CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 050360 | A. BUILDING ______ B. WING ______ | 10/15/2009 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| MARIN GENERAL HOSPITAL | 250 BON AIR ROAD, GREENBRAE, CA 94904 MARIN COUNTY |

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| | The following reflects the findings of the California Department of Public Health during an ENTITY REPORTED INCIDENT visit.<br><br>Inspection was limited to the specific entity reported incident #CA00202782 investigated and does not represent the findings of a full inspection of the facility.<br><br>Representing the Department of Public Health: Surveyor [redacted], Medical Consultant 1 (MC1).<br><br>E347 T22 DIV5 CH1 AER3-70223(b)(2) Surgical Service General Requirements<br>(b) A committee of the medical staff shall be assigned responsibility for:<br>(2) Development, maintenance and implementation of written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.<br><br>THE DEPARTMENT SUBSTANTIATED A VIOLATION OF THE REGULATIONS.<br>Based on medical record review, document review, and interview, the hospital staff failed to implement policies and procedures regarding sponge/instrument counts to ensure removal of all foreign objects from Patient 1's abdominal cavity prior to closure of the abdominal incision. This resulted in Patient 1 requiring a second surgery to remove a retained surgical | | The following constitutes Marin General Hospital's plan of correction of the alleged deficiencies cited by the Department of Public Health in the Statement of Deficiencies Form CMS-2567 dated October 15, 2009. Preparation and/or execution of this corrective action does not constitute admission or agreement by the provider of the truth of the facts or conclusions set forth on the Statement of Deficiencies. It has been prepared and/or executed solely because it is required by federal and state law.<br><br>The Medical Staff's OR Management Committee is assigned responsibility for the development, maintenance and implementation of written policies and procedures in Perioperative Services in consultation with other health professionals and administration.<br><br>Immediately upon learning that there was radiological confirmation of a retained foreign object the physician informed the patient and her spouse on 9/23/2009 at 0925 and discussed the plan to return the patient to surgery for removal. | |

Event ID:V1HU11 1/28/2010 4:31:48PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Joan McCready, RN Director, Quality Management TITLE (X6) DATE 3/12/2010

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3/10/10 Hospital notified that POC is acceptable. TG

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| | Continued From page 1<br>pad.<br><br>THE VIOLATION OF LICENSING REQUIREMENTS CONSTITUTED AN IMMEDIATE JEOPARDY (IJ) WITHIN THE MEANING OF HEALTH AND SAFETY CODE SECTION 1280.1 IN THAT IT CAUSED, OR WAS LIKELY TO CAUSE SERIOUS INJURY OR DEATH TO THE PATIENT, WHEN MEDICAL AND NURSING STAFF FAILED TO IDENTIFY THAT A FOREIGN OBJECT (SURGICAL SPONGE OR LAP TAPE) HAD BEEN RETAINED IN A PATIENT AFTER SURGERY. THIS VIOLATION PLACED THE PATIENT AT INCREASED RISK FOR COMPLICATIONS AND DEATH FROM THE RETAINED SURGICAL SPONGE.<br><br>FINDINGS:<br><br>On 10/14/09, review of Patient 1's medical record demonstrated that she weighed 300 pounds and was admitted on 9/18/09 for elective Cesarean Section at 40 weeks of gestation, with an estimated fetal weight of greater than 8 pounds and a small pelvis. The 40 minute surgery was complicated by a 900 cc. blood loss and was completed at 11:35 am according to the operative record. Sponge counts were documented at 11:05 am, 11:15 am, and 11:25 am and were declared correct. No sponge count was recorded after the closure of the final incision at 11:35 am. On 9/21/09 (postoperative day 3), Patient 1 developed signs of possible ileus (intestinal | | The patient was returned to the operating room on 9/23/2009 at 1930 for successful removal of a retained lap sponge.<br><br>On 9/24 /2009 leadership from Quality Management, Risk Management, Women Infants and Children (WIC), the Chief Nursing Officer and the involved medical and hospital staff met to review the event and develop an action plan.<br><br>This action was undertaken to ensure that such an event would not occur again in WIC or Perioperative Services.<br><br>On 10/1/2009 reeducation of staff was initiated and commenced over a two-week period in huddles, informal meetings held with members of the care team, and also through observational audits during C-section deliveries. The observational audits were part of an ongoing audit process since August 2008.<br><br>Disciplinary action was taken for the registered nurse and OB technician, who failed to follow the hospital's policy and procedure for sponge counts. | |

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| | Continued From page 2<br>obstruction). CT scan of the abdomen on 9/21 suggested the possibility of an intra-abdominal foreign body. A follow-up CT was recommended to reassess the finding, and on 9/23/09, repeat CT scan located a radiopaque foreign body in the right lower abdominal cavity. On 9/23/09, Patient underwent an exploratory laparotomy, a second surgical procedure/anesthesia, to remove the retained lap tape. Patient 1 was discharged on 9/25/09.<br><br>In interview on 10/14/09 at 1:30 p.m., Administrative Staff A stated that on 9/18/09, during an elective Cesarean Section performed on Patient 1, sponge counts were performed at various intervals according to protocol. The, "easy count," sponge counter bags were used for the counts. She stated that each sponge must end up in a, "shoe bag," apparatus, one sponge per bag. There were 14 of 15 sponges in bags during the count prior to closure of the incision. The protocol mandates that the count is not complete unless all of the sponges are in separate bags. According to Staff A, the surgeon, the scrub technician, and the circulating nurse stated that there was confusion prior to closure, and the staff thought the last sponge was on the operative field. Patient 1 was obese; the bowel was in the way and the sponge (a lap tape) was placed to hold the bowel back. Staff A stated that the surgeon did not announce that she had placed the lap tape in the abdomen. Staff A stated that 5 lap tapes that been opened, but not used, were not placed in the easy count bags. Staff A | | On 10/28/2009 there was discussion of the event and "just in-time" reeducation of the OB/GYN medical staff and allied health professional midwife staff at the OB/GYN Department meeting. The focus of the discussion was the need to optimize teamwork among the medical staff and hospital staff in order to achieve improvement in the sponge accounting process, thereby eliminating any reoccurrence of a retained foreign object.<br><br>On 10/30/2009 annotation of sponge placement on the whiteboards in the WIC operating and delivery rooms was achieved by adding headers entitled "lap-in" and "lap-out".<br><br>On 11/5/2009 the Chief Administrative Officer met with key leaders from Administration, Quality, Risk, WIC and Perioperative Services to review the action plan to ensure that it was comprehensive and included physician involvement.<br><br>On 11/12/2009 and 11/20/2009 a mandatory sponge count retraining was held on WIC. | |

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| | Continued From page 3<br>stated that all 20 lap tapes should have been placed in bags to verify a correct count.<br><br>On 9/14/09, review of the hospital policy, "Perioperative Services Sponge and Sharp Accounting," dated 9/2008, demonstrated the requirements that after the initial sponge count, subsequent counts will be done when sponges are added to the sterile field, before closure of any body cavity, before closure of any deep or large incision, immediately before completion of the surgical procedure, and when each incision is closed. In addition, all sponges will be accounted for in the sponge holding bags by completion of the final count.<br><br>The facility's failure to implement the policies and procedures regarding sponge/instrument counts is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280.1. | | In December 2009, the supply of 4x8 radio-opaque sponges was changed to larger 4x18 radio-opaque mini lap sponges with radio-opaque ribbons. Radio-opaque sponges also replaced non-radio-opaque sponges in the vaginal delivery packs.<br><br>On 1/11/2010 the Chief Nursing Officer convened a meeting of WIC, Perioperative, Quality and Administrative leadership to review and amend the previously developed action plan. This included the appointment of the Director, Perioperative Services to oversee the Retained Foreign Bodies Prevention process by ensuring one standard of practice for counting lap sponges and vaginal sponges in Perioperative and WIC Services.<br><br>The audit tool was revised and a decision was made to institute 100% audit for C-sections.<br><br>Perioperative Services would continue the audit process at the current frequency and volume. | |

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| | Continued From page 3<br>stated that all 20 lap tapes should have been placed in bags to verify a correct count.<br><br>On 8/14/09, review of the hospital policy, "Perioperative Services Sponge and Sharp Accounting," dated 9/2008, demonstrated the requirements that after the initial sponge count, subsequent counts will be done when sponges are added to the sterile field, before closure of any body cavity, before closure of any deep or large incision, immediately before completion of the surgical procedure, and when each incision is closed. In addition, all sponges will be accounted for in the sponge holding bags by completion of the final count.<br><br>The facility's failure to implement the policies and procedures regarding sponge/instrument counts is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280.1. | | On 1/12/2010 WIC and Perioperative staff and physicians present at the OR Management Committee attended a PowerPoint presentation entitled *Recommendations for Prevention of Retained Foreign Bodies* developed by the system-wide Retained Foreign Body Task Force. This presentation was mandatory for the Labor and Delivery nursing staff and was offered again on 1/19/2010, 1/21/2010, and 1/26/2010. All WIC staff has completed the PowerPoint presentation and a post-test.<br><br>On 1/18/2010 the Director, Perioperative Services and Manager, Labor and Delivery met to review the process for documentation for vaginal sponge counts and handoff communication using SBAR (Situation, Background, Assessment and Recommendation) when vaginal packings were left in place for treatment of post-partum hemorrhage. | |

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| | Continued From page 3<br>stated that all 20 lap tapes should have been placed in bags to verify a correct count.<br><br>On 9/14/09, review of the hospital policy, "Perioperative Services Sponge and Sharp Accounting," dated 9/2008, demonstrated the requirements that after the initial sponge count, subsequent counts will be done when sponges are added to the sterile field, before closure of any body cavity, before closure of any deep or large incision, immediately before completion of the surgical procedure, and when each incision is closed. In addition, all sponges will be accounted for in the sponge holding bags by completion of the final count.<br><br>The facility's failure to implement the policies and procedures regarding sponge/instrument counts is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280.1. | | On 1/27/2010 the Chief Nursing Officer met with the Director, Perioperative Services and Manager, Labor and Delivery for a progress update of the current action plan. The Perioperative Educator attended the OB/GYN meeting and reported on the Retained Foreign Body Task Force's findings and recommendations and the hospital's responses to the event.<br><br>On 2/4/2010 kick buckets were placed in each Labor and Delivery Room for lap sponges. The kick buckets were placed to allow for centralized collection of sponges for placement in the sponge counting bags.<br><br>On 2/5/2010 the team that met on 1/11/2010 reconvened for follow-up and reassessment of the action plan.<br><br>Monitoring<br><br>Audits are conducted on all C-section deliveries and for 10 cases of sponge counts for vaginal deliveries. Perioperative Services conducts 10 audits per month in the Main OR and the ambulatory surgery center. | 2/5/10 and ongoing |

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| | Continued From page 3<br>stated that all 20 lap tapes should have been placed in bags to verify a correct count.<br><br>On 9/14/09 review of the hospital policy, "Perioperative Services Sponge and Sharp Accounting," dated 9/2008, demonstrated the requirements that after the initial sponge count, subsequent counts will be done when sponges are added to the sterile field, before closure of any body cavity, before closure of any deep or large incision, immediately before completion of the surgical procedure, and when each incision is closed. In addition, all sponges will be accounted for in the sponge holding bags by completion of the final count.<br><br>The facility's failure to implement the policies and procedures regarding sponge/instrument counts is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an Immediate jeopardy within the meaning of Health and Safety Code section 1280.1. | | Audit data is compiled on spreadsheets and submitted to the Director, Quality Management Services monthly for three months. The results of the audit will be reported by the Director to the Quality Improvement Committee monthly.<br><br>Ongoing audits to date have indicated 100% compliance. | |

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California Department of Public Health

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| NAME OF PROVIDER OR SUPPLIER: MARIN GENERAL HOSPITAL | STREET ADDRESS, CITY, STATE, ZIP CODE: 250 BON AIR ROAD, PO BOX 8010 GREENBRAE, CA 94904 | | |

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| E 000 | Initial Comments<br><br>The following reflects the findings of the California Department of Public Health during an ENTITY REPORTED INCIDENT visit.<br><br>Inspection was limited to the specific entity reported incident #CA00202782 investigated and does not represent the findings of a full inspection of the facility.<br><br>Representing the Department of Public Health: Surveyor 20307, Medical Consultant 1 (MC1).<br><br>THE DEPARTMENT SUBSTANTIATED A VIOLATION OF THE REGULATIONS. | E 000 | The following constitutes Marin General Hospital's plan of correction of the alleged deficiencies cited by the Department of Public Health in the Statement of Deficiencies Form CMS-2567 dated October 15, 2009. Preparation and/or execution of this corrective action does not constitute admission or agreement by the provider of the truth of the facts or conclusions set forth on the Statement of Deficiencies. It has been prepared and/or executed solely because it is required by federal and state law. | |
| E1908 | T22 DIV5 CH1 ART7-70703(b) Organized Medical Staff<br><br>(b) The medical staff, by vote of the members and with the approval of the governing body, shall adopt written by-laws which provide formal procedures for the evaluation of staff applications and credentials, appointments, reappointments, assignment of clinical privileges, appeals mechanisms and such other subjects or conditions which the medical staff and governing body deem appropriate. The medical staff shall abide by and establish a means of enforcement of its by-laws. Medical staff by-laws, rules and regulations shall not deny or restrict within the scope of their licensure, the voting right of staff members or assign staff members to any special class or category of staff membership, based upon whether such staff members hold an M.D., D.O., D.P.M., OR D.D.S. degree or clinical psychology license.<br><br>This Statute is not met as evidenced by: | E1908 | The Medical Staff will enforce its bylaws and rules and regulations by monitoring physician compliance with completion of dictated operative reports within 24 hours of surgery and completion of discharge summaries that include all required elements.<br><br>Immediately upon learning that the operative reports were delinquent and the discharge summary was incomplete, the physician was notified by the Chair, Obstetrics/Gynecology to complete the delinquent reports | |

Licensing and Certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [signature] Director, Quality Management
TITLE
(X6) DATE 2/12/2010



3/10/10 Hospital notified that POC is accepted.
[initials]

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| E1908 | Continued From page 1<br><br>Based on document review and medical record review, the medical staff failed to enforce implementation of its bylaws, rules and regulations regarding operative notes and discharge summaries in one case.<br><br>Findings:<br><br>Review of Patient 1's medical record on 10/14/09 demonstrated that it was absent dictated operative reports for operative procedures performed on 9/18/09 and 9/23/09. Handwritten notes were present in the record on forms labeled, "interim post-operative progress note." The forms stated at the top that the interim note was to be completed immediately post-operatively and then stated, "dictated report to be completed within 24 hours of surgery."<br><br>On 10/14/09, review of the hospital's medical staff rules and regulations addressing operative reports demonstrated that all operations performed shall be fully described by the operating surgeon. "The full operative report must be dictated within 24 hours after surgery."<br><br>Review of Patient 1's medical record on 10/14/09 demonstrated that the, "Perinatal Discharge Summary," dated 9/26/09 was absent any mention of the retained foreign body after Cesarean Section or the exploratory laparotomy performed on 9/23/09 to remove the foreign body.<br><br>Review of the medical staff rules and regulations on 10/14/09 demonstrated that, "a discharge summary shall be written or dictated by the attending physician," and shall, "include the final diagnosis, reason for admission, hospital course, including procedures performed and treatment rendered, significant findings, [and] the patient's | E1908 | and dictate a complete discharge summary.<br><br>The physician completed the operative reports and dictated a discharge summary that included all of the required elements.<br><br>Beginning in December 2009 Health Information Management (HIM) generated physician-specific reports on delinquent operative reports and discharge summaries.<br><br>At the January 2010 meeting of the Medical Executive Committee members of the committee discussed how physicians were notified regarding delinquent medical records.<br><br>The Medical Director has requested that HIM send weekly lists of delinquent operative reports and discharge summaries to the medical staff department/division chairs/chiefs.<br><br>The most current reports will also be brought to the regular department/division meetings.<br><br>Content of the discharge summaries and time frames for completion of operative reports and discharge summaries will be reviewed with physicians at the department/division meetings. | |

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FORM APPROVED

California Department of Public Health

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | CA110000361 | A. BUILDING ______ B. WING ______ | C 10/15/2009 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| MARIN GENERAL HOSPITAL | 250 BON AIR ROAD, PO BOX 8010 GREENBRAE, CA 94904 |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|---|---|---|---|---|
| E1908 | Continued From page 2<br>condition on discharge." | E1908 | The Director, Quality Management Services completed an audit of the involved practitioner's delinquent operative reports and discharge summaries from September 2009 through February 5, 2010. The Medical Director shared the results of the audit with the Chair, Obstetrics/Gynecology. The Chair will have a discussion with the practitioner.<br><br>Monitoring<br><br>The Director, Quality Management Services will continue to audit the involved practitioner's medical records for delinquent operative reports and incomplete discharge summaries monthly, for a minimum of three months.<br><br>The Medical Executive Committee (MEC) will review the results of the audits monthly. The MEC will determine the need for ongoing audits and will intervene. with the practitioner, as appropriate. | 2/5/10 and ongoing |