ABSTRACT

The Ethics of Medical Devices: The Rise of the da Vinci Robot and a New Model for Its Ethical Use

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The da Vinci® robot is a new surgical system for minimally invasive surgical procedures created by the private company Intuitive Surgical. Since its first appearance on the medical device market in 1999, the da Vinci robot has grown significantly in popularity and two newer versions of the operating platform have been developed. Despite the rapidly increasing use of the da Vinci, several medical studies completed in the past few years question the worth of its widespread utilization as well as the marketing techniques involved and the training system in place. A review of multiple studies illustrated that in many respects the robotic surgical platform does not provide additional benefits for the patient compared to laparoscopy, yet it costs significantly more. There do seem to be certain merits to this technology, but only in the correct circumstances. This paper uses four principles of biomedical ethics (beneficence, non-maleficence, autonomy, and justice) to evaluate when use of the da Vinci robot is ethical and when it would not be. Furthermore, an ethical model for surgical training and dissemination of this robotic surgical technology is proposed.

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THE ETHICS OF MEDICAL DEVICES: THE RISE OF THE DA VINCI ROBOT AND A NEW MODEL FOR ITS ETHICAL USE

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By

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CHAPTER ONE

Introduction

What is the da Vinci Robot?

In the past decade, a new medical technology has been rapidly gaining popularity and renown in the surgical field, and hospitals and surgeons worldwide have added this new tool to their operating rooms or are seriously considering it. Surgical robots have been an increasingly popular topic of discussion in the medical field since they began gaining popularity in the late 1990s and several models have been created and modified in the past couple of decades. But only one model has made a notable impact on the surgical front in the United States thus far. The surgical robot named the da Vinci® was created by the medical device company Intuitive Surgical® and appeared on the market in 1990 and currently stands as the only robot cleared by the FDA for use in general laparoscopic surgery. Lately this complex surgical aid has been growing very rapidly in popularity among surgeons and patients alike for minimally invasive surgeries, but the quick diffusion of this new innovation has not been without its setbacks. While Intuitive Surgical and its supporters have touted the possible benefits of this new procedure, clinical trials and related studies have yet to prove definitely if getting an operation with the da Vinci robot truly does provide noticeable benefits over established laparoscopic procedures or open surgery. In addition, questions have begun to appear about the high cost and potential complications of this procedure, bringing the future widespread use of the da Vinci robot into question.

The da Vinci robot is a surgical tool consisting of a patient side cart with three or four robotic arms kept by the operating table, a three-dimensional Vision System which creates a high resolution, 3D video of the procedure, and a surgeon's operating console generally located nearby in the operating room ("da Vinci Surgery - Minimally Invasive Robotic Surgery with the da Vinci Surgical System," n.d.). The da Vinci system cannot be programed to operate on its own and so requires the surgeon's input and control for the execution of every movement; thus the da Vinci is also termed a "slave robot". The surgeon remains seated at the console from which he controls the movements of the robot's arms by use of pedals and two jointed-wrist joystick hand controllers. The surgeon then performs the procedure by making three or four (depending on the type of surgery) small incisions, usually less than an inch wide, through which the surgical team inserts the camera and other instrument arms. Throughout the procedure the surgeon looks into an eyepiece on the console to see a colored, magnified, three-dimensional view of the patient's interior produced by the endoscopic camera always attached to one of the four robot arms. The other two or three arms can hold various miniaturized surgical tools such as scalpels, electro-cautery instruments, scissors, and pincers. A surgical assistant can exchange these instruments during the surgery if necessary.

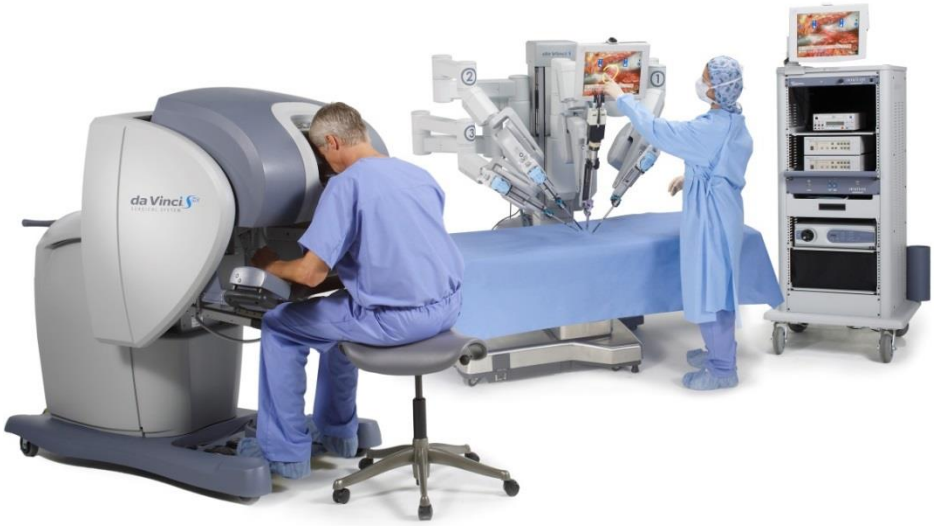

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Figure 1: The da Vinci S System

With this technology, a surgeon has the capability to perform a variety of minimally invasive operations using the same robot and equipment. The da Vinci robot scales down the surgeon's actions at the console to miniature movements of the instruments held at the end of the robotic arms. The surgical instruments attached to the robot's arms also have seven degrees of freedom, which Intuitive Surgical states will provide the surgeon with a greater range of motion than may be possible in open surgery or laparoscopy ("da Vinci Surgery - Minimally Invasive Robotic Surgery with the da Vinci Surgical System," n.d.). In this way, very small precise movements can be carried out within the patient with greater ease.

As the da Vinci robot cannot be programmed, the surgeon remains directly responsible for all of its movements throughout the surgery, and as such all surgeons

[1] [Photograph of the da Vinci S System]. Retrieved April 14, 2014, from http://www.robotsurgery.ie/assets/images/animation/da_Vinci_S_HD_System.jpg

must complete a training program before being able to utilize this technology. Even after completing training, an assistant surgeon must generally also be present throughout the operation. Additionally, the da Vinci cannot be used to operate on all patients. Intuitive Surgical reports that robotic surgery performed with the da Vinci system should not be used for pregnant women, morbidly obese patients, individuals who bleed easily, or those who have abnormal blood clotting due to increased surgical risk.

Intuitive Surgical, an American company founded in 1995 which creates surgical devices and equipment, developed the da Vinci robotic surgical system in 1999. The idea for this innovation originated in another project funded in the 1980s by the United States' Defense Advanced Research Project Agency (DARPA), which focused on the potentials of telemedicine and aimed at creating a robotic surgical system that could be used to operate on wounded soldiers on the battlefield from a remote location (Yates, Vaessen, & Roupret, 2011). Since that time, various robotic systems have been developed for certain surgical procedures, but da Vinci has been the only surgical robot to significantly impact the surgical field and gain widespread popularity. With the da Vinci robot, Intuitive Surgical sought to develop an alternative from open surgery or laparoscopy which would allow the surgeon to perform complex procedures through small incisions with greater precision and control than otherwise possible—partially due to better ergonomics. Furthermore, the da Vinci was intended as a way to bring minimally invasive procedures to a greater number of patients since certain operations, which would historically have only been possible with an invasive surgery, can now be conducted as a robotic minimally invasive operation. Also some advocates predict that robotic surgery could

improve surgeon residency training as it is believed it would be easier for a new surgeon to learn robotics as opposed to laparoscopy.

The US Food and Drug Administration (FDA) cleared the da Vinci robot for use in general laparoscopic surgery in 2000, and since then its application has been steadily increasing. The widespread use of the da Vinci system originated in urological and general procedures (Yates, Vaessen, & Roupret, 2011), then it became common in gynecological surgeries and has now also gained approval for cardiac, colorectal, thoracic, and certain head/neck procedures.

Since its clearance at the beginning of the twenty-first century, the use of Intuitive Surgical's robot has diffused very rapidly. By 2009, upwards of 200,000 robotically assisted operations had been completed worldwide—triple the numbers in 2007—and the numbers continue to rise (Weissman & Zinner, 2013). From 2007 to 2009, the number of da Vinci systems available in hospitals grew by 75% from approximately 800 to 1400. At the beginning of 2013, more than 1900 hospitals throughout the world reported owning a da Vinci robot, bringing the current number of robotic systems installed to around 2,500 (Sharkey & Sharkey, 2013). In the field of gynecology, the number of total hysterectomies carried out with the da Vinci robot climbed from 0.5% to 9.5% overall in the United States (Wright et. al, 2013), and in hospitals capable of performing robotic assisted minimally invasive procedures, da Vinci was utilized in 22.4% of all hysterectomies (Weissman & Zinner, 2013). Also as of 2009, 85% of men who underwent prostatectomies had their prostate removed with the da Vinci robot. For US patients being treated for prostate or gynecological cancer, robotic surgery is now one of the top options for treatment. Intuitive Surgical reports that to date a grand total of

approximately 1.5 million procedures have been performed using the da Vinci robot system ("da Vinci Surgery - Minimally Invasive Robotic Surgery with the da Vinci Surgical System," n.d.).

Throughout the United States, advertisements for the da Vinci robot have become increasingly noticeable in recent years. Many hospital lobbies, billboards, and websites display glowing ads for the robot and its potential. Until recently, only the potential benefits of the robot were widely discussed and significant or considerably serious claims were not widely reported ("FDA Seeks Data on Surgical Robots - WSJ.com," n.d.). However, in the past couple of years, doubts about the da Vinci robot's performance and worth have surfaced and gained the medical community's attention. Now more than before, doctors and medical organizations are weighing the risks and drawbacks of this technology against its promoted advantages.

A large portion of the campaigns created by Intuitive Surgical and hospitals owning the da Vinci robot focus on the possible benefits that robotic minimally invasive surgery may have over other existing surgical procedures (such as open surgery or laparoscopy). The benefits advertised include reduced blood loss and pain, less scarring, fewer potential complications shorter hospital stay, lower risk of infection, and faster recovery. Proponents of the da Vinci robot also point out surgeon benefits, which include better ergonomics and less bedside fatigue since the surgeon operating remains seated at the console and so does not have to stand about the patient. On the other hand, the risks of robotic surgery, other than those common for any form of surgical procedure, have not been publicized nearly as extensively. Risks unique to robotic surgery include possible adverse effects from the longer operation time, possible electrical burns, and as of yet

unknown long term effects. Additionally, the surgeon's learning curve for this procedure could also increase a patient's risk of complications (Sng et al., 2013).

When the FDA first approved the da Vinci robot more than a decade ago, limited data existed to support the manufacturer's claim of the robots effectiveness. Since its introduction to the market, more studies have been completed to determine the cost-effectiveness and worth of Intuitive Surgical's robot, but the results are as of yet inconclusive because of the many ways the data can be analyzed and the indirect effects of this procedure which are difficult to measure. All the while robotic surgeries continue to occur more frequently in hospitals around the country. As noted by Mirheydar and Parsons, "diffusion of a surgical innovation usually outpaces the availability of robust clinical evidence supporting its safety and efficacy" and this has proven to very true for the da Vinci robot (Mirheydar & Parsons, 2012). Even now, more than ten years after the robot's introduction to the medical market, the robot's popularity still grows more quickly than the data supporting it. Now that significantly more literature and data dedicated to studying the uses of the da Vinci exists, it is time to reevaluate its use, determine how the surgical robot ought to be used in our medical environment, and seek ways to achieve this usage.

The lack of decisive data exists in part because of the multifaceted nature of the variables involved and the difficulty in measuring some of the effects directly. Skeptics of the da Vinci state that the benefits broadcasted result from the fact that the da Vinci platform is a minimally invasive procedure, not because it is a robotic procedure. Various studies have been conducted focusing on specific procedures possible with the da Vinci robot, and conclusions regarding whether it improved upon the laparoscopic or

open surgery alternatives depended upon that particular procedure. For instance, it was shown that when compared to laparoscopic hysterectomies, robotically assisted hysterectomies were not cost effective and produced similar results. However in the case of prostatectomies and pediatric urologic surgical procedures, data suggests that the da Vinci robot could prove cost-effective and/or preferable to other methods. To date very few to no randomized control trials or large population studies have been conducted to provide robust significant evidence for the effectiveness of the robot on a large enough scale to tip the favor definitively towards or away from robotic surgery.

Another potential issue regarding the diffusion of the da Vinci robot is the learning curve associated with beginning to perform robotic operations. Given its similarity to laparoscopy, some studies have found a smaller learner curve for the da Vinci robot than for other procedures because most surgeons are already familiar with minimally invasive techniques such as manipulating long instruments and looking at the patient's internal environment on a monitor (Sng et. al, 2013). However, the learning curve for such a tool remains dependent on the previous laparoscopic operations performed by the surgeon, the types of cases performed, and the quality of guidance provided by a more experienced colleague. The learning curve also depends on the medical specialty of the procedure being performed, and there does not yet exist a reliable baseline number of procedures necessary before minimum competency has been achieved. Completed studies list the number of necessary procedures to be around thirty for robotic partial nephrectomy, at least 90 for gynecologic procedures, and between 110 and 200 for prostatectomies (Mirheydar & Parsons, 2012). Thus the issue of which

surgeons should be conducting robotic procedures and how many surgeons should be trained in each institution to best benefit patients must also be examined further.

A large concern in regard to robotic surgery that continues to attract attention is the da Vinci robot's cost-effectiveness or the lack thereof. Healthcare spending as a whole has become a large, heated issue in the United States, and robotic surgery within this context remains a topic of discussion and debate. A single da Vinci system costs between $1 and $2.5 million US dollars initially, and after the purchase of this expensive apparatus there are also maintenance fees and costs of single-use and consumable instruments (Barbash & Glied, 2010). Furthermore, a robotic operation generally takes longer than the corresponding laparoscopic or open procedure, and so the additional costs of being in the operating room and under anesthesia for a longer period of time must all be added to the total.

The additional cost of selecting a robotic surgery as opposed to one of the other forms of surgery varies depending on the type of procedure to be performed. For example, when compared to a laparoscopic nephrectomy, a robotic nephrectomy costs $2,700 more; and in comparison to an open surgery, a robotic kidney removal costs an additional $1,300 ("Breakthrough: Robotic Surgery (Harvard Women's Health Watch)," n.d.). For hysterectomies, procedures carried out with the robot had a 6% increase in cost over the laparoscopic alternative. A different study found that on average for all types of surgeries possible with the da Vinci, the robotically performed procedure cost $1,600 extra (Barbash & Glied, 2010). When the cost of purchasing the actual robot is added to this average cost, the total additional price of a robotic procedure climbs to about $3,200 (Barbash & Glied, 2010). Furthermore, prices of the da Vinci robot and its additional

instruments do not look to be decreasing anytime in the immediate future as Intuitive Surgical continues to be the only company whose technology has been cleared for such versatile surgical functions and so remain immune to the forces of competition. Only with the arrival of a serious competitor to the da Vinci robot or the introduction of large healthcare reforms can the cost of this surgical robot be expected to fall to a more cost-effective value. Moreover, a majority of insurance companies do not distinguish between robotic and laparoscopic minimally invasive procedures, and therefore the hospital must absorb the additional costs of the robotic procedure or charge the patient more to cover the costs.

Advocates for the da Vinci robot state that these higher costs at the beginning are balanced by lower hospital stay costs, since the patients generally have a shorter stay in the hospital. In addition, hospitals and surgeons in favor of the da Vinci robot point to the potential benefits of a "halo effect." New technology has long been associated with improved service, and this trend can be observed in the attitude of many patients towards the da Vinci surgical platform. Even though acquiring a robot proves to be a large expense for a hospital, simply the option of having a robotic surgery draws more patients to a robotically equipped hospital because it creates the impression that that institution is more innovative. Also, many surgeons feel pressure to become trained in robotic procedures from patients who have begun to seek care from surgeons capable of performing a robotic procedure (Sharkey & Sharkey, 2013). As a result, some surgeons have adopted the da Vinci robot in order to help keep up with market demands and to remain on the "cutting edge." Thus with the potential threat of losing business, more hospitals working to remain active and competitive have added robotic surgery to their

list of available procedures to help attract a greater number of surgeons and patients to their institution. So although the da Vinci robot may be a huge purchase, hospitals have found it a necessary investment to help retain patients and surgeons alike as the popularity of robotic surgery continues to rise.

However, in recent months complaints being reported about the da Vinci robot have increased along with the continual increase in the number of robotic surgeries performed. News media attention to these adverse effect reports has also grown ("Study Raises Doubts Over Robotic Surgery - WSJ.com," n.d.). These complaints and adverse events reports have caught the attention of the FDA, and Intuitive Surgical has come under additional scrutiny in 2013. Critics of the robot point to insufficient training and issues in the instrument function as possible causes of the reports, while others state that this growth in complications and complaints results from the similarly increased number of procedures being completed with the da Vinci robot.

While the best way to address the problems presented in the reports has yet to be determined, there can be no doubt that the continued widespread use of the da Vinci robot must be reevaluated in light of recent studies questioning its cost-effectiveness and worth in the US healthcare system. Adoption of the da Vinci robot was not done in a proper, ethical manner and this has resulted in the concerns currently being examined by healthcare professionals. The da Vinci robotic technology developed by Intuitive Surgical was intended to improve surgeries and while it seems to possess the capability of being very beneficial in a future surgical environment, at this time doubts have been cast on whether its current application accomplishes that goal. In addition to reviewing the current criteria for the use of the da Vinci robot (and conducting further studies to assess

its possible benefits) we must also examine the public's attitude towards such new innovations, the way in which the surgical robot entered the market, the ethical issues surrounding this technology, and the opinions of the surgeons who carry out the robotic procedures that have become so widely discussed in the medical field.

CHAPTER TWO

How the Development of New Medical Innovations has Changed and Its Impact on the Spread of New Technologies

The arenas of scientific research and technological innovation, particularly in relation to the medical field, have undergone significant changes throughout the twentieth century. A shift in modern medicine has occurred during the past hundred or so years in which new medical technologies and procedures which were generally created by scientists and innovators in academia are now being introduced by companies in the private and corporate industry domain. In the last fifty years or thereabouts, corporations have begun to conduct their own research and develop a multitude of new medical technologies. While this has led to a marked increase in the number of new pharmaceuticals and medical devices available for use by physicians, the shift to private industry sponsored medical innovations has also created many potential problems for both the physician and the patient. The changes resulting from this shift of medical innovation have led to some of the issues now related to the da Vinci robot and affecting its adoption at hospitals nationwide.

While the features of the da Vinci objectively appear advantageous and useful for some surgical procedures, the current environment of fragmented device regulation and diminished ethical prioritization makes the robot's current utilization questionable in certain situations. Many diverse factors have led to the current predicament surrounding the cost-effectiveness and safe use of the da Vinci thus far, and studying how a few of

these factors originated explains in part why there is concern regarding how the da Vinci is applied. Furthermore, attention to the historical events and situations that have given rise to the ethical deliberations medicine is continually working to resolve may provide some guidelines for how to move forward.

Private industries and academic organizations have the common objective of advancing medical knowledge and improving therapeutic agents. However, as identified by Geyman, they have different values and needs that affect how they go about working to achieve their goal. For those individuals in academia, the primary motivation is to "seek new scientific knowledge and techniques" and their success is measured by "such standards as the quality and number of scholarly publications…the level of support by the NIH, and their advancement…in the university" (Geyman, 2004). Thus, in the medical university environment the driving forces are the knowledge itself and the possible for prestige and support that comes with successfully obtaining it. On the other hand, researchers in the corporate field seek discoveries which can be "widely marketed as a successful business venture" and individuals working in the industries are often motivated or at least influenced by "financial considerations" (Geyman, 2004). Therefore, though both groups must go about conducting their research in a similarly specialized manner and must maintain an organized and efficient infrastructure to attain successful results, there is a difference in their motivations and preoccupations which lead to a difference in procedural speed, approval process, and implementation.

In addition, the style of research conducted differs between the corporate industry and the medical academic community. For instance, private industry has surpassed the Nation Institutes of Health as the major source of funding for medically related research.

In fact, according to a report in the Journal of the American Medical Association, nearly "sixty percent of biomedical research and development is privately funded" (Bekelman et. al, 2003). Even many universities and medical schools now receive funding from industry sponsors. While it is a positive thing that "clinical research has been greatly expanded and the pace of innovation [has] accelerated" (Geyman, 2004) this is also problematic because various academic centers have come under the sway of corporate interests and in some cases have altered their research process to meet the desires of industry. For example, industries generally desire to produce new innovations as quickly as possible in order to maximize revenue from the new product or technology, which may compromise the integrity of the clinical trials conducted to validate the worth of these innovations. In addition, the desire to gain financial support available from private companies increases the possibility that researchers might undertake research projects that otherwise would not be a priority—as a result of industrial influence and scientific advancement, there is overall more focus on drug therapy and new medical instruments than on traditional priorities such as causes and mechanisms of disease (Angell, 2000). Conflicts of interest are becoming increasingly complex and frequent in such an environment. In fact, many industries (the pharmaceutical industry being a prime example) have begun attempting to bypass academia by shifting their research from academic centers to commercially oriented networks. Among the reasons for this is the fact that medical corporations have found that they can "conduct clinical trials more quickly, more efficiently, and for less money in community settings than in academic settings" so that "instead of having to deal with…complex negotiations of clinical-trial agreements with medical schools and universities," these industries can collaborate with

"commercially oriented, for profit networks" such as contract-research organizations (Geyman, 2004).

Furthermore, it has been shown that studies conducted by the respective industry are more likely to report favorable research results. Geyman sites an aggregate analysis which showed that "industry sponsorship was almost four times as likely (odds ratio 3.60) to lead to pro-industry conclusions than other sources of support" (Geyman, 2004). It was also discovered that "the quality of industry-sponsored research methods were at least as good as the methods used by other sponsors of research" which suggests that the different likeliness of favorable results could be attributed to publication bias or the avoidance of publishing unfavorable results. Such factors can explain why early da Vinci research and the data cited in Intuitive Surgical advertisements helped robotic surgery gain support when it was first introduced, but now in retrospect there is literature which questions these earlier claims. Furthermore, the integrity of research must be examined when it is carried out by private companies who do not have to report raw data to any academic or institutional review, thereby creating the ability for data to become skewed. This can be accomplished through "initial trial designs favoring a drug, biased analysis, 'spinning' of results, misleading reports for publication, selecting journals with less rigorous peer review…and suppressing the publication of unfavorable research findings" (Geyman, 2004). Many useful and now commonplace devices have been produced by industry, but potential conflicts of interest must be kept in mind. This contributes to why peer review and additional studies must be operative.

Thus, because of the growing role of industry in the creation of new medical innovations, it is increasingly important to evaluate the way that corporations produce

and test what they create: the da Vinci robot being an example. This scrutiny of effectiveness and safety is especially important in regard to medical devices since industry plays a nearly exclusive role in their production and distribution. A study done by Monsein found that the medical device industry worldwide is a $130 billion business, and almost fifty percent of the global production and consumption of these devices occurs in the United States alone (Malsel, 2004). This data seems logical given that the United States is at the forefront of medical innovation and the American populous supports new technologies. The medical device approval process is long and complex, and many companies in the industry have sought out ways to shorten this procedure for various reasons. One reason is the financial burden these industries carry. Therefore companies wish to have devices reach the market as quickly as possible for society's and their own benefit.

A crucial step in the adoption of a new product is approval by the Food and Drug Administration (FDA), without which a medical device is not allowed to be used in medicine. The FDA has a set procedure that a company must go through to have a product approved, and while the process for a medical device is not as lengthy or rigorous as that for a pharmaceutical, it can still take several years for a product to be approved (estimated by Fargen et. al to generally take 3-7 years). The FDA classifies medical devices in one of three risk-based categories which also depend on the intended use and indications for use (Center for Devices and Radiological Health, n.d.). Devices in all categories are subject to General Control which includes "proper labeling and adherence to predefined Good Manufacturing Practices, such as a demonstration of adequate packaging and storage" (Malsel, 2004). Class I medical devices are those which are "low

risk" and have "minimal potential for harm," such as bandages, stethoscopes, tongue depressors, etc. These devices are generally not required to undergo any further regulations beyond the General Control requirements mentioned above (Health, n.d.-a). Class II medical devices are listed as those of moderate risk, so the general control is not sufficient to ensure their safety and effectiveness, but neither are they essential or life-sustaining devices. Thus in addition to General Control they are also subject to Special Controls, which includes post-market surveillance, performance standards, special labeling requirements, and premarket requirements (among other more device-specific guidelines). Some diverse examples of Class II devices are surgical masks, computed tomography scanners, and gastroenterology endoscopes. Several devices identified as either Class I or II must still satisfy various general controls, but they may be exempted from submission of a pre-marketing submission if the devices meet certain FDA requirements which will be discussed later on.

The highest risk classification is Class III. A device in this category is described as one which "supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury" (Health, n.d.-d). Pacemakers and hip joint acetabular prostheses are examples of this class of medical device. New medical products for which there are no predicate or existing equivalent devices are also listed as Class III. All medical devices in this class must go through the "most stringent type" of a pre-market approval process (in addition to the general controls) which consists of a "scientific and regulatory review to evaluate the safety and effectiveness" (Health, n.d.-d) of the device. The pre-market approval application includes studies already conducted by the owner of the medical

device seeking approval, and the FDA reviews these studies and the results of their data as part of the process to approve the device or not. Approval is granted by the FDA following the determination that there is "sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)" (Health, n.d.-b). Once granted, pre-market approval is in effect a private license which gives the owner/creator of the device permission to market said device. In order to have the ability to conduct such trials and studies to test the safety and efficacy of the apparatus, the applicant must obtain an Investigational Device Exemption (abbreviated IDE). The IDE "provides manufacturers of new devices a means to evaluate for device safety and effectiveness" (Fargen et. al, 2013) to support they application for pre-market approval. The company or individuals seeking the IDE must complete an application either to a local Institutional Review Board (IRB) and the FDA if the device to be studied "presents a potential for serious risk" (Health, n.d.-b), or only to an IRB if it is an insignificant risk device. Each IRB has different guidelines and levels of stringencies for approving such applications, so the ease with which a company may obtain an IDE may also depend on the institutional review board selected. The manufacturer of the medical device in question must prove through the data represented in the studies they conducted that "the device is safe (its benefits outweigh the risks) and effective (it reliably does what it is intended to do)" (Malsel, 2004).

The process of gaining approval for marketing from the FDA may be a lengthy process which can be unfavorable in some cases to patients who have a health condition which could stand benefit from the new innovation as soon as it is available and also to companies in the industry seeking to manufacture and sell a product as soon as possible.

The FDA has included certain qualifications in an attempt "to keep product-to-market time short to allow patients to benefit from medical advances while continuing to ensure the safety of those who enjoy the product's benefits" (Malsel, 2004). These qualifications can also work to the advantage of some companies as well. One way the process can be shortened is through priority/expedited review if the device "is intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition… no approved alternative treatment or means of diagnosis exists" or if the innovation "represents a breakthrough technology... or offers significant, clinically meaningful advantages over existing approved alternatives" (Health, n.d.-a). Similar to this is the Humanitarian Device Exemption (HDE), the goal of which is also to make the innovation available to benefit the patient as soon as possible. The HDE is granted for Humanitarian Use Devices, which are medical devices "designed to treat or diagnose a condition that affects <4000 individuals in the USA annually" (Fargen et. al, 2013). These devices must obtain approval from an IRB to be approved for use.

The last method by which a company may shorten the FDA approval process is by completing a Premarketing Notification (also known as 510(k)). This premarket submission is a "fast-track process" in which the applicant must "demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device" (Health, n.d.-c). The FDA defines the legally marketed device as one which "was legally marketed prior to May 28, 1976…for which a PMA [pre-market approval] is not required, or a device which has been reclassified from Class III to Class II or I, or a device which has been found substantially equivalent through the 510(k) process" ("510(k) Premarket Notification," n.d.). While this application process

results in faster turn-over from bench to bedside, “it also introduces an element of risk should the equivalence assumption be invalid” (Fargen et. al, 2013). In addition, in 1997 the FDA passed the Modernization Act which allows submitters to petition the FDA to reclassify a device from Class III to Class II/I by providing ample evidence that Class III status is not necessary. This “de novo” petition is utilized “when no predicate exists but there are substantial data to suggest that the device does not carry high-risk status” (Fargen et. al, 2013). These shorter approval processes may result in great benefit for the patient, depending on the nature of the device, but it can be a risky manipulation of the system if the application is made by a member of a for-profit industry which could be motivated by one of the conflicts of interest mentioned earlier.

An example of the latter situation was exemplified by the Stryker hip prosthesis recall in 2007 and 2012. The FDA granted approval for the devices through the 510(k) approval process based on Stryker’s representation that the design was substantially equivalent to a previous product that had already been approved by the FDA. Thus the new hip implants only underwent minimal laboratory testing instead of the rigorous pre-market approval process it would have otherwise had to undergo. However, since then the company has had to recall this hip prosthesis because of certain adverse patient complications.

The U.S. Food and Drug Administration approved Intuitive Surgical’s Da Vinci robotic surgical system and the endoscopic instruments it uses through the 510(k) process. The initial endoscopic system the company created, the Monarch Laparoscopic Manipulator, was cleared for intended use in general laparoscopic surgeries and approved by the FDA under the title “Intuitive Surgical Endoscopic Instrument Control System and

Tools." It was declared to be substantially equivalent to "a combination of the Computer Motion AESOP Laparoscope Positioning and Control System, the Adept/andronic Laparoscopic Positioning and Manipulation System and various other Class I Exempt endoscopic instruments in terms of intended use and basic functionality…[and] in terms of the capability of precisely moving and controlling endoscopic tools" as well as "substantially equivalent to the cited predicates in terms of the tissue effects" it had ("510(k) Premarket Notification," n.d.-a). The substantial equivalency of this early predecessor to the da Vinci robot was verified, according the FDA, through design analysis and in vitro data confirmation of testing which "included evaluation of reproducibility, hysteresis, and functional adequacy" ("510(k) Premarket Notification," n.d.-a). Several subsequent alterations to the instruments and system were approved by the FDA, leading to the da Vinci Surgical System which was also approved by a 510(k) application in which the improved system was substantially equivalent with the older models. The FDA approval summary cites for the clinical data supporting the safety and effectiveness of the robotic system "an extensive prospectively randomized and concurrently controlled clinical study" which was "performed to demonstrate substantial equivalence to the predicate devices cited in terms of safety and effectiveness" ("510(k) Premarket Notification," n.d.-b). All of the updates and alterations made to Intuitive Surgical's robotic system or its instruments—the most recent upgrade being the newest generation of the surgical console, the da Vinci Si in 2009— have been approved by the FDA through the 510(k).

Not only is the creation and government FDA approval of the da Vinci robot and surgical instruments representative of the quick production and abbreviated approval

process various industries wish to participate in, but it also reveals how inconsistencies in data and adaptation of new medical technologies can occur. There is quite a bit of conflicting data present in the literature written on the da Vinci robot given the different ways studies are conducted and focused. Additionally, since the da Vinci went through an abbreviated approval process, proper attention was not given to creating a universal and specific training program for robotic surgery because of its similarities to laparoscopy. Unfortunately, this has proven harmful for some patients. Since there were no fixed training requirements set into place for the da Vinci, not all surgeons have received adequate training and skill acquisition which has resulted in some patients suffering unnecessary complications and injuries because of this.

Another concern that has arisen with the diffusion of new medical innovations by industrial companies has been the direct-to-consumer advertising often implemented by such corporations. This method of promotion uses advertisements displayed in well-frequented public areas such as websites, highway billboards, etc., to gain attention from potential patients and physician consumers directly. In this way the company can obtain positive patient opinion without the input of a mediating organization or physician. One example of how these industrial marketing strategies are affecting the medical field can be seen in the recent growth of the diagnostic/screening test industry. This industry has seen significant expansion in recent years as various companies within it have produced new blood tests, imaging instruments, and other devices to screen and/or diagnose various conditions. Many of the innovations from these groups, such as CT scans and MRI, have proved vastly beneficial in the medical setting, but the problem which arises is that some of these tests "are increasingly being marketed directly to the public without a

physician's referral" through the internet and other commercial means (Geyman, 2004). This can become problematic in instances when patients come to doctors requesting extra or unnecessary tests at least partially due to advertising influence. An example Dr. Geyman cites for this offence is the screening company Inter Fit Health, which provides medical assistants at corporations and in chain pharmacies to draw blood from patients either without the patient's physician referral or with the referral of physicians this company staffs who will approve the request. While individuals with abnormal tests in such events are recommended to consult their personal physicians, the company that carried out the test usually does little to insure the medical follow-up (Geyman, 2004).

Practices such as these are particularly problematic when these self-referred or company-advocated tests do not yet have evidence to illustrate effectiveness for general screening and result in false positives or negatives that are detrimental to the patient. This example of the screening/diagnosis tests industry illustrates how the shift from academia to industry can lead to inefficient or unnecessary use of new medical technologies that serve to contribute to increased healthcare costs while exposing the patient to avoidable potential harm. A similar phenomenon has been seen in regard to the da Vinci robot in which advertisements are made directly to potential patients which focuses on the features of robotic surgery which were not studied in its market approval and have yet to be definitely proven in comparative studies. Advertisements focus on the advantages robotic procedures have over open invasive procedures but which have yet to be definitely proven or disproven in comparison with traditional laparoscopy.

Looking at how medical devices such as the da Vinci are approved and marketed attributes to the validity of the concerns considering how hospitals and surgeons use the

da Vinci. Conflicts of interest seem to be at play in at least some instances of robotic surgery promotion. From this point onward, the medical community can focus on how to rectify these issues by evaluating the use of the da Vinci based on certain important ethical principles. Past and current events in medical technology development can serve as example of what precautions we can take to give patients the greatest benefits with these advanced devices.

CHAPTER THREE

An Ethical Model for the Utilization of the da Vinci Robot

It is evident that the da Vinci robot offers an improved surgical experience for the surgeon through improved ergonomics and freedom of movement through the robotic arms, which could indirectly benefit the patient. In certain complicated procedures or cases where the patient has a unique pathology, a robotic minimally invasive procedure may also provide the best outcome for the patient. However, robotic surgery with the da Vinci robot has also proved to be significantly more expensive than traditional laparoscopic surgeries without resulting in truly noteworthy marginal benefits compared to laparoscopy. Currently, multiple hospitals and surgeons feel pressed to utilize these da Vinci robots partly to compensate for its high cost, partly to satisfy the public's desire for the latest cutting-edge technology, and partly for improved surgical experiences in addition to the proposed potential benefits for patients. Thus, while the da Vinci robot can play a useful role in the surgical field, its utilization in multiple circumstances ought to be reevaluated to insure that surgeons and hospitals use it in accordance with accepted standards of medical ethics. Through the study and understanding of a selection of the common ethical concepts prevalent in the medical profession today, an ethical protocol for the use of the da Vinci robot can be implemented.

The Hippocratic Oath

One of the oldest ethical documents that has affected the Western medical culture by establishing certain ethical foundations is the historic Hippocratic Oath. Perhaps one of the earliest codes of standards for physicians and the best known example of a medical pledge, this ancient text has served as a template for oaths taken by newly graduated physicians for centuries. While the Hippocratic Oath established certain ethical concepts which are prominent today, it has also become a prime example of how blurred the guidelines of medical ethics have been over the centuries. The Hippocratic Oath has been revised and rewritten countless times to fit the cultural, religious, and moral beliefs of every given age and Western society since its origin.

The Hippocratic Oath has been commonly attributed to Hippocrates, a well-respected physician alive from 460-375 B.C in ancient Greece. While it is now debated where or not this oath was actually penned by Hippocrates,[2] there is no doubt that Hippocrates was a famous and well-respected physician who laid some of the fundamental principles we still follow in medicine. In fact, some have even dubbed him the "Father of Medicine" (Jhala, 2012). Historians have acknowledged him as the first known holistic healer in western civilization "to systematically attack the pervasive, age-old belief in the supernatural origin of disease" and place value on a patient's disease prognosis (Adler, 2004). His methods and innovative medical ideas are reflected in the Hippocratic Corpus, a collection of around sixty medical writings from this time period which is still read today. In addition, Hippocrates called attention to the physician-patient relationship, and the common doctor adage to at least "do no harm" is also

[2] Some historians contest that the Hippocratic Oath originated in the second century BC, which is after Hippocrates' death (Winau, 1994).

attributed to this ancient pioneer. Many of the topics he wrote on are still discussed and deliberated in medical ethics today. Regardless of whether or not Hippocrates truly wrote the Hippocratic Oath, the values and mandates of this pledge arose from the teachings of this Greek physician.

The Hippocratic Oath has been translated many times over the centuries and in recent times altered rather extensively by different medical schools and groups of physicians. The original oath begins with an invocation of the gods followed by a declaration of loyalty to fellow physicians and future generations of physicians, to whom one must impart all medical knowledge gained. The rest of the oath outlines how the physician ought to interact with patients following certain ethical principles, which includes prohibitions against the practices of euthanasia and abortion, refraining from sexual contact with patients and their household, not performing surgery (for the removal of bladder stones), maintaining patient confidentiality , and preserving the "purity" of the art of medicine. The conclusion of the oath states that any breach of the promises made by the pledged physician would result in suffering and heavy penalty for that physician. The Hippocratic Oath also instructs the physician to bring no harm or deleterious actions to the patient (Graham, 2000; Winau 1994).

Since the resurfacing of the Hippocratic Oath during the Renaissance, it has been altered and adapted time and time again to mirror the changes that have occurred in the medical profession. It did not make a noticeable impression on the graduation of medical students until the beginning of the nineteenth century. But even then it was not very common for medical school graduates to swear by the Hippocratic Oath, and by 1928 the

percentage of medical schools that administered the oath in some form or another was only 26% (Graham, 2000).

Yet since that time some form of oath-taking upon completion of medical school has significantly increased in popularity. The root of the word professions means "to profess," and so for new physicians, some variance of the Hippocratic Oath serves as young professionals way of acknowledging their dedication to the values and practice of the medical field. Especially in the latter half of the 20th century, after the atrocities of the Second World War, renewed interest surfaced in creating a relevant ethical code for physicians. The oath has been altered in response to changing "social pressures and new medical realities" (Smith, 2008), and "given the large size of our communities, desire for privacy, and the developments in urology [and surgery], such changes in the oath are welcome" (Graham, 2000). So while 98% of medical graduates in 1993 swore to a form of the Hippocratic Oath, all of these oaths varied in specific content. A drastically reduced number of oaths still mention a deity or outlaw euthanasia and/or abortion, which reflects the shifting moral beliefs and values of today's society as a whole. Perhaps most surprising is the fact that less than half of the modern versions of the Hippocratic Oath allude to a penalty for breaking this vow that new doctors make, which suggests that "we don't seem too faithful to our oaths these days, nor as a society do we seem to care too much" (Graham, 2000). For hundreds of years such an oath was a solemn declaration of true dedication with severe ramifications if broken, yet in our modern society these oaths have generally devolved into a "rite of passage" which most medical students do not treat with reverence. The enormous variance in oaths taken today by new medical professionals illustrates how diverse and disjointed ethical principles in medicine are

which explains why certain moral dilemmas currently exist. It seems almost natural that the disputes surrounding the da Vinci robot would arise given the lack of unified ethical guidelines for medical practice. This concern about the frayed relationship between theoretical ethical ideas and practical medical applications is one which several medical organizations and committees have been seeking to reform over the years.[3]

These ethical concepts and concerns have been gaining considerable attention in more recent years as certain new technologies developed in the past several decades have brought some very powerful and serious ethical deliberations with them. Examples include extended life support systems, in vitro fertilization, stem cell research and technology, and various forms of birth control. This includes some of the procedures clearly delineated as good or bad in the Hippocratic Oath (such as invoking religion, abortion, euthanasia) which have been called into controversy with people arguing strongly either for them or against them given the diversity and changes in modern societal values. The marvels of modern medicine have done much to improve the quality of life for millions of individuals but in the process they have also complicated medical ethics. Fortunately the ethical concerns which have come into the medical field along with practices of modern medicine are being given attention and many studies and articles have entered the literature on these topics.

Bioethics has become a sophisticated and complex field within itself in the past century due to the many advancements of modern science and medicine, and countless

[3] The American Medical Association created Ethical Guidelines through the AMA Code of 1847 to morally guide physician practice and protocol. The Declaration of Geneva was created in 1948 in the aftermath of World War II to declare physician's dedication to the bettering of humanity and to establish humanitarian goals for medicine (Davis, 2003).

books and articles have been written on the many ethical concepts and controversies present in the Western medicine of our time. Not all of the ethical ideologies in existence could be described in relation to the da Vinci due to the large ethical variance and disagreements (exemplified in the modern Hippocratic Oath discussed above). Instead, it seems fitting to focus to a small number of ethical values which appear to be the most accepted by Western medical culture.

Four Principles of Biomedical Ethics

One of the foundational modern works in medical ethics was T.L. Beauchamp and J.F. Childress's book *Principles of Biomedical Ethics* which was first published in 1979—and since that time five editions have been released, with the sixth and most recent one being published in 2009. Beauchamp and Childress present several foundational elements of an ethical medical practice in a modern American society and discuss certain virtues desirable in a competent and moral physician. Perhaps the most influential ideas presented in *Principles of Biomedical Ethics* are those of four principles the authors found to be central to a correct and thriving medical practice. These principles are Beneficence, Non-Maleficence, Autonomy, and Justice. These four ethical ideologies are considered to be the most commonly known and accepted among physicians in the United States today, and are occasionally referred to as the four "pillars of medicine."

Non-maleficence

The first of these medical principles to be discussed (and perhaps the one with the oldest origin) is non-maleficence. This principle refers to the noninfliction of harm on

another individual. The idea of not harming the patient has been present in the medical and healing community for centuries, going back at least to the time of Hippocrates. This duty of non-maleficence encompasses and prohibits both intentional harm and the risk of doing harm. In their discussion of non-maleficence, Beauchamp and Childress include "intending, causing, permitting, and imposing" the risk of pain, suffering, disability, and death (Beauchamp & Childress, 1979). In order to avoid these problems, physicians must act carefully and thoughtfully when advising and treating patients. Part of being careful and thoughtful involves being clear about risk and probability of certain outcomes when making assessments regarding harm and benefit. Non-maleficence and beneficence (doing good) are closely related, but non-maleficence is the antecedent to beneficence because there can be circumstances in which we have or may recognize no obligation of beneficence to others yet we still have an obligation to not harm them (Gillon, 1994).

Beneficence

The next ethical principle is beneficence. According to Beauchamp and Childress, beneficence is believed to be more altruistic and farther-reaching than non-maleficence because it "requires positive steps to help others" which can also include the prevention of harm and removal of harmful conditions (Beauchamp & Childress, 1979), unlike non-maleficence which is restricted to not causing or inflicting of harm. Within the principle are two categories of beneficence: providing benefits—positive beneficence— and balancing benefits and harms—principle of utility. The biomedical principles of ethics understand beneficence to be a duty of the healthcare provider, not mere acts of kindness or charity, meaning that if physicians find themselves in a position

to increase the good of patients they must do so and the failure to do so is a moral wrong. Other philosophers and ethicists cited in *Principles of Biomedical Ethics* view beneficence as a virtue rather than a duty since situations can arise in which it can be difficult to provide all the goods and beneficial services given limitations of resources and time. But through both viewpoints of beneficence, this principle's goals are to bring benefits and positive outcomes to others in our society given certain understood limitations of resources and human error.

Beneficence serves as a primary objective for caring for patients and caring for society as a whole. Certain biomedical and health fields are geared towards helping individual patients, while other fields focus more towards benefiting entire populations and future generations. For example, research and clinical trials conducted on individuals may not necessarily provide enough direct benefits for study participants to outweigh the risks of these procedures, yet biomedical research is still considered beneficent if it will bring additional positive outcomes for other members of that community/society and future generations. Sometimes situations arise in which it can be difficult to determine whether an action is being carried out to help the subject or to bring some advantage to the implementer, thus peer review and ethics panels are becoming increasingly important. Beneficence and non-maleficence together are perhaps the most well-known biomedical principles since they are more obviously related to the fundamental goals of medicine: to provide patients with maximum benefits and minimal risks.

Justice

The third of the four principles of biomedical ethics to consider is Justice. This value is potentially more difficult to define in a unified, standard sense because it encompasses many different facets of righteous and fair action, and different schools of thought emphasize different aspects of it. Furthermore, a study published in The Journal of the American Medical Association (JAMA) in 2009 studying the ethical foundation of the United States medical community stated that there appears to be an imbalance in attention to the four principles in which less emphasis is given to the principle of justice compared to the other three (Kirch & Vernon 2009). The article reasoned that this could be in part due to the lack of an absolute theory of justice. Beauchamp and Childress define just action towards a person as one in which the recipient "has been given what he/she is due or owed, and therefore has been given what he deserves or can legitimately claim…what persons deserve or can legitimately claim is based on certain morally relevant properties which they possess, such as being productive or being in need" (Beauchamp & Childress, 1979). They go on to state that similarly it would be morally unjust to place a burden or reward on an individual if that person does not possess the relevant characterics that would naturally result in that burden/reward. Other experts have taken this further and subdivided justice into one of three categories. These are distributive justice (fair distribution of limited resources), rights-based justice (respect for people's rights), and legal justice (respect for morally acceptable laws) (Gillon, 1994). Regardless of the minor variations in the delineations of justice, many major sources have agreed that justice as a moral and ethical principle constitutes more than merely equality.

In the medical world, attaining a just practice involves adherence to multiple guidelines of action. The first idea of how a physician ought to act justly involves

treating patients equally, based originally on an Aristotelian guide to action which states that equals should be treated equally while unequals should be treated unequally. In this context being equal or unequal is based on perceived similarities or differences between people which are relevant to the treatment at stake (Beauchamp & Childress, 1979). The issue with this "formal" definition of justice is that it does not specify what are the criteria are that make two individuals equal or unequal. But as Gillon points out, persons can still be treated unjustly even as they are being treated equally. Thus specific, moral criteria for who is equal and unequal in all types of medical situations must be discussed, and to this concept of equality we must add distributive justice, principle of need, and conflicting interests (Gillon, 1994). Distributive justice pertains to how to beset allocate our limited resources based on need and merit, as well as how to define relevant properties by which distribution of limited resources can determined. What specifically constitutes these relevant properties depends on the service being rendered and what the outcome of its application will be. The principle of need, as described by Beauchamp and Childress, states that distribution of health resources is justly done when it is allotted based on need. An individual's need for a certain item or service is generally defined by the authors as something without which he or she will be harmed or detrimentally affected. In healthcare the definition of this need generally refers to fundamental necessities for life.

A major threat to just medical practice is a conflict between the physician's interest for some form of self-promotion and the patient's wellbeing. Conflicts of interest generally describe when "the self-interest of an individual is in tension with an obligation" (McCullough, 1998). When applied to medicine, conflicts of interest arise

when a physician's or healthcare group's financial or other self-interest motivates an action or behavior that is divergent from the needs and interests of the patient. This can manifest itself in the physician over-treating a patient, recommending unnecessary or more expensive treatment options, skewing the presentation of study results, or overcharging for services. As Kirch and Vernon view this, such conflicts of interest tend to occur when concerns for physician independence and revenue outweigh concerns for societal needs in a given situation. Additional conflicts of interest can be created by conflicting obligations or potential career benefits and elevated social status—especially in the spreading of new technology and innovations (Sharkey & Sharkey 2013). These conflicts of interest do not necessarily arise out of malicious or selfish intent; oftentimes in medical practice subconscious biases lead to these conflicts of interest. Addressing conflicts of interest is a complex and ongoing process, and no one simple change would have the ability to solve them. Historically, codes and sanctions were created by medical societies and organizations to prevent the formation of conflicts of interest. But the last half of the twentieth century brought numerous changes to medicine, some of which made it more difficult for these established ethical codes to be enforced or else altogether negated them. For example, conflict of interest concern was further complicated in the 1970s when physician advertising became an acceptable practice. Prior to this time advertising by physicians was forbidden according to the American Medical Association Code of Ethics, but then in 1975 it became tolerated and suddenly an entire new potential for financial conflicts of interest arose.

Thus, self-policing, promotion of virtue among physicians and institutions, bringing self-interest into greater concordance with obligations, and reinforcing sanctions

against violations are some of the solutions to these problems proposed by McCullough. Justice is a very complicated value given its interaction with social obligations and pressures, government policies, and personal values. Given their position of influence and the trust patients place in them, physicians have an ethical and moral responsibility to analyze their role individually and collectively in promoting a just or unjust society (Kirch & Vernon 2009).

Autonomy

The last of the four "pillars of medicine" is Autonomy. Autonomy literally means "self-rule," but Beauchamp and Childress extend this definition and describe medical autonomy as "a form of personal liberty of action where the individual determines his or her own course of action in accordance with a plan chosen by himself or herself" (Beauchamp & Childress, 1979). Therefore being an autonomous person requires a person to not only consider and choose a plan of action but also to act on the basis of this; it involves the will of an individual and their action in society. In the medical profession, this principle of autonomy applies to both the physician and the patient. The physician has a right to participate in procedures he or she feels are best (as long as they are ethical and there are no conflicts of interest) as well as to dismiss patients from their care when there are just grounds and refuse to give a patient a certain treatment if it does not align with his or her moral values. Given the privileges and responsibilities granted to physicians in their role as advocates for patients and their partners in care, physicians must be very cautious not to abuse their autonomous position. Patients also have certain healthcare rights as autonomous beings. Historically the physician and patient engaged

in a paternalistic relationship in which the patient was subordinate to the doctor and simply followed whatever orders the physician would decide were best. The relationship between the doctor and patient has evolved greatly in the last century however, and now the paradigm of a good physician-patient relationship is that of a partnership based on mutual trust and respect. This includes greater rights for patients to decide their own course of treatment which naturally also leads to greater responsibility. Patients have the right to refuse treatment and the right to medical confidentiality. Part of all this deliberation and decision making on the part of the patient is the concept of informed consent. In order for patients to be able to act as autonomous beings and decide whether or not to undergo certain courses of treatment or procedures, they must be well-informed and understand in context the reasoning, risks, and potential benefits behind a proposed course of action.

The capability of the patient to give informed consent relies on the communication and relationship present between the physician and patient. As Gillon explains, good communication involves careful listening as well as telling and explaining, all of which are essential for providing the patient with enough information to make as much of an informed decision as possible (Gillon, 1994). Given that the physician has much more knowledge and understanding on the particular medical subject than the patient, it is very difficult for a patient to provide a completely informed consent, but the physician has the responsibility to educate the patient as thoroughly as possible. In a way, informed consent also aids to protect autonomy because people are granted the right as patients to make—to some degree—important decisions affecting their own lives, even though the physician likely possesses far more knowledge and training on the

subject (Beauchamp & Childress 1979). This also enhances respect for autonomy. Respect for autonomy in a medical relationship includes keeping the promises made by both parties: not deceiving one another, effective communications, and respect for the personal beliefs and values of the other individual.

There are many more ethical principles and models in existence besides the four Principles of Biomedical Ethics, but most have certain features in common and hold similar values. Within the world of surgery, the principles of beneficence, non-maleficence, autonomy, and justice can be specialized and adapted to fit the circumstances of surgical procedures. Surgery presents much greater risks to the patient than most non-invasive treatments, therefore the idea of informed consent and balancing the risks and potential benefits of the patient's outcome become paramount because of the severe complications that could result for the patient. It is also very important to respect the patient's cultural, religious, and personal wishes given that certain consequences of surgery could conflict with these wishes. Furthermore, surgery is a very expensive medical procedure given the costs of surgical skill, anesthesia, and the many tools and devices used. Therefore keen awareness and avoidance of conflicts of economic interest are essential on the part of the surgeon so that the patient does not have a procedure done or instrument used unnecessarily. Considering the precise technical skill that surgery entails, professional self-evaluation among surgeons is essential in maintaining competency and low error rates. Surgeons should strive to insure that they remain clinically competent, and acknowledge when they or a colleague display incompetence. As discussed in chapter two, proper surgical practices also involve ethical development and promotion of surgical devices and new procedures. Conflicts of interest

are an area of concern not only for physicians but also for industries and innovators who create new medical technologies. The FDA must also follow the four ethical principles to insure that clinical trials for new tools and procedures are rigorous and valid, and that regulation of training and use of these new technologies also follow ethical codes in order to maximize their potential beneficence and minimize chances of non-maleficence. One situation in which the four principles can be further explored and developed is the new robotic surgery procedures possible through the da Vinci robot.

The new da Vinci robotic procedures present various ethical dilemmas given that these surgeries currently seem to lack cost-effectiveness and in recent studies have shown no significant additional benefit for the average patient compared to laparoscopy, yet there appear to be certain instances in which the da Vinci robot can be used to improve the probability of a positive surgical outcome for certain groups of patients and physicians. However, strong advertising campaigns, patient pressure, and utilization of the robot chiefly to balance its high cost have shown the need to revisit the most common ethical principles and analyze how they can interact with this new technology so that the patient's wellbeing is given priority, while still keeping the needs of the physician in mind. Especially as the long-term effects of robotic surgery have yet to be proven, and since clinical studies and surgeon groups have not reached a consensus regarding the benefits and drawbacks of robotic surgery as compared to laparoscopy, it is vital that surgeons and other medical professionals in the current health setting consciously evaluate their use of the da Vinci robot within the context of medical ethics. There are many ethical schools of thought and disagreement exists between bioethicists concerning many controversial subjects and ideas, but among practicing Western physicians the four

medical principles outlined by Childress and Beauchamp—grounded in certain Hippocratic concepts—are the most commonly accepted ethical guidelines. Thus we will use these four principles of medicine (beneficence, non-maleficence, autonomy, and justice) to present ethical suggestions specific for the use of the da Vinci robot in surgery.

Non-maleficence and the da Vinci

First we shall consider how the concept of non-maleficence applies to robotic surgery. Non-maleficence, within its Hippocratic origin of "do no harm," is perhaps the most basic of the four medical pillars proposed by Beauchamp and Childress. If no additional benefit or good would come to the patient from a physician's advice or intervention, at least no avoidable injury or harm should accompany it. Many medical procedures of course involve some risk of possible complication or side effect, thus all possibilities must be considered and revealed to the patient. Robotic surgery naturally involves certain risks inherent to all forms of surgery/laparoscopy and these must always be effectively communicated to the patient.[4]

In addition, a robotic surgical procedure entails various further potential hazards which must be carefully evaluated by the surgeon and the patient. There have been certain recalls in recent months for da Vinci robotic equipment due to malfunctions ("MAUDE Adverse Event Report: INTUITIVE SURGICAL,INC.DA VINCI SI SURGICAL SYSTEMENDOSCOPIC INSTRUMENT CONTROL SYSTEM," n.d.). Thus, technicians and medical staff must diligently inspect the components of the robot

[4] Intuitive Surgical lists major surgical complications which could result at the bottom of their webpages. These include internal scarring, infections, pain, temporary nerve injury, etc. ("da Vinci Surgery - Minimally Invasive Robotic Surgery with the da Vinci Surgical System," n.d.).

regularly in an effort to prevent unintentional harm coming to the patient to do malfunctioning robotic instruments.

Another area of concern falling under this principle of non-maleficence is the competency of the surgeon in performing this procedure. As the da Vinci robot was created by a private industry, instruction and training recommendations for the use of this surgical robot come from its manufacturer, Intuitive Surgical. However, Intuitive Surgical only recommends a certain training, thus actual training programs vary in length and intensity depending on the medical institutions decisions. The current training procedure proposed by Intuitive Surgical involves a course which involves theoretical lectures about robotic surgery, learning how to use the robot, and practice on animal cadavers. Following this, the first five procedures the surgeon performs on actual patients must be proctored by an already experienced robotic surgeon. For a surgeon already well-experienced and successful in performing laparoscopic minimally-invasive procedures, this training program may suffice; while for other surgeons who are not very familiar with laparoscopic techniques and features, this will not provide enough training. An effective means to insure that everyone has sufficient training would be to an examination procedure to credential surgeons who have the skill necessary to operate on real patients. This idea will be developed more in the following chapter. Such a measure of competence should be created not by the company creating the device but ideally by a panel of un-biased and trained surgeons. Furthermore, surgeons ought to inform patients of how many robotic procedures they have successfully completed up to that point (particularly if the surgeon is still fairly new to robotics) so that the patient may account for this when considering the risks of electing to have a given surgery.

Beneficence and the da Vinci

Beyond non-maleficence comes the principle of beneficence, wherein the physician not only does not harm, but in fact provides significant benefit to the patient with the medical intervention. The application of this ethical concept to robotic surgery is still difficult to define since several studies conducted about the benefits of robotic surgery over laparoscopy have called into question its reported additional benefits for the patient. The robotic technology has shown potential in certain forms of surgery in which the improved visibility and reduced hand tremor may contribute to reduced risk of complications for the patient. In cases in which tiny, precise movements and a more flexible range of motion are needed, such as prostatectomies, the da Vinci robot may assist the surgeon in performing better and reduce the chances of damaging nearby nerves or other organs. Given current studies and knowledge of robotic surgery's outcomes, the surgeon should weigh the higher cost of a robotic procedure with the potential improved outcomes likely for each individual patient given their specific risks and condition. The possibility of better surgical results through a da Vinci robotic surgery must be objectively considered and balanced with the increased cost of the procedure.

Justice and the da Vinci

The next principle of biomedical ethics to consider in its relation to robotic surgery is Justice. Surgeons ought to participate in just promotion and utilization of the da Vinci robot free from conflicts of interest. Additionally, justice in the medical field also involves treating all patients fairly and providing high quality of care that proves to

be equal and appropriate for all patients. These aspects of biomedical justice are in various stages of application across the United States, and disparities will likely continue to exist in certain facets of healthcare. Some factors which can influence the provision of just healthcare are highly variable and very difficult to adjust for and rectify. Examples of these complex factors include variance in access to care caused by geographical location, varying amounts of federal funding to a medical institution, and difference in means of patient transportation, among others. But in regard to robotic surgery, guidelines for judicial use can more clearly be outlined and presented.

Naturally, justice in surgeons' recommendation and use of robotic surgery is very complex and difficult to evaluate given the many factors involved and the multiple motivations of physicians and hospitals. The da Vinci robot is very expensive surgical equipment, costing between $1 and $2.5 million per da Vinci system (Barbash & Glied 2010). Thus when a hospital or surgical group purchases a surgical robot, the organization may feel compelled to use it as frequently as possible in order to compensate for the cost. This practice can prove problematic however, because as a result of these financial pressures surgeons may recommend a robotic procedure to patients who could receive comparable treatment through a less expensive, established laparoscopic procedure. This conflict of interest will remain a potential factor until such time as the base cost of the da Vinci robot and its accompanying instruments either decreases or the costs of robotic and laparoscopic minimally invasive procedures become comparable. Until a time when this type of change could occur, the physician must justly respond to this financial motivation to overuse the da Vinci robot by consciously reviewing the balance between the rights of the patient and the financial success of the

physician/hospital. In such situations, the physician must remember that the needs of the patient ought to take priority over the financial objectives of the physician.

These concerns are further augmented by aggressive marketing of robotic surgery by Intuitive Surgical and occasionally by hospitals and physicians. While American society today generally accepts healthcare advertising as a part of the modern system, this advertising by respectable medical institutions and physicians has been accepted only recently. In 1975 the Federal Trade Commission filed suit against the American Medical Association's ban on physician advertising. The first American Medical Association *Code of Ethics*, from 1847, opposed physician advertising, stating that it would be "derogatory to the dignity of the profession…to resort to public advertisements" (Tomycz, 2006). As a result of the dismissal of this ban on physician advertisement, many medical doctors began to participate in advertising by promoting their services and providing testimonials for various devices and procedures. Since then physician advertising has become a commonplace occurrence and indeed played a significant role in the promotion of the da Vinci robotic system.

Thus surgeons must strive to remain unbiased in their use of the da Vinci robotic device and respectfully inform all patients of potential risks/benefits. Furthermore, conflicts of interest regarding recommendation of the da Vinci robot in physician consultations and clinical studies/trials must be avoided and openly stated if any exist. Additionally, learning to use a new device such as the da Vinci involves a learning curve for surgeons. This complicates the just use of such technologies because it is nearly impossible to provide all surgical patients with equal care, since between the first 15 and 30 patients on which a surgeon performs a robotic surgery are likely to have less positive

outcomes because they are part of the learning curve (Steinberg ec. al. 2007). On the opposite side of this issue, a surgeon who does a very large number of laparoscopic surgeries, particularly ones involving complicated anatomy, may be able to improve the quality of the procedures as a whole by doing them robotically. Ergonomically, the da Vinci robot is known to provide a more comfortable and precise surgical experience for the surgeon. Thus if a surgeon has very large patient volume, using the provided ergonomic benefits of the da Vinci system may improve the quality of the surgery for the patient and lower chances of human error by reducing the fatigue and physical stress of the surgeon. However, if this is the case, the surgeon must be certain that he uses the advantages of the robot in line with physician self-effacement (placing the good of the patient above his or her own) and strive to insure beneficence towards the patient and not simply doing robotic procedures to seek his own comfort.

Autonomy and the da Vinci

Lastly, the principle of autonomy can also be applied to the developing technology of robotic surgery. The physician has the responsibility to present the patient with unbiased information regard robotic surgery so that the patient can make an informed decision of treatment; following which the surgeon must respect the patient's decision regardless of whether or not they decide they wish to have a robotically-assisted surgical procedure. Just as the surgeon must respect the autonomous rights of the patient, patients must respect the rights of autonomy of the physician. Thus physicians have a right to refrain from performing a robotic procedure if they do not feel that it will have enough benefits to outweigh the risks, or if they feel they are as yet incompetent in

performing this form of surgery. This is an issue illustrated in an article quoting physicians who stated that they began doing robotic surgery because they felt patient pressure (Sharkey & Sharkey, 2013). Some patients felt that they would like to have a procedure using this new technology, and these patients were leaving their surgeon to seek out new surgeons who did robotic surgeries. Similarly, a physician may propose the da Vinci procedure if he or she truly feels it will be the best course of action in keeping with the four ethical principles, such as in the circumstance of a specialist physician with a very high patient volume as described above.

The four principles of biomedical ethics thus provide a good framework through which new technologies such as the da Vinci can be evaluated, and in using these four values physicians and hospitals can create ethical guidelines and suggestions for the use of robotic surgery and other new technologies that will surely come into the medical field in the future. Technology has given us many benefits, but the medical community must make sure to seek these benefits and not forget ethics in its medical treatments and healing. These ethical practice recommendations can be instantly implemented for da Vinci robots already in use and for surgeons who have already integrated this technology into their practice. But further guidelines will need to be implemented for the training of new physicians and the addition of more robots.

CHAPTER FOUR

A New Training Model for the da Vinci Robot and Conclusion

The previous three chapters have explained the growth in popularity of the da Vinci robotic surgical platform and how it could be beneficial to patients and physicians, but attention has also been drawn to the need for training guidelines and careful assessment of the utilization and dispersion of this surgical technology. In this concluding chapter a general system of training and evaluation (based on a similar strategy currently in place for laparoscopy) will be proposed that could hopefully capitalize on the surgical benefits of robotic surgery and provide a way for it to become more cost-effective within an ethical framework. But prior to making such recommendations, a review of the issues and concepts regarding the da Vinci robot and presented in this paper is in order.

In summary, the da Vinci robot is a new surgical platform for minimally invasive procedures created by the company Intuitive Surgical. It was created not necessarily to compete with current laparoscopic techniques but rather as an alternative with improved ergonomics for the surgeon and more degrees of freedom in comparison to laparoscopy, which could improve surgical outcomes for complicated surgical cases. The original da Vinci robot was developed and marketed by the company in 1999 and since that time two new models have come out, the latest in 2009. The da Vinci surgical system consists of a patient side-cart with three or four robotic arms that carry out the surgeon's directions: one of these robotic arms is equipped with an endoscopic camera and the others hold

various laparoscopic surgical instruments, all of which are inserted into the patient's body from incisions that are a couple of centimeters wide. The surgeon manually makes the incisions wherever needed and insures the instruments are inserted properly and then sits at the surgeon's console. The surgeon carries out the surgery from the surgical console, which nearby in the operating room and manipulates the master controls for the robotic arms while viewing a three-dimensional image of the patient's internal anatomy. The da Vinci robot was originally cleared for general laparoscopic surgical procedures and then spread to other surgical disciplines. Today it can be used for procedures in multiple surgical fields including urological, general laparoscopic, gynecologic, certain trans-oral otolaryngology, general thoracoscopic, and thoracoscopically assisted cardiotomy procedures ("da Vinci Surgery - Minimally Invasive Robotic Surgery with the da Vinci Surgical System," n.d.).

From a technical perspective, the da Vinci robot was created to overcome some of the limitations of laparoscopic devices. Laparoscopy instruments only have four degrees of freedom whereas the da Vinci's Endowrist® instruments have seven degrees of freedom which allow for a greater range of precise motion. The robotic arms also reduce surgeon hand tremor, which in conjunction with the increased freedom of motion could reduce chances of surgical error. In addition, the da Vinci robot is far more ergonomic for the surgeon. Instead of leaning over the patient holding laparoscopic instruments, the surgeon sits at the console and uses the hand controls. This reduces surgeon fatigue, which affects the likeliness of physician errors. All of these features of robotically-assisted laparoscopic surgery combined create the potential of making minimally-invasive surgeries possible for certain types of procedures which historically have been

invasive. Furthermore, proper and skilled use of the da Vinci robot could extend the availability of minimally invasive procedures to individuals with certain anatomical characteristics or comorbidities which would otherwise make a laparoscopic surgery unsuitable.

However, the da Vinci robot costs significantly more than regular laparoscopic devices. The price of a da Vinci robot is nearly two million dollars (with additional maintenance costs) whereas laparoscopy instruments are generally one to three thousand dollars. Also, various recent studies have shown that laparoscopic and robotic procedures produce comparable results and rates of complications for the average patient. This suggests that robotic surgery does not necessarily provide the normal patient with additional benefits over the laparoscopic alternative but costs significantly more. This great cost-ineffectiveness of the da Vinci robot is a large concern for some in the medical community. Attempting to recover the enormous cost of the da Vinci surgical procedure has also led to certain ethical concerns regarding this device.

To balance the high cost of acquiring a da Vinci robot, many hospitals and physicians strive to do a significant number of robotic procedures, which as a result leads to marketing and advertising of the surgical robot by medical groups. The company Intuitive Surgical also engages in intense advertisings for their device which sometimes appear to exaggerate the potential benefits of having a robotically assisted surgery. All these advertisements can lead to a situation in which a patient may come to feel a surgery using the da Vinci robot seems better for them than it may be in actuality. In addition, the American population at large tends to be a technologically driven society. In this case, many individuals maintain the belief that new is better in technology, and thus they

seek out new technologies that become available (Paul, 2013). In surgery this has led to pressure from patients for physicians to adapt the new da Vinci robot; and for hospitals this could result in a halo effect for robotic surgery and success of the institution.

The other concern that has arisen in response to the surge of robotic surgery is the training process required for surgeons and the regulations in place for the use of the da Vinci. This originates the Food and Drug Administration's (FDA) approval process for the da Vinci robot. Intuitive Surgical presented the robotic surgery platform as an equivalent to laparoscopy, and so it was subject to an abbreviated approval process. Since the da Vinci is a modification of an already legally market device (regular laparoscopic instruments) it did not have to undergo the stringent pre-market trials as an entirely new medical device/procedure. Therefore it was not necessary to conduct clinical trials with the same rigor to insure its efficacy, and some medical professionals believe that for the da Vinci robot there were not enough studies and supportive evidence to merit the mass dispersion of the device that occurred once the FDA cleared the robot. Also, surgeon training regulation and evaluation of competency was largely left to the company and hospitals. The training requirements currently in place involve a day-long training session including robotic simulation and various practice procedures on animal patients, following which a surgeon must have a certain number of his/her first real robotic procedures proctored by a surgeon already experienced in the given robotic procedure. Continued evaluation of competency is fragmented, varying from hospital system to system, and so there is a possibility for physician incompetence to possibly go undetected. Hopefully these concerns will be addressed by the training program that will be presented.

The third chapter of this thesis dealt with the predominant ethical principles acknowledged in medicine and how they can apply to robotically-assisted laparoscopic surgery done by the da Vinci. The ethics of Western medicine are grounded in the Hippocratic Oath, which emerged in the medical environment of ancient Greece in around the 4th century B.C. The tradition of medical students swearing by the Hippocratic Oath when they become physicians continues today, but the oath has been altered extensively over the centuries in response to changing social principles. However the original Hippocratic Oath had certain themes which persist to modern times. Among these are the idea of "do no harm," maintain the "purity" of the medical profession, render only the services one is competent in, and do as much as possible to help the patient.

In the latter half of the 20th century, Dr. Beauchamp and Dr. Childress focused on four concepts of medical ethics which have now become some of the most commonly known and accepted principles in the medical field. The first biomedical principle these two philosophers presented was autonomy, which refers to an individual's right to self-determination and to have an active role in making decision that will affect him or her. The next principle discussed is non-maleficence, which correlates to Hippocrates' concept of do no harm. This principle states that at the very least, a physician ought not to worsen the patient's condition if the doctor cannot improve it. Non-maleficence ties to insurance of medical competency and physician self-regulation/evaluation. The third principle is beneficence, which relates to healing the patient or alleviating pain. The goal of beneficence for a physician is to improve a patient's well-being and health, but the definition of what this precisely entails changes with society and technical advancements.

Beauchamp's and Childress' fourth principle is justice. In a medical setting justice has many applications and includes such values as fairly distributing resources, treating all patients fairly and with respect, and using one's medical knowledge and treatments in a just manner. There are many other ethical codes in existence, but these four have become the most commonplace among practioners in the Western medical culture. These four medical principles cannot solve many ethical dilemmas and do not always align with one another; however, they still provide a good foundation for physician conduct guidelines and ethical discussion. Evaluation of how these principles of beneficence, non-maleficence, autonomy, and justice apply to robotic surgery can help address some of the concerns created by issues of cost-containment, monetary pressures, patient requests and physician recommendations, conflicts of interest, etc. Active application of such an ethical system to the use of the da Vinci robot would improve its likelihood of bringing maximum benefit to the surgical community and becoming a sustainable part of surgical practice for the future.

In light of all these facts and conflicts, a framework must be created to insure that robotic surgery can ethically become a lasting and efficacious medical procedure. One way to reach this goal is to focus on training of surgeons new to the da Vinci robotic surgery and to insure that physicians are competent when they begin performing robotic surgeries on patients. Currently, training for the da Vinci robot is rather fragmented. Before being able to perform a robotic procedure on a real patient, a physician must participate in product training recommended by the company Intuitive Surgical to learn to properly use the da Vinci robot. It generally involves a one to two day training course with sessions explaining the features/uses of the da Vinci, followed by hands-on practice

on a da Vinci Skills Simulator as well as practice of common procedures on a test animal. Following this, specific skills training for specialized surgical robotic procedures and continuing education is planned and coordinated by individual academic institutions, surgeon groups, and hospitals. This could lead to discrepancies in physician credentialing and levels of competency in between regions and hospital systems. Therefore, a more structured and universally implemented training and testing method ought to be introduced. A current example that could be a guide for the da Vinci system is the Fundamentals of Laparoscopic Surgery (FLS) education model and simulator which is already used and currently gaining popularity for teaching surgical residents how to perform laparoscopy and improve their proficiency. The FLS was created by the Society of American Gastrointestinal and Endoscopic Surgeons, is now endorsed by the American College of Surgeons, and in 2009 was made a pre-requisite for the general surgical board qualifying exam by the American Board of Surgery ("FLS Program Description - Fundamentals of Laparoscopic Surgery," n.d.). According to the FLS website, the Fundamentals of Laparoscopic Surgery program is "a comprehensive, educational module and assessment tool designed to teach the fundamental knowledge, clinical judgment and technical skills required in the performance of basic laparoscopic surgery" (FLS Bulletin of Information, 2013). The FLS consists of multiple web-based study guides which cover didactics and interactive scenarios, hands on manual skills practice and training via the FLS Laparoscopic Trainer Box to train technical skills, and at the conclusion an assessment exam to measure the cognitive and technical skills of the surgeon ("FLS Program Description - Fundamentals of Laparoscopic Surgery," n.d.). The assessment exam has two parts, the first consisting of a timed multiple-choice exam

to measure cognition of laparoscopic terms and scenarios, and the second component of this exam is a based on speed and accuracy of the FLS provides a more controlled and cost-effective setting to obtain laparoscopic experience compared to the operating room (Scott ec. al, 2000). Multiple studies have shown that training with the simulator improves performance for surgeons (Fried ec. al., 1999; Feldman ec. al., 2008; Derossis ec. al., 2008; Scott ec. al., 2008). Laparoscopy and robotic surgery share several surgical traits, thus the organization and framework of this laparoscopic simulation lab could be adapted for da Vinci robot training. In fact, Intuitive Surgical has already created a da Vinci Skills Simulator console for the newest robot model, and so this can be standardized for a formal training course and expanded to be compatible with the two older generations of the da Vinci ("Intuitive Surgical - da Vinci Si Surgical System - Skills Simulator," n.d.). Creating an assessment component based on the assessment exam of the Fundamentals of Laparoscopic Surgery would implement an objective and unbiased way to insure surgeons beginning to perform da Vinci procedures have reached a certain level of competency and quality. Hospitals and surgical groups can translate the FLS in a uniform, organized fashion to the da Vinci system so that clinicians can receive proper training, and clinicians who feel they need greater amounts of training will be able to practice on the simulator before progressing to caring for true patients.

Furthermore, in considering the common features between laparoscopy and the da Vinci, it is understandable that physicians who are already well-experienced in performing laparoscopic procedures would require less formal training for robotic surgery using the da Vinci considering the relationship between the two forms of surgery. Creating a uniform certification exam for competence with the da Vinci robot would

make it possible to evaluate such skilled surgeons in a more efficient manner. Within the training program modeled on the FLS, an option can be created for surgeons to be tested for their proficiency and cognition before they would go through an entire training course; that way their skill can be verified and they can be approved to begin performing da Vinci procedures after a shorter course. Surgeons should not be given privileges of doing robotic surgeries until they can demonstrate competency in robotically-assisted laparoscopic simulation.

Following this, a continuing education curriculum can be added to the simulation program to assure that physicians maintain a high-proficiency level even when not performing large numbers of surgeries regularly with the da Vinci robot. For instance, a standard number of procedures a surgeon ought to perform within a given time interval to remain competent should be established, and if a surgeon does less than that amount over a significant period of time, he or she can participate in this continuing education simulation in order to maintain competency even when actual patient volume is low. If these guidelines are followed in an ethical frame this could also reduce the number of robotic procedures that surgeons perform simply to maintain skill and volume. These measures and simulations all combined will not only protect the patient and reduce likelihood of surgeon error but could also work to make the da Vinci robot more cost-effective. If surgeons are trained thoroughly in the procedure (and are given a way to maintain that proficiency in times when they may not be getting as much clinical experience with the robot) they can perform at an expert level—surgeons can have already advanced along the learning curve somewhat before even beginning to operate on patients. Surgeons further along the learning curve generally require shorter operating

room time, which would cut down the costs which accrue with the longer robotic operations many surgeons have when they first begin.

Lastly, such a robotic surgery training program as the one described here should not be created by Intuitive Surgical (the industrial maker of the device) but rather by a surgical organization with input from many surgeons, as happened in the formation of the FLS. In this way industrial conflicts of interest will hopefully be minimized and experienced physicians can design a training program for the benefit of new or improving robotic surgeons and their patients. Also, in regions of the United States where the da Vinci robot has not yet been introduced, this robotic surgical procedure and its training program should first be brought to large/regional hospitals and medical centers in the area. Once the technology has been firmly established at these hospitals and its reception studied, then, if it eventually proves it can be used in a cost-effective manner, it can gradually diffuse out to other hospitals in that region. In this way, efficient and appropriate utilization of the technology can be implemented from the start.

New medical technologies develop continually, and the da Vinci robot is a recent example of how the innovative face of the medical field has shifted in the past century to include industry as well as academic institutions. In addition to the complex moral and ethical deliberations that have become a significant part of medicine today because of all the advanced technologies we have developed, we must also bear in mind the importance of continuing to address conflicts of interest, monitoring of for-profit activity, and the continuing need to prioritize the patient's wellbeing. Medical advancements in technology have brought many important developments to medicine and improved standards of living and longevity, but as new technologies continue to develop, we must

be very vigilant in how we implement them. We must continually evaluate the technologies we use in light of the ethical and moral principles our culture and medical tradition value. As Herman De Dijn explains, "ethics has to do with the question of how we ought to live or act; technology with new ways and means to do new things" (Herman De Dijn, 2002) and medicine must continually keep them in balance. Ethics cannot be separated from the customs, values, and norms of a given culture or way of life. So in a culture like ours which prizes technological advancements, we must make sure that our ethical principles actively interact with and shape how we use new technologies. Medical Technology Assessment can play a very useful role in this, as new technologies should be evaluated before they are applied; "systematic research, which includes consideration of the ethical, legal, and social implications of a new technology as well as rational decision-making based on results" must be a part of our ever-changing medical innovations (H. t. Have, 1995).

The da Vinci robot presents certain benefits for the surgeon and the way that he/she can perform certain surgical procedures, but the goal of medicine is to benefit the patient (and by extension his or her community), and so we must be sure that we keep this ethical priority in mind as the use of this new surgical technology becomes wide-spread. Da Vinci robotic surgery could potentially have various long-term effects for our medical culture that deserve to be kept in the medical conversation about robotic surgery. Its use could one day be expanded into military and battlefield medical practices, as well as influence the development of advanced telemedicine and use of computerized algorithms to supplement physician actions. But in the current situation in which the da Vinci robot is very expensive and its long-term results and halo-effect benefits are still

being studied and debated, physicians should use it with great ethical deliberation and care. Some of the ethical concerns surrounding the da Vinci robot which are now coming to light could possibly have been avoided or reduced, if diffusion of this technology had been more organized and systematic between hospitals and surgeons. Technology changes what we do, or how we go about doing it, but at times our culture changes in regard to a new development before we can ethically determine how the technology ought to be handled which can lead to complicated interactions between different facets of our medical culture. Part of this is that "progress inevitably produces side-effects which are unforeseeable" (Herman De Dijn, 2002) as is seen with the da Vinci, and thus we must keep these ethical considerations in mind now and also in future instances when introducing and promoting new technologies. Particularly in an age of diminishing resources—and especially given the current changes occurring in United States healthcare and concerns of spending—new technology will increasingly need to be efficacious and cost-effective for the patient and the health system (Shi and Singh, 2013). Using the context of similar past technological developments, we must try to understand how a new technology could ethically affect the medical landscape and the society within which it operates. Perhaps we have entered a time in which it may be wise to "adopt a conservative policy vis-à-vis technical progress" (H. t. Have, 1995) and integrate technology with greater care.

We have come to discover that "technology is not only a cultural product, but itself a producer of culture" and application of such technologies require the creation of a sound social network for their appropriate use (H. t. Have, 1995), lest we allow the technology to shape us more than we do it. Medical technologies and innovations have

brought many positive changes to patient care and treatment, but as a culture we must be wary of becoming so caught up in the rapid expansion of technology's role in medicine that we focus less on the human and moral priorities that ought to underlie it. Currently, medical technologies are generally not evaluated according to an ethical basis, which has led to the problems discussed in this paper. A solid ethical foundation for the use of medical technologies must be created in order to eliminate these issues. "Not despite of technology, but because of it, man is able to obtain a better understanding of the *condition humaine*," (H. t. Have, 1995) and this relationship is one that must be ethically preserved and assessed for the great advancements that it can produce.

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