Washington State Health Care Authority, HTA Program
FINAL Key Questions and Background
Robotic Assisted Surgery

Introduction

Robotic assisted surgery was selected for review by the HTA program. Robotic assisted surgery involves use of a computerized system operated by a surgeon at a computer console connected with robotic arms. The system is used to assist in laparoscopic surgical procedures. Robotic assisted surgery may allow for finer more precise control of the instruments by the surgeon, though surgery may take longer. Laparoscopic surgery may be associated with improved postsurgical pain and recovery and with lower risk of infection and blood loss for some procedures compared with open surgery.

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: Hospital length of stay, health care resource utilization, recovery of activities of daily living, quality of life, overall mortality, disease specific mortality or survival, cancer recurrence, adverse events (e.g. morbidity, mortality, reoperation, complication rates, increased bleeding), healing time, cost, cost effectiveness

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.

KQ 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.

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. Other patient characteristics or evidence based patient selection 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

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

Public comment and Response

HTA received 3 public comments; 1 comment included evidence. The comments and evidence were forwarded to the technology assessment center for consideration and were reviewed by HTA program staff and nominating agencies. Detailed response below:

Number	Cited Evidence	Public Comment	Response
1	No	"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. **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?	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 KQ1. KQ 3 is modified to include experience and setting.

		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.	
2	No	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: o The data should compare robot to open *and* traditional minimally invasive procedures versus one *or* the other; o That the evidence asked for is segmented by procedure, as the outcomes can greatly vary based on the type of surgery performed; and o A broad term such as "traditionally minimally invasive" would be a more inclusive and appropriate terminology. **KQ1:** What is the procedure and indication (e.g. benign vs. malignant disease) specific evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open ~~or~~ AND traditionally minimally invasive, i.e., laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes compared to open AND laparoscopic procedures? Include consideration of short and long-term outcomes including complete cancer eradication, reduced hospital stay, and reduced anesthesia use. **KQ2:** For robotic assisted surgery, what is the procedure and indication specific evidence of the severity and incidence of safety or adverse event concerns compared with open	No changes to context, PICO sections, KQs. The report will be organized by procedure. No changes to KQs to affect "or"/"and". Will not impact the meaning. Terminology change (e.g., traditionally minimally invasive) will not affect report evidence base.

		~~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.	
3	Yes	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. o 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	All references forwarded to TAC. These studies provide evidence. No changes to KQs The report will describe all cost perspectives and model assumptions as described by the identified evidence.

		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: o (1). Publication from the Mayo Clinic in Urology (Urology Oct. 2011; 78(4), pages 827-31. Epub 2011 July 29) o (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). o (3). Article published in the Journal of Urology in 2009 (J Urol 2009 Sept; 182(3), pages 866-72. Epub 2009 July 17). o (4). National Inpatient Sample was published in European Urology (Eur Urology: 2011 Dec. 22)	

For additional information on key questions and public comments

Washington State Health Care Authority
Health Technology Assessment

Robotic Assisted Surgery

Clinical Expert

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Oregon Health & Science University
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3303 SW Bond Street, CH10U
Portland, OR 97239

CURRICULUM VITAE
OREGON HEALTH & SCIENCE UNIVERSITY

NAME **Jeffrey C. La Rochelle, M.D.**

PRESENT POSITION AND ADDRESS

Academic Rank:	Assistant Professor
Department/Division:	Department of Surgery, Division of Urology
Professional Address:	3303 SW Bond Street, CH10U, Portland, OR 97239
E-Mail Address:	larochel@ohsu.edu

II. EDUCATION

Undergraduate and Graduate (Include Year, Degree, and Institution):

1993	Indiana University, Bloomington, Indiana – Bachelor of Science, Finance
1995 - 1998	Northwestern University, Evanston, IL – Post-Baccalaureate Program
1998 - 2002	Rush Medical College, Chicago, IL – Medical Doctorate

Postgraduate (Include Year, Degree, and Institution):

7/2002 – 6/2007	Rush University Medical Center, Chicago, IL – Residency in Urology
7/2007 – 6/2009	University of California, Los Angeles – Fellowship in Urologic Oncology

Publications/Creative Work:

1. La Rochelle J, Klatte T, Dastane A, Rao N, Seligson D, Said J, Shuch B, Zomorodian N, Kabbinavar F, Belldegrun A, Pantuck AJ. Chromosome 9p deletions identify an aggressive phenotype of clear cell renal cell carcinoma. Cancer 2010; epub 13 Jul 2010.
2. La Rochelle JC, Shuch B, Riggs S, Liang LJ, Sadaat A, Kabbinavar F, Pantuck A, Belldegrun AB. Functional and oncologic outcomes of partial nephrectomy in solitary kidneys. J Urol 2009; 181: 2037-43.
3. La Rochelle J, Kamat A, Grossman HB, Pantuck AJ. Chemoprevention of bladder cancer. BJU Int 2008; 102 : 1274-8.
4. La Rochelle J, Amling CL. Prostate cancer screening: what we have learned from the PLCO and ERSCP trials. Curr Urol Reports 2010: 11: 198-201.
5. La Rochelle JC, Coogan CL. Urologic manifestations of sarcoidosis. AUA Update series 2008; 27 (14).
6. Shuch B, Said J, La Rochelle JC, Zhou Y, Li G, Puoliot F, Kabbinavar FF, Belldegrun AS, Pantuck AJ. Histologic evaluation of metastases in renal cell carcinoma with sarcomatoid transformation and its implications for systemic therapy. Cancer 2009; Dec.
7. Shuch B, Said J, La Rochelle JC, Zhou Y, Li G, Klatte T, Kabbinavar FF, Pantuck AJ, Belldegrun AS. Cytoreductive nephrectomy for kidney cancer with sarcomatoid histology- is up front resection indicated and, if not, is it avoidable? J Urol 2009; 182: 2164-71.
8. Shuch B, La Rochelle JC, Klatte T, Riggs SB, Liu W, Kabbinavar FF, Pantuck AJ, Belldegrun AS. Brain metastasis from renal cell carcinoma: presentation, recurrence, and survival. Cancer 2008; 113 : 1641-8.
9. de Martino M, Klatte T, Seligson DB, La Rochelle J, Shuch B, Caliliw R, Li Z, Kabbinavar FF, Pantuck AJ, Belldegrun AS. CA9 gene: single nucleotide polymorphism predicts metastatic renal cell carcinoma prognosis. J Urol 2009; 182: 728-34.

10. Klatte T, Rao N, de Martino M, La Rochelle JC, Shuch B, Zomorodian N, Said J, Kabbinavar F, Belldegrun A, Pantuck A. Cytogenetic profile predicts prognosis of patients with clear cell renal cell carcinoma. J Clin Oncol 2009; 27 : 746-53.
11. Shuch B, La Rochelle J, Onyia T, Vallera C, Margulis D, Pantuck AJ, Smith RB, Belldegrun. Intraoperative thrombus embolization during nephrectomy and tumor thrombectomy : critical analysis of the University of California- Los Angeles experience. J Urol 2009; 181: 492-8.
12. Belldegrun AS, Klatte T, Shuch B, La Rochelle JC, Miller DC, Said JW, Riggs SB, Zomorodian N, Kabbinavar FF, deKernion JB, Pantuck AJ. Cancr-specific survival outcomes among patients treated during the cytokine era of kidney cancer (1989-2005): a benchmark for emerging targeted cancer therapies. Cancer 2008; 113: 2457-63.
13. Shuch B, Riggs SB, La Rochelle JC, Kabbinavar FF, Akavian R, Pantuck AJ, Patard JJ, Belldegrun AS. Neoadjuvant targeted therapy and advanced kidney cancer: observations and implications for a new treatment paradigm. BJU Int 2008 ; 102: 692-96.
14. Shuch B, La Rochelle JC, Pantuck AJ, Belldegrun AS. The staging of renal cell carcinoma. Curr Opin Urol 2008; 18: 455-61.
15. Shuch B, La Rochelle JC, Wu J, Klatte T, Riggs SB, Kabbinavar F, Belldegrun AS, Pantuck AJ. Performance status and cytoreductive nephrectomy: Redefining management in patients with poor performance. Cancer 2008; 113: 1324-31. .
16. La Rochelle JC, Levine LA. A survey of primary-care physicians and urologists regarding Peyronie's disease. *J Sex Med*, 2007; 4: 1167-73.
17. Latchamsetty KC, La Rochelle J, Hoeksema J, Coogan CL. Is routine postoperative chest radiography needed after open nephrectomy? Urology 2005; 65: 256-9.

Chapters

1. La Rochelle JC, Shuch B, Belldegrun AB. "Urologic Surgery" in Schwartz Principles of Surgery, 9th ed. Brunicardi, Ed. McGraw Hill. (Sched for pub 2009).
2. Pouliot F, La Rochelle J, Pantuck AJ. "Renal cell carcinoma" in Evidence-Based Urology. Dahm, ed. (Sched for publication 2009)
3. La Rochelle JC, Levine LA. "Evaluation of Patients with Erectile Dysfunction" in Male Sexual Function: A Guide to Clinical Management, 2nd edition. J. Mulcahy, Ed. 2006, Humana Press, Totowa, NJ.
4. La Rochelle J, Levine LA. "Complications of Benign Adult Penile and Scrotal Surgery" in Complications in Urologic Surgery. K Loughlin, Ed. 2007, Informa Healthcare, London.

Invited Lectures, Conference Presentations or Professorships:

International and National

1. La Rochelle JC, Riggs S, Shuch B, Reiter R, deKernion J. Predictive value of an undetectable ultrasensitive PSA after radical prostatectomy. Poster presented at the Society of Urologic Oncology annual meeting, Bethesda, 2008.
2. Klatte T, Said JW, Seligson DB, La Rochelle J, Shuch B, Kabbinavar FF, Zisman A, Pantuck AJ, Belldegrun AB. Molecular prognostic tumor profiling of type 1 and 2 papillary renal cell carcinoma : relevance to the development of tumor-specific targeted therapies. Poster presented at American Urological Association annual meeting, May 2008, Orlando, FL,
3. Jaeger E, Waldman F, Royadasgupta R, Klatte T, McDermott D, Signoretti S, Atkins M, La Rochelle J, Belldegrun AB, Pantuck AJ. Array-based genomic hybridization (CGH) identifies chromosomal imbalances between interleukin-2 complete and non-responders. Poster presentation at the American Society of Clinical Oncologists annual meeting, June 2008, Chicago, IL.

4. La Rochelle J, Coogan CL, Gattuso P, Gould V, Bostwick D. "Demonstrability of the Epstein-Barr Virus in Prostatic Carcinoma." Poster presented at the ASCO/SUO Multidisciplinary Prostate Cancer Symposium, Feb, 2005, Orlando, FL and at North Central Section of the AUA annual meeting, Sept 2005, Chicago, IL.
5. La Rochelle J, Levine LA. "A Survey of Primary Care Physicians and Urologists About Peyronie's Disease." Podium presentation at the American Urological Association annual meeting, May 2005, San Antonio, TX.

Regional and Local

1. La Rochelle JC, Shuch B, Liang LJ, Riggs S, Pantuck A, Belldegrun. Partial nephrectomy in solitary kidneys. Poster presentation at AUA annual meeting, Chicago 2009. Podium pesentation at the Western Section of the AUA annual meeting, Monterey, 2008.
2. La Rochelle JC, Dastane A, Shuch B, Belldegrun A, Pantuck A. 9p chromosomal deletions in clear cell renal cell carcinoma. Poster presentation at ASCO annual metting, Orlando 2009. Podium presentation at the Western Section of the AUA annual meeting, Monterey, 2008 and poster presentation at ASCO 2009.
3. "Primary adenocarcinoma of the bladder." Irving J. Shapiro Radiology Conference of the Chicago Urologic Association; April 2005.
4. "Adrenal carcinoma in a young girl." Irving J. Shapiro Radiology Conference of the Chicago Urologic Association; April 2004.

V. SERVICE

Membership in Professional Societies:
American Urological Association
American Society of Clinical Oncology
Northwest Urological Association

VI. TEACHING

Honors and Awards for Education
Alpha Omega Alpha, 2001
Rush University Medical Center Surgical Intern of the Year, 2002-2003

Washington State
Health Care Authority

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000		X
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status of position as an officer, board member, trustee, owner		X
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

_____

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	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

7. If yes, Provide Name and Funding Sources: _____

_____

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	Potential Conflict Type	Yes	No
8.	Travel: if an organization or company has financially paid your travel accommodations (e.g. airfare, hotel, meals, private vehicle mileage, etc).		X

8. If yes, Provide Name of Organization / Company and Disclose Travel Accommodations:

_____

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Washington State
Health Care Authority

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may ***attach additional sheets*** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 5/3/12 Jeffrey La Rochelle

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

Washington State Health Care Authority

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000	✓	
2.	Equity interests such as stocks, stock options or other ownership interests		✓
3.	Status or position as an officer, board member, trustee, owner		✓
4.	Loan or intellectual property rights		✓
5.	Research funding		✓
6.	Any other relationship, including travel arrangements		✓

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

I have been Retained by Intuitive Surgical as a Health Policy Consultant since 2004. My travel to attend the May 18, 2012 meeting was been arranged by Intuitive Surgical.

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).	✓	

7. If yes, Provide Name and Funding Sources: I am Representing Intuitive Surgical as its U.S. Health Policy consultant.

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may ***attach additional sheets*** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X Kathryn Barry 5/1/12 KATHRYN BARRY

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742, PO Box 42712, Olympia, WA 98504-2712

LAPAROSCOPIC SURGERY
completed with robotic-assistance

Kathryn Barry, MPH, MSN, RN

- Disclosure: Health Policy Consultant to Intuitive Surgical since 2004.
- Purpose: To share decisions from AMA, CMS & leading payers:
  - Explain rationale for Level I CPT & ICD-9-CM coding considerations.
  - Summarize plethora of robotic-assisted coverage decisions.
  - Defer facility reimbursement to payer mix & contract terms.
- Established conclusions:
  - Per AMA, primary surgical procedure is a LAPAROSCOPIC procedure.
  - Per leading payers, robotic-assistance is integral to the base procedure.
  - Coding, coverage & reimbursement should be consistent with a payer's established laparoscopic policies & procedures.

Kathryn Barry & Associates LLC
Medical Device Reimbursement Consultants

CODING DECISIONS

- AMA: Convened a Robotics Work Group in 2005
  - Professional Societies included AUA, ACOG & AAGL.
  - Surveys determined surgeon time, risk & skill comparable to established laparoscopic CPT code relative values.
  - Surgical outcome remains a laparoscopic procedure.
  - June 2007, "Robotic assistance does not require a new code or unique modifier".
- Recent CPT Editorial Revision, effective January 1, 2011:
  - CPT 55866: Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, *includes robotic assistance*, when performed.

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CODING DECISIONS

- CMS: ICD-9-CM Procedure Codes, effective October 1, 2008:
  - Use routine & customary code for primary procedure
  - 17.4X Robotic assisted procedures
  - 17.42 Laparoscopic robotic-assisted procedure
- Local Carrier Code, S2900
  - Issued in 2004 by a local BCBS-plan in upstate NY.
  - Issued prior to AMA Robotics Work Group 2007 decision.
  - Since 2007, leading payers consider S2900 non-payable.
  - Hospital may use it for internal OUTPATIENT tracking purposes.

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COVERAGE

ROBOTIC ASSISTED SURGERY policies:	
BC – Idaho	Health Plan of Nevada
BCBS – Delaware	Humana
BCBS – Florida	Independence BC
BCBS – Kansas	MEDICA
BCBS-Kansas City	Medicare Advantage – Highmark
BCBS-IL	Medicare Advantage – United Healthcare
BCBS-Texas	Priority Health
CareFirst BCBS	Oxford Health Plan
CIGNA	Regence
HealthNet	United Healthcare
	WPS
"Robotic-assisted surgery is considered integral to the primary procedure and not separately reimbursable. Payment will be based on the reimbursement for the standard surgical procedure. Any additional charges for the robotic assisted surgery will be bundled into the standard surgical procedure".	

CONCLUSIONS

- For appropriately selected patients, the medical necessity of surgery is based upon the need for performing a laparoscopic procedure, coded with existing laparoscopic CPT codes & reimbursed as a laparoscopic procedure.
- Facility Reimbursement:
  - Depends upon the payer & specific contract terms.
  - This is left to the sole discretion of the facility & payer.
  - Variances arise from complexity of hospital contracting terms:
    - "Percent of Charges" versus Surgical Case Rate.
    - "Per Diem" versus Surgical Case Rate.
  - Perhaps a contracting correction is needed in Washington?

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(203) 271-3366

Kathryn Barry & Associates LLC
Medical Device Reimbursement Consultants

Washington State Health Care Authority

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000		X
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status or position as an officer, board member, trustee, owner		X
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6.	Any other relationship, including travel arrangements		X

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	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

7. If yes, Provide Name and Funding Sources: _____

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I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X Douglas E. Sutherland, MD 5/8/2012 Douglas Edward Sutherland, MD

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

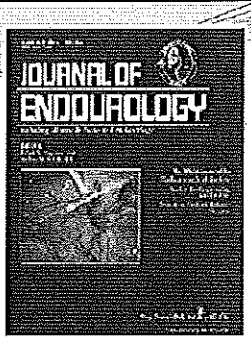
Surgical Complications and Comparison Between Open and Robotic Urologic Surgery

Douglas E. Sutherland, MD

May 8, 2012

Robotic Prostatectomy

Clavien Grade	N	%
I	56	48.3
II	27	23.3
IIIa	15	12.9
IIIb	13	11.2
IVa	5	4.3
IVb	0	0
V	0	0
	116	100



Ref	Method	Year	N	Complication rate (%)	Reoperation rate bleeding (%)	Transfusio n rate (%)	Bowel injury rate (%)
Catalona	Open	1999	1870	10.5	0	NA	0.05
Lepor	Open	2001	1000	6.5	0.2	9.7	0.5
Coelho	Robotic	2010	2500	5.1	0.08	0.48	0.08
Agarwal	Robotic	2011	3317	9.8	0.42	1.7	0.27
Ahmed	Robotic	2011	1000	9.7	0.4	1.5	0.5

Ahmed R, Rhee J, Sutherland D, et al. J Endourol 2012; 26(2): 135.

Hospital Volume, Utilization, Costs and Outcomes of Robot-Assisted Laparoscopic Radical Prostatectomy

THE JOURNAL of UROLOGY®

Hua-yin Yu, Nathanael D. Hevelone, Stuart R. Lipsitz, Keith J. Kowalczyk, Paul L. Nguyen and Jim C. Hu*

Table 2. *Propensity adjusted outcomes*

		Hospital RALP Volume Quartile				
	Overall	Low	Medium	High	Very High	p Value
% Complications*						
Cardiac	0.7	0.8	0.7	0.5	0.8	0.68
Respiratory	1.2	1.3	1.1	0.9	1.3	0.90
Genitourinary	1.1	1.8	0.7	1.0	0.9	0.20
Wound	0.2			Data suppressed*		0.80
Vascular	0.2			Data suppressed*		0.21
Miscellaneous	5.2	7.5	5.3	3.7	3.4	0.01
Miscellaneous medical	1.9	3.1	1.3	1.6	1.4	0.26
Any surgical	8.6	11.2	7.6	6.7	6.9	<0.01
% Blood transfusion	1.5	2.4	2.3	1.0	0.7	0.09
% Routine discharge home	94.9	93.5	94.5	96.5	94.2	<0.01
Mean ± SE LOS (days)	1.7 ± 3.0	1.9 ± 4.8	1.6 ± 2.3	1.6 ± 2.0	1.6 ± 3.3	<0.01
Median $ costs (IQR)	11,978 (9,315–13,860)	12,754 (10,284–17,356)	10,378 (8,553–12,714)	10,787 (8,543–13,543)	8,378 (7,324–11,538)	<0.01

* Data suppressed according to NIS for 0 or fewer than 11.

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Comparative Effectiveness of Minimally Invasive vs Open Radical Prostatectomy

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JAMA®

Table 2. Unadjusted Outcomes by Surgical Approach

	MIRP	RRP	*P* Value
Length of stay, median (IQR)	2 (1–2)	3 (2–4)	<.001
Heterologous blood transfusion, No. (%)	79 (2.5)	1583 (20.1)	<.001
30-Day postoperative complications, No. (%)			
Overall	422 (21.9)	1606 (23.4)	.31
Cardiac	39 (2.0)	206 (3.0)	.03
Respiratory	60 (3.2)	455 (6.6)	<.001
Genitourinary	77 (4.0)	150 (2.2)	<.001
Wound	31 (1.6)	129 (1.9)	.41
Vascular	56 (2.9)	265 (3.9)	.08
Miscellaneous medical	181 (9.4)	598 (8.7)	.40
Miscellaneous surgical	91 (4.7)	397 (5.8)	.16
Death	2 (0.1)	12 (0.2)	.46
Anastomotic stricture, No. (%)[a]	99 (5.9)	916 (11.2)	<.001
Incontinence per 100 person-years[c]			
Diagnosis	10.2	11.9	<.001
Procedures	9.5	8.5	.30
Erectile dysfunction per 100 person-years[b]			
Diagnosis	33.8	18.2	<.001
Procedure	2.8	2.1	.04
Additional cancer therapy per 100 person-years			
Overall	6.1	6.9	.18
Radiation	4.3	4.9	.16
Hormone	3.5	3.7	.58
Death during the study period	0.7	0.9	.11

Abbreviations: IQR, interquartile range; MIRP, minimally invasive radical prostatectomy; RRP, open retropubic radical prostatectomy.
[a] Men who underwent surgery in 2007 were excluded because of insufficient follow-up to capture this outcome.
[b] Men who underwent surgery in the latter half of 2006 through the end of 2007 were excluded because of insufficient follow-up to capture this outcome.

Perioperative Outcomes of Robot-Assisted Radical Prostatectomy Compared With Open Radical Prostatectomy: Results From the Nationwide Inpatient Sample

Table 4 – Propensity score–matched intraoperative and postoperative outcomes during hospitalization stratified by open or robotic surgery

	Open, n = 7389	Robotic, n = 7598	Robotic vs open, odds ratio (95% CI)	p value
Homologous blood transfusion, n (%)	572 (7.7)	184 (2.4)	0.30 (0.25–0.35)	<0.001
Intraoperative complication, n (%)	73 (1.0)	33 (0.4)	0.44 (0.29–0.66)	<0.001
Postoperative complication* n (%)				
Overall	823 (11.1)	705 (9.3)	0.82 (0.73–0.91)	<0.001
Cardiac	98 (1.3)	68 (0.9)	0.69 (0.5–0.94)	0.018
Respiratory	191 (2.6)	103 (1.4)	0.53 (0.42–0.67)	<0.001
Vascular	45 (0.6)	30 (0.4)	0.65 (0.41–1.03)	0.065
Operative wound	48 (0.6)	35 (0.5)	0.71 (0.46–1.1)	0.121
Genitourinary	86 (1.2)	90 (1.2)	1.02 (0.76–1.37)	0.907
Miscellaneous medical	459 (6.2)	432 (5.7)	0.91 (0.79–1.04)	0.173
Miscellaneous surgical	121 (1.6)	122 (1.6)	0.98 (0.76–1.26)	0.877
Length of stay >2 d, n (%)	2923 (39.5)	1105 (14.5)	0.26 (0.24–0.28)	<0.001
In-hospital mortality, n (%)	6 (0.1)	1 (0.0)	0.16 (0.02–1.35)	0.092

CI = confidence interval.
* Rates of complication are not additive, as patients may have had multiple complications.

Trinh et al. Eur Urol. 2012; 61:679.

Perioperative Outcomes of Robot-Assisted Radical Prostatectomy Compared With Open Radical Prostatectomy: Results From the Nationwide Inpatient Sample

Table 3 – Multivariable analyses of propensity score–matched intraoperative and postoperative outcomes, adjusted for age, race, Charlson comorbidity index, hospital region, hospital location, hospital academic status, annual hospital caseload, pelvic lymphadenectomy (yes vs no), and insurance status

	Robotic vs open, odds ratio (95% CI)	p value
Homologous blood transfusion	0.34 (0.28–0.4)	<0.001
Intraoperative complication	0.47 (0.31–0.71)	<0.001
Postoperative complication		
Overall	0.86 (0.77–0.96)	0.007
Cardiac	0.73 (0.53–0.99)	0.037
Respiratory	0.54 (0.42–0.69)	<0.001
Vascular	0.59 (0.37–0.95)	0.029
Operative wound	0.74 (0.47–1.15)	0.183
Genitourinary	1.06 (0.78–1.45)	0.691
Miscellaneous medical	0.95 (0.83–1.09)	0.478
Miscellaneous surgical	1.07 (0.82–1.39)	0.605
Length of stay >2 d	0.28 (0.26–0.3)	<0.001
In-hospital mortality	0.21 (0.02–1.94)	0.168

CI = confidence interval.

Trinh et al. Eur Urol. 2012; 61:679.

Temporal National Trends of Minimally Invasive and Retropubic Radical Prostatectomy Outcomes from 2003 to 2007: Results from the 100% Medicare Sample

Keith J. Kowalczyk[a], Jesse M. Levy[b], Craig F. Caplan[b], Stuart R. Lipsitz[c], Hua-yin Yu[d], Xiangmei Gu[c], Jim C. Hu[c,d,]*

Table 4 – Comparison of overall complications of minimally invasive radical prostatectomy and retropubic radical prostatectomy from 2003 to 2007

	MIRP n = 19 594	RRP n = 55 638	p value
Mean length of stay, d, plus or minus standard deviation n (%)	2.0 ± 0.1	4.2 ± 0.1	<0.001
Any perioperative complication	3836 (19.6)	17 369 (29.8)	<0.001
Cardiac	431 (2.2)	2756 (4.7)	<0.001
Genitourinary	933 (4.8)	4068 (8.9)	<0.001
Miscellaneous medical	1721 (8.8)	7360 (12.6)	<0.001
Miscellaneous surgical	816 (4.2)	3498 (6.0)	<0.001
Respiratory	808 (4.1)	5535 (9.4)	<0.001
Vascular	520 (2.7)	2529 (4.3)	<0.001
Wound	349 (1.8)	2294 (3.9)	<0.001
Death	30 (0.2)	367 (0.6)	<0.001
Perioperative blood transfusion	502 (2.6)	10 135 (17.3)	<0.001
Cystography utilization	7194 (36.7)	6468 (11.6)	<0.001
	MIRP n = 11 108	**RRP n = 45 277**	**p value**
Late complications			
Anastomotic stricture	333 (3.0)	1225 (2.7)	<0.001
Ureteral complications	58 (0.5)	610 (1.3)	<0.001
Rectourethral fistula	33 (0.4)	159 (0.4)	0.999
Lymphocele	146 (1.3)	1003 (2.2)	<0.001
Surgical intervention for incontinence	30 (0.3)	132 (0.3)	0.734

MIRP = minimally invasive radical prostatectomy; RRP = retropubic radical prostatectomy.

Temporal National Trends of Minimally Invasive and Retropubic Radical Prostatectomy Outcomes from 2003 to 2007: Results from the 100% Medicare Sample

Keith J. Kowalczyk[a], Jesse M. Levy[b], Craig F. Caplan[b], Stuart R. Lipsitz[c], Hua-yin Yu[d], Xiangmei Cu[c], Jim C. Hu[c,d,]*

Table 5 – Multivariate model for perioperative mortality, perioperative complications, and late complications

	Perioperative mortality		Perioperative complications		Late complications	
Variable	Odds ratio (95% CI)	p value	Odds ratio (95% CI)	p value	Odds ratio (95% CI)	p value
Highest quintile HCC score	1.54 (1.38–1.71)	<0.001	1.67 (1.61–1.73)	<0.001	1.32 (1.26–1.39)	<0.001
Surgeon volume	1.00 (0.99–1.01)	0.897	0.99 (0.99–1.00)	0.075	0.99 (0.99–0.99)	0.043
Year (vs 2004)						
2005	0.61 (0.37–1.01)	0.054	1.02 (0.96–1.09)	0.491	1.01 (0.92–1.10)	0.765
2006	0.99 (0.65–1.53)	0.975	1.07 (1.00–1.14)	0.043	1.04 (0.95–1.14)	0.409
2007	0.83 (0.52–1.30)	0.408	1.05 (0.98–1.12)	0.185	–	–
RRP vs MRP	2.67 (1.55–4.59)	<0.001	1.60 (1.45–1.76)	<0.001	2.52 (2.20–2.89)	<0.001
Region (vs Northeast)						
Midwest	0.86 (0.50–1.46)	0.626	0.88 (0.69–1.00)	0.065	1.01 (0.87–1.18)	0.885
West	0.71 (0.30–1.59)	0.444	0.84 (0.71–1.00)	0.052	0.98 (0.77–1.26)	0.930
South	0.80 (0.48–1.35)	0.408	0.78 (0.68–0.88)	<0.001	1.05 (0.91–1.21)	0.459
Other	1.08 (0.44–2.66)	0.860	1.10 (0.91–1.33)	0.336	1.09 (0.83–1.42)	0.444
Age, yr (vs 65–69)						
70–74	2.04 (1.27–3.27)	0.003	1.15 (1.10–1.20)	<0.001	1.04 (0.97–1.13)	0.264
≥75	7.35 (4.74–11.36)	<0.001	2.47 (2.29–2.66)	<0.001	1.16 (1.04–1.30)	0.008

CI = confidence interval; HCC = Hierarchical Condition Category; RRP = retropubic radical prostatectomy; MRP = minimally invasive radical prostatectomy.
* Late complications from 31 to 365 d.

Robotic Cystectomy

Comparative Analysis of Outcomes and Costs Following Open Radical Cystectomy Versus Robot-Assisted Laparoscopic Radical Cystectomy: Results From the US Nationwide Inpatient Sample

Table 3 – Unadjusted and propensity-adjusted outcomes

	Unadjusted			Adjusted		
Primary outcomes	Open n = 7168	Robotic n = 1144	p value	Open	Robotic	p value
Categorical	No. (%)			%		
Deaths	170 (2.4)	0	<0.001	2.5	0	<0.001
Inpatient complications	4318 (60.2)	541 (47.3)	0.004	63.8	49.1	0.035
Blood transfusion	2966 (41.4)	351 (30.7)	0.075	37.9	32.0	0.448
Parenteral nutrition	906 (12.6)	82 (7.2)	0.025	13.3	6.4	0.046
Routine discharge	1924 (27.5)	342 (29.9)	0.726	23.2	19.4	0.099
Lymph node dissection	4954 (69.1)	987 (86.3)	<0.001	67.0	76.8	0.248
Continuous	Median (IQR)			Median (IQR)		
Length of stay, d	8 (7.6–8.2)	7 (6.6–7.4)	<0.001	8 (7.8–8.2)	8 (7.2–8.8)	0.999
Costs, $	24 607 (23 741–25 474)	30 563 (28 911–32 215)	<0.001	24 303 (23 265–25 341)	28 100 (25 015–31 185)	0.023
Secondary outcomes						
Categorical	No. (%)			%		
Complication subtype						
Cardiac	645 (9.0)	55 (4.8)	0.013	10.3	5.6	0.110
Respiratory	1282 (17.9)	144 (12.6)	0.067	18.4	15.2	0.421
Genitourinary	798 (11.1)	91 (8.0)	0.243	11.3	6.6	0.112
Wound	526 (7.3)	48 (4.2)	0.059	7.8	4.6	0.185
Vascular	258 (3.6)	31 (2.7)	0.636	3.6	1.8	0.316
Miscellaneous medical	3115 (43.5)	380 (33.3)	0.035	47.6	35.9	0.096
Miscellaneous surgical	739 (10.3)	69 (6.0)	0.043	10.3	6.7	0.217

IQR = interquartile range.

Yu H, et al. Eur Urol 2012; 61:1239.

Robotic Partial Nephrectomy

Comparative Effectiveness and Trends in Treatment of Small Renal Masses from 2005-2007. *Unpublished data.*

Kowalczyk, Choueiri, Hevelone, Lipsitz, Nguyen, Yu, Hu

Events per 100-person years	Ablation	MIPN	Open PN	MIRN	Open RN	P Value
	n = 211	n = 160	n = 330	n = 535	n = 404	
Overall Mortality	19.6	3.7	11.8	18.7	26.7	<0.001
Cancer-specific Mortality	0.0	0.0	0.6	3.4	4.7	<0.001
Renal insufficiency diagnosis	19.0	15.3	25.1	38.3	35.9	<0.001
Length of Stay, days	2.3 ± 2.5	3.7 ± 3.1	5.4 ± 4.3	3.9 ± 2.8	5.4 ± 3.6	<0.001
30-day postoperative complications (overall)	83 (39.7)	83 (51.6)	210 (65.4)	305 (57.0)	260 (64.0)	<0.001
Renal insufficiency 31-365 days post procedure	74 (35.3)	31 (19.3)	92 (28.7)	179 (33.5)	136 (33.5)	<0.001
Chronic Renal Failure	40 (19.0)	28 (17.5)	74 (23.0)	191 (35.6)	138 (33.9)	<0.001
Mean Total Cost ± Std Dev	$10,720 ± 14,997	$15,695 ± 11,564	$16,986 ± 16,258	$15,373 ± $13,117	$17,803 ± 15,217	<0.001

Washington State Health Care Authority

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000		X
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status or position as an officer, board member, trustee, owner		X
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

_____

_____

_____

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

7. If yes, Provide Name and Funding Sources: _____

_____

_____

_____

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may ***attach additional sheets*** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 5/8/12 Christie Shah

Signature *Date* *Print Name*

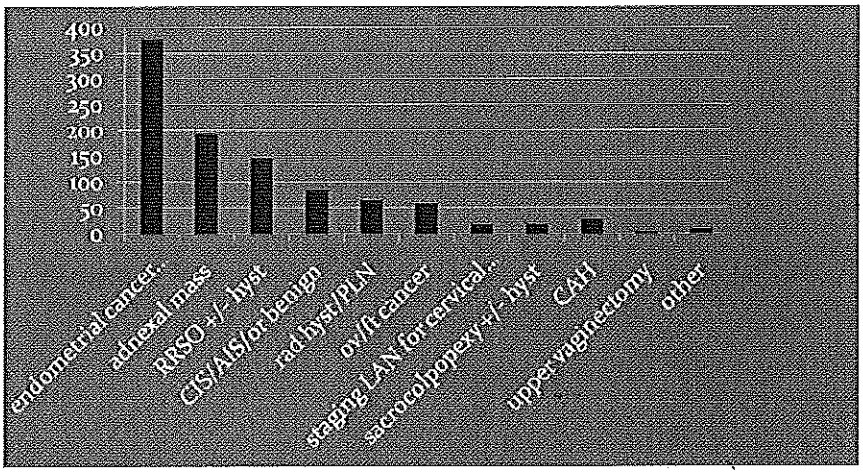
FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

Robotic Surgery in Complex Gynecology

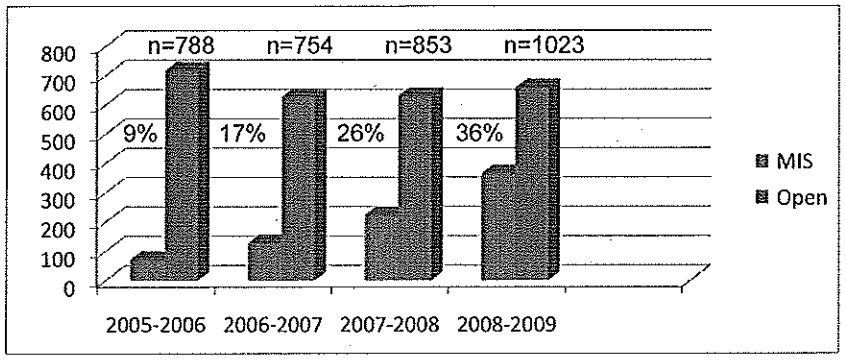
Chirag A. Shah MD MPH
Pacific Gynecology Specialists
Clinical Assistant Professor
University of Washington Medical Center

RESULTS: Robotic Surgery in Gynecologic Oncology

Pre-Op Diagnosis (n=1000)



Trend in MIS for Pacific Gynecology Specialists: *Pre- and Post-Robotics*



robotics

Robotic vs. Open Surgery in Endometrial Cancer Staging:

Patient Characteristics

Variable	Robotic (n=377)	Laparotomy (n=131)	*P* value
Age (yr)	62.1	63	0.08
Range	*27-90*	*30-92*	
BMI (kg/m2)	31.3	32.2	0.47
Range	*18-60.9*	*16.4-65.8*	
OR time (min)	184	139	<0.0001
Range	*73-444*	*69-294*	
EBL (mL)	46.9	197.6	<0.0001
Range	*10-1000*	*25-900*	
Node counts	15.4	13.1	0.007
Range	*2-52*	*1-42*	
LOS (days)	1.4	5.3	<0.0001
Range	*0.25-8.9*	*0.54-23.1*	
Previous abd surg	*51%*	*37%*	0.1028

Comparisons of major complications for robotic vs open surgery:

Endometrial Cancer Staging

Complication	Robotic (%) n=377	Open (%) n=131	P *value*
Cardiac	1 (0.26%)	5 (3.8%)	
Pulmonary	3 (0.79%)	1 (0.76%)	
DVT/PE	3 (0.79%)	1 (0.76%)	
Infectious	4 (1.1%)	6 (4.6%)	
ARF/ureteral injury	0	4 (3.0%)	
Wound dehis/sep	0	9 (6.9%)	
Maj vessel inj	1 (0.26%)	0	
Anemia req tx	2 (0.53%)	1 (0.76%)	
Labile BS	2 (0.53%)	0	
Ileus/SBO	2 (0.53%)	0	
Cystotomy	1 (0.26%)	0	
Chylous Ascites	1 (0.26%)	0	
Cuff dehiscence	4 (1.2%)	0	
Total	**24/377 (6.4%)**	**27/131 (20.6%)**	**<0.0001**

Outcomes for Robotics vs Laparotomy:

Endometrial Cancer Staging

	n	BMI (kg/m2)	EBL (mL)	Complications	*P* value
Paley					
Robotics	377	31.3	46.9	**6.4% (major c/o)**	<0.0001
Laparotomy	131	32.2	197.6	**20.6% (major c/o)**	
Bell					
Robotics	40	33	166	**7.5%**	0.015
Laparotomy	40	31.8	316	**27.5%**	
Boggess					
Robotics	103	32.9	74.5	**5.8%**	<0.0001
Laparotomy	138	34.7	266	**29.7%**	
DeNardis					
Robotics	56	29	105	**3.6% (major c/o)**	0.007
Laparotomy	106	34	241	**20.8%(major c/o)**	

Conclusions

- The technological advantage allowed for widespread integration in to our practice which did not occur with standard laparoscopy
- As compared to traditional laparotomy, robotic surgery in complex gynecology leads to improved clinical outcomes
  - Fewer major complications
  - Decreased hospital length of stay
  - Decreased blood loss

Washington State Health Care Authority

Disclosure

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	Potential Conflict Type	Yes	No
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5.	Research funding		X
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If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

____Intutive Surgical-physician training and proctor

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

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I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

XJames R Porter 5/8/12

Signature *Date* *Print Name*

Robotic Surgery at Swedish Medical Center

James Porter, MD
Director, Robotic Surgery
Swedish Medical Center
Seattle, WA

Credentials and Training

- Urology Residency: 1990 -1996
  - University of Washington
- Fellowship in Laparoscopic Surgery: '96-'97
  - Heilbronn, Germany
- Faculty: 1996-2005
  - University of Washington, Dept of Urology
- Head of Laparoscopic and Robotic Urologic Surgery

Credentials and Training

- Swedish Medical Center: July 2005
  - Director of Robotic Surgery
- ~1600 Robotic Procedures
  - Over 1300 Robotic Prostatectomies
  - Over 200 Robotic Partial Nephrectomies
- Fellowship Director in Robotic Surgery
  - 9 fellows

Robotic Prostatectomy Swedish Medical Center

- Aug 2005 to Aug 2011: 1200 patients
- IRB approved database
- Single surgeon experience

Robotic Prostatectomy Swedish Results

- Mean OR time: 186 mins (100 to 395)
- Mean EBL: 187cc (25 to 600)
  - 11/1200 (0.9%) transfusions

Robotic Prostatectomy Swedish Results

- Mean hospital stay: 1.06 days
  - 1140/1200 (95%) home < 24 hrs
- Mean catheter time: 7.8 days
- No open conversions

Cancer Control

- Positive margins overall:
  - 15.8%
- Positive margins by pStage:
  - pT2 = 8.9%
  - pT3 = 34.6%
  - pT4 = 80%

Robotic vs. Open Prostatectomy

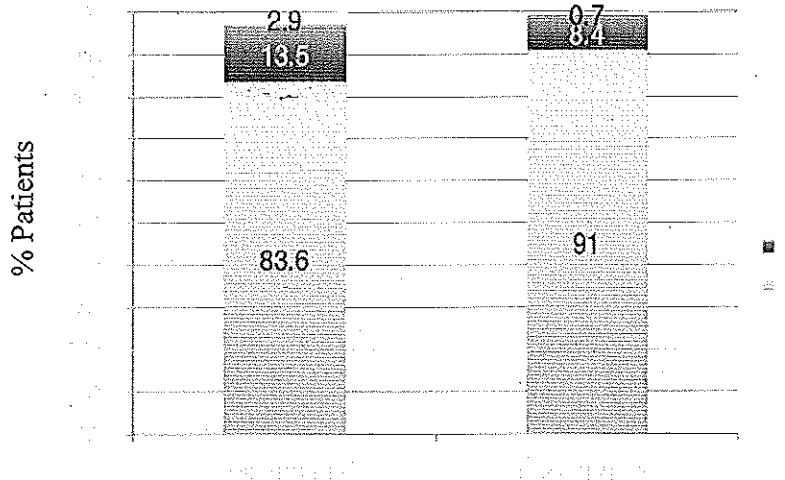
	LOS (days)	EBL (cc)	Transfusion	Pos Margin
Swedish (1200)	1.06	187	0.9%	15.8%
Lepor (1000)	2.3	818	9.7%	19.9%

J Urol 166: 1729, 2001

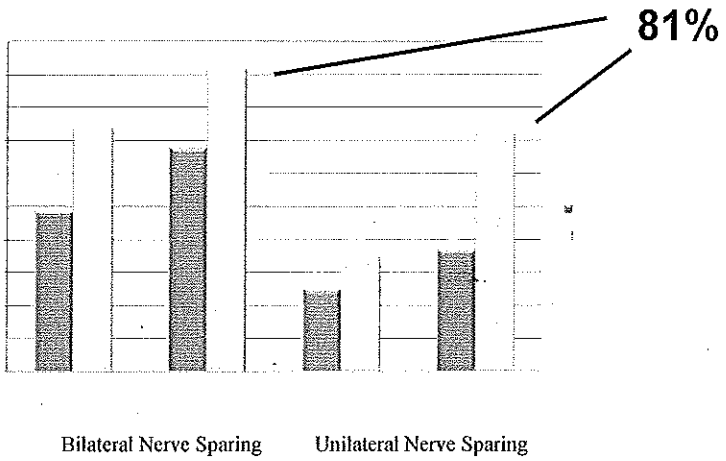
Robotic Prostatectomy Functional Outcomes

- Validated questionnaire
- Continence: 0 pads
- Potency: sufficient of intercourse

Continence after Robotic Prostatectomy: 12 months



Erectile Function After Robot Prostatectomy



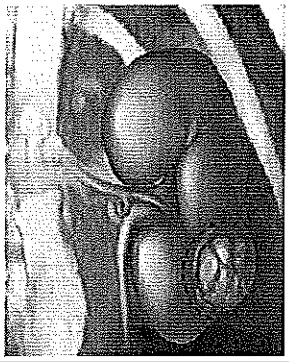
Functional Outcomes Comparison - Prostatectomy

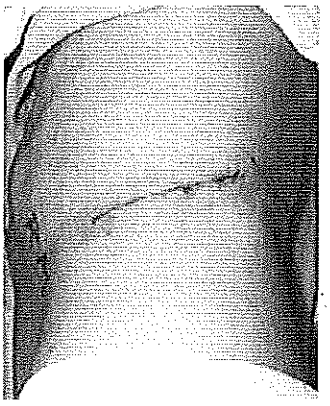
	N	EBL	Transfusion	Continence	Potency
Scardino* (open)	818	1,267	49%	83%	59%
Guillonneau* (lap)	612	315	3%	62%	58%
Swedish (robotic)	1200	187	0.9%	91%	81%

*J Urol 179: 1811, 2008

What is Partial Nephrectomy?

- Removal of kidney tumor while maintaining the remainder of kidney
- Technically more difficult
- Flank incision - painful





Laparoscopic Partial Nephrectomy

- Advanced laparoscopic procedure
- Technically challenging
  - Limit warm ischemia time < 30 minutes
  - Intracorporeal suturing
- Performed at high-volume centers

Laparoscopic Partial Nephrectomy is Difficult!

	WIT	Transfusion
Group 1 (n=276)	31.9 min	14.1%
Group 2 (n=289)	31.6 min	8.7%
Group 3 (n=235)	14.4 min	15.3%

Warm ischemia time 31.7 mins for first 565 patients!

Early Unclamping with significant transfusion rate

Gill et al. "800 Laparoscopic Partial Nephrectomies: a Single Surgeon Series." J Urol:183, 33, Jan 2010.

Laparoscopic Partial Nephrectomy University of Washington

N = 91

Warm ischemia (mean)	**35 min**	**(10-60)**
First 10	**38.6**	
Last 10	**26.2**	

Could Laparoscopic Partial Nephrectomy Be Made Less Challenging?

Robotic Partial Nephrectomy

Robotic Partial Nephrectomy Swedish Medical Center

- 182 patients:
  - Mean OR time: 135 min (60-339)
  - Mean EBL: 121 cc (20-1600)
  - Transfusions: 3 / 182 (1.6%)
- Mean warm ischemia time: 19.9 min
  - First 20 cases: 30.35 min
  - Last 20 cases: 15.5 min

Robotic Partial Nephrectomy Complications

Retroperitoneal	
Pseudoaneurysm	4
CO2 retention	1
Acute MI	1
Urine leak	1
	7/106 (6.6%)
Transperitoneal	
Pulmonary embolus	1
CVA	1
Chylous ascites	1
	3/76 (3.9%)

Robotic Partial Nephrectomy Multi-Institutional Study

Robotic-Assisted Partial Nephrectomy: An International Experience. Benway, B, Bhayani, S, Rogers, C., Porter, J., Buffi, N., Figenshaw, R., Mottrie, A. Eur Urol 57:815-820, 2010.

Lap vs. Robotic Partial Nephrectomy

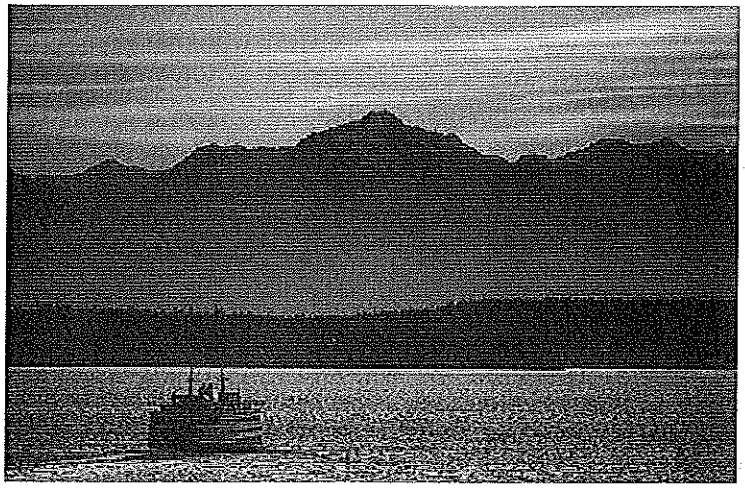
	WIT	EBL	Transfusion	Complications
Gill	31.7	300	4.5%	24.9%
Swedish	19.9	121	1.6%	5.5%

Gill et al: J Urol 178:41, 2007.

Robotic Surgery in Urology Conclusions

- Robotic Prostatectomy
  - Less blood loss
  - Shorter length or stay
  - Improved functional outcomes
- Robotic Partial Nephrectomy
  - Shorter warm ischemia time
  - Fewer complications

Thank You!



Washington State Health Care Authority

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000	X	
2.	Equity interests such as stocks, stock options or other ownership interests	X	
3.	Status or position as an officer, board member, trustee, owner		
4.	Loan or intellectual property rights		
5.	Research funding		
6.	Any other relationship, including travel arrangements		

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Intuitive Surgical

Chief Medical Advisor

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		

7. If yes, Provide Name and Funding Sources: _____

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may ***attach additional sheets*** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 8/4/2012 MyriamCuret

Signature *Date* *Print Name*

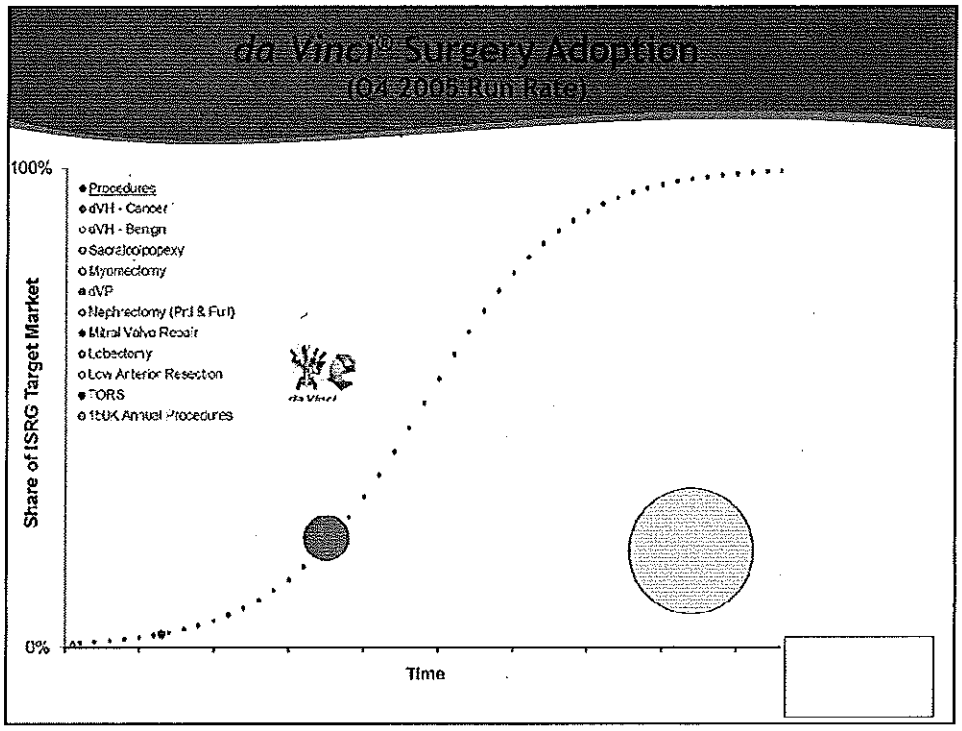
FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

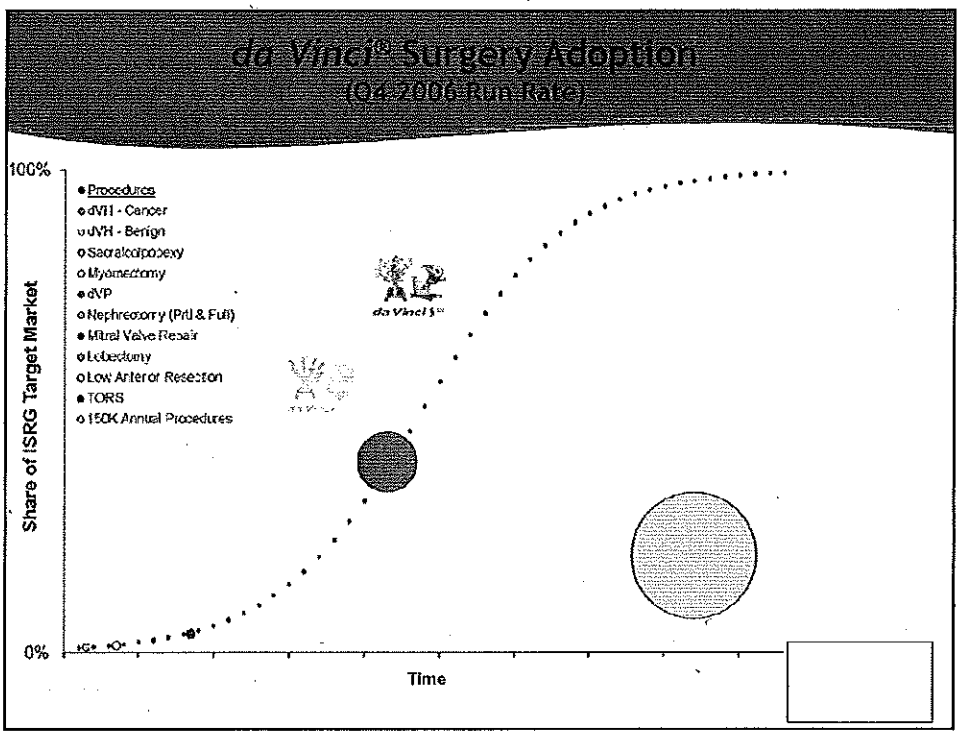
Comments on HTA 5/18/2012

Myriam J. Curet, MD, FACS
Chief Medical Advisor,
Intuitive Surgical

Adoption of Robotic Surgery

- ...happens procedure by procedure
- Different procedures adopt at different rates
- Published data lags adoption
  - True for all technologies, not just robotics
- Robotic surgery is a form of minimally invasive surgery
  - da Vinci is a sophisticated tool, not a new form of therapy
  - Important to note - no separate or incremental billing of robotics


da Vinci® Surgery Adoption
(Q4 2006 Run Rate)
100%
0%
Share of ISRG Target Market
Time
Procedures
dVH - Cancer
dVH - Benign
Sacralcolpopexy
Myomectomy
dVP
Nephrectomy (Prtl & Full)
Mitral Valve Repair
Lobectomy
Low Anterior Resection
TORS
150K Annual Procedures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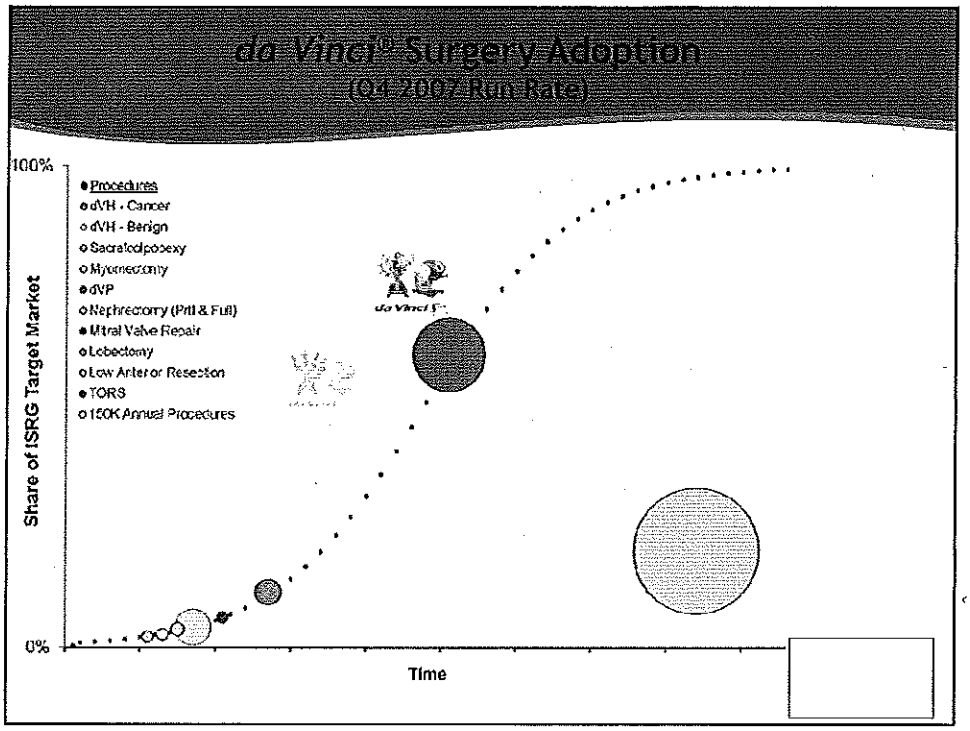
da Vinci® Surgery Adoption
(Q4 2007 Run Rate)
100%
0%
Share of ISRG Target Market
Time
Procedures
dVH - Cancer
dVH - Benign
Sacralcolpoexy
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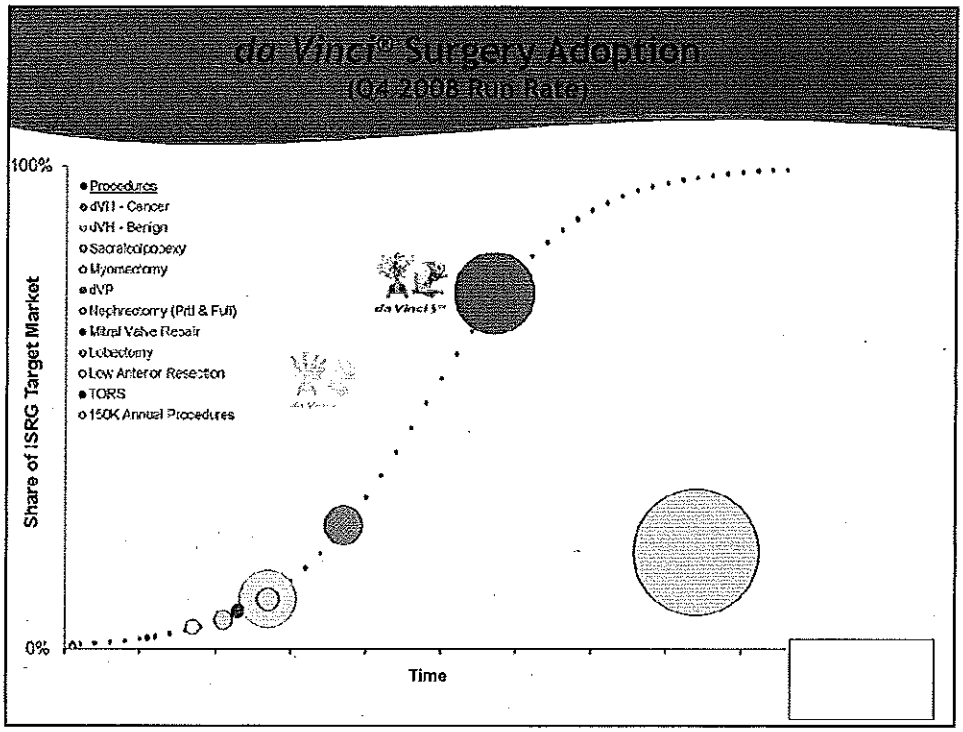
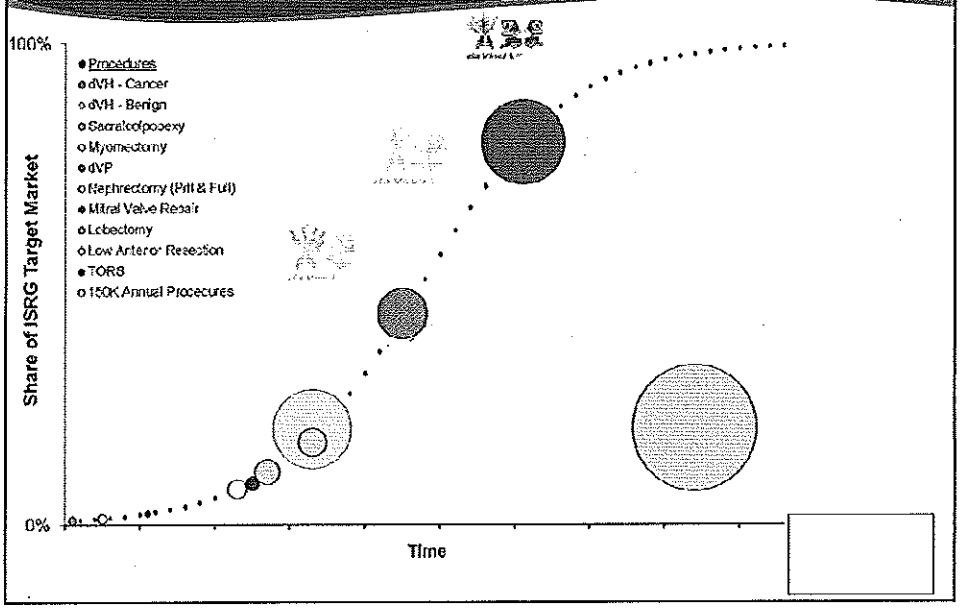
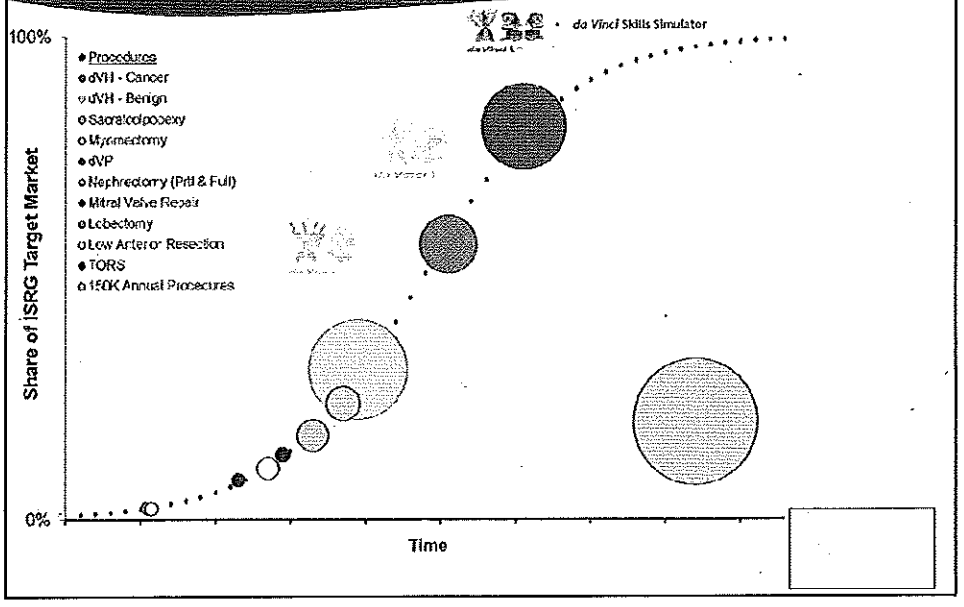
150K Annual Procedures

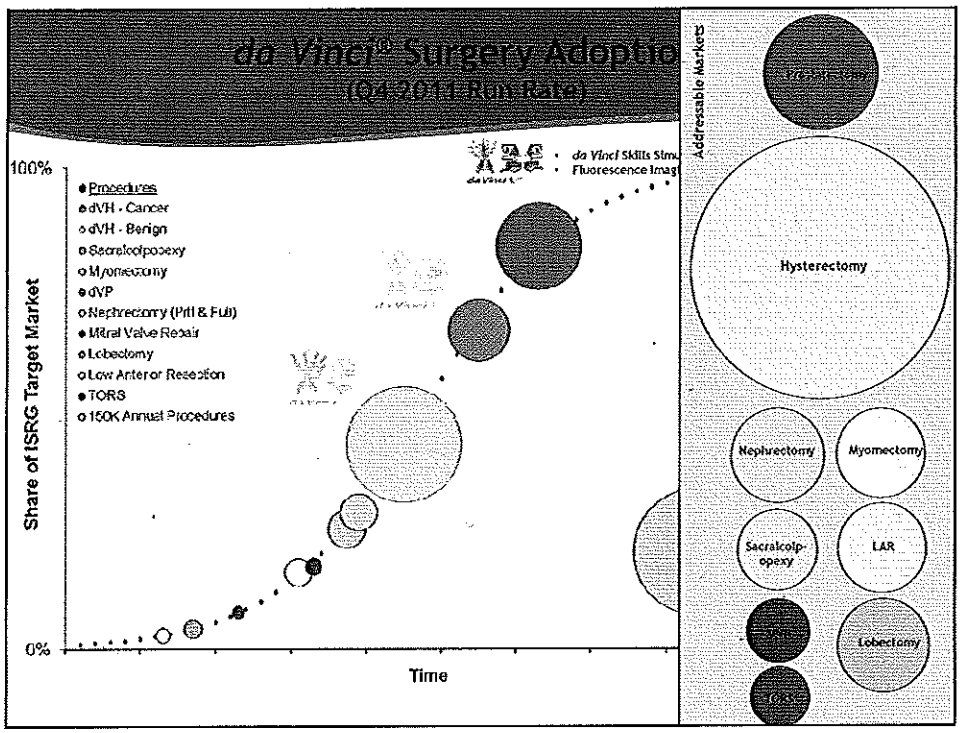

da Vinci® Surgery Adoption
(Q4 2008 Run Rate)
100%
0%
Share of ISRG Target Market
Time
Procedures
dVH - Cancer
dVH - Benign
Sacralcolpoexy
Myomectomy
dVP
Nephrectomy (Prtl & Full)
Mitral Valve Repair
Lobectomy
Low Anterior Resection
TORS
150K Annual Procedures

da Vinci® Surgery Adoption
(Q4 2009 Run Rate)



da Vinci® Surgery Adoption
(Q4 2010 Run Rate)





da Vinci® Procedures

Urology | Gynecology | Cardiothoracic | General

Urology	Gynecology	Cardiothoracic	General
Prostatectomy	Hysterectomy	Mitral Valve Repair & Replacement	Gastric Bypass
Nephrectomy	Myomectomy	Single Vessel Beating Heart Bypass	Nissen Fundoplication
Partial Nephrectomy	Sacral Colpopexy	Multi-Vessel Beating Heart Bypass	Heller Myotomy
Pyeloplasty	Pelvic Lymphadenectomy	Single Vessel Arrested Heart Bypass	Gastrectomy
Cystectomy	Tubal Reanastomosis	Multi-Vessel Arrested Heart Bypass	Colon Resection
Donor Nephrectomy	Vaginal Prolapse Repair	IMA Harvesting	Thyroidectomy
Ureterolithotomy	Dermoid Cyst	Coronary Anastomosis	Arteriovenous Fistula
Pelvic Lymphadenectomy	Oophorocystectomy	Atrial Septum Aneurysm	Toupet Fundoplication
Adrenalectomy	Oophoroectomy	Atrial Septal Defect Repair	Pancreatectomy
Cystocele Repair	Ovarian Cystectomy	Tricuspid Valve Repair	Adrenalectomy
Excision of Renal Cyst	Ovarian Transposition	Thrombectomy	Hemi-Colectomy
Lymphadenectomy	Trachelectomy	Thymectomy	Sigmoidectomy
Testicular Resection	Cervical Cerclage	Esophagectomy	Splenectomy
Renal Cyst Decortication	Salpingectomy	Pericardial Window	Pyloroplasty
Ureteral Transplant	Salpingo-Oophorectomy	Lobectomy	Gastroplasty
Nephropexy	Colposuspension (Burch)	Pneumonectomy	Appendectomy
Ureterectomy	Tubal Ligation	Pacemaker Lead Implantation	Intra-rectal Surgery
Rectocele Repair	Tubalplasty	Mediastinal Resection	Bowel Resection
Varicocelectomy	Endometriosis Resection	Pulmonary Wedge Resection	Lumbar Sympathectomy
Ureteroplasty	Deep Infiltrating Endometriosis Resection		Liver Resection
Ureteral Implantation			Cholecystectomy
Vaso-vasostomy			Hernia Repair

DRIVING THE CURVE

da Vinci Surgery

da Vinci® Procedures

Urology	Gynecology	Cardiothoracic	General
Prostatectomy	Hysterectomy	Mitral Valve Repair & Replacement	Gastric Bypass
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Ureteroplasty	Deep Infiltrating Endometriosis Resection		Liver Resection
Ureteral Implantation			Cholecystectomy
Vaso-vasostomy			Hernia Repair

RED FONT Indicates Procedures Where, Prior to Robotics, MIS Adoption Has Been Limited

INTUITIVE SURGICAL

DRIVING THE CURVE

da Vinci Surgery

Outcomes and Cost Comparisons after Introducing a Robotics Program for Endometrial Cancer Surgery

Lau S, Vaknin, Z, Ramana-Kumar AV, Halliday D, Franco EL, Gotlieb WH.
Obstetrics & Gynecology. 2012; 119(4):717-724.

	Historic Cohort* (n=160)	da Vinci Cohort (n= 143)	p-value
Median operation time (min)	206	233	<.001
Complications (%)	42	13	<.001
Median blood loss (mL)	200	50	<.001
Median hospital stay (days)	5	1	<.001
# Short-term cancer recurrences (w/in 2 yrs of surgery)	19	11	<.001

*Historic cohort includes consecutive patients who underwent both open and laparoscopic surgery. Consecutive patients before robotics program (2003-2007), consecutive da Vinci patients (2007-2010).

INTUITIVE SURGICAL

DRIVING THE CURVE

da Vinci Surgery

PN876246A 04/12

Lau et al (cont)

	Historic Cohort	da Vinci Cohort	p-value
Hospital accommodations	$6,623	$2,658	<.001
OR Costs	237	2,977	<.001
Overall Costs*			
Without amortization	10,368	7,644	<.001
With amortization	10,368	8,370	.002

Data are mean Canadian dollars

**The amortization cost of the da Vinci Surgical System was calculated on the basis of the sum of the cost of the robotic system and the service cost of 10% per year for 10 years divided by the total number of cases expected to be performed during that period (i.e., 5,200 patients, $726 Can. per patient) based on the current case load of two cases per day.*

Symptomatic and Anatomic 1-year Outcomes after Robotic and Abdominal Sacrocolpopexy

Siddiqui NY, Geller EJ, Visco VG,
AJOG, 2012; 206 (5): 435.e1-435.e5 .

	Robotic Sacrocolpopexy (n = 125)	Abdominal Sacrocolpopexy (n = 322)	p Value
Symptomatic Failures	8%	4%	0.16
Anatomic Failures	6%	6%	0.57
EBL (mL)	90.0 ± 89.3	227.9 ± 195.0	< .01
Concomitant hysterectomy (%)	49	28	<.01
Wound disruption (%)	0	4.3	0.01
Febrile morbidity (%)	4.8	10.9	0.04
Ileus (%)	5.6	11.6	0.05

Positive Surgical Margin and Perioperative Complication Rates of Primary Surgical Treatment for Prostate Cancer: A Systematic Review and Meta-Analysis Comparing Retropubic, Laparoscopic and Robotic Prostatectomy

Tewari A, Sooriakumaran P, Bloch DA et al. *Eur Uro* 2012
doir:10/1016/j.eururo.2012.02.029

	Open	Lap	Robotic	P-value
PSM rate (%)	24.2	20.4	16.2	<0.001
Estimated Blood Loss (ml)	745.3	377.5	188.0	<0.001
Intraoperative complications	1.6%	1.9	0.4%	<0.001
Perioperative complications	9.1%	9.6	6.3%	<0.001
Mean length of stay (d) (US)	3.1	2.1	1.4	<0.001
In-hospital mortality	0.1%	0.14%	0.1%	NS

INTUITIVE SURGICAL

DRIVING THE CURVE

da Vinci Surgery

Perioperative Outcomes of Robot-Assisted Radical Prostatectomy Compared with Open Radical Prostatectomy: Results from the Nationwide Inpatient Sample

Trinh AD, Sammon J, Sun M et al. *Eur Uro* 2012; *doi:10.1016/j.eururo.2011.12.027*

	Open N = 7389	Robotic N = 7598	P-value
Homologous blood transfusion	7.7%	2.4%	<0.001
Intraoperative complication	1%	0.4%	<0.001
Postoperative complication			
Overall	11.1%	9.3%	<0.001
Cardiac	1.3%	0.9%	0.018
Respiratory	2.6%	1.4%	<0.001
Vascular	0.6%	0.4%	0.065
Operative Wound	0.6%	0.5%	0.121
Genitourinary	1.2%	1.2%	0.907
Misc. Medical	6.2%	5.7%	0.173
Misc. Surgical	1.6%	1.6%	0.877
Length of stay > 2 days	39.6%	14.5%	<0.001
In-hospital mortality	0.1%	0%	0.092

Propensity score-matched intraoperative and postoperative outcomes during hospitalization stratified by open or robotic surgery

INTUITIVE SURGICAL

DRIVING THE CURVE

da Vinci Surgery

Temporal National Trends of Minimally Invasive and Retropubic Radical Prostatectomy Outcomes from 2003 to 2007: Results from the 100% Medicare Sample

Kowalczyk KJ, Levy JM, Caplan CF et al. *Eur Uro* 2011
doi:10.1016/j.eururo.2011.12.020

	Open N = 58,638	MIRP N = 19,594	P-value
Homologous blood transfusion	7.7%	2.4%	<0.001
Intraoperative complication	1%	0.4%	<0.001
Perioperative complication	29.8%	19.6%	<0.001
Cardiac	4.7%	2.2%	<0.001
Respiratory	9.4%	4.1%	<0.001
Vascular	4.3%	2.7%	<0.001
Operative Wound	3.9%	1.8%	<0.001
Genitourinary	6.9%	4.8%	<0.001
Misc. Medical	12.6%	8.8%	<0.001
Misc. Surgical	6.0%	4.2%	<0.001
Mean length of stay (d)	4.2	2.0	<0.001
In-hospital mortality	0.6%	0.2%	<0.001

Kowalczyk et al (cont)

	Open N = 45,277	MIRP N = 11,108	P-value
Late complications			
Anastomotic stricture	9.3%	3.0%	<0.001
Ureteral complications	1.3%	0.5%	<0.001
Rectourethral fistula	0.4%	0.4%	0.999
Lymphocele	2.2%	1.3%	<0.001
Surgical intervention for incontinence	0.3%	0.3%	0.734

Conclusions

- Robotic surgery has been adopted across numerous surgical procedures
  - Already the standard of care in many urologic and gynecologic procedures
  - Rapid adoption in other areas underway as well
- Most reimbursement authorities throughout the US do not pay additional fees for the use of robotics
  - Improved clinical outcomes
  - Same DRG codes as lap, in most cases
- Withholding robotic surgery from many of the patients in the state of Washington does not seem to be in the best interests of the stakeholders of the Washington State HTA

Washington State Health Care Authority

Disclosure

Any unmarked topic will be considered a "Yes"

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3.	Status or position as an officer, board member, trustee, owner		X
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

1) SPEAKER, PROCTOR, EPICENTER SURGEON FOR INTUITIVE SURGICAL, SUNNYVALE CA.

2) PROCTOR & GYN CONSULTANT FOR ETHICON WOMENS HEALTH & UROLOGY, CINCINNATI, OH

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

7. If yes, Provide Name and Funding Sources: _____

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I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

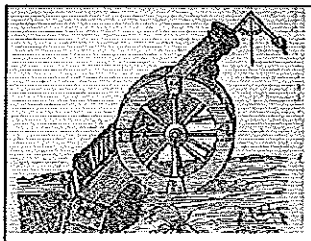
X John Lenihan Jr MD 5/7/2012

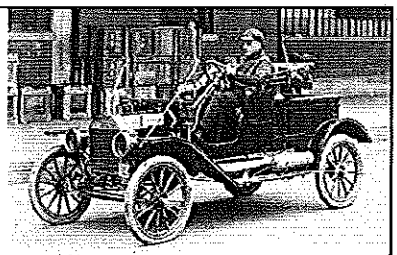
Signature *Date*

John P. Lenihan Jr., MD
Tacoma Women's Specialists, PS
314 Martin Luther King Jr. Way Ste 104
Tacoma, WA 98405
(253) 272-5572

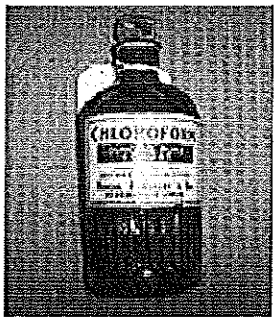
Print Name

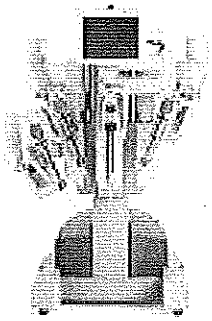
FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742, PO Box 42712, Olympia, WA 98504-2712





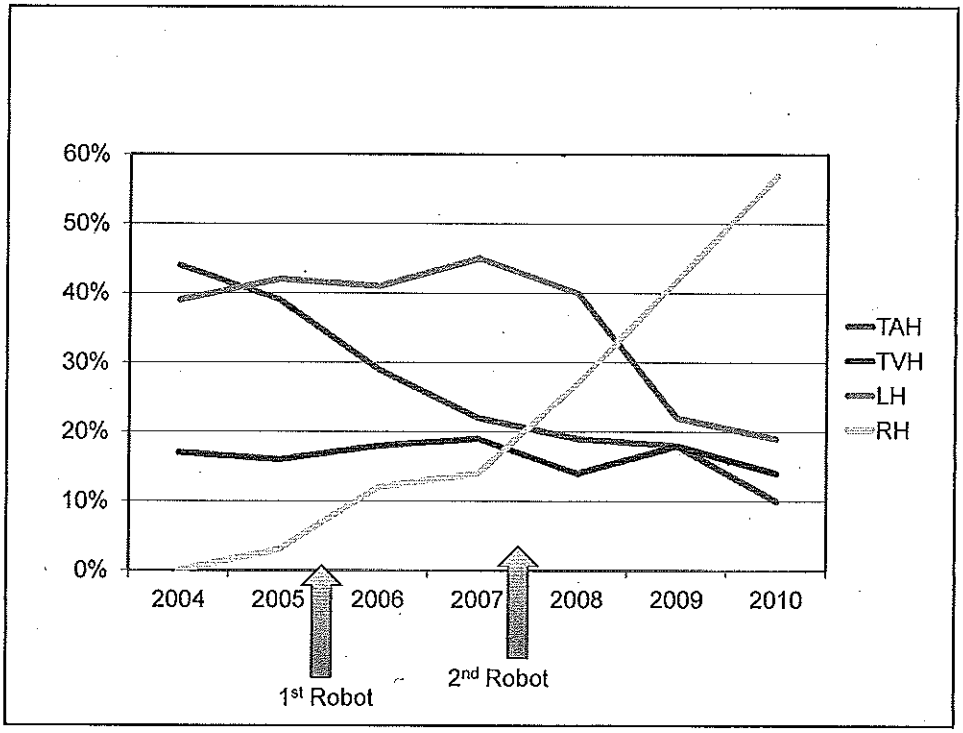
Disruptive



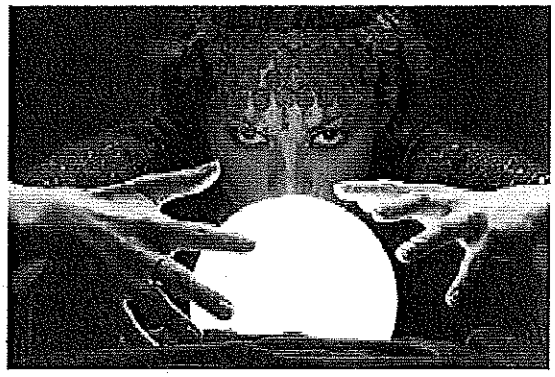


Benefits

Choices


60%
50%
40%
30%
20%
10%
0%
2004
2005
2006
2007
2008
2009
2010
TAH
TVH
LH
RH
1st Robot
2nd Robot

FUTURE



Washington State Health Care Authority

Disclosure

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1.	Salary or payments such as consulting fees or honoraria in excess of $10,000		XX
2.	Equity interests such as stocks, stock options or other ownership interests		XX
3.	Status or position as an officer, board member, trustee, owner		XX
4.	Loan or intellectual property rights		XX
5.	Research funding		XX
6.	Any other relationship, including travel arrangements	XX	

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Medical Director, Swedish Medical Center/Ballard
Medical Executive Committee, Swedish Medical Center

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		XX

7. If yes, Provide Name and Funding Sources: _____

_____

_____

_____

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may ***attach additional sheets*** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 5/8/12 Raymond F. Jarris Jr. MD

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

Washington State
Health Care Authority

Disclosure

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1.	Salary or payments such as consulting fees or honoraria in excess of $10,000		X
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status or position as an officer, board member, trustee, owner		X
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

I do some Physician training for Intuitive Surgical but 2011 honoraria were less than $10,000

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

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X [signature] MD 5-6-12 LELAND SIWEK, MD

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

PROVIDENCE
Sacred Heart
Medical Center &
Children's Hospital

Washington HTA

Leland Swack, M.D.
Cardiac Surgeon
Spokane, WA
5/18/2012

Why Robotic Heart Surgery?

PROVIDENCE
Sacred Heart
Medical Center &
Children's Hospital

- Reduce morbidity of open heart surgery thereby allowing more rapid return to normal function
- Conventional Sternotomy
  - No driving or lifting for 1 month
  - Restricted lifting & physical activities for 2–3 months
- Robotic endoscopic approach
  - NO restrictions on physical activities
  - Return to lifting & even strenuous physical activities (personal & or work) as patient comfort allows

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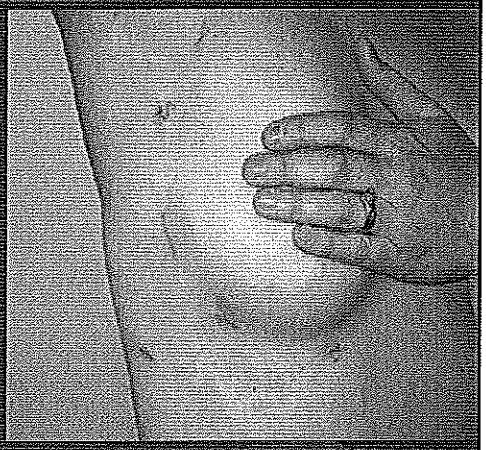
VS



Median Sternotomy	20-25 cm Sternum divided	Total Endoscopic	1-2 cm Between ribs

Why Robotic Heart Surgery?

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Children's Hospital

- Early mitral valve repair, often before onset of symptoms or significant deterioration of heart function, provides the best long term outcome and survival.
- Patients are reluctant to "do the right thing" because of the morbidity associated with conventional open heart surgery.
- Robotic surgery provides an option that is sufficiently acceptable to patients so they will choose the therapy that is in their best interest.

The Patient's True Comfort Zone

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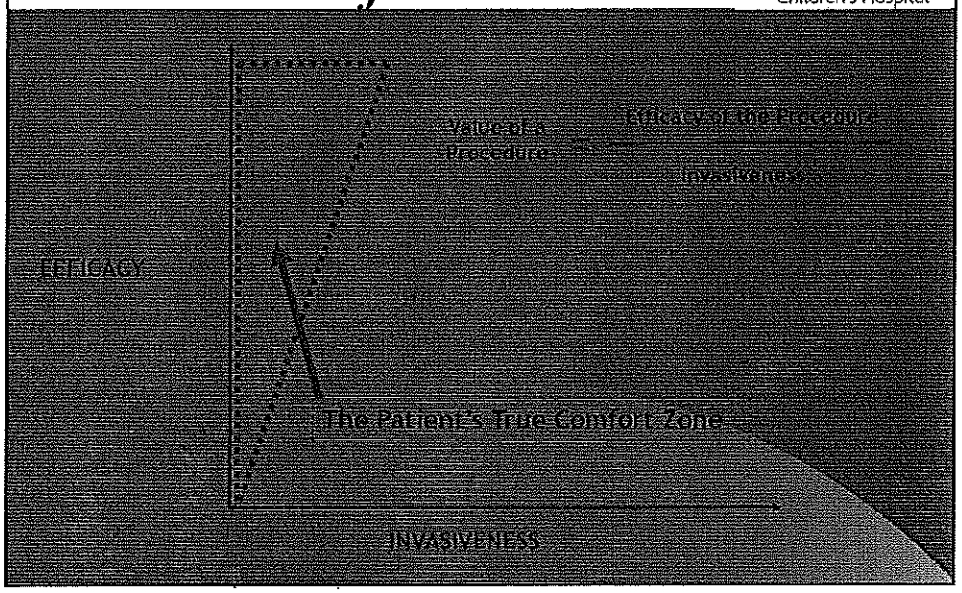

The Possible Solution

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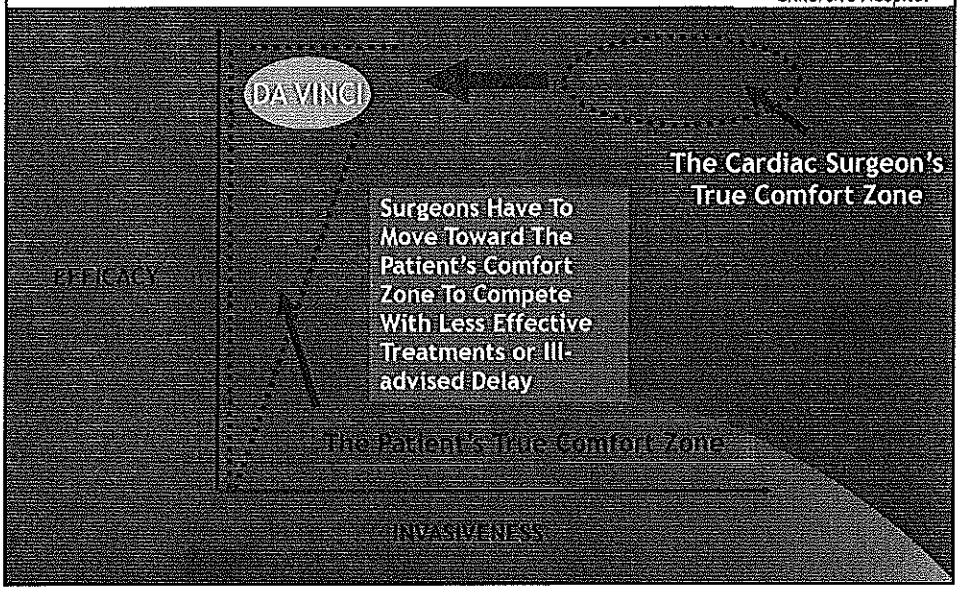

Why Robotic Heart Surgery?

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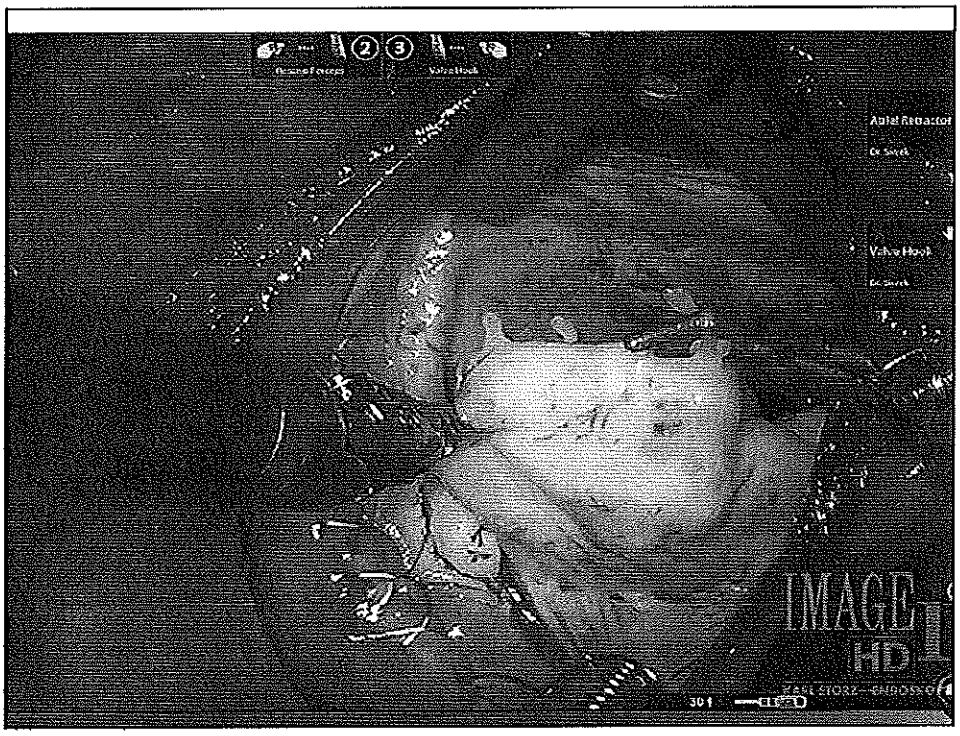
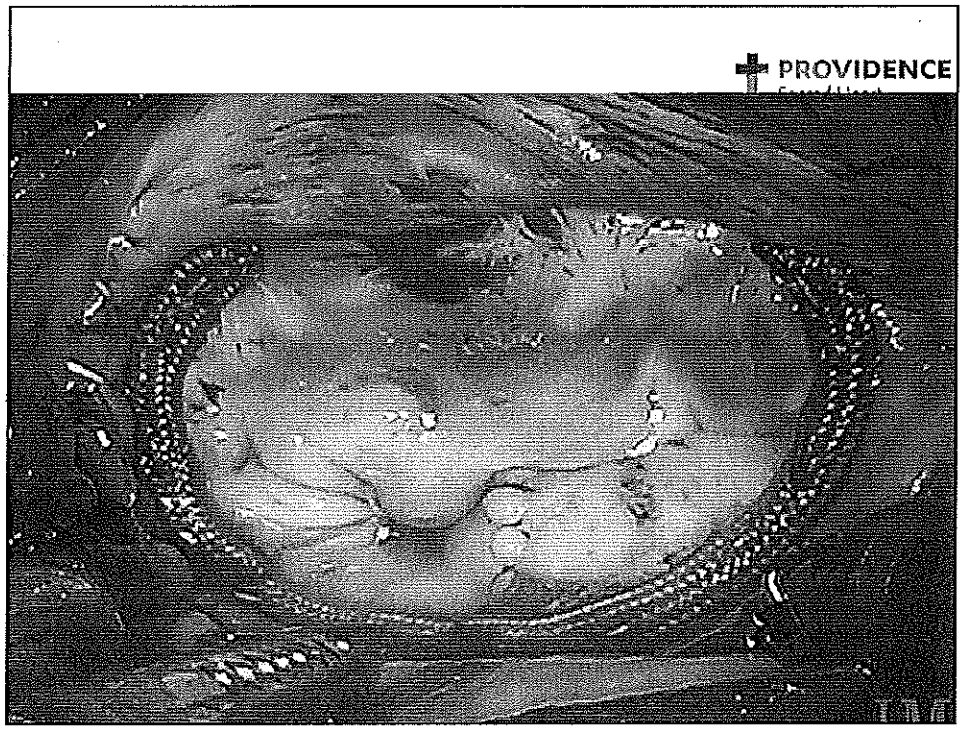
- Outcomes/success at least as good or even better than conventional surgery
- ASD closure, Mitral valve Replacement & removal of intra-cardiac tumors:
  - Surgical result the same as open procedures
  - Advantage is avoidance of sternotomy, reduced complications and rapid return to normal function
- Mitral Valve Repair
  - Successful repair rate *superior* to conventional approach (>95% in experienced centers)

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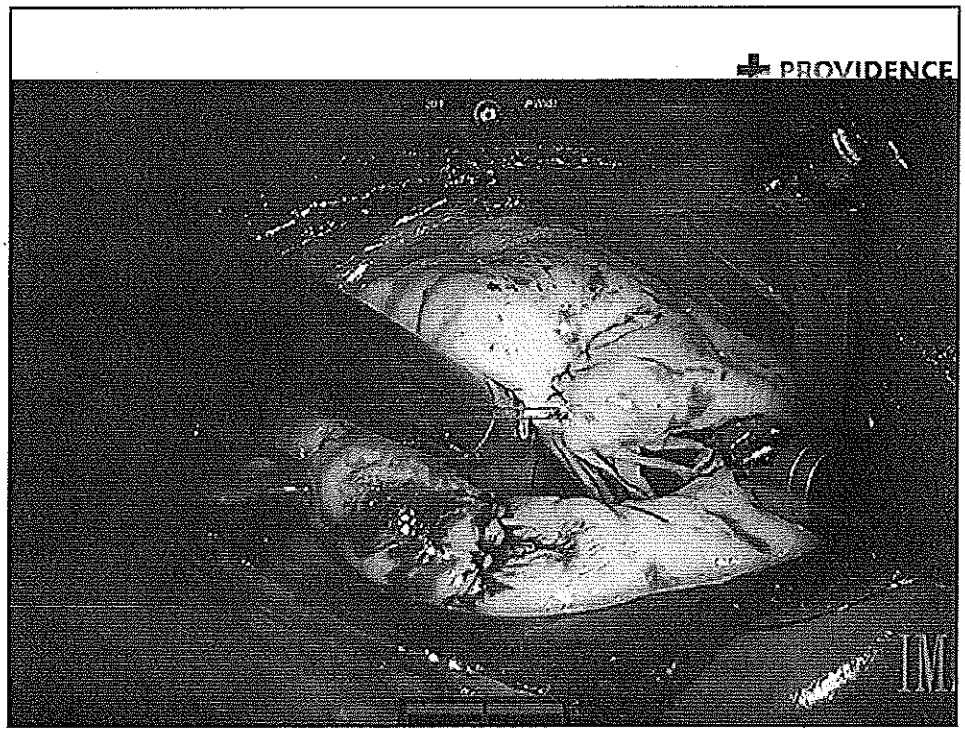
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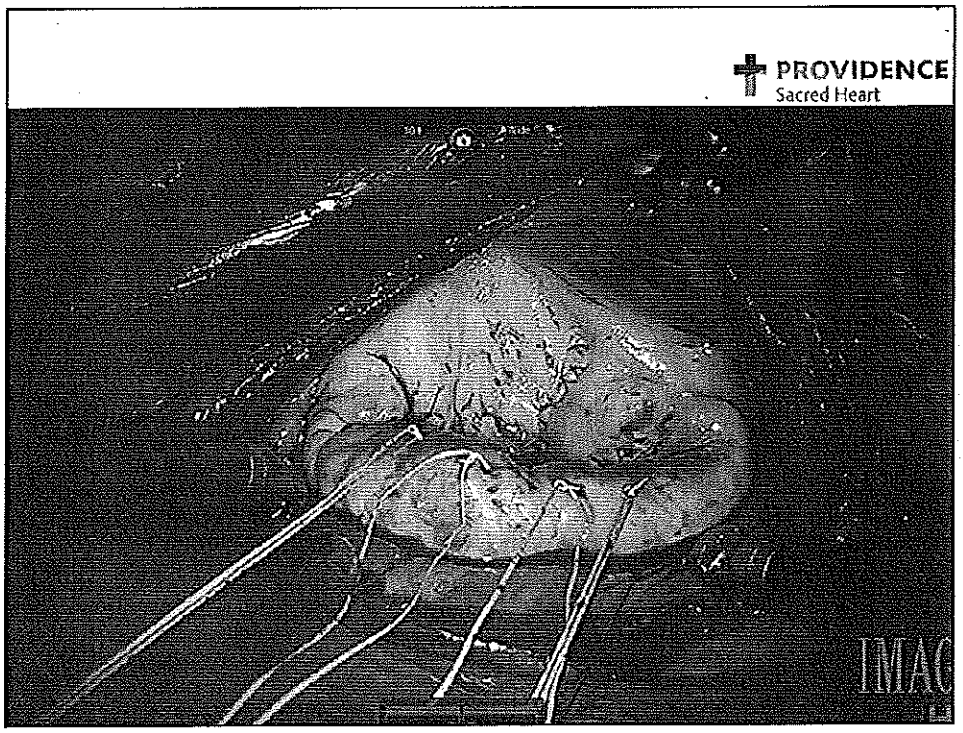

Our Cardiac Robotic Experience (through 3/12)

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- ASD – 72
- Mitral Valve Repair – 461
- Mitral Valve Replacement – 56
- MAZE – 89 (mostly concomitant)
- Myxoma/Cardiac Tumor – 22
- LHCAB – 52

Our Robotic Mitral Valve Repair Experience

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- Of 462 planned repairs only 0.4% conversion to replacement & 2 conversions to sternotomy
- Complex repair (sliding leaflet reconstruction or artificial chordae) performed in 38%
- No or trace regurgitation in 98%
  - No patients > II+ regurgitation
- One death (84 yo with perfusion related aortic dissection)
- *>99% successful repair rate!*
- Average LOS 4 days! – 50% discharged by day 3

Recent Publications

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Robotic mitral valve repair for all prolapse subsets using techniques identical to open valvuloplasty: Establishing the benchmark against which percutaneous interventions should be judged

[redacted]

- Included initial "learning curve" experience
- 100% successful repair, 0% mortality
- Comparable rate of complications despite longer bypass & crossclamp times (which improved with experience)
- Shorter post-op ventilation time, ICU stay & hospital LOS

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Quality of Life After Early Mitral Valve Repair Using Conventional and Robotic Approaches

Rakesh M. Suri, MD, DPhil; Ryan M. Antiel, MA; Harold M. Burkhart, MD; Marianne Huebner, PhD; Zhuo Li, MS; David T. Eton, PhD; Tal Topilsky, PhD; Maurice E. Sarano, MD; and Hartzell V. Schaff, MD

Ann Thorac Surg 2012;93:761-9

- Excellent QOL after early mitral valve repair at 1-2 years
- During the first year robotic patients had improved QOL vs conventional patients
- Robotic patients had quicker return to work

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Comparison of Economic and Patient Outcomes With Minimally Invasive Versus Traditional Off-Pump Coronary Artery Bypass Grafting Techniques

Robert S. Poston, MD, Richard Tran, BS, Michael Collins, MD, Mary Reynolds, MD, Ingrid Connerney, RN, PhD, Barry Reicher, MD, David Zimrin, MD, Bartley P. Griffith, MD, and Stephen T. Bartlett, MD

Annals of Surgery, Volume 248, Number 4, October 2008

- Increased OR cost
- Decreased ventilation time, hospital LOS & transfusion led to decreased post operative cost
- Overall cost and hospital margin comparable
- Highest risk group had most significant cost benefit
- Robotic patients had shorter duration of pain, higher patient satisfaction, earlier return to work and better freedom from MACCE at 1 year

Case Example

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- 50 yo male Vietnamese immigrant
- Self-employed carpet & flooring contractor, supporting himself & family
- Back to work *laying carpet* 2 weeks after robotic mitral valve repair

Case Example

PROVIDENCE Sacred Heart Medical Center & Children's Hospital

- 83 yr old woman, afraid to follow her doctor's recommendation for mitral valve repair because of worry about recovery
- Chose to proceed with surgery when advised of robotic option
- Discharged 4 days after surgery, returned home, fully recovered within 1 month

Case Example

PROVIDENCE Sacred Heart Medical Center & Children's Hospital

- 43 yo woman with rheumatic mitral valve stenosis and congestive heart failure
- Single mother. *On Medicaid*. Works as care-giver
- Robotic mitral valve replacement
- Discharged POD #3
- Returned to caring for her family and *returned to work 2 weeks after surgery*
- *It would be a shame to tell her she had to have a sternotomy just because of her medical insurance!*

Summary

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- Robotic cardiac surgery, while requiring specialized training & experience, is:
  - Safe
  - Highly effective
  - Provides more rapid return to normal function
  - Is far more acceptable to patients allowing them to comfortably proceed with life saving surgery
- Access to robotic cardiac surgery should NOT be denied to the citizens of Washington, especially the working poor who may have the most to gain from the rapid return to physical activities.

Washington State Health Care Authority

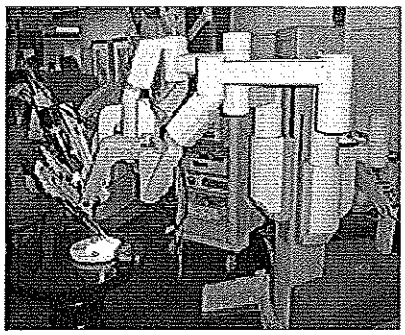
Agency Medical Director Comments
Health Technology Clinical Committee

Robotic Assisted Surgery

Kerilyn K. Nobuhara, MD MHA
Senior Medical Consultant
HCA Benefits and Utilization Management
May 18, 2012

Robotic Assisted Surgery: Background

- Da Vinci™ Robotic system assists surgeons during laparoscopic, thoracoscopic and open surgical procedures
- 2007 AMA determination that additional CPT codes for robotic assisted procedures was not necessary
- Trend for increasing utilization in Washington state and nationally



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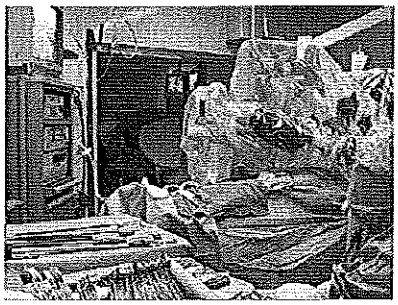
Robotic Assisted Surgery: Background



Fixed Costs:

$1-2.5 million

Annual maintenance fees
$ 140,000

Variable Costs:

$ 1600/procedure

Additional consumables:
Single-use robotic appliances

Operative and anesthesia time during learning curve

Barbash , "New Technology and Health Care Costs—The case of Robot-Assisted Surgery," NEJM 363; 701-704, 2010.

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Robotic Assisted Surgery: AMDG Perspective

Primary Criteria Ranking

- Safety = Medium
- Efficacy = Medium
- Cost = Medium

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Robotic Assisted Surgery: Current State Agency Policy

Labor and Industries
- HCPCS S2900 Non covered
- No specific policy addressing robotic assisted surgery

PEB
- No additional reimbursement for robotic procedures
- Coverage/reimbursement based on the surgical procedure

Medicaid
- HCPCS S2900 on prior authorization
- No additional reimbursement for robotic procedures
- Coverage/reimbursement based on the surgical procedure

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Robotic Assisted Surgery: Key Questions

Safety = Medium Concern

- How are clinicians, technologists, and facilities trained and certified in the use of the robotic system?
- How is robotic assisted surgery competency established for different surgical specialties?
- What is the incidence of adverse events?
- AMDG selected considerations: morbidity, mortality, reoperation rate, intraoperative blood loss, postoperative stay

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Robotic Assisted Surgery: Key Questions

Effectiveness = Medium Concern

- What are the appropriate comparators for robotic assisted surgery?
- What is the evidence supporting clinically meaningful short and long-term outcomes for robotic assisted surgical procedures?
- Can robotic assisted technology be judged separately from the experience of the operating surgeon?

Robotic Assisted Surgery: Key Questions

Cost = Medium Concern

- What is the evidence supporting cost-effectiveness of robotic assisted surgery compared with laparoscopic and/or open approaches?

Robotic Assisted Surgery Billing Codes

Code	Description	Type
S2900	Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure)	HCPCS
17.41	Open robotic assisted procedure	ICD9 Procedure
17.42	Laparoscopic robotic assisted procedure	ICD9 Procedure
17.43	Percutaneous robotic assisted procedure	ICD9 Procedure
17.44	Endoscopic robotic assisted procedure	ICD9 Procedure
17.45	Thoracoscopic robotic assisted procedure	ICD9 Procedure
17.49	Other and unspecified robotic assisted procedure	ICD9 Procedure

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Robotic Assisted Surgery State Agency Utilization

Robotic Assisted Surgeries	2007	2008	2009	2010	Overall	Overall Avg Paymnt
PEB						
Patients	1	28	142	217	388	
Payments	$15,625	$253,421	$1,610,844	$3,235,319	$5,115,209	$13,184
Medicaid						
Patients	0	16	78	133	227	
Payments	$0	$201,329	$1,398,773	$2,228,764	$3,828,866	$14,875
L&I						
Patients				2	2	
Payments				$16,866	$16,866	$8,433
All Agencies						
Patients	**1**	**44**	**220**	**352**	**617**	
Payments	**$15,625**	**$454,750**	**$3,009,617**	**$5,480,949**	**$8,960,941**	**$14,523**

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Robotic Assisted Surgery
State Agency Utilization

PEB Robotic Assisted Surgery by Category, 2007-2010

Procedure Type	Totals 2007-2010		Averages		Variability		
	Payments	Pt Cnt	Per Procedure	Per Procedure (Prime only)	Max Paid	Min Paid (Prime)	Std Dev
Prostate	$1,963,137	171	$11,480	$20,297	$82,030	$3,639	$11,270
Gynecologic	$1,718,408	136	$12,635	$16,130	$75,940	$4,272	$12,862
Urinary Tract	$561,101	27	$20,782	$27,276	$83,901	$3,839	$19,324
Other	$559,332	29	$19,287	$39,363	$92,396	$12,435	$22,056
Pelvic	$222,435	19	$11,707	$13,377	$24,388	$8,168	$4,423
Combination	$90,796	6	$15,133	$15,133	$19,293	$12,511	$2,928
All Types	**$5,115,209**	**388**	**$13,184**	**$21,761**	**$92,396**	**$3,639**	**$14,014**

Washington State Health Care Authority

Robotic Assisted Surgery
State Agency Utilization

Medicaid Robotic Assisted Surgery by Category, 2007-2010

Procedure Type	Totals 2007-2010		Averages		Variability		
	Payments	Pt Cnt	Per Procedure	Per Proc (Non Medicare)	Max Paid	Min Paid	Std Dev
Gynecologic	$1,512,792	144	$10,506	$23,642	$189,788	$2,148	$21,738
Other*	$1,007,370	22	$45,790	$28,803	$112,068	$493	$69,153
Cardiac	$684,642	16	$42,790	$25,431	$97,671	$1,150	$26,962
Gastro/Chole	$336,479	9	$37,387	$39,115	$112,776	$8,048	$39,115
Urinary Tract	$225,861	21	$10,755	$15,371	$55,542	$2,066	$14,425
Prostate	$61,723	15	$4,115	$3,278	$37,219	$104	$3,936
All Types	**$3,828,866**	**227**	**$16,867**	**$19,082**	**$189,788**	**$104**	**$32,419**

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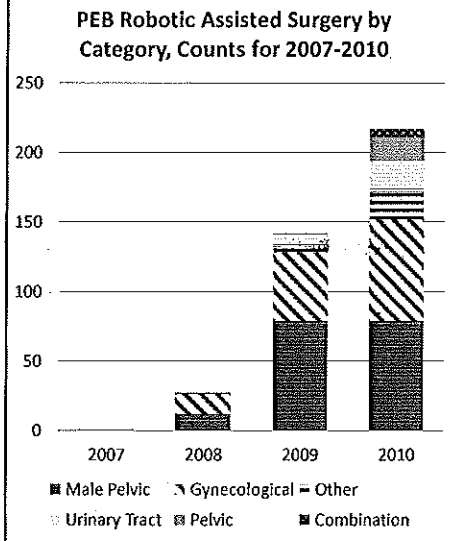
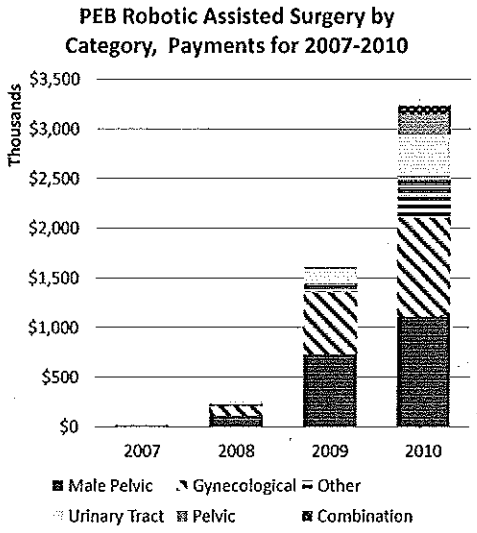
Robotic Assisted Surgery State Agency Utilization





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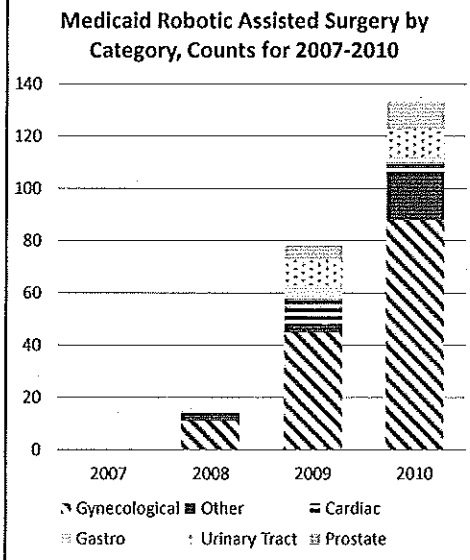
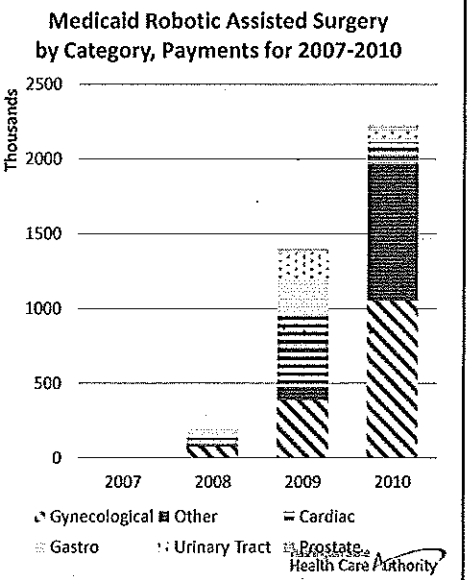
Robotic Assisted Surgery State Agency Utilization





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Robotic Assisted Surgery: Other Centers, Agencies and HTAs

Centers for Medicare & Medicaid

- No NCD
- No LCD
- HCPCS Code S2900 added in July 2005, remains on list of non-reimbursable codes

Hayes

- Robotic Assisted Prostatectomy (April 28, 2008) = C
- Robotically Assisted Nephrectomy for Renal Malignancy = C
- Robotically Assisted Coronary Artery Bypass Surgery (Oct 1, 2008) = C/D
- Pediatric Robotically Assisted Surgery (July 2, 2010) = C
- Robotically Assisted Hysterectomy (June 7, 2010) = C
- Robotically Assisted Adrenalectomy (report archived June 9, 2006) = D

Robotic Assisted Surgery: Private Payers

Aetna

- No specific policy addressing robotic assisted technology

Cigna

- Reimbursement Policy R04: Does not provide additional reimbursement for the use of robotic surgical devices (da Vinci™ Surgical System, ZEUS™ Robotic Surgical System)

Group Health

- No specific policy addressing robotic assisted technology

HealthNet

- Does not provide additional reimbursement for the use of robotic surgical devices

Robotic Assisted Surgery: Risks & Benefits

Risks

- Escalation of costs with increased utilization
- May bias care decisions towards a surgical approach, without supporting comparative effectiveness evidence
- Widespread adoption of technology without evidence to support equivalent or superior outcomes
- Lack of externally regulated certification and determination of clinician, technician, and facility competency

Benefits

- Enable minimally invasive approach which otherwise may not be technically feasible

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Robotic Assisted Surgery State Agencies Summary

- To date, there is a lack of high quality medical evidence addressing the impact of robotic assisted technology on clinically meaningful surgical outcomes.

- Robotic assisted surgery is a method of performing the procedure and is not a separate service, it is a matter of choice of the surgeon.

- Determination of medical necessity is based upon the surgical procedure and not the technology, with reimbursement also based upon the surgical procedure.

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Robotic Assisted Surgery
State Agencies Recommendation

- Evidence on safety is not robust, particularly with respect to reoperation rate, intraoperative blood loss, postoperative stay.
- Evidence on effectiveness for clinically meaningful outcomes is limited.
- Cost: substantial provider cost (utilization incentive), add-on codes, longer procedures

Robotic Assisted Surgery
State Agencies Recommendation

Evidence is not compelling and may have added safety risks.

If covered, limit to conditions where added benefit is proven, or when a surgical procedure cannot otherwise be performed.

Leave authority to determine added payment to agencies.

Questions?

More Information:
http://hta.hca.wa.gov

Washington State Health Care Authority

OREGON HEALTH & SCIENCE UNIVERSITY

Robotic Assisted Surgery

Presented by: Kori Gieltshnam MD, MPH and Kendra Sunker, MPH
Center for Evidence-based Policy
Date: May 18, 2012

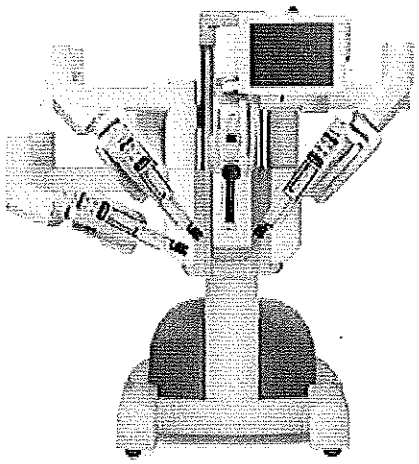
Introduction

- Background
- PICO
- Methods
- Key Questions
- Results
- Guidelines and Policy Summary
- Overall Summary

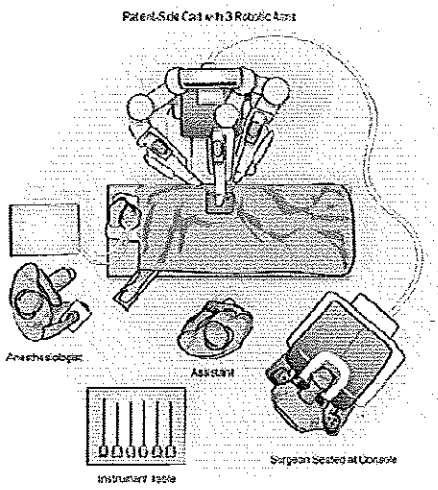
Background – *Clinical Overview*

- Robotic surgical systems assist surgeons in performing minimally-invasive procedures
- The *da Vinci*® robot (Intuitive Surgical) was FDA approved in 2000 for general laparoscopic surgery
- In 2010, 278,000 *da Vinci*® procedures were performed
  - 35% increase from 2009
  - 30% increase in the number of procedures expected for 2011

Background – *The da Vinci® Surgical System*



Background – *The da Vinci® Surgical System*



PICO

- **Population:** Adults with planned surgeries that could be performed with the help of a robot-assisted surgery (RAS) device
- **Intervention:** Surgery with the assistance of robotic control
- **Comparator:** Surgeries without robotic assistance (open or laparoscopic)
- **Outcome:** Hospital length of stay, health care resource utilization, recovery of activities of daily living, quality of life, overall mortality, disease specific mortality or survival, cancer recurrence, adverse events (e.g., morbidity, mortality, reoperation, complication rates, increased bleeding), healing time, cost, cost effectiveness

Methods

- Canadian Agency for Drugs and Technologies in Health (CADTH), *Robot-Assisted Surgery Compared with Open Surgery and Laparoscopic Surgery: Clinical Effectiveness and Economic Analyses (2011)*
  - Prostatectomy, hysterectomy, nephrectomy, and cardiac surgeries
- 'Best evidence' systematic review methodology by procedure
  - Recent, good quality SR/TA
  - MEDLINE search for subsequently published individual studies
  - 10 year MEDLINE search for individual studies if no SR/TA identified

Methods (cont)

- Quality Assessment
  - Methodological quality of SRs and individual studies assessed
    - Good
    - Fair
    - Poor
  - CADTH studies– two extra levels (good-fair, fair-poor)
- GRADE system used to rate the overall strength of evidence (SOE)

High	⊕⊕⊕⊕	Low	⊕⊕OO
Moderate	⊕⊕⊕O	Very low	⊕OOO

Results

- 644 citations reviewed
  - 59 met inclusion criteria
    - 5 SRs and 54 individual studies
    - Most studies were retrospective cohort studies
- ~ 200 citations submitted during public comment period
  - 20 studies met inclusion criteria

Key Questions and Results

Key Questions

- KQ #1 Clinical efficacy and effectiveness
- KQ #2 Adverse events
- KQ #3 Sub populations including operative experience, patient characteristics
- KQ #4 Costs and cost effectiveness

Findings are presented grouped by strength of evidence (SOE)

- SOE Moderate (by CADTH, then other procedures for KQs #1 & #2)
- SOE Low and Very Low are presented in aggregate (KQs #1 & #2)
- KQs #3 & #4 findings are presented in aggregate

Robotic Prostatectomy (Prostatic Cancer)

Number of Studies: 55
Quality rating: 1 high, 7 good, 35 good-fair, 1 fair, 8 fair-poor, 3 poor

	⊕⊕⊕O **Moderate**
Laparoscopic	KQ #1 *Efficacy* ↓Operative time, LOS, EBL, transfusion risk ↔ Positive margin rates KQ #2 *Harms* ↔Complication rate
Open	KQ #1 *Efficacy* ↓ LOS, EBL, transfusion risk, positive margin rates (pT2 pts) ↑ Operative time, urinary continence (12 months), sexual function return (12 months) KQ #2 *Harms* ↔ Complication rate

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Robotic Hysterectomy (Endometrial or early stage cervical cancer)

Number of Studies: 34
Quality rating: 7 good, 16 good-fair, 2 fair, 5 fair-poor, 4 poor

	⊕⊕⊕O **Moderate**
Laparoscopic	KQ #1 *Efficacy* ↓ LOS, EBL ↔ Operative time, transfusion risk KQ #2 *Harms* ↓ Complication rate
Open	KQ #1 *Efficacy* ↓ LOS, EBL, transfusion risk ↑ Operative time KQ #2 *Harms* ↓ Complication rate

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Robotic Radical Cystectomy (Bladder Cancer)

Number of Studies: 1 SR (3 studies) + 5 subsequent studies
Quality rating: 1 good quality SR, 2 good studies, 3 fair studies

	⊕⊕⊕O **Moderate**
Open	KQ #1 *Efficacy* ↓ EBL, LOS ↑ Operative time KQ #2 *Harms* ↔ Complication rate

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Robotic vs. Laparoscopic Procedures

1 Good quality SR	⊕⊕⊕O **Moderate**
Fundoplication SR (9 studies) + no subsequent studies	KQ #1 *Efficacy* ↔ LOS, operative time KQ #2 *Harms* ↔ Risk of complications
Colorectal Procedures SR (7 studies) + 7 subsequent studies of poor quality	KQ #1 *Efficacy* ↓ EBL, LOS ↔ Bowel function return, oral diet return
Roux-en-Y Gastric Bypass SR (4 studies) + 2 subsequent studies of poor quality	KQ #1 *Efficacy* ↔ Operative time KQ #2 *Harms* ↑ Odds of conversion

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Other Procedures – Low & Very Low SOE (KQs #1 & 2)

- High risk of bias limited findings
- Common robotic group statistically significant findings:
  - Longer operative times
  - Shorter LOS
  - Decreased EBL
  - Similar complication rates

Adjustable gastric banding	Lung surgery
Adnexectomy	Myomectomy
Adrenalectomy	Nephrectomy
Cardiac surgeries	Oropharyngeal surgery
Cholecystectomy	Pancreatectomy
Esophagectomy	Pyeloplasty
Fallopian tube reanastomosis	Rectopexy
Gastrectomy	Sacrocolpopexy
Heller myotomy	Splenectomy
Ileovesicostomy	Thymectomy
Liver resection	Thyroidectomy
	Trachelectomy
	Vesico-vaginal fistula repair

KQ #3 Differential Efficacy in Sub populations Surgeon Experience

Prostatectomy

- **Moderate SOE** that surgeons experienced in robotic prostatectomy had improvements for most clinical outcomes (e.g., operative time, LOS, complications, PSM rates)
  - Example: LOS shorter by 1.5 days less experienced group vs. 2 days shorter for experienced group
  - Exception was EBL which was unchanged with experience

KQ #3 Differential Efficacy in Sub populations Surgeon Experience

- **Low or very low SOE** that robotic proficiency influenced outcomes for several procedures:

Colorectal resection	Cholecystectomy
Heller myotomy	Hysterectomy
Lobectomy	Mitral valve repair
Thyroidectomy	

KQ #3 Differential Efficacy in Sub populations High BMI

- **Low SOE for three procedures**
  - **Hysterectomy (robotic vs. open)**
    - ↑ Operative time
    - ↓ EBL, LOS, complication rate, complication severity
  - **Roux-en-Y gastric bypass (robotic vs. laparoscopic)**
    - ↓ Operative times as obesity increased
  - **Adjustable gastric banding (robotic vs. laparoscopic)**
    - ↓ Operative times in patients with BMI ≥ 50
    - ↔ LOS, weight loss at one year, conversions to open

KQ #4 Costs and Cost Effectiveness

- Overall, robotic procedures were more costly than laparoscopic or open procedures
  - Potential cost offsets were:
    - Shorter LOS; and
    - Increased robotic caseloads
- Prostatectomy had **moderate SOE** but most studies offered **very low to low SOE** to address economic questions
- Cost-effectiveness studies were limited by lack of long-term efficacy results for interventions

Guideline and Policy Summary

- 15 relevant guidelines identified
  - 1 good, 13 fair, 1 poor quality (tool adapted from AGREE)
  - When laparoscopic procedure indicated, the robotic procedure typically considered acceptable alternative
- No Medicare National or Local Coverage Determinations
  - Since 2005 Medicare has identified robotic assisted surgery as a non-reportable code and does not provide additional reimbursement
- Aetna, Group Health, BCBS
  - Do not provide additional reimbursement for robotic assisted surgery

Overall Summary – Moderate SOE Findings Robotic vs. Open Surgery

- Operative times – increased
  - Prostatectomy, hysterectomy, cystectomy
- LOS – decreased
  - Prostatectomy, hysterectomy, cystectomy
- EBL – decreased
  - Prostatectomy, hysterectomy, cystecomy

Overall Summary – Moderate SOE Findings Robotic vs. Laparoscopic Surgery

- Operative time – similar or decreased
  - Prostatectomy, hysterectomy, fundoplication, Roux-en-Y gastric bypass
- LOS – similar or decreased
  - Prostatectomy, hysterectomy, cystectomy, fundoplication, colorectal resection
- EBL – similar or decreased
  - Prostatectomy, hysterectomy, cystectomy, colorectal resection

Overall Summary (cont)

- Adverse events and rates of complications are generally similar
- Lack of evidence regarding improvements in surgical outcomes with increasing experience for most procedures
- Robotic procedures were more costly than comparators, some offsets were shorter LOS and increased robotic caseloads

Overall Limitations of the Evidence

- Largely retrospective cohort studies with methodological limitations
  - Small sample sizes, variable control groups, baseline group differences, and inadequate control of confounders
- Heterogeneity noted across trials
- Long-term outcomes not studied for most procedures
- Economic studies limited by lack of long-term outcomes

Questions or comments?

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards. [2]

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms.[3]

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

Using Evidence as the basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- the amount of evidence (sparse to many number of evidence or events or individuals studied);
- consistency of evidence (results vary or largely similar);
- recency (timeliness of information);
- directness of evidence (link between technology and outcome);
- relevance of evidence (applicability to agency program and clients);
- bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion at vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- risk of event occurring;
- the degree of harm associated with risk;
- the number of risks; the burden of the condition;
- burden untreated or treated with alternatives;
- the importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- the degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- value variation based on patient preference.

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

Medicare Coverage

Medicare

Medicare has not issued national or local coverage determinations addressing robotic assisted surgery. Since 2005, Medicare has identified robotic assisted surgery as a non-reportable code (S2900), and does not provide additional reimbursement for the use of robotic surgical techniques. Reimbursement is based on the underlying surgical procedure performed.

Guidelines (Page 110 of WA HTA Report)

Author, year	Condition	Evidence Base	Quality	Recommendation
Prostatectomy				
American Urological Association, 2010	benign prostatic hyperplasia	Systematic review and panel consensus	Poor	When laparoscopic prostatectomy is indicated, use of robotic technology is included in recommendation
NICE, 2008a	benign prostatic obstruction	Systematic review	Fair	Laparoscopic prostatectomy with or without computer (robotic) assistance is not recommended
NICE, 2008b	prostate cancer	Systematic review	Fair	When laparoscopic prostatectomy is indicated, use of robotic technology is included in recommendation
NICE, 2006	prostate cancer	Systematic review	Fair	Robotically assisted laparoscopic prostatectomy is a development of this procedure but it is not recommended
Spanish NHS, 2008	prostate cancer	Systematic review	Good	When laparoscopic prostatectomy is indicated, use of robotic technology is included in recommendation
National Comprehensive Cancer Network (NCCN), 2012a	prostate cancer	Systematic review	Fair	Laparoscopic & robotic-assisted radical prostatectomy are used commonly
Cystectomy				
European Association of Urology, 2011	bladder cancer	Systematic review	Fair	Laparoscopic and robotic-assisted laparoscopic cystectomy is feasbile but still investigational
NICE, 2009a	bladder cancer	Systematic review	Fair	Laparoscopic cystectomy recommended including with computer (robotic) assistance.
Other procedures				
NCCN, 2011	Esophagogastrectomy for esophageal and esophagogastric junction cancers	Systematic review	Fair	Robotic considered acceptable operative approach
NCCN, 2012b	Radical and partial nephrectomy for kidney cancer	Systematic review	Fair	Open, laparoscopic or robotic surgical techniques may be used
NICE, 2008c	Coronary artery bypass grafting (CABG) for coronary artery disease	Systematic review	Fair	Totally endoscopic robotically assisted procedure not recommended
NICE, 2009b	Pyeloplasty for pelviureteric junction obstruction	Systematic review	Fair	When laparoscopic pyeloplasty is indicated, use of robotic technology is included in recommendation
Society of American	Myotomy for esophageal	Systematic	Fair	Weak recommendation for use of

Author, year	Condition	Evidence Base	Quality	Recommendation
Gastrointestinal and Endoscopic Surgeons (SAGES), 2011	achalasia	review		robotic assistance
SAGES, 2010	Fundoplication for GERD	Systematic review	Fair	Robotic recommended
NCCN, 2012a	Pelvic lymph node dissection for prostate cancer	Systematic review	Fair	Can be performed using an open, laparoscopic or robotic technique

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

	Robotic Assisted Surgery
Safety Outcomes	**Safety Evidence**
Adverse events	
Morbidity	
Mortality	
Reoperation	
Excess blood loss	
Extended hospital stay	
Operative time	
	Efficacy / Effectiveness Evidence
Morbidity	
Mortality	
Healing time/recovery of ADLs	
Length of stay	
Blood loss	
Positive margin rate	
Cancer recurrence	
Quality of life	
Operative time	

Special Population / Considerations Outcomes	**Special Population Evidence**
Gender	
Age	
Comorbidities (including smoking, alcohol use, psychological)	
BMI	
Other characteristics	
Provider type, setting, experience, other	
Payer or Beneficiary Type	
Cost	**Cost Evidence**
Total Health Care Costs / Societal Costs	
Direct and indirect	
Cost Effectiveness	

Clinical Committee Evidence Votes

First voting question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second vote
Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not Covered. _____ Covered Unconditionally. _____ Covered Under Certain Conditions.

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions
If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
    - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
    - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?