Florida Board Of Medicine

PCP South
July 17, 2015

Meet-Me #: 1 (888) 670-3525
Participation Code: 125-528-7056

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Medicine

The **Board of Medicine - Probable Cause Panel South** announces a public meeting to which all persons are invited.

DATE AND TIME: Friday, July 17, 2015, 2:00 p.m.

PLACE: Meet-Me #: 1 (888) 670-3525, Participation Code: 125-528-7056

GENERAL SUBJECT MATTER TO BE CONSIDERED: To conduct a public meeting to reconsider disciplinary cases with prior findings of probable cause.

A copy of the agenda may be obtained by contacting: Sheila Autrey at (850) 245-4444 ext. 8210 or email her at sheila.autrey@flhealth.gov or Robert Wilcox at (850) 245-4444 ext. 8142 or email him at robert.wilcox@flhealth.gov.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Sheila Autrey at (850) 245-4444 ext. 8210 or email her at sheila.autrey@flhealth.gov or Robert Wilcox at (850) 245-4444 ext. 8142 or email him at robert.wilcox@flhealth.gov.

If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Sheila Autrey at (850) 245-4444 ext. 8210 or email her at sheila.autrey@flhealth.gov or Robert Wilcox at (850) 245-4444 ext. 8142 or email him at robert.wilcox@flhealth.gov.

Florida Board of Medicine
South Probable Cause
Agenda

July 17, 2015
2:00 pm

Meet-Me-Number: 1(888) 670-3525
Conference Code: 125-528-7056

RECONSIDERATIONS

RN-01	**Alberto F. Padron, M.D.**	**2014-12822**

MEMORANDUM FOR RECONSIDERATION

TO:	7/17/15 South Probable Cause Panel
FROM:	Corynn Gasbarro, Assistant General Counsel CG
RESPONDENT:	Alberto Padron, M.D.
CASE NO.:	2014-12822
DATE:	May 13, 2015

This case was presented at the January 16, 2015 Probable Cause Panel meeting, at which time probable cause was found. On January 20, 2015, a one-count Administrative Complaint was filed, alleging Subject violated section 456.072(1)(cc), Florida Statutes, for leaving a foreign body in patient SS.

After the Administrative Complaint was filed, the Department received a response from Subject, through counsel, which detailed the events that led to the incident in this case.

The Department is bringing this matter before you for reconsideration so that the Subject's response can be considered by the Panel. Additionally, after further review of the file, and in consideration of the unique set of facts in this case, the Department is requesting that the Panel dismiss the Administrative Complaint and recommends closure.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

BOARD:	Medicine
CASE NUMBER:	2014-12822
COMPLAINT MADE BY:	Code 15 Report
COMPLAINT MADE AGAINST:	Alberto F. Padron, M.D. 801 North Orange Ave., Suite 640 Orlando, FL 32801
SUBJECT'S ATTORNEY:	Gregory A. Chaires, Esquire Chaires Brooderson & Guerrero 283 Cranes Roost BV, Suite 165 Altamonte Springs, FL 32701
DATE OF COMPLAINT:	August 1, 2014
INVESTIGATED BY:	Cathi Q. Mitchell; ISU/Orlando
REVIEWED BY:	Corynn Gasbarro, Esquire CG Assistant General Counsel
RECOMMENDATION:	Dismiss (4099)

NOTICE OF DISMISSAL

THE COMPLAINT: The Complaint alleges Subject violated Section 456.072(1)(cc), Florida Statutes (2014), by leaving a foreign body in a patient.

THE FACTS: This complaint is predicated upon receipt of a Code 15 Report from the Risk Management Director at Orlando Regional Medical Center indicating that a blue towel was found in the abdomen of Patient SS (SS), following an exploratory laparotomy.

On or about July 3, 2014, SS, a 45 year old female, presented to Winnie Palmer Hospital with complaints of severe, ongoing abdominal pain one week after having a total hysterectomy. After evaluating SS, Subject diagnosed her with perforated viscus, acute abdomen and early signs of sepsis and scheduled her for an emergent exploratory laparotomy.

On July 3, 2014, Subject performed the exploratory laparotomy on SS. In his operative note, Subject documented that upon entering SS's abdomen, he found dense adhesions and large amounts of fecal material, blood and fluid. He later attributed these to a perforated sigmoid colon. Throughout his repair of SS's abdomen, Subject used laparotomy sponges to pack the small intestine. However, at some point, Subject requested and was given a small blue towel to pack the small bowel. Once the procedure was completed, SS's abdomen was irrigated, evaluated and closed. SS initially tolerated the procedure well; however, SS's condition failed to improve the following week. On July 14, 2014, Subject performed wound exploration surgery on SS. It was at that time that a blue towel was found in SS's left upper abdomen, tucked behind a loop of the small intestine.

On January 20, 2015, a one-count Administrative Complaint was filed charging Subject with violating Section 456.072(1)(cc), Florida Statutes (2014), for leaving a foreign body in SS. On March 12, 2015, Subject responded to the Complaint through his attorney in a lengthy response detailing the events that led to the incident in this case.

In his response, Subject notes that the exploratory laparotomy performed on SS was particularly difficult due to the large amounts of fecal contamination, free ascites and diffusely edematous large and small intestine he discovered upon incising her abdomen, as well as the patient's elevated BMI. Laparotomy sponges were used but were inadequate as the small intestine continually filled the operative field. This is why he requested and used the blue towel. He notes that use of the towel was something he learned in training, and that it allowed him to safely resect SS's injury and complete the procedure on her abdomen. Additionally, Subject points out that he appropriately requested a count of all instruments and textiles on three occasions prior to closing the abdomen, and that he relied on hospital staff who confirmed the counts were correct

each time. The intraoperative nursing record for SS's procedure on July 3, 2014 supports this assertion. Subject believed that the blue towel that was requested and used during SS's surgery would be added to the count. It was only after the surgery that Subject found out blue towels, such as the one he used on SS, are not routinely added to the count, which is why he was told the counts were correct when the towel was still inside of SS's abdomen.

Since this incident, the Subject has worked with the hospital's Quality Control Team and hospital system to modify the count policies to ensure that this does not happen again.

In consideration of all of the circumstances in this case, including that this was a complicated surgery, that the Subject appropriately requested the counts on three occasions, and that the Subject relied upon the representations of the staff that the counts were correct, the Department recommends closure of this case.

THE LAW: Based on the foregoing, and pursuant to Section 456.073(4), Florida Statutes, there is no probable cause to believe Subject violated Chapter 458, Florida Statutes, or the rules of the Board or Department.

It is, therefore, ORDERED that this case should be and the same is hereby DISMISSED.

DONE and ORDERED this _____ day of _____, 2015.

_____
Chairperson, Probable Cause Panel
Board of Medicine

PCP Date: July 17, 2015
PCP Members: Mark Avila, M.D.; Nabil El Sanadi, M.D.; Joy Tootle

CHAIRES
BROODERSON
& GUERRERO
ATTORNEYS AT LAW

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March 12, 2015

VIA EMAIL TRANSMITTAL
Ms. Corynn Gasbarro, Esq.
Department of Health
4052 Bald Cypress Way, Bin C-85
Tallahassee, FL 32399

Re: Department of Health vs. Alberto Padron, M.D.
DOH Case No. 2014-12822
FD File No. 15-0020-A-15

Dear Ms. Gasbarro:

Please accept this letter on behalf of Alberto Padron, M.D., in the above-referenced Department of Health (the "Department") matter as our request for reconsideration of this case by the Probable Cause Panel of the Board of Medicine (the "Panel"). As you recall, a copy of the complete investigative file was provided to the undersigned this week. An Administrative Complaint was filed against Dr. Padron's medical license on January 20, 2015. After review of the investigative file materials, we ask that you present this matter back to the Panel for their reconsideration of the Administrative Complaint.

On January 20, 2015, a single-count Administrative Complaint (the "Complaint") was filed alleging a violation of Section 456.072(1)(cc), Fla. Stat. (2014). It is alleged that Dr. Padron left a foreign body, specifically a blue towel, tucked behind a loop of the small intestine in the Patient's left upper abdomen. As you will see below, Dr. Padron completely met the standard of care in his diagnosis, care and treatment of the Patient.

We note that the basis for the Department's is that a blue towel was left in the Patient during the exploratory laparotomy. It is abundantly clear that the procedure at issue was quite difficult, particularly given the Patient's abdomen, which contained large amounts of diffuse fecal contamination, free ascites and diffusely edematous large and small intestine. These significant challenges were further complicated by the fact that:

1. This was an emergent case in a patient with an elevated BMI.
2. The procedure was performed at an institution not accustomed to performing "damage control" laparotomy with an operating room staff that was not familiar with techniques where towels are used to pack off the operating field.
3. A change of plan during operating was required when it was necessary to convert from a pfannestiel to a midline incision.

At the conclusion of his surgery, Dr. Padron thoroughly irrigated and explored the Patient's abdominal cavity and did not observe the retained towel prior to closure of the Patient's abdomen. Importantly and critical in consideration of this case is that Dr. Padron then appropriately asked both the circulating nurse and scrub nurse if all instruments and textiles had been accounted for prior to closing the Patient. Dr. Padron was told on **three** occasions that the counts were correct. Being so informed, he closed the Patient. It is clear that Dr. Padron clearly acted as a prudent physician in this matter.

In evaluating this case after the fact, the reason as to why a blue towel was retained is absolutely crystal clear. It was learned that the blue towels that Dr. Padron was provided with by the surgical staff were not routinely added to the count. As such, Dr. Padron's appropriate belief and reliance upon the standard that anything and everything placed in the abdomen/operative field would be accounted for, was not the case with regard to the blue towels. Clearly, the institutional count protocol was quite incomplete, as each and every item placed in the surgical field should certainly be appreciated by the surgical staff members conducting instrument and textile counts. Based upon the representations made to Dr. Padron prior to closure that all the counts were correct, he properly concluded the procedure.

Despite the charge in the Administrative Complaint, Dr. Padron was not responsible for the retained blue towel. He properly relied on hospital staff to make the counts and contemporaneously make reports to him regarding same. It was totally appropriate and reasonable for Dr. Padron to rely on the representations of the peoples whose job it was to count items in and out of the operative field.

Upon review of the Department's investigative file, we note an interview conducted with the Patient on September 17, 2014. As you can see, the Department's investigator noted her discussion with the Patient, "Dr. Padron is wonderful and he saved her life."

By way of background, this matter involved the care of a 45 year old female patient who presented to the Emergency Department at Winnie Palmer Hospital in Orlando with complaints of severe, ongoing abdominal pain one week following a total abdominal hysterectomy performed by her gynecologist. A CT scan was ordered by the emergency physician and showed large amounts of free intraperitoneal air. Upon request for consultation, Dr. Padron evaluated the Patient in the Emergency Department and diagnosed her with perforated viscus with a delay in diagnosis, acute abdomen and early sepsis. Thus, Dr. Padron immediately scheduled an emergent exploratory laparotomy and the Patient was taken directly to the operating room.

Upon initiation of the procedure, Dr. Padron entered into the Patient's hysterectomy incision, as it was in the process of dehiscence. Upon entering the abdomen, he encountered large amounts of diffuse fecal contamination, free ascites and diffusely edematous large and small intestine. This combination led to a very "hostile abdomen" making exposure extremely difficult. It became clear that adequate exposure would not be possible through the pfannenstiel incision and thus, Dr. Padron placed a midline incision. The Bookwalter retractor was placed and an injury was identified in the sigmoid colon. This consisted of a 1 cm perforation in the antimesenteric border with free spillage of fecal material. Dr. Padron set out to perform a damage control operation by resecting the injury and placing a diverting colostomy.

Mobilization of the descending colon was extremely challenging due to the extent of edema of both the large and small intestine, leading to a lack of exposure. Laparotomy sponges were initially used but were inadequate as the small intestine continually filled the operative field. Thus, Dr. Padron asked for a moist blue towel for packing the small bowel. This technique, which he learned during training and had effectively used numerous times throughout his career, allowed Dr. Padron to safely resect the injury, place a diverting colostomy and complete the damage control procedure. At the conclusion of the case, the retractor was removed, along with what appeared to be all towels and laparotomy pads used for packing. The abdomen was

thoroughly irrigated and Dr. Padron performed a cavity search and found no additional pads or towels. Prior to closure of the abdomen, Dr. Padron asked if the instrument and textile counts were correct. Dr. Padron was informed by both the circulating nurse and the scrub nurse that the counts were correct on three occasions. In reliance upon this confirmation, the Patient's abdomen was closed.

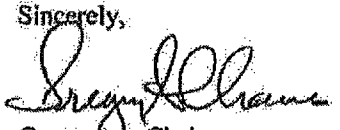
Unfortunately, the Patient's condition failed to improve and a CT scan was performed, which showed what appeared to be a large complex abscess as well as evidence of small abscesses. Interventional Radiology was consulted and percutaneous drainage of the large abscess was performed, with return of what appeared to be infected and continuously draining fluid. Given these circumstances, Dr. Padron returned the Patient to surgery for wound exploration and operative irrigation and drainage of all collections. Upon re-exploration, multiple interloop abscesses were disrupted and Dr. Padron identified a blue towel in the Patient's left upper abdomen, behind a loop of the small intestine. Also, it became apparent that the percutaneous drain had caused a tangential injury to what looked like the descending colon. Dr. Padron repaired this injury and closed the Patient's abdomen with a temporary VAC dressing as return for further washout was anticipated. The Patient's subsequent hospital course involved multiple trips to the operating room for irrigation and VAC changes. She developed multiple entero-atmospheric fistulas which were treated with non-operative management. The Patient was subsequently discharged home stable with an enterocutaneous fistula controlled with a collection bag and multiple drains. Her fistulas have all closed, her abdominal wounds have healed and all drains have been removed.

As a result of this matter, Dr. Padron has worked with the Quality Control Team and the hospital system to change policies so this never happens again. At this time, the plan is to prohibit blue towels in the abdomen and instead, obtain towels of a different color that contain radio-opaque markers. Additionally, the operating room staff have been counseled to ensure meticulous counting. As was discussed in the initial response, Dr. Padron acknowledges that that the Patient did have a retained foreign body. However, this occurred despite his very best efforts to safely and effectively perform the Patient's emergent surgery, as well as despite his repeated efforts times three to obtain a surgical count from staff, who reported that all three counts were correct. The fact that the surgery staff failed to account for the blue towel when conducting their instrument and textile counts in no way resulted from any substandard action or inaction by Dr. Padron. It was completely appropriate for Dr. Padron to rely on the hospital staff, particularly at such a large institution.

Based on the foregoing, we respectfully request that you take this matter back to the Panel for reconsideration of the Administrative Complaint that was issued in this case with our respectful request that the Panel dismiss this matter.

Thank you for giving us this opportunity to submit this information on behalf of Dr. Padron.

Sincerely,



Gregory A. Chaires
JoAnn M. Guerrero

cc: Alberto Padron, M.D.
Ms. Tamla Lloyd (via email transmittal)

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NUMBER 2014-12822**

ALBERTO F. PADRON, M.D.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, hereby files this Administrative Complaint before the Board of Medicine against Respondent, Alberto F. Padron, M.D., and alleges:

1. Petitioner is the state agency charged with regulating the practice of medicine pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 458, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed physician within the State of Florida, having been issued license number ME 75038.

3. Respondent's address of record is 801 North Orange Avenue, Suite 640, Orlando, Florida 32801.

4. Respondent is board certified in general surgery by the American Board of Surgery.

5. On or about July 3, 2014, patient S.S., a 45 year old female, presented to the emergency room at Winnie Palmer Hospital in Orlando, Florida, with complaints of severe, ongoing abdominal pain one week after having a total abdominal hysterectomy.

6. Respondent assessed S.S. and diagnosed her with perforated viscus, acute abdomen and early signs of sepsis.

7. On July 3, 2014, Respondent performed an emergency exploratory laparotomy on S.S.

8. Throughout the course of S.S.'s surgery, Respondent used laparotomy sponges to pack the small intestine; however, at some point, Respondent requested and was given a blue towel to pack the small bowel.

9. Once the procedure was completed, the abdomen was irrigated and closed.

10. S.S. initially tolerated the procedure well; however, in the following week, S.S.'s condition failed to improve.

11. On July 14, 2014, Respondent performed wound exploration surgery on S.S., at which time a blue towel was found in S.S.'s left upper abdomen, tucked behind a loop of the small intestine.

12. Section 456.072(1)(cc), Florida Statutes (2014), provides that leaving a foreign body in a patient, such as a sponge, clamp, forceps, surgical needle, or other paraphernalia commonly used in surgical, examination, or other diagnostic procedures is grounds for disciplinary action by the Board of Medicine.

13. On or about July 3, 2014, Respondent left a foreign body (a blue towel) in patient S.S. during an exploratory laparotomy.

14. Based on the foregoing, Respondent has violated Section 456.072(1)(cc), Florida Statutes (2014), by leaving a foreign body in a patient.

WHEREFORE, the Petitioner respectfully requests that the Board of Medicine enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of

fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 10th day of January, 2014.

JOHN ARMSTRONG, MD, FACS
Surgeon General and Secretary of Health

Corynn Gasbarro

Corynn Gasbarro
Assistant General Counsel
Florida Bar Number 68814
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444, Ext. 8243
Facsimile: (850) 245-4684
Email: Corynn.Gasbarro@flhealth.gov

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JAN 20 2015

PCP Date: January 16, 2015

PCP Members: Mark Avila, M.D.; Nabil El-Sanadi, M.D. and Joy Tootle

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition any other discipline imposed.

STATE OF FLORIDA

DEPARTMENT OF HEALTH

Florida HEALTH

INVESTIGATIVE REPORT

Office: Area VII - Orlando	Date of Complaint: 08/01/14	Case Number: 201412822

Subject: ALBERTO FRANCISCO PADRON, M.D. 801 North Orange Avenue, Suite 640 Orlando, Florida 32801 (407) 730-3627	Source: CODE 15 REPORT/ADVERSE INCIDENT REPORT (SS%) 0004393
Profession: Medical Doctor	License Number and Status: 75038/Clear
Related Case(s): None	Period of Investigation and Type of Report: 08/22/14 to 10/13/14 - FINAL

Alleged Violation: F.S. 456.072(1)(k)(cc)(dd), F.S. 458.331(1)(g)(t)(nn)

Synopsis: This investigation is predicated upon the receipt of a Code 15 Report/Adverse Incident Report submitted on 08/01/14 by CAROL PARIS, Risk Manager Director at Orlando Regional Medical Center, 1414 Kuhl Avenue, Orlando, Florida, 32806, reporting on 07/03/14, SS (46 y/o female) was admitted to UF Health Cancer Center at Orlando Health with complaints of persistent lower abdominal pain and fever status post total abdominal hysterectomy on 06/26/14 at Winner Palmer Hospital for Women & Babies. SS underwent an emergent exploratory laparotomy with possible bowel resection and possible colostomy. In addition, stat abdomen x-rays, 3 views were taken which revealed the presence of abnormal air and abnormal appearance. Post-operative diagnosis revealed multiple interloop abdominal abscesses, retained blue towel in the left upper abdomen and possible tangential injury to the descending colon from a percutaneously placed drainage tube. ALBERTO FRANCISCO PADRON, M.D. was the surgeon.

ALBERTO FRANCISCO PADRON, M.D. indicated in a statement dated 09/25/14 that he scheduled SS for emergent surgery at Winnie Palmer Hospital due to a perforated viscus with a delay in diagnosis, sepsis and an acute abdomen. He indicated upon re-exploration, multiple interloop abscesses were disrupted and a retained blue towel was identified and removed. DR. PADRON indicated as a result, he has met with the Quality Control Team as well as all personnel present in the operation room and identified several factors which led to the error, discussed prohibiting the use of standard blue towels for placement in the abdomen and is working on obtaining towels of a different color equipped with radio-opaque markers for this purpose in order to ensure no objects are left behind.

☒ Yes ☐ No Subject Notification Completed?
☒ Yes ☐ No Patient Notification Completed?
☒ Yes ☐ No Above referenced licensure checked in database/COMPAS?
☒ Yes ☐ No Board certified? Name of Board: American Board of Surgery Date:
Specialty: General Surgery

Law Enforcement
☐ Notified Date:
☐ Involved Agency:

☐ Yes ☒ No Subject represented by an attorney?
Attorney information:

RECEIVED-LEGAL
14 OCT 16 AM 7:26

Investigator/Date:	Approved By/Date:
Cathi Q. Mitchell 10/13/14 Cathi Q. Mitchell, OI-105 Medical Quality Assurance Investigator	Kimberly Haley, RN Investigation Manager Received Investigative Services 10/14/14

Distribution: HQ/ISU

OCT 15 2014

INV FORM 300, Revised 8/14 4/14, 3/14, 2/08, Created 07/02

DOH/MQA
Tallahassee HQ

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Interview of SS (Patient) 3

IV. EXHIBITS

* 1. Case Summary and attachments 4-9
* 2. Copy of Notification letter, dated 08/22/14 ..... 10/11
* 3. Patient Notification letter, dated 08/22/14 ..... 12/15
* 4. Subpoena Duces Tecum A-0085685 directed to Orlando Health (OH) 16-23
* 5. Response from OH 24-26
* 6. Subpoena Duces Tecum A-0085703 directed to Winner Palmer Hospital 27-31
* 7. SS's Medical Records on CD (1) from OH 32-257
** 8. SS's X-rays (26 Views) on CDs (4) from OH 258-283
* 9. SS's Billing Records from OH 284-288
* 10. Subpoena Duces Tecum A-0085704 directed to UF Health Cancer Center 289-293
* 11. SS's Medical Records on CD (1) from UF Health Cancer Center 294-4546
* 12. SS's Billing Records from UF Health Cancer Center 4547-4613
* 13. Subpoena Duces Tecum a-0085684 directed to Orlando Regional Med Ctr 4614-4615
* 14. Letter dated 09/29/14 from CAROL PARIS, Risk Mgr Director at ORMC 4616
Policies and Procedures (7) from ORMC 4617-4638
* 15. Statement of ALBERTO FRANCISCO PADRON, M.D. 4639-4641
* 16. Confidential Index 4642

* Exhibits contain information which identifies patient(s) by name and are sealed pursuant to section 456.057(9)(a) Florida Statute.

***This exhibit contains confidential records concerning reports of abuse, neglect or exploitation of the vulnerable adult, including reports made to the central abuse hotline, and is sealed pursuant to section 415.107(1), Florida Statutes

INVESTIGATIVE DETAILS

INTERVIEW OF CAROL PARIS, Risk Manager Director (Source)
Orlando Regional Medical Center
1414 Kuhl Avenue
Orlando, Florida 32806
(321) 241-5894

On 09/08/14, Investigator MITCHELL contacted CAROL PARIS, Risk Manager Director and left a message requesting a return call.

On 09/17/14, Investigator MITCHELL contacted CAROL PARIS, Risk Manager Director and left a message requesting a return call.

On 09/18/14, Investigator MITCHELL contacted CAROL PARIS, Risk Manager Director and left a message requesting a return call. Per EILEEN it was reported that PARIS has been in court this week and is not expected to return until next week.

On 09/22/14, CAROL PARIS, Risk Manager Director contacted Investigator MITCHELL and was interviewed. She stated she would check receipt of the subpoena requesting specific information regarding the adverse incident.

PARIS stated patient SS was returned to surgery due to the abscess which was emergent. She stated SS was not returned to surgery due to the retained towel. PARIS stated the blue towel was used to drap so that copious material could be absorbed in the incisional cavity. She stated due to the fact that towels are not part of the accountable items, blue towels will be purchased with opaque strips on the outside that can been seen on x-rays. In addition, PARIS stated blue towels will be taped and draped on the outside as not to get into the surgical site. She stated the nurses did not understand about the use of the towels and that large lap sponges or larger sponges should have been used to absorb. PARIS stated nurses have been advised not to use towels. She stated she would review which personnel had direct contact regarding the incident and notify this office when the staff are available for interviews in her office. PARIS stated that SS was advised of the retained towel.

On 10/07/14, Investigator MITCHELL contacted PARIS via telephone and a message was left requesting a return call regarding scheduling interviews with the staff.

On 10/13/14, Investigator MITCHELL contacted PARIS regarding scheduling interviews with the staff, particularly with the circulating nurses. She stated the circulating nurses are not willing to submit to an interview without an attorney present. PARIS reiterated that the nurses should not have utilized the blue towels during surgery and did not follow policy.

INTERVIEW OF SS (Patient)

On 09/17/14, Investigator MITCHELL contacted SS via telephone but was unable to leave a message because her mailbox was full. SS saw the telephone number and returned the call. SS was asked if she had received a letter from this office. She stated she did not receive a letter from this office and her address was verified. SS was advised that another letter will be sent to her address and to please respond. She stated that DR. PADRON is wonderful and he saved her life. SS did not provide any additional information.

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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Danelle K. Chambers, M.D., F.A.C.S.
Michael B. Freeland, M.D.
Alberto F. Padron, M.D., F.A.C.S.
Daryl D. Wier, M.D., F.A.C.S.

September 25, 2014

Florida Department of Health
Division of Medical Quality Assurance
Bureau of Enforcement
400 West Robinson Street, Suite S-827
Orlando, FL 32801

The purpose of this letter is to provide a written response to Case Number: 2014-12822, retained foreign object.

The patient SS was seen in the Emergency Room at Winnie Palmer Hospital approximately one week after having a total abdominal hysterectomy by her gynecologist. She was complaining of severe, ongoing abdominal pain and was found by the emergency physician on call to have signs of sepsis and an acute abdomen. CT scan showed large amounts of free intraperitoneal air. I was consulted and saw the patient in the ER. My assessment was that she had a perforated viscus with a delay in diagnosis, sepsis and an acute abdomen. I immediately scheduled emergent surgery and she was taken directly to the operating room at Winnie Palmer Hospital.

The exploratory surgery was initially approached through the pfannenstiel incision that was used for her hysterectomy as it was in the process of dehiscence. Upon entering the abdomen, we encountered large amounts of diffuse fecal contamination, free ascites, and diffusely edematous large and small intestine. This combination led to a very "hostile abdomen" making exposure extremely difficult. It became clear that adequate exposure would not be possible through the pfannenstiel incision and we placed a midline incision. The Bookwalter retractor was placed and an injury was identified in sigmoid colon. This consisted of a 1cm perforation in the antimesenteric border with free spillage of fecal material. We set out to perform a damage control operation by resecting the injury and placing a diverting colostomy. Mobilization of the descending colon was extremely challenging due to the extent of edema of both the large and small intestine leading to a lack of exposure. Lapartomy sponges were initially used but were inadequate as the small intestine continually filled the operative field. I then asked for a moist blue towel for packing the small bowel. This is a technique that I have used many times throughout my career and was trained to use during my residency. This technique allowed me to safely resect the injury and place a diverting colostomy completing the damage control procedure.

EXHIBIT 15

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4639

At the end of the case, the Bookwalter retractor was removed along with what seemed to be all towels and laparotomy pads used for packing. The abdomen was thoroughly irrigated and a cavity search was performed finding no additional lap pads or towels. Prior to closure of the abdomen, I inquired if the instrument and textile counts were correct. I was told by both the circulating nurse and the scrub nurse that the count was correct. Believing that all was accounted for, we closed the abdomen.

Over the next week SS's hospital course was complicated by a wound infection which required opening of the wound at the bedside. She failed to progress so a CT of the abdomen was ordered which showed what appeared to be a large complex abscess as well as evidence of smaller abscesses. Given the patient was stable, Interventional Radiology was consulted to attempt percutaneous drainage of the large abscess. This was performed and what appeared to be infected fluid was aspirated and continued to drain from the catheter. Again, it was felt that she was not improving and the decision was made to return to the operating room for operative irrigation and drainage of all collections.

Upon re-exploration, multiple interloop abscesses were disrupted and a retained blue towel was identified and removed. Also, it became apparent that the percutaneous drain had caused a tangential injury to what looked like the descending colon. This injury was repaired in two layers with interrupted silk sutures and the abdomen was closed with a temporary VAC dressing as return for further washout was anticipated.

The remainder of her hospital course involved multiple trips to the operating room for irrigation and VAC changes. She developed multiple entero-atmospheric fistulas. These were treated with non-operative management. After a prolonged hospital course, she was eventually discharged home stable with an enterocutaneous fistula controlled with a collection bag and multiple drains.

Since her discharge, all the fistulas have closed. Her abdominal wounds have all healed and all drains have been removed.

Since the discovery of the retained foreign object, I have met with the Quality control team at Winnie Palmer Hospital as well as all personnel that were present in the operation room that day. We have identified several factors that may have led to the error.

Firstly, this was an emergent case in a patient with an elevated BMI. In addition to emergent nature of the case, it involved a very hostile abdomen with gross fecal contamination and bowel edema due to the initial delay in diagnosis.
Secondly, the operation was performed at an institution not accustomed to performing "Damage Control" laparotomy with an OR staff not familiar with techniques used such as the use of towels to pack off the operating field. Thirdly, a

change of plan during the operation was required when we had to convert from a pfannenstiel to a midline incision. All of these are known risk factors for retained foreign objects.

Lastly, and possibly most importantly, it was discovered that blue towels placed in the abdomen are not routinely added to the count. I assumed that anything handed to me to be placed into the abdomen would be added to the count by the operative team. They were not in this case.

Since this meeting with the Quality Control team and the operating room staff, we are working to change the policy at Winnie Palmer and throughout the ORHS system. These changes will prohibit the use of standard blue towels for placement in the abdomen. We are working on obtaining towels of a different color and equipped with radio-opaque markers for this purpose.

Also, I am investigating newer technologies available today such as Radio-frequency identification (RFID), bar codes – COUNT, and Electronic Article Surveillance. These have the potential to dramatically decrease the occurrence of retained objects and I plan on presenting the Surgical Quality Committee with information regarding their use.

Also, steps have been taken to educate all OR staff on meticulous counting and utilizing a team approach to ensure no objects are left behind.

I would be happy to discuss any portion of this letter in further detail. I can be reached at the Surgical Group of Orlando office.

Sincerely,

Alberto F. Padron, MD, FACS

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