatectomy surgeon volume." Urologic Oncology: Seminars and Original Investigations.
79. Cooperberg, M. R., C. J. Kane, et al. (2010). "Adequacy of lymphadenectomy among men undergoing robot-assisted laparoscopic radical prostatectomy." BJU International **105**(1): 88-92.
80. Djavan, B., E. Eckersberger, et al. (2010). "Oncologic, Functional, and Cost Analysis of Open, Laparoscopic, and Robotic Radical Prostatectomy." European Urology, Supplements.
81. Kang, D. C., M. J. Hardee, et al. (2010). "Low Quality of Evidence for Robot-Assisted Laparoscopic Prostatectomy: Results of a Systematic Review of the Published Literature." European Urology **57**(6): 930-937.

82. Kermarrec, I., P. Mangin, et al. (2010). "Is robotic improve laparoscopic radical prostatectomy in complex surgical cases?" Le robot améliore-t-il la prostatectomie totale laparoscopique dans les cas complexes ?
83. Lo, K. L., C. F. Ng, et al. (2010). "Short-term outcome of patients with robot-assisted versus open radical prostatectomy: For localised carcinoma of prostate." Hong Kong Medical Journal **16**(1): 31-35.
84. Trabulsi, E. J., J. C. Zola, et al. (2010). "Transition from pure laparoscopic to robotic-assisted radical prostatectomy: A single surgeon institutional evolution." Urologic Oncology: Seminars and Original Investigations **28**(1): 81-85.
85. Truesdale, M. D., D. J. Lee, et al. (2010). "Assessment of lymph node yield after pelvic lymph node dissection in men with prostate cancer: A comparison between robot-assisted radical prostatectomy and open radical prostatectomy in the modern era." Journal of Endourology **24**(7): 1055-1060.
86. Uvin, P., J. M. De Meyer, et al. (2010). "A comparison of the peri-operative data after open radical retropubic prostatectomy or robotic-assisted laparoscopic prostatectomy." Acta Chirurgica Belgica **110**(3): 313-316.
87. Abdollah, F., L. Budus, et al. (2011). "Impact of caseload on total hospital charges: A direct comparison between minimally invasive and open radical prostatectomy a population based study." Journal of Urology **185**(3): 855-861.
88. Albadine, R., M. E. Hyndman, et al. (2011). "Characteristics of positive surgical margins in robotic-assisted radical prostatectomy, open retropubic radical prostatectomy, and laparoscopic radical prostatectomy: a comparative histopathologic study from a single academic center." Human Pathology.
89. Ferronha, F., F. Barros, et al. (2011). "Is there any evidence of superiority between retropubic, laparoscopic or robot-assisted radical prostatectomy?" International Braz J Urol **37**(2): 146-158.
90. Hatiboglu, G., D. Teber, et al. (2011). "Robot-assisted prostatectomy: the new standard of care." Langenbeck's Archives of Surgery: 1-10.Heer R A Rev Recent Clin Trials 2011 Critical Systematic Review of
91. Heer, R., I. Raymond, et al. (2011). "A Critical Systematic Review of Recent Clinical Trials Comparing Open Retropubic, Laparoscopic and Robot-Assisted Laparoscopic Radical Prostatectomy." Rev Recent Clin Trials.
92. Kasraeian, A., E. Barret, et al. (2011). "Comparison of the rate, location and size of positive surgical margins after laparoscopic and robot-assisted laparoscopic radical prostatectomy." BJU International.
93. Kommu, S. S., C. G. Eden, et al. (2011). "Initial treatment costs of organ-confined prostate cancer: A general perspective." BJU International **107**(1): 1-3.
94. Kowalczyk, K. J., A. C. Weinburg, et al. (2011). "Comparison of outpatient narcotic prescribing patterns after minimally invasive versus retropubic and perineal radical prostatectomy." Journal of Urology **186**(5): 1843-1848.
95. Kowalczyk, K. J., H. y. Yu, et al. (2011). "Outcomes assessment in men undergoing open retropubic radical prostatectomy, laparoscopic radical prostatectomy, and robotic-assisted radical prostatectomy." World Journal of Urology: 1-5.

96. Ku, J. H., C. W. Jeong, et al. (2011). "Nerve-sparing procedure in radical prostatectomy: A risk factor for hernia repair following open retropubic, pure laparoscopic and robot-assisted laparoscopic procedures." Scandinavian Journal of Urology and Nephrology **45**(3): 164-170.
97. Lallas, C. D., M. L. Pe, et al. (2011). "Comparison of lymph node yield in robot-assisted laparoscopic prostatectomy with that in open radical retropubic prostatectomy." BJU International **107**(7): 1136-1140.
98. Lowrance, W. T., J. A. Eastham, et al. (2011). "Costs of medical care after open or minimally invasive prostate cancer surgery: A population-based analysis." Cancer.
99. Plainard, X., E. Valgueblasse, et al. (2011). "[Urinary continence following radical prostatectomy: Comparison of open, laparocopic, and robotic approaches.]." Presse Medicale.
100. Rochat, C. H., J. Sauvain, et al. (2011). "Mid-term biochemical recurrence-free outcomes following robotic versus laparoscopic radical prostatectomy." Journal of Robotic Surgery: 1-7.
101. Tollefson, M. K., I. Frank, et al. (2011). "Robotic-Assisted Radical Prostatectomy Decreases the Incidence and Morbidity of Surgical Site Infections." Urology.
102. Weerakoon, M., S. Sengupta, et al. (2011). "Predictors of positive surgical margins at open and robot-assisted laparoscopic radical prostatectomy: a single surgeon series." Journal of Robotic Surgery: 1-6.
103. Barry, M. J., P. M. Gallagher, et al. (2012). "Adverse Effects of Robotic-Assisted Laparoscopic Versus Open Retropubic Radical Prostatectomy Among a Nationwide Random Sample of Medicare-Age Men." Journal of Clinical Oncology.
104. Gianino, M. M., M. Galzerano, et al. (2012). "Costs in surgical techniques for radical prostatectomy: A review of the current state." Urologia Internationalis **88**(1): 1-5.
105. Kowalczyk, K. J., H. Yu, et al. (2012). "Outcomes assessment in men undergoing open retropubic radical prostatectomy, laparoscopic radical prostatectomy, and robotic-assisted radical prostatectomy." World Journal of Urology **30**(1): 85-89.
106. Masterson, T. A., L. Cheng, et al. (2012). "Open vs. robotic-assisted radical prostatectomy: A single surgeon and pathologist comparison of pathologic and oncologic outcomes." Urol Oncol.
107. Schroeck, F. R., T. L. Krupski, et al. (2012). "Pretreatment Expectations of Patients Undergoing Robotic Assisted Laparoscopic or Open Retropubic Radical Prostatectomy." Journal of Urology.
108. Trinh, Q. D., J. Sammon, et al. (2012). "Perioperative Outcomes of Robot-Assisted Prostatectomy Compared With Open Radical Prostatectomy: Results From the Nationwide Inpatient Sample." European Urology.
109. Villamil, W., N. Billordo Peres, et al. (2012). "Incidence and location of positive surgical margins following open, pure laparoscopic, and robotic-assisted radical prostatectomy and its relation with neurovascular preservation: a single-institution experience." Journal of Robotic Surgery: 1-7.
110. Wang, R., D. P. Wood Jr, et al. (2012). "Risk factors and quality of life for post-prostatectomy vesicourethral anastomotic stenoses." Urology **79**(2): 449-457.
111. Tewari, A., P. Sooriakumaran, et al. (2012). "Positive Surgical Margin and Perioperative Complication Rates of Primary Surgical Treatments for Prostate Cancer: A Systematic

Review and Meta-Analysis Comparing Retropubic, Laparoscopic, and Robotic Prostatectomy." European Urology.

112. Ball, A. J., B. Gambill, et al. (2006). "Prospective longitudinal comparative study of early health-related quality-of-life outcomes in patients undergoing surgical treatment for localized prostate cancer: a short-term evaluation of five approaches from a single institution." J Endourol **20**(10): 723-731.

113. Chan, R. C., D. A. Barocas, et al. (2008). "Effect of a large prostate gland on open and robotically assisted laparoscopic radical prostatectomy." BJU International **101**(9): 1140-1144.

114. Drouin, S. J., C. Vaessen, et al. (2009). "Comparison of mid-term carcinologic control obtained after open, laparoscopic, and robot-assisted radical prostatectomy for localized prostate cancer." World J Urol **27**(5): 599-605.

115. Durand, X., C. Vaessen, et al. (2008). "Retropubic, laparoscopic and robot-assisted total prostatectomies: comparison of postoperative course and histological and functional results based on a series of 86 prostatectomies." Prostatectomies totales re?tropubiennes, laparoscopiques et robot-assiste?es: comparaison des suites postope?ratoires, des re?sultats anatomopathologiques et fonctionnels: a? propos de 86 prostatectomies. **18**(1): 60-67.

116. Gosseine, P. N., P. Mangin, et al. (2009). "Pure laparoscopic versus robotic-assisted laparoscopic radical prostatectomy: Comparative study to assess functional urinary outcomes." Prostatectomie totale laparoscopique standard versus laparoscopique robot-assistée : étude comparative sur les résultats fonctionnels urinaires **19**(9): 611-617.

117. Herrmann, T. R., R. Rabenalt, et al. (2007). "Oncological and functional results of open, robot-assisted and laparoscopic radical prostatectomy: does surgical approach and surgical experience matter?" World J Urol.

118. Hu, J. C., X. Gu, et al. (2009). "Comparative effectiveness of minimally invasive vs open radical prostatectomy." JAMA - Journal of the American Medical Association **302**(14): 1557-1564.

119. Hye, W. L., M. L. Hyun, et al. (2009). "Comparison of initial surgical outcomes between laparoscopic radical prostatectomy and robot-assisted laparoscopic radical prostatectomy performed by a single surgeon." Korean Journal of Urology **50**(5): 468-474.

120. Joseph, J. V., A. Leonhardt, et al. (2008). "The cost of radical prostatectomy: Retrospective comparison of open, laparoscopic, and robot-assisted approaches." Journal of Robotic Surgery **2**(1): 21-24.

121. Kaufman, M. R., J. A. Smith, Jr., et al. (2006). "Positive influence of robotically assisted laparoscopic prostatectomy on the collaborative-care pathway for open radical prostatectomy." BJU Int **97**(3): 473-475.

122. Krambeck, A. E., D. S. DiMarco, et al. (2009). "Radical prostatectomy for prostatic adenocarcinoma: A matched comparison of open retropubic and robot-assisted techniques." BJU International **103**(4): 448-453.

123. Laurila, T. A. J., W. Huang, et al. (2009). "Robotic-assisted laparoscopic and radical retropubic prostatectomy generate similar positive margin rates in low and intermediate risk patients." Urologic Oncology: Seminars and Original Investigations **27**(5): 529-533.

124. Madeb, R., D. Golijanin, et al. (2007). "Transition from open to robotic-assisted radical prostatectomy is associated with a reduction of positive surgical margins amongst private-practice-based urologists." Journal of Robotic Surgery **1**(2): 145-149.

125. Martinez-Salamanca, J. I. and A. Allona Almagro (2007). "[Radical prostatectomy: open, laparoscopic and robotic. Looking for a new gold standard?]." Actas Urol Esp **31**(4): 316-327.

126. Menon, M., A. Shrivastava, et al. (2002). "Laparoscopic and robot assisted radical prostatectomy: establishment of a structured program and preliminary analysis of outcomes." J Urol **168**(3): 945-949.

127. Menon, M., A. Tewari, et al. (2002). "Prospective comparison of radical retropubic prostatectomy and robot-assisted anatomic prostatectomy: the Vattikuti Urology Institute experience." Urology **60**(5): 864-868.

128. Mouraviev, V., I. Nosnik, et al. (2007). "Financial comparative analysis of minimally invasive surgery to open surgery for localized prostate cancer: a single-institution experience." Urology **69**(2): 311-314.

129. Munver, R., I. A. Volfson, et al. (2007). "Transition from open to robotic-assisted radical prostatectomy: 7 years experience at Hackensack University Medical Center." Journal of Robotic Surgery **1**(2): 155-159.

130. Nadler, R. B., J. T. Casey, et al. (2009). "Is the transition from open to robotic prostatectomy fair to your patients? A single-surgeon comparison with 2-year follow-up." Journal of Robotic Surgery: 1-7.

131. Orvieto, M. A. and V. R. Patel (2009). "Evolution of robot-assisted radical prostatectomy." Scandinavian Journal of Surgery **98**(2): 76-88.

132. Ou, Y. C., C. R. Yang, et al. (2009). "Comparison of Robotic-assisted versus Retropubic Radical Prostatectomy Performed by a Single Surgeon." Anticancer research **29**(5): 1637-1642.

133. Pow-Sang, J. M., J. Velasquez, et al. (2007). "Pure laparoscopic and robotic-assisted laparoscopic radical prostatectomy in the management of prostate cancer." Cancer Control **14**(3): 250-257.

134. Tewari, A., A. Srivasatava, et al. (2003). "A prospective comparison of radical retropubic and robot-assisted prostatectomy: experience in one institution." BJU Int **92**(3): 205-210.

135. Webb, D. R., K. Sethi, et al. (2009). "An analysis of the causes of bladder neck contracture after open and robot-assisted laparoscopic radical prostatectomy." BJU International **103**(7): 957-963.

136. Hu, J. C., R. A. Nelson, et al. (2006). "Perioperative complications of laparoscopic and robotic assisted laparoscopic radical prostatectomy." J Urol **175**(2): 541-546; discussion 546.

137. Hu, J. C., Q. Wang, et al. (2008). "Utilization and outcomes of minimally invasive radical prostatectomy." J Clin Oncol **26**(14): 2278-2284.

138. Jae, W. C., H. K. Tae, et al. (2009). "Laparoscopic radical prostatectomy versus robot-assisted laparoscopic radical prostatectomy: A single surgeon's experience." Korean Journal of Urology **50**(12): 1198-1202.

Nephrectomy/Partial – Additional Comparative Papers:

87. Kandaswamy, R. (2006). "Laparoscopic donor nephrectomy (ldn): robotic-assisted (raldn) vs pure (pldn) vs hand-assisted (haldn)." Transplantation **82**(1 Suppl 2): 796-797.
88. Heuer, R., I. S. Gill, et al. (2009). "A Critical Analysis of the Actual Role of Minimally Invasive Surgery and Active Surveillance for Kidney Cancer." Eur Urol.
89. Jeong, W., S. Y. Park, et al. (2009). "Laparoscopic partial nephrectomy versus robot-assisted laparoscopic partial nephrectomy." Journal of Endourology **23**(9): 1457-1460.
90. Wang (2009). "Robotic Partial Nephrectomy Versus Laparoscopic Partial Nephrectomy for Renal Cell Carcinoma: Single-Surgeon Analysis of >100 Consecutive Procedures." Urology **73**(2): 306-310.
91. DeLong, J. M., O. Shapiro, et al. (2010). "Comparison of laparoscopic versus robotic assisted partial nephrectomy: one surgeon's initial experience." Can J Urol **17**(3): 5207-5212.
92. Walz, J., S. Rybikowski, et al. (2010). "Role of robotic surgery in treatment of renal cancer." Intérêt de la robotique dans le traitement du cancer du rein: 1-6.
93. Anderson, J. E., J. Kellogg Parsons, et al. (2011). "Hospital costs and length of stay related to robot-assisted versus open radical and partial nephrectomy for kidney cancer in the USA." Journal of Robotic Surgery: 1-4.
94. Hyams, E., P. Pierorazio, et al. (2011). "A Comparative Cost Analysis of Robotic-Assisted vs. Traditional Laparoscopic Partial Nephrectomy." Journal of Endourology.

95. Lavery, H. J., A. C. Small, et al. (2011). "Transition from laparoscopic to robotic partial nephrectomy: The learning curve for an experienced laparoscopic surgeon." Journal of the Society of Laparoendoscopic Surgeons **15**(3): 291-297.
96. Lendvay, T. S. (2011). "EARLY COMPARISON OF NEPHRECTOMY OPTIONS IN CHILDREN (OPEN, TRANSPERITONEAL LAPAROSCOPIC, LAPARO-ENDOSCOPIC SINGLE SITE (LESS), AND ROBOTIC SURGERY)." BJU International.
97. Masson-Lecomte, A., D. R. Yates, et al. (2011). "A prospective comparison of the pathologic and surgical outcomes obtained after elective treatment of renal cell carcinoma by open or robot-assisted partial nephrectomy." Urol Oncol.
98. Pierorazio, P. M., H. D. Patel, et al. (2011). "Robotic-assisted Versus Traditional Laparoscopic Partial Nephrectomy: Comparison of Outcomes and Evaluation of Learning Curve." Urology.
99. Seo, I. Y., H. Choi, et al. (2011). "Operative outcomes of robotic partial nephrectomy: A comparison with conventional laparoscopic partial nephrectomy." Korean Journal of Urology **52**(4): 279-283.
100. Sprenkle, P. C., N. Power, et al. (2011). "Comparison of Open and Minimally Invasive Partial Nephrectomy for Renal Tumors 4-7 Centimeters." European Urology.
101. White, M. A., R. Autorino, et al. (2011). "Robotic Laparoendoscopic Single-Site Radical Nephrectomy: Surgical Technique and Comparative Outcomes." European Urology.
102. Williams, S. B., R. Kacker, et al. (2011). "Robotic partial nephrectomy versus laparoscopic partial nephrectomy: a single laparoscopic trained surgeon's experience in the development of a robotic partial nephrectomy program." World Journal of Urology.
103. Guillotreau, J., G. P. Haber, et al. (2012). "Robotic Partial Nephrectomy Versus Laparoscopic Cryoablation for the Small Renal Mass." European Urology.

Pyleoplasty Additional Comparative Papers:

92. Lee, R. S., A. B. Retik, et al. (2006). "Pediatric robot assisted laparoscopic dismembered pyeloplasty: comparison with a cohort of open surgery." J Urol **175**(2): 683-687; discussion 687.
93. Yee, D. S., A. M. Shanberg, et al. (2006). "Initial comparison of robotic-assisted laparoscopic versus open pyeloplasty in children." Urology **67**(3): 599-602.
94. Hemal, A. K., S. Mukherjee, et al. (2010). "Laparoscopic pyeloplasty versus robotic pyeloplasty for ureteropelvic junction obstruction: a series of 60 cases performed by a single surgeon." Can J Urol **17**(1): 5012-5016.
95. Garcia-Galisteo, E., E. Emmanuel-Tejero, et al. (2011). "Comparison of the Operation Time and Complications between Conventional and Robotic-Assisted Laparoscopic Pyeloplasty." Actas Urologicas Espanolas.
96. Lucas, S. M., C. P. Sundaram, et al. (2012). "Factors That Impact the Outcome of Minimally Invasive Pyeloplasty: Results of the Multi-Institutional Laparoscopic and Robotic Pyeloplasty Collaborative Group." Journal of Urology.

Cystectomy: Additional Comparative Papers:

112. Atallah, M. M., & Othman, M. M. (2009). Robotic laparoscopic radical cystectomy inhalational versus total intravenous anesthesia: A pilot study. [2a]. *Middle East Journal of Anesthesiology, 20*(2), 257-264.

113. Chade, D. C., Laudone, V. P., Bochner, B. H., & Parra, R. O. (2010). Oncological Outcomes After Radical Cystectomy for Bladder Cancer: Open Versus Minimally Invasive Approaches. [Si]. [2b]. *Journal of Urology*. doi: S0022-5347(09)02908-5 [pii10.1016/j.juro.2009.11.019 [doi]

114. Challacombe, B. J., Bochner, B. H., Dasgupta, P., Gill, I., Guru, K., Herr, H., . . . Wiklund, P. (2011). The Role of Laparoscopic and Robotic Cystectomy in the Management of Muscle-Invasive Bladder Cancer With Special Emphasis on Cancer Control and Complications. [2b]. European Urology. doi: 10.1016/j.eururo.2011.05.012

115. Davis, J. W., Gaston, K., Anderson, R., Dinney, C. P. N., Grossman, H. B., Munsell, M. F., & Kamat, A. M. (2010). Robot Assisted Extended Pelvic Lymphadenectomy at Radical Cystectomy: Lymph Node Yield Compared With Second Look Open Dissection. [2b]. Journal of Urology.

116. Guru, K. A., Wilding, G. E., Piacente, P., Thompson, J., Deng, W., Kim, H. L., . . . O'Leary, K. (2007). Robot-assisted radical cystectomy versus open radical cystectomy: assessment of postoperative pain. [2b]. Can J Urol, 14(6), 3753-3756.

117. Kane, C. J. (2008). Robotic assisted laparoscopic radical cystoprostatectomy: Operative and pathologic outcomes Pruthi RS, Wallen EM, Division of Urologic Surgery, University of North Carolina at Chapel Hill, Chapel Hill, NC. [2b]. Urol Oncol, 26(2), 221-222. doi: S1078-1439(08)00009-4 [pii]
118. 10.1016/j.urolonc.2008.01.007 [doi]

119. Lee, R., Chughtai, B., Herman, M., Shariat, S. F., & Scherr, D. S. (2011). Cost-analysis comparison of robot-assisted laparoscopic radical cystectomy (RC) vs open RC. [2b]. BJU International, 108(6 B), 976-983. doi: 10.1111/j.1464-410X.2011.10468.x

120. Lee, R., Ng, C. K., Shariat, S. F., Borkina, A., Guimento, R., Brumit, K. F., & Scherr, D. S. (2011). The economics of robotic cystectomy: cost comparison of open versus robotic cystectomy. [2a]. BJU International. doi: 10.1111/j.1464-410X.2011.10114.x

121. Martin, A. D., Nunez, R. N., & Castle, E. P. (2011). Robot-assisted radical cystectomy versus open radical cystectomy: A complete cost analysis. [2a]. Urology, 77(3), 621-625.

122. Nepple, K. G., Strope, S. A., Grubb Iii, R. L., & Kibel, A. S. (2011). Early oncologic outcomes of robotic vs. open radical cystectomy for urothelial cancer. [2b]. Urologic Oncology: Seminars and Original Investigations. doi: 10.1016/j.urolonc.2011.06.009

123. Niegisch, G., Rabenalt, R., & Albers, P. (2011). [Robot-assisted radical cystectomy : Pilot study for the prospective evaluation of perioperative parameters compared to open radical cystectomy.]. [Si]. [2b]. *Urologe. Ausgabe A*. doi: 10.1007/s00120-011-2580-0

124. Palou Redorta, J., Gaya, J. M., Breda, A., Gausa, L., Rodríguez, O., & Villavicencio, H. (2010). Robotic Cystectomy Versus Open Cystectomy: Are We There Yet? [2b]. *European Urology, Supplements, 9*(3), 433-437.

125. Pruthi, R. S., & Wallen, E. M. (2007). Robotic Assisted Laparoscopic Radical Cystoprostatectomy: Operative and Pathological Outcomes. [2b]. *J Urol*.

126. Smith, A., Kurpad, R., Lal, A., Nielsen, M., Wallen, E. M., & Pruthi, R. S. (2010). Cost Analysis of Robotic Versus Open Radical Cystectomy for Bladder Cancer. [2b]. *Journal of Urology, 183*(2), 505-509.

127. Sung, H. H., Ahn, J. S., Seo, S. I., Jeon, S. S., Choi, H. Y., Lee, H. M., & Jeong, B. C. (2011). A Comparison of Early Complications Between Open and Robot-Assisted Radical Cystectomy. [2b]. *Journal of Endourology*. doi: 10.1089/end.2011.0372

Appendix C:
Additional Gynecological Publications for Consideration

Hysterectomy for Cancer Additional Comparative Papers – Not Cited in Washington HTA review

2008

128. DeNardis, S. A., R. W. Holloway, et al. (2008). "Robotically assisted laparoscopic hysterectomy versus total abdominal hysterectomy and lymphadenectomy for endometrial cancer." Gynecol Oncol **111**(3): 412-417.
129. 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 woman?" Gynecologic Oncology.
130. Ko, E. M., M. G. Muto, et al. (2008). "Robotic versus open radical hysterectomy: A comparative study at a single institution." Gynecologic Oncology **111**(3): 425-430.
131. Magrina, J. F., R. M. Kho, et al. (2008). "Robotic radical hysterectomy: comparison with laparoscopy and laparotomy." Gynecologic Oncology **109**(1): 86-91.
132. Magrina, J. F. and V. L. Zanagnolo (2008). "Robotic surgery for cervical cancer." Yonsei Med J **49**(6): 879-885.

2009

117. Cohn, D. E., L. G. Seamon, et al. (2009). "Comprehensive surgical staging for endometrial cancer in obese patients." Obstetrics and Gynecology **114**(1): 16-21.
118. Feuer, G., B. Benigno, et al. (2009). "Comparison of a novel surgical approach for radical hysterectomy: Robotic assistance versus open surgery." Journal of Robotic Surgery **3**(3): 179-186.
119. Lowe, M. P., A. V. Hoekstra, et al. (2009). "A comparison of robot-assisted and traditional radical hysterectomy for early-stage cervical cancer." Journal of Robotic Surgery: 1-5.
120. Maggioni, A., L. Minig, et al. (2009). "Robotic approach for cervical cancer: Comparison with laparotomy. A case control study." Gynecologic Oncology **115**(1): 60-64.

2010

125. Barnett, J. C., J. P. Judd, et al. (2010). "Cost comparison among robotic, laparoscopic, and open hysterectomy for endometrial cancer." Obstetrics and Gynecology **116**(3): 685-693.
126. Cardenas-Goicoechea, J., S. Adams, et al. (2010). "Surgical outcomes of robotic-assisted surgical staging for endometrial cancer are equivalent to traditional laparoscopic staging at a minimally invasive surgical center." Gynecol Oncol **117**(2): 224-228.
127. Göçmen, A., F. Şanlikan, et al. (2010). "Comparison of outcomes between laparotomy and robotic technique for cervical cancer." Journal of Robotic Surgery: 1-6.

128. Halliday, D., S. Lau, et al. (2010). "Robotic radical hysterectomy: comparison of outcomes and cost." Journal of Robotic Surgery: 1-6.
129. Jung, Y. W., D. W. Lee, et al. (2010). "Robot-assisted staging using three robotic arms for endometrial cancer: comparison to laparoscopy and laparotomy at a single institution." J Surg Oncol **101**(2): 116-121.
130. Nevadunsky, N., R. Clark, et al. (2010). "Comparison of robot-assisted total laparoscopic hysterectomy and total abdominal hysterectomy for treatment of endometrial cancer in obese and morbidly obese patients." Journal of Robotic Surgery: 1-6.
131. Schreuder, H. W. R., R. P. Zweemer, et al. (2010). From open radical hysterectomy to robot-assisted laparoscopic radical hysterectomy for early stage cervical cancer: aspects of a single institution learning curve. Gynecological Surgery**:** 1-6.
132. Zapardiel, I., V. Zanagnolo, et al. (2010). "Avoiding vaginal cuff dehiscence after robotic oncological surgery: reliable suturing technique." International Journal of Gynecological Cancer **20**(7): 1264-1267.

2011

145. Boruta, D. M., 2nd, W. B. Growdon, et al. (2011). "Evolution of surgical management of early-stage endometrial cancer." American Journal of Obstetrics and Gynecology.
146. ElSahwi, K. S., C. Hooper, et al. (2011). "Comparison between 155 cases of robotic vs. 150 cases of open surgical staging for endometrial cancer." Gynecologic Oncology.
147. Escobar, P. F., M. Frumovitz, et al. (2011). "Comparison of Single-Port Laparoscopy, Standard Laparoscopy, and Robotic Surgery in Patients with Endometrial Cancer." Annals of Surgical Oncology.
148. Espada, M., R. Muñoz, et al. (2011). "Minimally invasive approach to endometrial cancer: Robotics and laparoscopy." Current Women's Health Reviews **7**(4): 332-337.
149. Estape, R., N. Lambrou, et al. (2011). "Robotic-assisted total laparoscopic hysterectomy and staging for the treatment of endometrial cancer: a comparison with conventional laparoscopy and abdominal approaches." Journal of Robotic Surgery: 1-7.
150. Fleming, N. D., A. E. Axtell, et al. (2011). "Operative and anesthetic outcomes in endometrial cancer staging via three minimally invasive methods." Journal of Robotic Surgery: 1-8.
151. Frey, M. K., S. B. Ihnow, et al. (2011). "Minimally Invasive Staging of Endometrial Cancer Is Feasible and Safe in Elderly Women." Journal of Minimally Invasive Gynecology **18**(2): 200-204.
152. Goel, M., T. W. Zollinger, et al. (2011). "Surgical staging of endometrial cancer: robotic versus open technique outcomes in a contemporary single surgeon series." Journal of Robotic Surgery: 1-6.
153. Hong, D. G., Y. S. Lee, et al. (2011). "Robotic uterine artery preservation and nerve-Sparing radical trachelectomy with bilateral pelvic lymphadenectomy in early-Stage cervical cancer." International Journal of Gynecological Cancer **21**(2): 391-396.
154. Krizova, A., B. A. Clarke, et al. (2011). "Histologic artifacts in abdominal, vaginal, laparoscopic, and robotic hysterectomy specimens: a blinded, retrospective review." American Journal of Surgical Pathology **35**(1): 115-126.

155. Lèguevaque, P., S. Motton, et al. (2011). "Robotic surgery in gynecologic oncology." Gynecological Surgery: 1-9.
156. Magrina, J. F., V. Zanagnolo, et al. (2011). "Robotic approach for ovarian cancer: Perioperative and survival results and comparison with laparoscopy and laparotomy." Gynecologic Oncology **121**(1): 100-105.
157. Martino, M. A., J. Shubella, et al. (2011). "A cost analysis of postoperative management in endometrial cancer patients treated by robotics versus laparoscopic approach." Gynecologic Oncology.
158. Mendivil, A. A., M. A. Rettenmaier, et al. (2011). "Acute and delayed complications from surgery and adjuvant radiotherapy in the treatment of high-risk endometrial cancer." Oncology **81**(2): 79-83.
159. Nick, A. M., M. M. Frumovitz, et al. (2011). "Fertility sparing surgery for treatment of early-stage cervical cancer: Open vs. robotic radical trachelectomy." Gynecologic Oncology.
160. Nick, A. M., J. Lange, et al. (2011). "Rate of vaginal cuff separation following laparoscopic or robotic hysterectomy." Gynecologic Oncology **120**(1): 47-51.
161. Pilka, R., R. Marek, et al. (2011). "[Robot assisted laparoscopic staging of endometrial cancer--comparison with standard laparotomy]." Ceska Gynekologie **76**(6): 462-468.
162. Soliman, P. T., M. Frumovitz, et al. (2011). "Radical hysterectomy: A comparison of surgical approaches after adoption of robotic surgery in gynecologic oncology." Gynecologic Oncology.
163. Subramaniam, A., K. H. Kim, et al. (2011). "A cohort study evaluating robotic versus laparotomy surgical outcomes of obese women with endometrial carcinoma." Gynecologic Oncology.
164. Venkat, P., L. M. Chen, et al. (2011). "An economic analysis of robotic versus laparoscopic surgery for endometrial cancer: costs, charges and reimbursements to hospitals and professionals." Gynecologic Oncology.

2012

150. Dennis, T., C. De Mendona, et al. (2012). "Study of surplus cost of robotic assistance for radical hysterectomy, versus laparotomy and standard laparoscopy." Étude du surcoût de la cœlioscopie assistée par robot dans l'hystérectomie élargie **40**(2): 77-83.
151. Dennis, T., C. de Mendonca, et al. (2012). "[Study of surplus cost of robotic assistance for radical hysterectomy, versus laparotomy and standard laparoscopy.]." Gynecologie, Obstetrique et Fertilite.
152. Leitao, M. M., Jr., G. Briscoe, et al. (2012). "Introduction of a computer-based surgical platform in the surgical care of patients with newly diagnosed uterine cancer: Outcomes and impact on approach." Gynecologic Oncology.
153. Lu, D., Z. Liu, et al. (2012). "Robotic assisted surgery for gynaecological cancer." Cochrane Database of Systematic Reviews **1**: CD008640.
154. Wright, J. D., W. M. Burke, et al. (2012). "Comparative Effectiveness of Robotic Versus Laparoscopic Hysterectomy for Endometrial Cancer." Journal of Clinical Oncology.

Benign Hysterectomy Additional Comparative Papers – Not Cited in Washington HTA review

2009

152. Nezhat, C., O. Lavie, et al. (2009). "Laparoscopic hysterectomy with and without a robot: Stanford experience." JSLS : Journal of the Society of Laparoendoscopic Surgeons / Society of Laparoendoscopic Surgeons **13**(2): 125-128.
153. Rebeles, S. A., H. G. Muntz, et al. (2009). "Robot-assisted total laparoscopic hysterectomy in obese and morbidly obese women." Journal of Robotic Surgery **3**(3): 141-147.

2010

154. Brölmann, H. A. M., A. J. BijdeVaate, et al. (2010). "Hysterectomy or a minimal invasive alternative? A systematic review on quality of life and satisfaction." Gynecological Surgery: 1-6.
155. Matthews, C. A., N. Reid, et al. (2010). "Evaluation of the introduction of robotic technology on route of hysterectomy and complications in the first year of use." American Journal of Obstetrics and Gynecology **203**(5).

2011

163. Ceccaroni, M., R. Berretta, et al. (2011). "Vaginal cuff dehiscence after hysterectomy: A multicenter retrospective study." European Journal of Obstetrics Gynecology and Reproductive Biology **158**(2): 308-313.
164. Dauterive, E. and G. Morris Iv (2011). "Incidence and characteristics of vaginal cuff dehiscence in robotic-assisted and traditional total laparoscopic hysterectomy." Journal of Robotic Surgery: 1-6.
165. Kilic, G. S., G. Moore, et al. (2011). "Comparison of Perioperative Outcomes of Total Laparoscopic and Robotically Assisted Hysterectomy for Benign Pathology during Introduction of a Robotic Program." Obstet Gynecol Int **2011**: 683703.
166. Krizova, A., B. A. Clarke, et al. (2011). "Histologic artifacts in abdominal, vaginal, laparoscopic, and robotic hysterectomy specimens: a blinded, retrospective review." American Journal of Surgical Pathology **35**(1): 115-126.
167. Landeen, L. B., M. C. Bell, et al. (2011). "Clinical and cost comparisons for hysterectomy via abdominal, standard laparoscopic, vaginal and robot-assisted approaches." South Dakota Medicine **64**(6): 197-199, 201, 203 passim.
168. Nick, A. M., J. Lange, et al. (2011). "Rate of vaginal cuff separation following laparoscopic or robotic hysterectomy." Gynecologic Oncology **120**(1): 47-51.
169. Sarlos, D. and L. A. Kots (2011). "Robotic versus laparoscopic hysterectomy: A review of recent comparative studies." Current Opinion in Obstetrics and Gynecology.

170. Scandola, M., L. Grespan, et al. (2011). "Robot-Assisted Laparoscopic Hysterectomy vs Traditional Laparoscopic Hysterectomy: Five Metaanalyses." Journal of Minimally Invasive Gynecology **18**(6): 705-715.
171. Shultz, T. M. (2011). "Preemptive multimodal analgesia facilitates same-day discharge following robot-assisted hysterectomy." Journal of Robotic Surgery: 1-9.

2012

168. Davenport, W. B., M. P. Lowe, et al. (2012). "Outcomes of obese versus non-obese subjects undergoing robotic-assisted hysterectomy: a multi-institutional study." Journal of Robotic Surgery: 1-6.

Myomectomy Additional Comparative Papers – Not Cited in Washington HTA review

2009

169. Nezhat, C., O. Lavie, et al. (2009). "Robotic-assisted laparoscopic myomectomy compared with standard laparoscopic myomectomy--a retrospective matched control study." Fertil Steril **91**(2): 556-559.

2011

170. Behera, M. A., C. E. Likes, 3rd, et al. (2011). "Cost Analysis of Abdominal, Laparoscopic, and Robotic-Assisted Myomectomies." Journal of Minimally Invasive Gynecology.
171. Nash, K., J. Feinglass, et al. (2011). "Robotic-assisted laparoscopic myomectomy versus abdominal myomectomy: a comparative analysis of surgical outcomes and costs." Archives of Gynecology and Obstetrics.

Sacrocolpopexy Additional Comparative Papers – Not Cited in Washington HTA review

2011

172. Tan-Kim, J., S. A. Menefee, et al. (2011). "Robotic-assisted and laparoscopic sacrocolpopexy: Comparing operative times, costs and outcomes." Female Pelvic Medicine and Reconstructive Surgery **17**(1): 44-49.