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