Introduction

Robotic-assisted surgery was first performed in 1985 to conduct a neurosurgical procedure requiring delicate precision. With its success, the first robotic-assisted laparoscopic cholecystectomy was then performed in 1987 (1). Despite these early successes, robotic surgery did not enter the mainstream until 2000, when da Vinci (developed by Intuitive Surgical) was first approved for use by the US Food and Drug Administration (FDA). The company’s marketing has focused heavily on da Vinci’s ability to deliver improved dexterity, visualization, and consistency when compared to the current standard laparoscopic surgical technique. Since that time, it has become a staple of the American healthcare system, with more than 2,800 hospitals investing in the technology by 2017 (2). Its success has been fueled in part by studies demonstrating quicker patient recovery times, less blood loss, and less pain, especially when compared to conventional open surgery. This has led to increasing patient and surgeon demand for access to robotic surgery. In 2017, Intuitive noted a 32% year-over-year growth in the use of its robotic surgery systems among general surgeons (3).
According to an RBC Capital Markets 2015 survey, surgeons expect that their robotic surgery volumes will account for up to 35% of their operative volume in 2018. Furthermore, surgeons expect significant growth in robotic colorectal, gastric, hernia, hepatobiliary, and pancreatic procedures (4).

The robotic surgery industry generates almost $3 billion in revenues per year, and this number is expected to grow by almost 15% per year until 2022 (5). For years, Intuitive has been the only major market player in the industry. Effectively a monopoly, Intuitive has been able to enjoy significant price control over the technology; enjoying huge profit margins as a result. Despite exponential growth, implementation costs of robotic surgery technology are often prohibitive for smaller health care systems and hospitals; many hospitals which invest in robotic surgery often take years to see a return on their investment, if at all. Additionally, surgeons and critics have noted some weaknesses and frustrations with the current technology, calling for easier docking/setup, haptic feedback, better stapling devices, and lower system/instrument costs (4). The continued growth in the industry combined with a need to address the perceived weakness of current technology have led to the emergence of new competitors; promising cutting-edge innovations, new uses, and/or lower costs.

When assessing the value of robotic-assisted surgery, several factors should be considered. While one individual or group may see value in a specific factor, another may not deem this factor nearly as valuable. For example, a surgeon may value the robot for its ability to facilitate an otherwise difficult surgery; a patient may value the robot because of its appeal as a state-of-the-art technology promising reduced incidence of pain and scarring; a hospital may value the robot based on its effect on decreasing length of stay (LOS) and the overall financial impact on its operations. With the understanding that these are all important factors, this report will focus on how hospitals and other health care systems can derive value in robotic surgery. It will provide a brief overview of the current players in the robotic surgery industry, discuss important factors that health systems must consider as they pursue further investments in the technology (including a discussion of some of the literature regarding outcomes and costs of robotics); discuss some of the ways that a healthcare executive can leverage robotic surgery to create value in patient care and continue its mission as a forward thinking and state-of-the-art healthcare system.

### The players

#### Intuitive Surgical

Intuitive surgical was founded in 1995 as a way to attempt commercialization of a robotic surgery prototype developed in conjunction with the U.S Army, originally funded with the interest in remotely performing battlefield surgery (6). In 1999, Intuitive launched the da Vinci system and in 2000, it became the first robotic surgical system cleared by the FDA for use in general laparoscopic surgery. Since that time, its indications have expanded into cardiothoracic, urologic, gynecologic, and pediatric surgery. In 2017, Intuitive estimates that over 875,000 da Vinci procedures were performed, up from 523,000 in 2013 (2).

The da Vinci system and its most advanced model, the Xi, is composed of a semi-enclosed master console and a mobile platform with movable robotic arms. Each arm has three degrees of freedom (DOF), and when combined with its proprietary EndoWrist instrument, adds an additional seven DOF to mimic the movements of the human wrist (2). The master console allows the surgeon a magnified high-definition 3D view of the surgical field; the surgeon is able to control the slave (robotic arms) from the console via finger-controlled cuffs. The console is created with surgeons in mind and includes multiple customizable adjustments to suit an individual’s preference. In combination with more than 50 available instruments for the Xi system, da Vinci facilitates precision through its high-resolution 3D visualization, tremor filtration, motion scaling, and a comfortable user interface (3).

The da Vinci system requires an upfront capital investment, ranging in price from $0.5 to $2.5 million, depending on the model, configuration, and geographic location. Recurring costs include: annual service contracts (ranging in price from $80,000–170,000 based on model and services desired), instrument and accessory costs (ranging from $700–$3,500 per procedure). Interestingly, in 2013 Intuitive’s instrument revenue exceeded robotic system revenue, bringing into clarity its corporate strategy, “the more cases, the better.” This led to a focus on increasing robotic case volume rather than selling more systems. To that end, Intuitive has begun a leasing program which aims to lower the entry barriers for lower-resource hospitals (3).

#### TransEnterix

Founded in 2006, TransEnterix is a medical device company with the goal of “digitizing the interface between the
surgeon and the patient to improve minimally invasive surgery by addressing the clinical and economic challenges associated with current laparoscopic and robotic options in today's value-based healthcare environment” (7). Its Senhance Surgical Robotic System is a multi-port robotic system which attempts to address the perceived weaknesses of da Vinci; offering similar surgeon control of multiple robotic arms while providing 3D-HD vision, haptic feedback, and surgeon camera control via eye movements. The overall control of the Senhance system is similar to laparoscopy, as opposed to the master console interface of the da Vinci system. In October 2017, Senhance was approved by the FDA for use in colorectal and gynecological surgery; in early 2018, its indications were expanded to include cholecystectomy (gallbladder removal) and ventral hernia repair. Additionally, FDA approval for the first robotic 3 mm instruments was received in October 2018. Ultrasonic devices as well as articulating instruments have already received CE Mark certification in Europe, and FDA approval is expected sometime in 2019 (7).

As of the end of 2018, TransEnterix has sold five Senhance systems in the US, at an estimated cost of $1.3 million (US revenue from a single sale in 2017 is listed as 18% of total revenues on its annual report). According to the company, Senhance's operational costs are lower than the competition, as its instruments are reusable for indefinite periods via standard hospital instrument reprocessing. Additionally, the system has the capability to leverage existing hospital visualization systems. The costs of service contracts and instruments are not disclosed at this time (7). However, preliminary trials have shown a fundamental difference in the pricing structure between Senhance and da Vinci—With da Vinci, hospital expenses increase in proportion to case volume (due to proprietary instruments with limited lifespans); with Senhance, hospital expenses remain relatively unchanged despite increased case volume (due to reusable instruments with “unlimited” uses) (8).

Titan medical
Titan Medical is a Toronto-based medical device company currently developing the Single Port Orifice Robotic Technology (SPORT) Surgical System. This system is comprised of a workstation and a robotic platform controlled by the surgeon via hand controls (similar to laparoscopic instruments), foot pedals, and a touchscreen. The robotic platform has a collapsible system that is inserted through a single 25mm incision and features multiple multi-articulated instruments. The instruments use single-use replaceable tips. The system has been validated on animal models and is pending FDA approval. Pricing has not been disclosed.

Human Xtensions
This Israeli startup focuses on developing handheld digital solutions for minimally invasive surgery. Its HandX system, designed as a light-weight, hand-held device which translates a surgeon's natural hand motions into complex movements inside the patient, received FDA approval in March 2018. It consists of a computerized, reusable handpiece which translates surgeon hand movements to a single-use articulating instrument tip. The instrument is highly customizable for any skill level, and the company believes that it offers an “affordable alternative to the heavyweight robotic systems that are operated remotely” (9). The first HandX case in the US was performed here at Buffalo General Hospital; multiple successful cases have since been performed around the country. As of October 2018, the cost of the handpiece is approximately $44,000, with pricing for the instruments estimated to be around 5% of the cost of Da Vinci (8).

Medrobotics
This Massachusetts-based company has developed the Flex® Robotic System, which is based on a flexible, steerable scope that surgeons can use to navigate around anatomy with an integrated 3D high-definition vision system. Once it is in place, the scope can become rigid to provide a stable platform through which flexible instruments can be deployed to perform procedures in a way that is not possible with line-of-sight approaches (10). Initially approved for limited applications in otolaryngology, the system has received FDA approval for marketing in general surgical, gynecological and thoracic procedures as of January 2018. The first commercial sale of the Flex Robotic System for GI applications came in October 2018 in Europe for an undisclosed amount. As of October 2018, approximately 100 cases have been performed with this device: 80% transoral and 20% transanal (11).

Systems in development
Versius
CMR Surgical (CMR) hopes to launch its Versius robot in the US in 2019. The system consists of a set of independent
arms, each with their own base, which are meant to be smaller, more lightweight, and portable enough to move around the table during surgery or between ORs as needed. Additionally, the arms are “built like a human arm,” with 3 joints meant to mimic the movement of the human shoulder, elbow and wrist, respectively. CMR will offer a several flexible payment models, from the traditional up-front capital model to a ‘managed service’ in which the robot, all required instrumentation, and maintenance are bundled into an annual contract based on agreed procedure volumes, with the intent to reduce the lifetime cost of robotic surgery (12).

Einstein
Medical device giant Medtronic is also in the late stages of development of its robot, with plans to begin patient trials in the coming year. There are very limited details on the specifications and design of the Medtronic robot. Its presumed benefit will be its interoperability with the Medtronic laparoscopic instruments which are commonplace at hospitals around the world. In fact, the purpose of the system is thought to be in response to the development of stapling and energy instruments by rival Intuitive, as a strategy to protect its core businesses.

Verb Surgical
A joint venture between Johnson & Johnson and Google, Verb Surgical was formed in 2015 to develop “a digital surgery platform that combines robotics, advanced visualization, advanced instrumentation, data analytics, and connectivity (13)” The goal is to advance robotic surgery by making technology and information available to more patients and reduce overall costs of care. No specifics have been disclosed.

Considerations
Indications/outcomes
With the advent of laparoscopic surgery in the 1980’s, surgeons were now able to perform complex surgeries with decreased pain, scarring, and length of stay when compared to open surgery. Today, minimally invasive surgery via laparoscopy has become the gold standard for some common surgical procedures across multiple surgical subspecialties. It has been proven to be as effective as open surgery, but is associated with decreased operative times, smaller incisions and postoperative pain, shorter LOS, and improved patient satisfaction (14). Today, advanced laparoscopic surgeons perform complex surgeries, such as pancreaticoduodenectomies for pancreatic cancer, or lung resections via the minimally invasive approach.

Despite major advances, laparoscopy does have limitations. These include a steep learning curve, limited maneuverability of instruments, poor ergonomics, and lower quality 2-D visualization. In response to some of these perceived weaknesses, robotic surgery surfaced as a natural progression. Today, da Vinci is approved for a wide range of procedures across a variety of specialties, including urology, gynecology, general surgery, thoracic surgery, and pediatric surgery. The important question then becomes: “Is robotic surgery better than the currently available technology?” As the field has expanded, the available literature on robotic surgery has grown exponentially. Unfortunately, the available data is inconsistent, with variable metrics and outcomes measured, especially across specialties. Additionally, there remains a paucity of prospective long-term outcomes data.

After it failed attempts to enter beachhead markets in cardiac and general surgery, Robotic-assisted surgery first gained prominence in the field of urologic oncology for the treatment of prostate cancer, where laparoscopic surgery was rarely performed due to complexity and difficult maneuverability in the deep pelvis. One large observational cohort study showed that patients undergoing robotic prostatectomy experienced shorter LOS (2.0 vs. 3.0 days), lower requirements for blood transfusion (2.7% vs. 20.8%), fewer postoperative respiratory and other complications when compared to open radical prostatectomy. Additionally, rates of additional cancer therapy use were similar; robotic surgery was associated with increased risk of genitourinary complications and diagnoses of incontinence and erectile dysfunction (15). Newer meta-analyses have demonstrated that rates of nerve-sparing, recovery of complete continence, and recovery of erectile function were significantly higher following robotic prostatectomy (16). It is likely that these improved functional outcomes are a result of improved surgeon education/experience, evolved technique, newer technology, or any combination of these.

While studies have demonstrated a benefit of robotic prostatectomy over the conventional open procedure, there has not been any significant research showing clear short-term benefits of robotic surgery over laparoscopy. Robotic-assisted hysterectomies (removal of the uterus) have increased in prevalence in recent years. While most studies have not shown improved effectiveness or safety...
over conventional laparoscopy, one study noted an increase in robotic hysterectomies attributed to several factors: (I) Robotic surgery is easier to learn than laparoscopy. (II) Robotic surgery was employed successfully in cases that would have otherwise required laparotomy. (III) Extensive marketing has led to increased demand, not just from surgeons, but from patients. Similarly, across several specialties and procedures, studies have not shown improved efficiency or outcomes. A large meta-analysis evaluating robotic surgery across different specialties (in attempt to increase statistical power) again did not note significantly better treatment outcomes (other than decreased blood loss) with robotic surgery. In fact, their findings showed operative time and complication rates were more favorable with conventional laparoscopy.

**Costs**

Accurate measurement of the costs of robotic surgery have proven difficult due to numerous variables, which include the type of procedure, cost attribution, facility, surgical volume, etc. There does appear to be a consensus that robotic surgery is costlier than both open and laparoscopic surgery. One retrospective study of national inpatient samples analyzed and compared costs of various robotic-assisted surgeries (RAS) with their laparoscopic equivalents and found that RAS appears to create higher costs when compared with traditional laparoscopy. Table 1 shows the various procedures reviewed and their respective costs.

### Finding the value in robotic surgery

Considering the classic healthcare value equation, $Value = \frac{Quality}{Cost}$, the preceding evidence would suggest that robotic surgery is not a valuable or cost-effective investment for hospital systems. Despite this, the number of hospitals with robotic programs and the number of robotic surgeries performed continues to grow every year. How then, can we find the value in robotic surgery?

### Changing our point of comparison

As demonstrated above, robotic surgery has not proven significantly better than laparoscopic surgery. It is also clear that open surgery is associated with increased patient hospital LOS, complications, pain, return to work time, and reoperations. Therefore, robotic surgery can derive its value as a means to convert an open procedure to a minimally invasive one. For example, the 2013 study by Wright et al. evaluating robotic hysterectomy noted that while laparoscopic hysterectomies had been performed since the early 1990’s, it was not until the advent of robotic surgery that the minimally invasive approach to hysterectomy began to gain traction. The value of robotic surgery can be partly derived from the fact that it can accelerate the transition to minimally invasive surgery; the benefits that accompany it.

### Considering long-term value

Much of the research to date has evaluated the short-term value of robotic surgery, which is negatively impacted by the significant additional equipment costs and time requirements. There may be additional value in considering the long-term effects of robotic assisted surgeries. For example, a 2015 study by Chandra et al. (funded by Intuitive Surgical) evaluated nephrectomy (removal of the kidney) for renal cancer. It found that robot-assisted surgery increased the rates of successful partial nephrectomy by 52%. Partial nephrectomy was associated with improved one-year survival.
survival, as well as significantly decreased rates of kidney failure when compared to radical nephrectomy (20). The improved quality-adjusted survival outweighs the costs of nephrectomy itself, thus creating value for both the patient and the health system. The long-term quality improvements and cost savings of robotic surgery may be particularly beneficial as reimbursement shifts from a “fee for service” model to a “value-based” model that incentivizes quality of care and better outcomes. Further research is needed to demonstrate long-term benefits of robotic surgery across other procedures and specialties.

**Lowering costs via increased volume**

The increased costs of robotic surgery are partly related to the high fixed costs of equipment. If these fixed costs can be spread across a higher volume, robotic surgery can potentially be cost effective. A 2010 study by Satava et al. noted that in robotic procedures which demonstrated the ability to reduce hospital LOS, such as robotic prostatectomy, may have a significant cost advantage (21). The justification behind this finding is based on that the availability of inpatient beds limited the volume of inpatient surgeries that could be performed; therefore, by decreasing LOS, robotic surgery can potentially increase volume, thus spreading its fixed costs. However, some hospitals may not be limited by bed availability; instead are limited by OR availability. So then, a hospital looking to lower costs of robotic surgery can increase volume by making robotic surgery cases a priority, investing in staff training to facilitate efficiency, and fostering the development of highly skilled robotic surgeons. While robotic surgery has a significant learning curve, surgeons with higher volumes can likely achieve significant improvements in efficiency over time that can create value.

**Considering the effect of competition**

New entrants to the robotic surgery market are focused on improving value via lowering cost and improved quality. For example, TransEnterix hopes to lower costs via its reusable instruments, which will result in significant cost-savings over Da Vinci. In fact, a recent internal review by our local healthcare system revealed an average instrument cost of $3,400 per da Vinci procedure, which is significantly higher than the projected $800–1,600 instrument costs for Senhance (8). CMR has a unique business model which will lower the initial costs of robotic surgery; thus, potentially improving access to robotic surgery across more health systems and procedures. New entrants have also cited new technology such as haptic feedback; improved instrumentation, etc., which can have a potentially positive effect on the quality of care. However, significant research will be needed to make that determination. Finally, as with all technologies before it, as competition expands, the costs of robotic surgery will inevitably decrease.

**Conclusions**

With annual revenues topping $3 billion and expected growth of 15% per year, it is clear the robotic surgery is here to stay. Intuitive Surgical has successfully marketed the benefits of robotic surgery (state-of-the-art technology, improved visualization, maneuverability, ergonomics; outcomes); now dominates the industry with its da Vinci system installed in over 2,800 hospitals. Despite its high initial costs and recurrent costs, demand for the system continues to grow. This growth has prompted competitors to enter the field with new products that address some of the perceived weaknesses of the current offerings at lower costs.

There is significant research comparing robotic surgery to conventional laparoscopy and open surgery. While superiority of robotic surgery has been demonstrated in some procedures, it has not proven superior to laparoscopy across a majority of procedures. Additionally, short term cost evaluations have demonstrated significantly higher costs associated with robotic surgery, bringing into question the value of such an investment (22). Despite the available outcomes and costs research, robotic surgery continues to grow, with increased demand from both physicians and patients.

As demonstrated, it is possible to derive value from robotic surgery in a variety of ways: by changing our point of comparison, considering long-term outcomes, lowering costs via increased volume, and as a natural result of competition. It is important to realize that robotic surgery is still a relatively new field, and it took almost two decades for laparoscopy to gain traction and prove its value. It is likely that as competition increases in the field, robotic surgery will demonstrate its value via lower costs and higher quality. Until robotic surgery has proven its value in the research, it is important for patients to choose an experienced surgeon whom they trust, rather than a specific surgical approach. We hope that this report will encourage the reader that there has never been a better time to invest in the continued...
development of robotic surgery.

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None.

Footnote

Conflicts of Interest: SD Schwaitzberg - Advisory Board Member/Equity Holder - Human Xtensions; Activ Surgical another author has no conflicts of interest to declare.

References


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