



Via Regular Mail & E-mail

August 8, 2016

Donna Jerry, Senior Health Policy Analyst
State of Vermont
Green Mountain Care Board
89 Main Street
Montpelier, Vermont 05620

*Re: Docket No. GMCB-010-16con, Replacement of the da Vinci Robotic Surgical System,
Project Cost: \$2,397,994*

Dear Donna:

This letter responds to the questions from your letter dated July 1, 2016. The questions are **bolded** followed by our responses in un-bolded font.

RESPONSES

1. **In a table format, for each year 2008-2019, provide the number of actual surgeries performed/projected with the da Vinci and for traditional laparoscopic surgery broken out by: 1) gynecological, 2) urological, and 3) other surgeries (specify surgery type if performed with da Vinci) and totals.**

RESPONSE: The table below reflects the volume of cases of the same procedure-type performed robotically and non-robotically, for the gynecology and urology service lines, for the time period FY 2008 to present. Case volumes for FY 2016 have been annualized based on data for the time period October 1, 2015 through March 31, 2016.

Since this is a replacement project, UVM Medical Center (UVMC) is not projecting any increase in volumes for future years. For this reason, volume projections are flat for FY 2017 – FY 2019.

Procedure Type	Fiscal Year	Robotic	Non-Robotic
Gynecological	2008	33	297
	2009	159	261
	2010	198	299
	2011	191	258
	2012	304	210
	2013	246	194
	2014	233	154
	2015	208	187
	2016 ¹	188	163
	2017	188	163
	2018	188	163
	2019	188	163
Urological	2008	31	87
	2009	118	76
	2010	113	82
	2011	136	83
	2012	115	60
	2013	120	48
	2014	130	63
	2015	135	69
	2016	118	53
	2017	118	53
	2018	118	53
	2019	118	53

¹ Case volumes for FY 2016 have been annualized for each service line based on data for the time period October 1, 2015 through March 31, 2016.

2. **Specify the number of surgeons who perform robotic assisted surgeries and of the total, specify the number who perform: a) gynecological and b) urological surgeries.**

RESPONSE: Currently, eleven surgeons perform robotic assisted surgeries at UVMHC. Of these eleven surgeons, 8 perform gynecological surgeries, and 3 perform urological surgeries. These numbers change from time to time based on new surgeons joining the UVMHC medical staff and departures of existing surgeons.

3. **On page 7 of the application, UVMHC identified the minimum threshold criteria to request clinical privileges to perform robotic assisted procedures. Provide a side-by-side comparison of UVMHC’s minimum criteria for da Vinci use, and those used by other professional organizations or other tertiary, academic medical center hospitals in New England or nationwide.**

RESPONSE: Three national professional societies have established guidelines for the criteria to request clinical privileges to perform robotic assisted procedures. The professional societies are the Society of American Gastrointestinal Endoscopic Surgeons (SAGES), the American Urological Association (AUA), and the American Association of Gynecologic Laparoscopists (AAGL). The chart below depicts the criteria of each professional society and the criteria adopted by UVMHC.

Criteria	SAGES	AUA	AAGL	UVMHC
Pre-requisite training requirements (Completion of Residency Program)	X	X	X	X
General Requirements (surgical privileges in a Department, good standing in Medical Staff)	X	X	X	X
Robotic Training requirements	X	X	X	X
Required proctoring for full privileges	X	X	X	X

Minimum number of robotic cases per year			X	X
Remediation guidelines			X	X
Participation in peer review process	X	X	X	X

4. **Provide additional detail about UVMHC’s Credentialing Committee’s criteria and process for credentialing surgeons to perform surgeries with the da Vinci. Include the number of actual surgeries which must be performed by a surgeon before he or she is credentialed.**

RESPONSE: Surgeons in the Urology Department and the Women’s Health Care Department may apply for robotic privileges only if they are already privileged to perform the equivalent procedure through traditional surgical techniques (i.e., open or laparoscopic, depending on the type of procedure). The specific requirements for obtaining privileges to perform robotic surgery at UVMHC, including the minimum number of cases that must be precepted and proctored, are outlined in the UVM Medical Center Robotic Assisted Surgery Credentialing Application, which is attached as Exhibit 1.

5. **The application states that pursuant to CON Standard 3.19: “the minimally-invasive approach that is used for certain robotic assisted procedures has demonstrated that compared to open surgery, there is a reduction in intraoperative blood loss, lower blood transfusion rates, reduced patient length of stay, and faster recovery time.” Based on peer reviewed literature, provide the same comparison between robotic assisted surgery and traditional laparoscopic surgery.**

RESPONSE: For prostatectomy cases, unlike hysterectomy cases, when comparing the effectiveness of robotic surgery to traditional surgical techniques, the proper comparison is to open surgery, not laparoscopic surgery. That is because very few prostatectomies can be performed laparoscopically due to limitations of the laparoscopic instruments and the surgical site that needs to be accessed for this procedure.² Therefore, any peer review articles comparing the approach for a prostatectomy will compare the robotic approach to open surgery. The tables below

² Finkelstein J et al. Open versus laparoscopic versus robot-assisted laparoscopic prostatectomy: The European and US experience. *Rev Urol* 2010 Winter; 12(1): 35-43.

reflect the outcomes for peer reviewed studies of robotic versus open prostatectomy and robotic versus traditional laparoscopic partial nephrectomy.

Prostatectomy	Robotic	Open
Length of Stay	1.71 days	2.9 days
Estimated Blood Loss	100 cc	250cc
Transfusion rate	0.3%	2.9%
Post-operative Complications	10.1%	10.6%
Operative Time	246 minutes	190 minutes

Leow JJ, et al.³

Partial Nephrectomy	Robotic	Laparoscopic
Length of Stay	3.6 days	5.6 days
Estimated Blood Loss	236 ml	244 ml
Warm Ischemia Time	22.4 minutes	27 minutes
Operative Time	204 minutes	213 minutes

Choi JE, et al.⁴

For gynecologic cancer cases, which are the type of gynecological robotic surgeries we perform here, data from peer-reviewed literature indicates that robotic assisted surgery is associated with less morbidity than traditional laparoscopic surgery. These studies demonstrate that length of stay, estimated blood loss, transfusion rates, overall post-operative complication rates, and conversions to open laparotomy are significantly less among women undergoing robotic assisted surgery versus traditional laparoscopy. The table below reflects outcomes for peer-reviewed studies of robotic versus traditional laparoscopic hysterectomy for patients with endometrial cancer.

³ Leow JJ, et al. Robot-assisted versus open radical prostatectomy: A contemporary analysis of an All-payer Discharge Database. *Eur Urol* 2016, <http://dx.doi.org/10.1016/j.eururo.2016.01.044>.

⁴ Choi JE, et al. Comparison of perioperative outcomes between robotic and laparoscopic partial nephrectomy: a systemic review and meta-analysis. *Eur Urol* 2015; 67: 891-901.

Hysterectomy & Lymphadenectomy	Robotic	Traditional Laparoscopy
Length of Stay	1 day	2 days
Estimated Blood Loss	100 cc	250cc
Transfusion rate	3%	18%
Conversion to Laparotomy	12%	26%
Body Mass Index	34	29

Seamon LG, et al⁵

Hysterectomy	Robotic	Traditional Laparoscopy
Length of Stay	1 day	1.2 days
Estimated Blood Loss	74 cc	145 cc
Conversion to Laparotomy	2.9%	4.9%
Post-operative complication	5.8%	13.6%
Operative time	191 minutes	213 minutes
Body Mass Index	32.9	29

Bogges J, et al⁶

6. **The articles included with the application indicate that the clinical benefits of robotic surgery over traditional laparoscopic surgery and the financial implications of this technology are still a matter of study and debate. Explain in more detail the process and oversight UVMHC has in place to make certain that unnecessary, more costly and/or inappropriate surgeries using the robot do not occur.**

⁵ Seamon LG et al. Minimally invasive comprehensive surgical staging for endometrial cancer: Robotics or laparoscopy? *Gynecol Oncol* (2009), doi: 10.1016/j.ygyno.2008.12.005.

⁶ Bogges JF, Gerhrig PA, Cantrell L, et al. "A comparative study of 3 surgical methods for hysterectomy with staging for endometrial cancer: robotic assistance, laparoscopy, laparotomy. *Am J Obstet Gynecol* 2008; 199:360.e9.

RESPONSE: UVMMC strives to be a high-quality, low-cost provider and our surgeons recognize that prudent decision making is crucial to cost containment. To that end, UVMMC has procedures in place to determine which patients are appropriate candidates for robotic assisted surgery, and which patients would benefit from more traditional surgical techniques (i.e., open or laparoscopic).

The decision to perform a procedure robotically is initially discussed between the surgeon and the patient. Prior to scheduling a robotic surgery, nursing care coordinators review all proposed robotics cases in advance for appropriateness. If the nursing care coordinators have any concerns with the choice to perform the surgery robotically, the case is brought to the Quality Assurance and Improvement Committee (the "QA Committee") and the respective Division Director. The Division Director and members of QA Committee will discuss with the surgeon whether the case is appropriate to be performed robotically.

At UVMMC, it is also important to emphasize that robotic surgery is limited to the Urology and Gynecology service lines. For certain urological procedures, such as prostatectomies and partial nephrectomies, robotic surgery has become the clear standard of care with well documented clinical advantages over traditional surgical interventions. For Gynecology cases, UVMMC only offers robotic surgery to patients with oncologic conditions, such as uterine, ovarian or cervical cancer, patients with a complicated surgical history, and patients with a complicated medical history, such as severe endometriosis or large uterine fibroids. These are the types of Gynecology cases where the peer reviewed literature has demonstrated advantages associated with robotic surgery, as described in response to Question No. 5 above.

7. Provide peer reviewed articles that compare effectiveness and outcomes of surgeries performed with the da Vinci, compared to traditional laparoscopic surgery for the same surgeries.

RESPONSE: The peer reviewed articles below compare the effectiveness and outcomes of robotic versus traditional laparoscopic or open surgeries for UVMMC's three highest volume procedures: prostatectomies, partial nephrectomies, and hysterectomies indicated by gynecological malignancies. Please note that all peer reviewed articles evaluating prostatectomy outcomes compare the robotic approach with open surgery since traditional laparoscopic prostatectomies are rarely performed. The peer reviewed articles are attached as Exhibit 3.

1. Haglind E, et al. Urinary incontinence and erectile dysfunction after robotic versus open radical prostatectomy: A prospective, controlled, nonrandomised trial. *Eur Urol* 2015; 68: 216-225.
2. Pearce S, et al. Comparison of perioperative and early oncologic outcomes between open and robotic assisted laparoscopic prostatectomy in a contemporary population based cohort. *J Urol* 2016; 196: 76-81.
3. O'Neil B, et al. The comparative harms of open and robotic prostatectomy in population based samples. *J. Urol* 2016; 195: 321-329.

4. Jackson M, et al. Experienced open vs early robotic assisted laparoscopic radical prostatectomy: A 10-year prospective and retrospective comparison. *Urology* 2016; 91:111-118.
 5. Leow JJ, et al. Robot-assisted versus open radical prostatectomy: A contemporary analysis of an All-payer Discharge Database. *Eur Urol* 2016, <http://dx.doi.org/10.1016/j.eururo.2016.01.044>.
 6. Choi JE, et al. Comparison of perioperative outcomes between robotic and laparoscopic partial nephrectomy: a systemic review and meta-analysis. *Eur Urol* 2015; 67: 891-901.
 7. Long J, et al. Robotic versus laparoscopic partial nephrectomy for complex tumors: comparison of perioperative outcomes. *Eur Urol* 2012; 61: 1257-1262.
 8. Loew JJ, et al. Outcomes after robotic versus laparoscopic partial nephrectomy: An updated meta-analysis of 4919 patients. *J Urol* 2016, doi: 10.1016/j.juro.2016.06.011.
 9. Ghani K, et al. Practice patterns and outcomes of open and minimally invasive partial nephrectomy since the introduction of robotic partial nephrectomy: Results from the nationwide inpatient sample. *J Urol* 2013; 191: 907-913.
 10. Seamon LG, et al. Minimally invasive comprehensive surgical staging for endometrial cancer: Robotics or laparoscopy? *Gynecol Oncol* 2009, doi: 10.1016/j.ygyno.2008.12.005.
 11. Boggess JF, et al. A comparative study of 3 surgical methods for hysterectomy with staging for endometrial cancer: robotic assistance, laparoscopy, laparotomy. *Am J Obstet Gynecol* 2008; 199: 360.e1 – 360.e9.
8. **Provide the infection rate at UVMMC for surgeries performed with the da Vinci system relative to traditional laparoscopic and surgery and open surgeries.**

RESPONSE: From 2008 until 2015, because of the procedure codes used for surgeries (which were the same for both traditional and robotic interventions), UVMMC was not able to track infection rates separately for da Vinci and non-da Vinci cases.

Starting with the implementation of the ICD-10 procedure code system on October 1, 2015, UVMMC gained the ability to differentiate between robotic assisted cases and non-robotic cases for infection rate data. For the time period October 1, 2015 – June 30, 2016, UVMMC performed 118 inpatient⁷ robotic procedures and had 1 post-operative infection, as compared to 129 non-robotic procedures of the same type and 0 post-operative infections.⁸

⁷ Infection rate data is only available for inpatient surgical procedures, not outpatient procedures. This is because if a patient had an outpatient surgical procedure and subsequently developed an infection and received treatment from a non-UVMMC provider (non-UVMMC surgeon or primary care provider), UVMMC would not necessarily be made aware of it. For this reason, hospitals do not typically track outcome data for outpatient surgical procedures, as it would yield an incomplete data set.

⁸ *Patient Outcomes by Post-Operative Infection*, Oct 1 2015 – Jun 30 2016. Burlington: The University of Vermont Medical Center [producer]. Clinical Data Base/Resource Manager, v. 1.5.1.10, Vizient, Inc. [distributor].

9. **For urologic and gynecological surgeries, provide a detailed explanation of the outcome measures UVMC tracks for the same surgeries performed with the da Vinci and for traditional laparoscopic surgery.**

RESPONSE: UVMC tracks and reports certain patient-level clinical outcomes data through the Vizient Clinical Data Base/Resource Manager registry on a monthly basis. The outcomes measures that are tracked include length of stay, mortality, and complication rates and types. While this data is tracked for inpatient surgeries, there is no comparable data readily available for outpatient surgeries.⁹ The outcome measures for the data we track are shown in the table below for the time period October 1, 2012 – June 30, 2016, for the highest volume procedures in each of the two service lines, prostatectomies and hysterectomies.¹⁰

Principal Procedure: Prostatectomy	da Vinci	Without da Vinci
Mean Length of Stay	1.96 days	3.50 days
Mortality Index ¹¹ (observed/expected)	0/.06 = 0	0/.28 = 0
% ICU Cases	.66%	5.88%
Cases with 1 or more Complications	13.2/1000	14.7/1000

Principal Procedure: Hysterectomy	da Vinci	Without da Vinci
Mean Length of Stay	2.36 days	3.5 days
Mortality Index ¹² (observed/expected)	0/.32 = 0	.32/.19 = 1.75
% ICU Cases	2.78	5.19
Cases with 1 or more Complications ¹³	55.5/1000	42.2/1000

⁹ See, *supra*, footnote 7.

¹⁰ *Patient Outcomes by Hospital*, Oct 2012 – Jun 2016. Burlington: The University of Vermont Medical Center [producer]. Clinical Data Base/Resource Manager, v. 1.5.1.10, Vizient, Inc. [distributor].

¹¹ The “expected” denominator comes from population risk models built by Vizient.

¹² See, *Id.*

¹³ As explained in our response to question #6 above, UVMC only offers robotic surgery to patients with oncologic conditions, such as uterine, ovarian or cervical cancer, patients with a complicated surgical history, and patients with a complicated medical history, such as severe endometriosis or large uterine

10. Explain in more detail whether UVMHC projects any new surgeries to be performed with the da Vinci Xi replacement equipment.

RESPONSE: At this time, UVMHC has no plans to expand the surgical robotics program to encompass new service lines or procedures. If robotic-assisted surgery becomes the new standard of care for other procedures, any request to perform such procedure robotically would be carefully vetted to ensure its appropriateness.

11. Provide details about any surgeries being performed with the da Vinci since 2008 that were transitioned to an open or laparoscopic procedure due to physical or technological complications.

RESPONSE: UVMHC does not formally track surgical conversion rates. Based on an informal survey of da Vinci surgeons, no case has ever been converted due to a technological complication. Anecdotally, a very small number of gynecology and urology cases have been converted due to medical complications indirectly related to the surgery, such as respiratory distress that may be associated with the positioning of the patient required for robotic procedures. Notably, the new da Vinci Xi model will allow the surgeon to adjust the surgical table during the procedure, thus eliminating the need for prolonged steep positioning. A small number of conversions have also occurred in cases with unforeseen anatomical abnormalities (e.g. one patient underwent a complete robotic hysterectomy, but a mini-laparotomy had to be done at the end of the case to extract an abnormally large uterus).

12. Explain whether the number of prostatectomies for prostate cancer using the da Vinci robot at UVMHC has declined from 2012 to 2015.

RESPONSE: Studies show that the overall use of radical prostatectomy for localized prostate cancer increased significantly from 2004 to 2011.¹⁴ However, from 2012 to 2015, anecdotal evidence suggests that overall rates have leveled out as new screening and treatment guidelines more strongly emphasize active surveillance as a treatment option for younger men with lower-risk prostate cancer.¹⁵

UVMHC's procedure volumes have remained relatively stable over the same period, with 79 prostatectomies performed in 2012, 79 in 2013, 88 in 2014, and 83 in 2015. Since robotic prostatectomies have become the standard of care, more patients are willing to travel to have the option of undergoing a robotically-assisted laparoscopic prostatectomy versus an open procedure. This, as well as the aging population in our

fibroids. Given this patient profile, we would expect a higher complication rate for those undergoing robotic hysterectomies.

¹⁴ Charnow, Jody. Radical Prostatectomy Rates Rising, *Renal & Urology News*, September 17, 2014.

¹⁵ Klotz, L. *Active Surveillance for Men with Early Prostate Cancer*. Available at: <http://www.uptodate.com/contents/active-surveillance-for-men-with-early-prostate-cancer>. Web. 02 Aug 2016.

region, may explain why UVMMC’s radical prostatectomy volumes have remained steady while rates nationally have slightly declined.

13. For the highest volume urologic and gynecologic procedures performed with the da Vinci and by traditional laparoscopic surgery, provide in a table format the cost comparison for Commercial, Medicaid and Medicare.

RESPONSE: In responding to this question, UVMMC believes that by “cost comparison,” we are being asked to provide the amount that UVMMC is paid by the various payers, because UVMMC’s surgical “costs” are not different by payer.

UVMMC’s third-party payers, in determining payment amounts, do not differentiate between procedures that are performed robotically and those performed with traditional surgical techniques. While commercial insurers, Medicaid and Medicare pay the same rates for surgeries regardless of how the procedure is performed, other factors such as length of stay and time spent in the operating room impact the total amount UVMMC is paid. The table below shows average payments for robotic and non-robotic hysterectomies and prostatectomies in FY 2015. Any variance in payment between procedures performed using the da Vinci and procedures performed without the da Vinci is attributable to the variables mentioned above.

Procedure	Payer	da Vinci	Non-da Vinci
Hysterectomy	Commercial	\$20,372	\$24,085
	Medicaid	\$7,970	\$7,708
	Medicare	\$15,466	\$13,462
Prostatectomy	Commercial	\$19,140	N/A
	Medicaid	\$7,991	N/A
	Medicare	\$11,575	\$11,813

14. List the facilities in New England that have a da Vinci robotic surgical system.

RESPONSE: There are sixty-five facilities in New England, including UVMMC, that utilize a da Vinci robotic surgical system. The complete list is attached hereto as Exhibit 2. Notably, UVMMC is one of only four facilities in New England that continues to use the oldest da Vinci platform, which will be obsolete in December 2017 when the manufacturer stops servicing the equipment.

15. Given that most hospitals do not offer robotic assisted surgeries, explain how physicians are trained to perform such surgeries without the aid of a robot.

RESPONSE: While not all hospitals offer robotic assisted surgeries, residency and fellowship programs in Urology and Gynecologic Oncology Surgery now universally include instruction and training in surgical robotics. In fact, in many sub-specialties of Urology, proficiency with surgical robotics is considered a “basic” skill, and robotic surgery is now included in the AUA’s core curriculum for urology residencies. This means that program directors must provide credentials to document satisfactory training and confirm competence of the urologist to independently perform robotic surgery. A urologist completing a residency or fellowship training program is expected to complete a minimum of twenty robotic cases.¹⁶

In 2011, the American Urological Association (AUA) adopted a set of Standard Operating Practices for Urologic Robotic Surgery to help guide institutions in credentialing urologists for privileges to perform robotic surgery. The AUA cautioned that while the robot adds a valuable new tool to the surgeon’s toolbox, robotic skill does not replace a need to learn open techniques, should a need to convert arise.¹⁷ The American Association of Gynecologic Laparoscopists (AAGL) advanced similar credentialing guidelines in 2014, emphasizing that surgeons “must have the judgment and training to complete the procedure safely as intended and have the capability to convert immediately to a conventional laparoscopic or abdominal procedure when circumstances so indicate.”¹⁸ Consistent with these guidelines, residency programs include instruction in robotic and non-robotic surgical techniques to ensure surgeon proficiency, regardless of the method of surgical intervention employed. At UVMMC, all surgeons must be privileged to perform equivalent open and traditional laparoscopic surgeries before being credentialed to perform the same procedure robotically. This ensures competence in all surgical techniques that the surgeon may need to deploy in the event that a case does not go as planned.

We should note finally that while most community hospitals do not have a surgical robotic system, the procedures for which robotic surgery has become the standard of care are being performed at tertiary medical centers that have well-established surgical robotics programs. This is borne out by the fact that 85% of all prostatectomies in the United States are performed robotically.¹⁹ The surgeons who are performing these procedures, and receiving robotics training during their residencies and fellowships, are practicing primarily in tertiary hospitals or cancer centers that offer complex urological and gynecologic oncology services, with well-established surgical robotics programs.

¹⁶ *Standard Operating Practices (SOPs) for Urologic Robotic Surgery*, American Urological Association (2011).

¹⁷ Tewari, Ashtosh. How minimally invasive surgery is changing the urology landscape. *Global Connections*, Fall 2011; 2:4-9.

¹⁸ AAGL. Guidelines for privileging for robotic-assisted gynecologic laparoscopy. *The Journal of Minimally Invasive Gynecology*, vol. 21; 4.

¹⁹ <http://www.cancer.gov/cancertopics/research/rise-of-robotic-surgery-for-prostate-cancer>

16. Provide a copy of the full vendor quote. If the costs are included, identify where they are reflected on Table 1:

- a. **costs for robotic specific instrumentation (e.g. endowrist instruments and components)**
- b. **costs of new supporting infrastructure (e.g. table, lights, surgical booms)**
- c. **annual maintenance contract (specify cost)**

RESPONSE: The full vendor quote was included as Exhibit 3 to the CON application. All costs are included in Table 1 under “Fixed Equipment.”

- a. UVMC obtained a quote for the initial instrumentation stocking order, which is attached hereto as Exhibit 4. It should be noted that the cost of the instrumentation²⁰ for the da Vinci Xi model is the same as for the current system. Therefore, the disposable cost per case will remain the same. It should also be noted that Exhibit 4, attached hereto, includes a second set of reusable endoscopes. The second set of scopes is necessary to facilitate scheduling of back-to-back da Vinci cases since the sterilization process can take up to 4 hours.
- b. No new supporting infrastructure is required or needed to replace the da Vinci.
- c. There is no cost for annual maintenance during the first year of ownership because the da Vinci Xi is accompanied by a one year warranty. Beginning in year two, the cost of a full coverage maintenance contract is \$174,000 annually. UVMC will enter into a maintenance contract at that time.

17. Explain whether UVMC has requested a statement of compatibility from the vendor confirming that the existing instrument inventory is compatible with the instrument mounting assembly of the da Vinci Xi.

RESPONSE: There is no compatibility between the existing inventory of da Vinci S instruments and the da Vinci Xi platform. However, upon UVMC’s purchase of the da Vinci Xi, if this application is approved, the vendor has agreed to replace any unused inventory with inventory that is compatible with the new system.

18. Explain whether there is a software interface of the da Vinci system with existing automatic patient data and/or charging systems. If so, explain whether UVMC will receive from the vendor a statement of compliance that the upgraded da Vinci Xi system will allow the same interface without additional cost. If additional cost will be incurred, itemize the cost and indicate whether it is reflected in the total project cost on Table 1.

²⁰ Most instrumentation used with the da Vinci robot is either reusable or reposable. Repposable instrumentation can be used for up to ten cases before replacement is required.

RESPONSE: The da Vinci system does not have a software interface with existing UVMMC systems, nor is one needed.

19. **Identify the total number of downtime hours annually for the years 2012, 2013, 2014 and 2015; quantify the percent of downtime relative to total capacity; and specify whether downtime resulted from scheduled maintenance and repairs or from unanticipated equipment failure. If downtime occurred due to equipment failure, explain whether any of the occurrences were during surgery, listing the date and details of the occurrence.**

RESPONSE: UVMMC tracks the number of equipment repair and scheduled maintenance incidents, as well as the total number of annual field service labor hours, but it does not track the total number of downtime hours annually. The table below shows the number of repair incidents due to equipment failure, the number of scheduled maintenance incidents, and the total number of field service labor hours associated with addressing the incidents. Since UVMMC does not track the **total** number of downtime hours (i.e., the time the robot went down until it was fixed), we are not able to calculate the amount of downtime relative to total capacity. However, since the da Vinci is serviced by a field service engineer who travels to UVMMC from Albany, we can say that the total number of downtime hours is significantly greater than the total number of field service labor hours listed in the table below. That is because UVMMC often has to wait several hours before the arrival of the field service engineer from Albany.

While minor equipment failures have occurred during surgery, albeit rarely, every *intraoperative* failure to date has been able to be addressed remotely through a service call to the manufacturer. For calendar years 2012 – 2016, equipment failures resulted in 2 case cancellations, 8 delayed starts, and 35 intraoperative delays.

Calendar Year (Jan. 1 – Dec. 31)	2012	2013	2014	2015	2016**
Number of Repair Incidents Due to Equipment Failure	18	23	21	22	15
Number of Scheduled Maintenance Incidents	5	3	5	3	1
Total Number of Field Service Labor Hours	98.25 hours	161.5 hours	99 hours	53.5 hours	42.5 hours

**2016 data is for the time period 1/1/2016 – 7/15/2016

20. Address whether UVMMC has any lawsuits pending related to surgeries performed with the da Vinci.

RESPONSE: UVMMC has never had a lawsuit related to a surgery performed using the da Vinci robot.

We hope that this letter answers any remaining questions that you have. If further information is needed, please do not hesitate to contact me.

Very truly yours,

A handwritten signature in black ink that reads "Spencer R. Knapp". The signature is written in a cursive style with a large, looped initial 'S'.

Spencer R. Knapp, Esq.
Senior V.P. & General Counsel

Enclosures

INDEX OF EXHIBITS

- Exhibit 1: UVMHC's Robotic Assisted Surgery Credentialing Form
- Exhibit 2: List of Hospital Facilities in New England with da Vinci Surgical Systems
- Exhibit 3: Peer Reviewed Journal Articles
- Exhibit 4: Quote for Instrumentation Stocking Order