

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

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|--|---|--|---|--|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050457 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 06/28/2010 |
| NAME OF PROVIDER OR SUPPLIER ST. MARY'S MEDICAL CENTER | | STREET ADDRESS, CITY, STATE, ZIP CODE 450 STANYAN STREET, SAN FRANCISCO, CA 94117 SAN FRANCISCO 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: CA00232109 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 25732, 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>Title 22</p> <p>70433(a) (4) Cardiovascular Surgery Service General Requirement (a) Written policies and procedures shall be developed and maintained by the person responsible for the service 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. These policies and procedures shall include provision for at least:</p> | 4/18/11 KS | <p>C.D.P.H.</p> <p>APR 18 2011</p> <p>L&C DIV DALY CITY</p> | |

Event ID: Z22C11

4/4/2011

3:37:19PM

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

TITLE *Manager* (X6) DATE

Shelley Hanes RN MS Accreditation + Regulatory *4/14/11*

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POC accepted

APR 18 2011

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| | <p>Continued From page 1</p> <p>(4) Recommendations regarding equipment used, procedures performed and staffing patterns in the catheterization laboratory and cardiovascular surgery units.</p> <p>These regulations were not met as evidenced by:</p> <p>Based on interview, observation and record review the facility failed to develop policies and procedures for the safe use of the portable ECMO (Extra Corporeal membrane Oxygenation device-a portable heart lung machine) bypass machine for intra-facility transport to prevent the sudden disconnection of tubing on the oxygenator venous blood inlet of the ECMO. The tubing was stretched and came off of the oxygenator inlet when Patient 1's gurney was being lifted into the ambulance at the facility's ambulance loading dock on [REDACTED] 10 at 8:20 P.M. The facility failed to follow the oxygenator manufacturer's recommendation to connect and band all blood lines. This failed practice resulted in the disconnection of the blood tubing from the oxygenator venous inlet and was the direct cause of the death of Patient 1.</p> <p>Findings:</p> <p>According to Facility A's Transfer Summary dated [REDACTED] 10, it indicated that Patient 1 had hypertension (high blood pressure), presenting with acute onset of continuous chest pain at rest and was found to be in new atrial</p> | | <p>Title 22 §70433(a) (4) The statute is not met as evidenced by: Based on interview, observation and record review, the facility failed to develop policies and procedures for the safe use of the portable ECMO bypass machine for intra-facility transport to prevent sudden disconnection of the tubing.</p> <p><u>How the correction will be accomplished, both temporarily and permanently.</u></p> <ol style="list-style-type: none"> ECMO tubing packs borrowed from UCSF while waiting custom tubing packs created for St. Mary's Medical Center by vendor. 6/10/10 Custom ECMO tubing pack configured for St. Mary's Medical Center. Purchased 3 packs to be available at all times. (Attachment A) 7/30/10 ECMO Transport policy developed for surgical services. (Attached B) 6/20/10 Transfer/ discharge to a higher level of care policy developed for medical center. Includes responsibilities and process. (Attached C). Policy approved by Medical Executive Committee and Community Board. 6/20/10 Table Top teaching exercise for patient evacuation on ECMO bypass for OR staff. 9/17/10 4/15/11 & quarterly Purchased BioMedicus PBS cart (portable bypass cart) to facilitate efficient transport. (Attachment D) 9/30/10 | |

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| | <p>Continued From page 2</p> <p>fibrillation (irregular and often rapid heart rate that commonly causes poor blood flow to the body) with EKG (electrocardiogram a graphic representation of the electrical activity of the heart) notable for ST depression (an irregular pattern on an EKG). Patient 1 was transferred to the facility on [REDACTED]10 for evaluation for coronary bypass surgery (surgery where veins are taken from other parts of the body and grafted to the heart to by pass diseased coronary arteries).</p> <p>Review of Patient 1's operative record, dated [REDACTED]10, indicated she was taken to the operating room on [REDACTED]10 and underwent triple coronary artery bypass surgery. During surgery, Patient 1 was placed on a cardiopulmonary bypass machine (machine that takes over the function of heart and lung during heart surgery). Following the surgery, several attempts were made to wean (switch from heart-lung machine to person's own heart and lung) Patient 1 from the cardiopulmonary bypass machine. An intra-aortic balloon pump (balloon placed in aorta to help heart pump more easily) was placed in Patient 1's descending aorta. Another attempt was made to wean Patient 1 off the bypass pump without success. The decision was made to transfer Patient 1 to Facility B's Intensive Care Unit so she could be placed on a long term left ventricular assist device (LVAD-device that helps maintain pumping ability of heart) to rest the heart. Surgeon 1 decided to place Patient 1 on an extracorporeal membrane oxygenation</p> | | <p><u>Description of Monitoring process to prevent recurrence of the deficiency.</u></p> <ol style="list-style-type: none"> 1. Monitoring of expiration date and package integrity of tubing packs on monthly basis. 4/7/11 & ongoing 2. Bypass machine, BioConsole 560 on preventive maintenance schedule every 6 months. 3/7/11 & ongoing 3. Table Top teaching exercise for patient evacuation on ECMO bypass. 9/17/10 4/15/11 & quarterly <p>Responsible parties: Director of Surgical Services Perfusionist/ Circulatory Support Manager of Biomedical Engineering</p> <p style="text-align: right;">C.D.P.H. APR 18 2011 L&C DIV DALY CITY</p> | |

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| | <p>Continued From page 3</p> <p>assist device (ECMO-a portable heart lung machine) in preparation for a critical care ambulance transfer. Patient 1 was taken from the operating room on an ambulance gurney to the facility's emergency room loading area so Patient 1 could be loaded into the ambulance. Patient 1 was accompanied by Surgeon 1, the anesthesiologist, Circulatory Support Perfusionist 1(CSP-1-a technician who operates and sets up heart/lung bypass and ECMO equipment under the direction of the surgeon), a Critical Care Transport Registered Nurse and two Emergency Medical Technicians. During movement of the ECMO equipment into the ambulance, the ECMO tubing became disconnected and the tubing could not be reconnected. Patient 1 expired during this transfer into the ambulance on [REDACTED] 10 at 8:20 P.M.</p> <p>Record review of Patient 1's Anesthesia Record note written [REDACTED] 10 indicated: "Unable to wear off Cardio Pulmonary Bypass(CPB) despite high dose pressors and inotrope (drugs to make the heart beat better), IABP(Intra-aortic balloon pump-balloon placed in aorta to help heart pump more easily), Plan to transfer to Facility B's Intensive Care Unit upon transfer into ambulance at 2020 (8:20 PM); portable cardio pulmonary bypass disconnected (the ECMO), not possible to reestablish CPB patient expired thereafter, brought back to OR."</p> <p>Record review of Patient 1's Discharge</p> | | | |

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| | <p>Continued From page 4</p> <p>Summary note dictated on [REDACTED] 10 indicated: "Patient was taken to the operating room. Surgery consisted of internal mammary left anterior descending, saphenous (large vein in leg) vein graft (use another vein to create a conduit so blood can flow around the heart) to the obtuse marginal right coronary. This was complicated by inability to come off pump as well as inability to place intra-aortic balloon pump via the groin. Ultimately, intra-aortic balloon pump was placed via the ascending aorta (major artery that carries blood away from the heart); however, patient could not come off the pump, and arrangements were to transfer the patient to the university medical center after placement of ECMO support. ECMO was placed, and patient was transferred out of the operating room and was being loaded on the ambulance when the ECMO circuit became disconnected and patient expired."</p> <p>In an interview on 6/25/10 at 1:15 PM, the Hospital Risk Manager (RM-1) was asked if there were any facility policies or procedures for setting up the portable ECMO bypass system for intra-facility transport. RM-1 said, "No, we are working on writing them up now."</p> <p>In the same interview RM-1 was asked if there were any performance standards for the Circulatory Support Perfusionist job description that addressed the set up of an ECMO bypass system for intra-facility transport. RM-1 said, "No, there are none."</p> | | <p>C.D.P.H.</p> <p>APR 18 2011</p> <p>L&C DIV DALY CITY</p> | |

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| | <p>Continued From page 6</p> <p>In a concurrent interview CSP-1 was asked if there was some kind of band that is applied to secure the tubing to the oxygenator. CSP-1 said, "Well on this case we did not have a band, no tie band (plastic tie band that secures the tubing to an outlet). This was the first time we have done this type of transport out of the OR into an ambulance. We had a lot of tubing... not the length that we needed, just for the transfer there could have been a little extra."</p> <p>CSP-1 was asked for a copy of any manufacturer's recommendations to follow when assembling the tubing to the oxygenator. CSP-1 said, "No, the only things that have warnings are about the pressure alarms on the machine."</p> <p>In the same interview CSP-1 was asked, "When was the last time that you set up the ECMO oxygenator for this type of transport?" CSP-1 said, "The last time was a couple of years ago; actually it was a different kind of situation."</p> <p>In an interview on 6/28/10 at 11:00 AM, Surgeon 1 said, "Patient 1 came from another hospital for coronary artery bypass surgery. During the surgery things were going relatively uneventfully until it was time to come off the Cardiac Bypass machine... we could not wean the patient off the pump so we put in a balloon (IABP) to rest the heart... the balloon was still not enough to get her off the bypass machine so the decision was made to put her on a</p> | | <p>C.D.P.H. APR 18 2011 L&C DIV DALY CITY</p> | |

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| | <p>Continued From page 7</p> <p>ECMO portable circuit to rest her heart and lungs... the ECMO is a more portable unit. We don't have a long term ECMO pump here so I arranged to transfer Patient 1 to the Facility B's ICU. It is just a set of tubes we switch from the big machine to the portable system... we switch the tubes to the oxygenator... two hoses in and out... basically we change hoses to the portable... she got transported over to the gurney for the ambulance... we are lifting up the patient to the rear of the ambulance then the tubing got disconnected."</p> <p>During the same interview, Surgeon-1 was asked which tube became disconnected. Surgeon-1 said, "I can't remember, basically there are only two tubes, it is a complete circuit... it is like a continuous column of water... if a tube becomes disconnected, it can not be reconnected, air gets in."</p> <p>Surgeon 1 was asked, "If the tubing gets disconnected from the oxygenator death results?" Surgeon 1 said, "Yes."</p> <p>In an observation in the facility's Operating Room No. 12 on 6/28/10 at 11:30 AM, a portable ECMO bypass system that was set up by CSP-1 was inspected. The unit consisted of an IV pole, portable blood pump, two sets of 6' clear tubing and a white colored Medtronic Affinity NT CB511 Oxygenator. One of the clear tubes was connected to the oxygenator bottom plastic inlet. This is known as the Venous Blood Inlet. The tubing had a plastic tie band around</p> | | | |

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