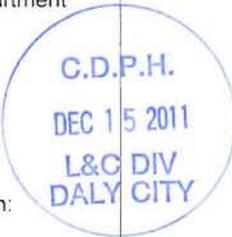


CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050754	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/23/2009
NAME OF PROVIDER OR SUPPLIER MENLO PARK SURGICAL HOSPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE 570 WILLOW ROAD, MENLO PARK, CA 94025 SAN MATEO COUNTY		
(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
	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00195291 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 21155, HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>Health and Safety Code Section 1280.1(c): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.</p> <p>T22 DIV5 CH1 ART3-70223(b)(2) Surgical Service General Requirements</p> <p>(b) A committee of the medical staff shall be assigned responsibility for: (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.</p> <p>This Regulation was not met as evidenced by:</p>		<p>The following Plan of Correction is applicable to Complaint #CA00195291; Health & Safety Code 1280.1(c). The Surgical Services General Requirements will be met as evidenced by the following:</p> <p>The policies "Universal Protocol Procedural Verification and Time Out" (NUR-2.0890); "Cystoscopy Procedure (MSA-1.0920) and "Hysteroscopy-Diagnostic/Operative (MSA-1.0910) were reviewed, discussed and approved by the Medical Staff committee and the Governing Board. All OR staff were educated on the facets of the root cause analysis of this incident including the implications for use of the Universal Protocol, Procedural Verification and Time Out (Attachment B). 7/11/09</p> <p>Immediately the Clinical Nurse Educator (CNE) revised the OR Skills Inventory Checklist to reflect current surgical practices (Attachment V). The OR Manager and the OR staff were re-educated on the process of Universal Protocol Procedural Verification process. The OR Manager was also educated on use of the OR RN Skills Inventory Checklist for new RN staff or a new Traveler RN. 7/27/09</p> <p>The Clinical Nurse Educator is responsible for administering the skills inventory checklist. 7/30/09</p>	



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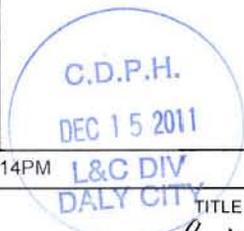
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accepted POC D Jordan 12/27/11
Acting HFES

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	<p>Continued From page 1</p> <p>Based on interview and record review, the facility failed to follow procedures to ensure the proper equipment was used during surgery. A hysteroscopy (Visual instrumental inspection of the uterine cavity) set-up was prepared and used on the patient instead of a cystoscopy (Inspection of the interior of the bladder by means of a cystoscope) set up causing Patient-A's bladder to rupture.</p> <p>Findings:</p> <p>Patient-A had a history of pelvic pain endometriosis, right ovarian cyst and possible interstitial cystitis. The patient was admitted to the facility on [REDACTED]/09 for a complex endometrial surgery that included cystoscopy with hydrodistention.</p> <p>Cystoscopy with hydrodistention is a procedure used to diagnose interstitial cystitis by inserting a cystoscope to examine the interior of the bladder. The bladder is filled with fluid which causes the bladder wall to stretch out allowing the physician to inspect for the changes of interstitial cystitis. The facility's protocol for this procedure was to hang the bag of fluid with no pressure gravity. Rather, the fluid was attached to a mechanical device, a hysteroscopy pump.</p> <p>The physician's operative report dated [REDACTED] 09 documented, "The cystoscope was inserted. The bladder was distended...Following what appeared to be glomerulation formation, it was noted that the integrity of the bladder was lost. The bladder was drained immediately. After inspecting the set-up it</p>		<p>The Clinical Nurse Educator has oversight for clinical education including the skills and competencies for all staff. The OR Manager is responsible to ensure educational compliance among the OR Staff and for the process in its entirety. Since the CMS exit conference, the OR RN Skills Inventory and education process have met 100% compliance. In order to avert future occurrences the "Universal Protocol, Procedural Verification and Time Out" were reinforced and monitored in the OR. This was accomplished by random observational audits (10x/week for 3 months and then on a quarterly basis (Attachment C). The OR Manager is responsible for the auditing process and additionally shares responsibility with the Chief Nursing Officer for oversight of the overall Universal Protocol and Time Out process. The results of the "Universal Protocol, Procedural Verification and Time Out" audit were tracked and trended on a monthly basis and submitted in a quarterly report to the Quality/Patient Safety Committee, Medical Executive committee and the Governing Board.</p> <p>8/1/09-11/30/09</p>	



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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: *[Signature]* TITLE: *[Signature]* (X6) DATE: *12/04/11*

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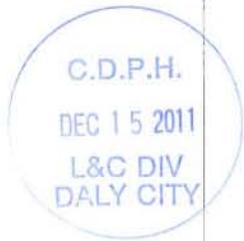
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NAME OF PROVIDER OR SUPPLIER MENLO PARK SURGICAL HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE 570 WILLOW ROAD, MENLO PARK, CA 94025 SAN MATEO COUNTY
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	<p>Continued From page 2</p> <p>was determined that the surgical pack had attached the fluid for the bladder to the hysteroscopy pump rather than hanging it to provide gravity insulation as per protocol".</p> <p>The urologist was called immediately to repair the bladder. The urologist's operative report dated [REDACTED] 09 documented, " (Patient-A) was undergoing an endometrial surgery, had her bladder distended and had a rupture of her bladder. The patient was in the operating room and cystoscopy was performed revealing a right dome rupture of the bladder". Consequently, Patient-A was discharged home with a foley catheter, a tube placed in the bladder for urine drainage, for two weeks.</p> <p>The facility's policy titled, "Universal Protocol, Procedural Verification and Time Out", MSA-1.0560, NUR-2.0890, ADM-8.422, review/revision date: 5/09, stated:</p> <p>1) "Purpose: The purpose of this policy is to establish a standardized approach throughout (the facility) for procedural verification and time out. This is to prevent wrong site, wrong procedure and wrong person incidence. The Universal Protocol is part of the National Patient Safety Goals and is based on the consensus of experts from the relevant clinical specialties and endorsed by professional medical associations and organizations".</p> <p>2) "Policy: The Universal Protocol shall be used throughout (the facility) in all operative and non-operative services where invasive procedures</p>			
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>[Signature]</i>	TITLE <i>CEO</i>	(X6) DATE <i>12/1/11</i>
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	<p>Continued From page 3</p> <p>are performed...The Universal Protocol consists of the following steps for eliminating wrong site, wrong procedure, and wrong person: pre-operative or procedural verification, marking the operative or procedural site, and "Time Out" immediately before starting the surgery or procedure..."</p> <p>3) "Procedure: Pre-Operative or Procedural Verification Process - Verification of the correct person, procedure and site will occur: #1 At the time the surgery or procedure is scheduled, #6 Before the patient leaves the pre-operative area or enters the procedure or surgical room, #7 Before the patient is prepped for bedside procedure".</p> <p>The same policy stated: " 'Time Out' immediately prior to starting the surgery or procedure:</p> <p>1) Must be conducted in the location where the procedure will be done, just before starting the surgery or procedure.</p> <p>2) When a regional block is performed, an additional "time out" will take place before the block is performed.</p> <p>3) Time Out must involve the entire procedural or operative team and requires active participation among all members of the team.</p> <p>4) The procedural pause must include: correct patient identification using patient's full name and date of birth, correct side and site, procedure consent and procedure to be done, correct patient position and availability of correct implants and any</p>			



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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Katherine J. Long

TITLE

CAO

(X6) DATE

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	<p>Continued From page 4</p> <p>special equipment, requirements and correct X-rays, correct antibiotics and/or irrigation fluids needed, as well as any safety precautions based on patient history or medication use.</p> <p>5) The procedure will not be started until any questions or concerns are resolved from the room.</p> <p>6) The circulating RN will ensure that the "time out" occurs. Verbal confirmation of agreement must occur among all members of the surgical team.</p> <p>7) Documentation of the Time Out will be done by the MD or RN on appropriate unit form.</p> <p>8) Documentation will include time and staff involved in the Time Out".</p> <p>The "Intra Operative Case Record" dated [REDACTED] 09 for Patient-A's surgery documented the Time Out at 8:14 and the following procedures to have been done: "correct patient identification with 2 identifiers, correct side site/laterality verification, implants, equipment, special requirements available, accurate consent for procedure to be done, agreement of procedure to be done, correct patient position, if needed antibiotics/irrigation fluids available, and safety precautions taken based on patient history medication use".</p> <p>In an interview on 9/10/09 at 11:45 am, the surgeon stated the cystoscopy with hydrodistention should be set up by gravity feed 30 inches above the patient's bladder. He was surprised to see the set up was with the hysteroscopy pump which caused</p>			



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