Center for Devices and Radiological Health (CDRH)
Office of Surveillance and Biometrics (OSB)
Medical Product Safety Network (MedSun)
Small Sample Survey – Final Report
Topic: da Vinci Surgical System
November 2013

Introduction

The da Vinci Surgical System is a computer-assisted device designed to facilitate surgery using a minimally invasive approach. The da Vinci Surgical System is used in several medical specialties and for multiple indications. There are three main integrated sub-systems: (1) the Surgeon Console, which is the control center of the system and allows the surgeon to view the surgical field and control movement of the endoscopic instruments and endoscope; (2) the Patient-Side Cart, with three or four articulated mechanical arms which supports the endoscopic instrument arms and camera arm during surgical procedures; and (3) an Electronic Cart, which contains supporting hardware and software components, such as the electrical surgical unit (ESU), suction/irrigation pumps, insufflator, and light source for the endoscope.

The FDA conducted the survey to speak with experienced surgeons who use the da Vinci Surgical System in a variety of procedures to better understand their perspectives on the different challenges raised when using the system interface to perform surgery versus using conventional surgical procedures.

Methodology

The survey queried a small sample of respondents to obtain detailed and in-depth perspectives from users of the da Vinci Surgical System who represent different medical specialties. Eleven surgeons from ten different institutions (located in the West, Midwest, East, and Southern regions of the U.S.) participated in the voluntary survey.

Most respondents were from hospitals with a bed size of 100 or more. The FDA made several attempts to include respondents from smaller size institutions but only one respondent was from a hospital with a smaller bed size. Six of 11 respondents came from institutions that participate in FDA's Medical Product Safety Network (MedSun) of hospitals, and the FDA selected the other five respondents based on referrals from other surgeons and device specialists. All selected respondents have some experience with the device.
The respondent sample of surgeons included:

- 4 obstetricians/gynecologists with a range of 8 to 25 years in practice;
- 3 otolaryngologists with a range of 8 to 22 years of practice;
- 3 urologists with a range of 5 to 28 years of practice; and,
- 1 cardio-thoracic surgeon who has been in practice more than three years.

Over the last three years, each respondent has performed 70 to 600 surgeries using the da Vinci Surgical System.

The survey was conducted between January and April 2013. Survey respondents were asked 10 questions about their use of the da Vinci Surgical System, some of which had sub questions (see attachment). The FDA asked additional questions when clarification was needed.

The following report begins with an overview of the surgeons' common responses followed by specific responses for each medical specialty.

Overview of Responses to the Survey

All respondents report needing to perform multiple surgeries before feeling fully proficient using the da Vinci surgical system. The actual numbers of surgeries needed vary among respondents. However, respondents say that the complexity of the device-user interface is not a major deterrent to its use. Respondents with laparoscopic experience reportedly have an easier transition to the da Vinci Surgical System than surgeons without laparoscopic experience. The biggest challenges mentioned most often are hand-eye coordination, use of the foot pedals, and learning the platform, (i.e., how to position the ports for instrument access to minimize collision of arms, and how to optimally place the arms to maximize positive surgical outcomes). The surgeons must rely on vision and judgment, since they are not directly touching the surgical instruments.

Some respondents say the manufacturer encourages them to participate in training at one of its 33 epicenters. Respondents have participated in a variety of training sessions sponsored by the manufacturer and by their institutions. Each respondent has had a different training experience that includes various combinations of the following types of training:

- Certification after completing approximately three to eight hours of online training;
- Dry lab training, including modules for system set-up, docking, and manipulation of the arms;
- Practice time in porcine, dog, and/or cadaver labs;
- Watching videos;
- Training on a simulator; and,
- Having proctors for three to five cases, who may be paid by the manufacturer.

The training programs and the approach to monitoring surgeons vary among institutions. Some programs are comprehensive, team-focused, and involve close monitoring by proctors. Others

depend on the individual surgeons determining what they need to successfully perform procedures using the system. Challenges include getting staff trained and trying to get an efficient process in place to deal with system setup. In one hospital, the surgical team of nurses, technicians, and physician assistants received training from the manufacturer's training team.

Some respondents have "robotic" or credentialing committees in their hospitals with representation from one or more specialty areas to monitor training and practice. In addition, most hospitals have their own criteria for proctors.

The instructions for use and for troubleshooting system problems are available to respondents online and in hard copy. However, if a problem occurs with the system, a manufacturer's representative is available by phone or in the hospital. Some respondents allow the representative in the surgical suite during a procedure.

Considerations for patient selection vary across the specialty areas and are primarily based on maintaining patient safety. These may include patient age, anatomy, Body Mass Index (BMI), risks/benefits, potential side effects, and anticipated post-operative recovery time. In addition, respondents say certain disease processes and the impact on surrounding structures are also a factor in patient selection.

When asked about patient problems using the da Vinci Surgical System, respondents include outcomes that may occur in any surgical procedure, such as bleeding, pulmonary embolus, and myocardial infarction; outcomes that may be specific to the type of procedure performed; and, outcomes that may only occur with the da Vinci Surgical System when it is used to perform a procedure. In this report, only the problems related to the da Vinci Surgical System are included.

Additionally, when discussing patient outcomes using the da Vinci Surgical System, respondents often use comparative words, such as "better," or "less." It was not always apparent if the respondents were making the comparison to patient outcomes with laparoscopic surgeries or to open surgeries.

Respondents use multiple instruments with the da Vinci Surgical System. The following instruments are generally used by all respondents during procedures:

- Scalpels;
- Clip appliers;
- Forceps;
- Cautery;
- Graspers; and,
- Scissors.

When asked about recalls, three of the 11 respondents are aware of manufacturer actions or

recalls initiated with the da Vinci Surgical System. Two respondents are aware of the recall on the monopolar scissors, and the third respondent did not know the specifics of any recall.

Obstetrics and Gynecology (OB/GYN) - Four Respondents

The da Vinci Surgical System models used

All four respondents have used both the S and Si models of the da Vinci Surgical System. The number of arms used during surgery depends on the type of surgery performed, however, respondents use three arms during most surgeries. One respondent uses the fourth arm specifically during sacrocolpopexies for moving and positioning the intestines.

Other devices used during OB/GYN Surgery with the da Vinci Surgical System

The OB/GYN respondents did not mention other devices used with the da Vinci Surgical System.

Training

Two respondents refer to their training as combinations of online, dry lab, pig lab, and case observations. One respondent has advanced laparoscopy credentials and just needed to finish the online program. Another respondent describes training in the dry lab for a day and the pig lab for a day but believes more time is needed in the labs for surgeons to become comfortable doing cases. All four respondents proctor new fellows and residents, but only those in their own hospitals. One respondent adds that proctors do not scrub-in for the surgery. They are only present to observe the surgeon or to teach using the teaching console. Proctors can observe the surgery on a standard monitor or in 3-D using the optional teaching console.

Procedures most and least suited for the da Vinci Surgical System

All four respondents primarily use the da Vinci Surgical System to perform hysterectomies. They also report sometimes using the da Vinci Surgical System for myomectomies, sacrocolpopexy, and to remove uterine tissue due to severe endometriosis. They use the da Vinci Surgical System less often to perform oophorectomies. All four respondents agree that the system is most suited for performing a radical or total hysterectomy for endometrial cancer, early cervical cancer, multiple adhesions, adenomyosis, and for myomectomies to remove fibroids.

Respondents report that the 3-D vision provides the ability to get behind the uterus, which can make it a better surgical option than standard laparoscopic surgery. One respondent can complete sacrocolpopexies in 2.5 hours versus 4 to 5 hours for an open procedure because of the precision and improved 3-D vision using the da Vinci Surgical System. According to another respondent, performing hysterectomies, myomectomies, and procedures for endometriosis usually takes 30 to 40 minutes for the da Vinci Surgical System versus an hour or more during open or laparoscopic surgery. However, another surgeon adds that they are just as fast doing cases robotically as they are performing standard laparoscopy cases.

None of the respondents specify least suited procedures.

Patient selection

One respondent does not use CT scans or other tools to determine if a patient is appropriate for surgery with the da Vinci Surgical System. This respondent always uses the system if it is available. If the system is not available, the surgery is performed laparoscopically. Another respondent indicates that the da Vinci Surgical System is an effective procedure for obese women (obesity determined by BMI) with endometrial cancer and adds that the challenges are less than with an open procedure. Some obese patients can tolerate being in the Trendelenburg position (used during surgery with the da Vinci Surgical System), while for others ventilation can be difficult. One surgeon reports that patients in the Trendelenburg position require different fluid management versus patients in the prone position, because they are subject to facial and pulmonary edema. This respondent had to convert a few obese patients to an open procedure because of positioning problems; however, positioning can also be difficult in an open procedure**.** One respondent did not comment on patient selection.

Patient outcomes

All four respondents report the following ***benefits*** to patients when using the da Vinci Surgical System:

- Less bleeding;
- Less time in the hospital—only 24 hours in most cases;
- Less pain and less pain medication needed; and,
- An earlier return to work—five days post-op.

Respondents report experiencing one or more of the following ***patient problems*** when using the da Vinci Surgical System:

- Seromas in obese patients (does not occur during laparoscopic surgery); and,
- Limb palsy from arms being taped while in the Trendelenburg position (palsy has been reversible).

According to respondents, post-operative monitoring of patients following surgery is the same for both the da Vinci Surgical System and conventional surgery.

Reported device problems

Three respondents report the following problems with the da Vinci Surgical System arms. No injuries to patients were reported during these events.

- Crack in one arm that caused an instrument to fail;
- Arm required servicing after instrument failed to read;

- Arm drifted during a procedure; and,
- Arm did not work and was replaced.

When asked about procedures to follow if a power outage occurs, respondents follow the manufacturer's "eject protocol" designed to prevent patient injury by quickly removing instruments and undocking the da Vinci Surgical System within 30 to 60 seconds.

Otolaryngology - Three Respondents

The da Vinci Surgical System models used

Two respondents have used the S and Si models. One respondent uses two arms and the device camera. Another respondent uses three arms and the device camera. One respondent did not indicate the specific device model used in their facility.

Other devices used with the da Vinci Surgical System with TransOral Robotic Surgery (TORS)

- Cannula; and,
- Suction devices.

Training

Responses vary concerning training experience and range from limited, self-initiated training to intensive training by the manufacturer. Training labs involved practice on pigs, dogs, mannequins, and cadavers. One respondent thinks the manufacturer's pig model for training is not good for head and neck surgery because pigs do not have tonsils or 2-sided tongues. Instead, respondents use the dog model in training labs because dogs have more similar head and neck anatomy to humans than do pigs.

Another respondent notes that because of having experience performing many endoscopic, skull-base surgeries and advanced sinus surgeries using a monitor and screen, learning TORS did not seem difficult. The respondent adds that there are always two surgeons present on a case; one at the console and one at the patient's side.

All three respondents proctor surgeons, but only in their hospitals. Two respondents state the device instructions for use are kept in their operating room (OR) near the device. However, one respondent indicates that the manufacturer's representative is in the hospital to respond to questions and to help minimize negative experiences.

Procedures most and least suited for the da Vinci Surgical System

All respondents use the da Vinci Surgical System for TORS. In general, respondents say that TORS is most suited for oral pharyngeal cancers, tonsil and tongue-base cancers, invasive tongue cancers, some glottis cancers, salivary gland malignancies, unknown primaries where it is hard to find the cancers, and human papilloma virus (HPV) cancers. Also, according to one respondent, use of the da Vinci Surgical System for HPV cancers is increasing. In addition, some

respondents mention TORS is most suited for patients with sleep apnea where the tongue-base is the ascending site and for patients where chemotherapy and radiation therapy have failed.

All respondents say TORS is least suited for thyroidectomies, tonsillectomies unrelated to cancer, and according to one respondent, for supraglottic laryngectomies because it is usually a one-hour operation. Another respondent states it is less suited for use on obese patients, and for oral cavity lesions, sinus surgery, and is not helpful for doing "free flaps" in surgery.

Patient selection

All respondents indicate that patient selection is important to patient outcomes; however, one respondent states that patient selection is not absolute and has stopped procedures when unable to access a tumor because of the patients' anatomy, size of teeth, size of mouth, and ability of patients to open their mouths. Another respondent believes that not every tongue cancer is suitable for the da Vinci Surgical System, and thus has a rigorous selection process. The respondent adds that if patient selection is appropriate, challenges during surgery are minimized.

Patient outcomes

One respondent reports that operator experience is a key factor in patient outcomes. Another respondent asserts that the death rate for TORS is lower across the board for all cases, although patient problems and surgical complications can occur. There is an interest on the part of a respondent to identify the benefits of TORS versus open surgery in specific areas such as, post-operative swallowing and the incidences of broken and chipped teeth that can occur during surgery.

All three respondents report one or more of the following ***benefits*** to patients:

- No external incisions;
- No tracheostomy, as would be necessary with a mandibulotomy;
- Faster recovery of swallowing and speaking; improved swallowing;
- Shorter hospital stays for some procedures; some patients may go home the next day; and,
- Fewer complications.

An additional benefit to patients mentioned with TORS in comparison to other non-surgical approaches:

- Chemotherapy avoided in almost half of the patients with advanced oropharyngeal cancer, when the non-surgical alternative would have been chemoradiation.

A respondent reports experiencing the following ***patient problem***:

- Temporary brachial plexus injuries occurred when using a transaxillary approach.

One respondent states post-operative monitoring of patients following surgery is the same for both the da Vinci Surgical System and conventional surgery. One respondent admits patients from one to five nights post-surgery with an average of three nights. However, after a neck dissection, patients may be discharged when pain is controlled and they can take feeding. Another respondent admits every TORS patient to the intensive care unit and depending on the extent of the resection, the patient may stay intubated overnight.

Reported device problems

One reported problem involves a cannula that cut the rubber coating on the system's arm. Subsequently, the manufacturer created a new cannula that is less sharp. Two respondents did not report problems with the device. Another respondent adds that the operative arms and instruments, such as cautery and graspers, are monitored for wear and tear and automatically replaced after being used 10 times.

Urology – Three Respondents

The da Vinci Surgical System models used

All respondents have used the S and Si models. One respondent has also used a third unspecified model.

Other devices used during Urology Surgery with the da Vinci Surgical System

- Ultrasound; and,
- Trocars.

Training

According to one respondent, the American Urological Association (AUA) has taken a role in standardizing training and credentialing for use of the da Vinci Surgical System, including patient selection and suggests that urology surgeons develop their own training and credentialing for use of the system.

Two respondents state they believe patient safety is directly related to the surgeon's training experience. One of these two respondents reports that there is no other certification that verifies a urologist is adequately prepared to use the da Vinci Surgical System for surgery other than the manufacturer's online training that issues a certificate at completion.

Respondents who have laparoscopic and robotic experience find training and credentialing less of an issue. However, one respondent who performed several hundred cases in a year using the da Vinci Surgical System during a fellowship did not feel proficient in the use of the device until after performing the first 40 to 50 procedures. All respondents believe laparoscopy experience and training is helpful in learning how to use the system. However, for one urologist, learning how to use the da Vinci Surgical System in the upper abdomen or peritoneal region took longer than expected. Also, one respondent reports that knowing where you are in the surgical field is

important in avoiding collision between the arms, which can occur often during prostate surgery. This particular respondent has developed training for residents.

Respondents say that the da Vinci Surgical System safety and operating manuals are available to all users. One respondent believes the instructions for use are good quality and can print the instructions, if needed. Another respondent keeps the instructions for use and operating manuals with other OR equipment materials and manuals.

Procedures most and least suited for the da Vinci Surgical System

The three respondents report that the da Vinci Surgical System is a widely accepted device used by urologists for pelvic surgery because the triangulation of the arms lends itself to the pelvic anatomy. All respondents state that the system is most suited for radical prostatectomy, distal ureterectomy, ureteral implantation, adrenalectomy, pyeloplasty, and procedures that require precise suturing and reconstructive techniques. It is least suited for radical cystectomy, and total and partial nephrectomy. According to the respondents, the latter procedures take between four and six hours with the system versus one to one and a half hours laparoscopically.

Generally, urology patients are placed in the Trendelenburg position during surgery; however, patients having kidney surgery are turned 90 degrees after they are intubated, in case the surgeon has to convert to an open procedure. In an attempt to remove kidney tumors, one respondent had to convert five cases to open procedures.

Patient selection

Two respondents have concerns about performing prostatectomies in obese men, based on BMI, in the Trendelenburg position. These concerns include problems with ventilation, anesthesia, and face swelling in patients with sleep apnea. Another respondent reported difficulty accessing the pubic arch in an obese patient and subsequently stopped the procedure on that patient. In addition, patients in the Trendelenburg position often have bowel pushing down into the pelvic area, which can make it technically difficult to perform the procedure.

Patient outcomes

One or more of the respondents report the following ***benefits*** to patients:

- Better access to a narrow pelvic area;
- Less time under anesthesia;
- Less blood loss;
- Less nerve damage;
- Less time in the hospital; patient discharge can be 12-18 hours earlier;
- Less re-admissions;
- Less pain medicine;
- Few, if any, bladder neck contractions following prostatectomy; and,
- Recovery time is less with follow up at three weeks and six weeks.

All respondents report no difference in ***patient problems*** with the da Vinci Surgical System versus laparoscopic surgery. However, one respondent believes complications occur because of errors in judgment primarily with patient selection. One respondent states that problems with urinary control following prostatectomy surgery are specific to the patient, such as age or size of prostate and abdomen. Another respondent reports the complications for kidney procedures performed using the da Vinci Surgical System are significantly lower and attributes this to faster cases. The respondent adds that the complication profile is less when patients are under anesthesia for shorter time periods and experience minimal blood loss.

Respondents report having experience with one or more of the following **patient problems**:

- Temporary neuropathy and numbness of the fingers related to positioning and securing the arm and wrist that gradually goes away;
- Loss of peripheral vision in one eye with the cause unknown; occurred in one case;
- Bleeding from perforated bowels; and,
- Urethral stricture/stenosis, but it is less common.

According to respondents, the post-operative monitoring of patients following surgery is the same for both the da Vinci Surgical System and conventional surgery.

Reported device problems

One respondent reports that maintenance is performed on their da Vinci Surgical System twice a year. The manufacturer's representative also runs diagnostics on the system periodically. Another respondent states maintenance occurs on their system every two weeks. There is a "wear" date on the light bulbs and one respondent makes sure the bulbs are changed. Another respondent notices that the coating on the optic lens starts to wear off after frequent washing. This particular respondent suggests follow-up metrics to determine the number of cases for the lens to remain effective before the coating wears off.

All respondents report one or more of the following device problems:

- Failure of memory function—working arms fail to recalibrate to appropriate settings when instruments are changed;
- Excessive collision between arms sometimes during prostrate surgery;
- An arm missed its mark by 1/2 to 1 centimeter a few times;
- Arm articulations (EndoWrist) stick/lock; when removed and rebooted, they usually work;
- Disposable instrument did not work;
- Harmonic scalpel had incorrect closure pressure and caused a stress point where the harmonic came out of the arm insert;
- Arcing of monopolar shears; and,
- 1-second delay on the console from wear and tear on the machine.

Cardiothoracic - One Respondent

The da Vinci Surgical System models used

The respondent has used both the S and Si models and is currently using the Si model. Most problems with the system are related to technical issues due to operator error. There have not been any system failures. When minor problems occur, the manufacturer's representative is called to assist the respondent.

Other Devices Used with the da Vinci Surgical System for Cardiothoracic Surgery

- Stabilizer;
- Microscopic Scissors; and,
- Clamps.

Training

The respondent states that the manufacturer has a good start-up training process. For many cardiothoracic surgeons, learning to use the da Vinci Surgical System is a tremendous leap, since they never trained laparoscopically. The respondent became more comfortable using the system after performing more than 100 surgeries. Post-operative angiograms are performed on the operating table to make sure there are no patient problems. Over time, conversion rates to open procedures have decreased. It is currently very low. The respondent does not proctor other surgeons at this time.

Procedures most and least suited for da Vinci Surgical System

The cardiothoracic surgeon uses the da Vinci Surgical System to perform non-invasive coronary artery bypass surgery and to harvest one of the bypass grafts through the ribs. The bypass vessels are prepared inside the chest and no cutting of the leg or arms is necessary. The respondent did not mention procedures least suited for surgery with the da Vinci Surgical System.

Patient selection

Patient selection depends on factors such as the coronary anatomy, co-morbidities, and patient weight. Obesity is the most common reason for non-selection. The respondent does not operate on children. When discussing types of patient referrals, the surgeon mentions two groups: young adults who want less invasive surgery and elderly patients whose physician feels a less invasive procedure is a better option. Inappropriate selection of patients can result in graft failure and post-operative myocardial infarction.

Patient outcomes

The respondent reports the following **benefits to patients**:

- No sternal fracture or broken bones;
- Small incision;
- Less operating time;

- Less external wound infections;
- Less bleeding;
- Less ventilation problems;
- Graft patency rate is higher;
- Fewer strokes;
- Fewer occurrences of atrial fibrillation;
- Fewer occurrences of renal insufficiency;
- Faster recovery; and,
- Earlier return to work.

The respondent notes no patient problems directly related to the da Vinci Surgical System.

According to the respondent, post-operative monitoring is different from conventional surgery because patients are off-pump with less time in the intensive care unit and require fewer infusions.

Reported device problems

- A minor problem occurred with one eye of the vision piece.

Summary

All but one respondent are currently using the da Vinci Surgical System Si model. All eleven respondents indicate that the system functions as intended. In addition, all respondents perform procedures with instruments that are commonly used with the system, while other devices used in the operating room may be more specific to the surgical procedure within a given specialty area.

All respondents report that learning how to use the da Vinci Surgical System is the biggest challenge because of the device's complex user-interface. All respondents have participated in some type of training, whether it was in their hospital or at one of the manufacturer's training centers. All respondents say they needed time for learning how to use the foot pedals, acquiring effective hand-eye coordination, and performing procedures without the ability to use their hands to touch or feel tissues, organs, or use sutures. For cardiothoracic surgeons, it may be more of a challenge learning to use the da Vinci Surgical System, since they may not have any prior laparoscopic training and experience. In terms of proficiency, respondents vary in the number of procedures they performed before feeling comfortable using the device. Seven of 11 respondents report proctoring other surgeons but only those in their own hospitals.

All respondents indicate that selecting the appropriate patient for surgery using the da Vinci Surgical System is a determinant for successful patient outcomes. All respondents report fewer patient complications and shorter hospital stays as a benefit of surgery with the system. Respondents who had to convert to an open procedure did so more often because of the patient's anatomy or co-morbidities, rather than because of system problems.

Ten of the 11 respondents report problems with the arms of the da Vinci Surgical System. Some of the arms were repaired by the manufacturer; others were replaced. Of note, only three of the 11 respondents are aware of any recalls with the da Vinci Surgical System. (Link to recalls)

Respondents' suggestions for enhancing the da Vinci Surgical System range from changes in the system design and training, to mounting the device on the ceiling to allow more space in smaller rooms.

Respondents offer the following suggestions:

- More training hours in the dry lab;
- Mandated hours for simulation training;
- Haptic or tactile feedback to determine the condition of the tissues and how hard to pull or push on tissues and sutures;
- Integration of ultrasound into the program for kidney procedures; ultrasound is currently controlled by the first assistant. According to one respondent, the manufacturer is developing a kidney ultrasound.
- Smaller arms;
- Smaller instruments;
- Integration of all information surgeons need when performing procedures, i.e., patient data including pulse rate, blood loss, oxygen saturation, etc. Staff in the operating room suite sees the data, except the surgeon. A button or pedal to push to see patient data as needed would be helpful; and,
- A clock would be helpful.

Survey Limitations

Although the findings add to FDA's knowledge of surgeons' experiences and perspectives about the use of the da Vinci Surgical System, there are several limitations to the survey methodology. These include the small convenience sample of respondents, surgeons who perform general laparoscopic procedures such as cholecystectomies, gastric bypass, or Nissen fundoplication were not part of the sample, and the majority of respondents were from large institutions. In view of these limitations, the respondents' perspectives may not represent the perspectives of all device users.

Therefore, these findings represent only one piece of information. No conclusions can be made about how the device functions in the broader clinical environment based on this report alone. Instead, the report should be considered along with other information that may include adverse event reports, scientific publications, clinical trials, enforcement/compliance information, and other data sources that are part of FDA's monitoring of device performance.

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Surveying device users is one of many tools the FDA uses to evaluate the public health impact of potential problems associated with the use of medical devices. Typically, small sample surveys

are used to collect qualitative information on post-market experiences of clinicians or facilities with medical device performance or use. The FDA selects survey respondents based on their experience with the topic or device, their availability, and their willingness to participate.

The FDA makes our scientific, medical, nursing, and engineering staff aware of the survey results as needed. If the FDA believes there is a significant risk of adverse events as noted from the survey, we will combine those results with data gained from other sources. The FDA will work with the manufacturers and health care provider organizations to make important information known to the clinical community. Additionally, the FDA continues to work with manufacturers to ensure the development, testing, and promulgation of methods for reducing the risk associated with these devices and to minimize the complications from adverse events that may occur in the course of normal usage. If the results of any survey raise serious concerns about the safety of these devices, the FDA may convene a group of clinical, scientific, and regulatory experts to discuss any necessary actions.

ATTACHMENT

Food and Drug Administration
Center for Devices and Radiological Health
Office of Surveillance and Biometrics
Medical Product Safety Network (MedSun)
Small Sample Survey
Topic: da Vinci Surgical System
Survey Questions

1. Approximately how many surgeries and what types of surgeries have you performed using the da Vinci Surgical System over the last three years?

    a) Which procedures do you believe are most suited for and least suited for the da Vinci system?

2. Do you prefer the da Vinci system over conventional surgeries?

    a) If yes, what are the reasons for using da Vinci system?

3. Have you had any problems or challenges when using the da Vinci system? If so:

    a) What actions did you or your facility take to help mitigate each problem?
    b) Are you aware of any other problems or concerns with use of the device?

4. What type of patient outcomes have you observed when there's been a problem or concern with this device?

    a) What kinds of complications are you seeing?
    b) Have you observed any differences in patient complications using the da Vinci system compared to conventional surgeries for the same procedure?

5. How is training usually conducted and how often does it occur?

    a) Is certification a part of the training? If so, can you describe the process?
    b) Are the instructions for use clear, easy to understand, and helpful to users? Are they used?
    c) Are the instructions for use available at the point of care?
        a. If no, where are they usually located?

6. Are there devices nearby or typically used with the da Vinci system that may have caused or contributed to problems with the system?

7. What are the most common repairs needed for the da Vinci Surgical System?

8. Are you familiar with the recalls and corrective changes for this device?

a) If yes, have you noticed any improvement following those modifications?
b) Have you noticed any new problems?
c) Has the manufacturer provided updated in-service training following a recall?

9. Tell us about your experience with:

a) System design

b) User training

b) Patient selection
b) Operative procedure (*operative procedures allowed, specific operative techniques)?*
c) Postoperative patient monitoring?

10. Is there anything else you would like to share with FDA?