VENTURA COUNTY MEDICAL CENTER
SANTA PAULA HOSPITAL
A Division of Ventura County Health Care Agency

Ventura County Health Care System Oversight Committee
Hospital Administrative Policies & Procedures

August 21, 2024

The following administrative policies were reviewed and recommended for approval by appropriate departments and committees.

1. PH.18.01 340B Drug Pricing Program: Disproportionate Share Hospital
2. L.02 Noise Exposure in the Laboratory
3. L.06 Terms of Accreditation by the College of American Pathologists
4. L.07 Ensuring Compliance with Laboratory Laws and Regulations
5. L.39 Collection, Labeling and Transport of Laboratory Samples
6. L.52 Laboratory Response To Hospital Emergency Call Codes
7. L.BB.09 Selection of Blood for Transfusion
8. L.BB.50 Crossmatch-Immediate Spin
9. L.CHEM 2.20 Thyroid-Stimulating Hormone (TSH3-Ultra)
10. L.SPH.16 Urine and Cerebrospinal Fluid Protein
11. L.SPH.55 Laboratory Protocol for Evaluating Quality Control Data
12. 100.011 Hospital Visitation

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Hospital Administrative Policies Procedures - August 21, 2024
Summary of Changes

#	Title	Review Period	Summary of Changes
1	PH.18.01 340B Drug Pricing Program: Disproportionate Share Hospital	Annual	In Material Breach section, updated material breach from 10% to 15% based and updated list of non-covered medications to include insulin, large volume IV's, and local anesthetics based on 340B consultant recommendations
2	L.02 Noise Exposure in the Laboratory	Biennial	Biennial review of policy. Revised references.
3	L.06 Terms of Accreditation by the College of American Pathologists	Biennial	Biennial review of policy. Minor edits made for clarity.
4	L.07 Ensuring Compliance with Laboratory Laws and Regulations	Biennial	Biennial review of policy. Revised checklist. Added reference from College of American Pathology Accreditation Checklist (8/24/2023).
5	L.39 Collection, Labeling and Transport of Laboratory Samples	Biennial	Biennial review of policy. Added "Materials and Equipment" section and made minor edits for clarity.
6	L.52 Laboratory Response To Hospital Emergency Call Codes	Biennial	Biennial review of policy. Added "Materials" section and made minor edits for clarity.
7	L.BB.09 Selection of Blood for Transfusion	Biennial	Revised #7 of Policy section to include transfusion of group A2B patients.
8	L.BB.50 Crossmatch-Immediate Spin	Biennial	Biennial review of policy. Updated referenced policy names and revised reference.
9	L.CHEM 2.20 Thyroid-Stimulating Hormone (TSH3-Ultra)	Biennial	In Results section, added reference range for infants (1-23months) based on the revised IFU.
10	L.SPH.16 Urine and Cerebrospinal Fluid Protein	Biennial	Biennial review of policy. In Procedure section, added link to Document Library for Siemens Dimension
11	L.SPH.55 Laboratory Protocol for Evaluating Quality Control Data	Biennial	Biennial review of policy. In Procedure section, new analyzers added and old analyzers removed.
12	100.011 Hospital Visitation	Triennial	In Procedure section, incorporated language from 107.025 regarding patients under guard surveillance (policy 107.025 to be retired). Also added hyperlink to policy 107.076 Accessibility - Animals in Healthcare Facilities.

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Owner	Beatriz Cachu: 340B Program Administrator
Policy Area	Pharmacy Services

PH.18.01 340B Drug Pricing Program: Disproportionate Share Hospital

I. Purpose

This policy serves as the basis for the covered entity (CE) Ventura County Medical Center's (VCMC, DSH050159) policy and procedures for the 340B Drug Pricing Program (340B Program), which requires drug manufacturers to provide outpatient drugs to eligible health care organizations, including the covered entity (CE) Ventura County Medical Center [DSH050159], at significantly reduced prices. The CE uses savings from the 340B Program following its intent to reach “more eligible patients and provide more comprehensive services."

II. Background

A. Section 340B of the Public Health Service Act (1992), *(See Reference I)*, requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of the Department of Health and Human Services (DHHS).

   1. This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs.

B. The 340B Program is administered by the federal Health Resources and Services Administration (HRSA) in the Department of Health and Human Services (DHHS).

C. Upon registration on 340B Office of Pharmacy Affairs Information System (OPAIS), the CE:

   1. Agrees to abide by specific statutory requirements and prohibitions.
   2. May access 340B drugs.

III. 340B Policy Statements

A. The CE shall comply with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than an eligible patient of the entity.

B. The CEs have systems and internal controls in place to ensure ongoing compliance with all 340B requirements:

    1. Audit Process *(See Section "340B Program Compliance, Monitoring and Reporting")*
    2. Purchasing process *(See Section "Inventory Management")*
    3. Shipping and receiving process *(See Section "Inventory Management")*

C. Registration & Recertification *(See Section "340B Program Enrollment Recertification")*

D. The CEs maintain auditable records demonstrating compliance with the 340B Program.

    1. These records are reviewed by the CE monthly as part of its 340B oversight and program compliance. *(See Section "340B Program Compliance, Monitoring and Reporting")*

E. Policy review, updates, and approval shall be updated and approved by the CEs' Compliance Committee whenever there is a rules clarification, regulations change, or change in guidelines to the 340B Program requirements. Otherwise, the policy shall be reviewed and approved annually by key stakeholders.

IV. Definitions

A. Child Site: An offsite location that is eligible to participate in the 340B Program because it is part of the Covered Entity but is separately registered with the Office of Pharmacy Affairs (OPA) because it has a different street address than the Covered Entity's main facility. A Covered Entity does not need to register outpatient clinics and departments located within the four walls of the entity's main facility. OPA guidance establishes a Medicare cost report test to determine whether an offsite clinic is part of the Covered Entity and, therefore, eligible to use 340B drugs. Under this test, an offsite clinic's costs must be reimbursable on the hospital's Medicare cost report. In implementing this guidance, OPA has taken the position that, to be 340B eligible, an offsite clinic's costs must appear on a reimbursable line of a hospital's most recently filed cost report. A Covered Entity pharmacy is not a Child Site.

B. Covered Entity: The statutory name for facilities and programs eligible to purchase discounted drugs through the 340B Program. Covered entities include federally qualified health center look-alike programs; certain disproportionate share hospitals owned by, or under contract with, State or local governments; and several categories of facilities or programs funded by Federal grant dollars, including federally qualified health centers, AIDS drug assistance programs, hemophilia treatment centers, STD and TB grant recipients, and family planning clinics.

C. Covered Outpatient Drug: The category of drugs for which manufacturers must give 340B discounts to covered entities under the 340B Program. In order for a product to qualify as a Covered Outpatient Drug, it must be FDA-approved, prepared and dispensed pursuant to a

prescription, and used on an outpatient basis. In order for a Covered Outpatient Drug to be paid for by Medicaid or Medicare Part B, a manufacturer must enter into both a Medicaid Drug Rebate Agreement and a Pharmaceutical Pricing Agreement (PPA) that covers the Covered Outpatient Drug. The Medicaid statute includes a limiting provision that excludes from the definition of "Covered Outpatient Drug" any drug, biological product, or insulin that is "provided as part of, or incident to and in the same setting as" certain specified services and paid for by Medicaid as part of payment for those services and not as direct reimbursement for the drug.

D. Disproportionate Share Hospital (DSH): A type of 340B covered entity that receives adjustment payments to provide additional help to those hospitals that serve a significantly disproportionate number of low-income patients. The primary method of qualification is based on the sum of the percentage of Medicare inpatient days and the percentage of total patient days attributable to patients eligible for Medicaid but not eligible for Medicare Part A. Among other requirements, DSHs must have a DSH Adjustment Percent >11.75% in order to be 340B eligible. VCMC qualified for the 340B Drug Pricing Program as a DSH covered entity.

E. Duplicate Discount: When a manufacturer gives both an up-front 340B discount to a Covered Entity at the time of purchase and a post-purchase discount to a state Medicaid agency after Medicaid pays the Covered Entity for the drug and submits a rebate request to the manufacturer under the Medicaid rebate program. Both the 340B and Medicaid rebate laws protect manufacturers from duplicate discounts. A Covered Entity must comply with the prohibition against duplicate discounts by: (1) billing Medicaid at no more than actual acquisition cost plus a dispensing fee; OR (2) "carving out" Medicaid drugs from its 340B program.

F. Eligible Patient Definition: An individual is a "patient" of a covered entity only if:

    1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
    2. The individual receives health care services from a health care professional who is either employed by the covered entity or under contractual or other arrangement such that responsibility for the care provided remains with the covered entity.

G. Parent Site: The main facility of the Covered Entity that becomes eligible to use 340B drugs by virtue of the entity's enrollment in the 340B Program. In contrast, outpatient clinics that have a different street address than the entity's main facility, which are commonly called "child sites," must be separately registered with OPA before they can begin using 340B drugs.

H. Mixed-use setting: A hospital area that serves a mixed patient type of both inpatients and outpatients. Often these are facilities such as surgery centers, cardiac catheter labs, infusion centers, and emergency departments.

    1. Inpatient Status: VCMC determines that patients have an inpatient status if the patient's admit type is one of the following in the electronic health record:
        a. Inpatient
        b. Inpatient Psych
        c. Trauma Inpatient
    2. Outpatient Status: VCMC determines that patients have an outpatient status if the patient's admit type is one of the following in the electronic health record:

a. Clinic
b. Day Surgery
c. ED Telehealth
d. Emergency
e. Observation
f. Outpatient
g. Outpatient Multiday
h. Outpatient in Bed
i. Recurring
j. Telehealth
k. Trauma Emergency
l. Trauma Observation

V. Covered Entity Eligibility

A. **Policy**

1. The CE must meet the requirements of 42 USC §256b(a)(4)(L), *(See Reference II)*, to be eligible for enrollment in, and the purchase of drugs through, the 340B Program.

B. **Purpose**

1. To ensure the CE's eligibility to participate in the 340B Program.

C. **Covered Entity**

1. The CE has locations where it would be appropriate to dispense, administer or prescribe 340B drugs to eligible patients. (*See Reference III*).
2. These locations include the following:
    a. Within the four walls of the parent site; and
    b. Within off-site outpatient locations that are fully integrated in the hospital, reimbursable on the most recently filed Medicare cost report, and registered on 340B OPAIS.

D. **Eligibility Requirements**

1. The CE is owned or operated by a unit of state or local government.
2. The CE has a disproportionate share adjustment percentage greater than 11.75%.
3. The CE does not obtain covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement for eligible locations, in accordance with GPO Policy Release. (*See Reference IV*)
    a. The CE may define non-covered outpatient drugs: Non-covered outpatient drugs may be purchased on GPO or non-340B contracts.
    b. The CE will maintain a list of all non-covered outpatient drugs. See

Attachment A: List of Non-Covered Outpatient Drugs.

c. CE does not dispense or administer covered outpatient drugs to individuals not meeting the 340B patient definition.

d. If a pharmaceutical manufacturer refuses to sell enough of a 340B priced drug to serve all of the CE's 340B eligible patients, the rest of the quantity needed will be purchased on a non-GPO account. The CE will notify OPA in writing that the manufacturer will not sell the drug at a 340B price. (*See Reference V*)

e. The GPO exclusion does not preclude CE from purchasing covered outpatient drugs through the Prime Vendor Program (PVP). OPA does not consider purchases made through PVP to be a violation of the GPO exclusion

4. The CE maintains a complete roster of 340B, GPO, and non-340B/non-GPO vendor accounts, including segregated GPO accounts for the primary care network.
5. The CE has tracking systems and safeguards in place to prevent GPO violations. *(See Section "340B Program Compliance, Monitoring and Reporting")*
6. The CE ensures that OPAIS is complete, accurate, and correct for all 340B eligible locations including the parent entity, off-site locations, and contract pharmacies. (*See Reference III*)
    a. All off-site locations that use 340B drugs are registered on 340B OPAIS.
    b. All main addresses, billing and shipping addresses, the authorizing official, and the primary contact information are correct and up to date.
    c. The CE regularly reviews its 340B OPAIS records quarterly.
    d. The CE will inform HRSA immediately of any changes to its information by updating the 340B OPAIS and or Medicaid Exclusion File.
    e. The CE will notify HRSA immediately of any changes to The CE's Medicare disproportionate share adjustment percentage resulting in a disproportionate share percentage less than 11.75%.
7. The CE annually recertifies information on 340B OPAIS.

E. **GPO Prohibition Exclusion**

1. The CE has identified exclusions to the covered outpatient drug definition.
    a. Drugs that are part of or incident to the service, these drugs are given in the same setting as the service provided, and they are paid (bundled) as part of the service rendered.
    b. Items that do not meet the covered outpatient drug definition are listed in *Attachment A: List of Non-Covered Outpatient Drugs*.
2. An offsite outpatient clinic that is not registered as a child site may purchase drugs using a GPO account as long as the purchase is made on a wholesaler account that is separate from the 340B Program accounts.

VI. 340B Program Enrollment Recertification

A. **Policy**

1. The CE shall maintain the accuracy of 340B OPAIS and be actively registered to participate in the 340B Program.

B. **Purpose**

1. To ensure the CE is appropriately registered and maintains accurate records on 340B OPAIS.
    a. Registration dates:
        i. January 1–January 15 for an effective start date of April 1
        ii. April 1–April 15 for an effective start date of July 1
        iii. July 1–July 15 for an effective start date of October 1
        iv. October 1–October 15 for an effective start date of January 1
    b. 340B Contract Pharmacy Guidelines (https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf).

C. **Enrollment**

1. The CE is eligible to participate in the 340B Program (See Section "*Covered Entity Eligibility*")
2. The CE identifies upcoming registration dates and deadlines.
3. The CE identifies authorizing official and primary contact.
4. The CE has available the required documents:
    a. Medicare cost report:
        i. Worksheet S, S-2, S-3
        ii. Worksheet E, part A, and
        iii. For outpatient facilities: Worksheet C, Worksheet A, and Working trial balance
    b. Certification of ownership status
5. The CE completes registration on 340B OPAIS (https://340bopais.hrsa.gov/).

D. **Recertification Procedure**

1. The CE shall recertify information listed on 340B OPAIS annually.
2. The CE shall verify and confirm cost centers listed on 340B a crosswalk and assure that it matches with the most recently filed Medicare Cost Report.
3. 340B Crosswalk is compared to the OPAIS database to ensure all contact and address information is listed accurately.
4. Any changes or corrections to clinic / contract pharmacy information can be completed during recertification period. However, new clinics cannot be registered at

this time.

5. Ensure there are no clinic termination(s) to be completed.
6. NPI numbers, Primary Contact and Authorizing Official's (AO) contact information is verified and confirmed.
7. Review and verify contract pharmacy name, store #, address listed on the OPA database match the covered entity's contract pharmacy agreement.
8. Ensure all contract pharmacy agreements are current and match the copy of the Third Party Administrators.
    a. Authorizing official completes the annual recertification by following the directions in the recertification email sent from HRSA to the CE prior to the stated deadline.
9. The CE submits specific recertification questions to 340b.recertification@hrsa.gov.

E. **New Outpatient Facilities**

1. The CE will determine that a new outpatient service or facility is eligible to participate in the 340B Program.
    a. The criteria used include that the outpatient service must be fully integrated into hospital, appear as a reimbursable service or clinic on the most recently filed cost report, have outpatient drug use, and have patients who meet the 340B patient definition.
2. The CE's authorizing official completes the online registration process during the registration window.
    a. Submit any updated Medicare cost report information, as required by HRSA: http://www.hrsa.gov/opa/eligibilityandregistration/hospitals/disproportionatesharehospitals/index.html

F. **New Contract Pharmacies**

1. The CE has a signed contract pharmacy services agreement.
    a. The CE's Contracts Division reviews the contract and verifies that all federal, state and local requirements have been met.
2. The CE has contract pharmacy oversight and monitoring policy and procedure developed, approved, and implemented.
3. The CE's authorizing official or designee completes the online registration during one of four registration windows.
    a. Within 15 days from the date of the online registration, the authorizing official certifies online that the contract pharmacy registration request was completed.
4. The CE begins using the contract pharmacy services arrangement only on or after the effective date shown on 340B OPAIS.

G. **Changes to Information in 340B OPAIS**

1. Ventura County Medical Center notifies HRSA immediately of any changes to Medicare disproportionate share adjustment percentage resulting in a disproportionate share percentage less than 11.75%.
    a. Ventura County Medical Center will stop the purchase of 340B drugs as soon as Ventura County Medical Center files its cost report with a disproportionate share percentage is less than 11.75%.
    b. Authorizing official will complete the online change request as soon as a change in eligibility is identified.
2. Ventura County Medical Center's registered and eligible clinics that move to new locations can continue with 340B eligibility if only a 'Change Request Form' is submitted with new address. Once approved by Office of Pharmacy Affairs, clinic can continue to be 340B eligible.
3. Clinic expansions and cost centers that are eligible and listed on the current Medicare cost report are registered during the next registration period by the Authorizing Official. 340B drugs shall not be used at the expansion location until clinic is registered and approved by OPA.

VII. 340B Program Roles, Responsibilities and Education

A. **Policy**
    1. The CE participating in the 340B Program must ensure program integrity and compliance with 340B Program requirements. 340B key stakeholders will participate in education and training as needed to ensure that these key stakeholders have the knowledge to guarantee compliant 340B operations.

B. **Purpose**
    1. To identify The CE's key stakeholders and determine their roles, responsibilities and education in maintaining 340B Program integrity and compliance.

C. **Committee Oversight**
    1. The CE will maintain a roster of all key stakeholder's roles, responsibilities and education within the CE's 340B Program.
    2. The CE's Compliance Committee is responsible for the oversight of the 340B Program.
    3. The CE's Compliance Committee:
        a. Meets on a quarterly basis with all key stake holders.
        b. The CE maintains readily retrievable meeting agendas and minutes.
        c. Reviews 340B rules, regulations and guidelines to ensure consistent policies procedures and oversight throughout the entity.
        d. Identifies activities necessary to conduct comprehensive reviews of 340B compliance.

i. Ensure that the organization meets compliance requirements of program eligibility, patient definition, 340B drug diversion and duplicate discounts via ongoing multidisciplinary teamwork.

ii. Integrate departments such as information technology, legal, pharmacy, compliance, and patient financial services to develop standard processes for contract/data review to ensure program compliance.

e. Oversees the review process of compliance activities and audits, as well as taking corrective actions based on findings.

f. The Compliance Committee assesses if the results of audits are indicative of a material breach. (*See Section "340B Material Breach and Noncompliance Disclosure"*)

g. Reviews and approves work group recommendations (process changes, self-monitoring outcomes and resolutions).

4. HRSA Audits:

a. Upon notification of a HRSA audit, all key stakeholders (Pharmacy, Compliance, Finance, Purchasing, Contract Pharmacies, etc.) will be informed of the audit.

b. The CE will comply with any and all requests for information from HRSA during the pre-audit period.

c. During an on-site HRSA audit, all key stakeholders will be involved, and the CE will fully cooperate with the auditor throughout the audit process.

5. Manufacturer Audits

a. The CE will respond to all manufacturer requests for information related to 340B purchases in a timely manner.

b. Upon notification of a manufacturer audit, all key stakeholders will be informed of the audit.

c. The CE will respond to all requests for information from a manufacturer in a timely manner

d. During the on-site manufacturer audit, all key stakeholders will be involved as necessary, and the CE will fully cooperate with the auditor throughout the audit process.

D. **Education and Stakeholder Certification**

1. Education

a. The CE determines any educational requirements for each 340B Program role.

b. Education and training may consist of any of the following:

i. Initial basic training upon hire

ii. On-demand modules on the Apexus website

iii. 340B University
iv. 340B conferences
v. Complete Advance 340B Operations Certification Exam
vi. Participate in HRSA and 340B Health webinars
vii. Participate in statewide 340B workgroup calls
viii. Other 340B related activities

2. The CE provides educational updates and training, as needed.

VIII. Patient Eligibility/Definition

A. **Policy**

1. Per the Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 340B drugs are to be provided only to individuals eligible to receive 340B drugs from covered entities. (*Reference VI*)

B. **Purpose**

1. The CE ensures that 340B drugs are dispensed, administered, and prescribed only to eligible patients.

C. **Patient Eligibility**

1. An individual is a patient CE is 340B eligible only if:
    a. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
    b. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity.
2. The CE recognizes observation patients, registered outpatients, hospital discharge patients and/or any status prior to admission from an eligible location may be eligible to receive 340B Covered Outpatient Drugs.
3. The CE often provides specialty care subsequent to a referral. The prescriptions written for conditions treated by the CE's specialty providers in the outpatient clinics are eligible for 340B prices at the CE's contracted pharmacies with the patient outcomes and follow-up remaining the responsibility of our contracted providers.
4. CE staff are eligible as patients ONLY when they meet all the same criteria required under the patient definition.

IX. 340B Program Compliance, Monitoring and Reporting

A. **Policy**

1. The CE is required to maintain auditable records demonstrating compliance with the 340B Program requirements.

B. **Purpose**

1. To provide an internal monitoring program to ensure comprehensive compliance with the 340B Program.

C. **Diversion and Duplicate Discounts**

1. The CE complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulation, public notices, and guidelines including, but not limited to, selling, giving, or otherwise transferring of covered outpatient drugs purchased under the program to anyone other than a "patient of the covered entity." (See Section "*Patient Eligibility/Definition*".)
2. The CE maintains compliance with 42 USC §256b(a)(5)(A)(i) which prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts.
    a. The CE will append the appropriate modifiers on all claims. Physician Administered Drug claims require a "UD" modifier. The "UD" modifier informs California Department of Health Care Services (DHCS) that a 340B purchased drug was used for the claim. The CE maintains and reviews Medicaid provider numbers and NPI numbers quarterly and assures that they are properly reflected in the Medicaid Exclusion File (MEF).

D. **Medicaid Carve-In**

1. The CE dispenses or administers 340B purchased drugs to Medicaid patients AND subsequently bills Medicaid for those 340B drugs (carve-in) for the mixed-use setting.
2. The CE bills Medicaid per state Medicaid reimbursement requirements. This is audited monthly using internal audits.
3. The CE reviews its 340B OPAIS Medicaid Exclusion File (MEF) records quarterly. Any changes in our MEF information shall be communicated to HRSA immediately by updating 340B OPAIS before the 15th of the month prior to the quarter when the change would take effect.
4. Medicaid reimburses the CE for 340B drugs per state policy and does not seek rebates on drug claims submitted by the CE.
5. All Medicaid prescriptions are excluded from the CE's contract pharmacies. This includes both fee-for-service (FFS) and geographic managed care (GMC) plans.
6. Covered outpatient drugs are only billed to Medicaid for the state of California.

E. **Program Assurance**

1. The designation of all outpatient clinics (340b-eligible or non-340B) are identified when clinics are first created. These clinics are reviewed thereafter on a monthly basis and audited quarterly.
2. The CE voluntarily contracts with an independent consultant to conduct an annual external audit of our program that has been approved by the Compliance Committee.
3. The CE ensures compliance with the GPO Prohibition.
    a. Segregated purchasing accounts are used for non-registered sites
    b. Orders for mixed use are placed through a split billing platform
    c. All orders for clean 340B only sites are placed on separate accounts
4. To demonstrate the ongoing responsibility for health care, the CE shall provide health care to the individual at a registered site of the CE within 15 months of a written prescription.
5. The CE determines outpatient locations and status that meet the following criteria:
    a. Registered hospital-based clinics that provide care to outpatients.
    b. Emergency departments that provide outpatient emergency and primary care to the insured, uninsured and underinsured.
    c. Non-admit patients seen in mixed-use areas (e.g., GI lab, OR, PACU and radiology).
    d. Discharge patients.
    e. Authorized Observation non-admit patients carrying the appropriate outpatient classification. or
    f. Any patient class prior to admission orders being written
6. The CE determines provider eligibility as either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the CE.
7. At no time are prescriptions rewritten solely for the purpose of patient eligibility for 340B prescriptions.
8. Patients treated in the Emergency Department may remain in the Emergency Department for extended periods of time, e.g., awaiting placement to a proper unit or facility, observation status, etc. Once inpatient orders are written for a patient in the Emergency Department, the patient's status shall change to inpatient and they will no longer be eligible to receive 340B drugs.

F. **Program Self Audits & Maintenance**

1. The CE routinely conducts internal monthly reviews of each registered contract pharmacy, mixed use areas and clinics for compliance with 340B Program requirements.
2. The following elements will be reviewed when conducting self-audits:
    a. The prescription shall be written from a site of care that is registered on

340B OPAIS and included as a reimbursed outpatient service cost center on the most recently filed Medicare cost report; and

b. The patient shall have had an eligible encounter in the last 15 months; and

c. The patient shall meet the eligibility defined by HRSA and DHHS; and

d. The provider shall be eligible at the time the prescription is written

3. The CE reviews 340B OPAIS quarterly to ensure the accuracy of the information for the parent site, off-site locations, and contract pharmacies.
4. The CE reviews the Medicaid Exclusion File (MEF) quarterly to ensure the accuracy of the information for the parent site, off-site locations, and contract pharmacies.
    a. Twenty randomly selected 340B medications dispensed to Medicaid patients are audited every quarter.
        i. The CE shall confirm that the Medicaid number and/or National Provider Index numbers used to bill Medicaid on the Medicaid Exclusion File are accurate.
5. The CE reconciles purchasing records and dispensing records to ensure that covered outpatient drugs purchased through the 340B Program are dispensed or administered only to patients eligible to receive 340B drugs and that any variances are not the result of diversion.
6. The CE shall maintain its split billing software program by conducing the following:
    a. Weekly review of unknown items.
    b. Quarterly audit of multipliers.
7. The CE reconciles dispensing records to patients' health care records to ensure that all medications dispensed were provided to patients eligible to receive 340B drugs.
    a. Thirty randomly selected dispensed 340B drugs are audited every quarter to confirm that the patients receiving 340B medications were qualified outpatients.
8. The CE will randomly select records from a drug utilization file and perform the audit monthly for all contract pharmacies.
9. The CE reconciles dispensing records and Medicaid billing practices on a monthly basis, to demonstrate compliance with Medicaid billing and duplicate discount.
10. Provider listing is retrieved from reporting on a monthly basis, reviewed for accuracy and is shared with a third party administrator for outpatient contract pharmacy operations.
11. All audit results shall be presented to the Compliance Committee every quarter.

G. **Record Keeping and Data Management**

1. The CE maintains records of 340B-related transactions for a minimum of 7 years in a readily retrievable and auditable format.
    a. This will be stored in a network location and kept up to date on a monthly basis for internal and external audit purposes

2. The CE reviews and maintains data being sent to all third parties as part of its audit and maintenance process
3. The CE maintains complete and auditable records of individual's health care.
4. The CE has an electronic medical records shared between hospital and clinics. No undocumented care is provided under the CE.

X. Inventory Management

A. **Policy**

1. The CE must be able to track and account for all 340B drugs to ensure the prevention of diversion.

B. **Purpose**

1. Ensure the proper procurement and inventory management of 340B drugs.

C. **Background**

1. 340B inventory is procured and managed in the following settings:
    a. In-house pharmacies
    b. Clinic site administration
    c. Contract pharmacies
2. The CE uses both of the following inventory methods:
    a. Physical 340B-only inventory
    b. Virtual mixed-use inventory

D. **Procedure for Purchasing and Logistics**

1. The CE has registered 340B eligible hospital based clinics.
    a. Clinics eligible for 340B pricing are listed on the Health Resources and Services Administration website. (*See Reference III*)
    b. Clinics eligible for 340B pricing shall receive medication using 340B eligible accounts dedicated to 340B-eligible clinics.
    c. Requisitions for 340B pharmaceuticals are submitted in the electronic health record by clinic staff.
    d. When the 340B order arrives at the hospital pharmacy, they are received, quantified and separated by clinic and delivered to the 340B eligible clinic or picked up by the 340B eligible clinic.
    e. Automated dispensing machines located in 340B eligible clinics are refilled with medications that are ordered through 340B accounts dedicated to 340B-eligible clinics.
2. The CE has outpatient GPO eligible clinics.
    a. Outpatient clinics eligible for GPO pricing are located at a different physical address than the parent site and are not registered in 340B

OPAIS.

b. Outpatient clinics eligible for GPO pricing shall receive medication using GPO accounts dedicated to outpatient clinics eligible for GPO pricing.

c. Requisitions for outpatient GPO purchases are are submitted in the electronic health record by clinic staff.

d. When the GPO order arrives at the hospital pharmacy, they are received, quantified and separated by clinic and delivered to the GPO eligible clinic or poicked up by the GPO eligible clinic.

3. Mixed use settings

   a. For the purposes of this policy, all areas within the four walls of Ventura County Medical Center (300 Hillmont Avenue; Ventura, CA 93003) and Santa Paula Hospital (825 North 10th Street; Santa Paula, CA 93060) are mixed use settings.

   b. Designated pharmacy purchasers will ensure all orders are placed appropriately through applicable systems.

   c. Orders for mixed use areas are split to the appropriate account (340B, GPO, non-340B/non-GPO) based on utilization data using an 11-digit NDC match.

   d. All direct non wholesaler vendor orders will be created using split billing software. *See policy PH.17 Direct Ordering Procedure*.

4. Transfers

   a. Transferring between inventories should only be done in the event of an immediate patient need. (e.g. emergency, delay of therapy, and pending discharge.)

   b. At no time should inventory be transferred for convenience or re-stocking purposes.

   c. All transfers should be documented on a Loan-Borrow form, which can be found as Attachment A of policy *PH.16 Pharmaceutical Borrowing and Loaning*.

   d. In the event of inventory transfer, a pharmacist shall sign the form to verify it is needed for immediate patient need.

   e. Inventory transferred from the mixed use areas are replenished at WAC.

   f. Inventory transferred from 340B only shall only be approved by the Director of Pharmacy or designee. Transfers from 340B only areas shall be replaced at WAC or adjusted into accumulation by the 340B team to reconcile the transfer.

5. Returns

   a. Returns shall be processed by inventory management staff and are returned for credit under their corresponding account in a timely manner.

6. Wasted 340B Medication
    a. The CE's mixed use areas use a virtual inventory system and does not define any inventory as 340b for the purpose of waste.
    b. Purchases made in clean 340b only areas have their inventory wasted on site in appropriately labeled medication waste bins without credit..

XI. Contract Pharmacy Operations

A. **Policy**

1. Covered entities are required to provide oversight of their contract pharmacy arrangements to ensure ongoing compliance. The covered entity has full accountability for compliance with all requirements to ensure eligibility and to prevent diversion and duplicate discounts. Auditable records shall be maintained to demonstrate compliance with those requirements.

B. **Purpose**

1. To ensure that the CE remains responsible for all 340B drugs used by its contract pharmacies in accordance with HRSA requirements and guidelines. (*See Reference VII*)

C. **Procedure**

1. The CE maintains regular contact with third party administrators (TPA) to ensure compliance with applicable federal and state policy and legal requirements. This includes at minimum monthly calls with each TPA.
2. The CE contracts with TPAs to facilitate both the design and implementation of the 340B contract pharmacy program.
3. The CE has a written contract in place for each contract pharmacy location that meets HRSA requirements. These contracts follow the suggested 12 essential elements of contract pharmacy agreements. (*See Reference VII*)
    a. Copies of the written contracts for each contract pharmacy location shall be maintained in the Pharmacy Department and shall be made available to HRSA or impacted drug manufacturer upon request.
4. The CE registers each contract pharmacy location on the CE's 340B OPAIS prior to the use of 340B drugs at that site.
5. The CE must notify OPA of any changes to its contract pharmacy program, including when a contract pharmacy relationship has ended.
6. The contract pharmacy may provide other services to the CE or its patients.
7. The CE may not restrict patients to use a contract pharmacy; all patients may use the pharmacy of their choice.
8. Both parties will adhere to all applicable federal, state and local laws.
9. The CE uses a virtual replenishment model using an 11-digit-to-11-digit NDC match for its contract pharmacies.

10. 340B-eligible prescriptions are presented to contract pharmacies via e-prescribing, hard copy, fax and/or phone.
    a. Each prescription is verified by the TPA for patient, prescriber, and outpatient clinic eligibility via encounter data file provided daily and provider file provided monthly.
    b. Updates are may be made to these mechanisms by the CE at minimum monthly intervals or as needed sooner if need be.
11. Contract pharmacies may dispense prescriptions to 340B eligible patients using non-340B drugs.
12. The CE implements a bill-to, ship-to arrangement with the contract pharmacies.
    a. Each individual contract pharmacy orders 340B drugs based on 340B eligible use as determined by the TPA, from CE's contracted wholesalers.
        i. Orders are created by the TPAs or pharmacy and placed using their preferred ordering method.
    b. Invoices are billed and review on a bi-weekly basis to the CE.
13. Contract pharmacy receives shipments directly.
14. Contract pharmacy will verify quantity received with quantity ordered.
    a. Identifies inaccuracies.
    b. Resolves inaccuracies.
    c. Documents resolution of inaccuracies.
15. The CE receives and reviews the invoice for drugs shipped to its contract pharmacies for accuracy on a bi-weekly basis.
16. Contract pharmacies are included in the CE's internal-audit process.
17. Prescriptions that are found to be ineligible in the event of monthly audit shall be submitted to the TPA to process a reversal. These reversal requests are to be tracked to ensure approval of the pharmacy and completion. In the event that a prescription cannot be reversed, it will need to be tracked accordingly and directly with the manufacturer during the next accumulator review.

XII. Material Breach and Non-Compliance Disclosure

A. **Policy**

1. Covered entities are responsible for contacting HRSA as soon as reasonably possible if there is any material breach by the covered entity or any instance of noncompliance with any of the 340B Program requirements. (*See Reference VIII*)

B. **Purpose**

1. To define the CE's material breach of 340B compliance and self-disclosure process.

C. **Non-Compliance**

1. The CE's established threshold of what constitutes a material breach of 340B Program compliance is any error that includes 15% of our total 340B purchases. Any errors less than that shall be reviewed by the Compliance Committee to determine materiality. Any instance of non-compliance that the Compliance Committee decides to consider material shall be reported to HRSA.
    a. The CE ensures that identification of any threshold variations occurs among all its 340B settings, including contract pharmacies during monthly audits.
    b. Such violations require self-disclosure. Violations identified through internal self-audits, independent external audits, or otherwise that exceed this threshold, and that remain non-correctable within a 6 month period from the time of review, shall be immediately reported to HRSA.
2. The CE assesses materiality.
    a. The CE maintains records of materiality assessments.

D. **Disclosure**

1. The CE reports identified material breach immediately to HRSA and applicable manufacturers along with a corrective action plan to address the violation.
    a. The CE will maintain records of material breach violations, including manufacturer resolution correspondence.

References

I. Section 340B of the Public Health Service Act (1992) http://www.hrsa.gov/opa/programrequirements/phsactsection340b.pdf

II. Title 42 USC 256b(a)(5)(A)(i) https://www.govinfo.gov/content/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapII-partD-subpartvii-sec256b.pdf

III. HRSA OPAIS Database https://340bopais.hrsa.gov/

IV. 340B Policy Releases https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf

V. GPO prohibition entity purchase via GPO https://www.340bpvp.com/content/contentSearch.html?category=content&Ntt=1242&main-submit.

VI. Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf

VII. Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/contractpharmacyservices082396.pdf

VIII. HRSA Entity Self-Disclosures https://www.hrsa.gov/opa/self-disclosures/self-disclosure.html

All Revision Dates

7/23/2024, 1/30/2024, 10/16/2023, 5/18/2020, 5/31/2017, 4/1/2016, 11/1/2015, 7/1/2015, 4/1/2015, 1/1/2015

Attachments

Attachment A: List of Non-Covered Outpatient Drugs

Approval Signatures

Step Description	Approver	Date
Authorizing Official	John Fankhauser, MD: Chief Executive Officer, VCMC & SPH	7/23/2024
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/23/2024
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	7/22/2024
Pharmacy Services	Beatriz Cachu: 340B Program Administrator	7/18/2024

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Last Revised	7/27/2024		
Next Review	7/27/2026		

L.02 Noise Exposure in the Laboratory

POLICY:

It is the policy of the Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) Laboratory to provide protection against the effects of noise exposure when sound levels are excessive. Noise levels are considered excessive when people must speak loudly or shout in order to be heard.

In the event that Laboratory staff must speak loudly or shout in order to be heard, the Laboratory will investigate the volume of noise and take appropriate steps in order to protect staff's hearing.

PROCEDURE:

1. Noise levels in each physical area of the Laboratory will be audibly observed on a routine basis by the Laboratory Safety Officer or designee.
    a. Audible observations of noise levels will be documented for each section of the Laboratory to include: Chemistry, Hematology, Blood Bank, Microbiology, Clerical and Central processing, Histology and Cytology.
    b. The determination if staff must talk loudly or must shout in order to be heard will be made and documented.
    c. Observational guideline: If noise levels exceed 85 decibels, people have to shout to be heard.
2. Noise levels in each physical area (see 1.a.) of the Laboratory will be observed audibly whenever an employee brings to the attention of Laboratory management that noise levels interfere with their work functions.
3. Noise levels in each physical area (see 1.a.) will be observed audibly whenever changes in major processes or instrumentation occur.

4. If noise is considered excessive, the Laboratory will work with the Facility Maintenance Department to measure existing noise levels, develop and implement a noise reduction plan, and re-measure noise levels to assess the effectiveness of the noise reduction plan.
    a. An 8-hour time-weighed average sound level of 85 decibels or greater is considered excessive.
5. If unable to reduce the noise level staff will be provided hearing protection for temporary relief.
6. Documentation will be incorporated into the Laboratory annual safety review.

REFERENCES:

College of American Pathologist Laboratory General Checklist GEN.77300, August 24, 2023.
VCMC Laboratory Safety Manual

All Revision Dates

7/27/2024, 11/1/2016

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	7/26/2024
Laboratory Services Department	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services	6/24/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	6/22/2024

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Last Revised	7/27/2024		
Next Review	7/27/2026		

L.06 Terms of Accreditation by the College of American Pathologists

POLICY:

A Laboratory that is accredited by the College of American Pathologists (CAP) must adhere to the Terms of Use for CAP Certification of Accreditation.

PROCEDURE:

The laboratories at Ventura County Medical Center and Santa Paula Hospital are accredited by the College of American Pathologists (CAP) and adhere to the following Terms of Accreditation:

- The Laboratory shall cooperate with any College of American Pathologists (CAP) investigation of inspection. The laboratory promptly notifies CAP, if the laboratory at Ventura County Medical Center or Santa Paula Hospital becomes the subject of:
    - An investigation by a government entity (including national, federal, state (or provicial), local, or foreign) or by another accreditation organization
    - A validation inspection
    - Adverse media attention related to laboratory performance
- The Laboratory promptly notifies CAP:
    - If the laboratory discovers laboratory personnel actions that appear to violate national, federal, state (or provincial), or local laws that regulate laboratories
    - Of any changes in laboratory activity menu prior to beginning that testing or implementing scope of service/analytic method changes, or the laboratory permanently or temporarily discontinues some or all testing

    - Of any changes in directorship, location, ownership, name, insolvency, or bankruptcy in the 30 days prior to the change. Laboratories subject to the US CLIA regulations must also notify the CMS of pertinent changes

- The Laboratory will provide an inspection team comparable in size and scope to that required for its own inspection if requested by the region and/or state commissioner at least once during the two- year accreditation period.
- The Laboratory is subject to the US CLIA regulations will:
    - On a reasonable basis, have the Laboratory's annual PT results available upon request of any person
    - Allow the CMS or its agent to perform a validation or complaint inspection at any time during the Laboratory's hours of operations and permit the CMS to monitor the correction of any deficiencies found during such an inspection
- Adherence to the Certificate Mark Terms of Use/Agreement for the CAP Certification Mark and Design if the laboratory is/or will use the CAP Certification Mark for accreditation. The agreement can be downloaded and printed from www.cap.org.

All Revision Dates

7/27/2024, 10/7/2022, 11/1/2016, 8/1/2012

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	7/26/2024
Laboratory Services Department	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services	6/24/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	6/22/2024

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Next Review	7/27/2026		

L.07 Ensuring Compliance with Laboratory Laws and Regulations

POLICY

It is the policy of the Ventura County Medical Center/Santa Paula Hospital Laboratory to ensure that all policies and procedures are compliant with state and local laws and regulations and to ensure that the Laboratory meets the CAP terms of accreditation.

PROCEDURE

NATIONAL/FEDERAL/STATE/LOCAL REGULATIONS

1. Updates to local laws, coding and regulations are received via emails, from journals, articles, hospital management etc. All Laboratory policies and procedures are reviewed and changes made when indicated, by the appropriate staff. Updates may include, but are not limited to the following areas:
    a. Shipping infectious or diagnostic materials
    b. Reporting infectious disease testing results
    c. Handling radioactive materials
    d. Personnel qualifications
    e. Retention of specimens or records
    f. Hazardous waste disposal
    g. Fire codes
    h. Medical examiner or coroner jurisdiction

i. Legal testing
j. Acceptance of specimens or orders from authorized personnel
k. Patient consent for testing
l. Confidentiality of test results
m. Tissue handling

2. Staff, supervisors and Pathologists keep abreast of regulatory updates via e-mails, internet review, journals, attendance at seminars, and participation on medical center committees. Pertinent information is shared with staff and appropriate compliance is maintained.

REFERENCE

GEN.20374 Laboratory General Checklist, College of American Pathologists, August 24, 2023.

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7/27/2024, 11/1/2016

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	7/26/2024
Laboratory Services Department	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services	6/24/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	6/22/2024

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Owner	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services
Policy Area	Laboratory Services

L.39 Collection, Labeling and Transport of Laboratory Samples

POLICY

The pre-analytical processes for Laboratory sample collection must be strictly adhered to. Correct patient identification, sample collection, processing and transport all are important parts of reporting accurate test results. The use of appropriate Transfer/Packing lists is required to avoid delays in sample testing.

MATERIALS AND EQUIPMENT

Test requisition

Labels: Accession Labels

Specimen Collection Materials: specimen collection containers, evacuated specimen collection tubes, syringes, needles, Vacutainer holders, tourniquet, adhesive tape, alcohol pads, gauze, blood transfer device

Personal protective equipment (PPE): gloves, laboratory coat, face mask

Blood bank armband

Ball point pen

Permanent marker

Biohazard ziplock bags

Sharps container

Calibrated centrifuge

Tube racks

PROCEDURE

PATIENT IDENTIFICATION

Identification of the patient is crucial. The phlebotomist/provider must ensure that the blood specimen is being drawn or sample collected is from the individual designated on the request form or label. Two (2) patient identifiers are required for patient identification.

Ask for *Full Name* and *Date of Birth.* (Never greet a patient by name).Verify with laboratory labels. Always check the name on the first and last label to make sure the label from another patient is not attached. Do not proceed if there are any discrepancies on the labels.

BLOOD SPECIMEN COLLECTION TECHNIQUES

VENIPUNCTURE/VACUTAINER

1. Wash your hands. Don appropriate gloves.
2. Identify the patient using two (2) patient identifiers.
3. Introduce yourself.
4. Reassure the patient. The phlebotomist must gain the patient's confidence and assure the patient that, although the venipuncture might be slightly painful, it won't last long. Never tell a patient, "This won't hurt."
5. Check tests ordered. If any test requires a fasting state, verify that the patient is fasting.
6. Select appropriate tubes and equipment needed for tests. Check Expiration Date. **DO NOT USE EXPIRED TUBES.**
7. Prepare Portex Vacutainer Holder: Remove cap from the rubber-stopper end or a Greiner Vacquette Safety needle. Thread needle into holder and tighten firmly.
    a. Place first collection tube into holder, carefully pushing tube forward until needle touches stopper.
8. Position patient. The arm should be supported, slightly downward and should not be bent at elbow.
9. Apply tourniquet. The tourniquet should stop blood flow in vein for *less than a minute* before the blood is drawn. A longer application can cause hemoconcentration. If necessary, release the tourniquet and reapply.
10. Have patient close and open hand, not pumping vigorously.
11. Select venipuncture site.
12. Clean area with appropriate antiseptic solution. Allow skin to dry to prevent hemolysis of the specimen and to prevent patient from having a burning sensation when venipuncture is performed. DO NOT touch vein site after cleaning it.
13. Draw skin tight about 1-2 inches below venipuncture site to "hold" vein in place.
14. With needle bevel facing up, line up needle with vein. Penetrate skin and enter vein at an angle less than 45 degrees. The needle should enter arm quickly and smoothly (without jabbing) to avoid unnecessary pain.

15. Holding flange of needle holder, push first tube forward until back end of needle punctures stopper.
16. Allow tube to fill, remove from holder. The needle's shut-off valve will stop blood flow until next tube is inserted. Insert next tube. Gently invert each tube after filling.
17. As last tube is filling, release tourniquet. After tube is filled, remove from holder.
18. Remove needle gently and smoothly while activating the needle safety device by snapping a plastic needle cover on the Vacutainer into place with one hand.
    a. Immediately apply & maintain pressure to puncture site with clean, dry gauze. Tell patient to keep pressure on site for two minutes.
19. If needed, immediately make and label slides for differential.
20. Label tubes with the printed label originally used to ID patient.
21. Check venipuncture site for any bleeding. Apply bandage to site. Tell patient to leave bandage on for at least 1 to 2 hours. Allow patient to leave.
22. Dispose of the needle still attached to disposable Vacutainer in 'Sharps' container with safety device activated.
23. Dispose of gauze in trash.
24. Place tubes in holding rack for delivery to appropriate Laboratory Department.
25. Remove gloves, and wash hands.

VENIPUNCTURE/SYRINGE

Follow basic procedure used with Vacutainers. Take note of the following considerations:

1. The rubber plunger may stick to the wall. To avoid problems, free stickiness before venipuncture, by moving plunger back and forth.
2. Once in vein, blood will fill the syringe as the plunger is pulled back. Pull back only as fast as blood will flow into syringe. Excessive pull is likely to collapse the vein or hemolyze the blood.
3. Activate needle safety device on the Kendall Monoject Magellan Safety needle by pushing the plastic sheath to cover the needle and remove needle from syringe, disposing of protected needle in the sharps container.
4. Using the blood transfer device on the syringe like a Vacutainer, transfer blood from syringe to the evacuated tubes required.
5. Dispose of syringe with blood transfer device attached in a biohazard container.

BLOOD SPECIMEN COLLECTION REQUIREMENTS

Coagulation Samples

Whole blood is collected in **Blue Top** vacutainer tubes containing 3.2% buffered sodium citrate anticoagulant. The tube MUST be filled to the indicated fill line. Inadequately filled tubes, clotted and/or, hemolyzed samples are not acceptable for analysis and will not be processed.

1. Specimen requirements:
    a. For the following coagulation samples to be tested at VCMC/SPH Laboratory (PTT,

Fibrinogen, and D-Dimer):

i. The patient MUST be drawn at VCMC or SPH Laboratory. Transported specimens received over 4 hours from time of collection will NOT be accepted.

b. For all specimens to be tested at VCMC/SPH Laboratory where **PT** testing is requested:

i. Transport specimens UNSPUN in the original unopened container at **room temperature** for testing within 24 hours from time of collection.

c. If any other coagulation test are requested (e.g. Thrombin time, Protein C, Factor V, Factor VIII, etc.) refer to the contracted reference laboratory's specimen storage and transport requirements for each individual test.

Testing will not be performed if coagulation specimens are received frozen (unless by prior arrangement), past stability limit, spun, and/or separated.

Hematology Samples

Blood for routine Hematology testing (CBC, CBCD, HGB, HCT, PLT, RETIC) is collected in a lavender top Vacutainer or microtainer (K2 EDTA) and mixed immediately upon collection. If RBC agglutinates are suspected, collect the sample in a pre-warmed lavender top tube and keep it warm while being transported to lab.

On rare occasions, when patients display an IN-VITRO reaction to EDTA in which platelet clumping occurs collect an additional sodium citrate blue top tube and **DO NOT SPIN**.

Refrigerate blood samples at 2°C to 8°C if analysis does not occur within 24 hours of phlebotomy.

Sample for performing **Sedimentation Rates:**

Collected using the lavender top tubes are stable for 4 hours after collection, or they can be stored at 2-8°C for up to 24 hours.

Urinalysis Samples

Urine for urinalysis and urine eosinophils is submitted in a sterile yellow top UA tube.

Urine for urinalysis with reflex to culture is submitted in a yellow top UA tube AND a gray top urine tube. Urine for culture only is submitted in a gray top urine tube.

A gray top urine tube MUST be submitted if a urine culture is ordered or needed for reflex. A gray top tube CANNOT be used for urinalysis testing. Similarly, a yellow top CANNOT be used for urine culture.

Urine Stability:

Urine submitted in a yellow top tube is stable for only one hour at room temperature. The stability is 24 hours after collection when refrigerated at 2-8° C.

Urine submitted in a gray top culture tube is stable for 48 hours after collection both at room temperature and refrigerated at 2-8° C.

Chemistry Samples

Recommended specimen types: serum and plasma (lithium heparin).

Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method. In the preparation of serum or plasma samples, avoid prolonged contact with separated red cells.

Follow the instructions provided with your specimen collection device for use and processing.

For Serum: Complete clot formation should take place before centrifugation. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection (this is accomplished by centrifugation of samples at 3700 RPM for ten minutes).

Serum and plasma specimens are stable for 8 hours at room temperature, 7 days at 2 – 8 °C and 6 months when frozen at -20 °C or colder. DO NOT freeze SST or green top tubes. Remove serum or plasma and place in an appropriately labeled sample tube with a leak proof cap. Avoid repeated freezing and thawing.

Blood Bank Samples

EDTA K2 pink top blood bank tube (7ml).

Fill tube completely. Sample should be centrifuged and refrigerated within six hours of collection.

Do not separate plasma from cells.

Microbiology Samples

All diagnostic information from the Microbiology Laboratory is contingent on the quality of the specimen received. Consequences of a poorly collected and/or poorly transported specimen may include failure to isolate the causative microorganism and recovery of contaminants or normal flora, which can lead to improper treatment of the patient. Often, direct specimen smears are used to determine the quality of the specimen, to provide rapid information for diagnosis and therapy, and to allow the physician to determine if additional, better-quality specimens need to be collected.

SPECIMEN COLLECTION

A. **Safety Considerations**

1. Follow standard precaution guidelines.
2. Laboratory workers should use appropriate PPE (personal protective equipment); i.e. gloves and lab coat or gown, when collecting or handling specimens. If splashing may occur, protective eyewear, face masks, and aprons may be needed.
3. Do not contaminate the external surface of the collection container and/or the accompanying paperwork.
4. Minimize direct handling of specimens in transit from the patient to the Laboratory. If there is little material in the syringe, a small amount of sterile non-bacteriostatic 0.85% saline or sterile broth should be drawn through the syringe and then transferred along with specimen into a sterile tube. Alternatively, and only if the specimen will be compromised by transferring it from a syringe, a small amount of 0.85% saline or broth

may be drawn into the syringe prior to removal of the needle before a protective cap is placed on the syringe. **Do Not Transport With Needle Attached.**

B. **General Guidelines for Proper Specimen Collection**

1. Before collecting the specimen, consider the risk to benefit ratio of the collection procedure to the patient.
2. Collect the specimen before administering antimicrobial agents.
3. Collect and place specimens in the appropriate transport container or sturdy, sterile screw cap, leak proof containers with lids that do not create aerosols when opened.
4. Collect the specimen with as little contamination from indigenous microbiota as possible to ensure that the sample will be representative of the infected site.
5. Use appropriate collection devices. Use sterile equipment and aseptic technique to collect specimens to prevent introduction of microorganisms during invasive procedures.
6. Clearly label the specimen container with the following:
    a. Patient's Full Name
    b. Medical Record Number
    c. The Source
    d. Date and Time of collection
    e. LIS ID/Username of the person collecting the sample.
7. Collect an adequate amount of specimen. Inadequate amounts of specimen may yield false negative results.
8. If certain organisms are suspected, please contact the Microbiology Department at 1-805-652-6046.
9. The primary specimen must clearly identify the site of origin, and as appropriate, the laterality of the specimen (right versus left). If more than one specimen container is submitted, each container must be labeled with the site of origin and laterality.

TRANSPORT TO THE LABORATORY

1. Follow the "DO NOT TUBE" list when sending specimens using the pneumatic tube system.
2. Specimens for culture should be processed as soon as possible after collection, preferably within 1 to 2 hours, and the correct transport medium used. If processing of urine samples will be delayed, they should be refrigerated or transported in gray top tube with preservative.
3. If delay in transport is anticipated, the appropriate transport method should be used. Dry swabs are unacceptable.
    a. BBL Culture Swab Plus with Amies transport medium may be used to support most aerobic and anaerobic bacteria.
    b. Enteric Plus medium may be used for stool culture transport. Fill only to line.
    c. Para-pak Modified (Cu) PVA and Formalin vials may be used for transport of specimens being analyzed for intestinal parasites
4. Prompt delivery to the lab (within 30 minutes) is critical for CSF, Sputum, and Stool for C.difficile testing.

BLOOD SPECIMEN LABELING REQUIREMENTS

I. **General Information**
Most Laboratory draws are generated by the computer/barcode labels used by the phlebotomists. However, when a nurse draws a specimen, "charting" labels are used until the computer/barcode labels are placed on the tube.
The specimen should only be drawn after identifying the patient according to the protocols in the procedure "Patient Interactions: Patient Identification" on pages 4.1-4.2 in the Specimen Collection Procedure Manual. . .

- Tubes should be labeled AFTER the specimen has been collected.
- Do not label an empty tube before drawing the patient.
- Complete labeling in the presence of the patient at the patient's bed/chair side.
- Do not re-label with computer labels.

The sample should be drawn from a fresh venipuncture site. If intravenous tubing is used, see procedure "*Intravenous Lines*" p. 6.22 in the Specimen Collection Procedure Manual

II. **Hematology, Chemistry, Immunology, Serology, Blood Bank and Sendouts.**

A. **The person that draws the blood should place the computer label(s) or charting label(s) on the tube at the patient bedside/chair side.**
The completed labels must include:

1. Patient's name: Last, first
2. Hospital/Medical Record Number
3. Collection date/time
4. Legible Cerner ID/Username of the phlebotomist or nurse that drew the blood. If a nurse drawing the specimen is accompanied by a phlebotomist, the Cerner ID/Username of both individuals should be on the label.

B. **Phlebotomists**

Attach a completed computer label(s) to the tube(s) at the bedside/chairside.

1. Place the label length wise on the tube with the left edge of the label near the top of the tube.
2. For the analyzers to read the barcode properly:
   a. The Chemistry barcode labels should be placed so that the top of the label is in the area of the colored strip on the tube.
   b. The Hematology barcode labels should be placed close to the bottom of the cap.
   c. For urine tests, body fluids, and sedimentation rates, place a small label on the specimen and send the barcode label with the specimen to the department.
   d. **Nurses**
   Attach a completed "charting" label with date, time and Cerner ID onto the tubes drawn.
3. **Blood Bank/ Crossmatch**

Patients receiving red blood cells, FFP, cryoprecipitate, and/or platelets must have a type and

screen ordered and be banded. The only Clinics currently collecting samples with product orders are the Oncology Clinic and Peds/Oncology Clinic. No other clinics will be collecting samples for blood bank products.

All Hematology Oncology patients, with orders for Type and Screen or Type and Crossmatch for the transfusion of blood products (red blood cells, platelets, plasma, cryoprecipitate), are currently drawn by the Laboratory phlebotomist during the week Monday through Thursday following the blood bank specimen collection protocol (BB 1.10/Phleb 5.5).
All Pediatric Oncology patients, with orders for Type and Screen or Type and Crossmatch for the transfusion of blood products (red blood cells, platelets, plasma, or cryoprecipitate), will be drawn by a Laboratory phlebotomist or the Clinic RN following the blood bank specimen collection protocol.

A. **Preparation of a Blood Bank Blood Recipient ID Wristband Label:**
Using a ***ball-point pen,*** write on the Blood Recipient ID Wristband hard enough so that the information will be transferred through to the part of the band which will be placed on the patient. The completed band **must** include the following:

1. **Patient's name**- last, first (include middle initial or full middle name as appears on the hospital wristband and the Laboratory requisition. All blood bank identification band labels must be identical with the hospital wristband and the Laboratory requisition.)
2. Medical Record Number
3. Collection date and time
4. Legible Cerner ID/Username of the phlebotomist or nurse that drew the blood. If a nurse drawing the specimen is accompanied by a phlebotomist, the Cerner ID/Username of both individuals should be on the label.

B. **Application of the Blood Bank Blood Recipient ID Wristband labels to the tubes:**

Labeling Procedure for Nursing and Phlebotomy:

1. Lift up white flap on blood bank band, and using a ball point pen, fill in the patient name, Medical Record Number, phlebotomist LIS ID, and the date and time on the draw tube label. Make sure that if the computer order has an initial to include it on the label.
2. Remove draw tube label with the patient information from the wristband (Right to Left) so the carbon copy of the written information remains on the wristband.
3. Peel away white liner from the clear cover flap. Press clear cover flap down firmly from left to right, on a flat surface several times.
4. Apply patient information label to the K2 EDTA BD vacutainer draw tube. Align the V-Notch for visibility and proper patient identification.
5. Separate draw tube tail from Bar Code Blood Band at the perforation. Then remove the liner on the back of the tail of labels and attach to the draw tube.
6. Apply Bar Code Blood Band to patient allowing one finger space between wrist and wristband closure. Close plastic snap, and cut off any excess band.
7. For increased length, attach white extension band to the Blood Bank Band. Size

band, close snap, and cut off any excess band.

8. The procedure for out-patients is the same because of the self- laminating shield.

Alternative Labeling Procedure for phlebotomists only:

1. Lift up self- laminating shield away from the patient information area on blood bank band. Place the Laboratory bar code label on the area that would be printed on. Place the other Laboratory bar code label on the K2 EDTA BD vacutainer draw tube.
2. Remove a red striped barcoded label from the tail of the blood bank band and place it on the K2 EDTA BD vacutainer draw tube.
3. The LIS ID for the phlebotomist, the date, and time should be written legibly on the label and the blood bank band and on the blood bank tube.
4. Peel away white liner from the clear cover flap. Press clear cover flap down firmly from left to right, on a flat surface several times to seal flap.
5. Apply Bar Code Blood Band to patient allowing one finger space between wrist and wrist band closure. Size band, close snap, and cut off any excess band.
6. Using the Laboratory bar code enables the Pro-Vue to automatically order the test required.

All other clinic patients with pre-operative type and screen orders or type and crossmatch orders must bring the orders to the Laboratory to have specimens collected by the Laboratory phlebotomist following the Blood Bank collection protocol. The patient will report to the hospital Laboratory where their surgery is to be performed (VCMC or SPH).

All Laboratory orders for tests that do not require the transfusion of blood products can be drawn in the clinic following the specimen collection protocol.

4. **Mislabeled Specimens:**
    1. All labeling information must be exact.
    2. If a discrepancy is found, the patient will need to be redrawn and a new specimen collected and correctly labeled. Additionally, if blood bank products have been ordered, the patient must be re-banded with a new blood bank recipient wristband with the redraw. ***Mislabeled specimens cannot be relabeled by Medical, Nursing, or Laboratory staff once they have left the bedside of the patient***. If a critical situation occurs, in which the patient must be transfused, before a new specimen can be recollected or before work is completed on the new sample, emergency released uncrossmatched O negative blood will be used.

NON-BLOOD SPECIMENCOLLECTION/LABELING REQUIREMENTS

1. Samples for PAP smear (GYN samples): Record the patient's name and ID number on the vial and record the patient information and medical history on the cytology requisition form. If slides are submitted they must be labeled with the patient's name and ID number.
2. Non GYN Samples: Record patient's name and ID number on the sample container. It is also

important to write the type of sample on the container. Medical history should accompany orders (these are required fields in the EHR when the order is placed).

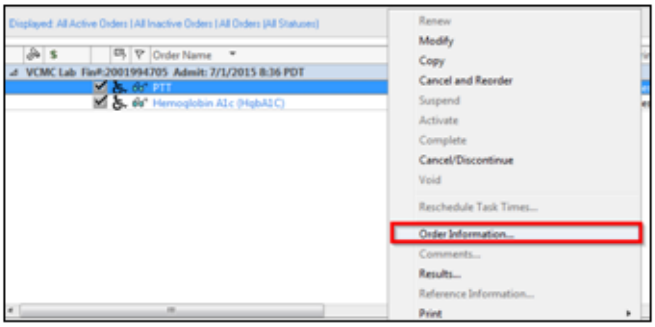
3. Tissue Samples: Each tissue specimen must be placed in a properly labeled container, which bears the name of the patient, tissue source, and additional patient identification such as hospital identification number, date of birth, or social security number. (Tissue from doctor's offices will be accepted if there is enough information on the specimen container to permit definite identification of the patient from which the tissue was obtained.
4. When tissue is obtained from more than one site, the tissue from each separate site will ordinarily be placed in a separate properly labeled container, which clearly distinguishes the source of each portion of tissue.
5. Tissue specimens for routine pathological examination should be placed in a proper size container and submerged in 10% formalin. There should be at least five parts formalin to tissue by volume. Note that certain tissue specimens require special handling (frozen section, hormone receptors, electron microscopy, immunofluorescence) as described below.
6. Tissue specimens for which microbiological cultures are requested should not be placed in formalin but should be placed in sterile container without fixative and transported to the Laboratory immediately.
7. All tissue specimens must be accompanied by a properly completed pathology requisition which includes the patient's name, the patient's date of birth, the patient's sex, the patient's hospital identification number, (except for doctors' office specimens), the date the tissue was obtained, the source(s) of the tissue, the name of the physician who performed the procedure, preoperative and/or postoperative diagnosis, and any additional relevant clinical information.

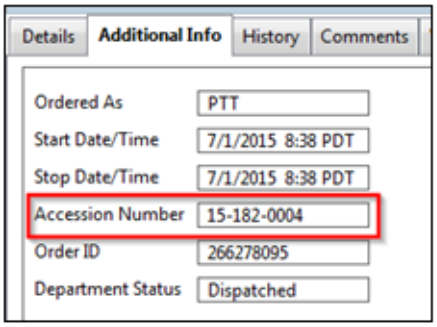
LOGGING AND TRANSFERRING LAB SPECIMENS

These instructions apply to all sample types and locations. Samples transferred directly from a clinic/provider's office to a reference lab must still follow these instructions. It is never acceptable to send a sample without a packing list to a reference lab, as this will cause a delay in sample processing.

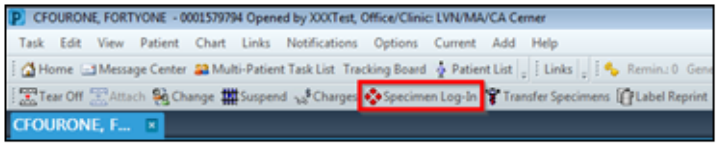
SPECIMEN LOG-IN
(This is telling the system the specimen is at your clinic)

1. Obtain the Accession Number – write it down
   From the Orders section in PowerChart, right click on Order > Order Information > Additional Info tab

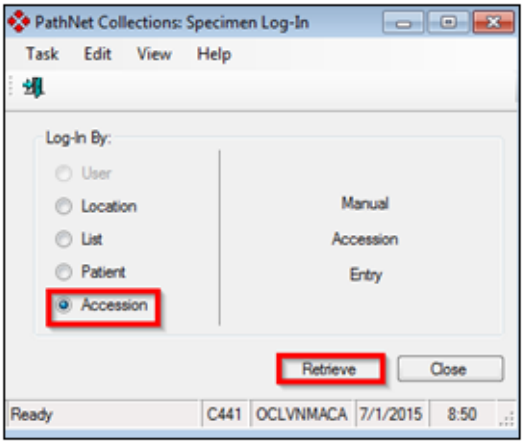




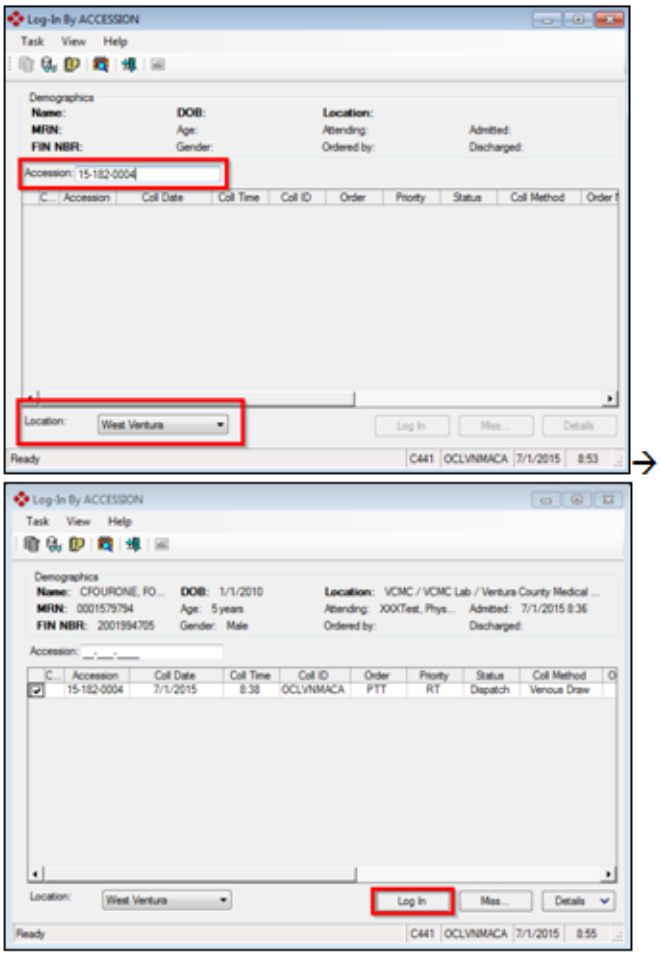
2. In PowerChart, click on "Specimen Log-In"



3. Select "Accession", then click on "Retrieve"



4. Enter the Accession Number then press Enter. Select the correct Location, then click "Log-In"

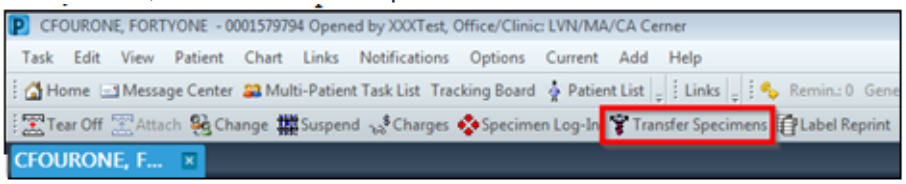


5. Repeat step 3 as needed. Close the Log-In By Accession and Specimen Log-In windows.

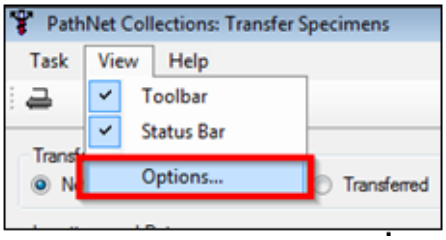
Transfer List

(This is telling the system the specimen is being transferred to another location)

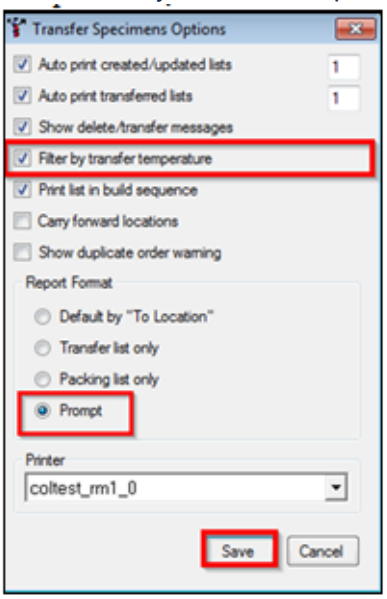
1. In PowerChart, click on "Transfer Specimens"



2. Include Filter by Transfer Temperature (This step will only need to be done once)
   Click View > Options

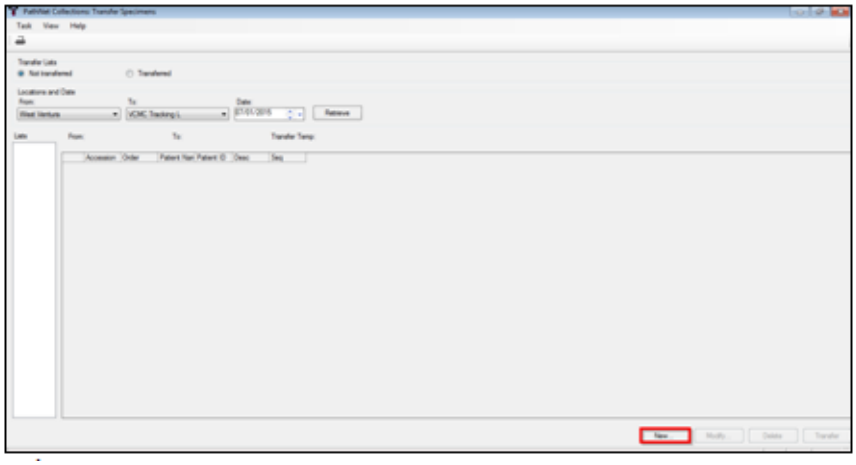


Check "Filter by Transfer Temperature", then click Save



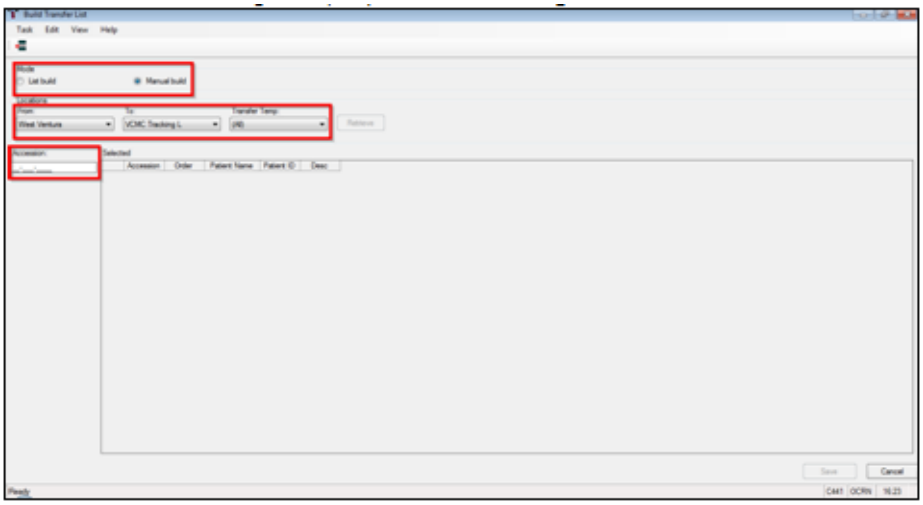
***Make sure the Report Format is set to "Prompt" – This is important for locations that order Quest Labs**

3. Click New…

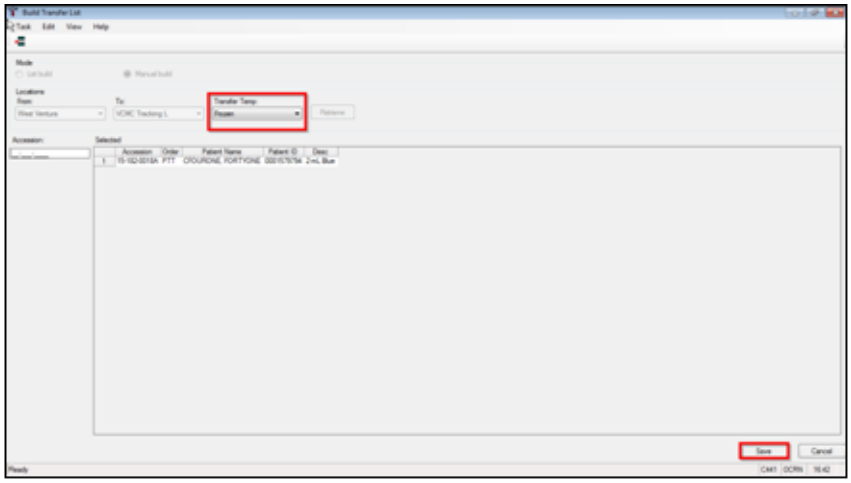


4. Building the List
   Mode: Manual Build
   Locations – **From:** (location where specimen is collected)
   Locations – To:(location where specimen is being sent)
   Use **Quest Tracking** for Quest Reference Lab Specimens
   Date: Defaults to today's date
   Transfer Temp: There are three types (Frozen, Refrigerated, Room Temp)*

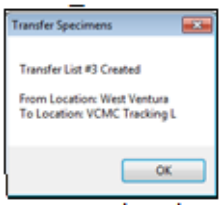
   Enter the Accession Numbers by Transfer Temp (enter all Frozen together, then all Refrigerated together, etc.) Use a Barcode reader if available.
   *Leave the Transfer Temp as "(All)" when entering Accession Numbers.



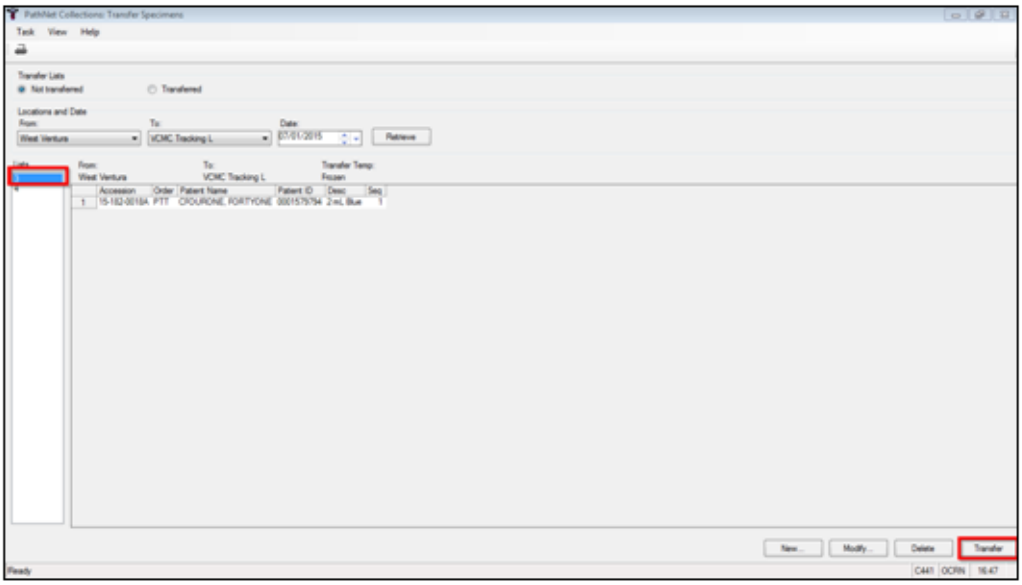
5. After entering all specimens of a particular Transfer Temp that are being transferred, **change the Transfer Temp to the appropriate type** , then click Save.



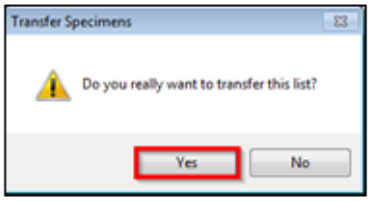
6. You will receive a message **Transfer List #_ Created.** Click OK



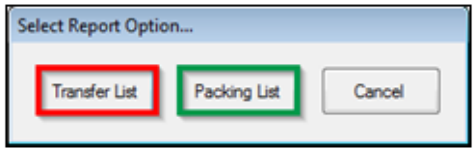
7. Select the correct List, and confirm the From and To locations are correct. Click Transfer



8. Click Yes



9. You will be prompted to Select a Report Option:



Use **Transfer List** for Clinic to Hospital
Use **Packing List** for Clinic to Quest

10. Include Transfer/Packing List with the specimens

LABORATORY SPECIMEN COLLECTION AND LABELING

When submitting specimens to the Laboratory for testing, all collected specimen tubes must contain the following on the label:

- Patient's name: Last, First and any middle initial/name (as registered)
- Medical Record Number
- Collection date
- Collection time

- Phlebotomist/RN - **legible** Cerner username

Please use a **ball point pen** only to label tub.

All Revision Dates

7/27/2024, 8/17/2022, 9/29/2020, 6/5/2020, 12/1/2016, 4/1/2016

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	7/26/2024
Laboratory Services Department	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services	6/24/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	6/23/2024

Status **Active** PolicyStat ID **16264690**

Origination	9/1/2022
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Next Review	7/27/2026
Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services

L.52 Laboratory Response To Hospital Emergency Call Codes

POLICY

The Department of Laboratory Services at Ventura County Medical Center and Santa Paula Hospital shall have a defined process for laboratory staff's response to hospital emergency call codes that require specimen collection and processing.

MATERIALS

1. Specimen collection tubes
    - Light blue (sodium citrate)
    - Red (no additive)
    - Gold (SST)
    - Green (lithium heparin)
    - Lavender (EDTA)
    - Pink (EDTA)
    - Gray (Sodium fluorite)
    - Blood culture bottles
2. Blood collection needles, multi-sample
3. Blood collection needle, butterfly
4. Blood collection single-use tube holder
5. Tourniquet

6. Alcohol pads
7. Chlorhexidine (Chloraprep pads and swabstick)
8. Disposable gloves
9. Blood bank armband
10. Disposable plastic biohazard bags

PROCEDURE

To ensure that patients are accurately diagnosed in the most expedient way possible, the hospital developed the following codes to ensure responders are activated promptly:

1. CODE STROKE (brain stroke): patients affected with central nervous system infarction
2. CODE BLUE/RAPID RESPONSE
3. CODE LAB (ICU ONLY for near-death situations)
4. CODE MATERNITY
5. CODE YELLOW (Tier 1 and Tier 2)
6. CODE SEPSIS

RESPONSIBILITIES

1. The laboratory is responsible for:
    a. Provision of laboratory services to support the hospital life-threatening codes
    b. Immediate attention and support for safe and timely patient care through accurate diagnostic testing.
    c. Communication is vital when responding to hospital codes.
        i. Immediately communicate with the ordering department when there are delays in provision of services.
        ii. Document dialogue in ED log or shift report log, or more appropriately on the specimen's accession number.
2. Designated responder from the laboratory shall carry a pager. Message is sent simultaneously upon announcement.
    a. Immediate response to the CODE announced.

CODE	ACTION
CODE STROKE	Draw specimens per protocol (4 lithium heparin, 2 lavenders, 1 blue, 2 gold, 1 pink) Tube specimens Call laboratory coordinator
CODE LAB	Draw specimens per protocol DO NOT TUBE Deliver specimens to the lab

CODE	ACTION
CODE YELLOW - TIER 1	Draw specimens per protocol (3 lithium heparin, 1 lithium heparin for RT, 1 lavender, 1 blue, 1 gold, 1 pink, 1 gray) Tube specimens Call lab coordinator
CODE YELLOW - TIER 2	Draw specimens per protocol (4 lithium heparin, 1 lithium heparin for RT, 1 lavender, 1 blue, 1 gold, 1 pink, 1 gray) Tube specimens Call lab coordinator
CODE MATERNITY	
CODE SEPSIS	Draw specimens per protocol (2 lithium heparin, 1 lavender, 1 blue, 2 gold) Tube specimens Call lab coordinator

b. Collect specimens following established protocol: A pre-assembled "CODE STROKE" packet (contains lavender, pink, green, blue, red top tubes, and gray (on ice), butterfly, blood bank armband, blood cultures, chlorhexidine pads and swabstick).

3. Immediately bring the specimens to the laboratory. DO NOT USE PNEUMATIC TUBE SYSTEM.
4. Receive and deliver specimens to respective testing areas, alert testing personnel:

TUBE COLOR	TESTING AREA	ACTION	
		Phlebotomist	Clinical Lab Scientist Medical Lab Technician
Pink	Blood Bank	Centrifuge specimen	• Load specimens into analyzer. • Monitor test completion. • Communicate critical results to ordering provider. • Document notification in Laboratory Information System.
Green	Chemistry	Centrifuge specimen	
Gray	Chemistry	Centrifuge specimen	
Purple	Hematology	• Mix sample. • Load in analyzer.	
Blue	Coagulation	Centrifuge specimen	
Blood Cultures	Microbiology	Follow instructions for loading.	

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Approval Signatures

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Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	7/20/2024

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VENTURA COUNTY HEALTH CARE AGENCY

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Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.09 Selection of Blood for Transfusion

POLICY:

1. The blood unit chosen should be of the same ABO group and Rh type as that of the recipient. AB Positive and AB Negative are not routinely stocked but may be ordered for a transfusion if time allows. **Do not order AB units for a Type and Screen.** When such blood is unavailable, the acceptable alternatives are listed below.

PATIENT GROUP	FIRST CHOICE	SECOND CHOICE	THIRD CHOICE	FOURTH CHOICE
O POS	O POS			
O NEG	O NEG			
A POS	A POS	A NEG	O POS*	O NEG*
A NEG	A NEG	O NEG*		
B POS	B POS	B NEG	O POS*	O NEG*
B NEG	B NEG	O NEG*		
AB POS	AB POS	AB NEG	A POS	A NEG
AB NEG	AB NEG	A NEG*		

KEY: * - give as Red Blood Cells only

2. Blood administration after non-group specific transfusion: Once a sample is received and the recipient's ABO group and Rh type are determined, the recipient can begin receiving transfusions of group-specific components after the infusion of up to 12 units of non-group specific red blood cells. (see procedural note 1).
3. Rh-negative blood may be given to Rh-positive patients if necessary or to prevent outdating.
4. Patients that have an unexpected clinically significant antibody will be given antigen negative,

antiglobulin (AHG) crossmatch-compatible blood. The unit of blood that is infused should be tested with commercial antiserum by Ventura County Medical Center/Santa Paula Hospital or Vitalant. When possible, screen donor units with patient's serum then type the compatible units. If two or more antibodies are present, screen first for the antigen of higher incidence.

5. Anti-I, -IH, -Le^a, - Le^b, and unidentified Cold Agglutinin- Use AHG crossmatch-compatible units.
6. Anti-M, -N, -P1 – Use AHG crossmatch-compatible if antibody reacts at room temperature and/or 37°C. Type units for antigen ONLY if the antibody reacts at the IgG phase.
7. Anti-A1 reacting at 37°C and/or IgG is clinically significant.
    a. Group A_2 patients with an anti-A1 that is reactive at 37 C should receive group A_2 or group O red cells.
    b. Group A_2B should receive group A_2, A_2B, B, or O red cells.
8. Any other antigen typing should be discussed with the Blood Bank Supervisor or the Pathologist before proceeding.
9. Irradiated units and/or CMV negative products may be requested by the physician for some patients. Place the order with the blood supplier, get an estimate time of arrival and document both the order and the ETA in the communication book.
    a. If special requirements are to be an ongoing request from the physician, update the "Transfusion Requirements" in the patient product inquiry application. Updating the transfusion requirements will prevent the end user from providing products without the special transfusion requirements. These can be removed when no longer required.
10. Patients with Sickle Cell Disease will be transfused with Hemoglobin S negative red blood cells. Hemoglobin S negative confirmed units can be ordered from the blood supplier.
    a. If a patient with Sickle Cell Disease has not been transfused red blood cells within the last three (3) months, phenotyping for antigens C, c, E, e, and K should be performed and red blood cells phenotypically matched with the patient's phenotype should be provided for those antigens.

PROCEDURAL NOTES

1. Group O RBC units stored in additive solution contain minimal residual plasma, which minimizes concerns regarding passive transfusion of anti-A and anti-B. In some cases, such as when large volumes of RBCs are transfused or small children or infants received transfusions, passively acquired anti-A and/or anti-B may be detected in the recipient's serum or plasma. If so, transfusion with RBCs that lack the corresponding A and/or B antigen (s) should be continued.

Testing for passively acquired anti-A and/or anti-B in serum/plasma:

1. Label two 12x75 mm tubes for A1 cells and B cells.
2. Add 2 drops of the serum/plasma to each tube.
3. Add 1 drop of A1 and B cells to the appropriately labeled tubes.
4. Incubate the tubes at 37C for 15 minutes.

5. Wash the tubes 4 times with saline and then add 2 drops of anti-IgG to each tube.
6. Spin at 3500 RPMs for 15 seconds.
7. Read macroscopically and microscopically.
8. Add check cells to all negative reactions.
9. If the antibody is present ABO-compatible red cells lacking the corresponding A or B antigen must be used.

In an extreme emergency, it may be necessary to transfuse Rh (D)-positive blood to an Rh (D)-negative patient. A pathologist must approve this procedure.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, Current Edition.
2. Cohn et. al.. Technical Manual. Bethesda, MD: American Association of Blood Banks, Current Edition


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Paper copy reviewed on 12/12/2023 by Janette O'Neill.
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All Revision Dates

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Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	7/26/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	7/6/2024

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VENTURA COUNTY HEALTH CARE AGENCY

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Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.50 Crossmatch-Immediate Spin

PRINCIPLE:

Current ***Standards for Blood Bank and Transfusion Services*** states that if no clinically significant antibodies are detected in the antibody detection test and there is no record of detection of such antibodies, only test methods to demonstrate ABO incompatibility are required for the crossmatch. An immediate spin saline crossmatch using patient plasma/serum and donor cells meets this requirement.

POLICY:

The immediate spin saline cross match is done for all compatibility testing, including when an antibody is detected in the antibody screening test or the patient has a previously detected antibody (see Policy and Procedure L.BB.08 & L.BB,55 "***Crossmatch-IgG***") requiring an IgG crossmatch. If blood is required to be given STAT to a patient whose ABO-Rh typing is complete but whose antibody detection testing is incomplete, ABO and Rh type specific or group O D-negative will be issued. The exception to this rule is for patients with a past history of an antibody. Those patients with a prior history of an antibody must be given units negative for the corresponding antigen. All of the aforementioned units will be dispensed Emergency Release. If time allows, perform the immediate spin crossmatch prior to dispensing units.

SPECIMEN COLLECTION:

1. Specimen must be less than 3 days old.
    a. EXCEPTION: For Pre-Op Surgery patients that have not been transfused or Pregnant in the past three months, specimens may be used up to 7 days.
2. No special preparation of the patient is required prior to specimen collection.
3. EDTA whole blood (Pink top blood bank tube)
4. Store 2 to 8°C.

a. All blood bank specimens are retained for 14 days after collection.

b. All donor segments are retained for 14 days.

REAGENTS – Materials and Special Equipment:

1. 12 x 75 glass test tubes
2. Normal Saline
3. Centrifuge

PROCEDURE:

1. Compare the patient's name and medical record number on the blood bank specimen with the information on the laboratory request label. Confirm the date, time, and phlebotomist's user name are on the specimen.
2. Prepare a 3-5% cell suspension, in normal saline, in a tube labeled with the first letter of the patient's last name.
3. As part of the cross match procedure, the patient must have an ABO/Rh Retype performed if there are no historical data prior to crossmatching type-specific or type compatible red blood cells..
    a. In Department Order Entry, order the ABO/Rh Retype test on a new accession number. A CBC that was drawn at a different time can be utilized for ABO/Rh Retypes. Perform both the forward and the reverse ABO typing.
    b. To perform the retype procedure for the patient, see procedure L.BB.19 "***ABO Grouping***" and Procedure L.BB.59 "***Rh(D) Typing***".
4. Perform ABO/Rh Retype and record results in Result Entry application in the computer. All documentation must be done concurrently with testing.
5. Select donor units compatible with the patient's blood type.
6. Remove the last two segments from each unit.
7. Label the detached segments with a Donor Identification Number label and place into a test tube. [Donor Identification Number Labels can be obtained from the back of the respective unit(s)]
8. Return the units to the refrigerator.
9. Prepare a 3-5% cell suspension, in normal saline, of donor cells in a test tube labeled with the last 2 digits of the donor unit number. Wash the cell suspension one time.
10. To perform the cross match procedure, label the tubes with the first letter of the patient's last name and the last two digits of the donor unit number.
11. To the labeled tubes, add two (2) drops of the patient's plasma/serum.
12. Add one drop of the donor cell suspension to the appropriate tube.
13. Mix well and centrifuge at 3400 rpm for the calibrated time.
14. Re-suspend the cell button with gentle agitation and examine for hemolysis and/or

agglutination.

15. Record results.
16. Dispose of the tubes.
17. Enter the interpretation of compatibility test results.
18. Label the unit (s) with the computer generated labels and the Blood Bank recipient wristband ID label.
19. Attached the segment(s) to the specimen with a rubber band and store in the appropriate day's container in the refrigerator. (The segments used for testing must be retained too)
20. Add CMV, IRR, Hgb S charges when appropriate.

CALIBRATION:

N/A

CALCULATIONS:

N/A

QUALITY CONTROL:

See Daily Reagent Quality Control.

RESULTS:

If there is no visible hemolysis or agglutination, the cross match is compatible. This compatibility test ensures that the donor blood cells are ABO compatible with the recipient. If there is incompatibility, an investigation into the discrepancy must be initiated and blood will not be released to the patient until the problem is resolved.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, Current Edition.
2. Cohn, CS, et. al. Technical Manual. Bethesda, MD: American Association of Blood Banks, Current Edition

All Revision Dates

7/27/2024, 8/8/2022, 12/1/2016, 12/1/2015, 12/1/2013, 6/1/2004, 11/1/1997

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	7/26/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	7/20/2024

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Owner	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services
Policy Area	Laboratory Services - Chemistry

L.CHEM 2.20 Thyroid-Stimulating Hormone (TSH3-Ultra)

Policy

Thyroid-Stimulating Hormone (TSH3-Ultra)

Clinical Application and Usefulness
For *in vitro* diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in serum, heparinized plasma, and EDTA plasma using the ADVIA Centaur and ADVIA Centaur XP systems.

Principle of the Test

The ADVIA Centaur TSH3-Ultra assay is a third-generation assay that employs anti-FITC monoclonal antibody covalently bound to paramagnetic particles, an FITC-labeled anti-TSH capture monoclonal antibody, and a tracer consisting of a proprietary acridinium ester and an anti-TSH mAb antibody conjugated to bovine serum albumin (BSA) for chemiluminescent detection.

Reagents

Storage and Stability

- Store the reagents upright at 2 – 8°C.
- Primary reagents stable until the expiration date on the pack label, or for 60 days onboard the system.
- Calibrators stable until the expiration date on the pack label, for 28 days at 2 – 8°C after reconstitution, or for 4 hours onboard the system.
- Multi-Diluent 1 stable until the expiration date on the pack label, or for 28 consecutive

days after accessing the ancillary reagent pack.

- Protect from sunlight. Protect reagent packs from all heat and light sources. Reagent packs loaded on the system are protected from light. Store unused reagent packs at 2–8°C away from light sources.
  CAUTION:
- Discard the primary reagent packs at the end of the onboard stability interval.
- Do not use reagents beyond the expiration date.

Ingredients

Reagent ingredients for the ADVIA Centaur TSH3-UL assay are as follows:

Reagent	*Volume*	*Ingredients*
Lite Reagent	6.0 mL/ reagent pack	bovine serum albumin (BSA) conjugated to monoclonal anti-TSH (~0.3 µg/mL) labeled with acridinium ester in HEPES buffered saline, mouse IgG, BSA, goat serum, surfactant, and preservatives
Solid Phase	21.0 mL/ reagent pack	anti-fluorescein monoclonal antibody covalently linked to paramagnetic particles (PMP) (~85 µg/mL) in HEPES buffered saline, BSA, goat serum, surfactant, and preservatives
Ancillary Reagent	6.0 mL/ reagent pack	FITC conjugated to monoclonal anti-TSH (~3 µg/mL) in HEPES buffered saline, mouse IgG, BSA, goat serum, surfactant, and preservatives
Calibrators	2.0 mL/vial	after reconstitution, low and high levels of thyroid-stimulating hormone (TSH) in HEPES buffered equine serum with sodium azide (< 0.1%) and preservatives
Multi-Diluent 1	25.0 mL/ reagent pack	equine serum with sodium azide (0.1%) and preservatives

Risk and Safety

HARMFUL: Harmful if swallowed. After contact with skin, wash immediately with plenty of soap and water. Contains: sodium azide; Solid Phase, Calibrators.
CAUTION: This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.
NOTE: Sodium azide can react with copper and lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent the buildup of azides, if disposal into a drain is in compliance with federal, state, and local requirements.

Specimen Collection and Handling

Specimen Collection

- Serum, heparinized plasma, and EDTA plasma are the recommended sample types for this assay.
- Allow samples to clot adequately before centrifugation.
- This assay requires 100 µL of sample for a single determination. Additional volume is

required for onboard dilutions.

- Before placing samples on the system, ensure that samples are free of fibrin or other particulate matter and that samples are free of bubbles.

BIOHAZARD
All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

Specimen Storage and Stability

- Keep tubes covered and upright at all times.
- Do not use samples that have been stored at room temperature (18 to 24°C) for longer than 24 hours.
- Tightly cap and refrigerate specimens at 2 to 8°C if the assay is not completed within 24 hours. Specimens can be stored at 2 to 8°C for 48 hours.
- Freeze samples at or below -20°C if the sample is not assayed within 48 hours. Specimens can be stored at or below -20°C for up to 3 days.
- Freeze samples only once and mix thoroughly after thawing.

Procedure

Test Steps

The system automatically performs the following steps:

- Dispenses 100 µL of sample into a cuvette
- Dispenses 50 µL of Ancillary Reagent and 50 µL of Lite Reagent and incubates for 2.75 minutes at 37°C
- Dispenses 200 µL of Solid Phase and incubates for 5.5 minutes at 37°C
- Separates, aspirates, and washes the cuvettes with Wash 1
- Dispenses 300 µL each of Acid Reagent and Base Reagent to initiate the chemiluminescent reaction
- Reports results according to the selected option, as described in the system operating instructions or in the online help system
  A direct relationship exists between the amount of TSH present in the patient sample and the amount of relative light units (RLUs) detected by the system.

Reagents Special Preparation
No special preparation of reagents is required.

Calibration

The ADVIA Centaur TSH3-Ultra assay standardization is traceable to the World Health Organization (WHO) 3rd International Standard for human TSH (IRP 81/565). Assigned values for calibrators are traceable to this standardization.

For detailed information about scheduling a calibration, refer to *Scheduling Calibrators*.

Preparing the Calibrators

Prepare the TSH3-Ultra Calibrators as described below:

1. Add 2.0 mL of reagent water into each calibrator vial using a volumetric or precision pipet.
2. Let the calibrators stand for 15 to 20 minutes at room temperature (20 – 30°C) to allow the lyophilized material to dissolve.
3. Gently swirl and invert the vials until homogeneous.

Calibration Procedure

For detailed information about processing calibrators, refer to the system operating instructions.

Calibration Material	TSH3-Ultra Calibrators in the ADVIA Centaur TSH3-Ultra kit*
Calibration Scheme	Two-point calibration
Calibration Interval	Every 14 days
Additionally, the ADVIA Centaur TSH3-Ultra assay requires a two-point calibration:	• When changing lot numbers of primary reagent packs • When replacing system components • When quality control results are repeatedly out of range

*** NOTE**: The TSH3-Ultra Calibrators provided in this kit are matched to the Solid Phase, Lite Reagent, and Ancillary Reagent. Do not mix TSH3-Ultra Calibrator lots with different lots of Solid Phase, Lite Reagent, and Ancillary Reagent.

Defining Calibrator Values for Two-point Calibration

Use the barcode reader to enter the calibrator values from the *Calibrator Assigned Value* card onto the system.

1. At the workspace, select **Calibration**.
2. Select **Calibrator Definition**.
3. Select **Scan Data**.
4. Use the handheld barcode reader to scan the barcodes (from top to bottom) on the *Calibrator Assigned Value* card.
5. Ensure that the calibrator values are correct. After you select Save, you cannot add or delete a test from a calibrator definition.
6. Select **Save**.

Defining the Master Curve

The ADVIA Centaur TSH3-Ultra assay requires entry of Master Curve calibration data when using a new lot number of Solid Phase, Lite Reagent, and Ancillary Reagent. Use the barcode reader to

enter the Master Curve values from the *Master Curve* card onto the system.
Ensure that the lot number on the *Master Curve* card matches the lot number of the ReadyPack.

1. At the workspace, select **Calibration**.
2. Select **Master Curve Definition**.
3. Select **Scan Data**.
4. Use the handheld barcode reader to scan the barcodes on the *Master Curve* card. **IMPORTANT:** Ensure you are scanning the side of the *Master Curve* card labeled ADVIA Centaur.
5. Select **Save**.

Quality Control (QC)

For detailed QC procedural information, refer to the *Operator's Guide*.
Use commercially available quality control materials with at least two levels (low and high).
Analyze all levels of quality control material on each day that samples are analyzed.
Analyze all levels of quality control material each time a two-point calibration is performed.

Troubleshooting Out-of-Range QC Values

If the quality control results do not fall within the Expected Values or within the laboratory's established values, do not report results. Take the following actions:

- Verify that the materials are not expired.
- Verify that required maintenance was performed.
- Verify that the assay was performed according to the instructions for use.
- Rerun the assay with fresh quality control samples.
- If necessary, contact your local technical support provider or distributor for assistance.

Results

Reporting Results

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference range(s) for the diagnostic evaluation of patient results.

Reference Interval

TSH reference ranges for pediatric, adolescent, and adult samples are:

- Infants (1- 23 months): 0.87 - 6.15 µIU/mL (mIU/L)
- Pediatric (2 to < 12 years): 0.64–6.27 µIU/mL (mIU/L)
- Adolescent (12 to < 18 years): 0.51–4.94 µIU/mL (mIU/L)
- Adult (≥ 18 years): 0.55–4.78 µIU/mL (mIU/L)

Units for Reporting Results

The system reports serum TSH results in µIU/mL (mass units) or mIU/L (SI units), depending on the units defined when setting up the assay. The conversion formula is 1 µIU/mL = 1 mIU/L. You

can define the units and the number of decimal places for test results using the Worklist – Test Summary window.

Procedure Notes

Calculations

For detailed information about how the system calculates results, refer to the *Operator's Guide*.

High Dose Hook Effect

Patient samples with high TSH levels can cause a paradoxical decrease in the RLUs (high dose hook effect). In this assay, patient samples with TSH levels as high as 3000 µIU/mL (mIU/L) will assay greater than 130 µIU/mL (mIU/L).

Disposal

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner, and in compliance with all federal, state, and local requirements.

Method Limitations

Reportable Range

The reportable range of the ADVIA Centaur TSH3-UL CP assay is from the Limit of Quantitation (LoQ) [0.008 µIU/mL (mIU/L)] to 130 µIU/mL (mIU/L).

Dilutions

- Patient samples with TSH levels greater than 130 µIU/mL (mIU/L) must be diluted and retested to obtain accurate results.
- For automatic dilutions, ensure that ADVIA Centaur Multi-Diluent 1 is loaded and set the system parameters as follows:
  Dilution point: ≤ 130 µIU/mL (mIU/L)
  Dilution factor: 2, 5
  For detailed information about automatic dilutions, refer to the *Operator's Guide* or online help system.

Other Limitations

- Interpret TSH levels with caution during the first trimester of pregnancy, or whenever very high levels of hCG are present.
- This assay has not been validated for testing samples from newborns (Age group < 1 month).
- Do not pour the calibrators back into the vials after calibration because evaporation could occur, which may affect performance.
- Dispose of any calibrator remaining in the sample cups after 4 hours.
- Do not refill calibrator sample cups when the contents are depleted. If required, dispense fresh calibrators.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins,

interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.

Specimens that are . . .	***Demonstrate ≤ 5% change in results up to . . .***
Hemolyzed	100 mg/dL of hemoglobin
Lipemic	1000 mg/dL of triglycerides
Icteric	40 mg/dL of conjugated bilirubin
Icteric	40 mg/dL of unconjugated bilirubin

Interference testing was determined according to CLSI Document EP7-A2.
For additional information on performance characteristics, see the product information in the ADVIA Centaur TSH3-UL product insert.

Equipment and Supplies

- ADVIA Centaur TSH3-Ultra ReadyPack
- ADVIA Centaur Multi-Diluent 1 (optional)
- ADVIA Centaur Acid Reagent (0.5% H_20_2, 0.1N HNO_3)
- ADVIA Centaur Base Reagent (0.25N NaOH and surfactant)
- ADVIA Centaur Wash 1 Regent (phosphate buffered saline with < 0.1% sodium azide and surfactant)
- ADVIA Centaur Cleaning Solution Concentrate (~52.5 g/L sodium hypochlorite)
- ADVIA Centaur Sample Cups and Caps
- ADVIA Centaur Cuvettes
- ADVIA Centaur Tips
- Reagent Water

References

1. Siemens Healthcare Diagnostics ADVIA Centaur TSH3-UL Product Insert.
2. Siemens Healthcare Diagnostics ADVIA Centaur Reference Manual.
3. Siemens Healthcare Diagnostics ADVIA Centaur XP Operator's Guide.
4. Clinical and Laboratory Standards Institute (CLSI). Clinical Laboratory Technical Procedure Manuals; Approved Guideline, GP2-A5, 2006.
5. Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry; Approved Guideline, EP7-A2, 2005.

All Revision Dates

8/13/2024, 6/17/2024

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	8/13/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	8/8/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	7/26/2024
Laboratory Services Department	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services	7/2/2024

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Last Approved	7/27/2024		
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Last Revised	7/27/2024		
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L.SPH.16 Urine and Cerebrospinal Fluid Protein

POLICY:

The UCFP method used on the EXL® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of total protein in **urine** and **cerebrospinal fluid** .

Clinical Significance

URINE PROTEIN

In the average adult, approximately 2,000 liters of blood flow through the kidneys each day. 180 liters of filtrate, containing 30 grams of protein, are formed. Ultimately 99% of the filtrate is reabsorbed. The final daily urine output is 1-2 liters, and it contains only 40-80 mg of protein. The ability to filter this large volume of blood without loss of significant amounts of protein is one of the most important characteristics of the normal kidney. Normal function of both the glomeruli and the tubules are required to achieve this. Damage to either (or both) tends to result in protein excretion. Proteinuria occurs in nearly all diseases of the kidney. The measurement of the protein content of urine is therefore one of the most sensitive and useful tests for detecting and following the course of kidney disease. The most common screening test for proteinuria is the testing of a single random or early morning sample. The protein concentration in such a sample may be misleading since the degree of proteinuria may vary from time to time during the day. More quantitative and clinically useful data are derived from determining the total amount of protein excreted during a fixed interval, usually 24 hours.

CSF PROTEIN

Diseases of the brain or spinal cord (which together make up the central nervous system or CNS) or of the meninges (the membranes which enclose the CNS) often produce an increase in CFP levels. Among these diseases are: infections, whether bacterial or viral; neoplastic, that is, tumors of the brain, spinal

cord, or meninges; vascular, such as hemorrhage or thrombosis (blood clot); degenerative, as in multiple sclerosis. Certain generalized metabolic diseases may also cause slight increases in CFP. These include diabetes mellitus, hypothyroidism, and hypercalcemia. The importance of measuring CFP lies in the fact that normally the level should be less than 45 mg/dL. Higher values are abnormal. Further diagnostic studies, both laboratory and x-ray, are required to determine the cause of the abnormality. Considerable additional information is gained through measurement of other CSF constituents such as glucose and white blood cells (with the latter an indication of infection). Electrophoresis of the protein may be helpful in certain diseases (multiple sclerosis).

Principles of Procedure

The UCFP method allows direct quantitation of proteins in urine and cerebrospinal fluid specimens. The UCFP method is an adaptation of pyrogallol red-molybdate method by Y. Fujita, I. Mori and S. Kitano. [1]

Measurement of the protein content in urine is used in diagnosis and treatment of kidney diseases.

Measurement of the protein content in cerebrospinal fluid is used in the diagnosis and treatment of central nervous system diseases.

In the reaction sequence, pyrogallol red combines with sodium molybdate to form a red complex with maximum absorbance at 470 nm. The protein in the sample reacts with this complex in acid solution to form a bluish-purple colored complex, which absorbs at 600 nm. The absorbance at 600 nm is directly proportional to the concentration of protein in the sample. The analyte concentration is determined by calculation using a logit curve fit on a previously stored calibration curve.

$$\text{Pyrogallol red molybdate} + \text{Protein} \longrightarrow \frac{\text{PR - MO - protein complex}}{(\text{absorbs at } 600 \text{ nm})}$$

Reagents

See the EXL Urine/CSF Protein insert sheet for deatails of reagents used in this method. Reagents are stored at 2-8°C.

Refer to carton for expiration date of individual unopened reagent cartridges. Sealed cartridge wells on the instrument are stable for 30 days. Once wells have been entered by the instrument, they are stable for 5 days.

Specimen Collection

Normal procedures for collecting urine and cerebrospinal fluid may be used for samples to be analyzed by this method.

Specimens stored at 4°C with no additives are stable for at least three days. [3]

Random urine specimens may be used but timed 24-hr specimens are preferred. No preservative is required during 24-hr collection, but thereafter urine aliquots should be stored at 2-4°C or frozen. Urine specimens must be free of any particulate matter before analysis.2

Cerebrospinal fluid specimens should be collected with care to avoid contamination with plasma proteins. Blood present in the cerebrospinal fluid invalidates the protein values since it reflects contamination with plasma proteins. Remaining cerebrospinal fluid specimens should be refrigerated or frozen. [2]

Known Interfering Substances

- Hemolyzed samples should be avoided since hemolysis increases UCFP results (at 25 mg/dL hemoglobin).
- Samples containing amikacin, gentamicin, kanamycin, and tobramycin should be avoided since these substances falsely increase UCFP results.
- Blood collection tubes containing sodium citrate should not be used.
- Neomycin sulfate at 15 µg/mL increases UCFP results by 11% and at 7.5 µg/mL the interference is less than 5%.
- Refer to the Urine/CSF reagent insert sheet for a complete list of substances tested for interference.

Procedure

The UCFP Flex ® reagent cartridge, Cat. No. DF26, is required to perform the UCFP test. This test is performed on the EXL® clinical chemistry system after the method is calibrated (see Reference Material in Calibration section). Document Library - Siemens Healthineers (siemens-healthineers.com)

Test Steps

Sampling, [d] reagent delivery, mixing, processing and printing of results are automatically performed by the EXL® system. For details of this processing, refer to the EXL® system manual.

[d.] The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus the dead volume. Precise container filling is not required.

Test Conditions

• Sample Size:	10 µL
• Reagent Volume:	350 µL
• Diluent Volume:	50 µL
• Test Temperature:	37°C
• Wavelength:	600 and 700 nm

• Type of Measurement:	bichromatic end point

Calibration

The general calibration procedure is described in the EXL® system manual (also see Appendix B). The following information should be considered when calibrating the UCFP method:

Assay Range:	6 - 250 mg/dL
Reference Material:	UP/CFP Calibrator (CAT. NO. DC45).
Suggested Calibration Levels:	6.0, 30.0, 60.0, 135.0, 270.0 mg/dL
Calibration Scheme:	Five levels in duplicate
Calibration Frequency:	Every new reagent cartridge lot. Every 2 months for any one lot
Assigned Coefficients:	C0 = -193.89C1 = 1337.5C2 = - 2.595C3 = 462.58C4 = 0.5

Quality Control

Two levels of controls are run once every 24 hours. Currently used controls with means and standard deviations are posted in the computer and on the analyzer. See the Chemistry Policy Manual: Chemistry QC Program for details.

Results

The instrument automatically calculates and prints the concentration of UCFP in mg/dL using the calculation scheme illustrated in the EXL® system manual.

Limitations of Procedure

Results:	>250 mg/dL
Manual dilution:	Make appropriate dilution with Purified Water to obtain result within the assay range. Enter dilution factor. Re-assay. Resulting readout is corrected for dilution.
Automated Urine (AUD) Dilution (for urine):	Refer to the EXL® system literature.

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to the EXL® system manual.

Reference Interval

Urine:	< 11.9 mg/dL< 149.1 mg/day
Spinal Fluid [2]	15-45 mg/dL

Bibliography

1. Fujita Y, Mori I, Kitano S. Color reaction between Pyrogallol Red - Molybdenum (VI) complex and protein. Bunseki Kagaku 1983; 32:379-386.
2. Burtis CA, Ashwood ER. Tietz Textbook of Clinical Chemistry, Philadelphia: WB Saunders Co., 1994:54-55 (techniques and procedures to minimize infections in laboratory workers), 58-69 (specimen collection), 75-76 (separation and storage of specimens), 717-730 (proteins in urine and cerebrospinal fluid).
3. Gadsden, RH, *et al* . An evaluation of the urinary protein method for the aca® discrete analyzer, DuPont, Wilmington, DE (October 1982).

All Revision Dates

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	7/26/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	6/22/2024

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VENTURA COUNTY HEALTH CARE AGENCY

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Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services

L.SPH.55 Laboratory Protocol for Evaluating Quality Control Data

POLICY:

To state the procedure for evaluating quality control data.

PROCEDURE:

DAILY

Quality control data is evaluated daily by the Clinical Laboratory Scientist (CLS) . Control Tolerance Limits and Out of Control Flow Chart are used for this purpose (see appropriate policy SOP documents). Any detected problem (i.e. results outside +/- 2SD, shifts, trends, etc.) are documented in the computer as to what corrective action was taken.

MONTHLY

The Laboratory Supervisor or designee performs the following tasks:

- Review of Quality Control (QC) results for each assay on each testing platform used for quantitative and qualitative testing.
    - Chemistry: Dimension EXL with LM, ABBOTT iSTAT
    - Hematology: Sysmex XN Series 450/550 Hematology Analyzers, Alcor miniiSED Analyzer
    - Coagulation: Siemens CS 2500 Coagulation Analyzer
    - Urinalysis: Clinitek Advantus
    - Microbiology: GeneXpert

- Perform statistical analyses of all quality control data
    - Calculate mean (shows accuracy or systematic error)
    - Calculate standard deviation (shows the spread of distribution of control results about the expected mean, shows imprecision or random error)
        - Higher standard deviation = greater random error = poor precision of method
        - Lower standard deviation = less random error = better precision of method
    - Calculate coefficient of variation (standard deviation as a percentage of the mean)
- Submission of QC data for each assay to appropriate inter-laboratory QC programs for peer group comparisons (e.g., the BioRad Unity, InSight IQAP)
- Review of the Monthly Evaluation and Laboratory Comparison reports as soon as they are available.
- Perform appropriate corrective action measures.

The following are guidelines for evaluation of the QC data:

CV (coefficient of variation) Follows the CLIA Proficiency Testing criteria for acceptable analytical performance)

- Chemistry
    - General Analytes: <10%
    - Enzymes: <15%
    - Very low concentration analytes (i.e. direct bilirubin, etc.): <30%
- Hematology
    - White blood cell differentiation: Target ±3SD based on the percentage of the different WBCs
    - Erythrocytes: Target ±6%
    - Hematocrit: Target ± 6%
    - Hemoglobin: Target ± 7%
    - White blood cells: Target ±15%
    - Platelet count: Target ±25%
- Coagulation
    - Prothrombin Time/Partial Thromboplastin Time: Target ±15%
    - Fibrinogen: Target ±20%

Mean/SD/SDI

Obtained monthly mean and SD are compared with the Peer Group mean and SD, and with the cumulate mean and SD. Shifts or trends are investigated and documented. Any SDI of > +/- 2 denotes poor control performance and is investigated for a possible cause, and documented as to what corrective action was

taken.

CORRECTIVE ACTION

- Review Levy-Jennings charts to determine problem (random vs systematic error)
- Determine which type of errors occurred:
    - Random: bubbles in reagents and reagent lines, inadequately mixed reagents, unstable temperature in storage and/or incubation, variations in operator pipetting, timing, etc.
    - Systematic: changes in reagents lots and/or calibrator lots, wrong calibrator values, improperly prepared reagents, changes in sample volume caused by misalignment or mis-adjustment, and deterioration of photo lamp source.
- Determine whether single test or multiple tests are affected
- Follow manufacturer troubleshooting guides to resolve issues

REFERENCES

1. QC - The out-of-control problem - Westgard. Retrieved September 25, 2022.

All Revision Dates

7/27/2024, 9/26/2022, 6/16/2006

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	7/26/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	6/29/2024

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100.011 Hospital Visitation

POLICY:

In order to ensure the safety and security of patients, employees and volunteers of Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH), to maintain an orderly environment and assist patients and visitors with finding their destination, there is controlled access to both facilities. Hospital visitation guidelines are available in English and Spanish in the Patient Information Booklet.

At designated entrances only, all guests will be required to check in as either a visitor or a vendor and will then be issued a wrist band or vendor identification (ID) badge.

Hospital visitation will not be restricted, limited or otherwise denied based on age (with the exception of children <13 year old), race, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, and gender identity and expression.

PROCEDURE:

There are specific designated entrances at both VCMC and SPH available for patients, visitors, vendors and employees. Any person in the hospital without a visitor or vendor wrist band, vendor ID badge or employee badge should be directed to one of the hospital entrances so that they may sign in and be issued a wrist band or vendor ID badge.

HOSPITAL VISITATION GUIDELINES

For the welfare of our patients and to contribute to each patient's recovery, we urge all visitors to observe the following visitation guidelines:

A. Regular visitation hours are from 9:00 a.m. to 9:00 p.m. daily.

B. Patient visits should not exceed two (2) visitors at any given time, unless there is a special circumstance and approved by the Department Manager or House Supervisor.

C. Visitors must be in good health. Visiting is not allowed if the visitor is ill.

D. Visitors are required to comply with all hospital infection control policies.

    1. Visitors of Neonatal Intensive Care Unit (NICU), Pediatrics Unit, Pediatric Intensive Care Unit (PICU), immunocompromised or other high-risk patients may be asked to mask based on community prevalence of respiratory illnesses or at the discretion of the provider or nurse in charge.

E. Shoes and shirts are required for all visitors.

F. Service animals will be allowed entrance. See policy *107.076 Accessibility - Animals in Healthcare Facilities* for more information.

G. No visitors under the age of 13 are permitted in patient care areas unless they are the parents of hospitalized children, the significant other of a laboring person, a brother or sister of a child who is a patient in NICU, Pediatrics Unit, PICU, Obstetrics Unit (OB) or family members of a terminally ill patient. Visitors meeting this criteria may visit under these conditions:

    1. Siblings may visit during regular visitation hours only. They must be accompanied by a responsible adult.
    2. Siblings must be in good health, as determined (when necessary) by a nurse or physician on the unit.

H. If the patient is under guard surveillance, clearance should be made through the arresting agency before anyone can visit the patient.

I. Noise levels should be kept to a minimum in the corridors and while in patient rooms.

J. No food should be brought in from outside the hospital unless approved by physician and/or nursing staff. Visitors should only eat in patient areas after conferring with nursing staff. Visitors may go to the cafeteria to purchase food.

K. Smoking is prohibited anywhere on hospital grounds, including all parking areas. Smoking includes the use of cigarettes, cigars, water pipes, pipes, hookahs, marijuana (including medical marijuana) and electronic smoking devices, such as e-cigarettes and vaping pens. There are no designated smoking areas on Hospital property. See policy *106.004 Smoking Policy* for more information.

L. Fresh or dried flowers, or potted plants, are not allowed in patient-care areas for immunosuppressed patients.

M. Pediatrics Unit and Pediatric Intensive Care Unit (PICU) - We invite parent participation in the Pediatrics and PICU Unit. One parent may stay with the patient at all times as space allows. Grandparents or other significant adult(s) may visit with a parent, unless otherwise specified. Prior to sibling visitation in the PICU, a joint discussion concerning the risks and benefits of visitation will be had with the charge nurse, Child Life Specialist, physician and parents. See policy *P.32 PICU, NICU and PEDS Visiting Policy* for more information.

N. Neonatal Intensive Care Unit (NICU)-We invite parent participation in the NICU Unit. Parents will be required to wear their identification armband when visiting. One parent may stay with the patient at all time as space allows. Grandparents or other significant adult(s) may visit

with a parent unless otherwise specified. See policy *P.32 PICU, NICU and PEDS Visiting Policy* for more information.

O. Emergency Department

1. No children under the age of 13 unless they are the patient, the parent of a patient, or the support person of a pregnant person.
2. Children must be accompanied by an adult, when in the ED or the waiting room.
3. In critical situations, family members can stay at bedside at the nurse's discretion.
4. To provide a safe environment, visitors are asked to refrain from multiple entries and exits from the patient care area.
5. The ED is not to be used as a thoroughfare to other areas of the hospital. Visitors should use an alternate entrance to gain entry into the hospital, with the exception of off hours when the front lobby is closed.
6. Visitation for ED Hold patients will follow the rules for visitation in the ED.

P. Addiction Medicine Unit (ADM)

1. There are no overnight visitors permitted in this unit. Visitation remains from the hours of 9:00 a.m. to 9:00 p.m. daily.
2. Due to potential for foodborne illness and/or contraband, family and visitors are asked not to bring food from the outside to ADM patients in the hospital. The Dietary Services department will make every effort to accommodate the dietary requests of the patients.

Q. Obstetrics Unit

1. The support person of the patient may stay in post-partum or ante-partum overnight. A sibling must be accompanied by an adult. The support person will receive an identification bands at the time of delivery.

R. Post Anesthesia Care Unit (PACU) - Visitors will be restricted to the parent(s) of a minor, the parents(s) or caregiver of persons with special needs and under special conditions.

S. Visitation hours for the Inpatient Psychiatric Unit (IPU) are Monday through Friday, 5:30 p.m. through 7:20 p.m., and on weekends and holidays, 12:30 p.m. to 2:30 p.m. We do attempt to accommodate visits during times other than those posted on an individual basis. It requires a physician's order and should be arranged in advance.

T. Exceptions to the visitation policy may be made in extenuating circumstances. This will be done with collaboration between Medical Staff, Nursing Supervisor, the patient and their family.

U. In the event of an infectious disease outbreak, the visitor policy may be adjusted at the recommendation of the Infection Control Committee, the Medical Director of Infection Control and Prevention, or the Hospital Chief Medical Officer. If adjusted, the policy will be reviewed on a monthly basis.

The VCMC entrance will be open daily from 5:00 am until 9:00 pm. The Customer Service desk at VCMC will be staffed by one to two Security Guards 24 hours a day, 7 days a week, as well as a Customer Service employee from 5:00 am to 9:00 pm. At SPH the entrance will be open from Monday through

Friday 6:30 am to 9:00 pm and Saturday through Sunday 8:30 am to 6:30 pm. Entrance can be gained through the Emergency Department when the front lobby is closed.

Upon entering, guests will check in as a visitor or a vendor and be issued either a wrist band or vendor ID badge. Employees entering the facility through the Main Entrance must wear hospital ID badges. Employees without hospital ID badges will be issued a visitor wrist band which must be worn for the duration of their time spent in the Hospital. If a visitor or vendor is noted anywhere in either hospital without an wrist band or vendor ID badge, they will be instructed to obtain a wrist band or vendor ID badge. All vendors shall comply with policy *106.083 Vendor Access and Registration*.

Emergency Department Entrance. The ED at VCMC and SPH will be staffed with a Security Guard 24 hours a day, 7 days a week.

VCMC Hillmont Surgery Entrance. This entrance will be designated for staff and providers only via badge access. No patients, visitors or vendors will be permitted to enter the Hospital through this entrance. Staff and providers may enter through this entrance 24 hours a day, 7 days a week.

VCMC Loma Vista MRI Trailer Entrance. This entrance will be designated for staff and providers only via badge access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff may enter through this entrance 24 hours a day, 7 days a week.

VCMC Radiology Entrance. This entrance is closed to everyone.

VCMC Lab Entrance. This entrance will be designated for staff and providers only via badge access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff and providers may enter through this entrance 24 hours a day, 7 days a week.

VCMC Boardwalk Entrance. This entrance will be designated for staff and providers only via badge access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff and providers may enter through this entrance 24 hours a day, 7 days a week.

SPH Staff Entrance. This entrance will be designated for staff and providers only via badge access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff may enter through this entrance 24 hours a day, 7 days a week.

REFERENCE:

Patient Information Booklet. Ventura County Medical Center and Santa Paula Hospital. [VCHCA-505-050 (01/2020)]

All Revision Dates

8/5/2024, 5/29/2024, 2/26/2024, 1/2/2024, 9/18/2023, 7/6/2023, 3/8/2023, 11/22/2017

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	8/5/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/30/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/30/2024
Policy Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/30/2024

VENTURA COUNTY MEDICAL CENTER

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CONFIDENTIAL

Medical Executive Committee Document Approvals

August 2024

a. Policies & Procedures / Forms / Orders

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*10/1/1986*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*7/15/2024*
Next Review:	*3 years after approval*
Owner:	*Jason Arimura: Associate Hospital Administrator-AncillaryServices*
Policy Area:	*Administrative - Patient Care*
References:	

100.273 Surgical Specimen Handling for Pathology Review

POLICY:

This policy outlines the procedure for preparing and submitting pathology specimens to the Laboratory within Ventura County Medical Center (VCMC), Santa Paul Hospital (SPH) and Ambulatory Care (AC) clinics.

PROCEDURE:

Wherever surgical procedures involve removal of tissues, including "foreign bodies," ~~whether in Operating Rooms, Outpatient Departments (OPD's), Ambulatory Care (AC) clinics, wards or physician offices,~~ the following procedures are to be adhered to in preparing and submitting such specimens to the Laboratory:

A. It is California State law and required by The Joint Commission (TJC) that ~~**ALL**~~ all surgically removed material, tissue and non-tissue~~,~~ be submitted to the Laboratory as soon as reasonably possible~~,~~ following removal with the exception of those listed under section *Exempt Specimens*. ~~The tissue types and other items that may be exempted from this requirement under the law, are on file in the Laboratory.~~

B. Regardless of exceptions and/or exemptions, gross and microscopic examinations will be performed:

   1. Whenever the attending physician requests it or
   2. At the discretion of the pathologist when such examinations are indicated by the clinical history.

C. The specimens shall be placed in a properly labeled container bearing the name of the patient, the patient's medical record number, the date the specimen was removed, the patient's attending physician, the identity of the specimen removed and where the request originated (i.e. surgery, clinics, Pharmacy, etc.). This data **must** accompany each specimen or group of specimens.

D. When specimens or biopsies are removed from different locations, they **must** be placed in separate, properly labeled containers and be properly identified.

E. Tissue specimens should be placed in a container of adequate size, to allow for the tissue to be submerged in formalin, with at least 4-5 parts of formalin to tissue (where practicable).

F. All frozen section requests should be made well in advance (at least 24 hours) of elective procedures. In emergency surgeries, the Pathologist should be contacted as soon as it becomes apparent that a frozen section may be ordered.

   1. Tissue for rapid frozen section examination must not be fixed in any solution; it is preferably submitted in a small sterile container such as a Petri dish. Whenever a lymph node is to be examined

during normal Operating Room hours (7:30 am to 6:00 pm), a Pathologist should be notified so that the lymph node can be delivered fresh, to allow for special processing.

2. Lymph nodes and tissue specimens suspected of an infectious process, should be brought promptly to the Laboratory in a sterile container, without fixative, so that culture studies can be performed. Alternately, a portion of the specimen may be removed in the Operating Room under sterile conditions and submitted separately for culture studies. The remaining portion of lymph node then may be placed in formalin and submitted as usual, if a Pathologist cannot be contacted during the evening and night hours. Every effort should be made to obtain the lymph node while a Pathologist is available.
3. Specimens that are too large to fit into a container should be wrapped in plastic or toweling and sent to the Laboratory as soon as possible. **Do not allow unfixed specimens to stand at room temperature for over a half hour** .
4. Unusually large specimens, for example amputated limbs, should be taken immediately to the Laboratory during regular Operating Room hours. ~~During evening and night hours, such large specimens should be placed in the large refrigerator in the Morgue (Hospital Security staff have the keys), and the Laboratory should be informed by submitting an order to request examination, within the patient's Electronic Health Record (EHR).~~

G. Prompt delivery of specimens to the Laboratory will aid substantially in swift processing. If you are uncertain as to where to deliver a specimen, give it to a Laboratory Technologist on duty or inform the Pathologist on call.

H. Tissue specimens removed during off-hours (i.e. at night or on weekends) and which are too large to place in formalin within the usual containers, must be placed in the refrigerator in the Laboratory. The Laboratory Technologist on duty or the Pathologist on call must be informed.

1. Unusually large specimens that will not fit in the refrigerator in the Laboratory should be placed in the large refrigerator in the Morgue (Hospital Security staff have the keys), and the Laboratory should be informed by submitting an order to request examination, within the patient's Electronic Health Record (EHR).

I. All large specimens will be better preserved if they are refrigerated even if they can be immersed in formalin. This is because of difficulty in penetration beyond 1.~~5-2~~5 - 2 cm (the refrigeration retards tissue autolysis only).

J. ~~**Body Secretions**: In the instance of aspirated fluid specimens (thoracentesis, paracentesis, joint aspirations, kidney and breast cyst contents, cerebrospinal fluid, bronchial aspirations, abscess contents) it is often appropriate to prepare a portion of the fluid for **tissue block preparation** and the remainder for Pap smears of its sediment. In such instances, submit one portion of the fluid specimen fixed in equal volume (approximate) of 95% alcohol for tissue block preparation; the remaining fluid should be **sent immediately to the Laboratory for immediate centrifugation** and Pap smear preparation. Inform a Laboratory technologist to call the Pathologist or call for directions.~~

~~**NOTE**: Pap smears and Thin Preps prepared from fluid specimens that have been allowed to stand, **refrigerated or unrefrigerated**, may be unsatisfactory for examination because the cells can break down. Drying artifact can be prevented by either placing the slides in 95% alcohol or spraying the sticks to preserve cellular detail.~~**Body Secretions**

1. Body secretions include fluid from thoracentesis, paracentesis, joint aspirations, kidney and breast cyst contents, cerebrospinal fluid, bronchial aspirations, abscess contents and aspirated fluid

specimens.

2. If microbiology orders are placed, the specimen should be placed in a sterile container and deliver to the microbiology lab.
3. If microbiology lab is not needed, then the specimen should be placed in the appropriate container with an equal volume of 95% alcohol and sent to the laboratory. If alcohol is not available, it can be sent fresh to the lab but must be delivered immediately where 95% alcohol can be added to the specimen.
    a. A portion of the fluid will be prepared for cytospin or smear, and will be stained with Pap stain.
    b. If additional material is present, a cell block tissue preparation can be prepared for hematoxylin and eosin (H&E) stain.
4. Consult with a Laboratory Technologist for any questions or further directions.

K. **Bullet and/or Knife Wounds**: California law requires that all physicians who treat bullet wounds or suspected knife wounds report this immediately to the local, appropriate law enforcement agencies, as soon as possible. This law overrides the confidentiality of the physician/patient relationship. This should be done as soon as possible and it is the responsibility of the Nursing Supervisor to remind the physician of this responsibility and to report to ~~her~~ supervisor if this task is not carried out.

   Bullets should be removed as carefully as possible, with knives, forceps or scissors, to **avoid indentation and/or any mark** on the bullet, which may interfere with ballistic testing. The bullet, eventually, should be given to the appropriate Sheriff's Deputy or Police Officer so that the legal chain of evidence, regarding identification of the specimen, is not broken. It is recommended that the specimen be sent to the Laboratory for documentation before turning it over to the appropriate Law Enforcement Agency. If it is returned to the Hospital after the investigation, by the law enforcement agency, the bullet should then be sent to the Pathology Department for documentation. Later, the specimen may be returned to the patient if they so desire.

   For more information, refer to policy *100.036 Disposition of Foreign Bodies Removed for Legal Evidence*.

L. Questions regarding surgical pathology specimens should be directed to the Pathologist who can be contacted via the Laboratory.

~~See the Nursing Manual for detailed procedures.~~

~~Questions regarding surgical pathology specimens should be directed to the Pathologist who can be contacted via the Laboratory.~~

Exempt Specimens

A. The following tissue specimens or implants do not need to be sent to Surgical Pathology for examination unless requested by the attending physician.
    1. Skin and tissue removed during cosmetic surgical procedures from body areas that have not had prior non-cosmetic surgery and can be reasonably examined visually in the operating room for pathological changes. This would include tissues obtained from procedures such as blepharoplasties, rhinoplasties, otoplasties, and rhytidectomies, as well as non-tumorous adipose tissue from liposuction, dermabrasion or chemosurgery. Note: Specimens containing breast tissue do not qualify for exclusion from examination by a pathologist.

2. Myringotomy tubes.
3. Teeth removed during routine dental care.
4. Placentas from uncomplicated deliveries/pregnancies.
5. Neonatal foreskins (if patient is less than 4 weeks of age).
6. Cataracts, paracentesis of anterior chamber, removal of vitreous.
7. Therapeutic radioactive implants.
8. Arthroscopy shavings,bone removed exclusively for exposure.
9. Donor fibroadipose tissue.
10. Remnant vessel from reconstructive procedure.
11. Toenails and fingernails.
12. Bunions and hammertoes.
13. Orthopedic hardware.
14. Joint contents (e.g. bone, cartilage, ligament, meniscus, tendon, synovium) from total joint arthroplasty.
15. Musculoskeletal tissue for which pathological examination is deemed not necessary as determined by the surgeon.

B. Regardless of exceptions and/or exemptions, gross and microscopic examinations will be performed:
   1. Whenever the attending physician requests it, or
   2. At the discretion of the pathologist when such examinations are indicated by the clinical history.

C. Documentation of the removal and disposition of specimens and devices not sent to Pathology is the responsibility of:
   1. Attending Surgeon
   2. Department/Service where such specimens are removed.

D. The vast majority of specimens accessioned in the Surgical Pathology Laboratory receive a microscopic examination. However, certain specimens such as foreign bodies (glass fragments, splinters, etc.) and breast implants receive a gross examination only. The type of examination (gross or microscopic) performed on specimens received in the laboratory is at the discretion of the pathologist.

All revision dates: 7/15/2024, 3/9/2021, 5/1/2006, 8/1/2001, 10/1/1995

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Surgery Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending

Step Description	Approver	Date
Laboratory Services	Brad Adler, MD: Medical Director, Laboratory Services	6/17/2024
Laboratory Services	Erlinda Roxas: Director, Laboratory Services	6/17/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/17/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/17/2024
Policy Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices	6/17/2024

VENTURA COUNTY
HEALTH CARE AGENCY

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Owner:	*Melody Donate: Stroke Coordinator*
Policy Area:	*Administrative - Nursing*
References:	

108.027 Nursing Swallow Screen

POLICY:

The Nursing Swallow Screen Protocol may be used to screen for impaired swallowing in high risk populations such as stroke, degenerative neurologic disease, head and neck cancer/surgery. The purpose of this policy is to establish a standardized procedure for nursing in assessing a patient's ability to swallow, before providing the oral intake of fluids, food or medication, thereby reducing the risk for aspiration.

It is the policy of VCMC/SPH to conduct swallow screens on patients considered at risk for aspiration. A swallow screen will be utilized and the findings will be documented. Nursing will implement the appropriate physician order in response to the findings of the swallow screen. Should neurological deterioration occur, nursing will perform another swallow screen.

PROCEDURE:

A nurse competent in swallow screening (see Attachment A, *Competency Checklist*) will accurately identify potential patients at risk for aspiration and perform a "Three step swallow screen" (see below). First, the patients' presentation and past medical history will be reviewed to identify the predisposition for aspiration. Secondly, a simple 3 ounce water test will conducted. The nurse will proceed to the third step if the patient tolerates 3 ounces of water. Third, two (2) sips of water will be conducted and a determination will be made for a pass or fail status. The "Three step swallow screen" will be conducted to determine if patients are at risk for clinically significant aspiration or require a speech referral for a definitive swallow evaluation.

NOTE: The 3 ounce water swallow screen is not intended to be a comprehensive dysphagia evaluation, nor does the screen replace a formal speech therapy consultation and evaluation.

Three Step Swallow Screen

Steps	Assessments	Actions
Step 1:	Physical presentation- Signs/symptoms Medical History • Commands- can't follow • Glasgow score less than-13 • Combative or lethargic • Voice- none or gurgles • Drools or can't manage secretions	If patient has any of the findings, **STOP** the swallow screen • Keep the patient NPO and do *not* proceed with the swallow screen. • Document: Patient failed Step 1 of Swallow screen • Keep patient NPO including oral

Steps	Assessments	Actions
	• Cough- weak or absent • Lips-can't close • Severe facial asymmetry • Tongue- asymmetry or can't move • Palate asymmetry • No rise of larynx during swallowing • Feeding tube present Past medical history • Prior stroke and dysphagia • Parkinson's • ALS, Multiple Sclerosis Dementia • Neurodegenerative disease • Cranial neurosurgery • Prior dysphagia • Baseline coughing • Recurrent or current pneumonia	medications If not already addressed, contact the physician for further orders, such as: • formal swallow evaluation by speech • seek order for alternate routes if indicated If patient has none of these conditions listed under physical presentation and past medical history, proceed to Step 2.
Step 2:	Before the "One sip of water (3 ounces of water) test" is started, the nurse ensures the following: • Patient is upright 90 • Suction and towel available • Mouth is moist and clean • Patient is alert • Patient is able to follow simple commands • Patient does not display a facial droop • Patient has understandable speech The patient will be instructed to take **one** sip of water (do not use straws). The nurse will observe for the following: • Water dribbling or drooling from mouth • Swallow multiple times • Immediate cough or within one minute of swallow • Voice Quality is wet or gurgling Note: If patient does not exhibit impairments after 3 ounces of water, proceed to Step 3, "Water-2 - sips ."	If patient has any of the findings in Step 2, **STOP** the swallow screen • Keep the patient NPO including oral medications and do *not* proceed with the swallow screen. • Document failed screen (Step 2) in the medical record. • If not already addressed, contact the physician for orders, such as: ◦ formal swallow evaluation by Speech ◦ orders for strict NPO for all food, fluids meds ◦ seek order for alternate routes if indicated If patient does not exhibit any of the impairments listed, after the one sip of water test, proceed to Step 3.
Step	Before the "two sips of water" test" is started,	If the patient exhibits impairment in any of the

Steps	Assessments	Actions
3	the nurse ensures the following: • Patient is upright 90 • Suction and towel available • Mouth is moist and clean • Patient is Alert • Patient is able to follow simple commands • Patient does not display a facial droop • Patient has understandable speech Instruct patient to take **2 sips** of water (no straws) and observe for: • Water dribbles or drools from mouth • Swallow multiple times • Immediate cough or within one minute • Voice quality becomes is wet or gurgling Note: If patient does not exhibit impairments after 2 sips of water, the screen is completed.	Step 3 assessments, **STOP** and: • Keep the patient NPO including oral medications • Document failed screen (Step 3) • If not already addressed, contact the physician for orders, such as: ◦ formal swallow evaluation by speech ◦ orders for strict NPO for all food, fluids meds ◦ seek physician order for alternate routes of nutrition, fluid and medication if indicated If patient does not exhibit any of the impairments, after the 2 sips water tests ,the screen is completed and the patient passed the swallow screen Follow the physician's prescribed orders for diet and nutrition intake • If not already addressed, contact the physician for a diet and nutrition order.

REFERENCES:

Fedder, W. N. (2017). Review of evidenced-based nursing protocols for dysphagia assessment. *Stroke*, *48*(4), e99-e101

Palli, C., Fandler, S., Doppelhofer, K., Niederkorn, K., Enzinger, C., Vetta, C., ... & Gattringer, T. (2017). Early Dysphagia Screening by Trained Nurses Reduces Pneumonia Rate in Stroke Patients: A Clinical Intervention Study. *Stroke*, *48*(9), 2583-2585.

The Joint Commission. Advanced Primary Stroke Center: Appendix. 2017. Retrieved from www.jointcommission.org

All revision dates: 7/19/2018, 7/1/2015

Attachments

A: Competency Checklist

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/12/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/12/2024
Policy Owner	Melody Donate: Stroke Coordinator	7/12/2024

VENTURA COUNTY HEALTH CARE AGENCY

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Owner:	*Kristina Swaim: Clinical Nurse Manager, OB*
Policy Area:	*Maternal Child Health*
References:	

MCH.14 Hypoglycemia in the Newborn

POLICY:

In most newborns, low blood sugar concentrations are not reflective of any particular problem, but rather representative of the transition to the extra-uterine metabolic state. The precise definition of hypoglycemia for every newborn in regard to gestational age, birth weight, metabolic needs, and illness or their wellness remains quite controversial. For the healthy term infant born after an uneventful pregnancy and delivery, recommendations are to monitor glucose levels only if risk factors are present.

This policy describes nursing actions necessary to ensure newborns are accurately identified, provides guidelines for the management of the newborn who is at risk for, or exhibits signs and symptoms of, hypoglycemia. Newborns which meet criteria and/or present with signs and symptoms as described shall be screened and treated for hypoglycemia. Newborns not meeting criteria for screening and not presenting with signs or symptoms of hypoglycemia shall be managed using standard procedure for preventing hypoglycemia. Skin-to-skin contact between mother and infant as soon as possible following birth will help maintain normal infant body temperature and reduce infant energy expenditure and can help maintain normal infant blood glucose levels. It will also stimulate infant suckling and maternal milk supply.

PROCEDURE:

A. Blood Glucose (BG) screening in the Perinatal units shall be performed on newborns who are at risk for, or exhibit signs of hypoglycemia.

1. The newborns BG will be checked via heel stick after warming the heel for at least three (3) minutes.
2. The physician or registered nurse (RN) will be responsible for identifying newborns that need to have glucose screening, feedings and dextrose gel following the algorithm: ***Hypoglycemia Algorithm*** **(Attachment A).**
3. Immediate skin-to-skin and breast feeding should be initiated within the first hour of life prior to the first BG check whenever possible.
4. If BG is less than 20, give glucose gel, contact Neonatal Intensive Care Unit (NICU) charge nurse or Neonaologist for consultation. Consider admission to NICU.
5. Up to 6 doses of dextrose gel may be given within 48 hours of birth as per the ***Hypoglycemia Algorithm. (Attachment A)***

B. The following factors will indicate a blood glucose check if not symptomatic within **1** hour of birth and screening for **12** hours following birth are:

1. **Risk Category**:
    a. An Apgar score of 6 or less at 5 minutes
    b. Infants of diabetic mothers (IDM)
    c. Large for gestational age (LGA) or ≥ 4000gm see chart

C.The following factors will indicate a blood glucose check if not symptomatic within **1** hour of birth and screening for up to **24** hours following birth are:

2. Risk Category:
    a. Small for gestational age (SGA) or BW ≤2500 grams
    b. Late preterm 35 0/7-36 6/7 weeks gestation
    c. Congenital Syndrome or midline abnormalities

D. The following requires immediate BG check upon demonstration of symptoms and notify physician, consider notifying the NICU Charge Nurse or Neonatologist for consultation.

a. Jittery, tremors, seizures

b. Lethargy, poor feeding

c. Apnea, respiratory distress

d. Hypotonic, floppy, irritable

e. Exaggerated Moro

f. High pitched, feeble cry

GUIDELINES:

Appropriate hand hygiene and glove use prior to patient contact shall be followed. Apply heel warmer for three minutes. Cleanse with alcohol. Use a lancet to pierce the heel using the lateral and medial posterior surface of the infant's heel. Wipe the initial blood drop and then collect sample (discard lancet appropriately).

A. **Glucose Screening** - Follow ***Hypoglycemia Algorithm*** **(Attachement A)**
    1. An asymptomatic newborn with risk factors may be transferred to couplet care after two consecutive BG results greater than 40 ml/dl. Continual BG checks every 2-3 hours prior to feeding for 24 hours. Treat according to Hypoglycemia Alogrithm, with no more than six (6) gel administrations in 24 hours.
    2. A newborn with signs and symptoms of hypoglycemia without risk factors may be transferred to couplet care after two consecutive BG results greater than 45 ml/dl. BG checks will continue every 2-3 hours prior to feeding until 3 consecutive BG results have reached 45 ml/dl. No further BG POCT are required, unless newborn again becomes symptomatic.

B. **Administration Guidelines**-Refer to Weight-Based Neonatal Dosing Guidelines **(Attachment A)**
    1. Squeeze Glucose gel into medication cup. Draw-up desired amount of gel based on weight of newborn.
    2. Dry the inside of the buccal mucosa with a gauze (2x2)
    3. Squeeze half of the dose onto gloved finger and massage into the buccal mucosa.

4. Repeat same steps on the opposite side of newborn with remaining half dose of glucose gel. DOCUMENTATION

    - All BG results shall be documented in the electronic health record (EHR)
    - Document dextrose gel in the Medication Administration Record
    - Document interventions performed

References:

- Bennett, C., Fagan, E., Chaharbakhshi, E., Zamfirova, I., Fricker, J. Implementing a Protocol for using gel to Treat Neonatal Hypoglycemia. Nursing for Women's Health February-March 2016.
- Harris D., Weston P., Battin M., Harding J.E. Dextrose Gel for Treating Neonatal Hypoglycemia: A Randomized Placebo-Controlled Trial (Sugar Babies Study). Lancet, 2013 published online 25 September
- AAP (2013). Management of Hypoglycemia in the neonate. http://www2.aap.org/sections/perinatal/pediatricians.html
- Rozance and Haye (2016). "New approaches to management of neonatal hypoglycemia." Rozance and Hay. Maternal Health, Neonatology and Perinatology (2016) 2:3

All revision dates: 5/30/2024, 12/8/2020, 2/18/2020, 4/1/2016, 2/1/2014, 7/1/2012, 5/1/2011, 3/1/2010, 9/1/2009, 11/1/2004, 11/1/2001, 3/1/2001

Attachments

OB Hypoglycemia Algorithm Flyer wDosing Chart 08-21-19.pdf

Approval Signatures

Step Description	Approver	Date
Pediatrics Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	6/13/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/1/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	5/30/2024
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	5/30/2024

VENTURA COUNTY HEALTH CARE AGENCY

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Owner:	*Jennifer Ferrick: Director, Peds/ PICU & NICU*
Policy Area:	*NICU*
References:	

N.27 NICU Discharge Criteria

POLICY:

~~To identify guidelines for discharge from the Neonatal Intensive Care Unit (NICU).~~

To identify guidelines for discharge from the Neonatal Intensive Care Unit (NICU). Case management includes discharge planning, which begins with admission to the NICU and is based on expected infant outcomes and family abilities, resources, and expectations. Coordinated, comprehensive discharge planning with a safe transition to home is critical for the health and well-being of high-risk infants and their families.

PROCEDURE:

Infants discharged from the ~~NICU~~Neonatal Intensive Care Unit will meet established criteria. Discharge planning begins on NICU admission and continues throughout the hospitalization.

EXCEPTIONS

If the infant's clinical condition precludes normal nipple feeding, the parent/caretaker shall be instructed in an alternate feeding program according to physician's order.

The following infants shall be referred to the discharge ~~planner~~coordinator/case manager assigned to the ~~NICU~~Neonatal Intensive Care Unit:

1. Those requiring other methods of feeding, such as gastrostomy tube (G-tube) or gavage feeding
2. Those being discharged on oxygen or with a home apnea monitor
3. Those requiring durable medical equipment (DME) or home health supplies (i.e., ~~G~~gastrostomy-tube or ostomy supplies)
4. Those requiring special formula
5. Those being discharged to hospice or requiring home health nursing services
6. Those being discharged to a caregiver other than the parents (i.e., foster care) or being discharged to an extended care facility

GUIDELINES

Discharge orders will be based upon physiologic stability, parental readiness, and a coordinated discharge plan. Criteria for discharge include:

A. Infant:

1. The ability to maintain an axillary temperature of at least 36.5 degrees Celsius in an open crib when the amount of clothing worn and the room temperature are appropriate.
2. The ability to tolerate oral feedings by breast/bottle or tolerating gastrostomy tube (G-tube) feeds; if appropriate, parent education and arrangements for supplies have been made.
3. Gaining weight at an appropriate rate (premature infant).
4. Without apnea or bradycardia requiring intervention for at least ~~five~~three (~~5~~3) days or discharged home on an apnea monitor and/or Caffeine therapy once stabilized and appropriate education completed and equipment obtained.
5. Infants with a chronic stable ~~FiO_2~~oxygen requirement may be discharged home on oxygen via nasal cannula ~~(NC)~~. Infants being sent home on oxygen ~~(O2), providing they require <0.3 LPM of O_2. Infants being sent~~via nasal canula must have appropriate arrangements for home ~~on NC O_2 must have appropriate arrangements for home~~ oxygen delivery.
6. Able to maintain adequate oxygen saturation in a car seat per MCH.05 Car Seat Challenge, as indicated
7. Infant discharged on home monitor/apnea monitor will have teaching on monitor application and maintenance from monitor rep.

B. Parents/~~Caretakers~~Caregivers:

1. Educated about and competent to feed the infant.
2. Competent to give any medications the infant needs. Parents are given written information regarding all medications including name, action, dose, route, side effects, and schedule. Prescription medications should be obtained prior to discharge.
3. Participate in an infant CPR class and Trained in infant cardiopulmonary resuscitation.
4. Demonstrate ability ~~and comfort~~ in providing care for the infant at home (parent teaching of well baby care shall be provided, which includes feeding, bathing, car seat safety, proper positioning (supine) for sleep; signs of illness, how to take a temperature, and when to call a doctor.)
5. Given the option to "Room In" (stay overnight) and provide independent care of their infant with a professional caregivers nearby for assistance prior to discharge if medically or socially indicated.
6. Parents demonstrate an understanding and agreement with the discharge plan including their infant's need for ophthalmologic follow-up and ~~Synagis~~RSV (Respiratory Syncytial Virus) prophylaxis as indicated and given necessary follow-up appointment dates.

C. Care team:

1. Ensure the state newborn screen has been done on all infants.
2. Ensure infants at risk for retinopathy of prematurity (ROP) have had an eye examination.
3. Ensure a hearing screen has been performed.
4. Ensure ~~cyanotic~~critical congenital heart defect (CCHD) screening has been performed.
5. Appropriate immunizations have been administered with instructions for follow-up.
6. Identify whether the infant requires ~~Synagis (Respiratory Syncytial Virus (~~RSV~~)~~ prophylaxis~~)~~. Provide appropriate treatment prior to discharge and/or recommendations for follow up.

7. Nutritional risks have been assessed, and dietary modification instituted, as indicated.
8. Hematologic status has been assessed and appropriate therapy instituted, as indicated.
9. A developmental exam has been performed on infants at risk for developmental delay.
10. Follow-up clinic appointment(s) have been scheduled and discussed with parents/~~caretakers~~caregivers.
11. Public Health Nurse or Visiting Nurse referral has been made as indicated.
12. Minimum discharge weight is ~~2000~~1800 grams, or at the discretion of the neonatologist.
13. Review of hospital course has been completed, unresolved medical problems identified, and plans for treatment instituted.

D. Written home care instructions shall be provided to parents. Discharge materials and information will be culturally and linguistically appropriate and can be provided in various formats:
   1. Written Materials
   2. Video
   3. Demonstration/return demonstration

E. Forms/items to be completed prior to discharge:
   1. Newborn Hearing Screening – Infant Reporting Form with Audiology referral arranged if hearing screen failed after two attempts.
   2. Newborn State Screening.
   3. Newborn Discharge Instructions completed.
   4. Immunization Record in CAIR2(California Immunization Registry) and Cerner.
   5. Multidisciplinary Discharge Planning Worksheet.
   6. Prescriptions – evaluation of caregiver ability to provide/follow-up prescriptions
   7. Documentation of follow-up appointments given to caregiver

F. Document patient condition at discharge in nursing notes and parental understanding of discharge instructions; document use of qualified translator, if applicable. Obtain duplicate copy of discharge instructions with mother's signature.

G. Physician has completed Discharge Note with copy to parents and follow-up Primary Care Physician/ Pediatrician.

REFERENCES:

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Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Pediatrics Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/17/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/17/2024
NICU	Jennifer Ferrick: Director, Peds/PICU & NICU	6/17/2024
NICU	Melissa Krebs: Director, NICU	6/3/2024

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N.37 Monitoring Neonates in the NICU

POLICY:

Define the standards of care for the Neonatal Intensive Care Unit (NICU) infants and their families that reflect utilization of the nursing process, are evidenced-based, and recognize that each infant is a unique individual with the right to developmentally supportive care environment.

All nursing care is provided in coordination and collaboration with the multidisciplinary health care team and the family to implement an individualized plan of care. The plan of care is continuously evaluated and updated. Neonatal nurses will assess, determine the diagnosis or issue, plan, identify expected outcomes, implement, coordinate, promote health and a safe environment, evaluate, and document the infant's plan of care to promote optimal outcomes.

Standards of Care reflect the values and priorities for the minimum level of nursing care for a neonate receiving care in the NICU.

Nursing staff in the neonatal care areas will be knowledgeable about and adhere to all applicable unit and hospital policies

The NICU provides a family centered care approach to nursing care recognizing that the parents are the core of the infant's long term support and development. The comprehensive approach facilitates meeting all the needs of the infant and family specifically related to disease, emotional/spiritual support, financial needs, and post discharge support.

Parents are recognized as an integral member of the health care team, involved in care of their infant upon admission and throughout the stay to optimize the bonding process, smooth transition to home or palliative care, and help parents make the best informed decisions for their infant.

Racial, ethnic, cultural, and socioeconomic diversity of the family is honored.

Frequency of "hands on" vital signs, assessments and appropriate interventions are performed according to the infant's acuity and ability to tolerate such handling.

PROCEDURE: PROCESS CRITERIA

A. All infants admitted to the NICU are continually monitored for cardiac/respiratory function with alarm systems activated.

B. Infants with cyanosis, respiratory distress, apnea, altered consciousness/sedation or requiring any mode of respiratory support are monitored with a pulse oximeter.

C. A transcutaneous oxygen/carbon dioxide monitor may additionally be used, usually to monitor $C0_2$ levels in parallel comparison with blood gas measurement.

D. Recognize and address life -threatening clinical signs.

E. Perform and document an initial physical assessment within 2 hours of admission, including airway, breathing, circulation, tone, level of consciousness, vital signs, pain and comfort.

F. Perform a comprehensive assessment in the first 12 hours of admission then every shift.

G. The Nurse is responsible for admission measurements including weight, length and head circumference..

H. Determine the need for support services and initiate referrals.

I. Complete an emergency medication reference based on current weight and post it in a designated area. The emergency medication reference is updated weekly or at other defined intervals with the current weight.

J. Apply identification bands per hospital policy.

K. Initiate a written or computerized multidisciplinary and individualized plan of care. Continually evaluate the plan of care and document updates at least every 24 hours.

L. Orient parents/families to the unit and inform parents/families regarding handwashing, infant security, and visitation policies. Document parent orientation to the unit.

M. The Nurse will weigh each medically stable infant daily.

N. Daily weight may be deferred for medically unstable infants per MD order.

O. The Nurse will measure head circumferences (OFC) and length weekly on Sunday night.

GUIDELINES FOR NURSING CARE AND MONITORING BASIC LEVEL OF CARE FOR ALL INFANTS

The nurse evaluates and records vital signs as part of the patient assessment. Heart rate and respiration may be alternately recorded from the monitor on critically ill infants to avoid disturbing them more often than every two hours. The nurse will obtain temperatures axillary unless a medical order specifies otherwise. The nurse will notify the physician if the vital signs are out of ordered limits. Four-limb blood pressures may be ordered for infants suspected of a cardiac defect.

ONGOING PATIENT CARE: Neonatal nurses will provide ongoing care in collaboration with the multidisciplinary team and family to implement an individualized plan of care. The care plan update is documented a minimum of every shift to reflect the infant's current needs.

A. **Process criteria; the neonatal nurse will**

1. **Perform a physical assessment within 2 hours of each shift with appropriate documentation in the infant's EMR**: All areas of the assessment that are not within defined limits need to be reassessed with all hands-on care or at least every 4 hours until resolved.
2. Weigh infants on a daily basis unless an order indicates otherwise and report excessive weight loss or gain to the physician. Document information in the EMR.
3. Neonates will have head circumferences (OFC) and lengths measured weekly on Sunday evenings.
4. Measurements:
   The nurse is responsible for admission measurements including weight, length and head

circumference.

Bed scale is zeroed with equipment on and neonate lifted off the mattress. The neonate is then placed on mattress and the weight noted.
Length is measured with the neonate supine and leg fully extended to achieve crown-heel measurement.
Head circumference is measured from just above the eyebrows and around the prominence of the occiput.
Abdominal girth is measured with a tape measure around the neonates abdomen at the level of the umbilicus.

5. 1. Vital sign Parameters:

   i. Temperature – normal 97.9° - 99.5°F. (36.6°-37.5°C.)
      1. Infant's temperature will be obtained with electronic thermometer at bedside.
      2. Place the tip securely in axilla, ensuring that skin surfaces touch each other.
      3. Hold stable until audible beeping. Remove gently and return to case. Clean tip with alcohol when soiled.

   ii. Heart Rate (Pulse) – normal 120-160 for preterm, 100-140 for term.
      1. Place stethoscope on left mid sternal border on the anterior chest.
      2. With infant quiet, count heart rate for 30 seconds.
      3. Note rhythm and presence of murmurs.
      4. Listen for the Point of Maximal Impulse (PMI) over the anterior chest. Listen posterior for murmurs.

   iii. Respirations – normal 40-60 for preterm and 30-60 for term infants.
      1.Watch or palpate the rise and fall of abdomen and chest, count for 60 seconds.
      2. Note periodic breathing, tachypnea, nasal flaring, grunting or retractions (location and severity)
      3. Auscultate breath sounds bilaterally: anterior, posterior, in axillas, upper and lower.

   iv. Apnea: 15 second delay

   v. Blood Pressure – normal dependent on gestational age.
      1. Select the widest cuff that can be placed around 2/3 length of the limb without touching the joints. The width of the cuff is approximately two thirds the length of the upper arm, the thigh or the calf.

   vi. 2. Never select an extremity that has an arterial line, compromised circulation or injury. Limbs with peripheral IV's to be used if no other limb is suitable.

   vii. 3.Secure cuff around limb and connect to monitor. Calm infant as much as possible. Oscillations in the pulse are measured to determine systolic, diastolic and mean blood pressures.
      4 If the monitor displays error or the reading is significantly different than expected, the Nurse will recheck cuff size and placement, stabilize the limb, wait 60 seconds and repeat the BP.
      5. Remove the cuff after each reading. Cuff may be left on up to four hours if Blood Pressure is checked every one or two hours. Monitor distal limb for signs of constriction.

   viii. NICU Admission – Vital Sign Frequency
      1. Temperature, heart rate and respirations with pulse oximetry upon admission.

2. Repeat in 15 minutes.
3. Repeat every 30 minutes if unstable or
4. Every hour if stable x2.
5. Blood pressure within 30 minutes of admission and repeat Blood pressure every 30 minutes if unstable until stable

ix. Continuing Care – Vital Sign Frequency
1. Intermediate Status (Acuity 1:3) – Temperature, Heart rate and Respirations every 3 hours with feedings. Blood Pressure 12 hours as ordered.
2. Critical Stable Infant (Acuity 1:2) – Temperature every 3-4 hours, Heart rate and Respirations every 2 hours, and Blood Pressure every 6-12 hours and as needed (unless arterial line in place).
3. Critical Unstable Infant (Acuity 1:1) – Temperature every 2-4 hours. Heart rate, Respirations, and invasive Blood Pressure hourly, and or blood pressure via cuff twice per shift (unless arterial line in place).

x. Postoperative every 15 minutes x4, every 30 minutes x2, every 1 hour x2 until stable then as indicated by the level of care.

xi. **Target oxygen saturations**; if infant is < 34 weeks: target oxygen saturation Goal 90-94%, Alarm Limits 88-96%

xii. If the infant is Greater than or = to 34 week: target oxygen saturations Goal 94-98%, alarm 92-98%

If the infant is on an FiO2 of 0.21, the upper alarm limit can be set to 100%

A. Document a complete physical assessment at least once per shift. Focused assessments will be completed at appropriate intervals during the shift.

B.Reposition infants with hands-on care. If this is not possible due to an infant's condition or care being provided, pressure reducing measures should be implemented. Document position changes in the EMR.

1. Replace monitor leads and the oxygen saturation probe during baths or when items become loose or soiled. Reposition the pulse oximeter probe at least every shift.
2. Maintain infants in neutral thermal environment. Continuous skin temperature monitoring is required for any infant on servo-control mode in a heated incubator or on a radiant warmer.
3. Provide oral care with sterile water or human milk as needed.
4. Lab sampling:
    1. All lab results will be reviewed each shift and physician informed of any abnormal results
    2. Implement comfort measures for venipunctures and heel sticks as appropriate.
    3. Heel warmers are applied prior to heel sticks.
5. Blood glucose per MD order and NICU policy.
6. Perform and document pain assessment with vital signs and changes in infant conditions. Refer to NICU Pain and Sedation management (NPASS) Policy
7. Notify the physician and charge nurse regarding significant changes in an infant's condition

1. when an infant's condition changes, nursing judgment warrants reassessment.
2. Document any notification in the EMR including any further assessment.

8. Offer a patient care conference to facilitate communication between the family and caregivers at the family's request and any time there is a change in the patient's health status and/or other needs arise.
    1. .
9. Neurological assessment: Outcome criteria: Neonatal nurses continually assess all data pertinent to the infant's neurological function and update the nursing care plan to promote optimal neurological status.
    1. Process criteria: Neonatal nurses assess:
        a. The anterior and posterior fontanel every shift and as needed
        b. Level of consciousness/behavior with vital signs and as needed unless otherwise ordered.
        c. Muscle tone, cry, and symmetrical movement each shift.
        d. Suck, swallow reflex present upon admission and with feedings via nipple or breast per appropriate gestational age.
10. Cardiovascular assessment: Outcome criteria: Neonatal nurses continually assess all data pertinent to the patient's cardiovascular system and update the nursing care plan to promote optimal cardiac function.
    1. Process criteria:
        a. Heart rate, respiratory rate, color, capillary refill time, perfusion, oxygen saturation and any changes in heart sounds and update the nursing care plan to promote optimal cardiac function.
        b. Critically Significant Cardiac event:
            i. Heart rate less than 80 for greater than 5 seconds or Apnea for greater than 20 seconds or Oxygen saturation less than 80% for greater than 10 seconds
            ii. Self-resolved episodes are not generally viewed as significant events. Apnea/bradycardia event must occur while infant is asleep or lying down. Events associated with feeding are not apnea of prematurity.
    2. Assess blood pressure for all infants in the NICU:
        a. Infants with arterial lines in place will have a transducer in-line. Blood pressure should be documented at least every 1 hour to these infants. Alert the physician to any changes in the Mean Arterial Pressure (MAP) including a dampened waveform. Monitor perfusion of toes, fingers, sacral and buttocks area hourly.
        b. Calibrate blood pressure transducer with change of caregiver, change of IV tubing and as indicated.
        c. Document blood pressure every hour if the infant is on vasopressors/antihypertensive drips. Mean arterial blood pressure > or = gestational age.
        d. If a change in vasopressor/antihypertenisve drip rate is made, document BP every 15 minutes x4 following the change
        e. Print or save monitor strips if an arrhythmia
11. Respiratory Assessment: Outcome criteria: Neonatal nurses continually assess all data pertinent to the infant's respiratory system and updates the nursing care plan to promote optimal respiratory function.
    1. Process criteria: Neonatal nurses will assess:

a. Breath sounds at least every 4 hours and as needed
b. Status of respiratory effort with each infant interaction(at least every 4 hours)
c. A pulse oximeter should be in use for every infant receiving oxygen and as ordered. When in use values will be documented every 2 hours for infants on oxygen and every 4 hours for infants in room air.
d. Episodes of desaturation, whether on oxygen or on room air, should be assessed; any action taken for recovery must be documented.
e. Any necessary respiratory support should be checked at least every 2 hours. This must be done by the nurses or respiratory care therapist.
f. Oxygen saturation monitoring:
    i. Apply neonatal oximeter probe to opposite sides of an artery in tissue that can be transilluminated
    ii. Select area of good perfusion: foot, hand, or wrist.
    iii. Follow manufacturer's instructions regarding probe placement.
    iv. Connect oximeter to the cable and turn on the monitor.
    v. The accuracy of the reading is determined with a pulsatile beat and when the oximeter pulse rate matches the apical pulse.
    vi. Alarm limits are set according to the ordered range for desired oxygen saturation
    vii. Monitor perfusion of extremity distal to the probe.
    In presence of bright light, cover oximeter with opaque material.
    viii. Change probe site every 12 hours and as necessary.
g. Transcutaneous monitoring:
    i. Set-up, maintenance, and site change is conducted according to Respiratory Therapy policies and procedures.
    ii. Assist the Respiratory Therapist in changing probe at least every 4 hours. Temperature range of the probe ranges between 42° and 44° C. Heat of the probe causes skin redness.
    iii. Notify the physician of skin breakdown or excoriation.
h. Oxygen/Ventilator support
    i. With each vital sign assessment the nurse will note FIO2 with oxygen saturations and mechanical vent/CPAP/HFNC settings as appropriate
    ii. **Target oxygen saturations** for an infant < 34 weeks: Goal 90-94%, Alarm Limits 88-96% if the infant is Greater than or = to 34 week: Goal 94-98%, alarm 92-98%

    If the infant is on an FiO2 of 0.21, the upper alarm limit can be set to 100%
    iii. Mechanical Ventilator
        a. Endotracheal tube (ETT) should be secured utilizing the ETT holder device or tape
        b. An in-line suction catheter must be attached to the ETT.
        c. Suctioning is performed as needed only and saline lavage administration should be avoided.

iv. CPAP

a. Infants on CPAP will have an OG tube of at least 6.5 Fr size in place and open to air.

b. Ensure proper fit of nasal piece and position infant so that the mouth remains closed.

c. Inspect nares and septum for breakdown at a minimum of evey 4 hours and alert physician of skin breakdown.

d. Suction nares with normal saline lavage as needed to avoid obstruction.

v. Nasal Cannula

a. Infants receiving oxygen via nasal cannula will have percentage of FIO2 and liter flow documented with vital signs

b. Inspect nares and observe for dryness or irritation and patency of cannula

c. Suction nares with normal saline as needed to avoid obstruction.

d. Replace nasal cannula when obstructed and/or visibly soiled

e. Cannula should be secured using a hydrocolloid dressing to protect the skin.

12. Gastro-Intestinal Assessment: Outcome criteria: Neonatal nurses continually assess all data pertinent to the infant's GI system and update the nursing care plan to promote optimal GI function

13. Process criteria: Neonatal nurses will:

1. Inspect and document abdominal discoloration; abnormalities, surgical drains and stomas

2. Auscultate all abdominal quadrants for presence and character of bowel sounds every shift and as needed if feeding intolerance, increased abdominal girth, or change in frequency or characteristics of stool occurs.

a. Assess for change in frequency or characteristics of stool .

b. Assess for feeding intolerance and notify physician of repeated episodes of emesis, increased apnea or bradycardia, coffee ground or frank blood residuals, presence of loops, discoloration or tenderness of abdomen, or changes in clinical presentation i.e. lethargy, increase in HR.

i. For infants receiving gavage feedings, document abdominal assessment prior to every gavage feed.

3. IV nutrition will be monitored in accordance with the NICU Clinical IV Therapy policy

4. Monitor frequency of stools and alert the physician if no stool for greater than 24 hours.

14. Genitourinary assessment: Outcome criteria:

1. Outcome criteria: Neonatal nurses continually assess all data pertinent to the infant's genitourinary (GU) system and update the nursing plan to promote optimal GU function.

2. Process criteria: Neonatal nurses will assess:

a. Check diapers as needed and weigh if keeping accurate intake and output. If the infant does not qualify for accurate intake and output, diaper counts may be recorded.

b. Perform accurate intake and output monitoring on all infants receiving intravenous (IV) fluids or diuretics and on other patients according to nurses' judgment or physician order.

c. Notify the physician if urine output is <1ml/kg/hr.

d. Assess for diaper rash or fungal-like infection. If diaper rash occurs; notify physician and refer

to Neonatal skin care Policy (N.45).

15. Psychosocial support
    1. Outcome criteria: Neonatal nurses continually assess all the data pertinent to the infant and family's psychosocial needs in a supportive manner.
    2. Process criteria: Neonatal nurses should
        a. Assess and document the infant and family's psychosocial status upon admission and daily in the infant's medical record
        b. Listen to family concerns in a supportive manner.
        c. Encourage parents and families to participate in care as appropriate.
        d. Identify family support systems upon admission and as needed.
        e. Enter appropriate consults/referrals into the infant's medical record as needed.
        f. Refer to social work as needed
16. Patient Education;
    1. Outcome criteria: The infant and family will have their educational needs regarding the infant's hospitalization addressed in a timely manner.
    2. Process criteria:
        a. Include the family and/or caregiver in teaching to increase their understanding of the infant's needs during hospitalization and upon discharge.
        b. Orient parents and families to the unit guidelines/routines upon admission and throughout hospitalization.
        c. Explain all procedures and interventions and the plan of care and encourage questions and discussions.
        d. Assess learning needs during family and or caregiver unit orientation and as needed thereafter and then document any specific needs in the infant's medical record.
        e. Provide the family/caregiver with educational materials as needed regarding the ongoing care of the infant and discharge information.
        f. Provide infant cardiopulmonary resuscitation instruction to families and caregivers of high-risk infants (infants on home monitor or home oxygen, siblings of victims or near-victims of sudden infant death syndrome, infants with heart disease, and any other infant believed to be at risk for an acute life-threatening event).
        g. Document all teaching and response to learning in the EMR.
17. Infant Safety:
    1. Outcome criteria: Neonatal nurses continually provide care in a safe manner
    2. Process Criteria:
        a. The infant and family can expect age-specific interventions will be implemented to prevent injuries while in the hospital.
        b. Environmental checks should be completed whenever a change of caregiver occurs Environmental checks include ensuring the infant's identification bands are present and correct and that the cardiopulmonary/oxygen saturation monitor is attached to infant. Alarms should be

turned on with the appropriate limit set and the emergency equipment such as mechanical suction with suction catheter, oxygen blender with 15 Lpm flow meter, resuscitation bag and appropriately sized mask and bulb syringe. Document all checks.

c. All high alert infusions should be clearly labeled with the name of the medication that is infusing as close as possible to the medication infusion site.

d. The nurse/caregiver will be in close proximity at all times. If leaving the unit, another nurse is to be responsible for the infant.

e. Bed wheels will be locked at all times except during transfer.

f. Side rails on radiant warmers and open cribs should be up at all times unless a caregiver is next to the bedside.

g. Locks on incubator doors, portholes, and warmer walls will be used at all times.

h. Safety belts should be used when infants are placed in swings, car seats, vibrating chairs or strollers.

i. Dedicated emergency equipment is verified to be present; functioning and labeled for each infant.

i. Environmental assessment should occur at the beginning of each shift and will include:

a. Equipment is in safe working order and has current Biomedical maintenance safety check.

b. Equipment is plugged into the appropriate outlet.

c. Emergency equipment is at each bedside to include a bulb syringe, bag or t-piece resuscitator and mask, and suction.

ii. Two forms of infant identification are present at all times.

iii. Telephone physician orders are read back for clarification.

iv. Critical lab values reported to the nurse by laboratory and read back for clarification, documented, and physician notified.

v. Time out is conducted prior to invasive procedures to verify the correct infant's name, procedure, location of procedure, and consent is properly completed.

vi. Medications are double checked prior to administration utilizing the 5 infant's right.

vii. The RN must be at the bedside for diagnostic testing to ensure protection of invasive lines, proper infant positioning and appropriate protection of the infant.

viii. Parents and/or caregivers are identified via identification bands.

18. Emergency equipments:

1. Outcome criteria:

a. Neonatal nurses have appropriate emergency equipment available for infant use.

2. Process criteria:

a. A neonatal crash cart will be available on the unit at all times and checked according to hospital Crash Cart Contents and Daily Check List policy.

b. Intubation boxes/kits are maintained by the Respiratory Department.

c. Emergency equipment present at the bedside should include:
    i. Mechanical suction with suction catheter
    ii. Oxygen blender with 15 Lpm flow meter
    iii. Resuscitation bag or t-piece resuscitator and appropriately sized mask
    iv. Bulb syringe

19. Hand off/Shift report
    1. Outcome criteria:
        a. Neonatal nurses assess all information pertinent to the infant's plan of care. They will communicate accurate and correct infant information to facilitate and support safe care, situational awareness, collaborative decision making, and continuity of care.
20. Process criteria: Neonatal nurses will
    1. Provide a report to the oncoming neonatal nurse, including review of the infant's plan of care and outcome goals following the situation, background, assessment, and recommendation format (SBAR),
    2. Review all physician orders placed throughout the shift and verify status.
    3. Review the medication administration record
    4. Assess the integrity of all vascular access sites, tubes and drains.
21. Infection Control
    1. Standard precautions are strictly adhered to by staff and family members. Family members are educated on infection reduction interventions including hand hygiene and visitation per PICU, Peds and NICU Visiting policy upon admission and throughout the stay.
    2. Perform hand hygiene with antimicrobial soap or gel upon entering the NICU, before and after infant contact, and/or after touching infant's inanimate objects.
    3. Preventing nosocomial infections related to invasive lines requires strict adherence to NICU policies.
    4. At the beginning of each shift, the RN wipes down the infant care area, monitors, keyboards, charts, pumps, telephones, and the nursing counter/table areas with the appropriate hospital antiseptic wipe.
    5. Infants in isolation are cared for per Infection Control for Airborne, Droplet, or Contact precautions. Parents are educated on specific protocol.
    6. Beds
        a. Incubators/radiant warmers/open cribs will be changed every 14 days and as needed with the date to be changed clearly marked.
        b. Bed linen will be changed every day when the infant is weighed and as needed.

EQUIPMENT

A. Digital thermometer
B. Neonatal stethoscope
C. Clock with second hand
D. BP Monitor with appropriate size cuff

E. Portable Infant scale or Bed scale
F. Stadiometer/infant length board
G. Blanket
H. Tape measure: single use, non-stretch
I. Cardiac-respiratory monitor
J. Transcutaneous oxygen-carbon dioxide monitor
K. Pulse oximeter
L. Mechanical suction with suction catheter
M. Oxygen blender with 15 Lpm flow meter
N. Resuscitation bag and appropriately sized mask
O. Bulb syringe

DOCUMENTATION

A. All assessments and patient care notes are documented in patient's EMR.

REFERENCES:

1. Kenner, C., Altimier, L.B., & Boykova, m.V. (Eds.). (2020) Comprehensive Neonatal Care, 6th ed. St. Louis, MO: Elservier.
2. Gardner, S., Carter, B., Enzman-Hines, M., Hernandez, J. (2021). Handbook of Neonatal Intensive Care, 9th ed. Elsevier.
3. Sundquist Beauman, S. & Bowles, S. (Eds). 2019. Policies, Procedures, and Competencies for Neonatal Nursing Care, 6th ed. National Association of Neonatal Nurses
4. R.NP.05 Monitoring in NICU – Transcutaneous Monitors
5. M. Terese Verklan; Walden, Marlen; Forest, Sharron. (2021) Core Curriculum for Neonatal Intensive Care Nursing; 6th Ed. Elsevier

All revision dates: 5/20/2024, 6/14/2023, 12/14/2022, 6/1/2013, 3/1/2010, 12/1/2004, 4/1/2002, 4/1/1992

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Approval Signatures

Step Description	Approver	Date
Pediatrics Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	5/23/2024

Step Description	Approver	Date
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	5/23/2024
NICU	Melissa Krebs: Director, NICU	5/23/2024
NICU	Jennifer Ferrick: Director, Peds/PICU & NICU	5/21/2024

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References:	

N.52 Transporting Patients Outside of the NICU

POLICY:

Intra-facility transport -To ensure patient safety while transporting Neonatal Intensive Care Unit patients at discharge, for tests or procedures which cannot be performed in the Neonatal Intensive Care Unit.

PROCEDURE:

A. A patient receiving ventilatory support requires a respiratory therapist and an RN for transport to another location within Ventura County Medical Center.

B. The Registered Nurse must be familiar with the emergency equipment available in the area to which the patient is transported.

C. Neonatal Intensive Care Unit patients will be transported in bassinets, radiant warmers, isolettes or transporter. .

EQUIPMENT

A. Isolette, radiant warmer, transporter or bassinet bed (condition appropriate). If used; the transporter must be heated with the temperature controlled to maintain a thermo-neutral environment.

B. Blankets, clothing, thermal equipment to meet the infant's need of thermal regulation and privacy.

C. Resuscitation bag, mask, and oxygen source (as appropriate to patient needs).

D. Cardiac monitor and pulse oximetry.

E. Restraints as indicated.

F. Emergency equipment as appropriate for the patient's condition and destination, i.e. code medications, code medication sheet, intubation equipment, etc.

G. Bulb syringe and/or suction set up (if applicable)

GUIDELINES

A. Notify family of patient and prepare for transport.

B. Assemble equipment. Warm isolette when appropriate.

C. Notify respiratory care, if appropriate.

D. Notify department of departure time.

E. Two patient identification bands should be attached to the patient.

F. Transport patient using patient elevator.

G. If patient is hemodynamically unstable, attending physician should accompany the patient.

H. Confirm the infant's identity with the technologist or RN before the procedure

I. Prepare and stabilize the infant prior to the procedure.

J. Remain with patient throughout procedure, except for procedures carried out in the operating room.

K. Stabilize infant post procedure then Transport patient back to Neonatal Intensive Care Unit.

TRANSPORT PROTOCOL – STANDING ORDERS

For assistance in any situation, contact the responsible staff Physician or medical provider.

A. Initial Patient Assessment and Stabilization:

1. Assure airway patency by positioning and suctioning as needed.
2. Assess the stability of patient:
    a. Vital signs upon arrival, every 30 minutes or more frequently if condition indicates until stable.
    b. Note color, respiratory pattern, and effort.
3. Attach cardio-respiratory monitor, pulse oximeter, and blood pressure monitor.
4. Assess need to empty patient's stomach – if needed place oro-gastric tube to gravity drainage.
5. Stabilize temperature; maintain axillary temperature 97.5– 99.5 F or 36.5--37.5 C.
6. Review current labs.
7. Obtain IV access for administration route for medications if indicated or ordered.

DOCUMENTATION

Record the following in the EMR

A. Time of departure, destination, type of procedure, and transportation mode.

B. Patient's tolerance of procedure.

C. Time returned to unit and clinical status.

D. All Assessments and interventions performed during the transport should be documented in the EMR as they would be in the neonatal unit.

REFERENCES

American Academy of Pediatrics. Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients. 4th ed. Elk Grove Village, IL; The Academy; 2016

Sundquist, Beauman S; & Bowles, S. Policies, Procedures, and Competencies for Neonatal Nursing Care. 6th ed. National Association of Neonatal Nurses. 2019

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N.60 Neonatal Tracheostomy Care

POLICY:

To provide guidelines for the safe and consistent care of Neonatal Intensive Care Unit (NICU) patients with a tracheostomy.

PROCEDURE:

A. All patients with a tracheostomy will be monitored by a cardiorespiratory monitor and pulse oximeter.

B. A licensed Health Care Professional (HCP) proficient in tracheostomy care including tracheostomy tube reinsertion must be present when a tracheo-stomized patient receives procedural sedation. A RN must be immediately available.

C. It is important to determine upon admission whether a patient is trach dependent, trach size and type, 0_2 /humidification requirements and appropriate suction equipment. This information should be posted at the bedside.

   1. Necessary equipment (replacement trach of same size as well as one size smaller), obturator, trach Velcro ties, suction catheters, manual resuscitation bag and 0_2 should be kept at the bedside.
   2. A "trach" guard is recommended for patients at risk of occluding their trach with neck or chin folds. A trach guard humidification collar may be sufficient for some patients.

D. A minimum of two (2) HCP's must be present to change tracheostomy ties.

E. The first post-op trach tie change is performed by the surgeon.

F. The first post-op trach tube change and any change up to two weeks post-op is always performed by the surgeon.

G. A minimum of two (2) people, one of whom is a licensed HCP, must be present to change the tube. One person will position the patient, while the other will insert the tube.

H. Tracheostomy patients who are transported for diagnostic testing or treatment may not be left unattended, and must be accompanied by a licensed HCP proficient in tracheostomy care.

GUIDELINES

I. Equipment:

   1. Suction machine and connecting tubing – wall suction or portable – set to appropriate setting

a. Neonate/Infant: 60-80 mmHg

2. Sterile suction catheter of appropriate size
    a. Neonate/Infant #-8 fr
3. Small sucker for neonates
4. Sterile water in a clean cup for clearing catheter (use liter bottles)
5. Sterile gloves, clean glove, mask, and goggles (if excessive secretions are expected)
6. Normal saline drops are only used on an as needed basis
7. Posy tie (appropriate size)
8. Replacement tracheostomy tube with obturator at bedside
9. Hemostat
10. Small blanket roll
11. Tracheostomy tube plug
12. Band-aid (for decannulization)
13. Scissors

J. Action:

1. Suctioning:
    a. Assess patient's need for suctioning is indicated by:
    Noisy, moist respirations
    Restlessness
    Abundant secretions
    Change in pulse and/or respirations
    Substernal intercostal or supra-clavicular retractions
    Color changed including cyanosis, pallor, mottling
    b. Observe the patient throughout the procedure for:
    Color and respiratory status
    Heart rate
    $TcC0_2$ if on a $TcC0_2$ monitor
    0_2 saturation via pulse oximeter
    c. HCP must wear a mask and goggles during suctioning.
    d. Turn suction on.
    e. Wear a sterile glove on the hand used to suction. A clean glove may be worn on the other hand.
    f. Use a new sterile catheter for each suctioning episode.
    g. Wash hand for 30 seconds.
    h. Open suction catheter. Attach suction catheter to connecting tubing.
    i. Insert suction catheter into entire length of tracheostomy tube (for most patients) use pre-measured technique. Please see posted measurement at bedside. Deep suctioning (WHEN RESISTANCE IS MET AT THE CARINA) is only recommended for patients with no gag or cough or with presence of abundant secretions. Cover suction portal with thumb and draw back catheter while suctioning with a twisting motion. Be sure to allow the patient time to recover

between passes.

j. **Note: Suctioning should not exceed 5 seconds per pass.Recommended pre-measured suctioning with catheters:**

k. a. Trach tube size 3.0 neo size French 8 catheter suction up to 5-6cm marker

l. b.Trach tube size 3.5 neo size French 8 catheter suction up to 6cm marker

m. c. Trach tube size 4.0 neo size French 8 catheter suction up to 6-7cm marker
d. Trach tube size 4.5 neo size French 8 catheter suction up to 6-8cm marker

n. Do **not** switch back and forth between oro-nasopharyngeal suction.
Complete trach suctioning first, then may use same catheter for oro-nasopharyngeal suction.

o. Reconnect patient to therapy equipment of present, and wait at least 3-5 minutes before repeating suctioning, unless airway is blocked with secretions.

2. Tracheostomy Tie Change:

Trach ties are changed q24 hrs and prn whenever soiled, wet or too loose:

a. Wash hands for 30 seconds.

b. Restrain neonate / infant as needed.

c. Place small blanket roll under shoulders to provide access to tracheostomy.

d. Suction patient.

e. Have assistant place his/her finger on each side of flanges to hold tracheostomy cannula as close to neck as possible.

f. Remove old ties and inspect skin for skin irritation, rash and/or breakdown.

g. Thread end of Velcro tie through flange of trach tube and secure snugly. Pass around back of neck and secure other end in same fashion.

h. Secure Velcro ties snugly around neck. Place 1 or 2 small pieces of non-stick gauze over any abraded area. Ties should fit so that one finger width can just fit between neck and tie, and tracheostomy tube is secure. If using 2 x 2 underneath trach flange make sure that 2x2 is maintained clean and dry at all times to prevent further skin breakdown. If possible, check the tension on the ties with the patient lying down and sitting up, with neck flexed toward the chest.

i. Adjust tightness as necessary.

3. Changing the tracheostomy tube:

a. A licensed HCP who has demonstrated competency may change the tube after verifying with Attending Physician.

b. Tracheostomy tubes are changed:

i. Prn, and as ordered.

ii. If dislodgement is suspected.

iii. If the tube is plugged and cannot be cleared.

iv. If the patient has a Bivona tracheostomy tube and is going for an MRI, a Shiley tube should be substituted before the procedure.

c. Dislodgement of a tracheostomy tube should be suspected if:

i. Respiratory distress is unrelieved by suctioning.

ii. Sudden pronation occurs.

iii. Tube protrudes significantly above skin surface.

iv. Suction catheter cannot be passed through tube.

v. Neck bulges and face puffs with ventilation.

Ventilation of a patient via a dislodged tracheostomy tube may cause subcutaneous emphysema, pneumomediastinum, tension peumothorax, and/or cardiac arrest. Ventilation should be performed with a resuscitation bag and mask over the nose and mouth as needed until the tracheostomy airway is re-established or the patient is intubated.

d. Wash hand for 30 seconds and don gloves.

e. Check the tracheostomy tube for any defects. Check that inner and outer cannulas (if present) and obturator fit smoothly. Ensure that cuff (if present) has been completely deflated and smoothed back.

f. Attach tracheostomy Velcro ties to new tube.

g. Lay the patient supine and place the small blanket roll under the shoulders.

h. Suction the patient prn.

i. Insert the obturator into the outer cannula. Obturator will be held in place with your thumb. Keep inner cannula (if present) within reach.

j. The tube may be wet with normal saline or water soluble lubricant to facilitate smooth entry during reinsertion.

k. Cut ties and remove old tracheostomy tube.

l. Standing at the patient's side, open the stoma by spreading the skin with your fingers.

m. Insert the tip of the new tube with the obturator into the stoma. Follow the curvature of the tube until it is completely in place.

n. Quickly remove the obturator while holding the outer cannula firmly at the flanges. Maintain appropriate oxygenation according to patient's condition.

o. Assess respiratory status. Listen for air exchange bilaterally.

p. If aeration is satisfactory, secure tracheostomy ties and suction as needed.

q. Insert inner cannula, if present.
Note: If unable to insert tracheostomy tube, notify physician immediately and bag the patient via mask.

4. Tracheostomy Plugging and De-cannulization:

a. A physician's order is required to plug a tracheostomy tube.

b. The tube may be plugged intermittently or continually, according to physician's order.

c. The order should include the time of day and the patient activity level during the time that plugging is to occur.

d. Plugging should be well tolerated prior to de-cannulization.

e. A physician performs the de-cannulization, with a nurse or RT in attendance.

- The stoma usually closes in 1-4 days after de-cannulization.

5. Plugging the Tracheostomy Tube: Action:
    a. Suction tracheostomy or have the patient cough effectively.
    b. Auscultate lung fields.
    c. Holding the flange of the tracheostomy tube firmly, insert the plug into the inner cannula of the tube.
    d. Observe the patient for signs and symptoms of respiratory distress (increased HR, restlessness, decreased 0_2-sat, retractions, stridor, asymmetrical chest expansion, cyanosis, increased secretions patient cannot clear by coughing).
    e. If respiratory distress occurs, remove the plug immediately and notify physician.
    Suction through tracheostomy tube only if necessary.
6. De-cannulization:
    a. Assist the physician with removal of the tracheostomy tube.
    b. After the tracheostomy tube is removed, dry the surrounding skin and occlude the stoma by covering with a Band-Aid.
    c. Observe for passage of air or drainage through stoma. Check appearance of stoma at least every 8 hours.
    d. Suction through stoma if patient becomes congested and cannot clear secretions by coughing.
    e. Change Band-Aid daily and PRN until stoma is healed.
    f. Maintain cardio-respiratory monitoring until stoma is closed and closure is well-tolerated.
7. Stoma Care:
    a. Fresh stoma may be cleansed if necessary with a solution of ½ strength hydrogen peroxide and blotted dry.
    b. Established stoma may be cleaned with warm soapy water and blotted dry. Assessments of the stoma area include observations for signs of infection and breakdown of the skin q4hours and prn. The stoma requires twice a day and prn. The skin is kept clean and dry utilizing dressings made of moisture-wicking material and/or hydrocolloid wafers under the tracheostomy flanges and extra-thin hydrocolloid wafers under the chin.

DOCUMENTATION

Document In the EMR:

A. Date, time and procedure performed
B. Patient tolerance of procedure
C. Post procedure assessment
D. Appearance of stoma
E. Date and time, size of tube, reason for change, and patient's tolerance of/response to the procedure
F. Appearance of the neck and security of the trach ties.

Transitioning to Home Care

1. Family must be educated and demonstrate understanding of signs of breathing difficulties and how to manage routine care.

2. CPR training-Family must be taught to establish a patent airway-trach tube change, mouth to mouth and nose if upper airway is patent, mouth to stoma.

3. Bedside care providers should foster positive interactions and active participation in the care of the patient and education of the family members with teaching techniques such as written material with pictures; videotapes, supplies and hands-on with the infant.

4. Coordinating care supplies for home--including tracheostomy tubes, tracheostomy Velcro ties, skin/stoma cleaning supplies; suctioning supplies including portable suction machine with internal battery and DeLee suction trap, humidification supplies, ambu-bag with appropriate -sized masks and oxygen supplies.

5. Emergency box or backpack of supplies (including suction device/machine) should be with the infant at all times, including car trips, doctor appointment and outdoor walks.

6 Home health nurses--must be trained in respiratory assessment and tracheostomy management (both routine and emergency response) and prior pediatric experience should be required.

REFERENCES:

Hockenberry, M. J.; Duffy, E.A.; Gibbs DiValerio, K. Wong's Nursing Care of Infants and Children. 2024. Elsevir Inc.

Ramasethu, J; Seo, S. MacDonald's Atlas of Procedures in Neonatology. 6th Ed Wolters Kluwer. 2020

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Step Description	Approver	Date
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Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/16/2024
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N.66 Standardized Procedure for Emergent Umbilical Vein Catheterization (UVC)

PURPOSE:

The procedure provides guidelines for the Neonatal Intensive Care Unit (NICU) Registered Nurse (RN) to insert an umbilical venous catheter (UVC) in a newborn during an emergency situation requiring central vascular access. Standards for Neonatal Resuscitation, the American Academy of Pediatrics (AAP) and the American Heart Association (AHA) all recommend the insertion of a catheter in the umbilical vein which is readily accessible in a newborn when an infant requires Epinephrine and/or volume expanders.

GOALS:

To provide standardized and safe guidelines for the catheterization of an umbilical vein of a neonate by non-physician staff.

POLICY:

A. In the absence of a Neonatologist, the trained Neonatal Intensive Care Unit Registered Nurse is responsible for initiating the Umbilical Vein Catheterization Standardized Procedure for neonates meeting the following indication: Emergency administration of medications and/or volume expanders.

B. The Neonatal Intensive Care Unit Registered Nurse will follow the Neonatal Resuscitation Program (NRP) guidelines for inserting an umbilical venous catheter and administering Epinephrine and/or volume expanders through the catheter.

C. Written records of Registered Nurses who have met the standardized procedure competency requirements will be maintained and updated annually.

D. Informed consent is not required prior to the performance of an emergent Umbilical Venous Catheter placement. The neonates medical record shall reflect the emergent need for the procedure.

E. The Neonatologist will be notified for the following:

   1. If significant bleeding occurs during insertion
   2. Before and after the procedure is completed

F. Parents/caregivers will be notified of the procedure and infant's condition.

G. Patient population is the neonate.

CIRCUMSTANCES UNDER WHICH THE RN MAY PERFORM THIS STANDARDIZED PROCEDURE

A. When performing neonatal resuscitation, the Neonatal Intensive Care Unit Registered Nurse may insert an umbilical venous catheter in a neonate on an emergent basis when the Neonatologist is physically unavailable.

B. The Neonatal Resuscitation Program indications for Umbilical Venous Catheterization insertion and medication administration will be adhered to.

SETTINGS IN WHICH TO PERFORM THIS STANDARDIZED PROCEDURE

A. Birth Center

B. Neonatal Intensive Care Unit (NICU)

C. Transport

EXPERIENCE/TRAINING/EDUCATION REQUIREMENTS

A. Experience

1. A qualified Registered Nurse with a minimum two years of experience level II or level III; in the Neonatal Intensive Care and (valid State of California Registered Nurse License) will have completed initial orientation (education/training/demonstration of competency) to the Neonatal Intensive Care Unit and have successful completion of the Neonatal Resuscitation Program course of the American Academy of Pediatrics and American Heart Association.

B. Education/Training

1. Completion of Neonatal Intensive Care Unit Registered Nurse orientation.
2. Initial Evaluation
    a. Initial competencies with return demonstration will be documented on the Neonatal Intensive Care Unit Registered Nurse orientation competency sheet and kept in the employee file.

C. Continuing Evaluation of Competence

1. Yearly competency evaluation is required.
2. Continuing competency and education of the Registered Nurse will be documented on an annual basis with return demonstration of an umbilical venous line placement procedure in a laboratory setting to the satisfaction of the Neonatal Intensive Care Unit Clinical Nurse Specialist or de-signee or Neonatologist.
3. The Annual Competency Summary Sheet is kept in the employee file.

D. Clinical Nurse Specialist or De-signee Competency Validation

1. Experience

a. Have at least three years of clinical experience in neonatal nursing care at least which shall have been in a facility with an Neonatal Intensive Care Unit that is equivalent to a Regional or Community Neonatal Intensive Care Unit.

2. Education/Training
    a. Have evidence of current successful completion of Neonatal Resuscitation Program course of the American Academy of Pediatrics and American Heart Association (instructor course recommended).
3. Initial Evaluation
    a. The Clinical Nurse Specialist will have knowledge on Umbilical Venous Catheter insertion which includes:
        i. Anatomy, indications for Umbilical Venous Catheter insertion during emergent situations, equipment needed to perform Umbilical Venous Catheter insertions, complications of Umbilical Venous Catheter insertion, medications.
        ii. Demonstration of Umbilical Venous Catheter insertion in a laboratory setting under the supervision of the Neonatal Intensive Care Unit Medical Director or physician de-signee.
    b. Initial competency will be documented on the Orientation Competency Form and kept in the employee file.
4. Continuing Evaluation of Competence
    a. After initial competency requirements are completed a yearly competency evaluation is required.
    b. Continuing competency of the Clinical Nurse Specialist or de-signee will be documented on an annual basis with return demonstration of Umbilical Venous Catheter placement procedure in a laboratory setting to the satisfaction of the Neonatal Intensive Care Unit Medical Director or physician de-signee.
    c. Annual competencies will be documented on an Umbilical Venous Catheter Competency Summary Sheet and kept in the employee file.

SCOPE OF SUPERVISION REQUIRED

Every two years the Interdisciplinary Practice Committee will review and approve the Standardized Procedure.

DEVELOPMENT AND APROVAL OF THE STANDARDIZED PROCEDURE

A. Method of Development
    1. Standardized Procedure developed by the Department of Nursing.
    2. Standardized Procedure approved by the Interdisciplinary Practice Committee.
    3. Standardized Procedure approved by the appropriate Medical Staff Department Committee and Medical Executive Committee.

PROCEDURE(S):

A. Put on sterile gloves and set up a sterile field.
    1. Although you should use sterile technique, it is often difficult to perform this procedure in a truly sterile manner while working quickly, do not delay resuscitation.
    2. If an ongoing need for catheter is identified after resuscitation and stabilization, the catheter should be removed and a new one placed by the Neonatologist using full sterile technique.

A. Clean cord with antiseptic solution. Place a loose tie of umbilical tape around the base of the cord. The tie can be tightened if there is excessive bleeding after you cut the cord.

B. Fill an umbilical catheter (under 1500 grams use 3.5 french and 1501 grams and above use 5 french) with normal saline using a 3 milliliter syringe connected to a stopcock. The catheter should have a single end hole. Close the stopcock to the catheter to prevent fluid loss and air entry.

C. Cut the cord with a scalpel below the clamp that had been placed at birth and about 1-2centimeters from the skin line. Make the cut perpendicular rather than at an angel, to the umbilical cord.

D. The umbilical vein will be seen as a large thin-walled structure, usually at the 11-12 o'clock position. The 2 umbilical arteries have thicker walls and usually lie close together somewhere in the 4-8 o'clock positions.

E. Insert catheter into the umbilical vein 2-4 centimeters (less in preterm infants) until you get free flow of blood when you open the stopcock to the syringe and gently aspirate.
    1. The course of the vein will be up toward the heart.
    2. The tip of the catheter should be located only a short distance into the vein.
        a. Only at the point at which blood is first able to be aspirated, any further is a risk and may cause damage to the liver due to the infused solutions.

F. Inject the appropriate dose of Epinephrine or volume expander, followed by 3 milliliters of Normal Saline to clear the drug from the catheter into the infant.

G. After medications have been administered, either remove the catheter or secure it in place for continued IV access as the infant is transported to the Neonatal Intensive Care Unit.
    1. Once the baby has been fully resuscitated, remove the catheter, tighten the cord tie and complete the knot to prevent bleeding from the umbilical stump.
    2. Do not advance catheter once the sterile field has been violated.

H. Document in the Electronic Health Record date, time, and procedure.

REFERENCE(S):

American Heart Association (AHA) & American Academy of Pediatrics (AAP). (2021). Neonatal Resuscitation Textbook. 8th ed.,

Board of Registered Nursing (BRN) (2017). Standardized Procedure Guidelines. http://www.rn.ca.gov/pdfs/regulations/npr-i-19.pdf

Seo, S. (2020). Umbilical Vein Catheterization. In J. Ramasethu & S. Seo (Eds.), *MacDonald's atlas of procedures in neonatology* (6th ed., pp. 217-223). LWW.

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Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/16/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/16/2024
Policy Owner	Jennifer Ferrick: Director, Peds/PICU & NICU	7/16/2024

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N.69 Infant-Directed Oral Feeding for the NICU

PURPOSE:

To provide and promote standardization of safe, developmentally-based oral feeding practices for infants in the NICU.

To establish developmentally appropriate criteria for assessing an infant's readiness to initiate oral feedings and progress toward breast and oral feeding competence.

To provide a framework in which the process of delivering feedings is structured to support individualized needs of the developing infant and family.

Provide learning opportunities for parents that promote safe and developmentally appropriate feeding techniques.

To outline and define developmentally appropriate guidelines for transitioning infants from orogastric/ nasogastric feeding tubes to oral feeding.

DEFINITION(S):

Cue-Based Feedings: a safe, efficient infant centered, oral feeding program that emphasizes the individual infant's developmentally driven oral feeding cues, commonly referred to as ""infant-driven feeding". The infant gives cues using physiological signals as well as motor and state systems to let caregivers know when to offer non-nutritive and nutritive oral feeding experiences.

Non-Nutritive breast feeding (NNBF): allowing the infant to go to the breast to nuzzle, root, and attempt latch, without requiring the baby to suck and express milk. This is particularly beneficial for infants that are not showing strong readiness for safe oral feeding (scores 4-5) but are showing the desire to orally feed. Providing NNBF during gavage feeding has been shown to facilitate as well as improve maternal milk production. (See Feeding Readiness Scale)

Non-nutritive suck (NNS): Rhythmical suck on pacifier, finger, or infant's own hand. Offer a pacifier to promote sucking and comfort. Often used as a pre-oral feeding activity, providing NNS during gavage feeding improves oral feeding mechanics and facilitates the development of feeding cues through increased association between sucking and receiving nutrition.

POLICY:

1. **Oral feeding process will focus on the infant's health, stability level, and developmental feeding readiness.**
    a. **Infant should be allowed to alert on their own within the defined time parameters. If self-alerting does not occur, nursing may begin basic care and monitor infant responses.**
    b. **Appropriate rest breaks will be given. If the baby is not tolerating a particular task, the task needs to be stopped and it will be the discretion of the RN, lactation, and Occupational/ Physical therapist when to begin stimulation again based on the infant's cues.**
    c. **RN completing the feeding will use the Feeding Quality Scale to evaluate the infant's state control, alertness and overall responses, giving appropriate rest breaks as needed. Techniques such as pacing of the suck bursts may be used to ensure best coordination and decrease the need for oxygen during oral feeds.**
    d. **RN will support the infant in an upright, side-lying, or cradled position for the oral feeding.**
    e. **Maximum 30 minute oral feeding time (breast feed and/or bottle feed). (See attachment for Oral Feeding Readiness Poster)**
    f. **Stop the oral feeding if the infant is demonstrating major stress signs or disengagement cues.**
    g. **RN will collaborate with Lactation and Occupational/Physical Therapist, for further techniques to assist in improving oral motor skills or coordination for oral feeding.**
2. The "Feeding Readiness Scale" is started once an infant has reached 32 weeks corrected gestational age (CGA).
3. An infant that has achieved at least 32 weeks CGA receiving advanced respiratory support (Bubble CPAP, High Flow Nasal Cannula) can nipple feed when physiologically stable.
4. Attempt to breastfeed prior to initiation of bottle feedings.
5. Nipple selection for bottle feeds is based on infant's gestational age at birth and feeding ability (See Attachment)
    a. Nipple selection should not change with each feeding.
6. RN to initiate and update interdisciplinary care plan to include cue-based feeding readiness and progression to oral feeding achievement.
7. RN to initiate and update parent education to include feeding readiness and feeding quality topics
8. Encourage active parent participation in recognition of infant' feeding cues upon implementation of feeding readiness assessment and throughout the infant's hospital course.
9. Request consultation for Occupational/Physical therapist for infants that are not progressing appropriately with nipple feedings.

PROCEDURE(S):

1. Once an infant has reached 32 weeks Post Menstrual Age (PMA) or Corrected Gestational Age (CGA) initiate " Feeding Readiness Scale"
2. Assign feeding readiness score before each feeding. (See Feeding Readiness Scale)

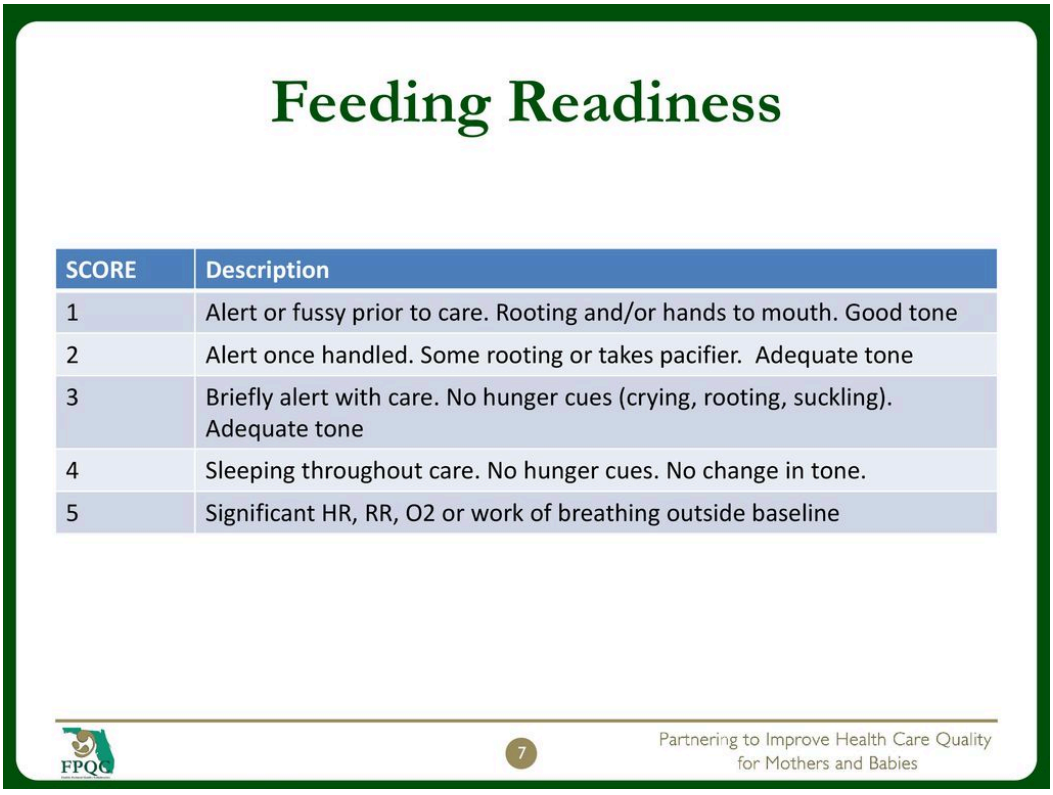
a. Scores of 1 & 2 bottle or breast feed infant.
b. Scores of 3, 4, & 5 gavage feed infant

3. Assess the quality of the oral feeding "Feeding Quality Scale"
    a. 1 Bottling well- Nipples with a strong coordinated suck throughout the feed
    b. 2 Bottling Fair- Nipples with a strong coordinated suck initially but fatigues with progression
    c. 3 Bottling Fair- Nipples with consistent suck but difficulty coordinating swallow; some loss of liquid or difficulty pacing. Benefits from external pacing.
    d. 4 Bottling Poor- Nipples with a weak/inconsistent suck. Little or no rhythm. May require some rest breaks.
    e. 5 Unable to Bottle Safely- Disorganized: unable to coordinate suck/swallow/breathe pattern or significant difficulty initiating suck. Frequent or significant A/B's. Large amounts of liquid loss. Tachypnea above baseline with feeding.
    f. 6 Unable to Bottle Safely-Dysfunctional: abnormal or deviant oral motor patterns. Unable to extract fluid from nipple. Flaccid jaw/tongue. Inability to maintain seal or suction when alert. Significant loss of liquid from mouth.
4. Assess the quality of the breast feeding using the "Breast Feeding Quality Scale"
    a. 1 Breast Feeding well-Latched well with a strong coordinated suck for >15 minutes.
    b. 2 Breast Feeding Fair;- Latched well with a strong coordinated suck initially but fatigues with progression. Active suck for 8 minutes.
    c. 3 Breast Feeding Fair - Difficulty maintaining a strong consistent latch. May be able to intermittently nurse but only for <8 minutes.
    d. 4 Breast feeding Poor - Latch is weak. Inconsistent with a frequent need to "re-latch." Limited effort that is inconsistent in pattern.
    e. 5 Unable to Breast Feed Safely- Unable to latch to breast and achieve suck/swallow/breathe pattern. May have difficulty arousing to state conducive to breastfeeding. Could result in frequent or significant Desaturations/Bradycardia/Apnea and/or tachypnea above baseline.
5. Document feeding techniques and assessment in the EMR.
6. If infant shows major stress cues and/or signs of disengagement during the feeding, stop feeding and reassess for signs of feeding readiness.
    a. Major stress cues:
        i. Coughing and/or choking
        ii. Color change
        iii. Bradycardia
        iv. Breath holding events or true apnea
        v. Stridor
        vi. Decreased Oxygen desaturations
        vii. Pharyngeal pooling, multiple swallows
        viii. Frequent/moderate drooling

b. Disengagement cues:
    i. No active rooting, no active sucking
    ii. Inability to re-alert, passivity
    iii. Pulling off the nipple, pushing the nipple out
    iv. Purposeful use of a weak or "compression-only" suck to signal a preference for return to only pacifier sucking instead of nutritive

7. Guidelines for breast feeding supplementation
    a. For breast feeding infants, unless otherwise directed by provider orders, the following feeding length guidelines in conjunction with the assessed quality of the breast feeding event are recommended for breast feeding supplementation:
        i. If infant breastfed <8 minutes; bottle or gavage the entire feeding volume.
        ii. If the infant breastfed 8-15 minutes; bottle or gavage half of the feeding volume.
        iii. If the infant breastfed >15 minutes; no supplementation with bottle or gavage unless the infant acts hungry.
8. Guidelines for feeding tube maintenance
    a. As infants acquire oral feeding competence, the following guidelines are recommended for the maintenance of feeding tubes;
        i. For any infant who is not able to complete oral feeding, gavage feed the remaining volume through the feeding tube. If infant has a shift minimum and is 20% behind for 2 consecutive feeds, consider gavage feeding.
        ii. Reinsert the feeding tube if an infant cannot complete their oral feedings.

Feeding Readiness Scale



Feeding Quality Scale

1	Bottling Well	Nipples with a strong coordinated suck throughout the feed
2	Bottling Fair	Nipples with consistent suck but difficulty coordinating swallow; some loss of liquid or difficulty pacing. Benefits from external pacing. Nipples with a strong coordinated suck initially but fatigues with progression.
3	Bottling Poor	Nipples with a weak/inconsistent suck. Little or no rhythm. May require some rest breaks. Moderate amount of liquid loss.
4	Unable to Bottle Safely	Disorganized: unable to coordinate suck/swallow/breathe pattern or significant difficulty initiating suck. Frequent or significant A/B's. Large amounts of liquid loss. Tachypnea above baseline with feeding.
5	Unable to Bottle Safely-Dysfunctional	Abnormal or deviant oral motor patterns. Unable to extract fluid from nipple. Flaccid jaw/tongue. Inability to maintain seal or suction when alert. Significant loss of liquid from mouth.

Breastfeeding Quality Scale

1	Breast Feeding Well	Latched well with a strong coordinated suck for >15 minutes.
2	Breast Feeding Fair	Difficulty maintaining a strong consistent latch. May be able to intermittently nurse but only for <8 minutes. Latched well with a strong coordinated suck initially but fatigues with progression. Active suck for 8 minutes.

3	Breast feeding Poor	Latch is weak. Inconsistent with a frequent need to "relatch." Limited effort that is inconsistent in pattern.
4	Unable to Breast Feed Safely	Unable to latch to breast and achieve suck/swallow/ breathe pattern. May have difficulty arousing to state conducive to breastfeeding. Could result in frequent or significant Desaturations/Bradycardia/Apnea and/or tachypnea above baseline.

Major stress cues:

- Coughing and/or choking
- Color change
- Bradycardia
- Breath holding events or true apnea
- Stridor
- Decreased O2 sats
- Pharyngeal pooling, multiple swallows
- Frequent/moderate drooling

Disengagement cues:

- No active rooting, no active sucking
- Inability to re-alert, passivity
- Pulling off the nipple, pushing the nipple out
- Purposeful use of a weak or “compression-only” suck to signal a preference for return to only pacifier sucking instead of nutritive

Nipple Used

- Slow Flow
- Soft Slow Flow
- Soft Extra Slow Flow
- Standard
- Orthodontic
- Dr. Brown’s Ultra Preemie
- Dr. Brown’s Preemie
- Dr. Brown’s Transition/Newborn
- Dr. Brown’s Level I
- Habermann
- Other (Comment)

REFERENCE(S):

Gardner, S. Carter, B., Enzman-Hines, M., Hernandez, J. (2016). Handbook of Neonatal Intensive Care. 8th ed. St. Louis, Elsevier

Kenner, C., Altimier, L, & Boykova, M. (2020). Comprehensive Neonatal Nursing Care. 6th ed. St Louis

Elsevier.

National Association of Neonatal Nurses. Infant-Directed Oral Feeding for Premature and Critically Ill Hospitalized Infants Guideline for Practice. Chicago, IL: NANN 2013

Sundquist, S., Bowles, Susan, Policies, Procedures, and Competencies for Neonatal Nursing Care. 6th Edition. 2019

Waitzman KA, Ludwig SM, Nelson CL. Contributing to content validity of the Infant-Driven Feeding Scales through Delphi surveys. Newborn Infant Nurs Rev. 2014: 14(3): 88-91

All revision dates:

Attachments

103367A_NeonatalOralFeedingReferencePoster_1604 (1).pdf #1.pdf
Feeding Readiness Documentation.docx
Ride the Feeding Wave.pdf

Approval Signatures

Step Description	Approver	Date
Pediatrics Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	5/28/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	5/27/2024
NICU	Pearl Dahm: Clinical Nurse Specialist	5/27/2024
NICU	Melissa Krebs: Director, NICU	5/23/2024
NICU	Jennifer Ferrick: Director, Peds/PICU & NICU	5/21/2024

VENTURA COUNTY HEALTH CARE AGENCY

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Owner:	*Kristina Swaim: Clinical Nurse Manager, OB*
Policy Area:	*OB Nursing*
References:	

OB. 47 Use of Magnesium Sulfate in the Obstetrics Department

POLICY:

To identify magnesium sulfate as a high-risk medication and to provide specific recommendations that apply.

~~To decrease the infant morbidity and mortality that is associated with preterm delivery.~~

1. ~~Definition: Preterm labor (occurring less than 37 weeks gestation) characterized by uterine contractions associated with changes in cervical parameters. Preterm labor may or may not result in preterm delivery.~~
2. ~~Preterm delivery accounts for 6% to 10% of all births. Low birth weight is associated with 75% to 85% of all non-anomalous neonatal deaths, most of which are preterm.~~
3. ~~Tocolytic agents are generally only successful if used early, i.e. before the cervix is 4cm dilated and before the fetal membranes have ruptured.~~
4. ~~Provides neuroprotection for preterm infants 24-34 weeks who are at risk for imminent delivery.~~

~~To prevent eclamptic seizures.~~

1. ~~Definition of pre-eclampsia: The development of hypertension in pregnancy with proteinuria and edema occurring after the 20th week of gestation.~~

Indications:

1. **Preeclampsia:** Magnesium sulfate is indicated for seizure prophylaxis and management in women with severe preeclampsia.
2. **Eclampsia**: Magnesium sulfate is the first-line treatment for preventing and managing eclamptic seizures
3. **Neuroprotection:**Magnesium sulfate may be considered for neuroprotection in preterm labor, particularly for fetal neuroprotection to reduce the risk of cerebral palsy.
4. **Preterm Labor:**Magnesium sulfate may be used as a tocolytic agent to delay preterm delivery in specific circumstances.

PROCEDURE:

Upon receiving the physician's order, a Registered Nurse (RN) may administer Magnesium Sulfate intravenously ~~in a labor room, delivery room, recovery room, Post-Partum, CCU, and PACU~~.

GUIDELINES:

A. ~~Identify patient in preterm labor or pre-eclampsia/eclampsia as quickly as possible.~~Identify patient who is a candidate for magnesium sulfate.

B. Position patient in lateral position to increase uterine blood flow.

~~Obtain physician order, specifying the grams of loading dose to be given and the grams per hour of continuous infusion, is required for the initiation of intravenous Magnesium Sulfate therapy.~~

~~Toxemia tray will be placed at patient's bedside to be charged if opened and returned to pharmacy to restock and lock.~~

C. For initiation of magnesium sulfate, obtain physician order, specifying the loading dose to be given (4-6 gm) and maintenance dose (1-2 gm/hr)

D. Independent double check with another licensed personnel to verify initial physician orders, drug, concentration, infusion rate, pump settings, line attachment and patient before administering the drug and upon transfer of the patient to another unit.

E. Have a second nurse check when every magnesium bag is added including loading dose and maintenance dose and each time a rate is changed.

F. Once magnesium therapy is discontinued remove the line from IV port to prevent accidental infusion or overdose.

G. IV Magnesium Sulfate is administered only by infusion pump by inserting tubing at the lowest possible portal site of the primary IV tubing. Label tubing with red medication label near the IV pump. When starting infusions or changing bags, trace the tubing by hand from the IV bag to the pump and then to the patient for verification. The usual loading dose is a piggyback premixed from Pharmacy magnesium of 4 grams in 100 ml sterile water. For patients weighing ≥ 113kg or 250 lbs a 6 gram bolus. The Magnesium ~~sulfate~~Sulfate bolus will be administered over 20 minutes. If using Magnesium Sulfate for Neuroprotection, only a loading dose is ~~not to be drawn from main IV~~required. The maintenance infusion~~. This~~ is administered ~~over 20 minutes. Neuroprotection only requires loading dose. The maintenance infusion is administered~~ as a premixed 4% solution (20 grams in 500 ml sterile water) through an infusion pump.
Maintenance Dose 2 – 4 gram/hr as ordered
(40 mg/ml in 500 ml)
1 gm/hr = 25 ml
2 gm/hr = 50 ml
3 gm/hr = 75 ml
4 gm/hr = 100 ml

H. Insert foley catheter as ordered by physician.

I. Magnesium Sulfate is a high risk medication that requires vigilance for safe care of mothers and babies~~:~~

~~As anti-seizure therapy:~~

~~a. Depresses the excited central nervous system by blocking the receptor site that produces the seizure.~~

~~b. Acts as a cerebral vasodilator, increasing vascular blood flow to the brain.~~

~~c. Affects the neuromuscular and neurocellular signal transmission which inhibits seizure activity.~~

~~As treatment of Preterm Labor (no longer first line therapy):~~

a. ~~Blocks neuromuscular transmission by decreasing levels of acetylcholine and norepinephrine. Communication from nerves to muscles does not occur and muscle depression occurs.~~

b. ~~The heart, lungs, uterus and intestines contain smooth muscle that responds to acetylcholine – enriched stimulus. Depression and cessation of function occur at much higher magnesium levels in the heart and lung tissue then in the uterine muscle.~~

1. Laboratory Data:
    a. Serum magnesium level will be drawn every 6 hours after bolus dose is infused.
    b. Therapeutic levels range from 4 – 7 mEq/L
    c. Only 0.3% of the body's total magnesium content is located in the serum, therefore, clinical manifestations are important indicators of physiological response.
    d. Electrolytes initially per PHYSICIAN order, repeat if indicated
    e. Calcium levels should be kept above 7mg/100ml
2. Monitoring, assess patient for signs of toxicity every 2 hours or as ordered by physician:
    a. Visual changes
    b. Somnolence
    c. Flushing
    d. Muscle paralysis (respiratory depression: O2 sat less than 95%)
    e. Loss of Deep Tendon Reflexes (DTRs) or pulmonary edema
    f. Lab values of magnesium levels
    g. Urine output
3. Maternal effects:
    a. Sense of heat (facial flushing due to vasodilatation)
    b. Complaining of nasal congestion
    c. Nausea and vomiting, headache
    d. Dizziness
    e. Lethargy
    f. Inability to sense full bladder
    g. Pulmonary edema can occur, causing shortness of breath
    h. Respiratory depression
4. Notify physician:
    a. Levels below 5mEq/L or greater than 6mEq/dl
    b. DTRs decreased or absent
    c. Urine output less than 120 ml/4hours
    d. Respirations less than 14 breaths/min or greater than 24
    e. Changes in breath sounds suggestive of pulmonary edema
    f. Changes in LOC

g. Tachycardia, bradycardia or significant changes in blood pressure from baseline values

5. Fetal/Neonatal effects:
    a. Decreased muscle tone
    b. Respiratory depression
    c. Drowsiness
    d. Low apgar scores when prolonged maternal treatment is used
6. Toxic effects:
    a. DTR depression, followed absence.
    b. Respiratory depression followed by arrest.
    c. Cardiac arrest, arrhythmia, bradycardia, heart block
    d. Death
7. Antidote: Calcium gluconate 1 gram IVP over 3 minutes per physician order
8. For seizures due to eclampsia:
    a. Use prepared ~~2 – 4~~4-6* gm IV loading dose of Magnesium Sulfate. Run in over ~~20~~20-30 minutes. ~~Or per physician discretion, use~~If using 6 gm bolus ~~and~~ run in over 30 minutes. Follow by a 1-2 gm/hour maintenance dose if renal function is normal.
    b. *If patient weighs ≥113 kg or 250 lbs a 6 gram loading dose is required, followed by 2 gm/hour mainteance dose.
    c. One or two minutes after ~~client~~patient should maintain respiratory function and show evidence of muscle relaxation. Should seizure activity continue, ~~Valium may be given IVP per physician~~give additional 2-4 grams of magnesium sulfate over 5 minutes.
    d. If patient has recurrent seizure after 2nd loading dose of magnesium sulfate, notify physician.
9. Maternal assessment:
    a. When initiating therapy, take temperature, blood pressure, pulse rate, respiratory rate, DTRs and chest assessment prior to initiation of drug.
    b. When giving a bolus, take vital signs every 5 minutes X 15 minutes; remain at the beside to continuously monitor and record vital signs q 15 minutes for the remainder of the first hour. For the second hour, record every 30 minutes and then hourly monitoring
    c. DTRs should be checked every 2 hours or per physician order and as needed, based on maternal signs and symptoms.
    d. Monitor uterine activity continuously.
    e. Measure intake and output every ~~hour~~hours by Foley catheter with urometer. If output < 30 ml/ hour, reassess Magnesium Sulfate dosage and notify physician.
    f. Auscultate chest every 2 hours to R/O lung fluid.
    g. Oxygen saturation should be assessed once per hour.
10. Fetal assessment:
    a. Continuous fetal monitoring and UC activity if drug is being used for preterm labor.
    b. If continuous FHR recording is not done, check FHT with each set of vital signs.

DOCUMENTATION

Record vital signs in Electronic Health Record (EHR) (including mother's temperature, blood pressure, pulse rate, Sp O2, lung sounds, respiration rate, DTRs and fetal heart rate). Indicate type and dosage of medication on ~~MAR~~EHR. Chart I&O hourly. Document lung sounds every 2 hours. Document uterine activity.

~~CONTRAINDICATIONS~~

~~A. Significant vaginal bleeding~~

~~B. Intrauterine infection~~

~~C. Fetal malformations incompatible with life~~

~~D. Fetal death~~

~~E. Any condition (maternal or fetal) which contraindicates prolonging the pregnancy~~

REFERENCES:

~~AWHONN: Perinatal Nursing, 4TH edition, 2014~~
~~Maternal-Newborn Nursing, 2nd edition, 2014~~

AWHONN: Perinatal Nursing, 5TH edition, 2021
Gestational Hypertension and Preeclampsia, ACOG Practice Bulletin #222,2020 Hypertensive Disorders of Pregnancy, California Maternal Quality Care Collaborative, 2021

All revision dates: 4/2/2024, 1/1/2015, 11/1/2013, 7/1/2010, 3/1/2009, 1/1/2005, 12/1/2001, 12/1/1991

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Staff Committees: Family Medicine & OB	Tracy Chapman: Director, HCA Medical Staff Administration	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	6/13/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	4/2/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/2/2024
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	4/2/2024

VENTURA COUNTY HEALTH CARE AGENCY

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Policy Area:	*OB Nursing*
References:	

OB.70 Newborn Bath

POLICY:

1. To provide guidelines for delaying the bath of the healthy newborn until the infant is at least eight (8) hours of age.
2. To educate the mother and family on the delayed bathing and proper method of bathing the newborn.
3. To maintain thorough technique, protecting the newborn from cold stress and energy expenditure.
4. To improve parental bonding and breastfeeding.
5. To encourage parental/familial participation.

PROCEDURE:

1. Universal precautions, including wearing gloves, should be maintained until after the first bath.
2. The bath should be delayed until the infant is at least eight (8) hours of age. Newborn bath will be done in the post-partum area.
3. The infant whose mother is HIV positive, Hepatitis B or C positive, Methicilin-resistant Staphylococcus aureus (MRSA) or who is overly soiled with meconium, etc. should receive a bath as soon as possible after delivery, once the temperature has been stabilized.
4. When cultural/spiritual practices or a parent's refusal prohibit delaying the bath, the infant may receive a bath prior to eight (8) hours of life. Document appropriately in the newborn electronic health record that education was provided and parents wish to receive bath sooner than eight (8) hours.
5. Following delivery, the newborn should be dried per Neonatal Resuscitaion Guidelines (NRP), removing excessive vernix, visible blood and secretions. A comb should be used to remove debris if infant hair is visibly soiled.

   ~~After eight (8) hours of life, the infant should be bathed using a tub/basin.~~
6. Encourage parent/familial participation.
7. Obtain and record temperature prior to bath. (Temperature must be greater than ~~97~~98.~~7~~0 axillary.)
8. Gather needed supplies (warmer is not necessary).
9. Fill basin with warm water.
10. Wash eyes from the inner cantus to outer cantus with clear water.

11. Wash face from the neck area behind ears, axilla, back, legs, groin and buttocks with mild cleansing liquid. Rinse skin with clear water and dry with warm towel.
12. Wash head last with mild soap and water, comb and brush. Rinse hair with warm clear water and dry thoroughly with warm towel. Place hat on head to maintain temperature.
13. Change water if needed.

a. After bath

    1. Dry the newborn immediately, diaper, and dress with shirt and wrap in blankets.
    2. Re-check and record baby's temperature after bath within 30 minutes to one (1) hour.
    3. If temperature is at or below 97.7 degrees F axillary return infant to mother for skin to skin
    4. If temperature does not stabilize within 30 minutes, take baby to Newborn Nursery to be placed under radiant warmer.

b. Change linen

c. Clean and disinfect the crib, basin and other equipment consistent with infection control policy.

~~Place "I had a bath" crib card in bassinet, once bath has been given.~~

Equipment

- ~~Pink~~ Basin or Tub
- Mild Soap
- Wash Cloth or soft 4 x New4
- Towels
- Diaper
- Shirt
- Hat
- Comb
- Gloves
- Bath Card

REFERENCES:

- American Academy of Pediatrics (2012) Guidelines for Perinatal Care. American Academy of Pediatrics and American College of Obstetricians and Gynecologists: (7th edition) Library of Congress.
- Lipka, D.V., & Schulz, M.K. (2012). “Wait for Eight”: Improvement of Newborn Outcomes by Implementation of Newborn Bath Delay. JOGNN: Journal of Obstetrics, Gynecologic & Neonatal Nursing, 41s46-7 1p.doi:10.1111/j.1552-6909.2012.01360_27.
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- Weiner, Gary M. & Jeanette Zaichkin. Textbook of Neonatal Resuscitation (NRP) 7th Ed.
- American Academy of Pediatrics and American Heart Association, 2016. WHO (2013). Guidelines of Maternal, Newborn, Child, and Adolescent Health: Recommendations of Newborn Health.

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Attachments

No Attachments

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Medical Staff Committees: Family Medicine & Pediatrics	Tracy Chapman: Director, HCA Medical Staff Administration	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/1/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	5/30/2024
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	5/30/2024

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Owner:	*Erin Olivera: Clinical Nurse Manager, IPU/CSU*
Policy Area:	*Inpatient Psychiatric Unit (IPU)*
References:	

PSYCHIATRIC WALK-UPS: REGISTERED NURSE TRIAGE

~~**PURPOSE:A registered nurse (RN) will triage all walk-in/up individuals promptly (prior to being seen in the Emergency Department (ED) to:**~~

PURPOSE:

To outline the triage process of all walk-in/up individuals in a properly organized manner, consistent with the defined capability of the hospital. This adheres to the standards of practice within the community and EMTALA (Emergency Medical Treatment and Active Labor Act) guidelines.

POLICY:

A Registered Nurse Mental Health (RN) will triage all walk-in/up individuals promptly (prior to being seen in the Emergency Department [ED]) to:

- Determine priority at a level consistent with their needs (emergent, urgent, or non-urgent)
- Recognize and intervene promptly in crisis situations.
- Maintain ~~good interpersonal~~professional relationships between walk-in/up individuals in crisis, their families ~~and~~ /friends, and community resources.

Nursing triage of individuals is used to determine if the individual needs to be seen in the ED for psychiatric evaluation.

~~**POLICY:To ensure the triage of all walk-in/up individuals in a properly organized manner, consistent with the defined capability of the hospital. This adheres to the standards of practice within the community and EMTALA guidelines.**~~

DEFINITION(S):

Triage is the process of determining individual mental health needs and the selection of the most appropriate treatment and setting.

Emergent is a situation wherein there is an imminent plan to harm self or others OR the plan to harm self or others has been acted upon. It is also a situation where ~~a non-psychiatric~~an individual may be experiencing a life-threatening event.

Urgent is a threat (or expressed thought) to harm self or others, but there is no specific plan, or the individual is acutely psychotic.

Non-urgent is any situation, which may not require acute psychiatric services, i.e., seeking referrals, counseling and medication.

Medical Screening Examination is the process required to determine whether an emergency medical condition exists.

PROCEDURE(S):

1. ~~Triage RN will determine the individual's chief complaint.~~
2. ~~Triage RN will assess the individual promptly.~~

A. Registered Nurse Mental Health will promptly determine the individual's chief complaint.

B. Registered Nurse Mental Health or other staff will obtain/assess vital signs.

C. Registered Nurse Mental Health will prioritize at a level consistent with the individual's needs (emergency, urgent, non-urgent).

~~A. Triage RN will determine the individual's chief complaint.~~

~~B. Triage RN will assess the individual promptly.~~

~~A. Assess an individual's chief complaint.~~

~~B. Assess vital signs.~~

~~C. Prioritize at a level consistent with the individual's needs (emergent, urgent, non-urgent)~~

~~A. Triage RN completes the Situation Background Assessment Response (SBAR). If the individual presents to triage expressing suicidal thoughts/intent, the triage RN will have security stay with the individual until they are able to be transported to the ED. Notify security immediately if an individual who has been triaged and/or assessed for suicidal thoughts/ideation, elopes prior to being transported to ED.~~

~~B. Triage RN will call ED Charge RN to give report at walk up.~~

~~C. Individuals will be transported by licensed staff and a security guard to the ED using gurney.~~

~~D. Ambulance bay entrance will be used to reduce potential stressors for individuals. Psychiatric staff will alert charge nurse to arrival of patient.~~

1. Registered Nurse Mental Health completes the Situation Background Assessment Response (SBAR). If the individual presents expressing suicidal thoughts/intent, the Registered Nurse Mental Health will have security stay with the individual until they are able to be transported to the ED. Notify

security immediately if an individual who has been assessed for suicidal thoughts/ideation, elopes prior to being transported to ED.
2. Registered Nurse Mental Health will call ED Charge Nurse to give report .
3, Individuals will be transported by licensed staff and a security guard to the ED using gurney.
4. Ambulance bay entrance will be used to reduce potential stressors for individuals. Psychiatric staff will alert charge nurse to arrival of patient.

REFERENCE(S):

All revision dates:

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Psychiatry Committee	Tracy Chapman: Director, HCA Medical Staff Administration	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	4/17/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/17/2024
Inpatient Psychatric Unit & Crisis Stabilization Unit	Erin Olivera: Clinical Nurse Manager, IPU/CSU	4/17/2024

VENTURA COUNTY
HEALTH CARE AGENCY

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Owner:	*Jennifer Ferrick: Director, Peds/ PICU & NICU*
Policy Area:	*PEDS/PICU*
References:	

P.36 Pediatric Early Warning System (PEWS) Scoring

POLICY:

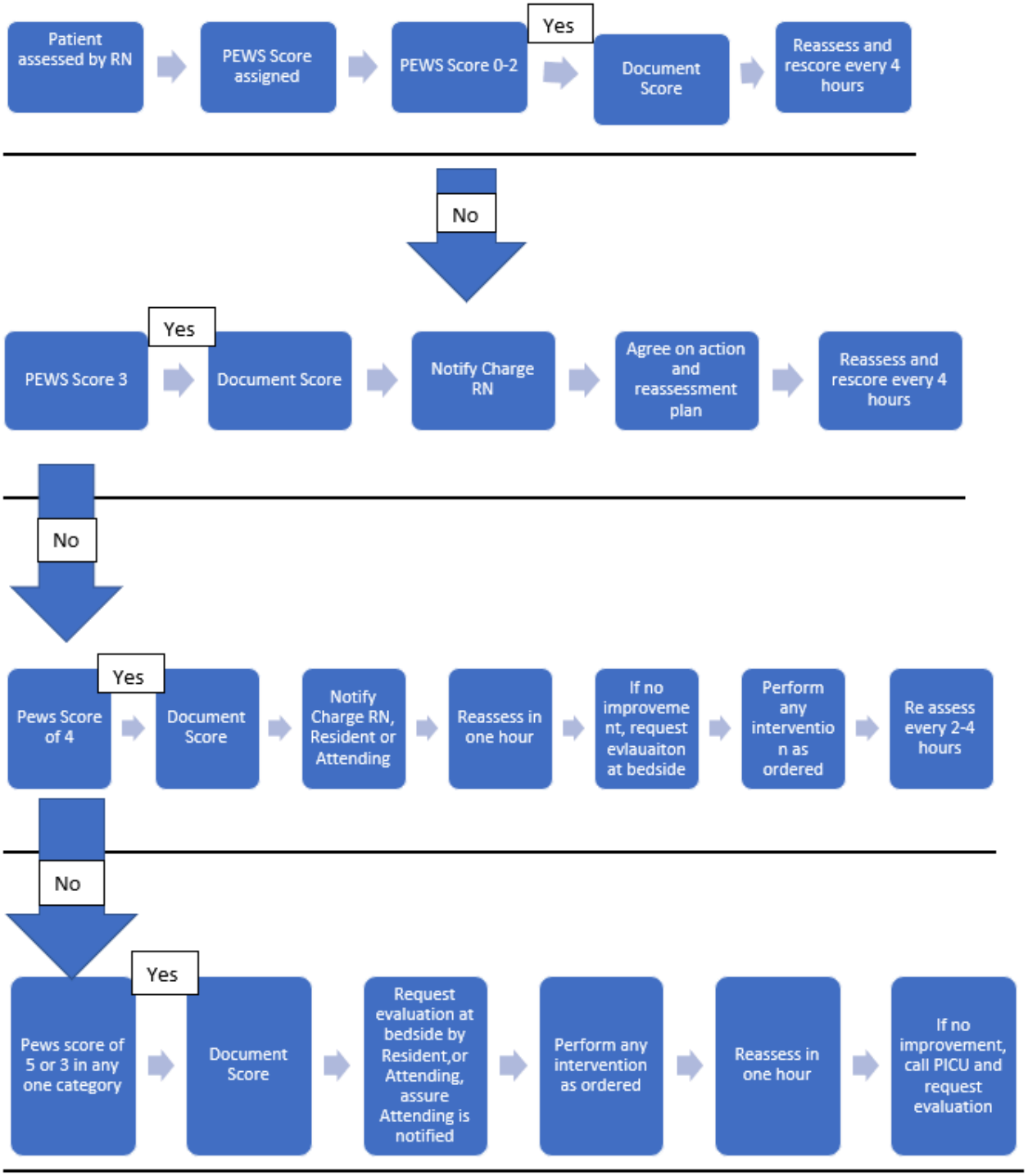
To aid in the early identification of pediatric patients at risk of clinical deterioration and to match the severity of illness to the appropriate level of care.

PROCEDURE:

1. All patients in Pediatrics, and any PICU patient being transferred to the Pediatric unit, shall have a PEWS assessment completed and a PEWS score calculated.
2. Once calculated, a PEWS score is assigned and action is taken according to the score:
    - For a PEWS score of 0-2, the PEWS score is to be repeated at least q4h.
    - For a PEWS score of 3, assess the PEWS score at least q4h and consult with the charge nurse. Agree on a plan of action as well as a reassessment plan. Reassess and rescore q4h.
    - For a PEWS score of 4, notify the Resident or Attending. Reassess in one hour and, if no improvement, request evaluation at bedside. Perform any intervention as ordered. Reassess every 2-4 hours.
    - For a PEWS score of 5 or greater or 3 in any one category, request evaluation at bedside by Resident or Attending and, if Resident, ensure Attending is notified. Perform any intervention as ordered. Reassess on one hour and, if no improvement, call PICU and request evaluation and possible transfer.

Pediatric Early Warning Score (PEWS)

	0	1	2	3	Score
Behavior / Neuro	Playing / appropriate	Sleeping	Irritable	▪ Lethargic / confused **OR** ▪ reduced response to pain	
Cardiovascular	▪ Pink **OR** ▪ capillary refill 1-2 seconds	▪ Pale **OR** ▪ capillary refill 3 seconds	▪ Grey **OR** ▪ capillary refill 4 seconds **OR** ▪ heart rate > 20 above normal rate	▪ Grey **OR** ▪ Mottled **OR** ▪ capillary refill ≥ 5 seconds **OR** ▪ heart rate > 30 above normal rate **OR** ▪ bradycardia	
Respiratory	Within normal parameters, no retractions	▪ >10 above normal parameters, using accessory muscles **OR** ▪ 30 % FiO2 or ≥3 L/min	▪ > 20 above normal parameters ▪ Retractions **OR** ▪ 40 % FiO2 or ≥6+ L/min	▪ 5 < normal parameters with retractions ▪ Grunting **OR** ▪ 50 % FiO2 or ≥8 L/min	
					Total:



Reference:

Akre, M., Finkelstein, M., Erickson, M>, Liu, M., Vanderbilt, L., & Billman, G. (2010). Sensitivity of the Pediatric early warning score to identify patient deterioration. *Pediatrics,* 125(4), e763-e769

All revision dates: 3/24/2018

Attachments

Flow Chart

Approval Signatures

Step Description	Approver	Date
Pediatrics Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/16/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/16/2024
Pediatrics	Jennifer Ferrick: Director, Peds/PICU & NICU	7/16/2024
Pediatrics	Andrei Bobrow: Medical Director, Pediatrics	4/23/2024

VENTURA COUNTY
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Owner:	*Jessica Rodriguez: Manager, Cardiopulmonary Services*
Policy Area:	*Respiratory-NICU/PICU*
References:	

R.NP.06 Neonatal Respiratory Therapist

POLICY:

The purpose of this policy is to outline the role of the Respiratory Care Therapist in the Neonatal Intensive Care Unit (NICU)

PROCEDURE:

Responsibilities

A. Knowledge of policies and procedures
   1. PolicyStat
   2. Lippincott

B. Performs procedures according to departmental policies and procedures

C. Attend and participate in daily rounds with multi-diciplinary team

D. Maintain presence in Neonatal Intensive Care Unit (NICU) when there is an intubated neonate
   1. Respiratory Therapist is expected to give bedside shift report

E. Possesses ability to correlate blood gas results with appropriate changes in oxygen therapy and ventilator settings within the ordered parameters established by the physician and/or Neonatal Nurse Practitioner (NNP)

F. Disassemble, clean, maintain, assemble, troubleshoot and calibrate equipment

G. Ability to assess the patient's clinical status and provide appropriate recommendations toward the care of the patient

H. Ability to identify adverse reactions to therapy and respond accordingly

I. Record all respiratory therapy in Electronic Health Record. Maintain the ability to perform the following respiratory modalities
   1. Provide and monitor oxygen therapy
      a. Bubble continuous positive pressure (BCPAP)
      b. Heated high flow nasal cannula therapy (HHFNC)
      c. Nasal cannula

d. Non-invasive positive pressure (RAM)
e. other modality licensed care provider deems appropriate

2. Nebulize medication
3. Mechanical ventilation
   a. Conventional ventilator
   b. High Frequency Oscillator (HFO)
4. Nitric Oxide
5. Chest Physiotherapy
6. Blood gas sampling and analysis
7. Administration of surfactant
8. Assists and performs tracheal intubation
9. Neonatal resuscitation

J. Possesses current Neonatal Resuscitation Program Certification (NRP).
K. Attendance at high-risk deliveries
L. Internal and external neonatal transports
M. Attends **yearly skills fair and completes competencies**
N. Assists with training of departmental personnel, residents and nurses
O. Participates in departmental Performance Improvement projects **as assigned**
P. Assists in evaluation of new equipment
Q. Completes billing/productivity assist with equipment ordering

All revision dates: 10/15/2020, 2/1/2014, 3/1/2010, 4/1/2008, 1/1/2006, 2/1/2004, 5/1/2001, 1/1/1999

Attachments

No Attachments

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Step Description	Approver	Date
Pediatrics Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending
Respiratory Care	Jessica Rodriguez: Manager, Cardiopulmonary Services	7/8/2024

VENTURA COUNTY
HEALTH CARE AGENCY

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Owner:	*Jessica Rodriguez: Manager, Cardiopulmonary Services*
Policy Area:	*Respiratory-NICU/PICU*
References:	

R.NP.12 Respiratory Scope of Care in the NICU

POLICY:

To define the objectives and scope of care given by Respiratory Care personnel to the newborn. The Respiratory Care Department maintains a team of Respiratory Care Practitioners trained and certified in the assessment, resuscitation and pulmonary management of the premature and pulmonary compromised newborn. Services are available 24 hours a day.

Services are provided on a 24 hour basis.

PROCEDURE:

SCOPE OF NEONATAL CARE SERVICES:

1. Oxygen administration:
    i. Hood
    ii. Isolette
    iii. Nasal trough/cannula
    iv. Comfort flow
    v. High flow nasal cannula
    vi. RAM cannula
2. Ventilatory support:
    i. Continuous Positive Airway Pressure (CPAP)
    ii. Intermittent Mandatory Ventilation (IMV)
    iii. Continuous Mandatory Ventilation (CMV)
    iv. High Frequency Oscillatory Ventilation (HFOV)
    v. Volume Guarantee Ventilation (VG)
    vi. Synchronized Intermittent Mandatory Ventilation (SIMV)
    vii. Pressure Support Ventilation (PSV)
    viii. Manual resuscitation bag ventilation

ix. RAM cannula with support

3. Cardio-Pulmonary Resuscitation (CPR) for the neonate as outlines by Neonatal Resuscitation Program (NRP)
4. Nitric Oxide Administration
5. Airway maintenance
    i. Tracheal intubation and endotracheal tube (ETT) stabilization
    ii. Oral, nasal and tracheal suctioning
6. Aerosol Administration:
    i. Aerosol
    ii. Bronchodilator aerosolization
    iii. Vasoconstrictor drug aerosolization
    iv. Mucolytic drug aerosolization
7. Surfactant therapy
8. Blood gas
    1. Sampling and Analysis
        i. Arterial puncture – radial sites
        ii. Heel punctures
    2. Organization and Maintenance of the Lab
9. Transcutaneous oxygen/carbon dioxide monitoring (TCM)
10. Pulse oximetry
11. Assist in Labor and Delivery Room/Operating Room
    1. Attend all High Risk Deliveries
    2. Attend Deliveries as requested by Labor and Delivery
12. Neonatal transport
    1. Intra-hospital
    2. Inter-hospital
13. Chest physiotherapy
14. Apnea monitoring

All revision dates: 7/8/2024, 5/12/2020, 11/1/2013, 3/1/2010, 1/1/2006, 2/1/2004, 5/1/2001, 1/1/1999

Attachments

No Attachments

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Pediatrics Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending
Respiratory Care	Jessica Rodriguez: Manager, Cardiopulmonary Services	7/8/2024

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Owner:	*Marcos Rodriguez: Manager, Rehabilitation Services*
Policy Area:	*Rehab Services*
References:	

RS.05 Rehab Services Patient Discharge

POLICY:

The Outpatient ~~Rebab~~Rehab Services Department planning for patient discharge begins when the patient is evaluated and continues to occur during the treatment program. The patient and patient care team participates in determining the needs to be addressed for discharge. The therapist consults with care team members and follow-ups with referrals as indicated.

PROCEDURE:

Discharge Criteria:

The plan of care shall be discontinued and the patient discharged when any one of the following occur:

- Patient has completed the ordered course of therapy
- Patient has achieved long and short-term goals
- Failure to obtain physician or payer re-authorization for services
- Patient voluntarily discharges him/herself or declines treatment
- Patient fails to comply with treatment program to extent that treatment is not beneficial
- Attendance is insufficient to achieve reasonable progress toward goals
- Patient/caregiver is disrupting the care of other patients
- Patient is unable to continue to progress toward goals because of medical or psychosocial complications
- Patient is not making progress and there is no further functional benefit to continued therapy
- Therapist determines that therapy intervention will no longer improve patient's functional status
- Patient fails to keep two (2) sequential appointments without canceling/rescheduling 24 hours in advance or cancels greater than 50% of their appointments
- Patient is seeking alternative care that in combination with the therapy treatment plan would place the patient at risk
- Patient requires services or skills not available in the department
- Patient is receiving skilled services from another agency (e.g., school, private OP that duplicate services provided by department)

Required Discharge Documentation:

A Discharge Summary is written by the therapist after completion of skilled therapy. A progress report may serve as the discharge summary if completed in close proximity to the termination of care and shall include:

1. Diagnosis

2. Number of treatments and dates of service
3. Summary of treatment programs
4. A review of functional goals and whether goals were met
5. A comments section which may address response to treatment, pain, etc.
6. Recommendation for further care, discharge or referral, if needed

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Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending
Rehab Services	Marcos Rodriguez: Manager, Rehabilitation Services	8/6/2024

VENTURA COUNTY
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Owner:	*Jeff Warren: Manager, Sterile Processing*
Policy Area:	*Sterile Processing Department*
References:	

S.05 Biological Monitoring and Indicator Use for Steam Sterilizers

POLICY:

A Biological Indicator is a sterilization process monitoring device consisting of a standardized, viable population of microorganisms known to be resistant to the mode of sterilization being monitored. Biological Indicators (BI) are intended to demonstrate whether conditions are adequate to achieve sterilization. At Ventura County Medical Center/Santa Paula Hospital, a Biological Indicator will be used for each sterilizer (when in use) every day. When implantable devices are processed, a Biological Indicator must be run with the load.

PROCEDURE:

A. To perform a steam sterilization test at Ventura County Medical Center/Santa Paula Hospital, place the rapid readout steam pack BI test pack flat on the bottom shelf of the empty sterilizer cart over the drain area.

B. After completion of the steam cycle, the BI is removed from the sterilizer, cooled, crushed and labeled with the load number, lot number, date and sterilizer number. The processed BI is then placed in the incubator.

C. An unprocessed BI with the same lot number as the processed BI is labeled with a "C" for control and is incubated as the positive control daily.

D. After twenty four (24) minutes, the processed BI is read and recorded in the high temperature sterilization log book. The control is also read at this time and should have a positive result.

E. A green light or negative sign indicates an acceptable sterilization process.

F. A red light or positive sign indicates positive biological growth thus a sterilization failure. All processed, positive BI results must be reported to the Sterile Processing Department (SPD) Manager and Perioperative Director. The load should not be used and a recall back to the last negative biological indicator is initiated.

G. The control (unprocessed) BI is read for positive growth in addition to a visual pH color change from purple to yellow up to 48 hours and documented if color change did not take place.

All revision dates: 8/14/2024, 10/15/2020, 9/1/2016, 8/1/2013

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Interim Manager, Medical Staff Office	8/14/2024
Surgery Committee	Stephanie Denson: Interim Manager, Medical Staff Office	8/14/2024
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	7/30/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/9/2024
Surgical Services	Gwendolyn Vontoure: Director Perioperative Services	4/9/2024
Sterile Processing Department	Jeff Warren: Manager, Sterile Processing	4/3/2024

VENTURA COUNTY
HEALTH CARE AGENCY

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Next Review:	*8/14/2027*
Owner:	*Jeff Warren: Manager, Sterile Processing*
Policy Area:	*Sterile Processing Department*
References:	

S.06 Biological Monitoring of the Sterrad Sterilization System

POLICY:

To document proper biological monitoring and performance of the Sterrad sterilizer.

PROCEDURE:

A. Biological monitoring using the Sterrad Rapid Readout Biological Indicator (BI) will be performed daily at a minimum. Every Load Monitoring (ELM) is best practice preferred to assure sterilization efficacy on every load and on all Sterrad sterilizer loads.

B. Daily biological monitoring of all cycles is required.

C. To prepare the BI for the sterilizer, place the Rapid Readout BI vial in a Tyvek peel pouch.

D. Place the pouch containing the Rapid Readout BI vial on the back of the bottom shelf inside the sterilizer chamber with the white Tyvek side facing up. Do not place any trays or pouches on top of the pouch containing the Rapid Readout BI vial.

E. Run the sterilizer cycle.

F. Remove the pouch containing the Rapid Readout BI from the sterilizer and check the chemical indicator for color change from blue to pink.

G. Remove the processed Rapid Readout BI vial from the pouch and press down on indicator vial until it is firmly seated. Place the vial in the tube crusher so the white label is showing. Keeping the vial upright, squeeze gently until the media ampule has been crushed.

H. Label the vial with the date and load number, then place the vial upright into the incubator rack. The incubator should be pre-warmed to 55-60 degrees C.

I. Perform incubation of BI as per the BI manufacturer's instructions for use (IFU) after the sterilization cycle.

J. Label an unprocessed Rapid Readout BI vial (with the same lot number) with a "C" to serve as the positive control. While holding the vial upright, press down on the cap to close the vial. Place the control vial in the crusher so the white label is showing and squeeze gently until the media ampule has been crushed. Place the vial in the incubator next to the processed Rapid Readout BI vial.

K. Incubate both vials for at least 24 minutes. The control vial may be incubated for up to 72 hours for visual color change to appear.

L. After 24 minutes, check both Rapid Readout BI vials and record the results in the sterilization log.

M. The processed Rapid Readout BI vial stripes on the top of the vial should change from blue to pink. This means conditions for sterilization have been met.

N. If the processed Rapid Readout BI stripes do not turn from blue to pink, this indicates that conditions for sterilization have not been met. Notify the operating room (OR) manager and the instruments from this load will need to be retrieved. Repeat the test and if a second positive change occurs report the positive BI to Advanced Sterilization Products and do not use the sterilizer until evaluation by the Biomedical Department.

O. Discard all Rapid Readout BI vials after reading into a biohazard waste container.

All revision dates: 8/14/2024, 7/22/2020, 2/12/2019, 9/1/2016

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Interim Manager, Medical Staff Office	8/14/2024
Surgery Committee	Stephanie Denson: Interim Manager, Medical Staff Office	8/14/2024
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	7/30/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/9/2024
Surgical Services	Gwendolyn Vontoure: Director Perioperative Services	4/9/2024
Sterile Processing Department	Jeff Warren: Manager, Sterile Processing	4/3/2024

VENTURA COUNTY
HEALTH CARE AGENCY

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Owner:	*Jeff Warren: Manager, Sterile Processing*
Policy Area:	*Sterile Processing Department*
References:	

S.35 Low Temperature Hydrogen Peroxide Gas Plasma Sterilization

POLICY:

To provide guidance to perioperative staff for low temperature hydrogen peroxide gas plasma sterilization of items to be used in the perioperative setting. The expected outcome is that the patient is free from signs and symptoms of infection.

It is the policy of Ventura County Medical Center/Santa Paula Hospital that:

- Low temperature hydrogen peroxide gas plasma will be used to sterilize moisture- and heat-sensitive items and when indicated by the device manufacturer.

PROCEDURE:

The following steps will be followed for low temperature hydrogen peroxide gas plasma sterilization of items for use in the perioperative setting:

- Follow the sterilizer manufacturer's written instructions for use (IFU) for operating, monitoring, and maintaining the low-temperature hydrogen peroxide gas plasma sterilizer.
  - Obtain written documentation for the acceptability of low-temperature hydrogen peroxide gas plasma sterilization for specific devices from the device and sterilizer manufacturers.
  - Evaluate devices with lumens to determine whether the lumen diameter and length are within the sterilizer manufacturer's acceptable dimensions as specified in the sterilizer manufacturer's written IFU.
  - Place items within the chamber in a manner that complies with the sterilizer manufacturer's written IFU.
- Clean and thoroughly dry items to be sterilized using low temperature hydrogen peroxide gas plasma before packaging.
  - Use only sterilization wraps, pouches, trays, mats, containers, and other accessories designed and validated for use with low temperature hydrogen peroxide gas plasma.
- Monitor each sterilization cycle to verify that parameters required for sterilization have been met.
- Use physical monitors (e.g., printouts, digital readings) for every load and review to verify cycle parameters for every load have been met.
- Use chemical indicators recommended by the manufacturer to verify that the parameters for sterilization have been achieved.

- Place a chemical indicator inside every package.
- Place a class 1 chemical indicator on the outside of every package unless the internal indicator is visible through the package material.

- Use biological indicators every first load ~~of~~at a minimum or Every Load Monitoring (ELM) of each sterilization cycle to monitor sterilizer efficacy according to the manufacturer's written IFU.

Competency

Perioperative staff sterilizing items for use in the perioperative setting using low temperature hydrogen peroxide gas plasma will receive education and complete competency verification activities on the principles and processes of low temperature hydrogen peroxide gas plasma sterilization.

Quality

Perioperative staff sterilizing items for use in the perioperative setting using low temperature hydrogen peroxide gas plasma will participate in quality assurance and performance improvement activities related to low temperature hydrogen peroxide gas plasma sterilization.

References

Guideline for sterilization. In: *Guidelines for Perioperative Practice 2019: 985-986* . Denver, CO: AORN, Inc.

Petersen C, ed. Infection. In: *Perioperative Nursing Data Set* . 3rd ed. Denver, CO: AORN, Inc; 2011:254-276.

All revision dates: 4/3/2024, 10/9/2019, 9/1/2016

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Surgery Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	7/30/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/9/2024
Surgical Services	Gwendolyn Vontoure: Director Perioperative Services	4/9/2024
Sterile Processing Department	Jeff Warren: Manager, Sterile Processing	4/3/2024

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Owner:	*Jeff Warren: Manager, Sterile Processing*
Policy Area:	*Sterile Processing Department*
References:	

S.59 Processing and Handling of Sterile and Clean Items

POLICY:

Clean and/or sterile supplies are separated from unprocessed supplies by maintaining the work flow pattern and physical plan area designation of the Decontamination, Assembly and Processing, and Distribution areas. Cross-contamination of supplies will be avoided by following the procedure described below.

PROCEDURE:

A. Processing of items is from dirty to clean. Designated traffic and pathway patterns in the Surgery Department and Sterile Processing Department will be followed to ensure dirty and clean supplies do not cross paths.

B. Traffic in the area of the autoclave should be minimized as much as possible.

C. Items will be moved into and out of the steam sterilizer chamber with extreme care to minimize risk of burns.

D. Items will be touched or handled only after they have completed the cooling process and the biological indicator (BI) results are read, which may vary from load to load but is generally at least 60 minutes.

E. Sterile items should be protected from excessive handling during movement and transport to minimize potential for sterile package contamination or compromise.

F. Items should be transported to the storage location as soon as possible after cooling or on a regular schedule.

G. Sterile Processing staff will inspect the integrity of each item before it is placed into storage or released for use; the person responsible for opening each package at the point of use assumes final responsibility for inspecting the integrity of the item.

H. Wrapped trays should be lifted when being moved on shelving, and should not be dragged across the shelving.

I. Sterile items transported outside the immediate perioperative areas must be in a closed cart or containment bin.

J. All storage shelving must be kept free of dust and other contaminants, and will be cleaned on an established schedule.

K. Sterility is event-related and department packaged items are considered sterile until the package has been opened or has been compromised, including but not limited to a breach (tear or hole), package material degradation, or contact with liquid, unless manufacturer's instructions for use (MIFUs) require an expiration date.

L. Sterile items reprocessed in either Ventura County Medical Center (VCMC) or Santa Paula Hospital (SPH) Sterile Processing areas may be used at the alternate site's operating rooms (ORs) without being reprocessed unless the sterility of the item has been compromised. If the integrity of a package is compromised, i.e., torn, punctured or wet, the item will not be used for patient care and will be returned to the Sterile Processing Department (SPD) for reprocessing.

M. All opened or used items brought to the SPD will be considered contaminated and must be sent to the decontamination area to begin processing.

N. All opened or used items will be thoroughly cleaned in accordance with manufacturer instructions for use (IFU) as the first step in the cleaning process.

O. All soiled or "non-clean, non-sterile" items will be separated from clean or sterile items upon arrival to the decontamination area.

P. All items that fall onto the floor will be reprocessed.

Q. All shelves for storage of sterile and clean items will be cleaned frequently and remain dust/lint free.

R. Evidence of moisture on any package requires the package to be reprocessed.

S. All worktables and assembly spaces are cleaned and disinfected daily.

T. All sterile items will be checked for package integrity before distribution to the required destination

All revision dates: 8/14/2024, 9/1/2016, 8/1/2013, 4/1/2011, 7/1/2006, 12/1/2001

Attachments

No Attachments

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Medical Executive Committee	Stephanie Denson: Interim Manager, Medical Staff Office	8/14/2024
Surgery Committee	Stephanie Denson: Interim Manager, Medical Staff Office	8/14/2024
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	7/30/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/9/2024
Surgical Services	Gwendolyn Vontoure: Director Perioperative Services	4/9/2024
Sterile Processing Department	Jeff Warren: Manager, Sterile Processing	4/3/2024

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Owner:	*Gwendolyn Vontoure: Director Perioperative Services*
Policy Area:	*Surgical Services*
References:	

S.74 Surgical Smoke Evacuation

POLICY:

To provide guidance to perioperative staff for creating an environment that reduces the exposure of patients and perioperative staff to surgical smoke. The expected outcome is that the patient is free from signs and symptoms of laser and electrical injury and staff are free from signs and symptoms of injury related to the use of laser technology and electrical devices.

It is the policy of **Ventura County Medical Center/Santa Paula Hospital** that when surgical smoke (ie, plume) is generated during operative or other invasive procedures by heat-producing instruments (e.g., electrosurgical units [ESUs], lasers), the smoke will be captured and filtered through the use of smoke evacuators or in-line filters positioned on suction lines.

PROCEDURE:

- The perioperative registered nurse (RN) will assess each surgical procedure requiring the use of heat-producing instruments that could generate plume and will provide the evacuation method to remove it from the operating room (OR) environment.
- Surgical smoke will be removed using a smoke evacuation system during open and laparoscopic procedures.
  - A smoke evacuation unit with a 0.1 micron filter (eg, ultra-low particulate air [ULPA] or high efficiency particulate air [HEPA]) will be used.
    - Connect the corrugated smoke evacuation tubing with a smooth inner lumen directly to the smoke evacuator.
    - Attach devices to the smoke evacuator that will automatically start and stop the smoke evacuator as surgical smoke is being generated, if available.
  - The suction wand will be kept as close as possible, but no greater than 2 inches, from the source of the smoke.
  - When a central suction system is used to evacuate smoke, a 0.1 micron in-line ULPA filter will be used.
    - The filter will be placed between the suction wall/ceiling connection and the suction canister.
    - If the Neptune portable device is used, a 0.1 micron filter will be used in the smoke evacuation chamber.
    - Suction tubing no longer than 12 feet in length with a suction tip attached will be used or the suction tubing may be attached directly to the ESU hand piece.
  - Surgical smoke will be evacuated throughout the laparoscopic procedure by using a laparoscopic

smoke evacuation device.
    - The smoke evacuation device will have a 0.1-micron filtration capability.
    - The release of the pneumoperitoneum will be performed using a closed system, which may involve a 0.1-micron in-line filter on the suction line, a smoke evacuation system that employs an irrigation/suction probe, or a smoke evacuator equipped to manually release insufflated gases.
- Standard precautions will be used when disposing of used smoke evacuator filters, tubing, and wands.
- Respiratory protection (e.g., fit-tested N95 filtering face piece respirator, high-filtration surgical mask) will be used during procedures that generate plume.

Documentation

The perioperative RN will document the use of surgical plume evacuation equipment and other devices used to evacuate plume during operative or other invasive procedures on the intraoperative record.

Quality

Perioperative staff participating in procedures where surgical smoke is produced will participate in quality assurance and performance improvement activities related to smoke evacuation equipment and reducing surgical smoke.

Glossary

Surgical smoke : The gaseous products of burning organic material created as a result of the destruction of tissue by lasers, electrosurgical units (ESUs), ultrasonic devices, power instruments, and other heat-producing surgical tools. Surgical smoke can contain toxic gases and vapors such as benzene; hydrogen cyanide; formaldehyde; bio-aerosols; dead and live cellular material, including blood fragments; and viruses. At high concentrations, surgical smoke causes ocular and upper-respiratory tract irritation in health care workers and creates obstructive visual problems for the surgeon. Surgical smoke has unpleasant odors and has been shown to have mutagenic potential.

References

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Attachments

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Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Interim Manager, Medical Staff Office	8/14/2024
Surgery Committee	Stephanie Denson: Interim Manager, Medical Staff Office	8/14/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	4/9/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/9/2024
Surgical Services	Gwendolyn Vontoure: Director Perioperative Services	4/9/2024

VENTURA COUNTY HEALTH CARE AGENCY

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Owner:	*Jeff Warren: Manager, Sterile Processing*
Policy Area:	*Sterile Processing Department*
References:	

S.77 Surgical Instruments Cleaning and Care

POLICY:

To provide guidance to perioperative staff for cleaning, transporting, decontaminating, inspecting, and preparing surgical instruments for terminal sterilization or high-level disinfection. The expected outcome is that the patient is free from signs and symptoms of infection.

It is the policy of **Ventura County Medical Center/Santa Paula Hospital** that:

- Instruments and devices used in surgery will be cleared by the United States Food and Drug Administration (FDA) for use in surgery.
- Before purchase of surgical instruments and other devices used for surgical or other procedures performed in the facility, the manufacturer's written instructions for use (IFUs) including instructions for preparation at the point of use, transport of the soiled device, cleaning, decontamination, inspection, functionality testing, packaging, and high-level disinfection or sterilization will be obtained and evaluated by **the Sterile Processing Department (SPD) Manager** to determine whether the facility has the capability to comply with the manufacturer's instructions.
- New, repaired, and refurbished instruments will be examined, cleaned, and sterilized according to manufacturer's written IFU before patient use.
- Cleaning and decontamination of instruments and equipment will occur as soon as possible after instruments and equipment are used.
- Surgical instrument, medical device, and equipment manufacturer's validated instructions will be followed.
  - Accessories for cleaning and processing specified by the manufacturer will be obtained at the time of purchase and used in accordance with the manufacturer's written IFU.
- The cleaning, decontamination, and care of instruments will be evaluated in a quality management program.
  - The quality management program will include monitoring or manual and mechanical cleaning.
- Adverse events and near misses will be investigated and reviewed for potential opportunities for improvement and the need for corrective action to prevent future occurrences.

PROCEDURE:

- Review the manufacturer's written IFU for requirements related to
  - utilities (eg, water, compressed air);
  - cleaning equipment;
  - device assembly required for cleaning;

- accessories for cleaning lumens, ports, and internal parts;
- cleaning solutions,
- lubricants; and
- procedures for handling, cleaning, transporting, decontaminating, inspecting, packaging, and sterilizing or high-level disinfecting.

New, Repaired, or Refurbished Instruments

- Remove new, repaired, or refurbished instruments and related accessories from external shipping containers and web-edged or corrugated cardboard boxes before transfer into the decontamination area.
- Inspect all new, repaired, or refurbished instruments for defects and correct function upon receipt by verifying
  - after each use,
  - to ensure cleanliness and proper functionality,
  - to identify missing parts,
  - using a lighted magnifying glass,
  - to identify and segregate broken, stained, or rusted instruments, instrument tip integrity and alignment,
  - security of screws,
  - ability of ratchets to hold,
  - sharpness of cutting edges,
  - integrity of lock boxes,
  - freedom of moveable parts, and
  - Insulation integrity should be tested after each use.; using an insulation tester (used for electrosurgery).
  - Rigid and Flexible endoscopes should be tested for light and image clarity after each use.
  - Hands should be cleaned prior to assembling instrument trays.
- Cleaning should not occur in the assembly area. Instruments found to be dirty after decontamination should be sent, along with the entire tray, back to decontamination to be properly cleaned.
- Disassemble, clean, decontaminate, inspect, package, and sterilize new, repaired, or refurbished instruments or equipment according to the manufacturer's written IFU before patient use.
- Instruments should be lubricated after each use, unless prohibited in writing by the manufacturer. This is normally accomplished within the automated wash cycle, but must be manually performed for instruments that either cannot withstand high heat or submersion.
- Instruments should not be received into SPD through Assembly. All instruments must be decontaminated prior to arriving in Assembly.
- Instruments should be handled with care to avoid damage. Dumping of instruments does not represent best practice handling.
- Instruments should be configured in the tray according to the count sheet.
- All instruments should be assembled in the fully open position.
- Metals should not be mixed in instrument sets. Only surgical-grade steel instruments should be placed on sets intended

Quality Management Program

- Perform testing to assess the efficacy of cleaning of medical devices.
- Evaluate manual cleaning using objective measures (e.g., chemical reagent tests for detecting clinically relevant soils, e.g., protein).
  - Use the instrument most difficult to clean when verifying the effectiveness of manual cleaning.

- Test mechanical cleaners (e.g., washer disinfectors/decontaminators) for correct function
  - on installation,
  - at least weekly (preferably daily),
  - during routine use,
  - after major repairs, and
  - after significant changes in cleaning parameters (e.g., changing cleaning solutions).
- Maintain and service instruments, equipment, and cleaning equipment in accordance with the device manufacturer's written IFU.
  - Use qualified staff to perform the maintenance and service.
- Report and document adverse events according to hospital **infection control plan.**

Competency

Perioperative staff involved in the cleaning and care of surgical instruments and equipment will receive education and complete competency verification activities on cleaning, transporting, decontaminating, inspecting, and preparing surgical instruments for terminal sterilization or high-level disinfection.

Quality

Perioperative staff involved in the cleaning and care of surgical instruments and equipment will complete quality assurance and performance improvement activities on cleaning, transporting, decontaminating, inspecting, and preparing surgical instruments for terminal sterilization or high-level disinfection.

Glossary

Cleaning: A process using friction, detergent, and water to remove organic debris; the process by which any type of soil, including organic debris, is removed to the extent necessary for further processing or for the intended use. Cleaning removes, rather than kills, microorganisms.

Decontamination: Any physical or chemical process that removes or reduces the number of microorganisms or infectious pathogens and renders reusable medical products safe for handling or disposal; the process by which contaminants are removed, either by manual or mechanical means, using specific solutions capable of rendering blood and debris harmless and removing them from the surface of an object or instrument.

References

Petersen C, ed. Infection. In: *Perioperative Nursing Data Set* . 3rd ed. Denver, CO: AORN, Inc; 2011:254-276.

Guideline for cleaning and care of surgical instruments. In: *Guidelines for Perioperative Practice.* Denver, CO: AORN, Inc.

ANSI/AAMI ST 79: 2017, A1, A2, A3, Basics of Sterile Processing, 6th Edition, Central Service Technical Manual, 8th Edition
CDC, OSHA

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Attachments

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Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Interim Manager, Medical Staff Office	8/14/2024
Surgery Committee	Stephanie Denson: Interim Manager, Medical Staff Office	8/14/2024
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	7/30/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/9/2024
Surgical Services	Gwendolyn Vontoure: Director Perioperative Services	4/9/2024
Sterile Processing Department	Jeff Warren: Manager, Sterile Processing	7/27/2023

VENTURA COUNTY HEALTH CARE AGENCY

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Owner:	*Laura Zarate: Clinical Nurse Manager, Case Management*
Policy Area:	*Social Services*
References:	

SS.05 Durable Medical Equipment (DME) Ordering

POLICY:

Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) will provide resources and assistance as needed to our patients in obtaining necessary durable medical equipment. Typical equipment needs include wheelchairs, walkers, bedside commodes, hospital beds, oxygen therapy, etc. Patients will be provided with a choice of DME vendors whenever possible.

PROCEDURE:

A. Elective Admissions (scheduled surgery or procedure)
   - Referring clinic to assess for post-procedure DME needs at the time of preop assessments.
   - Anticipated DME prescription and list of vendors may be given to the patient or family prior to scheduled procedure.
   - If patient or family desires assistance with obtaining DME, clinic may refer the DME Order ~~form~~ to the VCMC/SPH Case Management/Social Services Department by FAX or Electronic HealthRecord (EHR) DME Pool.
   - Patient/family to obtain equipment directly from vendor.
   - Clinic staff must follow-up with the patient to ensure equipment obtained prior to procedure.

B. Pediatric considerations
   - Vendor or Case Management/Social Services will need to know if California Children's Services (CCS) referral has been made or if child is already active CCS.

C. Trauma/Unscheduled Admissions
   - Physicians may order DME for inpatients ~~on the DME order form~~via EHR .
   - Unit staff will refer orders to Case Management/Social Services.
   - Case Management/Social Services will process requests and assist patients/families in obtaining needed DME equipment for discharge during regular business hours. Payor-source clarification may involve verifications of coverage with the patient ~~representatives, utilization staff or pre-admitting staff~~'s health plan. (After-hours ~~and week-end assistance~~ can be obtained from the nursing supervisor.)

D. Home Respiratory Equipment

- Home oxygen therapy, nebulizers, etc. orders should be placed by physician order ~~using the Home Respiratory Care Order form~~ and processed by the same method as the DME orders. ~~After 5:00 pm and on week-ends, Respiratory Care Services will assist with obtaining respiratory equipment for discharge.~~

E. Documentation
Chart on ~~multidisciplinary~~ progress notes ~~and~~for assistance needed, referrals or follow-up in Electronic Health Record (EHR).

F. Resources

~~Vendor List~~

~~DME Form~~

~~Respiratory Care Order Form~~

~~Medi-Cal Case Management Pre-Approval for TARS~~

- Case Management/Social Services
- Nursing Supervisor

~~Care Management Services~~

- ~~DC Planning Nurse,~~
- ~~Utilization Review~~
- ~~Preadmitting~~

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No Attachments

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Medical Executive Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending
Utilization Management Committee	Cheryl Lambing: Medical Director, Utilization Management	8/7/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	10/17/2022
Utilization Management Committee	Laura Zarate: Clinical Nurse Manager, Case Management	8/16/2022
Case Management	Laura Zarate: Clinical Nurse Manager, Case Management Department	7/12/2022

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Owner:	*Laura Zarate: Clinical Nurse Manager, Case Management*
Policy Area:	*Utilization Review*
References:	

UR.02 Condition Code 44

POLICY:

In accordance with ~~the hospital~~Title 42 Code of Federal Regulations (CFR) § 482.30 Conditions of Participation ~~(COPs)~~: Utilization Review, Ventura County Medical Center and Santa Paula Hospital utilization review (UR) Registered Nurses (RN) or Physician Advisors (PA) review Medicare ~~requires~~and Medi-Cal patients to ensure that all ~~hospitals conduct utilization~~requirements of 42 CFR 482.30 are met with respect to the medical necessity of admissions to these facilities. Condition Code 44 is used to address those relatively infrequent occasions in which a Medicare beneficiary is admitted to inpatient status but upon subsequent review ~~(~~it is determined that the patient does not meet criteria for inpatient care. All PAs reviewing medical necessity of admissions are members of the UR~~) to ensure that all UR requirements of 42 CFR 482.30 are met. Condition Code 44 is used to address those relatively infrequent occasions when the patient was admitted to inpatient status and care does not meet medical necessity to warrant inpatient status.~~ Committee.

~~PROCEDURE:~~

~~When the UR nurse conducting a concurrent review finds the patient does not meet the evidence-based guidelines for inpatient admission and a physician on the hospital utilization review (UR) committee concurs, the hospital may change the beneficiary's status from inpatient to outpatient and submit an outpatient claim for medically necessary Medicare Part B services that were furnished. All assigned Physician Advisors (PA) are representatives of the UR committee.~~

INPATIENT TO OUTPATIENT STATUS CHANGE CRITERIA:

I. When a physician orders inpatient status but the hospital's UR committee determines that the level of care does not meet inpatient criteria, the hospital may change the status to outpatient but only when all of the following conditions are met:

   A. The change in patient status from inpatient to outpatient is made prior to discharge or release, while the beneficiary is still a patient of the hospital.

   B. The hospital has not submitted a claim to Medicare for the inpatient admission.

   C. A physician responsible for the care of the patient concurs with the UR committee's decision; and

   D. The concurrence of the physician responsible for the care of the patient and the UR committee is documented in the patient's electronic health record (EHR).

PROCEDURE:

~~The change of inpatient to outpatient status is permissible if all of the following conditions are met:~~

- ~~The change in patient status from inpatient to observation is made prior to discharge or release, while the beneficiary is still a patient of the hospital.~~
- ~~The hospital has not submitted a claim to Medicare for the inpatient admission.~~
- ~~A physician responsible for the care of the patient concurs with the utilization review committee's decision.~~
- ~~The physician's concurrence is documented in the patient's medical record.~~

I. The UR ~~nurse~~RN or PA determines the patient does not meet medical necessity for inpatient admission according to evidence-based care guidelines and/or the Centers for Medicare and Medicaid Two-Midnight Rule.

II. ~~The UR nurse contacts the UR Physician Advisor (PA) for secondary level review after gathering more medical information from attending physician.~~If it is the UR RN who has determined the patient does not meet medical necessity, the UR RN gathers more medical information from the physician responsible for the care of the patient and contacts the PA for secondary review.

III. The PA contacts the physician responsible for the care of the patient and discusses the rationale of inpatient admission if medical necessity is not apparent before making a final determination ~~by UR PA is made~~.

IV. If the physician responsible for the care of the patient concurs with the PA, the ~~PA changes inpatient~~UR RN enters a patient status ~~to~~order (PSO) for outpatient with observation services and follows the Condition Code 44 process.

V. If the physician responsible for the care of the patient does not concur with the UR Committee physician member, a second UR Committee physician member will be consulted and the UR process for review may proceed according to the written UR Plan.

~~Condition Code 44 process:~~

1. ~~An order is written in the medical record for outpatient with observation services, documentation stating who was involved in the decision and the reasoning that brought them to that conclusion.~~
2. ~~On the UR notes, a notation is to be made including the change in order, why it was made and who was involved in making the decision.~~
3. ~~Letter (Form: VCHCA-546-056/s Medicare Outpatient Observation Notice) is generated and given to the patient with verbal explanation and patient is to sign this notification. If the patient is unable to sign, the guardian is given the letter. The patient is to keep the original and a copy is placed in the medical record.~~
4. ~~The UR nurse notifies financial services of Code 44 to place on bill, Admitting or Registration department to change patient status, and Patient Accounting needs to ensure the final charges (status) are correct.~~
5. ~~Observation hours can only be billed from the time the order is written for observation services.~~

~~REFERENCES:~~

~~Medicare Conditions of Participation Title 42 CFR 482.30~~

CONDITION CODE 44 PROCESS:

I. An order for "PSO Place in Observation" with communication type "Protocol/Standardized Procedure – Co Sign" is entered after agreement by the physician responsible for the care of the patient or after agreement by a second physician member of the UR Committee. This order must be co-signed by the attending physician prior to discharge or release, while the patient is still a patient of the hospital.

II. Documentation by the UR RN or PA is added to the patient's electronic health record noting the change in status, persons involved in the decision-making, and that Patient Financial Services (PFS) will be notified of the change in status.

III. Prior to the patient being discharged, form: VCHCA-546-056/s Medicare Outpatient Observation Notice (MOON) is generated and given to the patient or their representative, with an oral explanation. If the patient or their representative declines to sign the MOON, the individual providing the form makes a note on the form with the declination and signs and dates the form. The patient is to keep the original, and a copy is scanned to the patient's electronic health record.

IV. The UR RN or PA adds Condition Code 44 to the UB04 tab in PM Conversation Case Management (Revenue Cycle) in the EHR to notify PFS of the status change.

V. Observation hours can only be billed from the time the order is written for observation services.

REFERENCES:

42 C.F.R. § 482.30 (2024)

Medicare Claims Processing Manual Chapter 1 - General Billing ~~Requirement5s~~Requirements Section 50.3.2 (rev~~07/31/2020~~02-15-24)

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Utilization Management Committee	Laura Zarate: Clinical Nurse Manager, Case Management	pending
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Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	8/7/2024
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