Robot-Assisted Surgeries
A Project for CADTH, a Decision for Jurisdictions

2012 CADTH Symposium Panel Discussion

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“We NEED this!”
What is a Surgical Robot?

The *da Vinci*® Surgical System
The da Vinci® Surgical System

- Surgeon Console
- Patient-side cart with 4 arms
- 3D HD vision system
- Miniaturized wristed instruments
Why Surgical Robotics?

• Less pain
• Less blood loss
• Shorter hospital stay
• Fewer complications
• Excellent cancer control
• Faster return to work
Why Surgical Robotics?

- Less surgeon fatigue
- Less repetitive strain
- Physician retention
- Physician recruitment
- Resident training
Why NOT Surgical Robotics?

- Significant costs – capital and operating
  - da Vinci Si Surgical System: $2,600,000
  - Start-up reusable equipment and accessories: $200,000
  - Disposables and consumables (per procedure): $2,500
  - Training of surgeons† (each): $6,000
  - Training of other personnel
    - Nursing and CPD in-service at no charge
  - Annual maintenance (after first year warranty): $175,000

- Limited budgets
- Limited evidence
- Cost/benefit uncertain
How to Choose?
Captain CADTH to the Rescue!
The Real Captain CADTH?
The Real CADTH...
Canadian Agency for Drugs and Technologies in Health (CADTH)

- Founded in 1989 by Canada’s federal, provincial, and territorial Ministers of Health
- Independent, not-for-profit
- Funded by Health Canada, the provinces, and territories
- 145 employees, $22.5M budget

CADTH supports informed decisions by providing impartial, evidence-based research and advice on drugs, medical devices, and other health technologies.
CADTH’s Customers and Users

- Government policy- and decision-makers
- Public drug plan managers
- Regional health authorities
- Hospitals and other health care facilities
- Health professionals
- Patients
CADTH’s Products and Services

CADTH conducts health technology assessments on drugs, non-drug technologies, and procedures

- Environmental Scans
- Rapid Response Service
- Drug Formulary Recommendations
- Therapeutic Reviews
- Optimal Use Advice, Recommendations, and Tools
How CADTH Helps

CADTH provides the EVIDENCE piece to the decision-making puzzle
In 2009/10, robot-assisted surgical programs were progressively developing in Canada due to the availability of the *Da-Vinci Surgical System* (Intuitive Surgical Inc.).

- Robot-assisted surgery may offer benefits to patients and surgeons, but the costs to acquire, maintain, and operate the system are significant.

- Information needed to inform decisions about the acquisition of the technology, its use or expanded use.
Need for CADTH work:

One RHA submitted a request for CADTH to undertake an HTA decision about expanding the RHA robot-assisted surgery pilot project to include procedures other than prostatectomy

+ 

Two provinces expressed interest in CADTH undertaking an evaluation of robot-assisted surgery to inform policy development
Project Background

Alberta Health and Wellness

Develop provincial policy on robot-assisted surgery

CADTH HTA report = source of the technical information (clinical and economic effectiveness) for Alberta policy development framework
Project Background

- CADTH Advisory Committee initially prioritized this topic for HTA work for urology and cardiac procedures.

- Through topic refinement activities, and in order to meet CADTH client needs, the HTA project was expanded to include the following indications: gynaecological, urological, renal, and cardiology procedures including but not limited to:
  - Hysterectomy
  - Prostatectomy
  - Nephrectomy (partial nephrectomy)
  - Cardiac surgery (atrial septal defect repair, mitral valve repair, CABG)
Methods

• **Clinical assessment:**
  • Systematic review with meta-analyses to compare the clinical effectiveness between robot-assisted, open, and laparoscopic surgeries

• **Economic assessment:**
  • Systematic review of economic studies
  • Primary economic evaluation (cost-minimization analysis) to compare the relative costs of robot-assisted radical prostatectomy with open and laparoscopic radical prostatectomy

• **Budget impact analysis**
Challenges

• No randomized clinical trials → observational studies (many retrospective) + heterogeneity → lower quality evidence

• Limited clinical data for cardiac surgery and total nephrectomy

• Limited Canadian economic evaluations

• Scarcity of data on long-term outcomes (e.g. survival rates, quality of life, time to return to work) → cost-minimization analysis
Key Findings – Clinical

• **Shorter length of hospital stay versus:**
  - Open and laparoscopic prostatectomy
  - Open and laparoscopic hysterectomy
  - Laparoscopic partial nephrectomy

• **Reduced blood loss and transfusion rates versus:**
  - Open and laparoscopic prostatectomy
  - Open hysterectomy

• **Reduced positive margin rates (cancer left after surgery) versus open prostatectomy in patients with stage II prostate cancer (tumor confined to prostate)**
Key Findings – Clinical

• Reduced post-operative complication rates (e.g. wound infection, blood clots, ...) versus open and laparoscopic hysterectomy

• Operative time:
  • Reduced versus laparoscopic prostatectomy
  • Increased versus open prostatectomy and open hysterectomy

• Cardiac surgery (mitral valve repair):
  • Data suggest shorter length of hospital stay
Key Findings – Economic

- Shorter length of stay after robot-assisted radical prostatectomy reduced hospitalization costs versus open and laparoscopic radical prostatectomy

  BUT

- High acquisition, operating, and maintenance costs of the surgical robot system

  ↓

  Higher per patient cost
### Key Findings – Economic

#### Incremental Costs per patient

<table>
<thead>
<tr>
<th>Robot-assisted versus open prostatectomy</th>
<th>Robot-assisted versus laparoscopic prostatectomy</th>
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<td>$3860</td>
<td>$4625</td>
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Key Findings – Budget Impact Analysis

• Estimated net institutional costs for operating a surgical robotic program using the *da Vinci Si Surgical System* for 7 years:

  ↓

  $2.9$ million

• Institutional costs (over 7 years) of robot-assisted surgery program vary depending on indications:
  - Cardiac surgery: $0.9$ million
  - Prostatectomy: $3.5$ million
Strategies to Optimize Cost-effective Use

• Maximize caseloads

• Operate the surgical robot for longer periods

• Use the surgical robot for different surgical indications
Alberta Health Technologies Decision Process: Policy Development on Surgical Robotics

CADTH Symposium
April, 2012

Nina Buscemi, PhD
Clinical Advisory and Research Branch, Alberta Health and Wellness
Challenges

- Health system growth
- Range of publicly funded services and benefits
- Cost escalation
- Competing priorities
- Sustainability
Decision Process

- Explicit bridge between evidence and policy
- Provincial level implications
- 4 principles (transparency, rigor, timeliness and flexibility)
- Uses STEP analytic framework
  - STE analysis conducted by HTA partners
  - P analysis conducted by AHW
  - EAG advises on review
- 4 stages
Scope of Decision Process

- Focus on high impact technologies

- Devices and procedures in scope
  - Diagnosis, treatment, management

- Health Canada licensed technologies
Alberta Advisory Committee on Health Technologies

• Advises on:
  – Decision Process
  – selection of technologies for review
  – findings and recommendations of reviews

• Membership:
  – Alberta Health and Wellness (Chair)
  – Alberta Health Services (Co-Chair)
  – Alberta Medical Association
  – College of Physicians and Surgeons of Alberta
  – College and Association of Registered Nurses of Alberta
  – Industry (MEDEC)
  – HTA partners (IHE, UofA, UofC)
  – CADTH (standing guest)
Provincial Review of Surgical Robotics

• Decision to review surgical robotics for various indications
  – CADTH report to inform policy

• Engaged a clinician and a senior administrator from Alberta
  – Advised on results and implications for policy development

• Should surgical robotics be established as a publicly funded health technology in Alberta?
Key Policy Considerations

• Legislative and regulatory frameworks

• Coverage and diffusion status

• Government’s strategic direction (AHW Business Plan, 2011-2014)

• Quality assurance

• Potential effects of the decision

• Ethical, psychosocial & care considerations
Legislative and Regulatory Frameworks

Federal Level:

- First-generation da Vinci® Surgical System licensed as Class 4 medical device in 2001
- Third-generation da Vinci® Si approved in 2010

Provincial Level:

- No obvious legislative impediments → licensed medical device used in 3 provincial hospitals
Coverage and Diffusion Status

- Provinces that have surgical robots: Quebec (4), Ontario (6) and BC (1)
  - prostatectomy most frequent procedure

- Purchased through charitable donations

- Physicians bill for standard laparoscopic procedure – no fee codes for robotic surgery
Alberta Context

• Edmonton:
  – Royal Alexandra Hospital
  – University of Alberta Hospital

• Calgary:
  – Rockyview Hospital

• Purchased through charitable donations

• 430 robot-assisted surgeries performed in 2010 (87% prostatectomy)

• AHS prostate cancer guideline lists RARP as treatment option for low risk patients
Government’s Strategic Direction

• **Goal 4 - Excellence in health care:**
  – Leading introduction, integration and management of new and existing technologies
  – Further implementing HTA processes to support evidence-informed decision-making

• Robotic surgery - innovative procedure with a number of potential applications

• Alberta in position to provide leadership
Quality Assurance

• No training and credentialing standards for surgeons

• Learning curve depends on procedure and prior experience

• Must be delivered in tertiary level hospitals with established QA processes
Potential Effects of Decision

Impact on Patients:
• Decision to establish, expand or terminate funding would likely have little impact on patients
  – No difference in patient pool for different approaches
  – Clinical and quality of life benefits unclear
  – Geographical access issues would remain
Potential Effects of Decision

Impact on Health System and Providers:

- Decision to establish or expand funding would require additional expenditures for robots

- Decision to establish or expand funding would likely have positive impact on physician stakeholders

- Decision to terminate provision could have negative impact on physicians’ practice patterns, and Alberta risks falling behind other jurisdictions
Potential Effects of Decision

Impact on Technology Providers:

• Decision to establish, expand or terminate funding would have minimal impact on the manufacturer
  – As of September 2011, about 2000 units shipped worldwide
  – Currently, only 14 in Canada
Ethical, Psychosocial and Care Considerations

• HTA suggests larger centers best suited

• Tertiary care environment required

• Presents geographical access issues
Policy Options

- **Option 1**: Maintain the *status quo* and reassess the technology when more evidence becomes available.
- **Option 2**: Maintain the *status quo* with formal data collection and reassessment in two years.
- **Option 3**: Establish public funding of surgical robotics—with a commitment to ongoing capital and operating costs—and incorporate into clinical practice guidelines.
- **Option 4**: Expand public provision—and establish public funding—of surgical robotics in Alberta.
- **Option 5**: Terminate use of surgical robotics in Alberta.
Next Steps

• Policy options will be discussed with Advisory Committee

• Review findings and options will be presented to key stakeholders

• Recommendation will be developed for Ministry’s senior leadership for decision